

# How to Submit an IRB Modification, Continuing Review, Protocol Deviation and Adverse Event

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.

# 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.

# Protocol Documentation

After a protocol has been approved, additional documentation may be required. These documents include:

**Modifications:** Any change to your protocol that impact study procedures, research staff, activities, time, recruitment or risk to subjects, etc.

**Continuing Review:** Once your full review IRB protocol has been approved, your protocol may undergo an annual continuing review. Depending on the risk level, some continuing reviews may be reviewed more than once a year. Continuing reviews is no longer required for expedited protocols. However, all expedited protocols are required to submit an annual “check in” (an abbreviated form that asks if the study is still ongoing). Researchers will be prompted by Mentor IRB on when to submit a continuation or “check in” report to TC IRB.

**Protocol Terminations:** A study can be terminated once it is closed to recruitment (with no direct participant follow-up), and all data collection has concluded. Data analysis can continue after the protocol is terminated. Researchers can also receive existing follow-up clinical data from healthcare providers after the IRB protocol is terminated (just note this possibility in the report).

# Protocol Documentation Continued

After a protocol has been approved, additional documentation may be required. These documents include:

**Protocol Deviations:** A minor or administrative departure from the study design or procedure that has not been approved by the IRB and does not have a major impact on the subject's rights, safety or well being, or the accuracy and reliability of the study data. A common protocol deviation is when researchers do not use the TC IRB approved and stamped consent forms. To avoid such administrative deviations (and the need for a report to IRB), follow the parameters outlined in your IRB protocol and use official documentation for all study activities.

**Adverse Events:** An event that occurs during the course of a research protocol that either causes physical or psychological harm, increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members). An adverse event may also include any serious/continuing noncompliance with the regulations or requirements of IRB.

# 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 several utility icons: Support (headset), Gmail (envelope), Calendar (calendar with "20"), Drive (Google Drive logo), Canvas (Canvas logo), and Library (book icon). Below the navigation bar, there are two tabs: "Welcome" and "Resources". The "Resources" tab is highlighted with a red rectangular 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." To the right of the callout box, there is a blue header for "Human Subjects Research Protocol" with two links: "Mentor IRB" and "Office of Sponsored Programs (OSP)".

myTC TEACHERS COLLEGE COLUMBIA UNIVERSITY

Support Gmail Calendar Drive Canvas Library

Welcome Resources

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

Human Subjects Research Protocol

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.

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 a text box on the left. Another red arrow points from the text box to a specific protocol entry in the main table.

**My Protocols**

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

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 Modification

When submitting a protocol, please be sure to follow the submission directions.

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

- ❖ Upload a New Modification
- ❖ Message the IRB with questions or concerns
- ❖ View past uploads and revisions

The screenshot shows a web interface with several tabs: "Cont. Review", "Modifications", "Adverse Events", and "Protocol Deviations". The "Modifications" tab is highlighted with a red box. Below the tabs is a text box with instructions: "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: [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." Below this is a button labeled "Upload New Modification", also highlighted with a red box. Underneath is a table with columns "Status", "Type", and "Status Date". A row is visible with the following data: "6", "05/31/2019", "Expedited Approved", "1. Minor Change (personnel, small changes to procedure)", and "05/31/2019". To the right of the table is a button labeled "Print Messages (2)", highlighted with a red box. Below the table are sections for "Additional Modification Documents", "Modification Memo", "Revised Application - Final", "Revised Application - Track Changes", "Revised Consent Form - Final", "Revised Consent Form - Track Changes", and "Notifications". Each section contains a list of documents with dates and file names, such as "Continuation Approval updated 10 12 2018.pdf", "PARENT\_MathReading\_Clean\_5.2019.docx", and "TEACHER\_MathReading\_Clean\_5.2019.docx".

Cont. Review **Modifications** Adverse Events Protocol Deviations

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: [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.

Upload New Modification

	Status	Type	Status Date
6	05/31/2019	Expedited Approved	1. Minor Change (personnel, small changes to procedure)

Print Messages (2)

**Additional Modification Documents**

- 05/31/2019 Continuation Approval updated 10 12 2018.pdf

**Modification Memo**

**Revised Application - Final**

**Revised Application - Track Changes**

**Revised Consent Form - Final**

- 05/31/2019 PARENT\_MathReading\_Clean\_5.2019.docx
- 05/31/2019 TEACHER\_MathReading\_Clean\_5.2019.docx
- 05/31/2019 ASSENT\_MathReading\_DOE\_5.2019.docx

**Revised Consent Form - Track Changes**

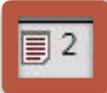
- 05/31/2019 PARENT\_MathReading\_TrackedChanges\_5.2019.docx
- 05/31/2019 TEACHER\_MathReading\_TrackedChanges\_5.2019.docx

**Notifications**

- 05/31/2019 Modification Approved - IRB ID: 17-030.pdf

Assigned to Exempt/Expedited

# Submitting a Modification

	Status	Type	Status Date
 2	08/13/2019 New - Revisions Required - Submitted: 08/13/2019	1. Minor Change (personnel, small changes to procedures, etc)	

[Print](#) [Admin Only Notes](#) [Messages \(1\)](#)

Once you have uploaded a Modification, you may receive a Request for Revisions from an IRB Reviewer.

Revisions should be submitted 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](mailto:IRB@tc.edu) when the response to revisions is submitted as the reviewer will not be notified when your response has been uploaded.

# Navigating the Continuing Review

1.

<b>Cont. Reviews</b>	Modifications	Adverse Events	Protocol Deviations
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2.

Status	Due Date
4 Due	06/03/2020

3.

4.

3 Approved	06/03/2019
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1. The **Continuing Review** tab will have a section for each year of review
2. Click the context menu (*little red notebook icon*) for other options
3. Be mindful of due dates!
4. This section indicates data analysis only, no new participants were added since the last continuing review
5. These were the last two signed consent forms

**Notifications**

Notifications	05/29/2019
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Assigned to Exempt/Expedited

2 Approved	06/21/2018	06/14/2018	06/18/2018
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View Report Lock Print Messages (3)

5.

**Documentation**

Two Signed Consent Documents	06/18/2018	Consent Form 1 and 2.pdf
Cont. Review	06/14/2018	PI Cont. Review Survey.pdf

**Notifications**

Notifications	06/18/2018	Cont. Review Approved Notification - IRB ID: 17-030.pdf
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Assigned to Exempt/Expedited

# Submitting Continuing Review

Cont. Reviews		Modifications	Adverse Events
Year	Status	Due Date	Date F
4	Due	06/03/2020	

**Complete & Submit**

No Panel Assigned

Once you are ready to submit a continuing review, click **Complete and Submit**.

t. Review

Cont. Review

IRB ID 17-030  
Protocol Title Mathematics and Reading  
Year Number 4

Total # Subjects Enrolled Since Last Cont. Review   
Total # Subjects Enrolled in Study to Date

\* Continuation Status  **– Select Continuation Status –**  
Subject Enrollment Not Yet Begun  
Subject Enrollment Will Continue  
Subject Enrollment is Complete but Continuing Follow-up  
Subject Enrollment is Complete - Data Analysis Only  
Terminate Protocol  
Terminate Protocol - Administrative

**Subject Information**

How many subjects have signed Consent forms?  
**Answer:**

How many subjects have provided oral consent?  
**Answer:**

**Risk/Benefit Evaluation**

You will be prompted to complete the following questionnaire. Select the appropriate continuation status and fill out all relevant information. If you would like to terminate your protocol, select **“Terminate Protocol”** and visit <https://www.tc.columbia.edu/institutional-review-board/how-to-submit/terminating-a-protocol/> for more information

# Submitting Continuing Review

Continue filling out the questionnaire as it pertains to your study.

Cont. Review Cancel

If you answered "yes" to the question above, please explain:

**Answer:**

Source B I U abc

Rich text editor toolbar with icons for bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert link, insert image, undo, redo, and other editing functions.

Have there been any voluntary or involuntary withdrawals of subjects from the research or any complaints about the research?

**Options:**  1. Yes  
 2. No

Cont. Review 05/31/2019 LEARNER\_MainReading\_Clean\_Modification\_0\_524

Please describe the current state of your study (i.e., what has occurred thus far and what you still need to do):

**Answer:**

Source B I U abc

Rich text editor toolbar with icons for bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert link, insert image, undo, redo, and other editing functions.

# Submitting Continuing Review

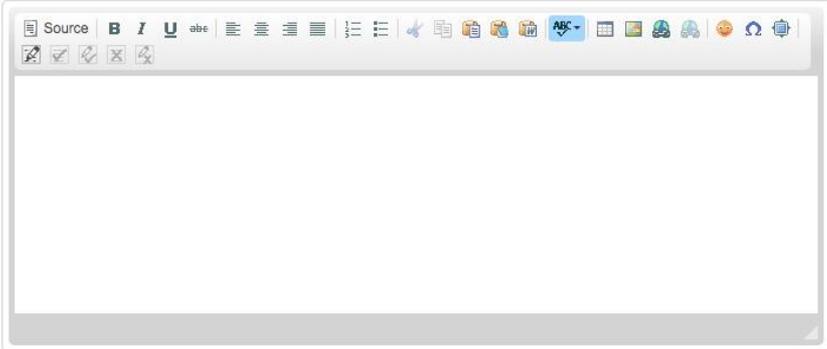
- ❖ All of your findings should be summarized in this section. At this time, you should include any changes made to your study.
- ❖ Upload all relevant documents, including two **signed** consent forms.
- ❖ For studies that have not had changes or updates since the previous continuing review, or have not yet started data collection, you do not have to upload to last two signed consent forms.

05/31/2019 TEACHER\_MathReading\_Clean Modification 6.5.2019.pdf (Approved) Cancel

Cont. Review

Summarize your research findings to date. Note any recent literature in the field, any amendments or modifications to the research including findings at collaborating institutions or any other relevant information since the last Continuing Review/IRB Approval:

**Answer:**



Upload File  No file selected.  
Allowed Extensions: doc, docx, pdf, rtf, xls, xlsx, ppt, pptx, mov, zip, jpg

Two Signed Consent Documents  No file selected.  
Allowed Extensions: doc, docx, pdf, rtf

An email will automatically be sent to the IRB Chair and Administrator upon successful upload of your Cont. Review. If you would like to send any message along in that email, please use the text box below.

Message

# Submitting Continuing Review

Info Page      Cont. Review Survey      [Back](#)

Documentation

**My Protocols**

Protocol Reports

Student Protocols

Research Coordinators

Reviewer

PI Documentation

Meetings

IRB Members

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**Subject Information**

1. written consent      Type: Numeric

How many subjects have signed Consent forms?

**Answer**

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2. oral consent      Type: Numeric

How many subjects have provided oral consent?

**Answer**

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**Risk/Benefit Evaluation**

3. adverse events      Type: Multiple Choice

Have there been any adverse events or unanticipated problems involving risks to subjects since the last Con application or the initial IRB approval?

**Options:**      1. Yes  
                         2. No

**Answer**

- ❖ Once you have finished the questionnaire, you will complete an 8 question survey about your research. Click on each **Answer** button to respond to each question.
- ❖ **“Type:”** indicates the response that should be given (e.g., **Numeric:** 1, 2 etc.; **Multiple Choice:** choose one answer; **Short Answer:** a few sentences describing your answer.

# Submitting Continuing Review

8. findings

Type: Short answer

Summarize your research findings to date. Note any recent literature in the field, any amendments or modifications to the research including findings at collaborating institutions or any other relevant information since the last Continuing Review/IRB Approval:

Answer

Once you have completed the questionnaire, your answers will be submitted to the IRB for review. Please allow 7-10 business days for review.

# Protocol Deviation

A **Protocol Deviation** is a minor or administrative departure from the study design or procedure that has not been approved by the IRB and does not have a major impact on the subject's rights, safety or well being, or the accuracy and reliability of the study data.

Cont. Reviews   Modifications   Adverse Events   **Protocol Deviations**

New Protocol Deviation

Event/Date	Status	Deviation File/Comments	Sub
1. New Report	Full Board Acknowledged	  Protocol-Deviation_Unstamped-signed-informed-consent.docx	

Print   Admin Only Notes

**Administrator Notes**

Meeting on 02/20/2019 11:00 AM - 1:00 PM EST

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02/15/2019

**Status Log**

02/15/2019	New	
02/20/2019	Full Board Acknowledged	Protocol deviation reviewed and acknowledged by the full board, no further action needed.

 **Additional Documentation**

**Notifications**

02/20/2019   Protocol Deviation - Full Board Acknowledged

Assigned to Full Board   Meeting Notes   Tracking Status: 11. Completed 

Skip Agenda   Time Tracking:

# Adverse Events

Cont. Reviews Modifications **Adverse Events**

Event / Date	Status / Comments / Files
2. 01/15/2016	Acknowledged

Request Revisions

Related

01/15/2016      New Adverse Event Reported

01/27/2016      Acknowledged

01/15/2016        Adverse Event Notification

 **Additional Documentation**

**Notifications**

01/15/2016        Adverse Event Receipt Confirmation

Assigned to Full Board       Skip Agenda      Tracking Status   

Time Tracking:

An **Adverse Event (AE)** is an event that occurs during the course of a research protocol that either causes physical or psychological harm, increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members). Types of AEs include:

- ❖ Internal (on-site) adverse events
- ❖ External (off-site) adverse events
- ❖ Expected adverse events
- ❖ Unexpected adverse events
- ❖ Serious adverse events

Researcher non-compliance may also be considered an adverse event.

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](mailto: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.