Application Steps for In-Person Research during the COVID-19 Pandemic

Amendments and New Applications

An amendment or new application is **only** to be submitted **after** the Request to Resume on-campus research involving human participants has been approved by the Research Queries team.

In the table below is a list of the documents and application form changes that are expected for all amended and new applications that are recruiting participants for in-person research during the COVID-19 pandemic.

Any changes made to the study procedures that will impact participant involvement to meet COVID-19 safety guidelines are to be described in the ethics application. This means updating relevant sections and documents in the application form.

The documents outlined below need to be added as new, separate materials. They are not meant to replace existing materials but rather to supplement them. The sections of the application form where they should be uploaded are stated below.

If participant vaccination status is being collected as part of the study data, this must be described and justified within the application form. However, if participant vaccination status is only being documented as part of the University of Waterloo COVID-19 vaccination policy for visitors, this does not need to be described within the ethics application. The guidance provided in the document “Participant vaccination confirmation guidance” should be used to explain this requirement and does not need to be uploaded to the ethics application form.

To minimize multiple rounds of revisions please be thorough and accurate when describing the procedural changes being made. For some studies, there may be only the need to upload a few new documents and make minimal changes to the application form. However, other studies may require numerous edits to the application form and new documents.

A careful review by the research team before submission is very important and all edits to the application form should be carefully reviewed by the PI before approving the submission. It is expected the PI will ensure the application is consistent with the safety plan and request form submitted to Research Queries.

**Changes made to the application form:** These will be automatically tracked by the research ethics system for the reviewer. Do not remove/delete previously approved procedures. Rather, add the new information to the bottom of the text box for the section to describe the new procedures. You can use RESEARCH RESTART as a header to identify these new or changed procedures. Flow charts and other documents can be uploaded to the appropriate sections (such as Methods) to provide additional details on the changes being made.
**Changes to the study materials:** Please add RESEARCH RESTART or COVID-19 to the file name. All edits to study 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 from the application form.* The addition of any new documents will be automatically tracked by the research ethics system for the reviewer.

In the table below is a list of the documents and application form changes that are expected for all amended and new applications that are recruiting participants for in-person research during the COVID-19 pandemic.

<table>
<thead>
<tr>
<th>APPLICATION SECTION</th>
<th>MANDATORY ATTACHMENTS AND CHANGES</th>
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| Justification (beginning of Amendment application) | 1. Use the title RESEARCH RESTART at the beginning of the Justification section  
2. Describe status of the Request to Resume On-Campus Research Involving Human Participants by outlining the request to resume research and a safety plan has been submitted to researchqueries@uwaterloo.ca.  
3. Explain why the study cannot be completed virtually/online, by phone, or by other means of remote research. Explain steps taken to minimize on-campus study activities.  
4. Describe the changes being made with details as to which sections of the application are affected and whether study materials have been edited.  
5. Indicate any risks to participants based on a vulnerability to COVID-19 and how your procedures will address these concerns.  
6. If there are changes to the study recruitment and/or or screening protocol, then these are to be uploaded in the Recruitment section of the application form. |
| Methods                                  | 1. Outline the modifications being made to conduct in-person research  
2. Outline the steps being taken to minimize in-person activities, such as having some tasks completed remotely.  ✓ ATTACHMENT: Supporting documents (e.g., revised study protocol) |
| Consent                                  | ✓ ATTACHMENT: updated study specific ICL if new procedures/activities are being added  
✓ ATTACHMENT: verbal consent script and log if participants are being re-consented or if the study design now contains elements done prior to the in-person visit (e.g., screening, virtual interviews, or questionnaires) |
| Other Attachments                        | ✓ ATTACHMENT: Approved study specific safety plan. |

**Materials not required in ethics applications:**
- Telephone and/or email script being use for vaccination confirmation and Campus Check-in COVID-19 screening
• COVID-19 on-campus information consent letter (or off-campus letter)
• Table for describing distance from participants