INSTITUT DE RECHERCHE
Bruyère
RESEARCH INSTITUTE

ADMINISTRATION /FINANCE PROCEDURE

Title: Procedure Manual on Conducting Face-to-Face Participant Research on Site or in the Community during the COVID-19 Pandemic	**Last review/revision date:** May 18, 2021
Approved by: Bruyère RI Senior Director of Operations	**Approval date:** October 8, 2020
Issued by: Bruyère RI	**Policy #:** RES TEMP 502

Quick Links

ACROYMS	
Bruyère REB	Bruyère Continuing Care Research Ethics Board
Bruyère	Bruyère Continuing Care
Bruyère RI	Bruyère Research Institute
FMS	Facilities Management Services
IMS	Incident Management System committee
IPAC	Infection Prevention and Control team
PPE	Personal Protective Equipment
REB	Research Ethics Board
ROM	Research Operations Manager
RP	Research Participant
RP/SP	Research Participant and Study Partner (if applicable)
SP	Study Partner
SST	Bruyère Senior Strategy Team

1.0 PURPOSE

The Bruyère Research Institute (Bruyère RI) is committed to promoting a safe environment and protecting the health and wellbeing of its investigators, staff, students, volunteers, participants, study partners, Bruyère's clinical staff, patients, residents, family members and the community. As a response to the COVID-19 pandemic, and in compliance with the guidelines from local, provincial and federal authorities, the Bruyère RI has implemented procedures to support the safe conduct of face to face participant research. The procedures to conduct research are guided by Bruyère and Bruyère RI Senior Leadership, following Bruyère policies on Infection Control Outbreak Management Planning.

This procedure manual focuses on the procedures that need to be followed in order for face-to-face research to be conducted during the COVID-19 pandemic, on-site and in the community. Research teams must use this information as a guide to help them develop a revised research plan.

Due to the rapidly changing nature of a pandemic event, procedures and policies may change. These changes may include the scaling-back or suspension of all research, the stopping of any research involving face-to-face participant contact, and the continuation of research with no in-person interaction. Always consult our website and your ROM for the latest information on conducting in-person research.

2.0 DEFINITIONS

Pandemic: an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people. [Last JM, editor. A dictionary of epidemiology, 4th edition. New York: Oxford University Press; 2001]

Epidemic: the occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy. [WHO Definition, https://www.who.int/hac/about/definitions/en/]

Infection Control Outbreak Management Plan: the process in which an infectious disease is to be dealt with at Bruyère. These procedures have been establish to best minimize the transmission of communicable diseases at Bruyère and are subject to change as needed.

Face-to-face Participant Research: any research that involves direct in-person face-to-face contact between a participant (inpatient, outpatient, resident, healthcare staff or community based) and research staff at any of Bruyère's campuses or in the community.

Disinfect: The act of applying a disinfectant solution (typically Cavi Wipes) to a surface for a sufficient length of time ("contact time") that bacteria/viruses on the surface are rendered harmless. If a surface is visibly dirty, it should be cleaned and then disinfected. Refer to Policy:
Routine Practices (bruyere.org)

Outpatient: Anyone who is not an employee or inpatient at Bruyère Continuing Care.

Personal Protective Equipment (PPE): clothing or equipment worn by staff to protect them from exposure to microorganisms. Refer to information and instructions on the Bruyère Infection Prevention and Control InfoNet page https://infonet.bruyere.org/en/covid19-ipac on types of PPE and on how to apply and remove PPE. Also refer to policy:
https://infonet.bruyere.org/bins/Policies_default.aspx?cid=981&lang=1 for glove use.

Research Participant (RP): is a person (inpatient, outpatient, resident, healthcare staff or community member) who voluntarily participates in human subject research after giving informed consent to be part of the research project.

Screening Questions/ Bruyère-approved COVID-19 screening questionnaire for staff: This refers to the latest version of COVID-19 screening questions in use at Bruyère for staff. These questions can be found at HealthQ Screener (bruyere.org)
Screening Questions/ Bruyère-approved COVID-19 screening questionnaire for visitors: This refers to the latest version of COVID-19 screening questions in use at Bruyère for visitors. See Appendix A.

Study Partner (SP): Is someone who lives with the research participant and is required in some research (e.g.. Clinical trials) and is someone who shares in the decision-making process to join the research study. The research study partner ensures trial compliance and acts as a knowledgeable informant, reporting on the research participant's cognitive and functional status to help evaluate the intervention's safety and efficacy.

3.0 OVERVIEW

3.1 Approval Process

Research teams with studies resuming or starting during the pandemic that will be recruiting participants from in- or out-patient units/clinics must have discussions with the Clinical/Unit Manager to ensure that research can occur and to determine how the research will be undertaken within the unit's workflow processes. A Research Summary Page (Appendix D) should be drafted and used as a tool for these discussions – it provides the information needed by the clinical unit and will simplify your approvals later.

All teams must review the current version of the **Procedure Manual on Conducting Face-to-Face Research** to ensure that the research processes they are planning, follow approved procedures. If you anticipate that your processes will need to differ from the standard processes outlined in the manual and have questions about feasibility, please consult your Research Operations Manager (ROM).

Steps to Complete

1. Review the current version of the Procedure Manual on Conducting Face-to-Face Research.

2. Complete the Restarting Research Approval Spreadsheet, either by:
   - 2.1. Directly adding it yourself into the Office 365 file if you have a Bruyère login & inform your ROM that you have updated a new study, OR
   - 2.2. Asking your ROM to provide you with an excel copy and your ROM will upload it once you provide her with the completed file
   - 2.3. Your ROM will inform IPAC and PPE that a new study requires their approval.

   Access the Restarting Research Approval Spreadsheet by clicking on the following link: https://bruyerehospital-my.sharepoint.com/:x:/r/personal/pfournier_bruyere_org/_layouts/15/guestaccess.aspx?e=4%3AQV86eI&web=1&at=9&share=EaLuG4Dl4OtGgBixBh-5TrUBkWF7Q5PnjbHbizmkOuJ1vA

3. If your study involves work on a clinical unit/program:
   - 3.1. In consultation with the impacted unit/program, complete a Research Summary Page (Appendix D) that outlines your project plans if you have not already done so.
   - 3.2. Provide the Research Summary Page to the clinical leads who must sign it (Clinical Director and/or the Medical Chief, as appropriate) and request their approval.
     - 3.2.1.1. *If your study was previously approved by the Bruyère REB and this is a restart request*, the clinical department lead must sign the Research Summary Page.
     - 3.2.1.2. *If your study is a new study looking to start at Bruyère*, the clinical department lead must sign Section 25 of the BREB application. They do not need to sign the Research Summary Page.
   - 3.3. Once the Research Summary Page is signed by the clinical department leads, provide this confirmation to your ROM or enter it yourself into the Restarting Research Approval Spreadsheet.

4. Once IPAC, PPE, and the appropriate departmental leads have approved your study, your ROM will inform the Bruyère REB that your study has received all approvals required by Bruyère to resume/start.

5. You can submit your BREB application prior to this approval being granted in order to speed up the review process, however you will only receive a conditional approval pending receipt of these sign-offs on your study.

6. The Bruyère REB will provide final approval for your study to commence once all approvals have been received and your REB application has been reviewed.

3.2 General Principles

When revising study plans, research teams need to consider the following general principles.

- To protect research staff, RP/SP and the community, as much research work as possible should be done remotely, visit interactions should be minimized and other methods of data collection (e.g. phone, mail-in, and video-conference) considered and implemented.

- In the event that face-to-face research **must** continue, careful consideration needs to be given to the risks associated with the following;
    - RPs and SPs (if applicable) traveling to the site and being on site.
    - Research staff working in the research area or the community.
    - Bruyère clinical unit staff coming into contact with research staff.
    - Third parties in the community such as other members of a RP's household being present while the research is be conducted.
    - The research methodology itself.

- Ensure that the study complies with all required PPE, IPAC and procedure requirements as outlined in this document.

- Determine if sufficient research staff are available to conduct the research.

- Ensure that the research areas is well ventilated by;
    - Having a window or door open during the visit (if appropriate),
    - Making sure the heating and ventilation system is working,
    - Turning on a ceiling fans if available,
    - Consider having the visit outside if possible.

- Make sure the research area is large enough to provide physical distancing of 2 meters. If distancing is not possible, the use of plastic screens (plexiglass) is strongly suggested.

- Ensure that the study adheres to government and institutional directives (including provincial directives and local public health guidelines).

- Determine how the study impacts the organization's infrastructure, ancillary services, patient/resident care, etc., and ensure that measures are added to the protocol to mitigate the impact.

- Ensure a plan is in place in the event that the research study is stopped due to a future outbreak.

3.3 Vaccinated Participants

Vaccinated participants must follow the same screening procedures and PPE requirements as non-vaccinated participants as outlined in Section 4.0.

4.0 PROCEDURES

4.1 On-site Outpatient Research Visits [1]

4.1.1 Number of RPs and SPs (if applicable) Outpatients Permitted on Site	Onsite outpatient research visits must be limited to only one RP and one SP (if applicable) in the research area at any one time [2].
4.1.2 Scheduling Call	A scheduling call **must** be made prior to the on-site visit, at which time the research team will; **Step 1**: Complete the latest version of the Bruyère-approved COVID-19 Visitor Screening Questionnaire with the RP/SP. See Appendix A. ▪ If passed by the RP/SP proceed to Step 2. ▪ If failed by the RP/SP contact the RP/SP in 14 days for another scheduling call. **Step 2**: Complete the verbal COVID Consent Form with the RP/SP. See Appendix B. ▪ If verbal consent is obtained from the RP/SP proceed to Step 3. ▪ If verbal approval is not received from the RP/SP the visit cannot occur. **Step 3**: Schedule the research visit and inform the RP/SP that if the RP/SP become symptomatic or if others around them are confirmed to have COVID before the scheduled visit, they must communicate that information to the research team, the visit will be cancelled and another scheduling call will be booked in 14 days.
4.1.3 Reminder Call	A reminder call **must** be done 24 hours before the visit or the Friday before a Monday morning visit with the RP/SP, at which time the research team will; **Step 1**: Complete the latest version of the Bruyère-approved COVID-19 Visitor Screening Questionnaire with the RP/SP. ▪ If passed by the RP/SP proceed to Step 2. ▪ If failed by the RP/SP inform the RP/SP that they will be contacted in 14 days for another scheduling call. **Step 2**: ▪ Remind the RP/SP of the requirements in the COVID Consent Form, including that if they feel unwell on the day of the appointment they should call the research team to reschedule[3]. ▪ Provide the RP/SP with the following information for their arrival to Bruyère; o Your contact details. o Arrival entrance:

[1] *In the event that a SP is required to accompany the RP to the on-site research visit, **both** the RP and SP **must** pass the Bruyère COVID screening questionnaire and provide verbal consent for the Covid Consent Form, before they are allowed on site.*
[2] *If research teams have approval to run multiple face-to-face research studies that share a common research space, only one RP with their SP (if applicable) are allowed in the research space at any one time. The research area must be thoroughly cleaned between RPs.*
[3] *If the RP/SP revoke their consent to the COVID Consent Form during the reminder call the visit must be cancelled.*

	▪ Research being conducted at EBH on 2Y – 75 Bruyère Street. ▪ Research being conducted at EBH on 7th – 43 Bruyère Street. o Wear their own mask while going through the entrance screening process. o Complete the Bruyère-approved COVID-19 visitor screening questionnaire at the entrance. o Complete hand hygiene. o Replace their mask with a procedural mask provided by Bruyère. o Wait in the designated entrance area for a member of the research team to come and accompany the RP/SP to the research area.
4.1.4 Bruyère Entrance Screening Notification Procedure	The Bruyère entrance screening staff must be made aware of the RP/SP visit **at least 24 hours** prior to the visit. An email must be sent to Bruyère Screening Team at telecebp@bruyere.org with a copy sent to Marie Maksoudian (Screening Manager) at MMaksoudian@bruyere.org.The following information must be included in the email. ▪ Name of RP/SP ▪ Site location and entrance ▪ Visit date and time ▪ **Research team phone extension**
4.1.5 Arrival at Bruyère	When the RP/SP arrive on site and pass the screening procedure, research staff; ▪ Will be notified by the screeners that the RP/SP has arrived. ▪ Should proceed to the appropriate Bruyère entrance to accompany the RP/SP to the research area. ▪ Ensure that hand hygiene is completed by the RP/SP before entering the research area. In the event that the RP/SP do not pass the Bruyère entrance screening, the RP/SP will be asked to leave the building and research staff [4]; ▪ Will be notified by the screeners that the RP/SP did not pass the screening questionnaire. ▪ Should follow-up with the RP/SP to re-schedule at a later date pending passing the screening questionnaire..
4.1.6 Procedure during the Visit	During the visit, research staff must ensure that the RP/SP; ▪ Complete hand hygiene when entering and leaving the research area. ▪ Limit the touching of surfaces. ▪ Follow masking and physical distancing 2 metre rules. ▪ Are accompanied by research staff when needing to use the washrooms.

[4] *Ensuring that the Reminder Call is done prior to the on-site visit will reduce the chance of this happening.*

	▪ Hand hygiene and 2 meter physical distancing is completed when the RP and/or SP (if applicable) need to remove their mask for any reason, including a hydration or nutrition break. ▪ Are provided with a disinfected table to put food and/ or drinks on. ▪ Do not use microwaves, water fountains, kettles, refrigerators, and coffee machines. Throughout the visit research staff must disinfect all equipment before and after use as per section 4.4. Personal Protective Equipment (PPE), Lab Coats and Cleaning. At the end of the visit, research staff must; ▪ Accompany the RP/SP to the exit of the Bruyère site. ▪ Disinfect all equipment and research surfaces that were used during the research visit.

4.2 On-site Inpatient/Resident/Clinical Staff Research Visits

4.2.1 Organizing and Conducting the Inpatient/Resident Visit	When organizing on-site inpatient /resident RP visits, the research team must; ▪ Consult with the Unit Manager/Supervisor/their Designate before scheduling and before conducting a visit to determine the status of the unit (eg on outbreak) and the health status of the RP. ▪ RPs cannot 1) be on quarantine for COVID-19; or 2) be on droplet & contact precautions; or 3) be on airborne precautions; or 4) be symptomatic and on contact precautions. Research staff should ensure regular and ongoing communication with the clinical staff to ensure that they are aware of any changes in the status of the inpatient/resident which could affect their participation in the study. ▪ If the research can be conducted in the RP's room ensure that research staff; o Complete hand hygiene before entering and the leaving the room. o Comply with PPE and IPAC procedures as per section 4.4. Personal Protective Equipment (PPE), Lab Coats and Cleaning. o Maintain a 2 meter distance between the RP and research staff member. o Use a chair if research staff need to sit and not sit on the RP's bed. o Inform the RP that privacy may be difficult to maintain if research staff have to speak louder to be heard while wearing their mask and face shield. If the study requires that the RP be transported to another location within the Bruyère site to conduct the research, research staff must; o Follow all PPE and IPAC procedures as per section 4.4. Personal Protective Equipment (PPE), Lab Coats and Cleaning. o Follow section 4.1.6. o Accompany the RP to and from their room. If the study requires that the RP be transported to another facility outside of Bruyère, this is treated by IPAC as an external appointment for the RP. The RP must: o Be transported to the appointment via medical transport (medical taxi, ambulance). o It is strongly advised that the RP be accompanied by a member of the research. o Wear a mask during transport and practice good hand hygiene.

4.2.2 Organizing and Conducting the Clinical Staff Visit	When organizing on-site clinical staff RP visits, the research team must; ▪ If appropriate, consult with the Unit Manager/Supervisor/their Designate before scheduling and before conducting a visit. ▪ If the research can be conducted on the unit, ensure that research staff; o Complete hand hygiene before entering and the leaving the room. o Comply with PPE and IPAC procedures as per section 4.4. Personal Protective Equipment (PPE), Lab Coats and Cleaning. o Maintain a 2 meter distance between the RP and research staff member. o Inform the RP that privacy may be difficult to maintain if research staff have to speak louder to be heard while wearing their mask and face shield. If the study requires that the RP be transported to another location within the Bruyère site to conduct the research, research staff must; o Follow all PPE and IPAC procedures as per section 4.4. Personal Protective Equipment (PPE), Lab Coats and Cleaning. o Follow section 4.1.6.

4.3 Community Research Visits [5]

4.3.1 Important Considerations of Community Research Visits	Conducting face-to-face research in the community during the pandemic may pose added risks to research staff, RPs and third parties (e.g. family members of the RP). A clear justification to continue this research in the community must be provided in the revised protocol, along with a clearly laid out plan that considers the following; ▪ Where will the research visit be conducted and what risks does this location pose to research staff, RPs and third parties? How will the research team mitigate these risks[6]? ▪ How will research staff ensure that PPE and IPAC procedures are followed? (See Section 4.4. Personal Protective Equipment (PPE), Lab Coats and Cleaning.
4.3.2 Scheduling Call	A scheduling call **must** be made prior to the community visit, at which time the research team will;

[5] *Every effort must be made to try to reduce the number of individuals in the community setting during the visit. In the event that household members of the RP will be present during the research visit, everyone must pass the Bruyère COVID screening questionnaire and provide their verbal consent to follow all elements of the COVID Consent form before the visit can occur.*

[6] *Research may not be conducted in Indigenous communities or in areas where vulnerable populations live (e.g., long-term health care facilities) until public health officials deem such activities safe. Research teams should consider the infection rate in the respective community and if the research team is allowed to enter the area and conduct research.*

	Step 1: Complete the latest version of the Bruyère-approved COVID-19 Visitor Screening Questionnaire with the RP and any third parties that will be present during the visit, e.g. family members (if applicable) (See Appendix A.) ▪ If passed by the RP and all third parties (if applicable) proceed to Step 2. ▪ If failed by either RP or any third party (if applicable) contact the RP in 14 days for another scheduling call. **Step 2**: Complete the verbal COVID Consent Form with the RP and any third party (if applicable). See Appendix B. ▪ If verbal consent is obtained from the RP and third party (if applicable) proceed to Step 3. ▪ If verbal approval is not received from the RP or any third party (if applicable), the off-site visit cannot occur. **Step 3**: Schedule the community visit and inform the RP that if the RP or any third party (if applicable) become symptomatic or if others around them are confirmed to have COVID before the scheduled appointment, the RP will communicate that information to the research team, the community visit will be cancelled and another scheduling call booked.
4.3.3 Reminder Call	A reminder call **must** be done 24 hours before the community visit or the Friday before a Monday community visit with the RP and any third party (if applicable), at which time the research team will; **Step 1**: Complete the latest version of the Bruyère-approved COVID-19 Visitor Screening Questionnaire with the RP and third party (if applicable). ▪ If passed by both RP and third party (if applicable) proceed to Step 2. ▪ If failed by either RP or third party (if applicable) inform the RP that they will be contacted in 14 days for another scheduling call. **Step 2**: Remind the RP and third party of the requirements in the COVID Consent form[7]. **Provide your contact details in case RP needs to cancel**.
4.3.4 Community Visit Day	On the day of the community visit, research staff must; ▪ Self-complete the Bruyère staff Covid-19 screening questionnaire. Research staff must pass the questionnaire before proceeding to the community visit. ▪ Prior to entering the off-site location (e.g. participant's home) administer the Bruyère-approved COVID-19 Visitor Screening questionnaire with the RP and any third parties (if applicable). This may be done via telephone before the research staff arrive at the meeting location or upon arrival. The RP and any third parties (if applicable) must all pass the questionnaire in order

[7] *If the RP and/or third party indicate any dissent concerning any of the elements of the COVID Consent Form at any time before or during the visit, the visit must be cancelled and if research staff have entered the off-site location, they should leave immediately.*

	for the visit to proceed. If this is not the case the community visit is cancelled, research staff must not enter the off-site location and a scheduling call is booked in 14 days. ▪ Don the required PPE before entering the home and follow Section 4.4 Personal Protective- Community to conduct the visit. If at any time during the visit, research staff feel that their safety has been comprised, the visit should be stopped and they should leave immediately.
4.3.5 Dropping Off or Picking Up Research Equipment in the Community	In the event that research staff are required to drop off or pick-up research equipment in the community **only procedural masks** are required as long as research staff; ▪ Do not enter the building. ▪ Have 100% certainty that a 6 feet distance from the RP or others can be maintained. If this cannot be maintained for certain a face shield should also be worn (face shields are available through Bruyère).

4.4 Personal Protective Equipment (PPE), Lab Coats and Cleaning

Research teams must carefully consider the PPE requirements of their studies and ensure that sufficient funds are available to cover PPE expenses[8]. All PPE and disinfectant products used must comply with Bruyère infection prevention and control policies and procedures and include the following considerations: *(For the most up to date information and resources see: https://infonet.bruyere.org/en/newcoronavirus)* *(To obtain PPE, disposal bins/hampers and disinfecting materials contact Bruyère SPB (SPD@bruyere.org) and provide a completed Supply Requisition* **On-Site**
• Minimize the research rooms/areas requiring disinfecting.
• The rooms that are used for research should be well ventilated and provide room for 2 metre physical distancing between the research staff and RP/SP. Plexiglass screens should be considered if this is not possible.
• Ensure that areas such as plexiglass screens, desks, equipment, exterior door handles, light switches, pencils, pens etc., or any other areas that are soiled/touched, are washed and disinfected after use and between RP/SP.
• Use approved disinfectant products to disinfect equipment and research supplies before and after use. Make sure that staff have easy access to gloves when using these projects and that they respect the surface contact time of the products (see https://infonet.bruyere.org/en/CDS for specific information).
• Have disposal bins/hampers readily accessible to staff for soiled PPE disposal.
• Have hand sanitizer or dedicated hand washing sinks available for hand hygiene in each research area or in the community.
• Limit bags or personal items brought into the research area, provide a designated area for the storage of personal belongings and disinfect this area after the visit.
• Do not conduct the visit if the RP (inpatient/resident only) is under any isolation precautions.
• Discourage the RP/SP from consuming food or water during the visit. If the research visit is lengthy and a nutrition/ hydration break is required, RP/SP should bring in their own food/drink and research staff should not be present when the RP/SP removes their mask. If this is not possible physical distancing must be maintained. Provide a disinfected table /surface for the RP/SP to use to put the food/drink on and wash/disinfect after use.
• Book daily cleaning by FMS in all the research rooms used by RP/SP. It is the study team's responsibility to arrange the cleaning schedule by contacting servicecalls@bruyere.org **in advance of your cleaning needs**
Community
• Ensure that the RP is wearing a mask during the visit. A three layered mask is recommended.
• Request that all household members (including animals) not involved in the research remove themselves from the visit area for the duration of the visit. If this is not possible, they must provide 2 meters of physical distance between themselves and the research staff member.
• Ensure that sufficient PPE, hand sanitizer and Bruyère approved disinfectant is brought to the community site. Note that hospital grade disinfectants may be too strong to use in RP homes and may cause reactions or damage personal property. Consult with IPAC for alternate products that could be used (See Table 1 for IPAC contact information).
• Do not place any research supplies on any contaminated surfaces at the community site, including PPE, hand sanitizer and disinfectant.

[8] *With the exception of approved procedure masks and face shields which are available on site at the site entrances for research staff.*

• Place all research supplies needed for the research visit into a plastic box and take that into community site. Disinfect the box using disinfectant wipes before and after the visit.
• Limit exposure time at the community site; abstaining from using washrooms whenever possible, limit the amount of study equipment/personal belongings going into the environment, and attempt to conduct the visit in only one location in the setting (e.g. living room),
• Only one member of the research team should conduct the visit and every effort should be made to maintain a 2 meter distance between the RP and research staff throughout the visit.
• Minimise cross contamination by not providing or accepting any food or drink during the community visit.
• Be prepared to stop the community visit if research staff or the RP become concerned for their safety.
• Ensure that hand hygiene is done before and after the visit and at any time during the visit if research staff touch a surface or equipment that has not been disinfected.
• Disinfect all surfaces touched by the research staff prior to leaving the premises.

Table1: Types of PPE required during the Research Visit (also see Appendix C)

	Movement within the Site or in the Community (to and from the site entrance and on the research unit)	Face-to-Face Interviews	Hands on Procedures (e.g. vital signs, ECG, physical examination)	Biological Sample Collection
Research Staff	o Procedural Mask o Face Shield	o Procedural Mask o Face Shield	o Procedural Mask o Face Shield o Lab Coat*(see below) o Hand hygiene before and after the procedure	o Gloves o Procedural Mask o Face Shield o Lab coat * (see below) o Hand Hygiene before and after the procedure
Research Participant	o Mask	o Mask	o Mask	o Mask

GENERAL PRINCIPLES

- Universal hand hygiene must be followed by all staff and RP/SP.
- Gloves should be easily accessible for research staff that prefer to use gloves for hands on procedures. Hand hygiene is required before putting on gloves and after they are removed.
- Gloves must be changed at the end of each biological sample collection procedure.
- The donning and doffing of PPE must follow Bruyère procedures, see InfoNet Bruyère - PERSONAL PROTECTIVE EQUIPMENT (PPE)
- It is advisable when conducting research visits in the community that research staff carry extra procedural masks in the event that RP/SP/third parties do not have a mask available.
- **Face shields;**
  - May be re-used between RPs using the following procedure;
    - Ensure no persons are within 2 meters.
    - Remove shield and place on clean paper towel. Have a second clean paper towel available.
    - Clean hands.
    - Put on gloves.
    - Use disinfectant wipes (not hand sanitizer), first disinfect the inside of the shield then the outside. Ensure that the surface remains wet for the minimum time period noted on the product being used (i.e. contact time). Set shield on second piece of clean paper towel.
    - Remove gloves.
    - Clean hands.
    - Allow shield to fully dry before placing it back on.
- *** Lab Coats;**
  - Are not classified as PPE.
  - Can be disposable or laundered.
  - If disposable, should be changed and disposed of in waste receptacles between RP, when soiled and at the end of the day.
  - If cloth, can be obtained through SPD and labelled with the study and room number. Laundry receptacles must be obtained through SPD and lab coats placed in the receptacle for laundering between RP, at the end of each day or when soiled. Laundry bags may need to be dropped off at a designated area by research staff.

- **IPAC Contact Information;**
  - Saint Vincent Hospital - ext. 2160 Office 0B40
  - Elisabeth Bruyère Hospital and Residence – ext. 1579 Office 730
  - Saint-Louis Residence – ext. 1900
  - Email - **Infection_Prevention_and_Control_Department@bruyere.org**

4.5 Sample Collection, Handling and Shipping

Human biospecimens must be treated as potentially infectious. All research studies that require sample collection must be handled by qualified trained staff who have their certification in Transportation of Dangerous Goods and with the highest regard for RP and staff safety. Study and Bruyère biosafety protocols must be followed. Samples that must be shipped using external couriers such as FedEx or UPS should follow the process below:

a) For small packages, the research team need to make arrangements in advance to leave the package at the information desk telecebp@bruyere.org on the day of the pick-up.

b) Couriers picking up packages at the information desk must be instructed that they need to pass the Bruyère screening questionnaire and wear a mask to pick up the package.

c) External delivery personnel (e.g. FedEx, UPS) must be instructed that they must pass the Bruyère screening and wear a mask prior to entering the site to deliver packages to the research area

d) In the event that the package is larger than the information desk will accept, arrangements need to be made by the research team to go down to the entrance and hand off the package to the courier.

4.6 Participant Reimbursement (Modification to Policy- [RES-FN301] Section 4)

The gift card and cash participant stipend process has been modified to limit research staffs' contact with the Bruyère Petty Cash Office. Research teams must take into account the following procedure when revising/developing their research plan:

STEP 1.	Complete the Petty Cash Stipend Request Form as per Policy Res-FN301 once per month.
STEP 2.	Send the form by email to Roxanne Giroux RGiroux@bruyere.org and copied to Alexandra Frenette AFrenette@bruyere.org
STEP 3.	Collect funds at the Petty Cash Office when notified by finance.
STEP 4.	Store funds behind three locking mechanisms (e.g. in a locked box, in a locked drawer, in a locked office).
STEP 5a).	Distribute funds by having the RP/SP; • Sign for the funds using a disinfected pen or electronic signature pad, • Complete hand hygiene procedures before and after handling funds, • Disinfect the plastic pen/ electronic signature pad.
STEP 5b).	Gift cards; • Must be disinfected, • Complete hand hygiene procedures before and after handling, • Consider using e-gift cards when possible.

4.7 Handling of Paper Consent Forms and other Paper Documents

If possible, minimize the use of paper documents, and consider oral consent options. However if paper must be used the following procedure should be followed;

- Hands must be sanitized prior to and after the handling of any paper documents.
- All tools used in the process of obtaining consent or dealing with paper documents must be disinfected prior to and after use.
- Items such as clip boards should be made of plastic and not cardboard so that they can be disinfected.
- Any item used in the process that cannot be disinfected must be discarded (other than the consent form itself).
- Consent forms signed by RPs should be stored in a clean envelop or folio for transportation.

4.8 COVID Consent and Contact Tracing

For all types of face-to-face research visits the research team must have a plan in place to ensure that if any member of the research team coming in contact with the RP/SP or the RP/SP or third party becomes symptomatic and COVID is confirmed, a plan is in place to ensure that everyone can isolate themselves and implement the best measures to prevent the transmission of COVID in the community. The new COVID Consent Form On-Site or Community is fundamental to this. For studies that are resuming, an REB amendment must be submitted informing the REB that this consent form is being added and approval received from the Bruyère REB before resuming research. For new studies the "COVID Consent Form On-Site or Community" must be included in their application.

Important to remember that;

- All studies which conduct face-to-face research using RPs who come on-site or where research staff go out to the community to see RPs, must include the "Consent for Face-to-Face Participation during COVID-19" Appendix B – COVID Consent Form On-Site or Community.
- Verbal consent of the "Consent for Face-to-Face Participation during COVID-19" must be obtained and documented during the scheduling call with RP/SP and any third parties that will be present during the visits. If consent is not obtained, the visit cannot occur.
- A copy of the Consent Form is provided to the RP/SP and or third party at the time of the first face-to-face visit.

4.9 Study Contingency Planning

Research teams need to prepare for possible future limits and/ or for the stopping of all research at Bruyère RI. Teams need to consider the implication of suspending their research study and how they might mitigate the effects of such an action. Consideration should be given to the following;

- What information will need to be reported to the Bruyère Research Ethics Board,
- Developing a communication plan to notify RP/SP, funders, collaborators, venders, and clinic staff,
- Ensuring that the research team remains current on all Bruyère infection control policies and procedures,
- How and if the study protocol might be modified to accommodate to virtual data collection.

Revision History

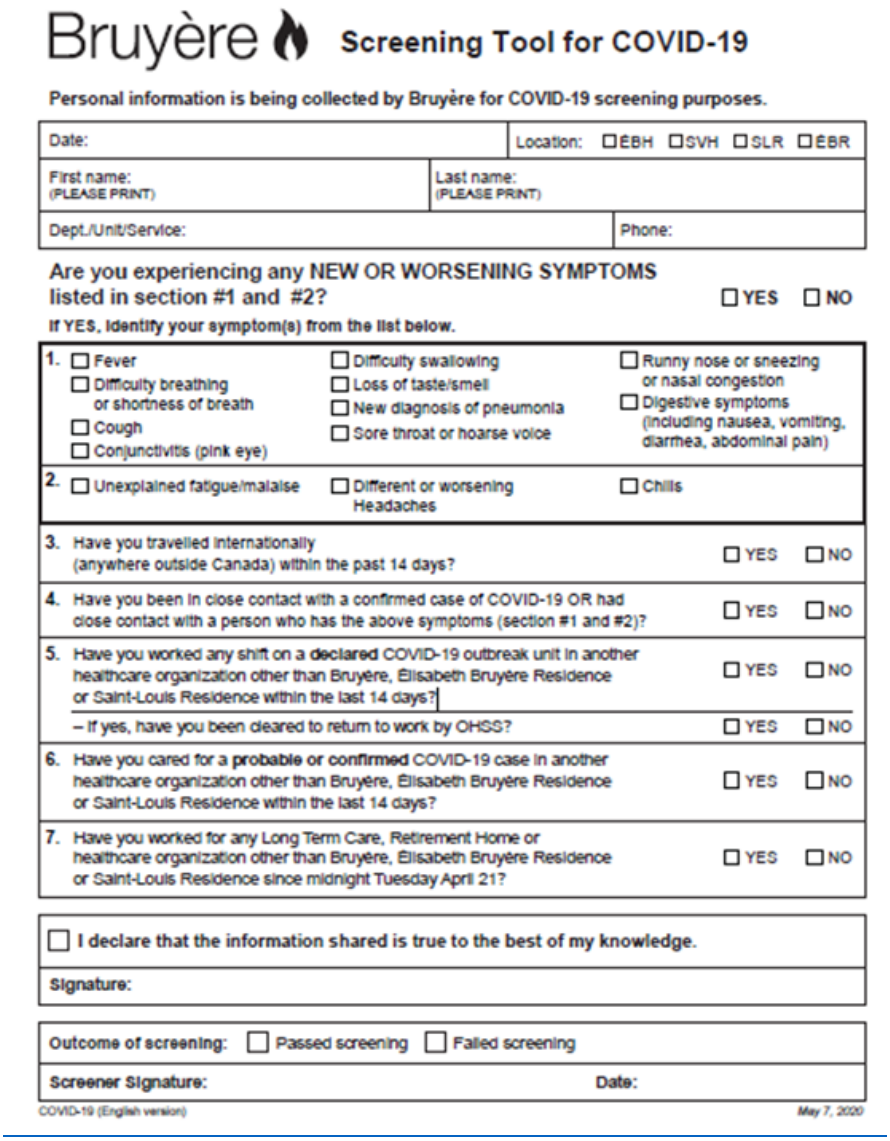
Rev. #	Date	Author	Reason for Change:
1.0	November 3, 2020	H. Niezgoda	Updating PPE and IPAC guidelines
1.1	December 9, 2020	H. Niezgoda	Updated Section 4.2 On-site Inpatient Visit. Added; "for in-patient research: Participants cannot be on quarantine for COVID-19; or be on droplet & contact precautions; or on airborne precautions; or symptomatic and on contact precautions.
2.0	January 27, 2021	H. Niezgoda	Entire document revised: reference to Resuming Research Template removed, acronym table inserted, content and procedures updated. ROMs reviewed and provided feedback.
3.0	March 23, 2021	H. Niezgoda	Version 1.1 and 2.0 combined and added comments from Philippe Fournier (Infection Control). Updated information Added Consent Forms, & hyperlinks for quick referencing. Formatting changed.
3.1	March 30, 21	H. Niezgoda	Removed reference to face shields being worn by participants while on site.
3.2	May 3, 2021	H. Niezgoda	Modified Section 3.1 - added point (6) Obtaining Medical Director/ Director Approval. Added Appendix D – Research Summary Page. Added definition of "Outpatient". Added Section 3.3 Vaccinated Participants.
3.3	May 18, 2021	H. Niezgoda	Updated section 3.1 Approval Process. Updated Appendix B with REB approved Covid-Consent Form (French and English) version 17May21. Updated Research Summary Page (Appendix D) 18May21 version.

5.0 Resources

The following resources were used in the creation/updating of this policy.

- Guidelines for Conducting In-Person Interactions & Research during COVID-19
- Resuming Research Flow Chart
- Bruyère Continuing Care Infection and Prevention policies and procedures. Refer to: https://infonet.bruyere.org/bins/Policies_default.aspx?cid=978&lang=1
- Putting On and Removing PPE https://infonet.bruyere.org/en/covid19-resources
- Clean and Disinfecting https://infonet.bruyere.org/en/CDS
- Screening tool for Covid-19 https://infonet.bruyere.org/uploads/IPAC/Outbreak/2019-nCoV/Covid_19_Form_May7%202020.pdf

Appendix A – Bruyère-approved COVID-19 Screening Questionnaire for Visitors



Bruyère **Screening Tool for COVID-19**

Personal information is being collected by Bruyère for COVID-19 screening purposes.

Date:	Location: ☐ÉBH ☐SVH ☐SLR ☐ÉBR
First name: (PLEASE PRINT)	Last name: (PLEASE PRINT)
Dept./Unit/Service:	Phone:

Are you experiencing any NEW OR WORSENING SYMPTOMS listed in section #1 and #2? ☐ YES ☐ NO

If YES, identify your symptom(s) from the list below.

1.	☐ Fever ☐ Difficulty breathing or shortness of breath ☐ Cough ☐ Conjunctivitis (pink eye)	☐ Difficulty swallowing ☐ Loss of taste/smell ☐ New diagnosis of pneumonia ☐ Sore throat or hoarse voice	☐ Runny nose or sneezing or nasal congestion ☐ Digestive symptoms (including nausea, vomiting, diarrhea, abdominal pain)
2.	☐ Unexplained fatigue/malaise	☐ Different or worsening Headaches	☐ Chills

3.	Have you travelled internationally (anywhere outside Canada) within the past 14 days?	☐ YES ☐ NO
4.	Have you been in close contact with a confirmed case of COVID-19 OR had close contact with a person who has the above symptoms (section #1 and #2)?	☐ YES ☐ NO
5.	Have you worked any shift on a **declared** COVID-19 outbreak unit in another healthcare organization other than Bruyère, Élisabeth Bruyère Residence or Saint-Louis Residence within the last 14 days?	☐ YES ☐ NO
	– If yes, have you been cleared to return to work by OHSS?	☐ YES ☐ NO
6.	Have you cared for a **probable or confirmed** COVID-19 case in another healthcare organization other than Bruyère, Élisabeth Bruyère Residence or Saint-Louis Residence within the last 14 days?	☐ YES ☐ NO
7.	Have you worked for any Long Term Care, Retirement Home or healthcare organization other than Bruyère, Élisabeth Bruyère Residence or Saint-Louis Residence since midnight Tuesday April 21?	☐ YES ☐ NO

☐ **I declare that the information shared is true to the best of my knowledge.**

Signature:

Outcome of screening: ☐ Passed screening ☐ Failed screening

Screener Signature: **Date:**

COVID-19 (English version) *May 7, 2020*

Appendix B (1) – REB Approved COVID Consent Form: On-Site and Community

Please note that all new studies applying for REB approval to begin their face-to-face research **must** include the new Verbal Consent for Face-to-Face Participant during COVID-19.

TEMPLATE

Verbal Consent for Face-to-Face On-Site Participation during COVID-19

Version Date: May 17, 2021

Bruyère Research Ethics Board Approval

Date of Approval: [05/18/2021]

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 and face shield protocols, which means that all staff must wear a procedural mask and face shield at all times while working at Bruyère.
- 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.
- Notify 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 screening 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 mask that will be provided to you at the screening entrance for the entirety of your visit.
- 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 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: May 17, 2021

Bruyère Research Ethics Board Approval

Date of Approval: [05/18/2021]

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 and face shield protocols, which means that all research staff must wear a mask and face shield 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.

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.
- 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 _____

Appendix B (2) – REB Approved COVID On-Site and Community Consent Form (French)

MODÈLE

Consentement verbal pour la participation en personne au site de recherche durant la pandémie de Covid-19

Date de la version: le 17 mai 2021

Approbation du Comité d'éthique de la recherche de Bruyère

Date d'approbation: [05/18/2021]

Sommaire

Ce document contient des informations importantes concernant la participation à des études en personne à l'Institut de recherche Bruyère (IR Bruyère) durant la pandémie de COVID-19. L'objectif de ce document est de vous informer des mesures que nous prenons à l'IR Bruyère pour assurer la sécurité des participants et de leurs partenaires d'étude et pour réduire le risque d'exposition à la COVID-19. Il décrit également vos responsabilités si vous choisissez de venir à l'IR Bruyère pour participer à un projet de recherche. Ces mesures ont été élaborées sous la direction de Santé publique Ottawa, de la province et de Bruyère.

Avant de donner votre approbation verbale à ce formulaire, veuillez poser toutes les questions que vous pourriez avoir, prendre tout le temps nécessaire et consulter d'autres personnes si vous le souhaitez.

Risques associés aux visites en personne au site de recherche

Bien que nous prenions de nombreuses mesures pour réduire le risque d'exposition à la COVID-19 dans notre hôpital, il existe toujours un risque que vous soyez exposé à la COVID-19. En raison de la nature du virus, les porteurs du virus ne présentent pas toujours de symptômes et peuvent tout de même être contagieux.

Les directives de santé publique nous permettent présentement d'effectuer des visites en personne au site de recherche. Toutefois, dans l'éventualité où ces directives de santé publique changeraient, il se peut que les visites en personne soient interrompues et/ou que le projet de recherche soit mis sur pause. Si cela se produit, vous en serez rapidement informé par un membre de l'équipe de recherche et serez mis au courant des mesures mises en place concernant le projet de recherche auquel vous participez.

Ce que nous faisons pour minimiser les risques d'exposition :

- Poser des questions de dépistage COVID à toutes les personnes qui entrent à Bruyère.

- Respecter les protocoles universels de port du masque et d'écran facial, ce qui signifie que tout le personnel doit porter un masque de procédure et un écran facial à tout moment lorsqu'il travaille à Bruyère.
- Maintenir une distance physique de 2 mètres entre tous les individus qui ne font pas partie du même ménage, dans la mesure du possible.
- Pendant les procédures médicales, le personnel portera toujours une blouse de laboratoire et pendant le prélèvement d'échantillons biologiques, il portera des gants. Le personnel se lavera aussi soigneusement les mains avant et après toutes les procédures.
- Limiter le nombre de personnes touchant aux différentes surfaces. Seul le personnel touchera aux objets comme les poignées de porte et les boutons d'ascenseur pendant votre visite.
- Suivre les directives de Bruyère en matière de prévention et de contrôle des infections (IAPC) pour une bonne hygiène des mains et la désinfection des surfaces.
- Restreindre l'accès du personnel, des participants et de leurs partenaires d'étude (s'il y a lieu) à certaines zones de l'hôpital.
- Accompagner les participants et leurs partenaires d'étude (s'il y a lieu) lors de leur visite depuis l'entrée et jusqu'à la sortie de Bruyère.
- Réduire en tout temps le nombre de membres du personnel travaillant au site de recherche.
- Ne pas autoriser plus d'un participant et son partenaire d'étude (s'il y a lieu) au site de recherche en tout temps.
- Prévenir le participant et son partenaire d'étude (s'il y a lieu) dès que possible si un membre de l'équipe de recherche avec lequel il a été en contact pendant sa visite devient symptomatique et qu'un diagnostic de COVID-19 est confirmé.

Votre responsabilité pour minimiser l'exposition/la transmission

Afin de pouvoir continuer à participer aux visites en personne pour la recherche à l'IR Bruyère, vous devez accepter de suivre les mesures de sécurité mentionnées ci-dessous. Ces précautions ont été mises en place pour assurer votre sécurité, celle de l'équipe de recherche et des patients de Bruyère, et pour prévenir une éventuelle exposition à la COVID-19. Si vous ne voulez pas suivre ces mesures de sécurité, il vous sera demandé de ne plus vous rendre à l'IR Bruyère pour des visites en personne, ce qui pourrait avoir un impact sur votre capacité à participer à nos différents projets de recherche.

- Vous et votre partenaire d'étude (s'il y a lieu) acceptez de compléter toutes les procédures de dépistage de la COVID-19 nécessaires, qui comprennent :
    - Un dépistage lors de l'appel téléphonique pour la prise de rendez-vous.
    - Un dépistage lors de l'appel téléphonique de rappel, qui peut avoir lieu 24 heures avant votre visite ou le vendredi précédant votre visite du lundi.
    - Un dépistage en personne à l'entrée de l'hôpital, rue Bruyère, où l'on vous demandera de vous présenter le jour de votre visite.
- Vous vous engagez à porter votre propre masque lorsque vous vous présentez à l'entrée de l'hôpital Bruyère.
- Vous vous engagez à changer votre masque et à porter le masque qui vous sera remis à l'entrée lors du dépistage pendant toute la durée de votre visite.
- Vous acceptez de ne pas retirer le masque, sauf si un membre de l'équipe de recherche vous demande de le faire.
- Vous acceptez de maintenir une distance de 2 mètres entre vous et les autres personnes qui ne font pas partie de votre ménage pendant votre visite, dans la mesure du possible, sauf pendant les interventions et procédures médicales qui ne permettent pas une distance de 2 mètres.

- Si vous avez besoin de boire ou de manger pendant votre visite pour des raisons médicales ou en raison de la durée de la visite, vous acceptez d'apporter vos propres boissons et nourriture et de suivre les instructions fournies par le personnel de recherche sur le moment et la manière de les consommer.
- Vous informerez immédiatement l'équipe de recherche [FOURNIR UN NUMÉRO DE CONTACT] si vous présentez des symptômes liés à la COVID-19 (par exemple, toux nouvelle ou aggravée, essoufflement, fièvre, frissons, fatigue ou faiblesse, nouveau symptôme de perte d'odorat ou de goût) ou si vous testez positif à la COVID-19 dans les 14 jours suivant votre visite à l'IR Bruyère.
- Vous acceptez que l'IR Bruyère communique votre nom et vos coordonnées au Service de santé et sécurité au travail de Bruyère et/ou à d'autres responsables de la santé publique si cela s'avère nécessaire pour retracer rapidement les contacts. Vous comprenez qu'en fournissant ces informations, votre anonymat ne peut être maintenu.

Ces politiques/procédures ont été révisées et approuvées par l'Institut de recherche Bruyère et le Conseil d'éthique de la recherche de Soins continus Bruyère.

Si vous souhaitez obtenir de plus amples informations ou si vous avez des questions à propos des informations décrites ci-dessus, veuillez contacter [CONTACT DE L'ÉQUIPE DE RECHERCHE, NUMÉRO DE CONTACT, COURRIEL DE CONTACT].

SIGNATURE DE LA PERSONNE OBTENANT LE CONSENTEMENT

J'ai personnellement expliqué le formulaire de consentement au participant (nom du participant - en caractères d'imprimerie) _____, et à son partenaire d'étude (s'il y a lieu) (nom du partenaire d'étude - en caractères d'imprimerie) _____ et répondu à toutes ses/leurs questions. Je pense qu'il/elle/ils/elles comprend/comprennent les informations décrites dans ce document et consent/ent librement à participer.

Je (nom de la personne obtenant le consentement) (en caractères d'imprimerie) _____,

Consentement verbal confirmé par téléphone le (date : jj/mmm/aaaa) _____

à (heure : hh:mm) _____

Signature _____ Date de signature _____

MODÈLE

Consentement verbal pour les visites en personne dans la communauté pendant la COVID-19

Date de la version: le 17 mai 2021

Approbation du Comité d'éthique de la recherche de Bruyère

Date d'approbation: [05/18/2021

Sommaire

Ce document contient des informations importantes concernant la participation à des projets de recherche en personne dans la communauté durant la pandémie de COVID-19. L'objectif de ce document est de vous informer des mesures que nous prenons à l'Institut de Recherche Bruyère (IR Bruyère) pour assurer la sécurité des participants, de leurs partenaires d'étude et de la communauté, et pour réduire le risque d'exposition à la COVID-19. Il décrit également vos responsabilités si vous choisissez de permettre à un membre du personnel de recherche de l'IR Bruyère de venir chez vous pour effectuer un projet de recherche. Ces étapes ont été élaborées sous la direction de Santé publique Ottawa, de la province et de Bruyère.

Avant de donner votre approbation verbale à ce formulaire, veuillez poser toutes les questions que vous pourriez avoir, prendre tout le temps nécessaire et consulter d'autres personnes si vous le souhaitez.

Risques associés aux visites en personne dans la communauté

Bien que nous prenions de nombreuses mesures pour réduire le risque d'exposition à la COVID-19 dans la communauté, il existe toujours un risque que vous soyez exposé à la COVID-19. En raison de la nature du virus, les porteurs du virus ne présentent pas toujours de symptômes et peuvent tout de même être contagieux.

Les directives de santé publique nous permettent présentement d'effectuer des visites en personne dans la communauté. Toutefois, dans l'éventualité où ces directives de santé publique changeraient, il se peut que les visites en personne soient interrompues et/ou que le projet de recherche soit mis sur pause. Si cela se produit, vous en serez rapidement informé par un membre de l'équipe de recherche et vous serez mis au courant des mesures mises en place concernant le projet de recherche auquel vous participez.

Ce que nous faisons pour minimiser les risques d'exposition :

- Dépistage de tous les membres du personnel de l'IR de Bruyère avant qu'ils n'effectuent une visite de recherche en personne dans la communauté.
- N'autoriser qu'un seul membre du personnel de recherche à entrer chez vous pour effectuer la visite.

- Respecter les protocoles universels de port du masque et d'écran facial, ce qui signifie que tout le personnel doit porter un masque de procédure et un écran facial à tout moment lorsqu'il se trouve à votre résidence.
- Maintenir une distance physique de 2 mètres entre tous les individus qui ne font pas partie du même ménage, dans la mesure du possible.
- Limiter le toucher des surfaces dans votre résidence pendant la visite.
- Suivre les directives de Bruyère en matière de prévention et de contrôle des infections (IAPC) pour une bonne hygiène des mains et la désinfection des surfaces.
- Prévenir le participant et son partenaire d'étude (s'il y a lieu) dès que possible si un membre de l'équipe de recherche avec lequel il a été en contact pendant sa visite devient symptomatique et qu'un diagnostic de COVID-19 est confirmé.

Votre responsabilité pour minimiser l'exposition/la transmission

Afin de pouvoir continuer à participer aux visites en personne dans la communauté pour un projet de recherche, vous devez accepter de suivre les mesures de sécurité mentionnées ci-dessous. Ces précautions ont été mises en place pour assurer votre sécurité, celle de l'équipe de recherche et des autres membres de votre foyer, et pour prévenir une éventuelle exposition à la COVID-19. Si vous ne voulez pas suivre ces mesures de sécurité, la visite en personne dans la communauté ne pourra pas avoir lieu, ce qui pourrait avoir un impact sur votre capacité à participer à nos différents projets de recherche.

Vous et tous les membres de votre foyer (s'il y a lieu) présents lors de la visite de recherche acceptez de :

- Compléter toutes les procédures de dépistage de la COVID-19 nécessaires, qui comprennent :
  - Un dépistage lors de l'appel téléphonique pour la prise de rendez-vous.
  - Un dépistage lors de l'appel téléphonique de rappel, qui peut avoir lieu 24 heures avant votre visite ou le vendredi précédant votre visite du lundi.
  - Un dépistage immédiatement ou peu avant que le membre du personnel de recherche n'entre chez vous.
- Porter un masque pendant toute la durée de la visite.
- Faire sortir tout animal (par exemple, un animal de compagnie) de la zone de visite pendant la visite pour le projet de recherche.
- Maintenir, dans la mesure du possible, une distance de 2 mètres entre vous et les personnes qui ne font pas partie de votre foyer pendant la visite.
- Vous informerez immédiatement l'équipe de recherche [FOURNIR UN NUMÉRO DE CONTACT] si vous présentez des symptômes liés à la COVID-19 (par exemple, toux nouvelle ou aggravée, essoufflement, fièvre, frissons, fatigue ou faiblesse, nouveau symptôme de perte d'odorat ou de goût) ou si vous testez positif à la COVID-19 dans les 14 jours suivant votre visite à l'IR de Bruyère.
- Vous acceptez que l'IR de Bruyère communique votre nom et vos coordonnées au Service de santé et sécurité au travail de Bruyère et/ou à d'autres responsables de la santé publique si cela s'avère nécessaire pour retracer rapidement les contacts. Vous comprenez qu'en fournissant ces informations, votre anonymat ne peut être maintenu.

Ces politiques/procédures ont été révisées et approuvées par l'Institut de recherche Bruyère et le Conseil d'éthique de la recherche de Soins continus Bruyère.

Si vous souhaitez obtenir de plus amples informations ou si vous avez des questions à propos des informations décrites ci-dessus, veuillez contacter [CONTACT DE L'ÉQUIPE DE RECHERCHE, NUMÉRO DE CONTACT, COURRIEL DE CONTACT].

SIGNATURE DE LA PERSONNE OBTENANT LE CONSENTEMENT

J'ai personnellement expliqué le formulaire de consentement au participant (nom du participant - en caractères d'imprimerie) _____, et au partenaire de l'étude (s'il y a lieu) (nom du partenaire de l'étude - en caractères d'imprimerie) _____ et répondu à toutes ses/leurs questions. Je pense qu'il/elle/ils/elles comprend/comprennent les informations décrites dans ce document et consent/ent librement à participer.

Je (nom de la personne obtenant le consentement) (en caractères d'imprimerie) _____,

Consentement verbal confirmé par téléphone le (date : jj/mmm/aaaa) _____

à (heure : hh:mm) _____

Signature _____ Date de signature _____

Appendix C – Table representing the degree of risk related to the type of research and type of PPE

COVID-19 Research Risk Level	Research Method	Examples	Direct Contact	PPE Required
Level 1	Interaction/observation	Interviews, focus groups, surveys, computer-based experiments and data collection (on site)	None or minimal contact, physical distancing can be easily achieved	Procedure mask, face shield
Level 2	Intervention	Introducing dietary or exercise regime, drug, or natural health product testing	Some physical contact (e.g. biospecimen collection, body measurements, participant sweating, breathing heavily), physical distancing sometimes challenging to maintain	Procedure mask, face shield, gloves
Level 3	Physical treatment / manipulation	Physical therapy, biopsy, taking blood sample	Sustained physical contact, physical distancing not possible	Procedure mask, face shield, gloves

Appendix D – Research Project Summary

Research Project Summary

(Ver1.0. 20210518)

This form must be completed if a study;
1. Requires departmental sign-off for the Bruyère Research Ethics Submission, or;
2. Has been previously approved by the BREB and is seeking approval to resume research during the COVID-19 Pandemic.

Contact Name | Date

E-mail | Phone

SECTON (1) STUDY INFORMATION

1. Study Title

2. REB#

3. List Bruyère PI, Investigators & Co-Investigators

4. Study Status

5. Briefly describe the study design

6. Briefly describe the study's primary objective.

7. Why is this study important and how will it impact the future care of patients at Bruyère.

SECTION (2) PARTICIPANTS

8. Briefly describe the study main inclusion and exclusion criteria.

9. Where will the research occur (e.g. EBH - Palliative Care, SVH - 5N etc) ?

10. Who are the participants?

11. How many participants will be recruited and over what period of time?

12. What are the activities and time commitments required of the participants and how will this fit into the unit workflow?

13. Are unit staff being asked to help ?

- ◯ Yes
- ◯ No
- ◯ N/A

13a. If yes, describe what unit staff are being asked to do, what the time commitment will be, when will this be done (during work hours, after hours) and describe any compensation the clinical unit will receive.

SECTION (3) COVID APPROVAL

14. Has the research project received IPAC/PPE approval?

- ◯ Yes
- ◯ No

14a. If no, please briefly explain why.

15. Does the research project follow the most current version of the Procedure Manual on Conducting Face-to-face research?

- ◯ Yes
- ◯ No

15a. If no, please briefly explain why.

Departmental Sign-off (IMPORTANT: please note that sign-off on this form is only required if the study already has REB approval and is seeking to resume research during the COVID pandemic.)
All new studies must obtain Departmental Sign-off on Section 25 of the Research Ethics Application.

Not Applicable ☐

Name & Title

Date

Signature