Application Steps for In-Person Research

Amendments and New Applications

For latest updates: https://uwaterloo.ca/coronavirus/research-information

Documents and modifications needed:
Below are listed the documents and application additions expected for all amended and new applications that are recruiting participants for in-person research.

Any changes made to procedures that impact participant involvement are required to meet safety guidelines should be documented in the ethics application. This means updating relevant sections and documents.

The required documents below should be added as new, separate materials. They are not meant to replace existing materials but rather to supplement them. The sections of the application where they should be attached are indicated below.

FOR AMENDMENTS:

Changes to the application: Changes made in the application in an amendment can be tracked by the reviewer. Do not remove previously approved procedures. Rather, add new text at the bottom of text sections to describe new procedures. You can use RESEARCH RESTART as a header to distinguish the different procedures. Flow charts and other documents can be added to appropriate sections (such as Methods) to provide details for reviewers.

Changes to the materials: Please add RESEARCH RESTART or COVID-19 to the start of the file name. All edits to materials should be highlighted and/or show track changes. *Materials that won't be used for this phase of return to research do not need to be removed.* Adding new documents can be tracked by the reviewer.

APPLICATION SECTION	MANDATORY ATTACHMENTS AND CHANGES
Justification (at beginning of Amendment application)	1. Use the title RESEARCH RESTART at the top of the Justification 2. Describe current status of the Request to Resume On-Campus Research Involving Human Participants. Confirm that the request to

	resume research and safety plan have been submitted to researchqueries@uwaterloo.ca. 3. Explain why your study cannot be completed virtually/online, by phone, or by other means of remote research. Explain steps take to minimize on-campus tasks. 4. Describe changes made to application with details on which sections of the application are affected and whether materials have been edited. 5. Indicate any risks to participants based on higher vulnerability to COVID-19 and how your procedures will address these concerns. If there are changes to the recruitment or screening of participants then these should be included in the Participant and Recruitment sections of the protocol.
Recruitment	✓ ATTACHMENT: Contact for re-consent script (Phone and/or Email) ✓ ATTACHMENT: Log for Recording Verbal Consent to be used with contact for re-consent script ✓ ATTACHMENT: Study visit reminder (Phone and/or Email)
Methods	✓ Outline of modifications for in-person research ✓ Steps taken to minimize in-person activities, such as having some tasks completed remotely ✓ ATTACHMENT: Supporting documents (e.g., revised protocol) ✓ ATTACHMENT: Table with a line for each procedure during each visit outlining modifications, physical distance, safety measures
Privacy	✓ Details for storing and destroying information for contact tracing (retain contact tracing documents for 30 days and then destroy securely). Ensure contact tracing information is stored separate from study data.
Consent	✓ ATTACHMENT: COVID-19 ICL and Contact Tracing Form ✓ ATTACHMENT: updated ICL for new procedures
Other Attachments	✓ ATTACHMENT: Self-Assessment Plan for researchers and participants ✓ ATTACHMENT: Self-Assessment Questions ✓ ATTACHMENT: Request to Resume On-campus Research Involving Human Participants. Note: this is not required if the Request was submitted using the online Resume Research System. If submitted online, explain this in the “Other Details” section of the application. ✓ ATTACHMENT: Safety Plan Template submitted with Request. Indicate whether approved or under review.

To minimize multiple rounds of revisions please be thorough and accurate in the amendment/application. For some studies it may be adequate to add the attachments and make minimal changes to the application. Some amendments may require much more detailed edits and therefore careful review by the research team before submission is important.

All edits should be carefully reviewed by the PI before approving the submission.

It is expected the PI will ensure that the ethics amendment/application is consistent with the safety plan and request form submitted to Research Queries.