Public Health Ontario | Santé publique Ontario

Ethics Review Board:

Information Letter, Consent Form Guidelines and Templates

Guidelines

April 2023

Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Ethics review board: information letter, and consent form guidelines and templates. Toronto, ON: King's Printer for Ontario; 2023.

Disclaimer

For Further Information

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Ontario

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Introduction

The following guidelines set out the ethics requirements for consent in research and related projects (e.g., program evaluation, enhanced surveillance) involving human participants. These guidelines should be used in conjunction with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2022).

The guidelines apply to PHO and Public Health Unit (PHU) staff developing consent materials for projects to be reviewed by Public Health Ontario Ethics Review Board (PHO ERB). Project leads submitting consent related materials are required to adhere to these guidelines.

This document is intended to serve as a guide. The templates include sample language that can be used when developing an information letter and consent form. Depending on the nature of the project, project leads may need to provide additional information and details than outlined in these templates.

The focus of these guidelines is on adult consent. For further guidance on projects that involve participants who may lack capacity or require alternate processes for seeking consent, refer to Chapter 3: The Consent Process of the TCPS 2.

Developing an Information Letter and Consent Form

Purpose

Research and related projects involving human participants requires consent of the participant.[1] Consent is the process of seeking either agreement or refusal to participate in a project from prospective participants.[1] This process requires that consent is voluntary, informed, and documented. The consent process is ongoing and continues throughout a participant's involvement in the project. The consent form acts as documentation of, but does not replace, a proper consent process. More importantly, potential participants must have decision-making capacity to provide individual consent, otherwise an authorized third party decision maker is required. Decision-making capacity refers to the ability of a participant to understand the project information presented as well as appreciate the potential consequences (e.g., risks and benefits) of their decision to participate or not.[1]

Consent materials should include two key components in the overall consent process:

1. project related information to help potential participants make an informed and voluntary decision, and
2. the documentation of consent.

For further guidance, refer to Chapter 3: The Consent Process of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2022) and Appendix A.[1]

Writing Style

- Keep the information portion as short as possible while including all essential points. Where appropriate, consider developing a separate FAQ page (to include as a hard copy or as a publicly-accessible online link) to convey helpful but non-essential details.
- Use bullets and headings to break up longer blocks of text.
- Write clearly, keeping the education level and the background knowledge of your intended audience in mind. The following elements may assist with clarity:
    - short sentences containing only one major idea
    - active voice (not passive)
    - positive statements not negative (e.g., "eat less red meat," not "don't eat lots of red meat")

    - consistent use of terms (e.g., don't use "survey" and "questionnaire" or "drugs" and "medications" interchangeably)

- Number pages in the form "Page x of y".
- Include version date in the footer, e.g., Version 1: month, day, year.
- Use current PHO/PHU letterhead for the first page.
- Choose a font size of 11 points or larger.
- Test the form on someone not involved in the project to ensure clarity and comprehensiveness.

Information Letter and Consent Form Requirements

Project Title

Provide the full and correct title of the project. A short title may be used thereafter.

Introduction

- Begin by inviting the person to participate in the project being conducted.
- Include the name and contact information of the project lead. Indicate if the lead is a student, and if so, include their supervisor's name as well.
- Include the full name of any agencies/organizations funding or supporting the project.
- Include a statement that participation is voluntary.
- See consent form template for suggested introductory language.

What is the purpose of this project?

This section should address the questions: **"Why is this project being conducted?"** and **"Why am I being invited to participate?"** by including the following information:

- Information on what the project intends to demonstrate or achieve.
- Why the participation of the selected sample is being sought.
- Information on how the participant was identified (if applicable).
- The number of participants expected to be enrolled in the project.
- The project phase or stage, if applicable; for example, "this is the pilot phase of a larger project."

What will participation involve?

This section should answer the questions **"How will the project be conducted?"** and **"How will I be involved?"** and include the following:

- **Step-by-step description** of the project as it will be experienced by the participant.
- Elements of the project that depart from **routine public health practice**.
- **Time commitment** for the various stages of the project, as well as the total time commitment. Also describe the frequency (e.g., every 3 months) of procedures, visits, interventions, etc.

- **Location:** Where the project/procedures will take place and how the potential participant may be accommodated to schedule a convenient time and place (if applicable).

- **Mode:** Procedures (e.g., oral vaccination, drawn blood) and/or data collection (e.g., online survey, focus groups, telephone-administered questionnaire, in-person interview). If you plan to use an online survey, see appendices C and D for more information.

- **Personal health record review:** If the participant's personal health record will be reviewed, explain why this is needed, regardless of whether or not data will be collected from the record.

- **Selection:** If randomization, sequential selection or pre-selection will be implemented, explain these terms and the probability of being assigned to each option. Explain these concepts in lay terms; for example, "'Randomization' is like the toss of a coin, and means that the participant may or may not receive the intervention". Include information about treatment as usual or placebo, as appropriate.

- **Survey, interview or focus group questions:** Indicate the nature of questions to be asked, and state whether some questions might be upsetting, embarrassing or otherwise sensitive for participants (e.g., level of income, history of abuse, sexuality). Inform participants that they may skip these questions if they so choose. Consider also attaching the data collection tool so potential participants may review the questions in advance of agreeing to take part.

- **Biological samples:** If blood, tissue, mucous, etc., will be taken, clearly state the method of collection, how much will be taken and why the samples are being collected. Clearly describe how long the samples will be stored, where and by whom, whether they will be banked and used in other projects, and if they will be identifiable.

- **Photos/recordings:** Clearly explain any procedures that involve taking photographs, videotaping or sound recordings, and whether the participant may opt out. Use of photos and audio recordings may involve obtaining consent during multiple stages of the project. For example, participants may be asked to consent to the final version of the photo, video or transcript of the recording that will be used in the project in addition to general project participation.

- **Future contact:** Indicate and explain if future contact is being requested. Separate consent is required for this request for future contact. Example: "May we contact you at a future date to ask you to take part in any other projects?" Yes ◯ No ◯

Are there any benefits to participating?

Benefits can include individual, community as well as societal benefits.[2] Summarize the potential benefits that the participant may reasonably expect as a result of participating as well as relevant details:

- **No direct benefit:** This should be stated clearly. Example: "You will not benefit from taking part in this project. However the results of this project may help us to better understand the mental health service needs of the LGBTQ2S+ community."

- **Test results** (e.g., diagnostic tests, psychological or social rating scales): Explain whether individual results will be shared with participants. Where applicable, the possibility of unexpected or 'incidental' findings should be included along with how reporting to the participant or a third party (with their consent) will be handled.

Are there any burdens or risks of harm from participating?

Burdens: include inconveniences such as travel to a project location, time required for lengthy questionnaires or time and effort needed to complete daily diaries for an extended time period.[2]

Harms: anything that has a negative effect on the welfare or interests of participants. The nature of the harm may be social, behavioural, psychological, physical or economic, and may consist of reputational harm to an organization or community.[2] With respect to each potential harm, indicate, when possible:

- probability (i.e., the likelihood of the harm occurring)
- magnitude (i.e., severity)
- expected duration
- potential impact to participants
- services or resources the participant may access to mitigate the harm (e.g., counselling or physician visit)
- in the case of participants recruited from an organization or distinct community, whether there has been collaboration or engagement in order to mitigate risks of reputational harm

Examples:

Harm from Nasal Swab

When we take a nasal swab, you may feel slight pressure or discomfort or a gagging sensation.

Emotional Distress

You may feel uncomfortable answering personal questions about your income or health. You do not have to answer these types of questions if you do not want to. If you feel upset at any time, project members will direct you to resources that can help.

Compensation

Participants should be informed whether they will, or will not be compensated for their time. Where participants are compensated for their time, state the monetary amount they will receive, the process

of disbursement (i.e., how and when the payment will be made) and that payment will be incremental (i.e., pro-rated) and not based on the completion of the project .[3]

Example:

The interviewer will provide you with [value of compensation] cash when you complete each of the three surveys. You will receive your compensation even if you decide to withdraw from the project.

Tokens of Appreciation

In some cases, tokens of appreciation such as gift cards/certificates, gifts (e.g., books) or food, may be a more appropriate method to recognizing the contributions of participants.[3] Gifts should be appropriate to the participant group, for example, a gift card for parents.

When using draws in lieu of compensation or tokens of appreciation, information on the prize(s) and its/their value, the probability of winning and the number of participants in the project, should all be provided.[4]

Example:

You will receive [sum of money/gift card value and type] as a token of our appreciation for taking part in the project. If you do not finish the project, you will still receive the token of appreciation.

Are there any costs to participating?

Participants should normally be reimbursed for direct or out of pocket expenses incurred due to participation. Examples of out of pocket expenses include, travel or parking costs, child or respite care, and in some cases food. Participants should be informed whether they will, or will not be reimbursed for their out of pocket expenses and if submission of receipts is required.[4] In addition, participants should be assured that their costs will be reimbursed irrespective of whether they decide to withdraw from participation in the project.

Examples:

There are no costs to you by participating in this project apart from your time and effort.

You will be reimbursed for travel and parking costs. Please submit receipts to the project coordinator during your interview to receive full reimbursement in the form of [cash or e-transfer].

Additional resources on best practices for compensating participants:

Wellesley Institute. Fair and inclusive compensation for research participants: a guideline. Toronto, ON: Wellesley Institute; July 2018. Available from: https://www.wellesleyinstitute.com/wp-content/uploads/2018/07/Fair-compensation-Guideline-.pdf

Becu, A and Allan, L. Peer payment standards for short-term engagements. Vancouver, BC: BC Centre for Disease Control; February 2018. Available from: http://www.bccdc.ca/resource-gallery/Documents/Educational%20Materials/Epid/Other/peer_payment-guide_2018.pdf

Canadian Centre on Substance Use and Addiction. Guidelines for partnering with people with lived and living experience of substance use and their families and friends. Ottawa, ON; Canadian Centre on Substance Use and Addiction; 2021. Available from: https://www.ccsa.ca/sites/default/files/2021-04/CCSA-Partnering-with-People-Lived-Living-Experience-Substance-Use-Guide-en.pdf

How will your information be protected?

Indicate the purpose(s) for which the potential participant's information is being collected, used and, if applicable, disclosed or reported. Also, indicate the steps taken to maintain confidentiality for each type of information (e.g., self-administered survey responses, samples, audio-recorded interviews or focus groups/group debriefings). This section should include the following information:

- Who will have access to personal or identifiable information at the various stages of the project?
- Whether there is a separate log linking identifiable participant information to participant project ID numbers (i.e., coded information), thus making it possible for information to be re-linked to a participant.[5]
- How security will be ensured in terms of collection, use, transportation and storage of participant information and/or biological samples.
- Whether the information is or will be identifiable, de-identified or anonymized, indirectly identifiable, and anonymous.[5]
- How long data or specimens will be stored and how they will be destroyed.
- Whether participants will have the option to consent to the disclosure of identifiable information to a third party (e.g., disclosing clinically relevant information to a participant's health care provider).

- Exceptions to confidentiality, such as when disclosure is required by law (e.g., reporting suspected child abuse, danger to self or others, reportable diseases). Where there is a reasonable likelihood that a disclosure may be required by law, this should be noted.

- Limits to the guarantee of confidentiality for focus groups, for example, state that while the project team is capable of promising confidentiality of information, no one can ensure that the other participants will observe each other's privacy.

- Limits to the guarantee of confidentiality for online survey tools, specifically, storage of information outside Canada. See appendices **C** and **D** for more information.

Examples:

Project involving personal Interviews

All information will be stored securely at PHO. Project information will be stored for [duration], and then destroyed/archived. Your information and the fact that you took part in this project will be kept private unless some disclosure is required by law. The project team will take steps to keep all of your information private. The chance that this information will accidently be given to someone else is small.

Project involving Reportable Diseases

Influenza is a contagious disease and must be reported by law. If you have a positive test result, we must send your full name and address to the local public health unit in your region.

Project involving identifiable information that a reasonable person would want to know

The project will involve a diagnostic test to determine whether you have coronary artery disease. With your consent, we will disclose this information to your health care provider. If you do not have a health care provider, we will provide you with a report.

How will findings or results of the project be shared?

Explain the plan for dissemination of project results, including:

- how the participant may be informed of the results when the project is complete (note that some form of reporting back to participants is required and the process of requesting results should not be difficult);

- possible methods of disseminating results; and

- how the participant's information will be used and disclosed in the project results (where applicable, whether quotes from participants will be used and the steps taken to ensure the quotes do not identify the participant or others or identifiable quotes will only be used with their consent).[6]

Examples:

We will write a paper and publish these results in academic journals. We may also share these results at public conferences, and with universities, hospitals or other agencies.

Where applicable, note that a summary will be provided if participants provide their contact information.

What are your rights to not take part or withdraw?

- Clearly explain that participants have a right to withdraw from the project at any point, how they can withdraw (e.g., by contacting the project contact) and how their information will be withdrawn (e.g., their information or biological materials will be destroyed immediately upon request). If applicable, remind participants they can skip any questions they do not wish to answer.

- Participants should be advised of any potential circumstances which would cause early termination of the project as well as circumstances that would result in their withdrawal by the project team (e.g., if the participant no longer meets study eligibility requirements).

- Limits to withdrawal should also be explained (e.g., individual level data can't be withdrawn when using anonymous data)

Examples:

You have the right to choose to take part or not take part in the project, or stop at any time. Your choice will not affect [participant's situation, e.g., employment, access to agency services, relationship with the project team]. If you decide to participate and change your mind later, you are free to withdraw. You may stop taking part at any time by contacting [the project contact]. You may receive new information during the project that is important to your decision to continue or stop taking part.

If you decide to stop taking part, your information will be destroyed unless it has already been grouped with other results.

After we group all results together without names, we cannot remove your information.

Conflict of Interest (if applicable)

The TCPS2 states a conflict of interest may arise when "activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to the research and personal, institutional or other interests."[7] Conflicts may arise from any role held outside the project, including consultant, employer, supervisor or caregiver, which might create conflict with the role of a project member. Benefits which may create a conflict of interest need not be purely monetary in nature.

Project leads must identify and declare their own actual, potential or perceived conflicts of interest, as well as those of every member of the project team. This declaration should include:

- the identity of the persons with the conflict of interest;
- the type of interest (e.g., professional, commercial, financial, personal);
- the source of the interest or benefit (if applicable, as in the case of financial benefits); and
- a description of how the conflict will be managed.

Example

X is working on this project, which is evaluating a service. X is also one of the staff who provides the service being evaluated. This may create a conflict of interest for X because of their different professional obligations. X will not be involved in the data analysis.

What if you have more questions about the project?

Please contact [project lead] at xxx-xxx-xxxx or xxx@xxx if you have any questions or concerns about taking part in this project.

What if you have questions about your rights as a participant?

Include a statement indicating the project has received ethics clearance from the Public Health Ontario Ethics Review Board.

Example

This project has received ethics clearance from the Public Health Ontario Ethics Review Board. When you agree to take part, you keep all your legal rights. If you have any questions about ethical issues in this project, you may contact the Research Ethics Coordinator, by e-mail at ethics@oahpp.ca or by phone at 647-260-7206.

Documentation of Consent

The TCPS2 2022 (Article 3.12) requires that consent be documented, either in a signed consent form or in documentation of another appropriate means of consent (e.g. implied consent and verbal consent).1 For more information on the different methods for obtaining and documenting consent, refer to Appendix A: Consent Process Guide.

- When documenting any form of consent (written, verbal or implied), consider the following:
    - Include a paragraph that reminds the participant of the voluntary nature of participation and that by consenting, participants have not waived any rights to legal recourse in the event of project-related harm.
    - **Do not** add any new information to this section that has not already been discussed in the information form.

- **Do** add tick boxes to confirm consent in specific areas (e.g., I agree to be video-taped; I agree to be contacted for future studies; I agree to the use of identifiable quotes).
- Include a statement indicating the belief that the participant understood and appreciated the information and that the participant received a copy of the form.
- The person who obtains consent should sign the form, indicating their name and role.

Appendix A: Consent Process Guide

TCPS 2 (2022) provides that consent must be informed and voluntary, and "shall be an ongoing process" that begins at recruitment and continues until the end of a participant's involvement in a project.[1] The informed consent process involves education and information exchange between the project team and the potential participant. This document provides an overview of important points and stages in the process of obtaining ongoing informed consent.

Consent process goals

The goals of the consent process are as follows:

- Give participant adequate information concerning the project.
- Provide adequate opportunity for the participant to consider all options.
- Respond to the participant's questions/concerns.
- Ensure that the participant understands the information about the project and appreciates the potential consequences of their decision to participate or not participate (i.e., determine decision making capacity).
- Obtain the participant's voluntary agreement to participate.
- Continue to provide information as the participant or situation requires.
- Continue to assess whether the participant wishes to participate or withdraw.

As the project team moves through the consent process, they should evaluate whether these goals are being achieved.

Answer AND ask questions

It is critical that project teams not only answer questions, but ask questions. Asking questions can further the discussion, elicit questions from the potential participant, prompt the potential participant to think more carefully about the project, and help the project team to decide whether the person has adequately understood the project and appreciated the consequences of their decision to participate or not.

Useful questions will be open-ended. Rather than asking for yes or no answers, ask questions that can be answered in a variety of ways, and do not already contain the correct answer.

Examples:

"Just so that I'm sure you remember what is expected of you, would you please explain to me what you think we're asking you to do?"

"What more would you like to know?"

"What interests you about participating in this project?"

“What do you think about [the subject being investigated]?”

"What would you do if you had questions or wanted to withdraw from this project?”

The consent process begins at recruitment

The consent process should begin when making initial contact with a potential participant. The project team member who makes contact should:

- Introduce themselves
- Give a brief description of the project and ask potential participants open-ended, related questions (e.g., if the project is about activity levels, you could ask “how do you feel about exercising/sports/being outdoors?”) This will allow you to begin assessing their language capacity and understanding.
- Begin asking questions touching on eligibility.
- Ask if it is all right to provide further information about the project, e.g., by providing link to a website or by delivering consent documents.
- Ask if the potential participant has any questions at that time.
- Provide a phone number or email contact and encourage them to call if they have questions after receiving the consent documents.

The consent process includes the method for providing information

Providing information in several different formats may assist with comprehension and memory. Aside from the written consent information form, information can be provided in many forms, including

- A link to a website or online FAQ
- A pamphlet that includes a brief overview of the project and project contact number
- Charts or diagrams
- A slide presentation or other audio-visual materials

Timing and setting are part of the consent process

It is important that the investigator give the potential participant time to read and consider the consent form information.

- The right amount of time will depend on the complexity or sensitivity of the project tasks or questions.
- Participants should be encouraged to ask any questions they might have during the time given to read and absorb the information.
- The setting for the discussion should be private and free from distraction: either a private room at the project site or a private area at the participant's home/school.

The project team member must assess comprehension and voluntariness before obtaining consent

Even if the potential participant has read the consent form or online materials, and even if they indicate they have done so and had ample time to do so, the project team member must ensure that the potential participant understands and appreciates the consequences of participating. Go through each section of the consent form with the participant.

- After each section, ask open-ended questions about what you have just gone over.
- Ask if they feel okay with what has been said, if they understand and still want to participate.
- Use an open-ended question to ask if they understand what has been read, e.g., "What other questions do you have?" instead of "Do you have any questions?"
- Describe the risks involved and ask them how they feel about them.
- Be alert to verbal or non-verbal signs that the potential participant does not understand, is not alert or feels anxious or uncomfortable.
- Be alert to signs of therapeutic misconception where a subject misconstrues the purpose of the project as providing a direct benefit. There are many factors which promote therapeutic misconception such as the way the information is presented (e.g., as an "opportunity to participate") or by whom (e.g., a public health nurse who has both treatment and project team responsibilities.)
- Re-iterate that participation is voluntary and they may refuse to answer any question or perform any task they don't want to.
- High risk projects may require project teams to allow participants sufficient time to decide whether they want to participate, and, if they wish, to consult with family or others.

Consent must be documented

The TCPS 2 2022 (Article 3.12) requires that consent be documented, either in a signed consent form or in documentation of another appropriate means of consent (e.g., implied consent and verbal consent). For example, if consent is obtained verbally or demonstrated solely by the action of the participant (e.g., through the completion of an on-line survey or participating in a focus group), the procedures used to seek consent must be documented. Determining the appropriate means of consent will depend on the type of project, (e.g., high versus low risk), and the types of groups or participants involved. For example, certain groups in vulnerable circumstances (e.g., HIV/AIDS community) may feel uncomfortable signing a formal document that could put them at risk by identifying them. A low risk project involving an on-line survey may only require implied consent where the participant demonstrates consent by completing and submitting the survey (See appendices **C** and **D** for more information and templates).

Project teams can consult with PHO's Ethics Services for help on determining the appropriate means of obtaining and documenting consent for their project.

The consent process is ongoing, even after consent has been given and documented

The consent process must continue after the potential participant has given their consent. This is true whether the participant's involvement is over a short time period (e.g., an hour-long survey) or over the course of several days, weeks or months. Even if no new information or change arises in terms of what the participant is being asked to do, the investigator must reaffirm that consent is still valid, for example:

- Pause during an interview to ask how the participant is feeling and if they wish to continue.
- Alert the participant before asking any especially sensitive question(s) and warn them that it may trigger negative feelings, e.g., "Now I am going to ask you about [x], which sometimes makes people not feel very good. Are you still okay with my asking?"
- Remind them that participation is voluntary and they may refuse to answer any question or perform any task they don't want to.

Appendix B: Information Letter and Consent Form Template

Project Title:

Introduction:

You are invited to take part in a project. The project is being led by [project lead] at [if at PHO: "Public Health Ontario. Public Health Ontario (PHO) is a Crown corporation dedicated to protecting and promoting the health of all Ontarians and reducing inequities in health" or name of PHU]. The project is being funded by [name of funding institution].

[Project lead's contact information].

Your participation is voluntary. Your decision whether or not to take part will not affect your [participant's situation, e.g., employment, access to agency services, relationship with the project team]. If you decide to take part and change your mind later, you are free to withdraw. Before you agree to take part, it is important that you consider the information in this form. It includes details that will help you decide if you wish to take part. If you have any questions or concerns regarding this project, please speak to project staff listed at the end of this form.

What is the purpose of this project?

What will your participation involve?

Are there any benefits to taking part?

Are there any burdens or risks involved?

Are there any costs to you?

There is no cost to you to take part in the project apart from your time and effort.

Or: Your [type of expense] costs will be reimbursed. Even if you do not complete the project your costs up to the date you withdraw will still be reimbursed.

Will I receive compensation or a token of appreciation?

How will your information be protected?

Your (identity and the information you provide) will be kept confidential unless reporting is required by law (e.g., suspected child abuse, danger to self or others, certain diseases).

The project team will take these steps to protect your identity and keep all information confidential: [list steps]. The chance that this information will accidently be given to someone else is small.

How will project results be shared?

What are your rights to take part or not take part?

You have the right to choose to take part or not take part in the project, or stop at any time. You may stop taking part at any time by contacting [the project contact]. You may get new information during the project that is important to your decision to continue or stop taking part.

- If you decide to stop taking part, your information will be destroyed unless it has been grouped with other results.
- After we group all the results together without names, we cannot remove your information.

Conflict of Interest:

What if you have questions about the project?

Please contact [project contact] at [project contact email address] or [project contact phone number] if you have any questions or concerns about taking part in this project.

What if you have questions about your rights as a participant?

This project has received ethics clearance from Public Health Ontario's Ethics Review Board.

When you agree to take part, you keep all your legal rights. If you have any questions about ethical issues related to the project, you may contact the Research Ethics Coordinator, by e-mail at ethics@oahpp.ca, or by phone at 647-260-7206. [Or if project is reviewed by a different REB, list the correct contact information.]

Documentation of consent:

Signature:

The project has been described to me. I have had enough time to consider whether or not to participate. Any questions that I had have been answered in full and I have received a copy of this information and consent form.

I consent to participate.

_____

Name of Participant (Please Print)

_____ _____

Signature of Participant Date Signed

I described the project to the participant and answered their questions. I believe the person signing this document understands and appreciates what is expected with regard to participation. I have given a copy of this information form to the participant.

_____

Name of Person Who Obtained Consent (Please Print)

_____ _____

Signature of Person Who Obtained Consent Date Signed

Appendix C: Anonymous and Low Risk Online Surveys Template

The following template can be used as a guide to help develop information and consent sections of online surveys that are anonymous and low risk. As part of developing the information and consent section of your survey, it's important to consider the following:

- Anonymous surveys do not involve the collection of direct or indirect identifiers.[5,9] Direct identifiers include any of the following identifiers on their own: name, email address, street address, phone number, IP (Internet Protocol) address of computer or any other unique identifier (e.g., OHIP number).[5,8] Indirect or "quasi-" identifiers include a combination of information that can be used to re-identify a survey participant, for example, date of birth, gender and full postal code or any other piece of information that can identify the individual (e.g., job title and organization).[9] These are partial lists; many other data elements can be direct or indirect identifiers.

- Survey platform features that track individuals and collect identifiers from individuals outside of your survey should be turned off to anonymize the survey.

- If the project involves collecting participant contact information (e.g., name and email address) for the purposes of (a) providing compensation, or (b) providing consent for future contact (e.g. to participate in a future project, share project findings or follow-up with participants), a separate survey should be used without any reference to the main survey or project.[8,9]

You are invited to take part in an online survey about [topic of project]. The information collected from this survey will help us [purpose of project]. You are receiving this invitation because [reason invitee was selected for participation]. This project is being led by [project lead] at [project lead's institution].

- Your participation in this survey is voluntary and your responses will be anonymous.

- You can withdraw from the survey at any time by stopping the survey. Once you have submitted the survey, you will not be able to withdraw your responses.

- The survey will take [duration] to complete and can be completed on or before [date].

- We will ask you questions about [general topics covered by survey questions]. You can skip any questions you don't want to answer.

Information in connection with your response to the survey will be stored on a secure sever at [institution] and is governed by [institution or survey platform] Terms of Use.

We will publish the findings in a [report, article in an academic journal or institution's public facing website]. We may also share these findings at/with [public conferences, and with universities, hospitals or other agencies].

A copy of the report/findings will be available to survey participants [if through a website, provide link or participants can contact project team].

If you have any questions regarding the survey, please contact [name, telephone and email of contact person].

This project has received ethics clearance from Public Health Ontario's Ethics Review Board. If you have any questions about ethical issues related to the project, you may contact the Research Ethics Coordinator, by e-mail at ethics@oahpp.ca, or by phone at 647-260-7206. [Or if project is reviewed by a different REB, list the correct contact information].

By completing and submitting this survey, you are providing your consent for participation.

To participate, please go to: [*hyperlink*]

Appendix D: Low Risk Online Surveys Collecting Identifiable Information Template

The following template can be used as a guide to help develop information and consent sections of online surveys that are low risk and collect identifiable information and/or use open-ended questions. As part of developing the information and consent section of your survey, it's important to consider the following:

- Where the project requires that the survey collect identifiers (either direct or indirect identifiers), the reason for collecting this information and assurances of confidentiality should be outlined in the information letter and consent text.
- Surveys using open-ended questions are considered potentially identifiable because survey respondents might include identifiable information in the free text response.
- If the project involves collecting participant contact information (e.g., name and email address) for the purposes of (a) providing compensation, or (b) providing consent for future contact (e.g. to participate in a future project, share project findings or follow-up with participants), a separate survey should be used without any reference to the main survey or project.[8,9]

You are invited to take part in an online survey about [topic of project]. The information collected from this survey will help us [purpose of project]. You are receiving this invitation because [reason invitee was selected for participation]. This project is being led by [project lead] at [project lead's institution].

- Your participation in this survey is voluntary and you can withdraw from the survey at any time by stopping the survey and logging out or by contacting the project contact below.
- Withdrawal may not be possible once the survey responses have been combined with those of other participants.
- Your decision to participate or not and your feedback will not have any impact on [your future participation in programs, services received by your public health unit, or employment].
- The survey will take [duration] to complete and can be completed on or before [date].

We will ask you questions about [general topics covered by survey questions]. You can skip any questions you don't want to answer. We are also asking for your [indicate identifier] to help us [indicate reason]. [If using open-ended questions] In the open-ended questions, please do not volunteer any information that may identify you or others.

The project team will keep your information confidential. Information in connection with your response to the survey will be stored on a secure sever at [institution] and is governed by [institution or survey platform] Terms of Use. Your information will be retained for [include institution's retention schedule].

Access will be limited to survey administrators and project staff involved in this project. Any information you give that might identify you [and/or organization] will be removed by the project team prior to being used or disclosed [OR] your responses will be kept separate from any identifiable information.

We will publish the findings in a [report, article in an academic journal or institution's public facing website]. We may also share these results at/with [public conferences, and with universities, hospitals or other agencies].

A copy of this report will be available to survey participants [if through a website, provide link or participants can contact project team].

If you have any questions regarding the survey, please contact [name, telephone and email of contact person].

This project has received ethics clearance from Public Health Ontario's ethics review board. If you have any questions about ethical issues related to the project, you may contact the Research Ethics Coordinator, by e-mail at ethics@oahpp.ca , or by phone at 647-260-7206. [Or if project is reviewed by a different REB, list the correct contact information].

By completing and submitting this survey, you are providing your consent for participation.

To participate, please go to: [hyperlink]

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