

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

Teachers College, Columbia University

A dark blue diagonal graphic that starts from the bottom left corner and extends towards the top right corner, covering the bottom half of the slide.

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/>

Continuing Face-to-Face Study Activities in Light of the COVID-19

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

myTC TEACHERS COLLEGE
COLUMBIA UNIVERSITY

Support Gmail Calendar Drive Canvas Library

Welcome **Resources**

Human Subjects Research Protocol

Mentor IRB [↗](#)

Office of Sponsored Programs (OSP) [↗](#)

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.

myTC TEACHERS COLLEGE
COLUMBIA UNIVERSITY

Support Gmail Calendar Drive Canvas Library

Welcome Student Resources Employee Resources Support Resources

My Account

My Account Summary

Account Balance \$0.00

View eBill Make a Payment

Enroll/Manage eRefund

Personal Information

TC Alert Signup Manage My UNI Account

My TC ID Number Update E-mail Addresses

Update Emergency Contacts Update Addresses and Phones

TC Gmail Terms of Agreement

Human Subjects Research Protocol

Mentor IRB

Office of Sponsored Programs (OSP)

Degree Audit

Track your progress towards your degree!
Degree Audit

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.

The screenshot shows the TC Mentor IRB interface. On the left sidebar, the 'My Protocols' option is highlighted with a red box. A red arrow points from this box to the 'My Protocols' section of the main content area. Another red arrow points from a text box on the left to the 'My Protocols' sidebar item. The main content area displays 'My Protocols' with a 'Create New Protocol' button, a 'Next Meeting' date of 07/17/2019, and a 'Deadline for Submission' of 07/07/2019. Below this are filters for 'Submitted' (set to 'All') and 'Primary' (unchecked). A dropdown menu shows 'I am the P.I., an R.C. or an R.A.' and another shows '- Show all P.I.'s -'. The main area contains a table of protocols with columns for IRB #, Title, PI, Approved, and A.R. Due.

IRB #	Title	PI	Approved	A.R. Due
	Pilot Study on the Effects of Group...		04/28/11	
	Evaluating		6/14	
	Evaluating			
	Evaluating		3/15	06/24/19
	Struggle		5/14	
	Promoting Science		9/14	
	Math Learning and How to Do Math Pr...		7/14	03/05/20
	Ideas Study		5/14	
	Settings for Encountering Math			20
	Evaluating Comprehensive			
	Defining an Identity			
	How Students Learn to Solve Problem...		1/16	
	Defining an Identity: What does it ...		1/16	11/21/17
	Mistake Recovery Instruction: Integ...		1/16	
	Education		8/16	
	Assessing the acceptability and fea...		4/16	05/09/20
	Mathematics and Reading		3/16	06/03/20
	Scaling up		2/17	02/15/20
	Decreasing		9/17	03/14/20
	Assessing the Feasibility and Accep...		1/17	05/23/18
	Collaborative		0/17	09/06/19
	Student Veterans		3/18	02/27/20
	Adolescent		8/18	
	Evaluation of guides to read pictur...		01/27/18	01/12/20
	School Climate: Teachers, Students,...		07/23/18	

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.


Modifications | Adverse Events | Protocol Deviations

Covid-19 Response

Pausing a Study:
Unless research subjects would be placed at risk by pausing/discontinuing your study temporarily, you may pause work on your study without filing any Modification to your IRB approved study.

Moving Research Methods Online:
If it is feasible to conduct some or all of your research methods online and/or your study site(s) have been closed, please submit a Modification to your protocol in Mentor IRB and select the Modification type:
"Research Site Closed for Covid-19 - Moving to Online Methods (no further approval needed)"
Please note that you need not wait upon the IRB to approve this modification to move your methods online.

Research Methods Cannot Be Moved Online or Paused:
It is necessary to continue this research study in person with the research subjects due to the nature of the study procedures and/or possible risks to subjects if the study were to be paused. In this case, please submit a Modification to your protocol in Mentor IRB and select the Modification type:
"My Study Methods Cannot be Moved Online for Covid-19 and Study Cannot be Paused"
You will be prompted with a short form to detail the reasons for continuing the study in person and the IRB will expedite review of your modification.

++++
When submitting a modification, please upload all the files to one Modification record. Please do not create multiple Modification records to upload additional documents. To upload additional files, click on the context menu (the small maroon page icon: ) to the left of the file type label. Also, if you have multiple changes to submit, please consolidate them into one Modification memo and one Modification record. Please do not create multiple Modification records.

Create New Modification

Submitting a COVID-19 Modification

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**.

10/09/2019 20-052_Principal Letter.docx (Recruitment Materials)


Create New Modification

Info This form will create a new Modification. You will be prompted after the Modification record is created to provide additional information and/or file uploads.

Covid-19 Response

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Protocol Title Ideas Study

Amendment Type Moving to Online Methods in Response to Covid-19 (**My Study Methods Cannot be Moved Online for Covid-19** Minor Change (personnel, small changes to procedures, etc) Significant Change (that may impact risks)

Create Modification **Cancel**

Submitting a COVID-19 Modification

	Status	Type	Status Date
6	03/10/2020 New - Submitted: 03/10/2020	My Study Methods Cannot be Moved Online for Covid-19	

Print Messages (0)

[Study Cannot be Moved Online or Paused Questions](#)

- Additional Modification Documents
- Modification Memo
Required File
- Revised Application - Final
- Revised Application - Track Changes
- Revised Consent Form - Final
- Revised Consent Form - Track Changes

No Panel Assigned

- ❖ 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

[Print to PDF](#) | [Back](#)

Study Cannot be Moved Online or Paused

1. Reasons

Type: Multiple Select

Required

* Please indicate the general categories that apply:

Options: Research subjects at risk if study is paused.
 Research methods cannot be conducted online.
 Other

Answer

The link will take you to a short questionnaire. Please click on the **Answer** box to indicate which options apply to your study.

Submitting a COVID-19 Modification

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.

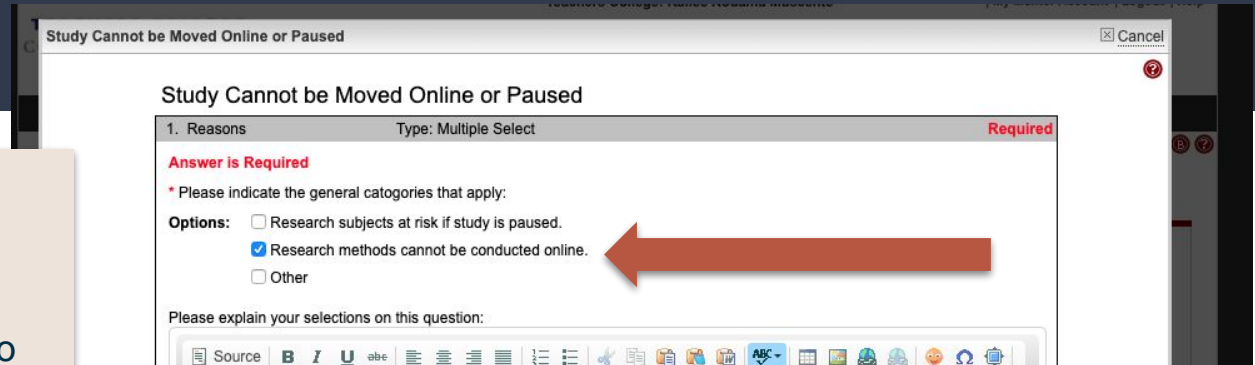
Once you are satisfied with your answer, click **Save Answer**. You will be directed to **Return to Protocol Page**, where you can then upload a modification memo.

The screenshot shows a web browser window with the title "Study Cannot be Moved Online or Paused". The browser's address bar shows "Teachers College: Kailee Kodama Muscente" and "My Mentor Account". The main content area has a heading "Study Cannot be Moved Online or Paused" and a sub-heading "1. Reasons" with "Type: Multiple Select" and a "Required" label in red. Below this, it says "Answer is Required" and "Please indicate the general categories that apply:". Under "Options:", there are three checkboxes: "Research subjects at risk if study is paused." (checked), "Research methods cannot be conducted online.", and "Other". Below the options, it says "Please explain your selections on this question:" followed by a rich text editor with a toolbar containing icons for source, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert image, insert video, insert audio, insert table, insert link, and insert code. At the bottom of the form, there are three buttons: "Save Answer" (highlighted with a red box), "Skip Question", and "Cancel".

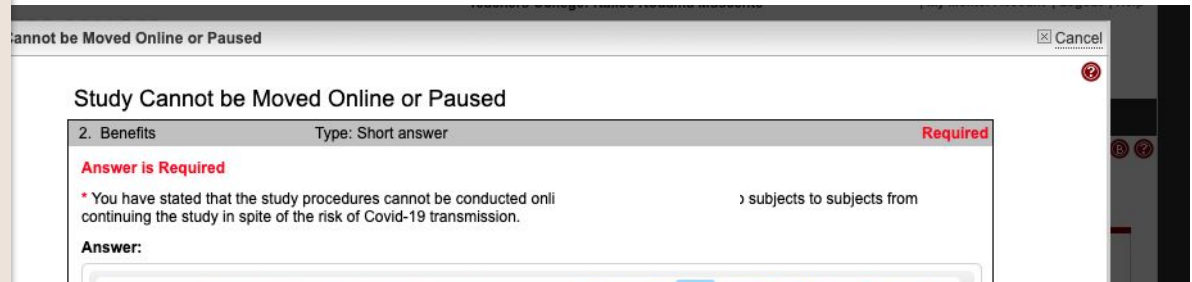
Submitting a COVID-19 Modification

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 your answers, click **Save Answer**. You will be directed to **Return to Protocol Page**, where you can then upload a modification memo.




This screenshot shows the first question of a form titled "Study Cannot be Moved Online or Paused". The question is "1. Reasons" and is a "Multiple Select" type. It is marked as "Required" and "Answer is Required". The instructions ask the user to indicate general categories that apply. There are three options: "Research subjects at risk if study is paused.", "Research methods cannot be conducted online." (which is selected with a blue checkmark), and "Other". A large red arrow points to the selected option. Below the options is a text box for explaining selections and a rich text editor toolbar.



This screenshot shows the second question of the form, "2. Benefits", which is a "Short answer" type. It is also marked as "Required" and "Answer is Required". The instructions state: "You have stated that the study procedures cannot be conducted online continuing the study in spite of the risk of Covid-19 transmission." followed by a partial sentence "subjects to subjects from". There is a text box for the answer below the instructions.

Submitting a COVID-19 Modification

	Status	Type	Status Date
 6	03/10/2020 New - Submitted: 03/10/2020	My Study Methods Cannot be Moved Online for Covid-19	

Print Messages (0)


Study Cannot be Moved Online or Paused Questions

Additional Modification Documents

 **Modification Memo**
Required File

 Revised Application - Final

 Revised Application - Track Changes

 Revised Consent Form - Final

 Revised Consent Form - Track Changes

No Panel Assigned

- ❖ 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.