

UNIVERSITY *of* GUELPH

Winter 2022 Guidelines for University of Guelph Human Participant Face-to-Face Research

February 16, 2022



OFFICE *of* RESEARCH

Introduction

The University of Guelph is committed to providing a safe environment for researchers and volunteers. The University of Guelph recognizes that the situation around COVID-19 is continually evolving. The University continues to follow emerging scientific evidence and public health directives to make safe decisions for our faculty, students, staff and the broader community. In moving forward, face-to-face human participant research will continue to comply with public health measures, as well as the Institution's requirements for being on campus. Protocols for face-to-face human research activities will align with the broader [University of Guelph requirements](#).

The University recognizes that face-to-face human participant research is a vital part of our research enterprise and has created guidelines that provide equitable access and opportunity for faculty to conduct research and for graduate students to make progress towards degree completion. Visitors to University of Guelph facilities for the purpose of participating in F2F research are defined as "volunteers" as specified in the [MCU August 31, 2021 'Postsecondary Education Health Measures Framework for Fall 2021'](#). The following guidelines address on- and off- campus and out of province research. This document supersedes older guidelines that were previously available. They are to be used in conjunction with the University of Guelph's Frameworks for Human Participant Face-to-Face Research at University of Guelph ([On Campus](#), [Off Campus](#)) and approved pre-existing Research Management Plans (RMPs). Guidelines for modification to RMPs are listed below.

Research involving populations at higher risk of negative outcomes (described as 'vulnerable populations' by the [Public Health Agency of Canada](#)) may proceed within baseline measures if these individuals are fully vaccinated. Consideration to work with unvaccinated higher risk populations is addressed within 'Special Circumstances' section, below.

Guidelines

Information:

- All research activities will comply with Public Health and University of Guelph guidelines.
- Currently, baseline measures are full vaccination status and appropriate masking according to institutional guidelines.
- Assessment of risk on campus assumes that these two measures are sufficient to curb the spread of the virus. As such, the face-to-face human research enterprise will adopt these baseline measures. Full vaccination ([or an exemption with a negative test within the last 72 hours](#)) will be mandatory for study participants who are volunteers. Children under the age of 12 are exempt from this requirement currently.
- Human face-to-face Research data collection can proceed under the guidelines approved in individual RMPs. *See RMP amendment guidelines below for new baseline COVID-19 protective and control measures.
- Participation in a research activity should follow University of Guelph guidelines for capacity, up to a maximum as per Public Health guidelines for indoor spaces.
- On-campus research can include participants from on or off-campus who follow the measures described above.
- Off-campus research requiring community participants may proceed with RMP approval by College/Department.

How to proceed; On-Campus Information for Principal Investigators (PIs):

- 1) PIs should assess their laboratory mitigation procedures and RMP.
- 2) **If protocols are working well, PIs are welcome to proceed using their existing approved RMP and protocols, including the maintenance of current PPE measures.** If risk mitigation procedures were highlighted to participants in the COVID-19 Consent document and removal could affect a participant's feeling of safety and willingness to remain involved with the research PIs should strongly consider keeping existing precautions in place. Please note amendments to safety procedures must be submitted to the REB for review (process detailed below).
- 3) Existing approved RMPs that describe lab mitigation procedures separately from REB methods can be amended to allow for changes in risk mitigation protocols currently in place. Consistent with requirements for all visitors to campus, all research participants must follow the most up to date guidelines regarding vaccination status, masks, and screening while maintaining physical distance as much as possible. The new changes to the RMP can include removal of PPE that is no longer deemed necessary when working with vaccinated populations (e.g., goggles, face shields, N95 masks, plexiglass).
- 4) If changes are required to an existing approved RMP, PIs should complete the RMP amendment form and outline the intended changes.
- 5) Existing approved RMPs will remain in place. In the event the University needs to revert to greater restrictions, researchers can anticipate returning to measures under the Red (Control) level (see below).
- 6) If working with populations more susceptible to negative outcomes as a result of COVID-19, or if study activities present greater than average risk, PIs should maintain PPE and

other risk mitigation procedures. Refer to additional steps outlined below (i.e., Special Circumstances) that can be put in place.

When participants come to campus

- All individuals participating in research on campus must comply with existing university regulations..
- At present, all individuals coming to campus must complete the [University of Guelph COVID-19 Daily Screening Form](#).
- Study participants must also complete the [COVID-19 consent form](#).
- All participants must wear a mask that complies with current university requirements.
- Additional steps, such as additional personal protective equipment (e.g., face shields), and engineering controls (e.g., plexi-glass shields) can be used at the discretion of the PI and where research protocols present greater than average risk (e.g., when close proximity for a prolonged period of time is required, when droplets or aerosols may be generated, when masks must be removed for a short period of time). These will be captured in the revised RMP.
- University of Guelph supported rapid testing may be available in some situations.

Human Participant Face-to-Face Research, Off-Campus, including outside of Ontario and international research:

- Human participant face-to-face research being conducted off campus, including outside of Ontario and internationally, must have an approved RMP, including clear adherence to relevant public health rules in the jurisdiction of research, REB approval, and be consistent with other existing University policies, (e.g., regarding travel).
- Vaccination of University of Guelph researchers and participants is not mandated in the off-campus setting but may be required if working with unvaccinated individuals who are more susceptible to negative outcomes as a result of COVID-19. More on this below within 'Special Circumstances'.
- As with On-Campus research, PIs may proceed with existing RMP if current protocols are working well. If changes are required to an existing approved RMP, PIs should complete the RMP amendment form and outline the intended changes.
- Please refer to the [Framework for Phasing-In Human Participant Face-to-Face Research at University of Guelph \(Off Campus\)](#) for further instruction.

Special Circumstances

There may be scenarios where extenuating circumstances warrant consideration of research with unvaccinated vulnerable/high-risk individuals (see Appendix III of Frameworks for Phasing-In Human Participant Face-to-Face Research). The University will consider these exemption requests and COVID-19 risk mitigation strategies on a case-by-case basis. This request should detail risk mitigation strategies (e.g., additional PPE, engineering controls, rapid testing, etc.)

within RMP amendment form and submit to College/Department for review. As always, the second-tier review committee is available for consultation on exemption requests.

REB and RMP Amendment Approval Process

Researchers are invited to reflect upon their approved RMP and consider if any safety measures can be removed. If a researcher would like to proceed under their approved Research Management Plan without change, no further action is required. To amend an approved RMP, please follow the steps below:

Step 1: Research Management Plan (RMP) Amendment:

- A. Complete [RMP Amendment Request Form](#) with proposed changes to safety procedures.
- B. Submit RMP Amendment Request to College/Department for review.
- C. Once approved, prepare REB amendment request, as described in Step 2.

Step 2: Amendment Request to Research Ethics Board (REB):

- A. Download COVID-19 Consent template posted on the REB Forms page and ensure “Safety Precautions” section aligns with amended RMP.
- B. Complete REB Amendment Form*.
- C. Submit REB Amendment Form with RMP Amendment Request Form and COVID-19 Consent to the REB for review. Please ensure email to reb@uoguelph.ca has “RMP Amendment” in the subject line to expedite the review.
- D. REB will issue an amendment approval certificate once review is complete.

*The REB will accept one RMP Amendment Request Form for multiple protocols that utilize the same RMP document. Protocols must all be under the same PI and the changes cannot go beyond the RMP amendment. The REB will issue individual amendment approval letters for each study.

Next steps

The COVID-19 pandemic is a dynamic situation, but it is likely the above-described baseline COVID-19 risk mitigation strategies will remain in place for the foreseeable future. It is possible, however, that some components of the screening may be removed by the university for all visitors, in which case these changes will be adopted to reflect the research enterprise as well. The University continues to monitor emerging scientific developments and will follow public health directives. Should circumstances warrant scaling back face-to-face activities, researchers should expect to adopt control measures consistent with the previous “Red (Control)” level, as described below in conjunction with original approved RMPs. The University recognizes the major impact that COVID-19 has had on human research and will only scale back human research in exceptional circumstances. In these circumstances human research restrictions will follow those imposed on other animal/wet lab facilities with respect to lab access.

Red (Control):

- All research activities will comply with Public Health guidelines
- Human face-to-face research data collection can proceed under the guidelines approved in individual RMPs. This includes strict adherence to approved RMPs, and appropriate PPE and mitigation procedures, including enhanced protections for protocols involving exercise.
- Participation in a lab activity should include the minimum number of people to perform data collection, following University of Guelph guidelines for capacity, up to a maximum as per Public Health guidelines for indoors spaces.
- On-campus research can include participants who are already part of the on-campus community such as staff, students and faculty as well as members of the community who are vaccinated. For on-campus recruitment, efforts will be made to recruit participants from the campus community, outside of the immediate study team, where at all possible.
- Off-campus research requiring community participants may proceed with RMP approval by College/Department.
- As with high-risk RMP applications, the second-tier review committee is available for consultation on exception requests.