**TEMPLATE**

**Verbal Consent for Face-to-Face On-Site**

**Participation during COVID-19**

**Version Date: November 2022**

**Bruyère Research Ethics Board Approval**

 Date of Approval: [29/Nov/2022]

**Overview**

This document contains important information regarding face-to-face study participation at the Bruyère Research Institute (Bruyère RI) during the COVID-19 pandemic. The purpose of this document is to inform you of the steps that we are taking at Bruyère RI to keep research participants and study partners safe and to lower the risk of COVID-19 exposure. It also outlines your responsibilities if you choose to come into the Bruyère RI to participate in research. These steps were built with direction from Ottawa Public Health, the province and Bruyère.

Before providing verbal approval of this form, please ask all of the questions you might have, take as much time as you need, and consult with others as you wish.

**Risks of face-to-face on-site study visits**

Although we are taking multiple steps to reduce the risk of exposure to COVID-19 within our hospital, there is still a risk that you may be exposed to COVID-19. Due to the nature of the virus, carriers of the virus may not always show symptoms and may still be contagious.

Public health guidelines currently allow us to conduct face-to-face on-site study visits. However, in the event that these public health guidelines change, face-to-face visits may need to be stopped and/or the study might need to be put on hold. If this happens, you will be informed promptly by someone from the study team and instructed on plans for your specific study.

**What we are doing to minimize risk of exposure:**

* Asking COVID screening questions of everyone who enters Bruyère.
* Following universal masking protocols, which means that all staff must wear [update based on requirements at time of your study – see <https://infonet.bruyere.org/en/covid-staff-ipac>].
* Maintaining physical distancing of 2 metres between all individuals who are not from the same household, where possible.
* During medical procedures, staff will always wear a lab coat and during biological specimen collection gloves will be worn. Staff will also thoroughly wash their hands before and after all procedures.
* Limiting the touching of surfaces. Only staff will touch things like door handles and elevator buttons during your visit.
* Following Bruyère Infection Prevention and Control (IPAC) guidelines for proper hand hygiene and disinfecting surfaces.
* Restricting access for staff, participants and study partners (if applicable) to certain areas in the hospital.
* Accompanying participants and their study partners (if applicable) to and from their visits to the Bruyère entrance/exit.
* Reducing the number of staff in the research area at any given time.
* Allowing no more than one participant and their study partner (if applicable) into the research area at any given time.
* Notifying the participant and study partner (if applicable) as soon as possible if any member of the research team they have come in contact with during their visit becomes symptomatic and COVID is confirmed.

**Your responsibility to minimize exposure/transmission**

In order to continue to participate in face-to-face study visits at Bruyère RI, you must agree to follow the safety measures below. These precautions have been put into place to help keep you, the study team, and patients at Bruyère safe, and to prevent possible COVID-19 exposure. If you do not agree to follow these safety precautions, you will be asked to stop attending the Bruyère RI for face-to-face visits, which may impact your ability to participate in our research studies.

* You and your study partner (if applicable) agree to complete all the necessary COVID-19 screening procedures, which include:
	+ Phone screening during your scheduling call,
	+ Phone screening at your reminder call which can be 24 hours before your visit or the Friday before your Monday visit.
	+ In-person or in advance online screening on the day of your visit to Bruyère, that must be shown to the screener at the Bruyère Street entrance that you will be asked to come to at the hospital on the day of your visit
* You agree to wear your own mask when you come to the entrance of Bruyère.
* You agree to change your mask and wear the type of mask provided by Bruyère at the screening entrance for the entirety of your visit if requested to do so [update based on requirements at time of your study – see <https://infonet.bruyere.org/en/covid-visitors-dcps-ipac>].
* You agree not to remove the mask unless you are instructed to do so by a member of the study team.
* You agree to maintain 2 metres of distance between you and others that are not in your household during your visit where possible, and except during medicals interventions and procedures that do not allow for 2 metre distancing.
* If you require beverages or food during your visit because of medical reasons or due to the length of the visit, you agree to bring your own beverages and food and follow the instructions provided by the research staff on when and how to consume them.
* You will notify the study team immediately [PROVIDE CONTACT NUMBER] if you experience any COVID-19 related symptoms (e.g. new or worsening cough, shortness of breath, fever, chills, fatigue or weakness, new loss of smell or taste) or if you test positive for COVID-19 within 14 days following your visit to the Bruyère RI.
* You agree to have the Bruyère RI provide your name and contact information to Bruyère Occupational Health and Safety and /or other public health officials if needed to facilitate prompt contact tracing and understand that by providing this information your anonymity cannot be maintained.

These policies/procedures have been reviewed and approved by the Bruyère Research Institute and the Bruyère Continuing Care Research Ethics Board.

If you require further information or have questions at any time about the information outlined above please contact [RESEARCH TEAM CONTACT, CONTACT NUMBER, CONTACT EMAIL].

**SIGNATURE OF PERSON OBTAINING CONSENT**

I have personally explained the consent form to the participant (name of the participant – print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and the study partner (if applicable) (name of the study partner-print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_and answered all of his/her/their questions. I believe that s/he/they understands the information described in this document and freely consents to participate.

I (name of person obtaining informed consent (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

Witnessed verbal consent by telephone on (date: dd/mmm/yyyy)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

at (time: hh:mm) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**TEMPLATE**

**Verbal Consent for Face-to-Face**

**Community Visits during COVID-19**

**Version Date: November 2022**

**Bruyère Research Ethics Board Approval**

 Date of Approval: [29/Nov/2022]

**Overview**

This document contains important information regarding face-to-face study participation at the Bruyère Research Institute (Bruyère RI) during the COVID-19 pandemic. The purpose of this document is to inform you of the steps that we are taking at Bruyère RI to keep research participants, study partners and the community safe and to lower the risk of COVID-19 exposure. It also outlines your responsibilities if you choose to allow a member of the research staff at the Bruyère RI come into your home to conduct research. These steps were built with direction from Ottawa Public Health, the province and Bruyère.

Before providing verbal approval of this form, please ask all of the questions you might have, take as much time as you need, and consult with others as you wish.

**Risks of face-to-face on-site study visits**

Although we are taking multiple steps to reduce the risk of exposure to COVID-19 in the community, there is still a risk that you may be exposed to COVID-19. Due to the nature of the virus, carriers of the virus may not always show symptoms and may still be contagious.

Public health guidelines currently allow us to conduct face-to-face community study visits. However, in the event that these public health guidelines change, face-to-face visits may need to be stopped and/or the study might need to be put on hold. If this happens, you will be informed promptly by someone from the study team and instructed on plans for your specific study.

**What we are doing to minimize risk of exposure:**

* Screening all Bruyère RI staff before they conduct a face-to-face community research visit.
* Only allowing one research staff member into your home to conduct the visit.
* Following universal masking protocols in place at Bruyère. This currently means that all staff will wear [STATE BRUYÈRE REQUIREMENTS CURRENTLY IN PLACE: SEE <https://infonet.bruyere.org/en/covid-staff-ipac>] while in your home.
* Maintaining physical distancing of 2 metres between all individuals who are not from the same household, where possible.
* Limiting the touching of surfaces in your home during the visit.
* Following Bruyère Infection Prevention and Control (IPAC) guidelines for proper hand hygiene and disinfecting surfaces touched by research staff.
* Notify the participant, study partner (if applicable) and/ or household members (if applicable) as soon as possible if the member of the research team they have come in contact with during the visit becomes symptomatic and COVID is confirmed, or tests positive for COVID within 14 days of the visit.

**Your responsibility to minimize exposure/transmission**

In order to continue to participate in community face-to-face study visits, you must agree to follow the safety measures below. These precautions have been put into place to help keep you, the study team, and other household members safe, and to prevent possible COVID-19 exposure. If you do not agree to follow these safety precautions, the community visit will not be able to occur, which may impact your ability to participate in our research studies.

You and any household members (if applicable) present during the research visit agree to:

* Complete all the necessary COVID-19 screening procedures, which include:
	+ Phone screening during your scheduling call,
	+ Phone screening at your reminder call which can be 24 hours before your visit or the Friday before your Monday visit.
	+ Screening immediately or shortly before research staff enter your home.
* Wear a mask for the entirety of your visit. A N95 or KN95 mask is recommended and can be provided by the study team.
* Remove any animals (e.g. pets) from the visit area during the research visit.
* Maintain 2 metres of distance between you and others that are not in your household during the visit where possible.
* Inform the study team immediately [PROVIDE CONTACT NUMBER] if you experience any COVID-19 related symptoms (e.g. new or worsening cough, shortness of breath, fever, chills, fatigue or weakness, new loss of smell or taste) or if you test positive for COVID-19 within 14 days following your visit to the Bruyère RI.
* You agree to have the Bruyère RI provide your name and contact information to Bruyère Occupational Health and Safety and /or other public health officials if needed to facilitate prompt contact tracing and understand that by providing this information your anonymity cannot be maintained.

These policies/procedures have been reviewed and approved by the Bruyère Research Institute and the Bruyère Continuing Care Research Ethics Board.

If you require further information or have questions at any time about the information outlined above please contact [RESEARCH TEAM CONTACT, CONTACT NUMBER, CONTACT EMAIL].

**SIGNATURE OF PERSON OBTAINING CONSENT**

I have personally explained the consent form to the participant (name of the participant – print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and other household members (if applicable) (name of the household members-print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_and answered all of his/her/their questions. I believe that s/he/they understands the information described in this document and freely consents to participate.

I (name of person obtaining informed consent (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

Witnessed verbal consent by telephone on (date: dd/mmm/yyyy)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at (time: hh:mm) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_