**Appendix IV.III: Informed Consent for In-Person Research**

***Guidance to Researchers:*** *This document serves as a template. This appendix will provide participants with pertinent safety information and instructions related to their in-person research visits and procedures. Please add, remove, or edit as needed using the tracked changes feature. Details of the approved Research Management Plan will be communicated here.* ***PLEASE DELETE ALL TEXT BOXES FROM FINAL DOCUMENT.***

**Study Title: [Title]**

**Principal Investigator: [Name and contact information]**

COVID-19 and Face-to-Face Research

This document contains important information about participating in in-person research in light of the COVID-19 public health crisis. COVID-19 refers to the virus being spread in communities across the globe. We are providing you with important information about COVID-19 and we ask that you consider the following information to determine if study participation is right for you at this time.

COVID-19 is a respiratory condition caused by SARS-CoV2, which can be spread by respiratory droplets and aerosols, 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. It is important to remain vigilant in all safety precautions until Public health deems it appropriate to change our behaviour.

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

Mandatory Vaccination (On-Campus) [Remove this section for Off-Campus]

The Council of Ontario Medical Officers of Health has indicated that vaccination against COVID-19 is the single most effective public heath measure to reduce the spread of COVID-19. The University of Guelph is committed to protecting the community and requires all faculty, staff, students and visitors to be vaccinated against COVID-19 in order be on campus. Continued safety measures such as wearing masks, handwashing and distancing will further protect everyone who engages in face-to-face research.

Those who cannot be vaccinated for medical reasons or on other grounds protected by the Ontario Human Rights Code are exempt from this requirement. However, individuals who have an exemption must receive a negative COVID-19 rapid test result no earlier than 72 hours before accessing University of Guelph facilities.

Participant Screening

**All participants will be screened 24 hours prior to scheduled study visit and must complete** **the** [University of Guelph COVID-19 Daily Screening Form](https://uoguelph.eu.qualtrics.com/jfe/form/SV_6lh1bNRMHDEU1OR) **the day of your appointment (prior to the study visit)**. The research team will confirm that the two screens are complete before proceeding with your visit. You will be asked about information regarding your health in the 14 days prior to the appointment, with special attention to the preceding 48 hours.

Where will the study take place?

[Please specify location of visit]

What will happen the day of the study visit?

1. On the day of testing, you will be asked to arrive at [campus/research location] at your scheduled time.
2. Participants are encouraged to travel to [campus/research location] in their own vehicles rather than public transportation, if possible. You are also encouraged to attend [campus/research location] alone.
3. All research participants are asked to wait outside until called to enter [research location].
4. You are required to wear a mask prior to and following entry into the building or if distance cannot be maintained with other patrons outside**. If you do not have access to a mask, please let the research team know prior to your appointment 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.
5. You will be asked to wash or sanitize your hands upon entry into the building and before exiting.
6. Participants will follow the research personnel to the designated study space and asked to follow their instructions once inside.
7. Participants are advised to use washroom facilities at home prior to coming to [campus/research location]. However, washroom facilities are available on campus. These facilities have approved procedures for use that must be followed.
8. Once the study visit is complete, a member of the research team will lead you to the designated exit. You are asked to go directly to your mode of transportation without entering any other University buildings as you leave.
9. If you are unable or unwilling to follow these guidelines, please notify the researchers 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:

***Guidance to Researchers****: Please specify the safety measures you have planned as part of your approved Research Management Plan. Examples are listed below.*

* Personal Protective Equipment (PPE) – masks, gloves and/or face shields
* 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: [Please describe]

Risks & Confidentiality

***Guidance to Researchers****: Please consider if there are added risks to participants because of COVID safety modifications. For example, in an effort to control the number of researchers in the room, there may not be extra personnel to help in an emergency situation, or participants may not be able to request a male or female researcher to conduct the visit as they previously could, etc.*

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 mild or moderate symptoms, such as fever and cough. For some, especially older adults (aged 60 and older) and people with compromised immune systems or underlying medical conditions who are not vaccinated against COVID-19, it can cause more severe illness, including pneumonia. 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, the University of Guelph is required by the Public Health Unit to collect and retain on file your email address or phone number to share with them for contact tracing purposes. **As such, anonymity as a research participant cannot be maintained. Should you choose to withdraw participation from this study, this personal information cannot be withdrawn from University of Guelph or Public Health records.** Please be assured that Public Health will not have access to any other data collected for this research study.

***Guidance to Researchers****: Please ensure main consent form does not have conflicting information about keeping participant information anonymized.*

Vulnerable Populations

Certain individuals or groups are at greater risk of getting an infection and developing severe complications from COVID-19 and these populations must be supported and protected during this time.

COVID-19 Vulnerable individuals/groups may include, but are not limited to:

* Individuals over the age of 60;
* Individuals with pre-existing medical conditions (e.g. immunocompromised, diabetes, lung disease);
* Individuals experiencing socio-economic challenges, such as inadequate or overcrowded housing;
* Indigenous communities who may suffer disproportionately due to systemic inequalities.

Face-to-face research involving COVID-19 vulnerable populations will require added considerations and measures for safety and, in some instances, participation in the research may not be advisable. Therefore, if you self-identify as COVID-19 vulnerable or are uncertain whether you fall within a vulnerable population, it is imperative that you inform the research team and ask for further guidance.

**Please note: If you fall within a vulnerable population described above but are fully vaccinated (i.e., you received a complete vaccine series ≥2 weeks ago), you are no longer considered a high-risk population in the COVID-19 context. All COVID-19 safety precautions listed above must be followed, even if you are fully vaccinated.**

|  |
| --- |
| Are you fully vaccinated against COVID-19? (Please select one of the following options): |
| [ ]  | **Yes**, I received a complete COVID-19 ≥2 weeks ago |
| Date of final dose: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | **No**, I have not been fully vaccinated for COVID-19(Please note a medical exemption and negative COVID-19 test within 72 hours of study visit may be required to participate in this study) |
| [ ]  | Prefer not to respond |

Who can I contact if I have questions?

If you have any questions, concerns or would like to speak to the study team for any reason, please contact [Principal Investigator] at [phone/email].

If you have questions regarding your rights and welfare as a research participant in this study (REB#.....), please contact: Manager, Research Ethics; University of Guelph; reb@uoguelph.ca; (519) 824-4120 (ext. 56606).

Consent

***Guidance to Researchers****: If participants are unable to return a scanned signature, consent can be submitted via email, by phone/video conference, or other documented means.*

I have read this Informed Consent for In-Person Research Activities and any questions about the study and/or COVID-19 have been answered. I freely consent to participate in this research.

 *Participant Name*

 *Participant Signature Date*