How to Submit an IRB Modification for Studies Affected by COVID-19 that Cannot be Moved Online

Teachers College, Columbia University
Changes to Protocols Due to COVID-19

Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio.

Given the current COVID-19 coronavirus outbreak and the real or perceived risk of exposure, the risk/benefit ratio for research participation must be reassessed for each IRB protocol.

While pausing studies to minimize the risks of transmission of COVID-19 will often outweigh the harms to research programs, TC IRB will also consider possible harms to subjects should a study be paused or ceased.
Changes to Protocols Due to COVID-19

For protocols affected by COVID-19, researchers have several options available to them including:

1. **Self-Determined Pause**: Researchers can choose to pause study activities at their discretion. Pausing researcher work, does not require an IRB protocol submission.

2. **Study Activities Cannot Be Moved Online**: In the event that online substitutes for face-to-face study activities are not practical or possible (e.g., administering of a drug trial), PIs can submit a modification with justification for continuing study activities in person (details included on the next slide).

3. **Study Activities Can be Moved Online**: In the event that all face-to-face study activities can be moved to online methods (e.g., conducting participant interviews via Skype or Zoom), PIs must submit a modification.

4. **Some Methods Can Be Moved Online While Others Cannot**: In some cases, some study activities in a protocol may be transferred online, while other activities in the same protocol are not substitutable. PIs must submit a modification designating a plan of action for all activities.

5. **TC IRB Determination**: Protocols are regularly reviewed by TC IRB on a case-by-case basis. For those PIs who do not self-select to change their study activities to accommodate evolving COVID-19 conditions, TC IRB reserves the right to assess study activities for the protection participants. In these circumstances, TC IRB will contact the PI’s directly about next steps.

“COVID-19-specific” modification guides are available at: https://www.tc.columbia.edu/institutional-review-board/updates/
Due to the spread of COVID-19, some research sites may have been shut down. In some cases, researchers may be able to move all face-to-face contact with research subjects online (e.g. Zoom or Skype interview). In other cases, the study procedures will be such that online substitutes are not practical or even possible (for example, participants receiving cancer treatments as a drug trial). If you are making these study changes due to COVID-19, submit a “COVID-19-specific” modification.

Researchers who are unable to move face-to-face contacts to online platforms must submit a “COVID-19-specific” modification. Once the modification has been submitted, researchers must wait for an acknowledgement letter before they can continue with study activities in-person.

For all typical “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities. The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”)
https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/
Navigating to Your Protocol

Please navigate to https://my.tc.columbia.edu/ and click the Faculty, Student, or Employee Resources tab.
Navigate to the **Mentor IRB** button on the right hand side of the screen. Mentor IRB should open in a new page.
Navigating to Your Protocol

Navigate to My Protocols found on the left hand sidebar of TC Mentor IRB.

Choose the study you would like to review.
Submitting a COVID-19 Modification

To view modifications, scroll down to the bottom of your protocol and you will see a **Modification** tab. Once in the tab, you can **Create a New Modification**.

When submitting a protocol, please be sure to follow the submission directions.
For studies that cannot be moved online, please choose the first checkbox, **My Study Methods Cannot be Moved Online for Covid-19**. Then click **Create Modification**.
Submitting a COVID-19 Modification

- You will be taken back to the Modifications tab.
- Scroll down until you see the latest modification titled, “My Study Methods Cannot be Moved Online for Covid-19.”
- PIs must fill out the Study Cannot be Moved Online or Paused Questions. Click on the link to be taken to the survey.
Submitting a COVID-19 Modification

20-052. Ideas Study

Study Cannot be Moved Online or Paused

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<thead>
<tr>
<th>1. Reasons</th>
<th>Type: Multiple Select</th>
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<tbody>
<tr>
<td>* Please indicate the general categories that apply:</td>
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<tr>
<td>Options: Research subjects at risk if study is paused.</td>
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<tr>
<td>Research methods cannot be conducted online.</td>
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<tr>
<td>Other</td>
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The link will take you to a short questionnaire. Please click on the Answer box to indicate which options apply to your study.
Mark the appropriate option(s). Make sure to explain your selection(s) in the answer box. Researchers who mark the first option must explain how pausing the study will harm participants.

Once you are satisfied with your answer, click **Save Answer**. You will be directed to **Return to Protocol Page**, where you can then upload a modification memo.
Submitting a COVID-19 Modification

Researchers who choose the second option OR a combination of both the first and second option will need to complete a second short answer.

Once you are satisfied with you answers, click **Save Answer**. You will be directed to **Return to Protocol Page**, where you can then upload a modification memo.
You will be taken back to the Modifications tab.

Scroll down until you see the latest modification titled, “My Study Methods Cannot be Moved Online for Covid-19.”

All modifications must be submitted with a Modification Memo. Click the red notebook icon to Upload a Memo.

The Modification Memo Template can be downloaded from Mentor IRB/Documentation/18_Modification Memo Template.
Submitting a COVID-19 Modification

Continuing Face-to-Face Study Activities in Light of the COVID-19: Once you have uploaded a “COVID-19-Specific” Modification, TC IRB will review your study on a case-by-case basis. Researchers must receive an acknowledgement letter before continuing with study activities.

If you receive a Request for Revisions from an IRB reviewer, submit the revisions (along with the Request for Revisions Memo Template) to the current Modification record, using the Upload option on the appropriate file types listed on the Modification. You will find the Upload option on the Context Menu to the immediate left of each file type title. Please check the “Submit Revisions for Review” check box on the Modification record to submit your revisions. Email IRB@tc.edu when the response to revisions is submitted as the reviewer will not be notified when your response has been uploaded.
For Typical Modifications (not related to Covid-19)

For all typical “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities. The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”)

https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/
Responsibilities of the Primary Investigator

As the PI of record for an Teachers College, IRB protocol, you are required to:

- Use current, up-to-date IRB approved documents
- Ensure all study staff and their CITI certifications are on record with the IRB
- Notify the IRB of any changes or modifications to your study procedures
- Alert the IRB of any adverse events

You are also required to respond if the IRB communicates with you directly about any aspect of your protocol.

Failure to adhere to your responsibilities as a study PI can result in action by the IRB up to and including suspension of your approval and cessation of your research.
If you have questions or concerns about the rights of a research subject, you should contact the Institutional Review Board (IRB) (the human research ethics committee) at 212-678-4105 or email IRB@tc.edu or you can write to the IRB at Teachers College, Columbia University, 525 W. 120th Street, New York, NY 10027, Box 151. The IRB is the committee that oversees human research protection for Teachers College, Columbia University.