***HEALTH RESEARCH ETHICS BOARD***
***INFORMED CONSENT FORM (ICF) TEMPLATE***

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| --- |
| ***INSTRUCTIONS TO RESEARCHER**** *This is a template that contains a combination of suggested wording and instructions*

*for content. Instructions and guidance are provided in blue, italicized and underlined font. Links are provided in grey, italicized, and underlined font.* * *Prior to submission, delete everything in grey and blue italicized and underlined font unless the wording is required for your study.*
* *If you are conducting a clinical study (involves an invasive clinical procedure, investigative drug, or medical device), please use the BC Clinical Research Informed Consent Form Guide and Template https://healthresearchbc.ca/?s=template*
* *Font: Depending on your study population, consider using a larger font size.*
* *Reading Level: Ensure that you use simple, lay language. Use the Flesch-Kincaid readability test in Microsoft Word to assess and ensure it is at a maximum Grade 8 reading level:* [*Get your document's readability and level statistics - Microsoft Support*](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2)
* *Spell out all acronyms at first use.*
* *Number the pages and include the current* ***Version Number, Date and your Ethics ID***

***Number*** *in either the header or the footer of every page.* * *Check that everything is gender neutral, especially when pregnancy related (use “they” instead of “she” or “he”)* [*Guidance: Using Gender Inclusive Language In Research*](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiZ54WtreyNAxW-IzQIHRABEeMQFnoECBcQAw&url=https%3A%2F%2Fdhr.research.northeastern.edu%2Fwp-content%2Fuploads%2F2023%2F05%2FUsing-Gender-Inclusive-Language-04.21.2023.pdf&usg=AOvVaw3vdKjhKDWDrN20ETZx-qBB&opi=89978449)
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***ENTER STUDY TITLE HERE***

**PARTICIPANT INFORMATION & CONSENT FORM**

**PRINCIPAL INVESTIGATOR AND STUDY TEAM:**

Principal Investigator (PI) Name and Affiliation/Title:

Address:

Phone Number:

Email:

*The contact information for* ***all*** *researchers should be listed here (Co/Sub-Investigator, Research Coordinator/Assistant, etc.)*

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## What Is the Background and Purpose of this Study?

You are being invited to participate in a research study. You cannot be required to participate if you do not want to do so (this is known as free and voluntary consent). You have the right to stop your participation in the study at *any* point. You may stop your participation in the study without providing a reason for the researcher. The purpose of this study is to: *Briefly state the background and purpose of the project in lay terms. Describe why the project is important and the contributions it hopes to make.*

**You Are Being Asked to Participate in This Study Because You Meet the Inclusion Criteria:**

## *Provide a description using inclusion and exclusion criteria to describe how people may or may not meet the study’s participation requirements. You can use a bulleted list or present it in sentences. Note: the* *age of majority in BC is 19 years of age. If it is not obvious, include how the participant has been invited to the study by stating how the researchers got their contact information, “we received your information through/via…”*

## Inclusion Criteria:

*State here whether participants need to already own their own mobile devices and data plan to join the study.*

Exclusion Criteria:

## Location of Research

This research study will be conducted:

*Include the location or locations where the study will be conducted.*

## Number of Participants

*Insert number* participants will be included in this study, including *insert* *number* participants from this region *(city, town, jurisdiction, province, etc.)*

## Project Funding

This project is funded by *include the full name of the study funder, granting agency, sponsor, or scholarship, and name of recipient if applicable. If not funded, exclude this entire section, including the heading “Project Funding”*

You may ask the PI for any information about this if you have any questions.

**What Will You Do as A Participant in This Study?**

If you decide to participate in this study, you will *describe the participant-related activities during the study; include description and number of interviews, surveys, etc., number of visits, time required per visit, when each visit/interview/survey will occur (for example at 3,6, & 9 months) and* ***total*** *time for participation in the study****.***

*Please list research activities in the order that the activities* *will occur. You may use bullet points, a chart/figure, or table – whichever format is best for participants to understand.*

*For studies that include different activities at different time points, consider presenting the information in table format or diagram format. This may be easier for participants to understand.
 If information is to be accessed, collected, and shared from the participants’ health or client record, briefly state it here and then* *state see “Confidentiality & How my Personal Information will be Used” section on Page # for more details.*

*Example: “For details about how information about you will be accessed, collected, used, or shared, see the section “Confidentiality & How my Personal Information will be Used” section on Page #.*

***Research Involving Patients (if applicable)***

*If you are conducting a study that involves your patients, describe the difference between participating in the study and routine care. Clarify that their participation in the study will not affect their access to and quality of routine care, even if they choose to leave the study (e.g. “If you decide not to participate, your regular health care or service will not be affected in any way”).*

***Research Involving Staff (if applicable)****:*

*Describe the research activities that differ from the daily activities of staff including the time commitment, and location where the research activities will occur. For staff-participant research, state whether the research activities will occur during work or personal time. Note that if others (Directors or Managers) are aware of the staff member participating in the research, you must identify this as a “Limit to Confidentiality” to participants.*

***Interviews or Surveys (if applicable):***

*Describe the nature of the information/data to be collected as part of the interview or survey. Include a couple of example questions so that participants are fully informed and understand what to expect. Mention whether participants will be asked any sensitive or personal questions, such as sexual orientation, history of substance use, and adverse childhood experiences (ACE).*  *Mention how this will be mitigated or supported in the context of the research. If questions are likely to stimulate emotional responses, mention that a list of mental health resources will be provided.*

*If a survey is involved, include a statement that the participant can decline to answer any question, should they choose. If some questions are mandatory, the number should be explicitly stated and, if applicable, described, so that the participant can decide whether to participate or not (e.g., you MUST indicate your address to participate)*

***Focus Groups/Group Activities/World Café (etc.) (if applicable):***

*Describe the nature of the information/data to be collected as part of the focus group/group activity/World Cafe. Please identify who on the study team will lead the focus group, any relevant qualifications they may have, and any attendants, observers, photographers, or intentions to record and/or transcribe the sessions. Include a few example questions.*

*Please note that while focus group participants will be requested to maintain confidentiality related to all discussions, confidentiality cannot be guaranteed due to the nature of group-related research activities.*

## What are the Possible Risks or Inconveniences of Participating?

You may be exposed to the following risks and inconveniences:

*Describe all relevant risks (e.g. physical, psychological, social, emotional, professional, financial). Any triggering, distressing, or discomforting questions should be mentioned here. Describe any risks to communities (e.g. stigmatization, discrimination, etc.). Consider consulting any groups that may be affected by the research to assess the risk of negative impacts such as stigmatization and discrimination. Describe any inconveniences to participants (distance to travel, daily logs etc.) and note that costs/reimbursements for research related activities are discussed below. If applicable, mention any possible work-related impacts/risks for participating in staff research. If applicable, mention the risk of data disclosure and whether data will be anonymized or de-identified and how this will be done.*

*Note to participants that by agreeing to participate, they are not giving up their right to legal recourse in the event of research-related harm (e.g. “by consenting, you have not waived any rights to legal recourse connected to research-related harm”).*

To reduce these risks, the following steps will be taken:

*Describe how the risks will be mitigated or addressed.*

## How Do I Withdraw from the Study?

*Include who participants should contact to withdraw from the study. Clarify that they may withdraw from the study at any time with or without explanation (e.g. “if you do decide to participate and then change your mind later, you can withdraw without any consequences or explanation”).*

*Clarify what will happen to participants’ data that has already been collected. Describe limits to withdrawing. For example, if the data is de-identified or anonymized, and there is no crosswalk between the study identifier and participant identity maintained, it may not be possible to re-identify a specific participant and remove them from the dataset. If this is the case, then researchers should provide a rationale to the REB for why they are using collection methods that do not allow subsequent withdrawal of data.*

*Describe why/when a participant will be removed from the study (this is so participants are prepared and informed in the event that they are removed from a study).*

## What are the Benefits of Participating?

*State whether there will be direct benefits (for example, the research participant experiences amelioration of a health condition or learns new information about social issues as a result of participation in a research focus group). Clarify explicitly if there will* ***not*** *be direct benefits. Please note that incentives are not a direct benefit. Benefits to collectives, groups, society at large, or the scientific enterprise are also not direct benefits to the individual research participant and should not be conflated as such.*

The possible benefits of your participation could include:

*State benefits to the participant and possible future benefits to others in similar circumstances. Researchers should state what (if any) helpful opportunity or intervention the participant will receive during the research project in the case that it would not be available to them outside of the research project. In the case that there is a placebo or control group, researchers should state which possible benefits will be withheld from some of the participants (e.g. those in the placebo or control group). Researchers might include the possibility of indirect benefits. These are outcomes that arise from the study but are not the primary goals of the study itself.*

*It is important not to overstate the benefits of the research or promise direct benefits to participants when unlikely or unknown. Researchers can insert possible benefits to participants, but they might also clarify that most research is not plausibly of direct benefit to the participants. Researchers might word this as, “There is unlikely to be any direct benefit to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit others.” Do not include reimbursements/honoraria/thank you’s here. The template includes a section for these below.*

*That there are* ***no*** *benefits to participation is an acceptable answer. If so, please be explicit that there are none.*

## Do I Have to Take Part?

***Research Involving Patients (if applicable)***

*Include the following:*

You are free to choose whether to participate or not. If you decide not to participate, your regular health care or service will not be affected in any way. By consenting, you have not waived any rights to legal recourse connected to research-related harm. If you do decide to participate and then change your mind later, you can withdraw without any consequences or explanation. If you do withdraw from the study, we will go over the options with you regarding what will happen to your collected data.

***Research Involving Staff (if applicable)***:

*Include the following:*

You are free to choose whether to participate or not. If you decide not to participate, your employment status will not be affected in any way. By consenting, you have not waived any rights to legal recourse connected to research-related harm. If you do decide to participate and then change your mind later, you can withdraw without any consequences or explanation. If you do withdraw from the study, we will go over the options with you regarding what will happen to your collected data.

*For both research involving patients and staff, a clear statement is required from researchers if data collected (e.g. surveys, interviews) to date will be used. It should also be stated if there are limitations and if data already collected cannot be removed. Participants should be informed of this prior to participating in the study.*

## Will You be Paid to Take Part?

*Payment, financial or otherwise, should be clearly outlined on the consent form. Payment should not be dependent on completion of the project but can be pro-rated for those who withdraw before completion.*

*If funding is available to cover the costs of out-of-pocket expenses such as travel, parking, childcare cost, include the following:*

We will reimburse any costs that you incur as a result of participating in this research study, including *specify transit, travel, parking and childcare costs, if applicable.*  If you decide to withdraw early, we will still reimburse you for the costs you incur until your withdrawal date.

*If studies will acknowledge participation with a stipend or gift etc. include the following:*

To thank you for your time and participation, you will be given *specify what will be given as a thank you, if applicable. Delete* *entire line if not applicable*. This is not meant to influence your decision to participate.

*If studies will not reimburse or provide a stipend etc. Include the following:* You will not be provided with any payments or coverage of costs for participating in this study

Researcher’s Relationship with Participants *(remove if not applicable)*

*Please declare whether you have a Dual Role or are in a Power-Over role with participants. You must also provide steps to mitigate this role; this should be outlined to participants*

*Dual Role: When the researcher has a pre-existing relationship with participants (i.e. a physician who is conducting research with patients; a manager who is conducting research with employees, employees conducting research with colleagues)*

*Power-Over Role: Any relationship where the researcher has some kind of power over the participant. This Power-Over may be used unintentionally or intentionally to influence an individual to be recruited or participate in a research activity that they would not otherwise participate in if there was no power influencing their decision making.*

As the researcher, I have a *specify whether you have a dual or power-over role over participants and describe the nature of this role.* To help prevent my relationship from influencing your decision to participate, the following steps have been taken: *Describe steps taken to mitigate any power-over or dual relationships or any other ethical issues. Add similar statements if applicable to Co-Investigators or other team members.*

## On-Going Consent

Each unique research activity will require your ongoing consent. This means that researchers will bring to your attention any changes to the research project that may affect you. This gives you the opportunity to consider whether you would like to continue to consent in light of new information.

## Confidentiality & How Your Personal Information will be Used

*If identifiable or potentially identifiable information is to be accessed, collected, used or shared from the participants or from their health or client record the following must be clearly stated:*

* *How the participant’s information will be accessed, collected, used and shared;*
* *All types of information being accessed, collected, used, and shared (Make sure that the information that you include here MATCHES exactly what you state you are collecting in your protocol. If it does not, questions will be raised by Island Health’s REB and by the Information Stewardship, Access & Privacy Office. For questions, contact Privacy@islandhealth.ca);*
* *Who on the study team and externally (transcriptionists, contract statisticians) will have access to the participant’s information.*
* *Where the information is being accessed and/or collected from (e.g., your Island Health* *health record, your Island Health electronic health record);*
* *If, with the participant’s consent, data collected during the research will be retained and later shared with other researchers or open access depositories for future research, describe this intent and have them fill out the second consent form for future use of data*
* *If personal information is being coded/de-identified or anonymized at any point, describe when and how it will be de-identified or anonymized (e.g., if it is being coded/de-identified after it leaves Island Health, this must be clearly stated to the participant). Include a statement that identifies if any linkages are being made (if applicable) between the participants’ information at Island Health and other sources of information about them.*
* *If information is being stored or accessed from outside of Canada, participants must explicitly consent to it. They should know what country it is being stored in or accessed from, the name of the organization, the purpose for which it is being sent to that country and be notified that laws in that country may differ from those in BC and Canada with respect to how their information is accessed, collected, used and shared. Use suggested wording below if applicable:*

The data collected on you for this research project will be stored in [enter name of country] at [enter name of organization] for the purpose of [enter reason]. For information that is stored or accessed from outside of Canada, Canadian & BC privacy laws may not apply, and it is possible that your information could be accessed without your knowledge or consent by that country’s government or other organizations in accordance with their laws (e.g., the USA Freedom Act, formerly known as the Patriot Act in the United States).

## Data*Data Definitions:*

* + *De-identified Data/Coded Data: Does not contain any personally identifiable information. Study code numbers or pseudonyms are used in place of participant names.*
	+ *Anonymized Data: Personally identifiable information was collected but has now been irrevocably destroyed; no linking of data to participants is possible.*
	+ *Anonymous Data: No identifiers were ever collected. Researchers do not know who the participants are.*

## Future Use of Data

*Make it clear whether you would like to use participants' data in the future and direct them to the second consent form template for future use of data. Separate consent forms are required by TCPS2 Article 3.13.*[*https://ethics.gc.ca/eng/tcps2-eptc2\_2022\_chapter3-chapitre3.html#a*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#a)

*Suggested wording:* We are interested in using the data collected from this study in the future. However, permitting the future use of your data is **optional.** You will not be excluded from this study if you choose not to allow your data to be used in the future. In the case that you consent, please carefully review and sign the separate and second consent form for future use of data.

**Technology We Will Use in This Research That Could Impact You**

*If an interview or focus group is audio-recorded or video-recorded, include a statement with this information and details on who will complete the transcription and when the recording will be destroyed. Include special precautions taken to protect the security/confidentiality of video recordings.*

*Include a statement that for participants who choose to withdraw after they begin* *focus group activities, it will be logistically impossible to remove individual data from a group session.*

*Include a statement that “While focus group participants will be requested to maintain confidentiality of all focus group discussions; confidentiality cannot be guaranteed.”*

## New Research Tools

## *Clarify the kind of research tools you will be using in the study (Zoom, Microsoft teams, e-diary, apps, electronic devices, etc.) and state whether these tools will be provided by the study team or if the participant is expected to use their own. Make it clear to participants what kinds of data may be incidentally captured or assessed by the app (e.g. contacts, location data). Use the template below if applicable (Examples included for illustrative purposes only, please fill in information specific to your study)*

|  |  |  |
| --- | --- | --- |
| Tool/App/Software  | How Will You Use It | What You Need to Know |
| *Zoom or MS Teams Teleconference* | *Participants will interview with researchers on this platform* | *How to use Zoom or MS*  |
| *Mobile Symptom Tracker App* | *Participants will log their symptoms on a bi-weekly basis into this app* | *This app may store personal data in the United States, and so may be subject to disclosure to their government under the U.S. Freedom Act (formerly The Patriot Act). How to use the Mobile Symptom Tracker App* |
| *SPSS (Statistical Package for the Social Sciences* | *Research data will be inputted to data analysis, statistical modeling, and visualization*  | *SPSS does not store personal data and has no direct sharing of data with third parties.* |

## *For any research that involves a mobile device or app, please ensure you research complies with this check list:* [*islandhealth-mobile-app-checklist-template-2024.docx*](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.islandhealth.ca%2Fsites%2Fdefault%2Ffiles%2Fresearch-ethics-and-approvals%2Fislandhealth-mobile-app-checklist-template-2024.docx&wdOrigin=BROWSELINK)

## Disposal of Data

Your data from this study will be disposed of in the following manner: *(examples included for illustrative purposes only, please fill in information specific to your study)*

|  |  |  |
| --- | --- | --- |
| **Data Source** | **How Will It Be Destroyed** | **When Will It Be Destroyed?** |
| *Digital documents* | *Permanently destroyed (double deleted)* | *These will be retained for XX (number) years after study completion. (If applicable: “This is required by my funding agency”.)* |
| *Paper notes/data* | *Confidentially shredded* | *Immediately following transcription* |
| *Interview notes* | *Confidentially shredded* | *These will be retained for XX (number) years after study completion. (If applicable: “This is required by my funding agency”.)* |

**Who Will Have Access to My Data?** *(Remove if not applicable)*

*Including this table is recommended for studies regarding sensitive topics like intimate partner violence, HIV, or substance use.*

|  |  |
| --- | --- |
| **Who Can Access My Data?**  | **What Can They Access?**  |
| *Name, Academic Affiliation, Email, Study Team Role* | *Can access raw data, interview transcripts, consent forms, etc.* |
| *Name, Academic Affiliation, Email, Study Team Role* | *Can only access de-identified data for analysis* |

## Sharing of Study Results

A summary of the study results will be provided to you [by e-mail/phone/mail] by [projected date]. The study results will also be published and presented to *(provide details on dissemination of study results. Include possible website address. Remove entire sentence if not applicable).* To be added to a mailing list to receive additional results of this research, please sign up by emailing [study team email].

## Commercial use of Results

This research may lead to a commercial product or service. *(If applicable, describe the relationship* *to the investigator and research team members. Describe whether and how financial benefits will be shared with participants. For the repurposing of knowledge acquired through research participants, groups, and/or First Nations communities, please consult TCPS2 Article 9.18.*[*https://ethics.gc.ca/eng/tcps2-eptc2\_2022\_chapter9-chapitre9.html#a*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html#a)

*Research participants may be legally entitled to commercial products or services developed through research activities. Delete section, including the heading, if not applicable)*.

## Who Should You Contact if You Need More Information About the Study?

The contact information for the Principal Investigator is provided on the first page of this Informed Consent Form. *If applicable, include the research coordinator or other study team member who will serve as a contact for participants as well by including the name, and telephone number/email address.*

**Contact for Complaints and Support**

For complaints and support about your rights as a research participant, please contact the Island Health Research Ethics and Compliance Office in Victoria at (250) 519-6726 or email: ResearchEthics@islandhealth.ca.

## CONSENT

My signature below indicates that:

1. All sections of this Informed Consent Form (ICF) have been explained to my satisfaction
2. I understand the requirements, potential risks, benefits, and responsibilities of participating in the research project, and;
3. I understand how my information will be accessed, collected, and used.
4. I understand that I can withdraw any time;

*Researchers: ensure you state if data can or cannot be withdrawn*

1. All of my questions have been fully answered by the researchers.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |   |  |  |
| Name of Participant |  | Signature  |  | Date |

 (print)

## EXPLICIT CONSENT FOR RECORDING (OPTIONAL) *(Remove if not applicable)*

## My signature below indicates that I give permission to be recorded and (check all that apply):

## I consent to being recorded during my participation in [x] research activities.

## I would like my full name to be anonymized in any publications in which I am quoted.

* I would like my full name to be used in any publications in which I am quoted.
* I would not like to have any direct quotes of mine used in publications.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |   |  |  |
| Name of Participant |  | Signature  |  | Date |

 (print)

*A blank Informed Consent Form (ICF) may be emailed to participants, but participants should not be emailing back a signed ICF. Doing so may pose a threat to the confidentiality and privacy of participants. Researchers who email blank ICFs typically collect and log the oral/verbal consent of participants. If written consent negatively impacts the participant’s welfare, or poses a threat to their confidentiality, ICFs do not need to be signed – verbal consent may be collected. If collecting verbal consent at the start of the interview or focus group, adjust the “signature” line on page 10 to read “verbal consent”. If appropriate, create a consent log (collecting name, date and time verbal consent was collected, and name of individual collecting consent.) A consent log may not be appropriate in all cases if this poses a threat to participant confidentiality. Consent may be inferred by the participation of the individual.*

***One copy for you.***

***One copy for the researcher*.**