

<p>INSTITUT DE RECHERCHE</p>  <p>Bruyère RESEARCH INSTITUTE</p>	<p>Subject: Procedure Manual on Conducting Face- to-Face Participant Research</p>
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TABLE OF CONTENTS

PREAMBLE.....2

PURPOSE3

SCOPE.....3

ACROYNMS3

DEFINITIONS.....4

RESOURCES & CONTACT INFORMATION5

 CURRENT STATUS: AS OF FEBRUARY 14, 2023 5

 FORMS/DOCUMENTS REFERENCED IN THIS MANUAL..... 5

 RESOURCES & POLICIES REFERENCED IN THIS MANUAL 6

 EXTERNAL ACCESS 6

 INTERNAL ACCESS..... 6

 ENTRANCE TO BRUYÈRE SITES 8

 CONTACT INFORMATION..... 8

OVERVIEW9

 GENERAL PRINCIPLES..... 9

 APPROVAL PROCESS 10

 PROCESS: AMENDMENTS to EXISTING REB- Approved Research..... 10

 PROCESS: NEW FACE-TO-FACE PARTICIPANT RESEARCH 11

PROCEDURES: RESEARCH VISITS.....12

 ALL RESEARCH PARTICIPANTS WHO ARE COMING ON-SITE FOR A RESEARCH VISIT 12

 ON-SITE RESEARCH VISITS: CLINICAL STAFF 14

 ON-SITE RESEARCH VISITS: INPATIENT/RESIDENT 14

 TRANSPORTATION OF RPs: INPATIENT/RESIDENT 15

 COMMUNITY RESEARCH VISITS 15

 DROPPING OFF OR PICKING UP RESEARCH EQUIPMENT IN THE COMMUNITY..... 17

PROCEDURES: PPE, LAB COATS AND CLEANING.....17

ON-SITE RESEARCH VISITS.....	18
<i>Cleaning and Disinfecting</i>	18
<i>Gloves and Hand Hygiene</i>	18
<i>Additional PPE Requirements</i>	18
<i>Lab Coats</i>	18
COMMUNITY RESEARCH VISITS	19
<i>GENERAL CONSIDERATIONS</i>	19
<i>Masks and Physical Distancing</i>	19
<i>Disinfection</i>	19
PROCEDURES: SAMPLE COLLECTION, HANDLING AND SHIPPING	20
SHIPPING OF SAMPLES.....	20
PROCEDURES: PARTICIPANT COMPENSATION.....	20
PROCEDURES: HANDLING OF PAPER CONSENT FORMS AND OTHER PAPER DOCUMENTS	21
PROCEDURES: COVID CONSENT AND CONTACT TRACING	21
PROCEDURES: STUDY CONTINGENCY PLANNING.....	21
PROCEDURES: RESEARCH VISITORS (RV).....	22
APPENDIX A – DEGREE OF RISK RELATED TO THE TYPE OF RESEARCH AND PPE REQUIREMENTS.....	23

PREAMBLE

The Bruyère Research Institute (“Bruyère RI”) is committed to promoting a safe environment and protecting the health and wellbeing of everyone involved in research and care at Bruyère, including researchers, staff, students/trainees, volunteers, participants, study partners, and 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 in-person face-to-face participant research. The procedures to conduct research are guided by Bruyère and Bruyère RI Senior Leadership, following Bruyère policies on Infection Prevention and Control.

This procedure manual (“Manual”) was developed to provide the information that research teams require to conduct in-person face-to-face research during a pandemic, however the information it contains is also useful outside of a pandemic context. The Manual has therefore been reformatted to provide general information about in-person research and links to pandemic-related information that is subject to change.

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.

It is the responsibility of researchers and their teams to ensure they are conducting their research in accordance with the latest guidelines and requirements as issued by Bruyère, the Bruyère RI, the Bruyère Research Ethics Board (“REB”), and local, provincial, and federal authorities.

PURPOSE

This Manual contains comprehensive information about how to conduct face-to-face research in general and during a pandemic on-site and in the community, taking into consideration the appropriate safety requirements. This Manual is posted on Bruyère’s external website (see *Resources & Contact Information: [External Access](#)* for link).

Research teams must use the information in this Manual to develop their research plan.

Links to information that may change on a regular basis, such as screening procedures, masking type and requirements for eye protection, are found on Bruyère’s InfoNet and links to these resources are found in this Manual to facilitate ease of access while avoiding errors and delays due to updating of information in the Manual. See *Resources & Contact Information* below. **These online resources must be considered the most current information. In situations where there is a discrepancy between this Manual and the information found on Bruyère’s websites, the information online should be followed.**

Notify your Research Operations Manager (“ROM”) of any identified discrepancy. If access to InfoNet is an issue, contact your ROM to identify a solution.

SCOPE

The information contained in this Manual applies to all individuals involved in face-to-face research conducted at or under the jurisdiction of Bruyère RI.

During a pandemic, if research can be conducted virtually, this is the preferred method as it reduces the risk to all those involved. For research that must occur in-person, this Manual outlines the procedures and approvals required for the research to be approved to proceed.

ACROYNMS

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
InfoNet	Internal Bruyère website (login required to access)
IPAC	Infection Prevention and Control team
OHSS	Occupational Health and Safety Services
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

DEFINITIONS

Epidemic: refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. [Principles of Epidemiology | Lesson 1 - Section 11 \(cdc.gov\)](#)

Face-to-face Participant Research: any research that involves direct in-person face-to-face contact between a research participant (see definition) and research staff at any of Bruyère’s campuses or in the community.

Infection Control Outbreak Management Plan(s): the processes in which infections and infectious diseases are to be dealt with at Bruyère, following best practices in infection prevention and control. These procedures have been established to best minimize the transmission of communicable diseases at Bruyère and are subject to change as needed.

Disinfect: The act of applying a disinfectant solution (typically Cavi or Accel Wipes) to a surface for a sufficient length of time (“contact time”) to effectively eliminate the bacteria/viruses on the surface. If a surface is visibly dirty, it should be cleaned and then disinfected. Refer to Policy [Infection Control 01 – Routine Practices](#).

Outpatient: An individual who is receiving care from Bruyère but is not hospitalized or admitted to a clinical unit as an inpatient.

Inpatient: Any individual receiving care at Bruyère who stays at the hospital while receiving treatment.

Resident: An individual who lives at one of Bruyère’s long term care homes.

Tenant: Individual living at one of the independent living facilities run by Bruyère.

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]

Personal Protective Equipment (PPE): clothing or equipment worn to provide protection from exposure to microorganisms. Refer to information and instructions on the Bruyère Infection Prevention and Control InfoNet page on types of PPE and on how to apply and remove (doff & don) PPE. See *Resources & Contact Information: Internal Access* for links to the latest PPE requirements and usage instructions. Also refer to Policy [Infection Control 11 – Gloves, Use of](#), for glove use.

Research Participants (RP): are persons who voluntarily participate in human participant research after giving informed consent to be part of the research project. They may be inpatients, outpatients, residents, or tenants of Bruyère, healthcare and/or research staff, community members, or other individuals. All Research Participants who are not Inpatients, Residents, or Tenants are treated as Visitors when coming onsite to Bruyère.

Research Visitors (RV): are persons who are not study partners or study participants and are coming to Bruyère in some type of research capacity (i.e., study monitor, contractor, or consultant). Research visitors must follow the guidelines for general Visitors (see Section 3 for links), though they do not need to complete the 5-minute training video.

Screening Questions/Bruyère-approved COVID-19 screening questionnaire for staff: refers to the latest version of COVID-19 screening questions in use at Bruyère for staff. See *Resources & Contact Information: External Access* for the link to the latest screening tool.

Screening Questions/ Bruyère-approved COVID-19 screening questionnaire for visitors: refers to the latest version of

COVID-19 screening questions in use at Bruyère for visitors. In this context, “for visitors” includes research participants, study partners, and research visitors. See *Resources & Contact Information: External Access* for the links to the latest information and screening tools for all types of visitors to Bruyère.

Study Partners (SP): are not classified as Research Visitors. They are persons who are required for a research study (e.g., clinical trial), sign an informed consent form to be part of the study, and share in the decision-making process with the research participant to join the research study. The research study partner ensures trial compliance and acts as a knowledgeable informant, reporting on the study participant's cognitive and functional status to help evaluate the intervention's safety and efficacy. Study Partners are treated as Visitors when coming onsite to Bruyère.

RESOURCES & CONTACT INFORMATION

The latest information, resources, and contact information related to all content included in this Manual is consolidated into this section to facilitate keeping information up to date.

CURRENT STATUS: AS OF FEBRUARY 17, 2023¹

Masking requirements	<p>Masks required</p> <p>See: https://infonet.bruyere.org/en/covid-staff-ipac</p>
Screening requirements	<p>Passive screening on all campuses</p> <p>See: https://www.bruyere.org/en/visitor-information</p> <p>Please stay home if you are sick. Employees should report their illness to OHSS via <i>Bruyère-approved COVID-19 Staff Screening Questionnaire</i> and to their supervisor & ROM.</p>

FORMS/DOCUMENTS REFERENCED IN THIS MANUAL

Research Summary Form	<p>https://www.bruyere.org/en/research-during-COVID-19 Found under RESOURCES & QUICKLINKS</p>
Face-to-Face Research Spreadsheet (IPAC/PPE Requirements)	<p>In-Person Research Spreadsheet</p>
COVID-19 Consent Forms (French & English)	<p>https://www.bruyere.org/en/research-during-COVID-19 Found under RESOURCES & QUICKLINKS</p>
Procedure Manual on Conducting Face-to-Face Participant Research (this manual)	<p>https://www.bruyere.org/en/research-during-COVID-19 under RESOURCES & QUICKLINKS</p>
Applying for REB approval of a new research project from	<p>https://www.bruyere.org/en/researchethicsboard</p>

¹ Effort will be made to keep this “Current Status” up to date, however as stated elsewhere in this manual, the information found on Bruyère’s websites takes precedence as it is updated first.

Bruyère REB	<i>Note: Updates to the REB’s websites are planning for winter/spring 2023. This link will be updated with a more specific reference once those updates are finalized.</i>
BREB – General, Section 25: Division/Department/Program Approval	https://www.bruyere.org/en/researchethicsboard <i>Note: Updates to the REB’s websites are planning for winter/spring 2023. This link will be updated with a more specific reference once those updates are finalized.</i>
Applying for REB approval of an Amendment to an existing research project from Bruyère REB	https://www.bruyere.org/en/researchethicsboard <i>Note: Updates to the REB’s websites are planning for winter/spring 2023. This link will be updated with a more specific reference once those updates are finalized.</i>
Bruyère-approved COVID-19 Visitor Screening Questionnaire <i>(used by research participants, study partners, and research visitors)</i>	https://forms.office.com/pages/responsepage.aspx?id=ctG_NyOk9UCPUTDpR3vX-TqKHSAApErtB5vw9s6L9UN0dXVjIOVUNLN1RJQ09XRkpDOEVCODk2Ni4u Note: When completing this questionnaire, RP/SPs should indicate they are an “Outpatient Clinic Attendee” or “Research Participant”. There is no requirement to click “submit” at the end of the form.
Bruyère-approved COVID-19 Staff Screening Questionnaire	https://forms.office.com/pages/responsepage.aspx?id=ctG_NyOk9UCPUTDpR3vX_xh59lo4txlGrf8FZ7e0dmpUODhZnk9NV1dBT0oxMjBTQjgxQk1RNThZUCQIQCN0PWcu
Supply Requisition Form <i>(InfoNet access required)</i>	https://infonet.bruyere.org/en/spd under SPD Forms

RESOURCES & POLICIES REFERENCED IN THIS MANUAL

EXTERNAL ACCESS

Research during COVID-19 <i>Research institute documents & updates</i>	https://www.bruyere.org/en/research-during-COVID-19
Bruyère Visitor Information	https://www.bruyere.org/en/covid19-visitor
Disinfectants for home use <i>(for disinfectants for use on-site at Bruyère, consult SPD)</i>	https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/list.html
Ottawa Public Health: COVID-19 information & guidelines	https://www.ottawapublichealth.ca/en/public-health-topics/novel-coronavirus.aspx
Ottawa Public Health: Isolation requirements for COVID-19 cases in Ottawa	https://www.ottawapublichealth.ca/en/professionals-and-partners/COVID-19_Symptoms_and_Management.aspx
Ontario government: COVID-19	https://www.ontario.ca/page/covid-19-coronavirus
Transportation of Dangerous Goods	https://tc.canada.ca/en/dangerous-goods/transportation-dangerous-goods-canada https://n2canada.ca (to access CITI training module)

INTERNAL ACCESS

InfoNet login required - If you require access and do not have access to InfoNet, please contact your ROM

COVID-19 Information Hub <i>Links to latest COVID-19 information on InfoNet</i>	https://infonet.bruyere.org/en/covid-overview
Newsroom: Thriving on change <i>Latest updates on changes at Bruyère</i>	https://infonet.bruyere.org/en/newsroom?newsid=7188
IPAC Expectations: Staff	https://infonet.bruyere.org/en/covid-staff-ipac
IPAC Expectation: Visitors	https://infonet.bruyere.org/en/covid-visitors-dcps-ipac
IPAC Expectations: Patients	https://infonet.bruyere.org/en/covid-patients-ipac
PPE Requirements: Mask & Eye protection <i>See Appendix A for additional information about PPE considerations for different types of research.</i>	For Staff: https://infonet.bruyere.org/en/covid-staff-ipac For Visitors: https://infonet.bruyere.org/en/covid-visitors-dcps-ipac For Patients: https://infonet.bruyere.org/en/covid-patients-ipac Current PPE Requirements for Staff, DCPs and Visitors – Masks & Eye Protection: https://infonet.bruyere.org/en/newsroom?newsid=8306#3
Masks – Proper wear	https://infonet.bruyere.org/en/respiratoryfittesting Download: How to properly put on a disposable respirator (N95)
Masks - N95 Fact Sheet	https://infonet.bruyere.org/en/respiratoryfittesting Download: N95 Fact Sheet
Personal Protective Equipment (PPE) <ul style="list-style-type: none"> • Order of don/doff • Summary of use 	https://infonet.bruyere.org/en/IPAC-PPE
Video tutorials on donning/doffing PPE	https://infonet.bruyere.org/en/covid-resources
The 4 moments of hand hygiene & How to wash hands	https://infonet.bruyere.org/en/IPACchandhygiene
Cleaning, Disinfection & Sterilization information	https://infonet.bruyere.org/en/CDS
Policy: Outbreak Management (Infection Control 06)	https://infonet.bruyere.org/bins/Policies_default.aspx?cid=978&lang=1
Policy: Email (ADMIN 29, Section 3)	https://infonet.bruyere.org/bins/Policies_default.aspx?cid=788&lang=1
Policy: Hand Hygiene (Infection Control 10)	https://infonet.bruyere.org/bins/Policies_default.aspx?cid=980&lang=1
Policy: Gloves, use of (Infection Control 11)	https://infonet.bruyere.org/bins/Policies_default.aspx?cid=981&lang=1
Fit testing for N95 masks	General information: https://infonet.bruyere.org/en/respiratoryfittesting

	Contact occupationalhealthandsafety@bruyere.org to arrange for fit testing
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ENTRANCE TO BRUYÈRE SITES

Review *Thriving on Change* (link above) on InfoNet for the correct information at the time of your study.

Elisabeth Bruyère Hospital (EBH)	Research being conducted at EBH on 2Y – 75 Bruyère St Research being conducted at EBH on 7th floor – 43 Bruyère St
Saint Vincent Hospital (SVH)	Enter via doors off parking lot
Residence Saint Louis (RSL)	Enter by main front doors
Greystone	Enter by main front doors

CONTACT INFORMATION

<p>IPAC <i>General inquiries about the content of this Manual or the latest procedures should be sent to your ROM. Reach out to IPAC directly only for study-related exception requests.</i></p> <p>Always cc your ROM on any communication with IPAC</p>	<p>IPAC Contact Information: Email - Infection Prevention and Control Department@bruyere.org</p> <p>Saint Vincent Hospital - ext. 2160 Office 0B40 Elisabeth Bruyère Hospital and Residence – ext. 1579 Office 730D Saint-Louis Residence – ext. 2678 Office A-108</p>
<p>OHSS <i>OHSS is responsible for PPE. Any questions about additional PPE needs specific to your study should be directed to them.</i></p> <p><i>General inquiries about the content of this Manual or the latest procedures should be sent to your ROM. Reach out to IPAC directly only for study-related exception requests.</i></p> <p>Always cc your ROM on any communication with IPAC</p>	<p>OHSS Contact Information: Email - occupationalhealthandsafety@bruyere.org</p>
<p>SPD <i>To obtain PPE, disposal bins/hampers and disinfecting materials.</i></p>	<p>SPD@bruyere.org</p> <p><i>Note: A Supply Requisition is required to obtain any items for any purchase</i></p>
<p>Screening (at entrances to Bruyère, when required)</p>	<p>When advance notice of RPs/SPs or RVs coming onsite is required:</p> <p>RP coming to Elisabeth Bruyère Hospital: telecebp@bruyere.org RP coming to Saint Vincent Hospital: tsvp@bruyere.org</p>
<p>REB Manager, Bruyère REB</p>	<p>reb@bruyere.org</p>
<p>Facilities Management</p>	<p>General & non-urgent: servicecalls@bruyere.org</p>

OVERVIEW

GENERAL PRINCIPLES

When creating study plans, research teams need to consider the following general principles:

1. 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.
2. The research methodology itself should ensure that a plan is in place in the event that in-person research is stopped due to an outbreak.
3. 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. Discuss these issues with the relevant members of clinical units/departments, as appropriate.
4. Ensure that the study complies with:
 - a. this Manual;
 - b. institutional directives, as outlined by the latest PPE, IPAC and procedure requirements on Bruyère websites; and
 - c. government directives (including provincial directives and local public health guidelines).
5. In the event that face-to-face research **must** occur, careful consideration needs to be given to the risks associated with the following:
 - a. RPs and SPs (if applicable) traveling to the site and being on site.
 - b. Research staff working in the research area or the community.
 - c. Bruyère clinical unit staff coming into contact with research staff.
 - d. Third parties in the community, such as other members of a RP's household, being present while the research is being conducted.
6. Determine if sufficient research staff are available to conduct the research and if required, have been N95 fit-tested. While masking requirements may change, in certain circumstances having key staff fit-tested provides additional flexibility to the research team.
7. Ensure that the research area is well ventilated by:
 - a. having a window or door open during the visit (if appropriate);
 - b. making sure the heating and ventilation system is working;
 - c. turning on a ceiling fan, if available; and/or
 - d. considering having the visit outside if possible.
8. The research area should be large enough to provide physical distancing of 2 meters. If distancing is not possible and procedures that may require the removal of masks are required, additional safety precautions such as plexiglass screens may be recommended. Contact your ROM and Occupational Health and Safety Services to

discuss.

9. Vaccinated RPs, SP, and Research Visitors must follow the same screening procedures and PPE requirements as non-vaccinated participants, as outlined in the Bruyère website links located in [Resources & Contact Information](#).

APPROVAL PROCESS

The approval process for engaging in in-person face-to-face participant research can be a stand-alone process (for existing projects requiring an amendment) or part of the initial BREB application (for new projects). Both processes are outlined below.

Research teams are required to adhere to the latest version of this Manual and associated Bruyère and Bruyère RI guidelines, irrespective of whether their research was approved to start under an earlier version.

In situations where the content of this Manual and the information found on Bruyère’s website conflict, Bruyère’s information should be considered the most up to date. Consultation with your ROM should occur to confirm this if you have any doubts.

Research teams undertaking new studies that will be recruiting participants from in- or out-patient units/clinics **must have discussions with the Clinical/Unit Manager or their designate to ensure that research can occur and to determine how the research will be undertaken within the unit’s workflow processes.** A Research Summary Form (see [Forms/Documents Referenced in this Manual](#) for link) 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.

PROCESS: AMENDMENTS TO EXISTING REB- APPROVED RESEARCH

To add an in-person face-to-face component to an existing active research project with an Amendment to the Bruyère REB, complete the following steps:

1. Ensure that all members of the research team have reviewed the most recent version of the Manual and the information available on Bruyère’s websites for staff and visitors (see links in section [Resources & Contact Information: Forms/Documents Referenced in this Manual](#)).
2. If clinical units/programs/departments are involved, consult with them to determine the feasibility of your work and to confirm that the workflow is appropriate. Use the Research Summary Form (see [Forms/Documents Referenced in this Manual](#)) for these discussions.
 - a. The applicable Clinical Director and/or Medical Chief must be provided a copy of the Research Summary Form, and they must sign a BREB Division/ Department/ Program Approval to confirm their approval of this component of the study.
3. Access the Office 365 [In-Person Research Spreadsheet](#) and complete the spreadsheet for all relevant information about your project.
 - a. When completing the column titled “*Personnel involved in the project*”, ensure you have verified that these individuals have reviewed the Manual and any applicable online information.
 - b. If you require assistance with accessing the In-Person Research Spreadsheet, contact your ROM.
 - c. If your study deviates from the procedures outlined in this Manual, contact your ROM to discuss, and

they will obtain IPAC and PPE approval for your study.

4. Submit your Amendment documents to the Bruyère [REB Manager](#) following the standard format for requesting an amendment to existing research (see <https://www.bruyere.org/en/researchethicsboard>).
 - a. Include in your email and amendment form that you have completed the In-Person Research Spreadsheet & provide your study's Plan # from the spreadsheet
 - b. Consent Forms: ensure you are
 - i. incorporating the relevant information about COVID-19 risks and on-site/community requirements into your booking and reminder call scripts (see Visitor Information in *Resources & Contact Information: External Access*), and
 - ii. either using the shortened COVID consent to share contact information consent form OR have incorporated the language required for obtaining approval to share contact information in the event it is required for contract tracing into the project's standard informed consent form.
 - c. **Your ROM must be cc'd on the submission email.**
5. Receive REB approval, and all other required approvals, before beginning face-to-face research.

PROCESS: NEW FACE-TO-FACE PARTICIPANT RESEARCH

New research projects that include a face-to-face component must submit a new ethics application to the Bruyère REB by completing the following steps:

1. Ensure that all members of the research team have reviewed the most recent version of the Procedure Manual on Conducting Face-to-Face Research and the information available on Bruyère's websites for staff and visitors (see links in section *Resources & Contact Information: Forms/Documents Referenced in this Manual* and *Resources & Policies Referenced in this Manual*).
2. If your study involves work on a clinical unit/program or in the community, consult with them to determine the feasibility of your work and that the workflow is appropriate. Use the Research Summary Form for these discussions.
 - a. The applicable Clinical Director and/or Medical Chief, or external approver in the case of community research, must be provided a copy of the Research Summary Form, and they must sign a BREB Division/ Department/ Program Approval to confirm their approval of the study.
3. Access the Office 365 [In-Person Research Spreadsheet](#) and complete the spreadsheet for all relevant information about your project.
 - a. When completing the column titled "*Personnel involved in the project*", ensure you have verified that these individuals have reviewed the Manual and any applicable online information.
 - b. If you require assistance with accessing the In-Person Research Spreadsheet, contact your ROM.
 - c. If your study deviates from the procedures outlined in this Manual, contact your ROM to discuss, and they will obtain IPAC and PPE approval for your study.
4. Submit your ethics application and applicable supporting documents to your ROM for review to obtain Bruyère RI's Division/ Department/ Program Approval, as per standard procedure.

5. Submit your ethics application and all applicable supporting documents to the [REB Manager](#) following the standard format for submitting a new ethics application.
 - a. Include in your email that you have completed the In-Person Research Spreadsheet & provide your study's Plan # from the spreadsheet.
 - b. Consent Forms: ensure you are
 - i. incorporating the relevant information about COVID-19 risks and on-site/community requirements into your booking and reminder call scripts (see Visitor Information in *Resources & Contact Information: External Access*), and
 - ii. using the informed consent form template(s) available on the Bruyère REB website, which has incorporated the language required for obtaining approval to share contact information in the event it is required for contract tracing into the project's standard informed consent form.
 - c. **Your ROM must be cc'd on this submission email.**
6. Receive REB approval, and all other required approvals, before beginning face-to-face research.

PROCEDURES: RESEARCH VISITS

ALL RESEARCH PARTICIPANTS WHO ARE COMING ON-SITE FOR A RESEARCH VISIT

Research Participants coming on-site for a research visit are treated similarly to individuals visiting ambulatory outpatient clinics. **They are not required to be vaccinated; however, they must follow all other requirements as per Bruyère's online Visitor Information.**

If more than one RP/SP is required in the research area at one time, the research team must outline the procedures that will be put in place to ensure the compliance of all Bruyère IPAC and safety procedures.²

STEPS	
<p>1. Scheduling Call</p> <p><i>This may be done via email if the RP prefers, in alignment with your REB approved study protocols. Confidentiality of information cannot be guaranteed with email, and the RP</i></p>	<p>A scheduling call with the RP must be made prior to the on-site visit, at which time the research team will:</p> <p>Step 1: Complete the research team's standard script for setting up an in-person research visit. This script must include the following:</p> <ul style="list-style-type: none"> ➤ Reference to the risk of contracting COVID-19 through coming onsite ➤ Informing the RP/SP of any requirements related to coming onsite, as per Bruyère's latest Visitor Information (see <i>Resources & Contact Information: External Access</i> for link), such as masking requirements, screening, etc. ➤ A reminder to the RP/SP that anyone who is planning to come onsite should not do so if they are sick. If the RP/SP have concerns about whether they should be coming onsite, recommend that they voluntarily complete the COVID-19 Visitor

² If research teams have approval to run multiple face-to-face research studies that share a common research space, there may be limits placed on the number of RPs and SPs (if applicable) allowed in the research space at any one time. The research area must be thoroughly cleaned/disinfected between RPs.

<p><i>must be made aware of this.</i></p>	<p>Screening Questionnaire (found under External Access)³.</p> <ul style="list-style-type: none"> ➤ If passed by the RP/SP proceed to Step 2. ➤ If failed by the RP/SP, contact the RP/SP in 5 days for another scheduling call. <p>Step 2: Ensure the RP/SP are comfortable with all information provided.</p> <ul style="list-style-type: none"> ➤ If yes, proceed to Step 3. ➤ If not, the RP/SP the visit cannot occur. <p>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.</p>
<p>2. Reminder Call</p>	<p>A reminder call must be done 24 hours before the visit or the Friday before a Monday visit with the RP/SP, at which time the research team will:</p> <p>Step 1: Complete the research team’s standard script for reminder calls. This script must include the following:</p> <ul style="list-style-type: none"> ○ Information about visitor requirements as per Bruyère’s Visitor information (see <i>Resources & Contact Information: External Access</i> for link) such as masking requirements, screening, etc. ○ Reminder to the RP/SP that if they feel unwell on the day of the appointment, they should call the research team to reschedule. ○ Provide the RP/SP with the following information for their arrival to Bruyère: <ul style="list-style-type: none"> ➤ Your contact details. ➤ Arrival entrance to be used (see <i>Resources & Contact Information: Entrance To Bruyère Sites</i> for locations). ➤ Completing hand hygiene (recommended). ➤ Follow Bruyère’s masking requirements, which may involve exchanging their mask for one from Bruyère. ➤ Confirmation of where you will meet them: either request that they wait in the designated entrance area for a member of the research team to come and accompany them to the research area, or ensure they have clear instructions on how to find the research area. <p>Step 2: Ensure the RP/SP are comfortable with all information provided.</p> <ul style="list-style-type: none"> ➤ If yes, the visit may proceed. ➤ If not, the RP/SP the visit cannot occur.
<p>3. Arrival at Bruyère</p>	<p>Research staff may meet the RP/SP at the entrance when they are arriving on-site, or ensure the RP/SP has clear directions on how to find the research area.</p> <p>Recommend that hand hygiene be completed by the RP/SP before entering the research area.</p>

³ In the event that a SP is required to accompany the RP to the on-site research visit & screening is required, **both** the RP and SP **must not be sick**.

	<p>In the event that the RP/SP do not pass any of the Visitor requirements as per Bruyère's Visitor requirements⁴, the RP/SP will be asked to leave the building and research staff should follow-up with the RP/SP to re-schedule, pending passing the screening questionnaire.</p>
<p>4. During the visit</p>	<p>During the visit, research staff must ensure that the RP/SP;</p> <ul style="list-style-type: none"> • Follow all Visitor requirements as outlined on Bruyère's website (see <i>Resources & Contact Information: External Access</i> for link) <p>In addition to Visitor requirements, the following practices are recommended for RPs/SPs:</p> <ul style="list-style-type: none"> • Complete hand hygiene when entering and leaving the research area. • Limit the touching of surfaces. • Follow masking and physical distancing of 2 meters whenever possible. • Show the RP/SP where washrooms are, if required, to avoid hallway wandering. • Complete hand hygiene and 2-meter physical distancing when the RP and/or SP (if applicable) need to remove their mask for any reason, including a hydration or nutrition break. • Provide them with a disinfected table to put food and/ or drinks on. • Avoid use of microwaves, water fountains, kettles, refrigerators, or coffee machines where possible. <p>Throughout the visit research staff must disinfect all equipment before and after use as per <i>Procedures: PPE, Lab Coats and Cleaning</i>.</p> <p>At the end of the visit, research staff must:</p> <ul style="list-style-type: none"> • Accompany the RP/SP to the exit of the Bruyère site or confirm the RP/SP know how to find their way out of the building. • Disinfect all equipment and research surfaces used during the research visit.

ON-SITE RESEARCH VISITS: CLINICAL STAFF

When organizing on-site RP visits with RPs who are Bruyère clinical staff, if the research visit is taking place on the unit, the research team must consult with the Unit Manager/ Supervisor/ their Designate before scheduling and before conducting the visit. The information shared must take into consideration the appropriate confidentiality requirements and research protocols.

Regardless of where the research visit is taking place, research staff must:

- Complete hand hygiene before entering and leaving the room.
- Comply with PPE and IPAC procedures as per IPAC Expectations: For Staff (see *Resources & Contact Information: Internal Access*).
- If not in a private room, inform the RP that privacy may be difficult to maintain if research staff have to speak louder to be heard while wearing their mask.

ON-SITE RESEARCH VISITS: INPATIENT/RESIDENT

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

When organizing on-site RP visits with an RP who is an inpatient/ resident, 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 (e.g., on outbreak) and the health status of the RP.

In general, 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 situations arise where an exception to the above restrictions are required, it must be approved on a project-by-project and possibly case-by-case basis by IPAC.

If the research can be conducted in the RP's room ensure that research staff;

- Complete hand hygiene before entering and the leaving the room.
- Comply with PPE and IPAC procedures as per [Procedures: PPE, Lab Coats and Cleaning](#)
- Maintain a 2 meter distance between the RP and research staff member, if possible.
- Use a chair if research staff need to sit, and not sit on the RP's bed.
- Inform the RP that privacy may be difficult to maintain if research staff have to speak louder to be heard while wearing their mask.

TRANSPORTATION OF RPS: INPATIENT/RESIDENT

If the study requires that the RP be transported to another location within the Bruyère site to conduct the research, research staff must;

- Follow all PPE and IPAC procedures as per IPAC Expectations: For Patients (see [Resources & Contact Information: Internal Access](#)).
- Accompany the RP to and from their room.

If the study requires that the RP be transported to another facility outside of the Bruyère site, this is treated by IPAC as an external appointment (Leave of Absence) for the RP. It is strongly advised that the RP be accompanied by a member of the research team. The RP must:

- Be transported to the appointment via medical transport (medical taxi, ambulance).
- Follow the masking requirements for an in-patient Leave of Absence as per IPAC Expectations: For Patients (see [Resources & Contact Information: Internal Access](#)) including masking requirements and practicing good hand hygiene.

COMMUNITY RESEARCH VISITS

Conducting face-to-face research in the community during a 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 to the Bruyère REB, 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?
- How will research staff ensure that any required PPE and IPAC procedures are followed? (See [Procedures: PPE, Lab Coats and Cleaning](#))
- Research may not be conducted in Indigenous communities or in areas where vulnerable populations live (e.g., long-term health care facilities) unless public health officials deem such activities safe and the community/

organization agrees to it. Research teams must consider the infection rate in the respective community and if the research team is allowed to enter the area and conduct research.

STEPS	
<p>1. Scheduling Call</p> <p><i>This may be done via email if the RP prefers, in alignment with your REB approved study protocols. Confidentiality of information cannot be guaranteed with email, and the RP must be made aware of this.</i></p>	<p>A scheduling call must be made prior to the on-site visit, at which time the research team will:</p> <p>Step 1: Complete the research team’s standard script for setting up an in-person research visit with the RP and any third parties that will be present during the visit, e.g., family members (if applicable).⁵ This script must include the following:</p> <ul style="list-style-type: none"> ➤ Reference to any risk of COVID-19 through having the research staff visit their home. ➤ Informing the RP/SP of any requirements related to the visit, as per Bruyère’s latest Visitor Information (see <i>Resources & Contact Information: External Access</i> for link), such as masking requirements, screening, etc. ➤ A reminder to the RP/SP that anyone who is planning to be present during the visit should not be sick. If the RP/SP have concerns about determining this, it is recommended that they voluntarily complete the COVID-19 Visitor Screening Questionnaire (see <i>Forms/Documents Referenced in this Manual</i>) <p>Step 2: Ensure the RP/SP and any applicable third parties are comfortable with all information provided.</p> <ul style="list-style-type: none"> ➤ If yes, proceed to Step 3. ➤ If not, the visit cannot occur. <p>Step 3: Schedule the community research visit and inform the RP that if the RP or any applicable third party 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 when the research participant has recovered.</p>
<p>2. Reminder Call</p>	<p>A reminder call must be done 24 hours before the visit or the Friday before a Monday visit, at which time the research team will:</p> <p>Step 1: Complete the research team’s standard script for reminder calls with the RP and any applicable third parties. This script must include the following:</p> <ul style="list-style-type: none"> ➤ Information about any requirements as per Bruyère’s Visitor Information (see <i>Resources & Contact Information: External Access</i> for link), such as masking requirements, etc. ➤ Reminder to the RP/SP that if they feel unwell on the day of the appointment, they should call the research team to reschedule. <p>Provide appropriate contact details in case RP needs to cancel.</p>

⁵ All individuals who will be present during the research visits **must meet Bruyère’s Visitor requirements as per the information on our website** before research staff may conduct a visit in the community.

3. Conducting the visit	<p>On the day of the community visit, research staff must;</p> <ul style="list-style-type: none"> • Self-complete the Bruyère staff Covid-19 screening questionnaire, as per IPAC Expectations: Staff (see <i>Resources & Contact Information: Internal Access</i>) <ul style="list-style-type: none"> ➤ Research staff must pass the screening questionnaire before proceeding to the community visit. • Prior to entering the off-site location (e.g. participant’s home) <ul style="list-style-type: none"> ➤ Confirm that the RP and any applicable third parties are in agreement with the research visit proceeding, and that any screening for COVID that is required is completed. This may be done via telephone before the research staff arrive at the meeting location or upon arrival. ➤ Don the required PPE before entering the home and follow IPAC Expectations: Staff (see <i>Resources & Contact Information: Internal Access</i>) and <i>Procedures: PPE, Lab Coats and Cleaning</i> to conduct the visit. <p>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.</p>
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DROPPING OFF OR PICKING UP RESEARCH EQUIPMENT IN THE COMMUNITY

If research staff are required to drop off or pick-up research equipment in the community, the same masking requirements as exist on-site at Bruyère must be followed by the research staff. See IPAC Expectations: Staff (see *Resources & Contact Information: [Internal Access](#)*).

PROCEDURES: PPE, LAB COATS AND CLEANING

General PPE requirements align with those for the provision of clinical care and are found in *Current PPE Requirements for Staff, DCPS, and Visitors* (see *Resources & Contact Information: [Internal Access](#)*).

Research teams must carefully consider the PPE requirements of their studies and ensure that sufficient funds are available through research projects to cover PPE expenses.⁶ All PPE and disinfectant products used must comply with Bruyère IPAC policies and procedures and include the following considerations.

The table below indicates who should be contacted for various needs. Contact information can be found in *Resources & Contact Information: [Contact Information](#)* above.

Topic	Department to contact:
Cleaning, disinfecting, and sterilization information if unclear after reviewing InfoNet	IPAC
PPE required under special circumstances, such as close-quarters, removal of masks required	OHSS
Purchasing PPE, including gloves, disposable gowns, disinfecting materials	SPD
Arranging for disposable bins/hampers	SPD
Arranging research space cleaning	FMS

⁶ With the exception of approved masks and face shields, which when required, are available at Bruyère site entrances for anyone coming on-site.

ON-SITE RESEARCH VISITS

CLEANING AND DISINFECTING

- Minimize the number of research rooms/areas requiring disinfecting.
- The rooms that are used for research should be well ventilated and provide room for 2 meter physical distancing between the research staff and RP/SP. If this is not feasible, discuss with OHSS whether other precautions, such as plexiglass screens, are needed.
- 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 if required 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 products and **that they respect the surface contact time of the products** (see IPAC: Cleaning, Disinfection & Sterilization information under *Resource & Contact Information: [Internal Access](#)* 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.
- 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 research visit.
- 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.

GLOVES AND HAND HYGIENE

- Universal hand hygiene must be followed by all staff and RP/SPs must adhere to Bruyère's Visitor requirements.
- 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) (link under *Resource & Contact Information: [Internal Access](#)* above).

ADDITIONAL PPE REQUIREMENTS

- Required PPE is outlined on InfoNet under the following pages (see *Resources & Contact Information: [Internal Access](#)* for links)
 - *Current PPE Requirements for Staff, DCPS, and Visitors* (high-level mask & eye protection)
 - *IPAC Expectations* for staff, visitors, and patients
- If staff wish to wear a higher level of protection, they may do so (indicated in the *Current PPE Requirements for Staff, DCPS, and Visitors* table as "when decided by a risk assessment", see also Appendix A).
- Staff interacting with patients on contact/droplet precautions must follow the requirements in *Current PPE Requirements for Staff, DCPS, and Visitors* listed for "when indicated by precautions", see also Appendix A.
- Staff performing procedures that themselves have PPE requirements, such as biological sample collections, must additionally follow the PPE requirements of these procedures. A higher level of PPE than that dictated only by pandemic protection guidelines may be required in these circumstances.

LAB COATS

- Lab coats are not classified as PPE.

- They may be worn as per Appendix A and IPAC Expectations for Staff (link in *Resource & Contact Information: Internal Access*)
- They 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.

COMMUNITY RESEARCH VISITS

GENERAL CONSIDERATIONS

- 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.
- Be prepared to stop the visit if research staff or the RP become concerned for their safety.
- Minimize cross contamination. Do not provide or accept any food or drink during the visit.

MASKS AND PHYSICAL DISTANCING

- Masks must be worn at all times during the visit, in accordance with Bruyère IPAC Expectations for Staff and Visitors (see *Resource & Contact Information: Internal Access* for link).
- Staff going into the community must wear a mask following on-site Bruyère requirements.
 - Check the type of mask required based on the study procedures to be completed (e.g., vital signs, ECG, blood draw)
- Ensure that the RP is wearing a mask during the visit, if masking is required on-site for Visitors.
 - A mask at least equivalent to those required on-site at Bruyère is recommended.
- It is advisable that research staff carry extra masks in case the RP/SP/third parties do not have a mask available.
- 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 maintain 2 meters of physical distance between themselves and the research staff.

DISINFECTION

- To limit the amount of disinfection required, limit exposure time at the community site; abstain 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),
- Place all research supplies needed for the research visit into a plastic box and take that box into the community site.
 - Disinfect the box using disinfectant wipes before and after the visit.
- Do not place any research supplies on any contaminated surfaces at the community site, including PPE, hand sanitizer and disinfectant.
- Ensure that sufficient PPE, hand sanitizer and Bruyère approved disinfectant is brought to the community site and all surfaces touched by research staff are disinfected prior to leaving the premises.
 - Hospital-grade disinfectants may be too strong to use in RP homes and may cause reactions or damage personal property.
 - **IPAC recommends using common disinfectants, which can be found in grocery stores.** A list is available in *Resources & Contact Information: External Access* – see *Government of Canada approved common disinfectants*.
 - **Ensure the contact time for any product used is adhered to, otherwise disinfection is not achieved.**
 - If additional information/clarification is needed, questions can be directed to IPAC (see

Resources & Contact Information: [Contact Information](#) for IPAC contact information).

- If the RP does not want their home or community surfaces disinfected, IPAC recommends that research staff speak with the RP about the importance of ensuring the safety of the research staff and the RP. If the RP continues to request that no disinfecting occurs, IPAC recommends that research staff try not to touch their face or any surfaces during their visit, decline any food or drink offered during the visit, and wash or disinfect their hands immediately after the visit.
- 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.

PROCEDURES: SAMPLE COLLECTION, HANDLING AND SHIPPING

All standard non-pandemic processes for the collection, handling, and shipping of specimens must continue to be followed.

- Study and Bruyère biosafety protocols must be followed.
- All research studies that require sample collection must be handled by qualified trained staff who have their certification in Transportation of Dangerous Goods⁷ and with the highest regard for RP and staff safety.

Human biospecimens must also be treated as potentially infectious.

SHIPPING OF SAMPLES

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 needs to make arrangements via phone, email, or in person in advance to leave the package at the information desk on the day of the pick-up.
- b) Couriers picking up packages at the information desk must be instructed that they need to follow Visitor requirements, which may include wearing a mask and passing screening to pick up the package. Consult Bruyère's website to provide the Courier with the most up-to-date information.
- c) External delivery personnel (e.g. FedEx, UPS) must be instructed that they must follow Visitor requirements, which may include wearing a mask and passing screening to deliver packages to the research area. Consult Bruyère's website to provide the Courier with the most up-to-date information.
- d) In the event that a package must be shipped and 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.
- e) If a larger package is being shipped to Bruyère, a Purchase Order ("P.O.") must be issued by Procurement to facilitate the receipt and delivery of the package. The appropriate documentation must be sent to Procurement by the research team, as per Bruyère RI's policy BRI FN 07, *Procurement of Goods & Services*.

PROCEDURES: PARTICIPANT COMPENSATION

⁷ CITI training on this topic is available to members of Bruyère RI via the Institute's N2 membership.

Follow Bruyère RI's *Compensation and Reimbursement: Research Participants & Research Partners Guidelines* for all participant payments, including compensation and reimbursement.

- Consider using e-gift cards when possible.

Hand hygiene procedures must be followed before and after handling anything that is exchanged between the RP/SP and research staff. This includes pens for signing any required documentation, physical gift cards, etc.

PROCEDURES: HANDLING OF PAPER CONSENT FORMS AND OTHER PAPER DOCUMENTS

If possible, minimize the use of paper documents, and consider oral consent options. 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 that are passed between the RP/SP and research staff.
- 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 consent 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.

PROCEDURES: COVID CONSENT AND CONTACT TRACING

For all types of face-to-face research visits the research team must ensure that if any member of the research team coming into contact with the RP/SP, the RP/SP themselves, or a third party becomes symptomatic and/or COVID is confirmed, a plan is in place to ensure that everyone can follow current provincial and local requirements for isolating themselves and implementing the best measures to prevent the transmission of COVID in the community, in accordance with local and provincial isolation guidelines.

The COVID Consent Form, On-Site or Community version, as appropriate, is an important guide for this. While it is no longer a requirement that it be used, it contains information that is relevant to this topic. Research teams should review the consent form to determine whether they wish to use this form or incorporate the necessary components of it into their main consent form or oral scripts.

If used, providing consent on the COVID Consent Form can be done verbally or in writing but must be documented as per standard informed consent form practices in research and included in the project's REB-approved procedures.

PROCEDURES: 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, vendors, and clinic staff;
- ensuring that the research team remains current on all Bruyère infection control policies and procedures; and
- how and if the study protocol might be modified to accommodate to virtual data collection.

PROCEDURES: RESEARCH VISITORS (RV)

Research teams are advised to check Bruyère's website *Visitor Information* (see *Resources & Contact Information: External Access* for links) for up-to-date information on Bruyère's Visitor Policy, which can change at any time.

When allowed on site, all Research Visitors must follow the procedures outlined on Bruyère's website. These should be confirmed with the RV in advance and may include completing screening and providing proof of vaccination at the screening desk before entering a Bruyère sites.

Research Visitors are required to follow the masking policy in place at the time of their visit.

Check latest information on Bruyère's Visitor Information website (*Resources & Contact Information: External Access*) before arranging for a RV to come on-site.

APPENDIX A – DEGREE OF RISK RELATED TO THE TYPE OF RESEARCH AND PPE REQUIREMENTS

Consult [InfoNet: Current PPE Requirements for Staff, SCPS and Visitors](#) for PPE requirements that correspond to this table.

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	Standard mask required at Bruyère, as per IPAC Expectations for Staff
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	Standard mask required at Bruyère, as per IPAC Expectations for Staff Gloves may be used if desired Lab coat may be worn if desired
Level 3	Physical treatment / manipulation	Physical therapy, biopsy, taking blood sample	Sustained physical contact, physical distancing not possible	Standard mask required at Bruyère, as per IPAC Expectations for Staff Gloves may be used if desired Lab coat may be worn if desired
Level 4	Aerosol-generating procedures (https://infonyet.bruyere.org/en/covid-staff-ipac#accordion-83-4) OR Interaction with patient with suspected or confirmed case of COVID-19	Intubation, extubation, cardiopulmonary resuscitation, spirometry	Sustained physical contact, physical distancing not possible/ Some physical contact with patient with suspected or confirmed case of COVID-19, physical distancing not possible	Mask required at Bruyère, as per IPAC Expectations for Staff Additional precautions are indicated Gloves may be used Lab coat may be worn, unless gown is required

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; <u>or symptomatic and on contact precautions.</u>
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.
3.4	February 28, 2022	H. Niezgoda	Added Flow Sheet 3.1.1 Added Section 5.0 Research Visitors Renumbered and renamed section 3.1.2 Resuming Research Spreadsheet Link Updated definition section and added information on Research Visitor Added information on N95 /KN95 masks and Appendix E Updated Appendix A with June 2021 version of the Visitor's Screening Questionnaire Revised COVID Consent Form to include reference to N95 /KN95 mask. Updated links Updated section 5.0 Research Visitor policy to include the wearing of face shields.
3.5	March 15, 2022	J. Joschko and H. Niezgoda	Updated PPE Guidelines 4.4 Information added 4.1.4 Updated Screening Manager
3.6	April 4, 2022	J. Joschko	Updated mask requirements Updated disinfectant guidelines Updated Appendix A to reflect current screening form
3.7	Feb. 23, 2023	A. Cornett K. Wilde H. Niezgoda	Updated/reformatted to consolidate links needing updates. Changed language to latest practices. Removed appendices and replaced with links to sources. Updates reviewed by: Jason Barrett, Nicole Cyr, Heather Hall