

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.

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 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/>

Moving Only Some (*not all*) Face-to-Face Study Activities to Online Methods in Response to COVID-19

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

The screenshot shows the myTC Teachers College Columbia University website. The top navigation bar includes the myTC logo, the text "TEACHERS COLLEGE COLUMBIA UNIVERSITY", and icons for Support, Gmail, Calendar, Drive, Canvas, and Library. Below the navigation bar, there are two tabs: "Welcome" and "Resources". The "Resources" tab is highlighted with a red box. A callout box with a light beige background and a drop shadow is positioned over the "Resources" tab, containing the following text:

Please navigate to <https://my.tc.columbia.edu/> and click the **Faculty, Student, or Employee Resources** tab.

On the right side of the page, there is a blue header for "Human Subjects Research Protocol" and a white content area with the following links:

- Mentor IRB [↗](#)
- Office of Sponsored Programs (OSP) [↗](#)

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.

Info Page Create New Protocol

Documentation My Protocols

Next Meeting: 07/17/2019
Deadline for Submission: 07/07/2019

All I am the P.I., an R.C. or an R.A. - Show all P.I.'s -

Submitted: All Primary

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 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.**

Pausing a Study


Create New Modification

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

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:
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"My Study Methods Cannot be Moved Online for Covid-19 and Study Cannot be Paused"
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
Protocol Title: *Idios Study*

Amendment Type

- Moving to Online Methods in Response to Covid-19
- My Study Methods Cannot be Moved Online for Covid-19
- Significant Change (that may impact risks)



Submitting a COVID-19 Modification

	Status	Type	Status Date
 8	03/10/2020	New - Submitted: 03/10/2020	Moving to Online Methods in Response to Covid-19 (no further approval needed), My Study Methods Cannot be Moved Online for Covid-19

Print Messages (0)

Moving Study Online Questions
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

- ❖ 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

20-052. Ideas Study

Moving Study Online

Add/Edit Answers

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.

1. Activities moved

Type: Short answer

Required

* Please detail what study procedures will be moved online (e.g. face to face interview will be moved to Zoom/Skype, etc.).

2. SitesClosed

Type: Short answer

Required

* 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**.

Moving Study Online

1. Activities Moved Type: Short answer Required

Answer is Required

* Please detail what study procedures will be moved online (e.g. face to face interview will be moved to Zoom/Skype, etc.).

Answer:

Face to face interviews will be moved to Zoom conferences.

body

2. Sites Closed Type: Short answer Required

Answer is Required

* Please list any of your study sites that have been closed due to Covid-19 response (write n/a if none have been closed):

Answer:

Teachers College, Columbia University

body


Save Answer

Moving Study Online

Return to Protocol Page

Review Answers

Submitting a COVID-19 Modification

	Status	Type	Status Date
 8	03/10/2020	New - Submitted: 03/10/2020	Moving to Online Methods in Response to Covid-19 (no further approval needed), My Study Methods Cannot be Moved Online for Covid-19

Print Messages (0)

Moving Study Online Questions
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**

- ❖ 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

[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.

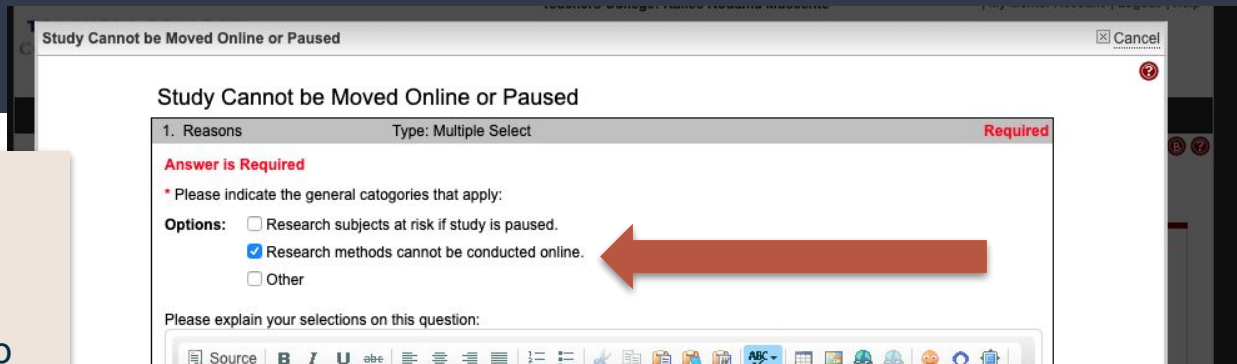
Once you are satisfied with your answer, click **Save Answer**. You will be directed to **Return to Protocol Page**, where you can then upload a modification memo.

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 the same title and a "Required" label in red. Below the title, it says "1. Reasons" and "Type: Multiple Select". A red heading "Answer is Required" is followed by the instruction: "* 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." (unchecked), and "Other" (unchecked). 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".

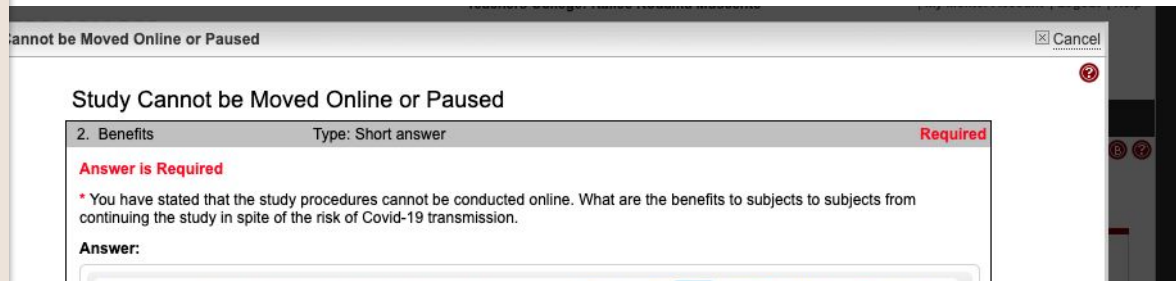
Submitting a COVID-19 Modification

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




The screenshot shows a dialog box titled "Study Cannot be Moved Online or Paused" with a "Cancel" button in the top right. The main heading is "Study Cannot be Moved Online or Paused". Below this is a question box for "1. Reasons" with a "Type: Multiple Select" and a "Required" label. The text "Answer is Required" is displayed in red. A red arrow points to the "Research methods cannot be conducted online." option, which is selected with a blue checkmark. The other options are "Research subjects at risk if study is paused." and "Other". Below the options is a text area for "Please explain your selections on this question:" with a rich text editor toolbar.



The screenshot shows the same dialog box, now on question "2. Benefits" with a "Type: Short answer" and a "Required" label. The text "Answer is Required" is displayed in red. The question text reads: "You have stated that the study procedures cannot be conducted online. What are the benefits to subjects to subjects from continuing the study in spite of the risk of Covid-19 transmission." Below the question is a text area for the "Answer:".


Submitting a COVID-19 Modification

	Status	Type	Status Date
 8	03/10/2020	New - Submitted: 03/10/2020	Moving to Online Methods in Response to Covid-19 (no further approval needed), My Study Methods Cannot be Moved Online for Covid-19

[Print](#) [Messages \(0\)](#)

Moving Study Online Questions
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**

- ❖ 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.