



Framework for Phasing-In Human Participant Face-to-Face Research at University of Guelph (On Campus)

July 30, 2020

Updated: October 19, 2021

Revision Log

Date	Update
September 23, 2020	Reference to off-campus guidance added; link to self-assessment screening tool added to Appendix I and Appendix IV.III; approval process revised (see Appendices IV.I, IV.II and IV.IV); parking instructions removed from Appendix IV.III
March 24, 2021	Vulnerability consideration changes (see Appendix III), including removal of children from COVID-19 vulnerable population; COVID- 19 Vaccination addressed in Appendices III, IV.III and V
April 29, 2021	Consent Appendix IV.III: Vaccination screening table revised
June 16, 2021	Updates with respect to face coverings throughout
September 27, 2021	Updates to Appendix IV.III and Appendix V with Fall 2021 Guidelines for Human participant Face-to-Face Research superseding older Guidelines that were previously available
October 19, 2021	Consent Appendix IV.III: Vaccination screening table removed, and new instructions added to Participant Screening



Preface

The University of Guelph recognizes the vital importance of human participation in its dynamic research enterprise. These activities have been severely impacted by COVID-19. This document aims to assist researchers in returning to human participant research as restrictions ease and is to be used in conjunction with the [Fall 2021 Guidelines for University of Guelph Human Participant Face-to-Face Research](#). It outlines return to research guidelines for decision-making, as well as a checklist to facilitate preparation for the phase-in of face-to-face human participant research. This guidance follows the University of Guelph [Research Phase-In Framework](#) and adheres to the overarching principle that health and safety are the top priorities. It emphasizes protocols for on-campus research, while the [Off-Campus Human Subject Face-to-Face Research Framework](#) has been developed with suggestions and considerations for resuming and implementing projects outside of University grounds.

Three levels of return-to-face to face human participant research are described below. They are based on level of contact with human participants. Guidelines are associated with each of the levels.

More guidance can be found here:

[Government of Canada -steps to mitigate community spread](#)

Instructions and guidelines for safe phase-in of human research

The following health and safety guidelines and procedures have been developed to minimize the spread of COVID-19 for those who are working in on-campus research facilities that engage in human participant research to ensure compliance with current [Ontario Public Health](#) and the [University of Guelph Environmental Health and Safety Guidelines](#) for physical distancing, cleaning, hygiene and related safety protocols. This coronavirus spreads through liquid droplets and from contaminated sites and surfaces; as such the proposed measures in this Return to face-to-face Human Research Guidance document are intended to reduce the risk of transmission of disease to people at the University of Guelph (staff, students, instructors, researchers, participants, cleaners, etc.) or others sharing spaces with them. Careful consideration must be given to the initiation of human participant research. Only human research that can be scaled back or shut down, safely, on short notice, should be initiated.



Key considerations for safe phase-in of human research

Above all, the safety of students, staff, faculty and our community is the number one priority

- DO NOT come to campus if you do not need to. The goal is to minimize people on campus and contact risk between researchers, staff, and participants.
- DO NOT come to campus if you are unwell, or if you are exhibiting any symptoms of COVID-19. Anyone coming to campus must complete the self-assessment tool prior to coming to campus. All individuals must have proof of vaccination or have an exemption (and present a negative test result from within the last 72 hours).
- No one should come to campus if they have symptoms of COVID-19, have been in close contact with someone with COVID-19, or have been told by a health official to self-isolate.
- If you have been in contact with someone with COVID-19, you should get tested and self-isolate until you get your results (testing three to four days following exposure is believed most effective). Follow Public Health instructions for testing positive or negative.
- No student, staff, faculty or community member should engage in face-to-face research if they feel unsafe.
- DO NOT bring people to campus if you do not need to. This includes participants for human face-to-face research. For example, participants should attend campus alone, except in special circumstances (e.g., children).
- If your human research is conducted virtually, continue to operate that way.
- If your human research can shift to being conducted entirely remotely, do so.
- If some face-to-face interactions are required, aim to shift any aspects that can be completed remotely (e.g. screening, questionnaires, check-in conversations) to minimize time on campus.
- Where possible, and with consent and without coercion, researchers may be limited to recruit from on-campus community for volunteers to participate in face-to-face research. Please refer to [Fall 2021 Guidelines for University of Guelph Human Participant Face-to-Face Research](#) for further direction.
- If research protocols cannot be modified to be conducted remotely, researchers should implement steps to maintain two metres physical distancing, as the next step to mitigate risk.
- Where two metres physical distancing cannot be maintained, engineering and administrative controls must be considered first, with PPE, as the only protection to individuals, being the last consideration (see table Appendix II).
- Any changes in a research protocol (e.g. moving to remote, administration controls, PPE etc.) will need to be captured in the Research Management Plan (RMP) AND the Research Ethics Board (REB) amendment or REB application (See flow chart in Appendix IV.I)
- On campus research with individuals more susceptible to negative outcomes as a result of COVID-19 (Appendix III) is able to occur if those individuals are vaccinated. Extra precautions may need to be taken in certain higher risk procedures. Research with vulnerable unvaccinated individuals is not able to occur unless there is compelling evidence to do so. In such cases, additional measures will need to be taken to ensure the safety of participants and researchers who may be vulnerable. Approval for these situations will be made on a case-by-case basis.
- If participants fall into a COVID-19 high-risk population (per Appendix III), please consult [Fall 2021 Guidelines for University of Guelph Human Participant Face-to-Face Research](#)

for further direction.

- Research with human participants will be guided by Public Health and based on the incidence and knowledge surrounding COVID-19 as the situation changes and new information becomes available.
- Children (defined by Public Health Ontario as <19 years) who contract COVID-19 are considered [no more vulnerable](#) than adults (<60 years) in the COVID-19 context. Safety measures described herein apply to both children and adult research participants.
- Tracking participants who visit campus for research will be required to allow for contact tracing. As such, participants will need to be informed of privacy limitations, and provide consent to share contact information for this purpose. Approved language to be added in the consent document is provided below for this purpose (See Appendix IV.III).
- All guidelines in this document will oversee the invitation or restriction of participation in face-to-face human research contingent on Public Health recommendations based on local numbers of COVID-19 cases, vaccination rates and community spread. This is a dynamic situation and research with human participants may need to be scaled back or halted, dependent on broader Public Health and University guidelines.
- This Framework document covers on-campus research activities. Off-Campus face-to-face research is addressed in its own independent [Framework document](#). Both framework documents are to be used with the [Fall 2021 Guidelines for University of Guelph Human Participant Face-to-Face Research](#).



Steps to mitigate risk

Physical Distancing: All individuals are required to keep two metres apart from one another whenever possible. Reduce time spent in close proximity.

- Keep two metres apart
- Move equipment and furniture around to enable two metres distance

Engineering Controls: Strategies to create physical barriers between individuals and reduce exposure to common surfaces.

- Increased access to hand washing facilities and hand sanitizers
- Place plexiglass between researcher and participant for interviews
- Reduce items in the space to reduce contact with surfaces
- Open windows or increase ventilation to areas when possible
- Move research outside where possible, or separated by rooms

Administrative Controls: Strategies to change the way people interact with the setting to reduce risk (through changes to lab policies or practices).

- Complete Forms (consent, questionnaire) prior to On Campus collection to minimize time of contact
- Control the number of researchers and assistants in the lab (follow guidelines per academic unit)
- Wipe down all surfaces frequently and definitely prior to and following data collection (Sanitizing will be with 70% alcohol, hydrogen peroxide (0.5%) or weak bleach (0.1%), in addition to the other biohazardous (e.g. Virox, Cydex) and cleaning (e.g. Lysol) agents.)
- Mark off areas where personnel can and cannot walk, or mark off areas where personnel may walk in only one direction. Identify acceptable physical distances

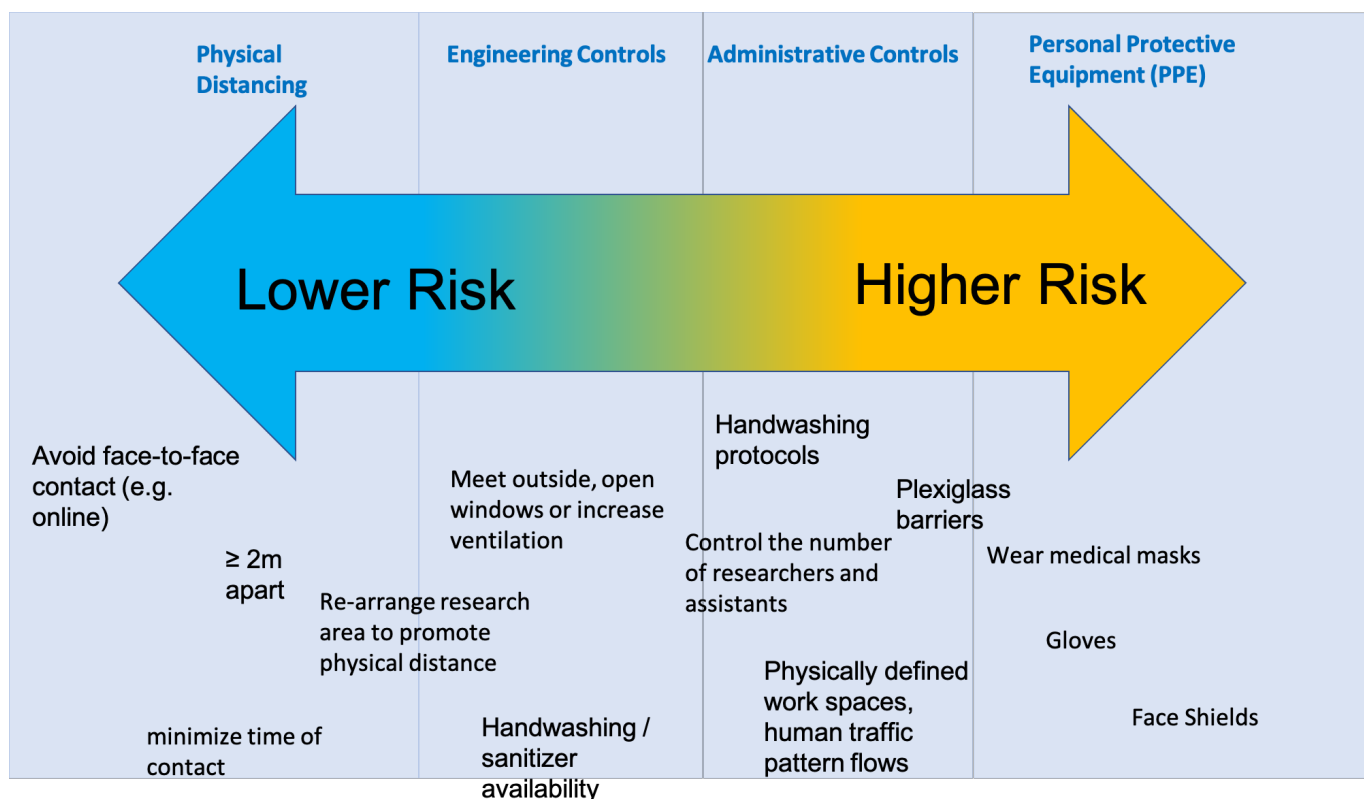
Personal Protective Equipment (PPE) and Face Coverings: Equipment worn/used by a person to reduce spread of the virus. The use of PPE (e.g. medical masks, gloves, etc.) are not a substitute for physical distancing measures; they may be considered as an additional precaution to the administrative or engineering controls available. Use of face coverings must adhere to the [University requirements](#).

- Use of masks must adhere to University requirements.
- Where physical distance cannot be maintained for short periods of time (<15 min): Use of masks or longer periods of time (>15 min): use of masks with face/eye shield
- Use of gloves only when in direct physical contact with a participant, particularly where there is potential transmission via bodily fluids (sweat, saliva, blood). Gloves are to be discarded after each individual participant interaction.
- In place of gloves (other than when specified above), use of hand sanitizer is preferred during data collection to enable frequent sanitization of hands
- Gowns for certain procedures, such as blood draws, biopsies, indwelling EMG

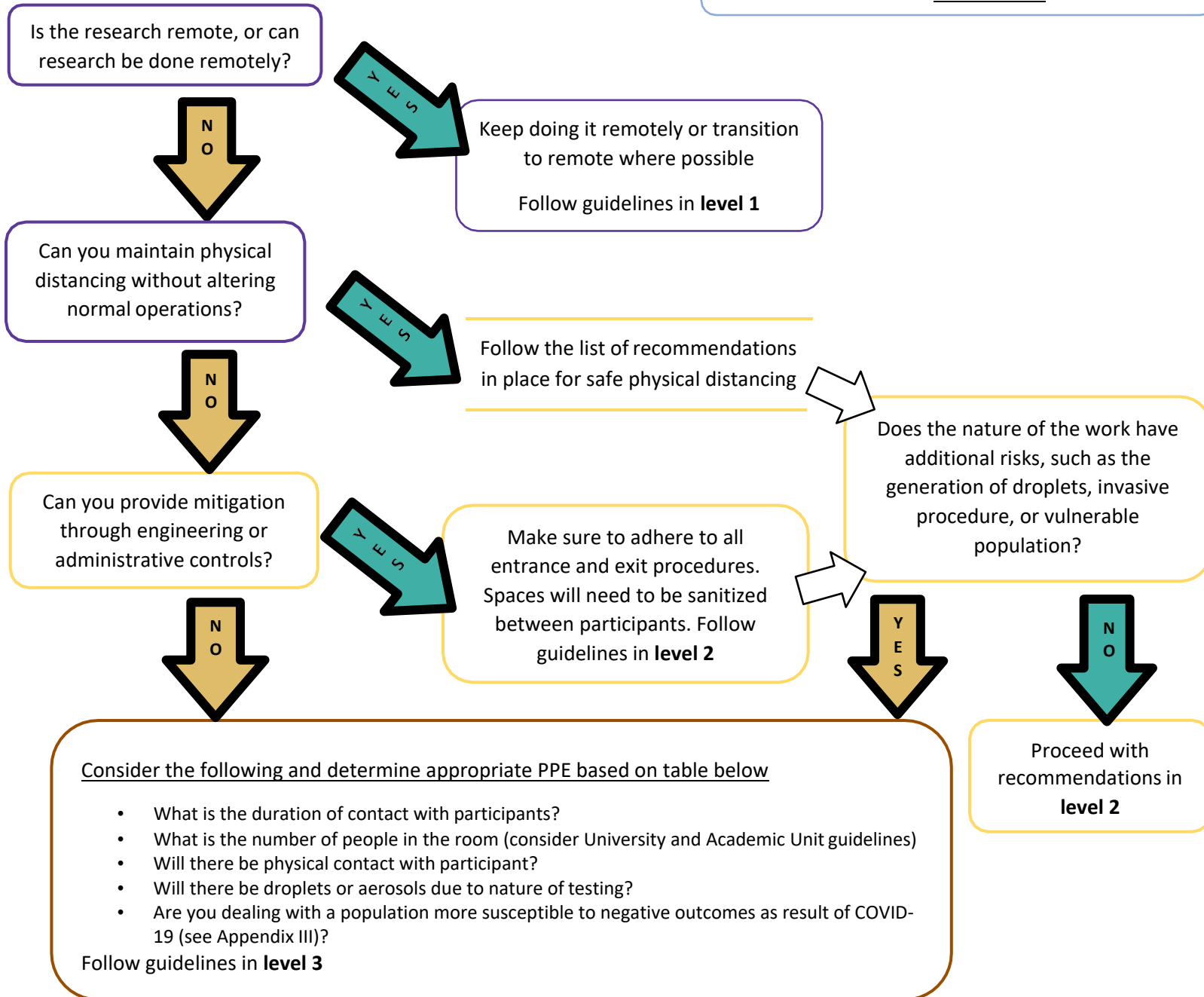
Summary: things to consider

1. How long will you be in contact with participants?
2. What is the size of the space?
3. What is the duration of testing?
4. How much time is spent within two metres of participants?
5. How many support personnel need to be there, and can be there?
6. Plan to transition to virtual means to collect consent, health information, questionnaires etc.
7. Does the nature of the work increase risk due to COVID-19?
8. What can be performed at a distance of greater than two metres during face-to-face interactions (e.g. remote instructions to participant)?

Human Research Mandate: Always aim for lowest possible risk by following mitigation steps below



*Prolonged exposure is defined as lasting for more than 15 minutes. The 15 minutes can be from one continuous exposure or cumulative duration. Ref: Public Health



Level 1 through 3 indicate levels of proximity of human interaction, and associated risk

Level 1: Research that can continue remotely, or transition to remote data collection but requires campus access

Guidelines

- Return to research will be contingent on both an approved Research Management Plan AND REB application or amendment approval.
- Continue to perform research remotely where possible. Only come to campus if approved to do so and it is REQUIRED to obtain documents or use software (e.g., for data entry). Access software remotely where possible.
- If not currently performing research remotely, but a transition to remote research is possible, consider steps to initiate remote data collection.
- If required to be on campus for data entry, and this cannot be performed through remote access to software, follow COVID-19 guidelines as outlined by [safe return to campus website](#). This includes guidelines for self-assessment prior to arrival on campus.
- Follow guidelines as outlined per academic unit (College/Department) to sign in and out of space to facilitate contact tracing.
- Adhere to College/Department guidelines for personnel access and coordination to limit number of individuals in a space. Wear a mask where two metres of physical distancing is not possible.
- Remote data collection does not include access to collection sites off campus (homes, gyms, clinical settings). This will be addressed below.

Level 2: Research that requires face to face interaction but can maintain physical distancing

Guidelines

- Return to research will be contingent on both an approved Research Management Plan AND REB application or amendment approval.
- Return to face-to-face research should begin with recruitment of healthy populations that fall outside of high-risk categories such as populations described in Appendix III.
- Follow all safe practices currently in place to perform the research (e.g. maintain regular safe practices around food preparation, face to face interviews).
- Follow guidelines as outlined per academic unit (College/Department) to sign in and out of space to facilitate contact tracing.

- Follow the general guidelines as outlined for interaction with Human Participants (SOP, Appendix I)
- Ensure physical space is arranged so that physical distancing can be maintained. Practice frequent sanitization of surfaces. See engineering and administration controls above.
- Researchers will have a mask available for self-use, and will provide an appropriate mask to participants.
- Limit unnecessary contact between individuals by scheduling participants at different times and pairing research team members with participants when repeat visits are required.

Level 3: Research that requires face to face interaction and cannot maintain physical distancing

Guidelines

- Return to research will be contingent on both an approved Research Management Plan AND REB application or amendment approval.
- Follow the general guidelines as outlined for interaction with human participants (SOP, Appendix I).
- In addition to engineering controls as outlined in Level 2 (traffic flow signs, proper cleaning of frequently touched surfaces) additional mitigation steps are necessary with the use of PPE.
- Where two metres of physical distancing cannot be maintained, proper PPE must be worn.
- Masks must be worn by researcher, assistants in the lab, and participant in accordance with University requirements.
- Masks must be worn by researcher and participant when interacting with participant, such as any research that entails physical contact. E.g. placing equipment on participants (electrodes, IMUs, amplifiers, patient packs etc.) in accordance with University requirements. Eye protection is recommended for researchers. Wash hands prior to and following placement of equipment on participant. (Refer to Table in Appendix II).
- Face shield/eye protection will be worn along with medical masks when proximity within two metres is for prolonged periods of close contact and during invasive procedures (multiple person procedures such as biopsies, spotting participants, microneurography).
- Gloves will be worn along with eye protection and masks during procedures that normally require this level of protection (blood draws, biopsies, indwelling EMG). Following the procedure gloves will be disposed and hand sanitizer will be used when operating equipment.
- When additional risks may be present due to the nature of the work (e.g. procedure is truly aerosol generating), the use of a properly fitted N95 medical mask is recommended for researchers.
- Once it can be shown that healthy individuals from the community can safely be engaged in on-campus research, more vulnerable populations can be considered.

Appendix I – SOP return to Face-to-Face Human Research

General Guidelines for all Human Participant Research that Require Face-to-Face Interaction

On Campus

1. Minimize time of interaction. Preliminary screening procedures and consent should be obtained over the phone prior to participant arrival. Include questions which enable identification of populations more susceptible to negative outcomes as a result of COVID-19. Research with these vulnerable populations will proceed following University directives.
2. Once remote preliminary consent has been obtained, screen all participants 24 hours prior to their scheduled session with inquiries regarding their health in the 14 days prior to the appointment, with special attention to the preceding 48 hours.
3. If participants have received clearance to participate in research, they will be required to complete an additional self-assessment screen on the day of testing prior to coming to campus. **All faculty, staff, students, visitors, and contractors must complete the [University of Guelph COVID-19 Daily Screening Form](#) every day before coming onto the Guelph Campus or other University of Guelph work location.** This will require participants to have access to the screening tool.
4. On the day of testing have them wait outside until called to enter the building.
5. Provide hand sanitizer when participant enters the lab space.
6. Masks are to be worn at all times when on campus when physical distancing is not possible. Situations in which face coverings can be removed are listed on the [University of Guelph Return to Campuses website](#) on the “[When are face coverings not required?](#)” section of the page.
7. Participants coming from off-campus: request participant use washroom facilities at their home if possible before coming on to campus. Where a participant requires to use washroom facilities, follow the approved practices for the location (i.e. only 1 person at a time regardless of number of stalls, use hand sanitizer entering and exiting a restroom, etc.). Encourage participants to travel to campus in their own vehicle rather than public transportation where possible.
8. Participants should be instructed to leave campus immediately following the completion of the research session, inclusive of any observational periods that may be required.
9. Reduce number of people in the lab space according to College/Department regulations based on space structure. Where this is not possible see guidelines for PPE in Level 3 and in Appendix II (below).

Appendix II – Personal Protective Equipment (PPE) and Face Coverings

Specific Guidelines for PPE can be found here: [Guelph EHS](#)

While highly visible, and an obvious form of protection against transmission, personal protective equipment (PPE) should be considered the last line of defense. It is not meant to replace other measures (engineering and administrative controls), but rather should be used alongside engineering and administrative controls to help address additional risks that are unavoidable when in close proximity to others for extended periods of time.

When to use personal protective equipment

If good hand hygiene and surface decontamination are practiced, and physical distance of greater than two metres preserved, the risk of disease transmission will be low and additional PPE beyond a face covering will not be mandatory in situations wherein this would not have already been used prior to COVID-19. The use of droplet and surface contact precautions, with airborne precautions only used for aerosol producing procedures, is consistent with current evidence on COVID-19, as well as guidance from Public Health Ontario, the Public Health Agency of Canada (PHAC) and World Health Organization (WHO). To determine which protective equipment should be used, the risk to the researcher and participant should both be considered. This will be both context and procedure specific, and the PI should help to determine exposure risks, using the general guidelines below.

Guidelines for PPE

ACTIVITY	RISK	PPE
<2m Proximity to participant	Droplets	Medical mask (both - researcher and participant)
<2m Proximity and physical contact with participant shorter duration*	Droplets, transfer via hands	Face mask (both) Hand washing pre and post exposure Face shield for researcher
<2m Proximity and contact with participant prolonged period*	Droplets, transfer via hands	Medical mask (both) Hand washing pre and post exposure, Apron/gown/lab coat Eye protection/face shield
<2m Proximity and contact with participant during invasive procedure (e.g. blood draw, indwelling EMG, Biopsy)	Droplets, transfer via hands	Medical mask Gloves Eye protection/face shield Apron/gown/lab coat
<2m Proximity and contact with participant prolonged period during risky procedures (e.g. exercise)	Droplets, transfer via hands, high ventilation rates, aerosols**	Medical mask, Participant exposure mitigation for high ventilation rates (e.g. microbial filter where appropriate) Gloves Eye protection/face shield Apron/gown/lab coat

*Shorter duration: <15 minutes continuous exposure or cumulative duration; Prolonged period: >15 minutes continuous exposure or cumulative duration (Ref: Public Health)

**if a procedure is truly aerosol generating, the use of a properly fitted N95 medical mask is recommended for researchers

Refer to the [EHS Guideline, COVID-19: Working in Close Contact \(less than 2 metres of others\)](#) for further information.

Face Masks

Face masks come in various forms of self-made or commercial, disposable or reusable masks or face coverings made of cloth, other textiles or other materials. Unlike specific surgical or medical procedure masks, non-medical face masks are not required to meet the certification standards nor are they intended for use in healthcare settings or by healthcare professionals. The Public Health Agency of Canada (PHAC) advises that all types of face masks, including non-medical disposable masks and self-made or commercial cloth masks, **may** reduce the risk of spreading COVID-19. Unlike N95 filtering facepiece respirators, non-medical face masks are neither designed to protect the wearer from exposure to airborne contaminants nor officially classified as PPE.

When to Use a Face Mask

Please follow the requirements for face coverings as outlined on the [University of Guelph Return to Campuses website](#).

Precautions:

- Maintain good hand hygiene and continue to practice physical distancing
- Wash hands immediately prior to putting on/taking off the mask to avoid contamination, especially if the mask is re-usable. Re-usable masks should be washed often.
- Avoid touching your face when removing mask, and try to avoid touching the front of the mask when putting it on or adjusting it (use ear-loops instead)
- Do not share your mask with others
- Avoid touching the mask while wearing it
- Please Consult with Environmental Health and Safety (EHS) at ehs@uoguelph.ca with any questions you might have around the use face masks.

For further information visit the EHS site: [COVID-19: Guidance for Using Non-Medical Facemasks](#) or the [Public Health Agency of Canada](#) website for instructions on wearing cloth masks.

PPE – Gloves

Gloves are not a replacement for hand hygiene, must be changed frequently, and must never be re-used. In general, if gloves were not needed prior to COVID-19, it is likely they are not required now, and unnecessary use of gloves can lead to a false sense of protection that can reduce proper hand hygiene practices. Wearing gloves should not be a replacement for practicing good hand hygiene (i.e., frequently [wash your hands](#) with soap and water for at least 20 seconds or [use an alcohol-based hand sanitizer](#) containing at least 60 percent alcohol).

The wearing gloves for prevention of COVID-19 is **NOT NECESSARY** for the following reasons:

- The human skin is an effective barrier against the viral infection. The virus is not absorbed through your hands. Therefore, you do not need another layer of protection on your hands.
- The virus adheres well to the materials of the gloves (e.g., latex, nitrile or vinyl). If you touch a surface contaminated with the COVID-19 virus, the gloves can be contaminated. If you then touch your face with the gloves on, the contamination goes from your gloves to your face and can infect you.
- Wearing gloves can mislead people into thinking this is enough to protect themselves from the virus. It can give people a false sense of security, as people tend to wash or sanitize their hands less frequently when they are wearing gloves.
- In health care settings, gloves are typically disposed of after every single interaction with suspected or confirmed COVID-19 patients. In non-health care settings, people often wear the same pair of gloves for touching various surfaces, including their phones. If one of the surfaces they touched is contaminated with virus, this may result in contaminating multiple surfaces, which may increase the risk of getting COVID-19 for you and others.
- The idea of washing hands with disposable gloves on or using a hand sanitizer on the gloves for disinfection may appeal to some workers. However, these practices are not recommended because washing can disrupt the integrity of the gloves, and the hand sanitizer is designed for use on the human skin, not on the materials of the gloves (e.g., latex or nitrile).

Wearing gloves is not a replacement for practicing good hand hygiene (i.e., frequently [wash your hands](#) with soap and water for at least 20 seconds or [use an alcohol-based hand sanitizer](#) containing at least 60 percent alcohol).

For more information, including practical instances wherein non-medical use of gloves may be beneficial, researchers are encouraged to visit [COVID-19: Use of Disposable Gloves in Non-Health Care Workplaces](#)

Aprons/Gowns/Lab Coats

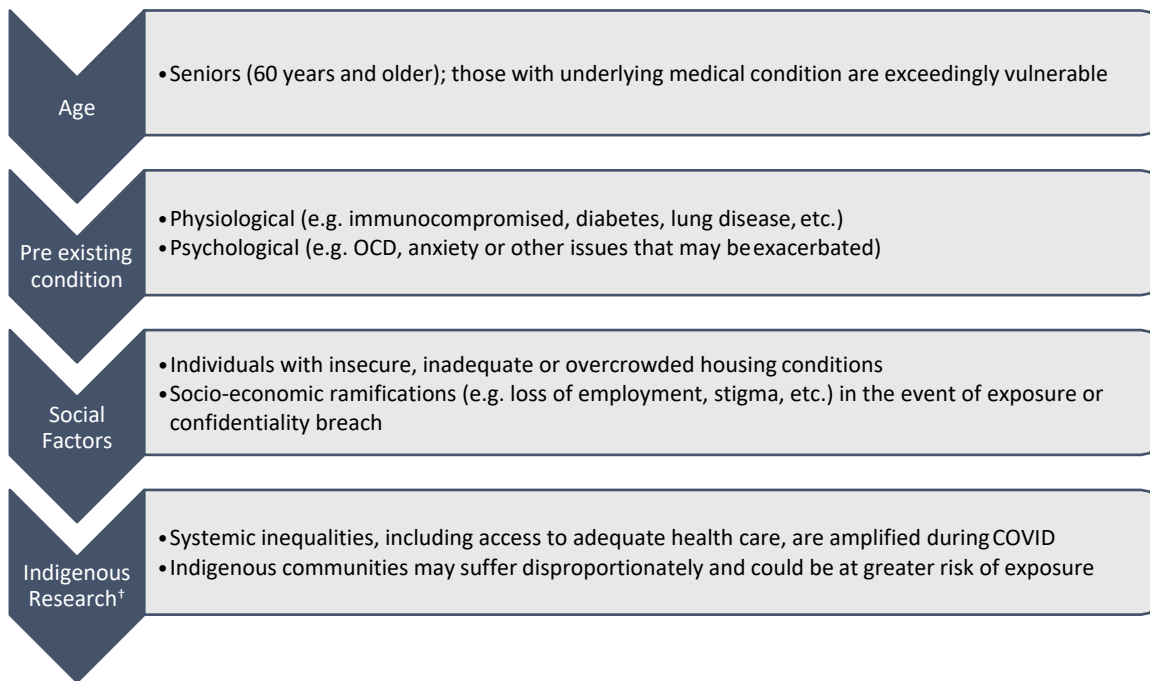
Lab coats are used to protect street clothing from contamination, particularly in instances where exposure to droplets may be likely given the context of the human testing, or exposure time (see guidelines above). Lab coats should not be worn outside of the primary work location, beyond the point of testing or individual workspace. To protect against COVID-19 transmission, the following precautions should be followed:

- Lab coats should be stored on hooks at the main entrance of the lab or workshop
- There should be separate racks/hooks for lab coats. Street clothes, backpacks, and other common items should be stored at desk spaces or in an office
- Lab coats should be laundered often, especially when contamination is suspected or evident
- To launder a lab coat, or to prepare it for transportation, wear gloves, place the lab coat in a plastic bag and seal it with a twist tie or other secure means. Dump the bag into the laundry by holding it from the bottom, as opposed to reaching into the bag.
- Dirty lab coats can be laundered with regular laundry using the highest heat settings possible in the wash and dry cycles
- Use hand hygiene after handling soiled lab coats

Appendix III

Populations More Susceptible to Negative Outcomes as a Result of COVID-19*

Please note individuals who have received the full COVID-19 vaccine for ≥ 2 weeks are not considered high risk/vulnerable in this context.

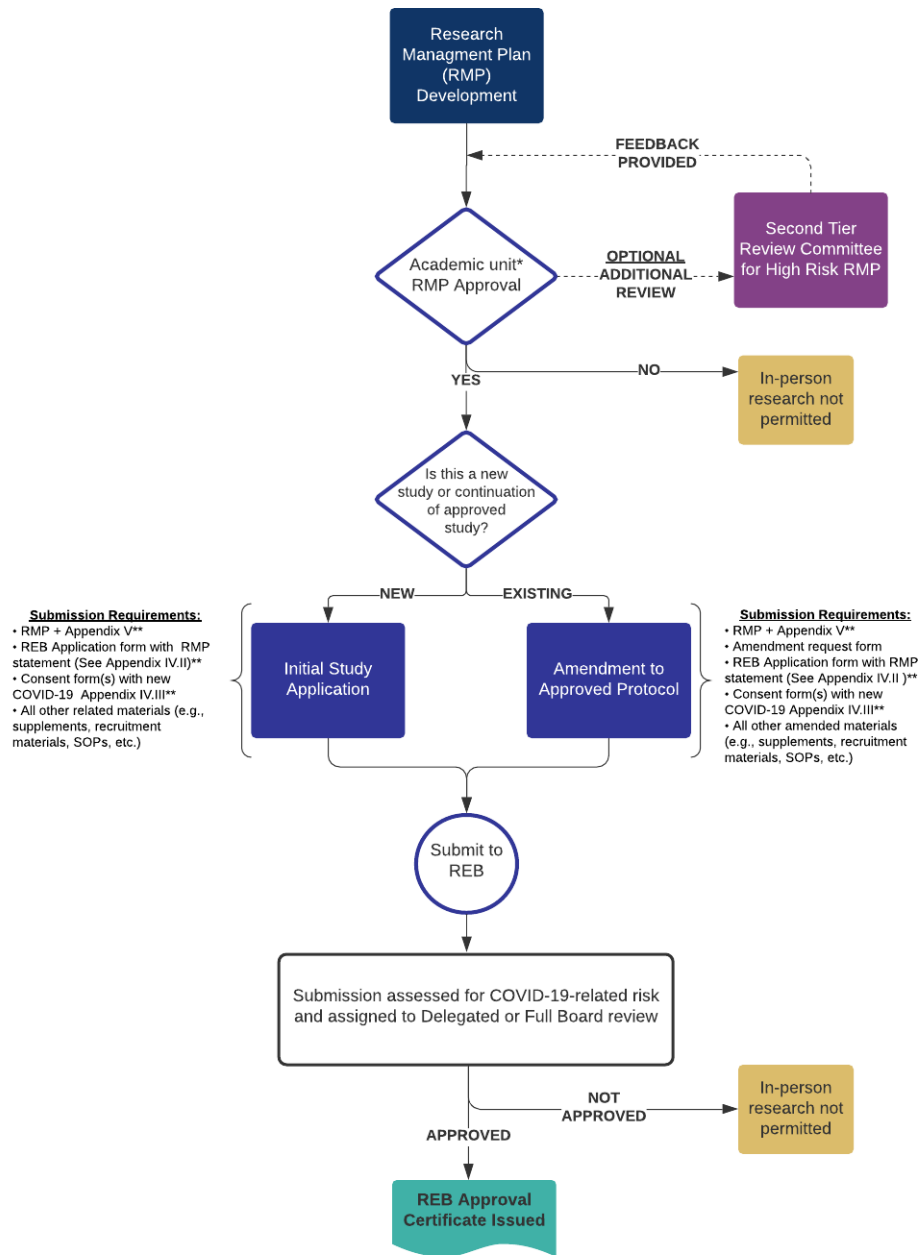


**Formerly referred to as vulnerable populations, individuals with higher risk of negative outcomes should they contract COVID-19. Defined by what is currently known about the COVID-19 virus and its effects; this information is subject to change as new data emerges.*

†Community in question must be consulted to ensure research collaboration can be continued and to learn what health and safety practices must be followed.

Appendix IV – REB and RMP Approval Process

IV.I Flow Chart



*Academic Unit = College and Department

**Please see Guidance document for submission requirements

IV.II REB Requirements

All research activities requiring in-person interaction must be approved by the REB prior to study initiation; this applies to both new and previously approved studies. Once the request to resume research has received approval from the College and Department, REB approval can be sought.

The [usual REB process](#) for submitting new study applications or protocol amendments still applies, with the addition of the following requirements:

1. Please include a copy of your Research Management Plans with Appendix V for face-to-face human research with the REB submission.
2. Modifications captured within Research Management Plans do not also need to be incorporated into the REB application form; however, the REB may ask for additional safety measures if it is not covered within the institutional plan. Kindly include the following statement to Section A.4 of the application:

To ensure appropriate safety precautions when conducting in-person study procedures, the plan for conducting in-person visits outlined in the 'Research Management Plans' document will be followed.

3. Consent form(s) must be amended to include the COVID-19 Informed Consent for In-Person Research Activities (See Appendix IV.III). Please review main study consent documents to ensure consistent information is provided around confidentiality and participant anonymity, as this is impacted with COVID contact tracing. All edits must be captured using the Tracked Changes feature in Word.
4. Please submit to reb@uoguelph.ca with “**Return to In-Person Research**” included in the subject line.

IV.III Consent Form Appendix

Informed Consent for In-Person Research Activities

Guidance to Researchers: *This document serves as a template. This appendix will provide participants with pertinent safety information and instructions related to their in-person research visits and procedures. Please add, remove, or edit as needed using the tracked changes feature. Details of the approved Research Management Plan will be communicated here. PLEASE DELETE ALL TEXT BOXES FROM FINAL DOCUMENT.*

Study Title: [Title]

Principal Investigator: [Name and contact information]

COVID-19 and Face-to-Face Research

This document contains important information about participating in in-person research in light of the COVID-19 public health crisis. COVID-19 refers to the virus being spread in communities across the globe. We are providing you with important information about COVID-19 and we ask that you consider the following information to determine if study participation is right for you at this time.

COVID-19 is a respiratory condition caused by SARS-CoV2, which can be spread by respiratory droplets and aerosols, mainly from person-to-person. This can happen between people who are in close contact with one another (less than 2 metres). It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose or eyes. It is important to remain vigilant in all safety precautions until Public health deems it appropriate to change our behaviour.

This study requires in-person visits and it is important to understand that this may increase your exposure to COVID-19. However, the University of Guelph and researchers have taken certain precautions to reduce the risk for you, the research staff, and their families (among others in the community) safe. The safety plans described below aim to minimize the spread of COVID-19 and are consistent with current Ontario Public Health and University of Guelph Environmental Health and Safety guidelines.

Mandatory Vaccination (On-Campus) [Remove this section for Off-Campus]

The Council of Ontario Medical Officers of Health has indicated that vaccination against COVID-19 is the single most effective public health measure to reduce the spread of COVID-19. The University of Guelph is committed to protecting the community and requires all faculty, staff, students and visitors to be vaccinated against COVID-19 in order to be on campus. Continued safety measures such as wearing masks, handwashing and distancing will further protect everyone who engages in face-to-face research.

Those who cannot be vaccinated for medical reasons or on other grounds protected by the Ontario Human Rights Code are exempt from this requirement. However, individuals who have an exemption must receive a negative COVID-19 rapid test result no earlier than 72 hours before accessing University of Guelph facilities.

Participant Screening

All participants will be screened 24 hours prior to scheduled study visit and must complete the [University of Guelph COVID-19 Daily Screening Form](#) the day of your appointment (prior to the study visit). While completing the Screening Form, please choose “Volunteer with the University” and click “Next;” you will then be asked to attest to your vaccination or exemption status. The research team will confirm that the two screens are complete before proceeding with your visit. You will be asked about information regarding your health in the 14 days prior to the appointment, with special attention to the preceding 48 hours.

Where will the study take place?

[Please specify location of visit]

What will happen the day of the study visit?

1. On the day of testing, you will be asked to arrive at [campus/research location] at your scheduled time.
2. Participants are encouraged to travel to [campus/research location] in their own vehicles rather than public transportation, if possible. You are also encouraged to attend [campus/research location] alone.
3. All research participants are asked to wait outside until called to enter [research location].
4. You are required to wear a mask prior to and following entry into the building or if distance cannot be maintained with other patrons outside. **If you do not have access to a mask, please let the research team know prior to your appointment and one will be given to you on the day of your visit.** Once your mask is on, you are asked to try not to touch your face or eyes with your hands.
5. You will be asked to wash or sanitize your hands upon entry into the building and before exiting.
6. Participants will follow the research personnel to the designated study space and asked to follow their instructions once inside.
7. Participants are advised to use washroom facilities at home prior to coming to [campus/research location]. However, washroom facilities are available on campus. These facilities have approved procedures for use that must be followed.
8. Once the study visit is complete, a member of the research team will lead you to the designated exit. You are asked to go directly to your mode of transportation without entering any other University buildings as you leave.
9. If you are unable or unwilling to follow these guidelines, please notify the researchers ahead of time.

Safety Precautions

In addition to participant screening before your in-person visit, you will find the following additional measures have been put in place to help reduce the risk of spreading or contracting COVID-19:

Guidance to Researchers: Please specify the safety measures you have planned as part of your approved Research Management Plan. Examples are listed below.

- Personal Protective Equipment (PPE) – masks, gloves and/or face shields
- Handwashing and sanitizing
- Physical distancing
- Minimized time of contact



- Open windows or increased ventilation
- Plexiglass barriers
- Hygiene and disinfection protocols and materials
- Signage and markings
- Precautions for common areas
- Biohazard protocol
- Other: **[Please describe]**

Risks & Confidentiality

Guidance to Researchers: Please consider if there are added risks to participants because of COVID safety modifications. For example, in an effort to control the number of researchers in the room, there may not be extra personnel to help in an emergency situation, or participants may not be able to request a male or female researcher to conduct the visit as they previously could, etc.

COVID-19 is a serious health threat, and the situation is evolving daily. The risk will vary between and within communities, but given the increasing number of cases in Canada, the risk to Canadians is considered high.

For most people, COVID-19 may only mild or moderate symptoms, such as fever and cough. For some, especially older adults (aged 60 and older) and people with compromised immune systems or underlying medical conditions who are not vaccinated against COVID-19, it can cause more severe illness, including pneumonia. Even in mild cases it is not known what the long-term health consequences may be.

There is a possibility that during your research activities you could come into contact with someone with COVID-19. If this were to occur, the University of Guelph is required by the Public Health Unit to collect and retain on file your email address or phone number to share with them for contact tracing purposes. **As such, anonymity as a research participant cannot be maintained. Should you choose to withdraw participation from this study, this personal information cannot be withdrawn from University of Guelph or Public Health records.** Please be assured that Public Health will not have access to any other data collected for this research study.

Guidance to Researchers: Please ensure main consent form does not have conflicting information about keeping participant information anonymized.

Vulnerable Populations

Certain individuals or groups are at greater risk of getting an infection and developing severe complications from COVID-19 and these populations must be supported and protected during this time.

COVID-19 Vulnerable individuals/groups may include, but are not limited to:

- Individuals over the age of 60;
- Individuals with pre-existing medical conditions (e.g. immunocompromised, diabetes, lung disease);
- Individuals experiencing socio-economic challenges, such as inadequate or overcrowded

housing;

- Indigenous communities who may suffer disproportionately due to systemic inequalities.

Face-to-face research involving COVID-19 vulnerable populations will require added considerations and measures for safety and, in some instances, participation in the research may not be advisable. Therefore, if you self-identify as COVID-19 vulnerable or are uncertain whether you fall within a vulnerable population, it is imperative that you inform the research team and ask for further guidance.

Please note: If you fall within a vulnerable population described above but are fully vaccinated (i.e., you received a complete vaccine series ≥ 2 weeks ago), you are no longer considered a high-risk population in the COVID-19 context. All COVID-19 safety precautions listed above must be followed, even if you are fully vaccinated.

Who can I contact if I have questions?

If you have any questions, concerns or would like to speak to the study team for any reason, please contact [Principal Investigator] at [phone/email].

If you have questions regarding your rights and welfare as a research participant in this study (REB#....), please contact: Manager, Research Ethics; University of Guelph; reb@uoguelph.ca; (519) 824-4120 (ext. 56606).

Consent

Guidance to Researchers: If participants are unable to return a scanned signature, consent can be submitted via email, by phone/video conference, or other documented means.

I have read this Informed Consent for In-Person Research Activities and any questions about the study and/or COVID-19 have been answered. I freely consent to participate in this research.

Participant Name

Participant Signature

Date



IV.IV Checklist for Researchers – Return to Human Participant Research

This checklist is intended for University of Guelph researchers to assist with the planning and implementation of in-person research during the COVID-19 pandemic. Please refer to the [Research Phase-In Framework](#) and Return to In-Person Human Participant Research guidance for the detailed approval processes and requirements.

CHECKLIST		NOTES
REQUIRED CLEARANCE/APPROVALS (LISTED IN ORDER)		
<input type="checkbox"/>	Research Management Plan (RMP) <ul style="list-style-type: none"> Preparation of RMP Submission to Academic Unit College and Department approval required 	Please see Research Phase-In Framework for RMP requirements. Include Appendix V for face-to-face human research with RMP.
<input type="checkbox"/>	Submit for Research Ethics Board Approval Option A: Amendment to Previously Approved Study	Included in the submission: <ul style="list-style-type: none"> RMP + Appendix V REB Amendment Request form Revised REB application with relevant COVID-19 statements Revised Consent form(s) with relevant COVID-19 statements All other revised study materials
	Option B: New Study Submission	<ul style="list-style-type: none"> RMP + Appendix V New REB application with relevant COVID-19 statements Consent form(s) with relevant COVID-19 statements All other revised study materials
PRE-STUDY VISIT PREPARATION		
<input type="checkbox"/>	Safety Training: COVID-19 Infection Prevention and Control Awareness (Courselink)	Ensure all study personnel have completed training module.
<input type="checkbox"/>	Consent (or re-consent) study participant	Provide participant with approved consent form (COVID appendix included) for their review; Obtain documented consent prior to study visit.
<input type="checkbox"/>	COVID screening (participant) <ul style="list-style-type: none"> Confirm phone number or email address for Public Health Tracing 	Screening 1 of 2 for participant; participant must be screened 24 hours prior to scheduled visit.
<input type="checkbox"/>	PPE, Administrative Controls, Engineering Controls in place	Procure PPE; Ensure physical barriers or policies/practices are prepared, per RMP.
DAY OF STUDY VISIT		
<input type="checkbox"/>	COVID screening (participant AND research personnel)	Screening 2 of 2 for participant; confirm screening has been complete before allowing in-person visit to proceed. Self-assessment screening 1 of 1 for research personnel. Do not proceed with in-person visit if exhibiting symptoms of COVID-19, if there has been close contact with individual with COVID-19 or have been told by health official to self-isolate.
<input type="checkbox"/>	Adhere to approved RMP and REB protocols	Deviations to protocols must be approved by REB prior to implementation (unless there is a need to eliminate or reduce an immediate hazard).

Appendix V – Research Management Plan (RMP) – Face-to-Face Human Research

This form is to be completed by each PI to document their lab's health and safety plans to support the safe continuation of research activities specifically related to the **return of human participant research**. Research plans must work to minimize the number of people necessary to undertake the research safely. Where the research necessitates interaction with human participants, additional procedures must be employed and are to be outlined below. **This is an example plan and can be modified to capture research specific to different Academic Units.**

It is appreciated that many labs may have a range of research that could fall under different categories of mitigation needs. Please include coverage of the main procedures that take place in the lab that involve face-to-face human research, where there may be increased risk of COVID-19 exposure. Specifically, consider proximity to participants, and duration of proximity, in addition to the nature of the research and the risks this may impose.

1. Are you currently completing your human participant research remotely or transitioning research remotely and still require access to campus to fulfill these requirements? If so, explain any changes that have been made to protocols. See Level 1 of return to face-to-face human research document for guidelines.

Briefly explain aspects of research with COVID-19 concerns. Identify protocol or procedure changes for each concern.

	Action	Comments/Description
<input type="checkbox"/>	Changes have been made to protocols to maintain remote research or transition research remotely	
<input type="checkbox"/>	Changes have been made to REB documents and COVID specific language has been added	
<input type="checkbox"/>	Research at this level is Not Applicable – see further details below	

2. If research requires face-to-face interaction, but physical distancing can be maintained, what engineering and administrative controls have been implemented to maintain two metres distance? If research also requires use of PPE for aspects of research that will involve periods of time within two metres, **administrative and engineering controls can still be listed here**. See Level 2 of return to face-to-face human research document for guidelines.

Briefly explain aspects of research with COVID-19 concerns. Identify administrative and engineering controls being proposed to mitigate risk for each concern.

	Action	Comments/Description
<input type="checkbox"/>	Equipment has been relocated where possible to support minimum physical distancing with participant	
<input type="checkbox"/>	Engineering controls have been implemented using change in location where possible, for example from outside to inside	
<input type="checkbox"/>	If more than one researcher is required to perform an activity, research members are paired up to minimize the number of discrete contacts with different individuals, thus limiting potential exposure to a potential positive case of COVID-19.	
<input type="checkbox"/>	Consent forms (and other documents) are administered online.	
<input type="checkbox"/>	Changes have been made to REB documents, and COVID specific language has been added.	

3. If it is not possible to maintain two metres distance from human participants, list engineering and administrative controls (listed above or here) in addition to specific PPE required to mitigate risk during close proximity (<two metres). Include consideration of duration and nature of testing. See Level 3 of return to face-to-face human research document for guidelines.

Briefly explain aspects of research with COVID-19 concerns. Identify administrative and engineering controls (describe here or above) as well as PPE being proposed to mitigate risk for each concern.

	Action	Detailed description
<input type="checkbox"/>	PPE has been sourced and will be available to researchers and participants, if required.	
<input type="checkbox"/>	All personnel working with participants have reviewed this form and it will be posted somewhere in the lab	
<input type="checkbox"/>	Changes have been made to REB documents, and COVID specific language has been added.	
<input type="checkbox"/>	Other (explain)	

4. Please outline your plan in the case of incidental close contact (less than two metres) with a participant, in the event of an Emergency.

5. Does the nature of the research impose additional risk (aerosol producing procedures, prolonged close contact)? Please explain below and document what mitigation strategies are being implemented to reduce risk specific to those concerns.

6. Does your target research population include high-risk/vulnerable populations in COVID-19 context, per Appendix III? If YES, please describe additional protection measures that will be utilized. Consideration of exceptional cases to work with higher risk populations can be requested, provided there are effective protection measures to reduce risk to these individuals (e.g., COVID-19 vaccination).

		Comments
<input type="checkbox"/>	YES	
<input type="checkbox"/>	NO	

7. Would you like your RMP to be reviewed at an additional tier to provide guidance for appropriate mitigation strategies for procedures with additional risk? If you choose NO, it does not mean your RMP won't be reviewed at the second tier if questions remain that require additional expertise prior to clearance.

		Comments
<input type="checkbox"/>	YES	
<input type="checkbox"/>	NO	

Explanatory Notes:

This document was specifically developed to support return to face-to-face human research activities during the COVID-19 pandemic.

Committee:

Return to Face to Face Human Research working group with guidance from the Research Continuity Board

Related Policies/Procedures:

[Public Health Ontario](#)
[UoG Covid Research Phase-In Framework](#)
[Off-Campus Human Subject Face-to-Face Research Framework](#)
[Guidelines for University of Guelph Human Participant Face-to-Face Research](#)

Related Legislation:

[A Framework for Re-opening Our Province](#)