

## Informed Consent

### Additions for COVID-19 and In-Person Research (Template)

*Researchers Note: This form is additional to the regular consent form and not a substitute*

Study Title: Click or tap here to enter text.

REB #: Click or tap here to enter text.

Principal Investigator (Name and contact information): Click or tap here to enter text.

The health and safety of both research participants and researchers are primary concerns of the University. The purpose of this consent is to provide you with important information about COVID-19 and in-person research in light of the COVID-19 public health crisis. Your participation may be affected because of COVID-19 related risk. All other information in the study consent remains the same.

The occupational health and safety measures that will be put in place during your study participation have been approved by the Yukon University President, based on current federal and territorial public health directives as well as recommendations from the World Health Organization (WHO).

Please read the following information to determine if participation is right for you at this time.

**What is COVID-19?** It is a respiratory condition caused by SARS-CoV2, which can be spread by respiratory droplets, mainly from person-to-person. This can happen between people who are in close contact with one another (less than 2 metres). It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose or eyes. At this time, there is no vaccination to prevent COVID-19.

**What are the risks of COVID-19?** For most people, COVID-19 causes mild or moderate symptoms, such as fever and cough. For some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia, and, more rarely, may cause death.

**Who is most at risk?** Persons aged 65 and over, those with a compromised immune system and those with underlying medical conditions such as some cancers, diabetes or heart, lung and kidney disease, are most at risk of developing serious complications if they contract the virus. **In-person research involving these vulnerable populations is not allowed at this time** in the absence of strong justification.

**Can COVID-19 be prevented?** Current evidence suggests person-to-person spread of COVID-19 is efficient when there is close contact, making physical distancing an important prevention measure. Proper handwashing, cough hygiene and cleaning with an appropriate disinfectant are also key to limiting virus transmission.

This study requires in-person visits and it is important to understand that this may increase your exposure to COVID-19. However, the University and researchers have taken certain precautions to reduce the risk for you, the research staff and their families (among others in the community). The safety plans described below aim to minimize the spread of COVID-19 and are consistent with the current Yukon Government Health and Yukon University guidelines.

It is important to understand that since study participation may include increased travel outside of your home and increased contact with others within a research site, it may increase your exposure to COVID-19.

### **What procedures will be in place to minimize risk of transmission of COVID-19 during your study participation?**

The assessments of risks and the protocols to mitigate them are guided by the practice of following the [Safe 6 Directive of Yukon Government](#) and the [Guidelines and Requirements for Research Involving Human Participants Under COVID-19 Restrictions](#). Measures that will be taken to reduce the risk include:

- maintaining 2-metre (6 feet) physical distancing;
- hand washing before and after study participation;
- providing you with a disposable facemask if you do not have one;
- limiting the number of times you have to come to a research site;
- reducing the time you are in contact with other people;
- ensuring all high-touch surfaces and objects are disinfected daily and disinfected between users.

All research team members are required to have training on preventing the spread of infection and all Yukon University students and employees must understand the requirements for self-assessment of health and recognize potential symptoms of COVID-19 infection.

**Participant Screening:** All participants will be required to complete the online [Yukon Government COVID-19 self assessment](#) before accessing the research site and will be asked if they have symptoms of COVID-19 or have been in close contact with anyone who has or has had COVID-19 within the past 14 days. Some of the questions you will be asked include:

1. Do you currently (and/or recently) have a cough, fever, or any other symptoms of COVID-19?

2. Have you travelled outside the Yukon in the past 14 days?
3. Have you ever tested positive for COVID-19 or had close contact with anyone that has tested positive for COVID-19?

Participation will be cancelled or postponed when responding yes to any of the assessment or screening questions.

Wearing a mask that covers the mouth and nose is required inside all University facilities and other research locations when the 2 metre distancing is not possible.

**Study location site:** Click or tap here to enter text.

### **What will happen the day of the study visit?**

1. On the day of your participation, you will be asked to arrive at Click or tap here to enter text. at a scheduled time.
2. Participants are encouraged to travel to the study location in their own vehicles and encouraged to attend alone.
3. You are required to wear a mask prior to and following entry into the research location or if distance cannot be maintained with other individuals. If you do not have access to a mask, please let the research team know and one will be given to you on the day of your visit. Once your mask is on, you are asked to try not to touch your face or eyes with your hands.
4. You will be asked to wash or sanitize your hands upon entry into the building and before exiting.
5. Once the study visit is complete, a member of the research team will lead you the designated exit. You are asked to go directly to your vehicle.
6. If you are unable or unwilling to follow these guidelines, please notify the researcher ahead of time.

### **Safety Precautions**

In addition to participant screening before your in-person visit, you will find the following additional measures have been put in place to help reduce the risk of spreading or contracting COVID-19.

*Researchers note that you should specify the safety measures they have planned as part of your approved Safe Research Plan. Examples are listed below*

- Personal Protective Equipment (PPE)
- Handwashing and sanitizing
- Physical distancing
- Minimized time of contact
- Open windows or increased ventilation

- Plexiglass barriers
- Hygiene and disinfection protocols and materials
- Signage and markings
- Precautions for common areas
- Biohazard protocol
- Other....

#### Risks and Confidentiality:

*Researchers note that you should consider if there are added risks to participants because of COVID safety modifications.*

COVID-19 is a serious health threat, and the situation is evolving daily. The risk will vary between and within communities, but given the increasing number of cases in Canada, the risk to Canadians is considered high. For most people, COVID-19 may only cause mild or moderate symptoms. For some, especially older adults or those with underlying medical conditions, it can cause more severe illness or death. Even in mild cases it is not known what the long-term health consequences may be.

There is a possibility that during your research activities you could come into contact with someone with COVID-19. If this were to occur, Yukon University is required by Yukon Chief Medical Officer of Health (CMOH) to collect and retain on file your email address or phone number to share with them for contact tracing purposes. **Anonymity as a research participant cannot be maintained. Should you choose to withdraw participation from this study once you have provided consent, your contact information cannot be withdrawn from the University.** In the event that contact tracing is required your contact information will be shared with the CMOH. Please be assured that the CMOH will not have access to any other data collected for this research study.

*Researchers Note that you should ensure main consent form does not have conflicting information about keeping participant information anonymized.*

#### Who should I contact if I have questions?

If you have questions, concerns or would like to speak to the study team for any reason, please contact [Click or tap here to enter text.](#) at [Click or tap here to enter text.](#)

If you have questions regarding your rights and welfare as a research participant in this study (REB #...), please contact: Research Ethics Coordinator, Yukon University at [vwalker@yukonu.ca](mailto:vwalker@yukonu.ca) or call 867-668-8857.

**Consent:**

By agreeing to participate in this study you acknowledge that you have been informed of the health and safety procedures in place and agree to follow them. Please be reminded that participation is voluntary and you may decline or postpone participation at any time.

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*Researchers Note: There are two ways to acknowledge receipt of this Participant Information Letter. The first and preferred way is digital confirmation (typically email) in advance of the research taking place. The second, acceptable approach is researcher documentation of verbal agreement.*

**I have read and understand these new research requirements in order to address the COVID 19 pandemic for in-person research. I freely consent to participate in this research.**

**Participant name:** Click or tap here to enter text. **agrees to these additional requirements**

**returned via email or**  **verbal agreement provided to researcher** Click or tap here to enter text.

**Date:** Click or tap to enter a date.