Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants at Laurentian University

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Acknowledgements

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Special thanks to Ryerson University who generously agreed to share their document *Principles and Guidance for the Limited Resumption of Critical Human Participant and/or Field SRC Activity*, which served as a starting point for the development of this document.

Section 1: Overview

Laurentian University's research resumption activities have and will continue to follow a cautious, coordinated, phased-in process. In order to facilitate a phased-in resumption of face-to-face research activities with human participants, this guidance document has been developed in-line with Laurentian University's Phased Reopening Plan, and the following core decision-making principles:

- Health and safety of all members of the Laurentian University and surrounding community is paramount
- Return to campus activities will be guided by direction from the Federal, Provincial and Municipal Governments including guidance from the Medical Officer of Health with Public Health Sudbury and Districts
- Research that can feasibly and safely be done remotely without significantly compromising the efficiency and integrity of the work, including adherence to ethical standards and maintenance of confidentiality, should continue to be done remotely
- Students and other researchers must not be compelled to conduct research on campus or in the field. They must feel free to voluntarily return to campus or field research activities.
- Supporting, graduate students, post-doctoral fellows, early career researchers, and others who may have their scholarship disproportionately impacted by COVID-19 including women, persons with disabilities, Indigenous Persons, racialized minorities, francophones, and/or other marginalized persons is a priority
- Access to campus is contingent on researchers and students completing required training on COVID-19 and passing a self-assessment screening for COVID-19
- Under all circumstances, if someone is experiencing symptoms associated with cold/flu or COVID19, they should not come to campus and/or access any Laurentian University space.
- Access to campus will be suspended if health and safety protocols and approved risk mitigation plans are not followed

All human participant research to be carried out on the Laurentian University campus, in Laurentian University leased spaces or in the field, must first be approved in principle by the Vice-President Research, through the research resumption approval process, and then follow the Research Ethics Board (REB) approval process for FINAL approval. Research with human participants must conform to any rules and regulations of building management in leased spaces (which may be at a different stage of their reopening process). Human research activity taking place within Indigenous, northern or rural communities, which may have different health protocols and needs, requires confirmation of approval from the community to continue the research activity. Approvals may be modified or rescinded at any time in response to directives from public health authorities or local situations. Faculty members should be prepared to quickly shut down their Human Research activities to comply with these directives should they arise.

Section 2: General Considerations for Research with Human Participants

Laurentian University will employ a phased (Table 1), systematic approach to resuming human participant research activities. This approach will align with our Return to Campus Plan, as well as provincial and local public health directives. Under Phase 2 of Laurentian University's Research Resumption Plan, research with human participants that requires-face-to-face interaction can be considered for approval with an approved risk mitigation plan and REB approval. To assist researchers in completing an application for research resumption approval risk-mitigation guidelines have been developed for human participant research activity that falls into one of three categories.

Researchers wishing to restart research activity with human participants should first determine what type of activity they will be conducting:

1. **Virtual participation**
2. **Research activity respecting 2-metre physical distancing**
3. **Research activity where 2-metre physical distancing is not possible.**

Guidance in this document applies to research with human participants that occur on the Laurentian University campus and off campus. Where appropriate guidance is also provided for research with human participants that takes place inside a building or outside (field research).

Table 1: Phased-In Approach to On-Campus and Off-Campus Research with Human Participants. Public Health Sudbury and Districts and Laurentian University's Research Ethics Board will inform the timeline for phased-in approval.

Category	**Description**
1	Virtual or on-line human participant research activities
2	Human participants research activities where 2 m physical distancing can be maintained - Participants are NOT part of a vulnerable population
2	Human participants research activities where 2 m physical distancing can be maintained - Participants are part of a vulnerable population
3	Human participant research with some physical contact (close physical activity is limited) - Intervention studies - Non-invasive measurement devices
3	Human participant research with physical contact involving biospecimen collection
3	Human participant research with sustained physical contact and research involving biopsies

Consider the Need to Resume Face-to-Face Human Participant Research Activities

Serious consideration needs to be given to the current public health emergency related to COVID-19 when contemplating a return to in-person human participant research activity. Faculty members and supervisors are responsible for developing plans for the resumption of human participant research activity that demonstrate how risk is mitigated and ensure compliance with the federal guidelines on ethical conduct of research with human participants. The guidelines below provide details of process considerations for human participant research activity and steps that can be taken to reduce COVID-19- related risks. When feasible, modifications should be made to eliminate in-person interactions and conduct the research activity virtually (e.g., conduct interviews or focus groups using video conferencing or phone calls, online surveys, etc.).

Population Considerations

Ontario's public health guidance strongly recommends that persons 70 years of age and older, those who are immunocompromised, and those who have chronic medical conditions stay home and avoid all but essential outings in public places. It is especially important for research involving

vulnerable populations to move to virtual participation. In the absence of a strong clinical imperative, in-person research with vulnerable populations is not allowed at this time.

Travel Restrictions
Travel for university-sanctioned activities remains suspended through the end of 2020, but it may be recommended by the VPR to the President for approval if deemed essential to resume in-person research with human participants and the field research activities can be conducted safely while complying with physical distancing and hygiene protocols. Refer to Laurentian University's Health & Safety and Risk Mitigation Guidelines for Field Research Conducted During the COVID-19 Pandemic for guidance.

Section 3: Approval Process for the Resumption of Human Participant Research

The process to request approval varies depending on the nature of the research activity and in all instances, researchers must obtain Laurentian University Research Ethics Board (LUREB) approval before commencing their research. Principal investigators that received LUREB approval, prior to the suspension of research activities, in March 2020, due to COVID-19, are required to file an amendment/modification to their project design. Principal Investigators wishing to start a new project with human participants are required to submit a full REB application. In all cases Principal Investigators must follow the research resumption application steps illustrated on page 5.

Other Considerations
Community safety must be balanced with the immediate benefits and long-term value of human participant research activities. Participant and staff safety are always the top priority. Due to the rapidly changing nature of the situation, recommended procedures and policies may change after the implementation of this guidance. In the event of major changes to the recommendations, investigators will be notified of the changes (The Laurentian University Resumption Committee will issue a communication), and a response that they are being complied with will be required within 48 hours Investigators must notify the LUREB as soon as they plan to change any study protocols and submit an amendment request. Investigators must notify the LUREB immediately if there are any adverse or unanticipated events that occur during the course of the research activity (e.g., contact tracing is required, breach of privacy, reported illness of Laurentian University staff or participants, community concerns, etc.) The LUREB may require submission of an adverse events report.

When preparing your application for research resumption please refer to Section 4 of this document and to the document linked below:

- Guidelines on Reporting Illnesses
- Health and Safety Guidance During COVID-19
- Guidelines for Disinfecting during COVID-19
- Procedures on Return to Campus Screening
- Face Covering Policy
- Request for PPE

Other guidance can be found on the COVID-19 website (https://laurentian.ca/covid-19/research)

- Health and Safety and Risk Mitigation Guidelines for Field Research Conducted During the COVID-19 Pandemic
- Health & Safety and Risk Mitigation Guidelines for On-campus Research Conducted During the COVID-19 Pandemic

<table>
<tr><th colspan="4">Steps to Resume Human Participant Research</th></tr>
<tr><td colspan="4">Do you have an existing LUREB approval?</td></tr>
<tr><td colspan="2">YES
I need to submit an amendment</td><td colspan="2">NO
I need to submit a new application</td></tr>
<tr><td colspan="2">What type of research with human participants do you wish to undertake?</td><td colspan="2">What type of research with human participants do you wish to undertake?</td></tr>
<tr><td>The research activity with human participants will be remote/virtual/on-line.</td><td>All other research activities with human participants</td><td>The research activity with human participants will be remote/ virtual/ on-line.</td><td>Research Activity Respecting 2-metre Physical Distancing

Research Activity where 2-metre Physical Distancing is Not Possible*</td></tr>
<tr><td>• Follow the LUREB amendment process to revise your data collection protocol to allow for virtual data collection, if this was not part of the original LUREB-approved plan
• Once LUREB approval has been obtained, you may begin virtual human participant research activity.</td><td></td><td>• Follow the regular LUREB process to obtain ethics approval.
• Once LUREB approval has been obtained, you may begin virtual human participant research activity.</td><td>• Complete the Laurentian University Permission to Resume On Campus or Field Research Form Phased-In Return to On-Campus and Field-Research Plan
• Ensure signatures of approval are included on the form:
1. Chair/Director
2. Health and Safety
3. Dean
• Send the completed form to the VPR. If approved, the VPR will provide a letter of approval
• Submit the letter of approval, along with your LUREB application (or amendment), to the Research Ethics Board
• If approved, the Chair of the LUREB will provide an approval letter
• Send a copy of the approval letter to the VPR and Manager of Health and Safety to prompt the coordination of card and building access</td></tr>
<tr><td colspan="4">* Under Phase 2 of Laurentian University's Research Resumption Plan research with human participants where 2-m physical distancing is not possible will be phased-in gradually if appropriate risk mitigation can be implemented and the REB deems the project to be justified.</td></tr>
</table>

Roles and Responsibilities: Approval Process for the Resumption of Human Participant Research Activities

Principal Investigator/Supervisor

- Complete the Permission to Resume on Campus of Field Research Form Including the section on Plan for Risk Mitigation
- Send to the Chair/Director for approval
- After receiving the approval letter from the VPR, submit your LUREB proposal and complete the LUREB review process.

Upon Receiving REB Approval

- Notify the Vice-President Research and Manager of Health and Safety (provides LUREB #)
- Ensure all highly qualified personnel are fully trained on the approved risk mitigation plan and receive a PASS on the COVID self-assessment survey prior to attending campus or field research

Chair/Director

- Review the Permission to Resume on Campus or Field Research Form
  **Note the request and if any departmental resources are required to support the proposed research. Provide comment on the form if there are any potential issues with access to shared department resources (technicians; labs; meeting rooms). Sign the form and send to the Manager of Health and Safety (or designate) for approval.*
- If there are potential issues with access to shared department resources, provide feedback to the Principal Investigator. The Principal Investigator can note the comments and make modifications to their proposed research plan if required.

Occupational Health and Safety

- Review the risk mitigation plan submitted in the Permission to Resume on Campus or Field Research Form
  - If approved, send to the Dean
  - If not approved, provide comments to Principal Investigator
- Provide access to on-line D2L training course for the Principal Investigator/Supervisor and all listed highly qualified personnel

Dean/Designate

- Review the Permission to Resume on Campus or Field Research Form
  - If approved, send to the Vice-President Research for approval
  - If not approved, provide comments to Principal Investigator

Vice President Research

- Review to ensure process followed and alignment with guidelines, criteria and overarching institutional coordination
  - If approved, in principal, the VPR will return a signed copy of the Permission to Resume on Campus or Field Research Resumption Approval Form (with a statement that indicates approval from the LUREB is required) to the Principal Investigator to include with their Research Ethics Board Application
  - If not approved, provide comments to the Principal Investigator

Laurentian University Research Ethics Board

- The Principal Investigator submits the VPR signed Permission to Resume on Campus or Field Research Form along with their REB application via the ROMEO portal
- The LUREB conducts a review to ensure that what is proposed abides by Laurentian University's policies and by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2018)

- If approved, LUREB Chair (or designate) notifies the Principal Investigator
- If not approved, LUREB Chair (or designate) provides comments to the Principal Investigator

Section 4: Risk Mitigation Guidelines for Research with Human Participants during the COVID-19 Pandemic

Prior to Interaction with Study Participants

Researchers should consider and plan for ways to ramp down or suspend physically interactive study elements of their research should public health conditions change. The following guidance should also be considered:

- Study visits should be restricted to only those individuals who are essential.
  - This would include the study participant and legal guardians, legally authorized representatives, family members, friends, or others (e.g., translators and interpreters) who must be present with the participant for health care, research-related decisions, or to provide support to the individual.

- Limit the number of people present in an area at any given time.
  - Create a schedule for study team members and use separate rooms for study visits.
  - Ensure that circulation paths are clearly identified to maintain 2-metre physical distancing.
  - Minimize the use of waiting rooms and, if a waiting space is used, ensure physical distancing provisions are in place.
  - It may be helpful to have a disinfection area outside the study space where participants and team members can wash their hands, obtain PPE (if required) and leave their outside belongings.
  - Consider whether it is possible to move study procedures to conference rooms or classrooms that have greater airflow and greater feasibility of maintaining physical distance.
  - Only those individuals who are essential to complete the study procedures should be present: study personnel, study participants and, if necessary, those who may be there to assist the study participant.
  - Consider using video conversations with individuals in different rooms/locations when possible to limit face-to-face interactions.
  - Consider approaches to train personnel on study procedures virtually, if possible. If this is not possible, researchers who require training on specific study procedures may only be present at study visits when training is required for them to perform their job. If this happens, the study team needs to be conscious of room occupancy and to maintain a safe environment for all.

- Use a schedule to ensure sufficient time between visits.
  - Plan for sufficient time between visits of different participants to ensure proper sanitation of any materials or equipment as well as sufficient turnover of air where the study visit is being performed. Groups sharing spaces for human participant research should have a schedule to enable this to be coordinated across groups and studies. Proper cleaning should occur after each visit.

Screening (See Screening Procedure and Questionnaire)
Screening of study team and participants is required as follows:

- Study Team
  - All study team members who will be present in the lab space and/or who may come in contact with study participants must complete and PASS the COVID-19 Self Screening Questionnaire prior to arriving on campus each day.

- Study Participants
  - Study participants should be provided with the link to the Laurentian University COVID-19 Self Screening Questionnaire and asked to complete the self-screening each day prior to arriving on campus. If the participant does not pass, they will not be able to attend campus. Any participants who do not pass the screening will have their visit cancelled or rescheduled. Immediately upon arrival a member of the research team should verify that the participant completed and passed the self-screening questionnaire. Participants must be symptom free to participate “in-person”.

Preparing Study Participants for the Visit
When preparing study participants for participation in a research study, the following guidance should be considered:

- Communicate with participants
  Research teams should communicate to participants before their study visit, and depending on the level of information to be shared, consider developing a simple informational sheet that can be provided to all participants, outlining the following:
  - How the study team is making the environment as safe as possible when participants come in for their visit and what to expect. Describe any special procedures for participants (e.g., parking, building access/which entry to use or location change).
  - Inform the participant of Laurentian University’s Face Covering Policy
  - Instruct participants to bring water and a snack, if applicable.
  - Advise participants that they should follow public health guidelines for safe practices when leaving their home.
  - Inform participants of transportation options. It is recommended that a risk-based approach be used when considering the best method of transportation. Consider whether the participants can safely walk to the lab or other research data collection location, or if they have their own transportation.

- Adapt cultural practices
  - If cultural practices such as smudging are a part of the in-person protocols for your research activity, work with the community to adapt the practice to allow participants to take appropriate precautions while engaging in cultural practices.

- Prepare the study visit area
  - When on-campus clean and disinfect the study lab/visit space according to Laurentian University’s Guidelines for Disinfecting during COVID-19 or the protocols of the host community/organization where the off-campus research activity is taking place. This may include tables, chairs, door handles, equipment such as VR headsets, wearable systems, and other non-disposable equipment or items used during the study visit.
  - Space used for study visits should be cleaned and disinfected daily in between each participant study visit and after all visits are completed for the day.
  - Designate experiment/data collection areas and areas for guardians/other visitors and their belongings.

- Prepare the space before the participant arrives (e.g., propping open doors, calibrating all equipment, etc.).
- Have PPE available for study participants, including face masks and hand sanitizer.
- In spaces where physical distancing cannot be maintained through the strategies outlined above, and if researchers determine additional engineering controls such as the installation of plexiglass is required, this should be identified in the risk mitigation plan submitted in the Permission to Resume on Campus or Field Research Form and Facilities and Health and Safety will provide further guidance.

Training
All essential personnel are required to complete the D2L Laurentian University COVID-19 training prior to resuming research activities on campus or in the field. This training is available on D2L. Individuals can self-register in the course called COVID19: Here is what you need to know (Français COVID19- Voici ce que vous devez savoir).

Best Practices for Travel when Research is Off-Campus
For guidance on travel consult:

- Health and Safety and Risk Mitigation Guidelines for Field Research Conducted During the COVID-19 Pandemic

During the Visit
Study visits will be planned in such a way as to emphasize participant, staff and trainee safety and make sure that all participants feel comfortable. An early part of the communication with participants should give them an overview of policies and practices, and give them the opportunity to ask questions so that they feel comfortable coming on-site. Study-specific activities may require specific customizations to this plan, but the following principles will govern in-person human participant research activity:

- Maintain appropriate physical distancing whenever possible.
- Maintain the highest standard of cleanliness, including regularly disinfecting high-touch surfaces, cleaning exam/procedure/study rooms between each participant, and good hand hygiene.
- Use appropriate PPE

Best Practices to Consider when Developing your Risk Mitigation Plan
Laurentian University is committed to provide and maintain healthy and safe working and learning environments for all workers, students, volunteers, visitors and stakeholders. COVID-19 is a new hazard in the workplace. Hazard mitigation should always focus on implementing measures to eliminate or reduce the risk – which, in this case, is contact with COVID-19. For up-to-date information on health and safety guidance during COVID-19 researchers and highly qualified persons are encouraged to visit https://laurentian.ca/COVID-19/health-safety

Strategies particularly relevant for research on-campus with human participants:

- Designate the direction of foot-traffic in main circulation paths such as corridors and entryways (use signage or other markings).
- If possible, designate a bathroom for participant use.
- Keep a daily record (preferably in electronic format) of who is in the space and the time that they are there for contact tracing purposes.
- Study staff should be prepared when meeting the study participant by wearing PPE and having all materials, equipment, and other items ready for the study visit. Study staff should wash or sanitize their hands just before the study visit begins, and throughout the study visit (i.e., both before and after making contact with a study participant or piece of equipment or surfaces in vicinity of the participant).

- Screen all study participants and family members, caretakers, legal representatives, etc. before they enter the lab/building. (Instruct individuals to utilize COVID-19 Self Screening Questionnaire)
- Provide all study participants with PPE to wear during the visit in accordance with university guidelines.
- If and when possible, study staff should maintain 2-metre physical distancing from the participant. When possible, and if participants are able, advise them to announce their movements in the space to avoid accidental broaching of the 2-metre distance.
- If study protocol prevents safe distancing, additional PPE measures should be taken (e.g., a face mask, and/or a face shield or goggles). Ensure that PPE is being used by all for the duration of the study visit. Also consider if it is possible to have the study team member and participant face in opposite directions.
- Disinfect rooms between each participant. Regularly disinfect additional high-touch surfaces, including door handles and light switches. Laurentian University will be providing disinfectant to all departments and units. Please refer to the Guidelines for Disinfecting during COVID-19 for procedure to use and to refill disinfectant bottles.

Researcher and Human Participant Controls for On-Campus

- Reorganize spaces to respect a 2-metre distance between all members of the research team and all participants if possible. If this is not possible, physical separation with barriers such as plexiglass or other partitions should be considered. Minimize the duration of live interaction as much as possible by prioritizing remote communication.
- Ensure that all research staff, students and participants are provided with necessary PPE and proper training as to its use.
- For research that entails physical contact with participants, PPE (i.e., procedure single-use masks, protective eyewear or visors) is required. Single-use gloves should only be used for short periods when touching mucous membranes or adjacent surfaces (e.g., lips) of participants. If gloves are required, hands must be washed immediately before donning and immediately after removal and safe disposal.
- Research staff should wash their hands thoroughly with soap and water or with alcohol hand sanitizer for at least 20 seconds before commencing work and when they have finished working with a piece of equipment. This includes when going from one room to another, when a touch-area changes, and the washroom. Research staff should keep a container of hand sanitizer with them for intermittent sanitization when soap and water are not available.
- Before putting on a mask (and after its removal), research staff should wash their hands according to the proper techniques noted above. The same is true for any PPE (e.g., gloves. If gloves are required for the work, research staff should wear them only at the point of care and wash their hands immediately after removal. Research staff should be careful not to touch personal items (e.g., phone) while wearing gloves. If touching a personal item is necessary, the personal item must be cleaned.
- Do not cross-contaminate surfaces and working areas – when you move from one area to another, wash your hands.
- Don gloves only when you begin close interaction with a participant if the interaction requires touching of mucous membranes or adjacent surfaces (as noted above) and discard them immediately after use. Hands must be washed after removing gloves.

Considerations when 2-metre Physical Distancing Cannot Be Maintained

- Research with children will often necessitate careful attention to environmental controls. For example, if you use toys or other shared objects in your research, ensure that all are made of materials that can be cleaned and disinfected easily (e.g., avoid plush toys, porous materials, books). Carpets or floors where young children may sit or crawl should be covered with a cleanable (non-porous) mat that is disinfected or replaced after each use.

- Towels or other materials that may be required for use by participants (e.g., for an electroencephalogram/EEG) must be placed into a closed plastic bag until they are laundered prior to next use. Sinks used for hair washing must be disinfected after each use, along with any shared shampoo bottles (single-use supplies are preferred).
- Handling and Processing Biological samples collected during study visits are always handled by qualified team members with the highest regard for safety. Samples will be collected by study technicians, nurses and/or physicians, as appropriate. They will be handled, processed, and/or shipped only by qualified team members.

After the Study Visit

- Clean and disinfect study lab/visit space and surfaces. This may include tables, chairs, equipment such as EEG machines, VR headsets, wearable systems, and other non-disposable equipment or items used during the study visit. Refer to the Guidelines for Disinfecting during COVID-19 for more information.
- Space used for study visits should be cleaned and disinfected between each participant study visit and after all visits are completed for the day.
- Ensure that stock of PPE is replenished. This may include face masks, hand sanitizer, disposable wipes, etc.
- If a study team member or study participant has contracted COVID-19 following a study visit please
    - Notify the Manager of Health and Safety, Gail Cowper-Benoit at gbenoit@laurentian.ca or at 705-923-7250
    - Please refer to the following for guidance:
        - Guidelines on Reporting Illnesses

Section 5: Research Ethics Board Application Considerations

REB applications and amendments to ongoing projects/studies should clearly outline all strategies being implemented to eliminate or reduce face-to-face interactions such as:

- Is it possible for some or all study visits to be completed via telephone or virtually? For example, is it possible to screen and to confirm an individual's consent prior to their coming into the lab? If the consent process will happen in person, consider a contactless method (i.e., not having to use pen and paper) by which to obtain consent, such as sending the form electronically and having the individual use their personal device.
- If participants are required to complete forms or questionnaires, can these be distributed and completed ahead of time? If they have to be completed in person, can they be completed electronically, ideally with the participant using their personal device, to minimize the use of paper and pens? If contactless methods can't be employed, develop procedures that mandate hand sanitizer be used before and after touching common devices.
- Is it possible to consider monitoring experiments and other research-related activities using (non-recording) cameras, if possible, to create additional physical separation?
- If the research is being conducted within a specific community/organization, has the community been engaged in the decision to initiate or resume research? It is best practice to consult with the communities to determine whether they wish to continue with the research collaboration at this time and to ensure that researchers are following their health and safety practices.

Informed Consent

The COVID pandemic and physical distancing measures have altered the conduct of human participant research significantly. TCPS (2018), Article 3.3 states that consent shall be an ongoing process. The researcher has an ongoing ethical and legal obligation to bring to participants' attention any aspects or changes to the research project that may affect them. These changes may have ethical implications, may be pertinent to their decision to continue research participation,

or may be relevant to the particular circumstances of individual participants. In particular, researchers shall disclose changes to the risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis for their consent in light of the new information.

Research-related risks may include:

- risks associated with travel (e.g., public transit)
- time within a university or community-based facility
- exposure to other people, including other research team members and research participants

Consent forms should be amended to include acknowledgement of the possibility that a participant could come into contact with someone with COVID-19 during their research pathway and to allow for contact tracing. For projects involving face-to-face interaction, an additional statement regarding COVID-19 risks should be added to the consent form. Two examples are provided below:

- "This study involves in-person interactions that require direct contact where 2-metre physical distancing may not be possible. Your travel to the study location may also involve increased exposure to other people. Because of these factors, there is some risk that you may be exposed to the COVID-19 virus during study participation. Researchers will take precautions in accordance with provincial, federal, Laurentian University and other public health guidelines to minimize the risk of transmission of COVID-19. We are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes in the unlikely event that you come into contact with someone with COVID-19 during your research activities. This information will be stored separately from any other data collected in this study and will be deleted/destroyed after 30 days."
- "There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes. This information will be stored separately from any other data collected in this study and will be deleted/destroyed after 30 days."

Modifications to Research Procedures

Additional details on methodological modifications to support physical distancing and hygiene should be included. For example:

- Study procedures that may prevent safe distancing or require modified use of PPE by participants. For example, if there is a need to take oxygen measurements for energetics, this will preclude a participant from wearing a surgical face mask. Document safety precautions and procedures that can be put in place to mitigate risk of infection for participants or research team members.
- Consideration of the study population and whether the research activity aims/questions could be sufficiently addressed without recruiting those at greatest risk of COVID-19 infection. It is recognized that some studies/projects require working with specific populations.
- Consideration of what adjustments can be made to procedures and locations when study participants may not be able to wear masks. Consideration should be given to not only mitigate risk for study team members interacting with the participant at the research activity space, but also for the entire time that the participant will be on campus.
- A plan for cleaning and disinfecting spaces, including determining what additional supplies may be needed, such as PPE, cleaning supplies and waste management.
- The research plan should address methods for screening participants within 24 hours preceding contact. All members of the research team must be asymptomatic of COVID-19 symptoms and this must be validated within 24 hours preceding interaction with participants.

- The research plan should allow for COVID-19 guidelines on physical distancing, facial coverings and PPE as relevant. The plan should address maintenance of the highest standard of cleanliness, including regularly disinfecting high touch surfaces, cleaning exam/procedure/study rooms between each participant, and good hand hygiene.
- Participant Consent forms should be composed to include acknowledgement of the possibility that a participant could come into contact with someone with COVID-19 during their research pathway and to allow for contact tracing. Specifically, consent forms may be amended with the following statement: “There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes”.

Researchers should consider and plan for ways to ramp down or suspend physically interactive study elements of their research should public health conditions change.

Appendix A:
Permission to Resume On-Campus or Field Research Form

The permission to resume on campus or field research form is found in:
Laurentian University's Phased-In Return to On Campus and Field-Research Plan