INSTITUT DE RECHERCHE
Bruyère
RESEARCH INSTITUTE

ADMINISTRATION /FINANCE PROCEDURE

Title: Instructions for Completing the Planning Template for Resuming Research: On-site and Community Based Studies	**Last review/revision date:** December 9, 2020
Approved by: Bruyère RI Senior Director of Operations	**Approval date:** October 8, 2020
Issued by: Bruyère RI	**Policy #:** RES TEMP 502

PURPOSE

As a response to the COVID-19 pandemic, and in compliance with the guidelines for local, provincial and federal authorities the Bruyère Research Institute (RI) has implemented several procedures to support the safe resumption of research that requires in person interactions with participants. The procedures to resume research are guided by the RI's Senior Leadership Team in collaboration with Bruyère and the **Guidelines for Conducting In-Person Interactions & Research during COVID-19**. This document is supported by Bruyère Continuing Care's (Bruyère) policies on Infection Control Outbreak Management Planning, to assist in the prevention, mitigation, and response concerning the spread of disease during a pandemic that may threaten the organization.

This instruction document focuses on how to complete the "Planning Template for Resuming Research: On-site and Community-based Studies" for face-to-face research on previously approved studies that have been suspended due to the pandemic and new studies that will require face-to-face in-person research. Research teams must use this information as a guide to help them develop a research plan when completing the form.

The Bruyère RI is committed to promoting a safe environment and protecting the health and wellbeing of its investigators, staff, students, volunteers and participants by being prepared and responding to a pandemic situation. 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.

DEFINITIONS

Pandemic: an outbreak of a communicable disease that spreads quickly and which has become prevalent throughout a wide geographic area such as; an entire country, continent, or the whole world.

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: means any research that involves direct in-person participant (inpatient, outpatient, resident, healthcare staff or community based) face-to-face contact with research personnel at any of Bruyère's campuses or in the community.

Disinfect: Refer to Policy: https://infonet.bruyere.org/bins/Policies_default.aspx?cid=978&lang=1.

Personal Protection Equipment (PPE): 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.

Screening Questions/ Bruyère-approved COVID-19 screening questionnaire: This refers to the latest version of COVID-19 screening questions in use at Bruyère. These questions can be found at https://infonet.bruyere.org/en/covid19-resources

PROCEDURES

1. Complete the Planning Template for Resuming Research: On-Site and Community Based Studies.

Resuming research will be done in stages with respect to both the type of research and the volume of research. All research teams wishing to resume a direct participant face-to-face research study at any Bruyère campus or in the community must complete the Planning Template for Resuming Research: On-site and Community Based Studies and receive formal approval from all required onsite departments, community partners and the Bruyère REB before restarting. Please refer to the "Resuming Research Flow Chart" for an outline of the approval process. Prior to completing the Planning Template, study teams need to carefully consider how the research study needs to be revised to ensure the following:

a) Adherence to government and institutional directives (including provincial directives and local public health guidelines).
b) The safety of all people involved in the research study, including the research team, participants (inpatient, outpatient and in the community), study partners and any others impacted by the research by considering the new norms for hygiene, physical distancing, disinfecting, and use of Personal Protective Equipment (PPE).
c) How the research may impact the organization's infrastructure, ancillary services, patient/resident care, etc.
d) Planning in the event that the research study is stopped due to a future outbreak.

The Planning Template must include comprehensive details regarding why the research needs to restart, measures to be taken to prioritize everyone's safety, and what exactly will be taking place. All completed forms will follow a review/approval process, starting with the Research Operations Manager's review.

2. 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 Petty Cash Office and to ensure sufficient time for the decontamination of stipend funds. Research teams must take into account the following procedure when developing their research plan:

Cash Stipend:

a) Research staff will complete the Petty Cash Stipend Request Form as per Policy Res-FN301 **once per month** to reduce the number of visits to the Petty Cash Office.
b) The form is to be sent by email to Roxanne Giroux RGiroux@bruyere.org and copied to Alexandra Frenette AFrenette@bruyere.org .
c) Once the research team is notified by finance that the stipend funds are ready, they will proceed to the Petty Cash Office and collect the funds.
d) The stipend funds will be brought back to the research area and each separate participant stipend amount will be placed in its own envelope with the amount and participant unique identification number (ID) written on the outside of the envelope and sealed. Envelopes must be stored for a minimum of three (3) days to decontaminate prior to being given to a participant. Envelopes must be stored behind three locking mechanisms (e.g. in a locked box, in a locked drawer, in a locked office). Stipends that are not yet assigned to a participant will be allocated into envelopes and placed in a locked box.
e) The stipend will be given during the research visit. The research staff will have the participant/study partner sign for the stipend amount using a disinfected pen or signature pad, remove the envelope with the participant's ID from the locked lock- box and provide it to the participant/study partner, who will then open the envelope and verify the stipend amount is correct. Hand hygiene procedures before and after touching the envelope will be completed by both the research staff and the participant/study partner.
f) The stipend pen/ signature pad will be disinfected.

Gift Card:

If physical gift cards are used, they must be disinfected with a Bruyère-approved disinfectant following the disinfectant's instructions, allowed to dry, and then stored in a sealed envelope before being given to the participant/study partner.

3. Recruiting Participants

Research teams must clearly lay out their recruitment plan and identify how they will try to minimize the number of participants on site at any one time and ensure that universal masking, appropriate PPE (see Section 5 of these Instructions & PPE Guidelines on the InfoNet for further information https://infonet.bruyere.org/en/covid19-ipac), physical distancing measures, disinfection and hand hygiene will be maintained during the process.

Consent forms must be updated to reflect any changes or new procedures that impact participants. Consent forms should include the need for participants to wear a mask and maintain physical distancing when possible while on site. Outdoor visits should be considered when possible. Participants and study partners must be made aware that their name and contact information may need to be shared for the purpose of contact tracing,

4. Scheduling & Conducting Study Visits

When scheduling and conducting outpatient, inpatient or community research visits, the safety of all involved must be ensured at all times. Whenever possible, visit interactions should be minimized and other methods of data collection (e.g. phone, mail-in, and video-conference) considered and

implemented.

4.1 On-site Outpatient Visits

a) When completing the Planning Template clearly identify the number of participants coming onsite per day, the total number of visits expected over the first three (3) months of the study, the length of the study visit, and if others, such as a study partner, need to accompany the participant. Onsite visits should be limited to only the participant if possible.
b) During the scheduling call (approximately 2 weeks prior to the visit), the research team will need to complete the latest version of the Bruyère-approved COVID-19 visitor screening questionnaire (see Resource at the end of this document) with both the participant and study partner (if required on site). If both pass and agree to wear a mask during the visit and complete the Bruyère screening entrance procedure on the day of the visit, an appointment can be scheduled.
c) **The Bruyère entrance screening staff must be made aware of the planned visit at least 24 hours prior to the visit.** Research participants/study partners coming to any of the research areas at the Elisabeth Bruyère Hospital on the 2Y wing must enter the facility through the 75 Bruyère entrance. All others must come through the 43 Bruyère entrance. Research staff must provide two **(2) paper copies** of the following information to the screening staff at the entrance where the participant /study partner will be entering Bruyère for their visit ;
    - site location,
    - entrance,
    - visit date and time,
    - name of participant /study partner,
    - phone extension of the research staff who will be accompanying the participant/study partner up to the research area.

d) The day before the appointment a reminder call must be made by research staff and the screening procedure above repeated. If both the participant and study partner (if applicable) pass, the appointment is confirmed. If either the participant or study partner (if applicable) fails the screening the visit must be re-scheduled after at least a 14 day period. If they both pass, the participant and study partner will be informed by the research team as to which Bruyère entrance to use for their visit.
e) When the participant and study partner (if applicable) arrive on site, they must pass the Bruyère screening process and agree to wear a mask throughout the visit to continue their participation in the research study.
f) Upon successfully completing the screening, the screening desk will notify the research team that the participant has arrived. If the participant /study partner do not pass the Bruyère screening process, the screening team will notify the research staff and the visit will be re-scheduled.
g) Once the research staff have been notified, they will go to the appropriate entrance and accompany the participant and study partner to the research area. Upon arrival at the designated research room, the participant and study partner will be asked to sanitize their hands and will be provided with instructions on the infection control procedures that need to be followed during their visit; hand sanitization, limiting the touching of surfaces in the rooms, mask on and off procedures, use of washrooms, and accompanying procedures. The reporting procedure for staff or participants/study partners testing positive for COVID-19 within 14 days following the visit will be reviewed.
h) If possible, the participant should remain in one designated research room for the duration of the visit. At the end of the visit all surfaces should be wiped down by staff using Bruyère-approved disinfectant wipes. See Section: 5.
i) At the end of the visit, staff will accompany the participant/study partner down to the exit maintaining the safety protocols outlined above.

j) If, at any time the participant or study partner needs to use the washroom, they will be accompanied by the research staff to the nearest washroom and back. Posters that demonstrate proper hand washing techniques will be displayed in all washrooms. Hand sanitizer must be used by all participants/study partners before re-entering the research area.
k) Participants should be discouraged from bringing any food or water to the visit, however some visits may be lengthy requiring a nutrition/hydration break. When this happens, research staff should leave the room, if possible. If leaving the room is not possible, staff should maintain physical distancing at all times.

4.2 On-site Inpatient Visits

a) When completing the Planning Template clearly identify at which Bruyère site and unit the visits will occur, the number of participant visits scheduled per day, who from the research staff will be interacting with the inpatient/resident, the specific room location of where the interactions will occur (e.g. participant room, research room, other), the total number of interactions expected over the first three (3) months of the study, the length of each interaction, and if others, such as a study partner/family members coming from outside of Bruyère need to interact with the research team. Every attempt should be made to minimize the face-to-face interactions with study partners/family members coming from outside of the Bruyère. If they are mandatory to the study, the steps above in section 4.1 On-site Outpatient Visits must be followed.
b) Research staff must check with the clinical manager or unit supervisory prior to scheduling an inpatient visit to determine the COVID-19 status of the participant and prior to directly engaging with the participant. Participants cannot be on quarantine for COVID-19; or be on droplet & contact precautions; or on airborne precautions; or symptomatic and on contact precautions. Research staff should ensure regular and ongoing communication with the clinical staff to ensure that research staff are made aware of any changes in the status of the inpatient/resident which could affect their participation in the study. If possible, scheduling interactions should be done by phone or email to limit contact with the patient/resident.
c) If possible, all research procedures and data collection should be done in the participant's room. Research staff need to follow the PPE use as described in section 4.1. If the participant needs to leave their room to go to a research area, they must be accompanied by research staff. Every attempt should be made to limit the number of research rooms accessed by participants in order to facilitate infection prevention and control measures and reduce burden on housekeeping/cleaning staff.
d) Should transfer to a research room be needed for the study, upon arrival at the research area, the participant and study partner (if required) are to be provided with instructions on the infection control procedures that need to be followed during the visit; limiting the touching of surfaces in the rooms, mask on and off procedures, use of washrooms and escorting procedures. The reporting procedure for staff or participants/study partners testing positive for COVID-19 within 14 days following the visit must be reviewed.
e) If possible, the participant should remain in one designated research room for the duration of the visit. Research staff need to indicate what equipment will need to be disinfected after use by the participant and at the end of the visit, who will be doing the disinfection procedure, what Bruyère-approved disinfectant product will be used and that staff have reviewed and followed the disinfect instructions. See section 5 for further information.
f) At the end of the visit, staff will accompany participants back to their room and the study partner back to the appropriate Bruyère entrance as per section 4.1.

4.3 Offsite Visits in the Community

a) When completing the Planning Template clearly identify the research staff who will be going into the community, how many participants they will be seeing in a day, the total number of participants over the first three (3) months of the study, where the interactions will occur (e.g. in or outside the participant's home, community center), the length of each interaction, and if others, such as a study partner/family members will need to be involved. Every attempt should be made to minimize the face-to-face interactions with participants in the community. If possible, outdoor visits should be considered as an option.
b) During the scheduling call (approximately 2 weeks prior to the visit), the research team will complete the latest version of the Bruyère COVID-19 visitors screening questionnaire (see Resources at the end of this document) on the participant and all people living in the household. If the participant and household members pass the screening and agree to wear a mask or socially distance from the research staff during the visit, an appointment can be scheduled. The research team needs to ensure that if the visit is being conducted in the participant's home sufficient space exists to conduct the visit safely. Research staff must wear a procedure mask and face shield during the visit.
c) The day before the appointment a reminder call must be made and the screening procedure above repeated. If the participant and household members pass the screening and consent to wear a mask or socially distance during the visit, the research visit can proceed. If anyone fails the screening or does not agree to comply with masking or social distancing the visit must be re-scheduled or the participant removed from the study. The day of the visit, the research staff must screen themselves with the Bruyère-approved COVID-19 screening questionnaires, as well as the participant and those living in their home. If anyone does not pass the screening, the visit will be rescheduled for a minimum 14 day period.
d) The research plan for community visits must clearly outline the process staff will use to conduct the visit in compliance with universal masking, face shields, social distancing, PPE requirements, hand hygiene and all Bruyère infection prevention and control policies and procedures. Research staff should limit exposure time in the community setting as much as possible, including 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). Staff should come prepared to disinfect all wipe-able surfaces used during the visit with disinfectant products that the participant uses in their home (see Section 5). The visit should be immediately stopped if staff become concerned about their or the participant's safety.

5. Personal Protective Equipment (PPE), Lab Coats and Cleaning

All PPE and disinfecting materials used by research teams must comply with Bruyère infection control policies and procedures and the Guidelines for Conducting In-Person Interactions & Research during COVID-19. Research teams need to contact Bruyère SPD (SPD@bruyere.org) to arrange for PPE and disinfection supplies. Research projects are responsible for all PPE expenses and should speak to their Research Operations Manager to explore cost and possible funding options. Research teams will need to consider the cost implications of PPE supplies on their budgets. The only exemption to this is that procedure face masks for on-site visits that will be provided by Bruyère. Research plans must include the disinfecting of all workspace surfaces, plexiglass screens, desks, equipment, exterior door handles, light switches, pencils, pens etc., immediately after use and in between participants.

Research teams need to contact SPD@bruyee.org to order the appropriate disposal bins/hampers to use for the disposal of soiled PPE and ensure that this are readily accessible to staff.

Research staff, participant and study partners must clean their hands upon entry into the building and any research areas, as well as upon exit. If equipment will be handled by multiple participants, in addition to disinfecting it between each participant's, participants should clean their hands before and after handling it to decrease their risk. Alcohol-based hand rub (or dedicated hand washing sinks) must be readily available for staff and participants.

Participants should be advised to limit the number of bags or personal items brought into the research area. Specifically assigned areas in the research rooms occupied by participants/study partners should be the only places where personal belongings can be stored. These areas must be carefully disinfected by research staff with approved disinfectant after each visit.

a) Each research team will be required to project the amount of all types of PPE required for the first three months of the study. This projection will need to account for all research team members, participants, study partners, and/or caregivers that will be involved in the research visit. Requirements are as follows:

    - All research staff will be required to wear a procedure masks and face shield at all times when in contact with participants/study partners and maintain physical distancing of 2 metres during room transitions, with other staff members and when in contact with participants from other studies taking place in the research area.
    - All participants/study partners will be required to wear procedural masks provided by Bruyère during the entire onsite visit, unless the participant is an in-patient who is unable to wear a mask. Participants/study partners should be discouraged in bringing in food or water during the visit, however some visits may be length and a nutrition /hydration break may be required. During these breaks when the participant /study partner removes their mask, research staff should not be present. If this is not possible physical distancing of at least 2 metres must be maintained.
    - Please refer to: https://infonet.bruyere.org/bins/Policies_default.aspx?cid=978&lang=1 for further information about the types of PPE required for different procedures and in different circumstances.
    - For in-patient research, the type of PPE required will depend on whether a patient is under any precautions (see InfoNet link above).
    - Research staff who will be collecting biological samples such as blood are required to wear full PPE: mask, gloves, and face shield or goggles. They must also wear a lab coat during the procedure.
    - Universal hand hygiene must be followed by all research staff and participants.

b) Gloves, face shields (when worn or stained) and masks must be disposed of in the proper waste receptacles which will be collected on a daily basis by Bruyère housekeeping and are located throughout Bruyère and at the entrances. Gloves must be changed at the end of each procedure. The donning and doffing of PPE will follow Bruyère 's approved procedures (see https://infonet.bruyere.org/en/covid19-resources).

c) All research staff working directly with participants, regardless of whether they are working within 2 metres of a patient/resident or not must wear a face shield. The plastic covering must be removed from both sides of the face shield before putting it on. Face shields may be re-used between participants and over multiple days provided that it has been properly cleaned with a disinfectant wipe following each use (see procedure below). Face shields should be ordered through SPD like other PPE. They must be worn at all times while interacting with participants/study partners and other staff and can only be removed when staff disinfect it between patients/residents or for meal time. Staff must ensure that they are at least 2 metres away from the patient/resident before removing the shield to disinfect it. When removed for

eating in breakrooms, face shields and masks must be placed on a clean paper towel and hand hygiene must then be performed to avoid the spread of infection.

d) Face shields can be reused between participants. They must be cleaned using disinfectant wipes after each participant contact using the following procedure;
   - Start by cleaning hands and putting on gloves
   - Using disinfectant wipes (not hand sanitizer), first disinfect the inside of the shield. Disinfect the outside of the shield
   - Remove gloves
   - Clean hands
   - Allow the shield to fully dry before placing it back on. Ensure that the surface remains wet for the minimum time period noted on the product being used (i.e. contact time)

e) Lab coats are not classified as PPE and can be disposable or laundered. Disposable lab coats should be changed on a daily basis or when soiled and disposed of in the appropriate waste receptacles. Cloth lab coats can be provided by Bruyère. Research teams need to contact SPD and arrange for lab coats to be assigned to their team. SPD will label the lab coats with the study and room. A laundry receptacle will be provided to the research team and the lab coats should be placed in this receptacle for laundering at the end of each day or when soiled. Laundry bags may need to be dropped off at a designated area by the research team. This should be discussed with SPD when making arrangement. SPD will return the clean lab coats to the assigned research room.

f) All research rooms to be used must be identified on the Planning Template. Once the study is approved an email must be sent by the research team to FMS informing them that these rooms will require daily cleaning (or the days that cleaning will be needed). Staff will be responsible for thoroughly disinfecting all surfaces between each participant's visit using approved Bruyère disinfectant products. Details need to be provided as to who will be completing the disinfecting, and what equipment needs to be disinfected. Gloves must be used when using disinfectant wipes or solutions and rag. Contact time for the product being used must be known and respected. Please refer to https://infonet.bruyere.org/en/CDS for more information.

g) Hospital grade disinfectants can be stronger than products used in the home of participants and may cause reactions or damage personal property. Alternate products are currently being considered by IPAC for research being conducted in the community. Until a decision has been made as to what products should be used, research staff should discuss this with the participant and use the disinfect products that the participant regularly uses in their home, being careful to glove before use and follow the product directions on contact time

6. Sample Collection, Handling and Shipping

All research studies that require sample collection are handled by qualified team members with the highest regard for participant and staff safety. Research studies that require samples be shipped using external couriers such as FedEx or UPS should follow the process below and include this in their research plan:

a) For small packages, the research team need to make arrangements to leave the package at the information desk telecebp@bruyere.org on the day of the pick-up.
b) 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.
c) Delivery personnel must only go to the entrance information desk to obtain the package and then exit the site.
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.

7. Study contingency plan.

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 participants, funders, collaborators, venders, and clinic staff,
- ensuring that the research team remains current on all Bruyère infection control policies and procedures,
- if possible, how 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.

Resources used in the creation/updating of this policy include:

- Guidelines for Conducting In-Person Interactions & Research during COVID-19
- Resuming Research Flow Chart
- Resuming Research Plan Template
- 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

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? – If yes, have you been cleared to return to work by OHSS?	☐ YES ☐ NO ☐ 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*