How to Submit an IRB Modification for Studies that Cannot be Paused and Only Some Activities Can 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.
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 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 (details included on the next slide).

3. **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.

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 of 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 only be able to move part of their face-to-face contact with research subjects online (e.g. Zoom or Skype interview) while the rest of the activities must be continued in person (e.g., 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 all face-to-face contacts to online platforms must submit a “COVID-19-specific” modification with a plan of action detailing which activities will be moved online, and which ones will stay in person. Once the modification has been submitted, researchers must wait for an acknowledgement letter before they can continue with the in-person study activities.

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.
Submitting a COVID–19 Modification

For studies activities that cannot be moved fully online, please choose the first checkbox, My Study Methods Cannot be Moved Online for Covid-19 AND the second checkbox, My Study Methods Cannot be Moved Online for Covid-19. Then click Create Modification.

These two selections signal reviewers that some (not all) of your studies will be online. Reviewers will focus on risk assessment for the in-person activities.
Submitting a COVID-19 Modification

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

The Moving Study Online Questions link will take you to a short questionnaire. Please click on the Add/Edit Answers box and answer each question.

20-052. Ideas Study
Moving Study Online

- **1. Activities Moved**
  - Type: Short answer
  - *Please detail what study procedures will be moved online (e.g. face to face interview will be moved to Zoom/Skype, etc.).

- **2. Sites Closed**
  - Type: Short answer
  - *Please list any of your study sites that have been closed due to Covid-19 response (write n/a if none have been closed):
Submitting a COVID-19 Modification

Once you are satisfied with your answers, click **Save Answer**.

You will be taken to the screen below. Click **Return to Protocol Page**.
Submitting a COVID-19 Modification

- You will be taken back to the **Modifications** tab.
- Scroll down until you see the latest modification titled, “Moving to Online Methods in Response to Covid-19.”
- Complete the second survey, **Study Cannot be Moved Online or Paused Questions**
Submitting a COVID-19 Modification

20-052. Ideas Study
Study Cannot be Moved Online or Paused

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 explaining benefits to participants.

Once you are satisfied with your answers, 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

❖ You will be taken back to the Modifications tab.
❖ Scroll down until you see the latest modification titled, “Moving to Online Methods in Response to Covid-19.”
❖ All modifications must be submitted with a Modification Memo. Click the red notebook icon to Upload a Memo.
❖ Your memo must detail which study activities are being moved online, and which ones will be continued in person.
❖ The Modification Memo Template can be downloaded from Mentor IRB/Documentation/ 18_Modification Memo Template
Submitting a COVID-19 Modification

Changing Some (not all) Study Activities in Light of the COVID-19 for: 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” checkbox 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.