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

Amendments and New Applications

Any changes made to the study procedures of an existing ethics application that will impact participant involvement to meet COVID-19 safety guidelines are to be described through an amendment. In-person time and activity with study participants should continue to be limited, and protocols may require changes to improve screening, or make elements such as questionnaires or interview virtual. This means updating relevant sections and documents in the application form as described in the table below. If there are no changes required to an existing ethics application, an amendment does not need to be submitted.

New applications should also be designed to limit in-person time and activity and contain documents and details as described in the table below.

COVID-19 information consent letters and templates of telephone email scripts for vaccination confirmation are available on the research ethics system login webpage. These materials do not need to be submitted as part of the ethics application.

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 facilitate the review of your new application or amendment:

- Be thorough and accurate when describing the procedures/procedural changes being made.
  - Some studies may require a few new documents and minimal changes to the application form. However, other studies may require numerous edits to the application form and new documents.
- Review Table 1 below.
  - This table outlines the documents and application form changes that are expected for all amendments and new applications that are recruiting participants for in-person research during the COVID-19 pandemic.
- Documents are to be uploaded to the research ethics as new, separate materials as outlined in Table 1.
- Carefully review the application as well as any changes or edits being made before submitting the new application or amendment.
- PIs must ensure the research ethics application is consistent with the safety plan.
- Changes made to the research ethics application are automatically tracked by the system for the reviewer so do not remove/delete previously approved procedures.
- Add new information to the bottom of the text box for the section to describe the new procedures.
- Use RESEARCH RESTART or COVID-19 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.

- Add RESEARCH RESTART or COVID-19 to the file name for any study materials that are changing.
  - All edits to study materials should be highlighted and/or show track changes.
  - The addition of any new documents will be automatically tracked by the research ethics system for the reviewer.

- Materials that won’t be used for this phase of return to research do not need to be removed from the application.

Table 1. Documents and changes for new applications and amendments.

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<thead>
<tr>
<th>APPLICATION SECTION</th>
<th>MANDATORY ATTACHMENTS AND CHANGES</th>
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| Justification (amendments only) | 1. Use the title RESEARCH RESTART at the beginning of the section.  
2. 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.  
3. Describe the changes being made with details as to which sections of the application are affected and whether study materials have been edited.  
4. Indicate any risks to participants based on a vulnerability to COVID-19 and how your procedures will address these concerns.  
5. 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 (new applications and amendments) | 1. Outline the steps being taken to minimize in-person activities, such as having some tasks completed remotely.  
2. Provide a rationale for all in-person activities.  
✓ ATTACHMENT: Supporting documents (e.g., study protocol) |
| Consent & Withdrawal (new applications and amendments) | ✓ ATTACHMENT: If amendment, provide the updated study specific ICL to outline the new procedures/activities that are being added.  
✓ ATTACHMENT: verbal consent script and log if participants are being re-consented or if the study design contains elements that will be done prior to the in-person visit (e.g., screening, virtual interviews, or questionnaires) |
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
- Safety plan for human participant research