

How to Terminate an IRB Protocol

Teachers College Institutional Review Board,
Columbia University

When to Terminate a Protocol...

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).

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 border. 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 box containing 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.

The screenshot displays the myTC Teachers College Columbia University website interface. At the top, the logo and navigation icons (Support, Gmail, Calendar, Drive, Canvas, Library) are visible. Below the navigation bar, there are tabs for Welcome, Student Resources (highlighted), Employee Resources, and Support Resources. The main content area is divided into three columns:

- My Account:** My Account Summary, Account Balance (\$0.00), View eBill, Enroll/Manage eRefund, and Make a Payment.
- Personal Information:** TC Alert Signup, My TC ID Number, Update Emergency Contacts, TC Gmail Terms of Agreement, Manage My UNI Account, Update E-mail Addresses, and Update Addresses and Phones.
- Human Subjects Research Protocol:** Mentor IRB (highlighted with a red arrow) and 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 terminate.

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	

Choose **Terminate Protocol** under **Date Closed** section. You will be prompted to set the date the protocol closed. Upon submission, the protocol will be listed as terminated under **My Protocols**.

Approval Expires

Approved Without Cont. Review

Proposed Start Date

01/22/2016

End Date

01/27/2017

Date Closed

Set Date

Terminate Protocol



Funding Source

Terminating a Protocol

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

Subject Information

How many subjects have signed Consent forms?

Answer:

How many subjects have provided oral consent?

Answer:

Risk/Benefit Evaluation

✓ - 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

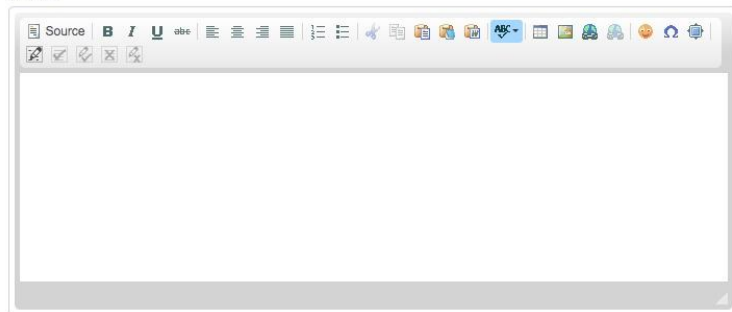
You will be prompted to complete the following questionnaire. Make sure the appropriate Continuation Status, **“Terminate Protocol”** is selected. Fill out all relevant information.

Terminating a Protocol

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

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

Answer:



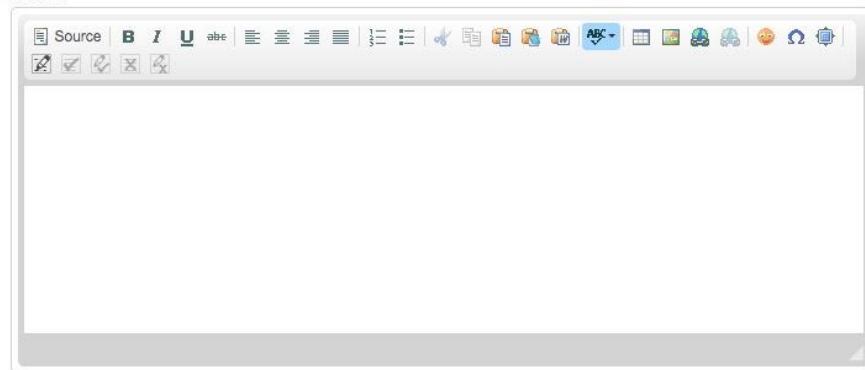
A rich text editor interface with a toolbar containing icons for source, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert link, insert image, insert video, insert audio, insert table, insert code, undo, redo, and print. The editor area is currently empty.

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

- Options:** 1. Yes
 2. No

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

Answer:



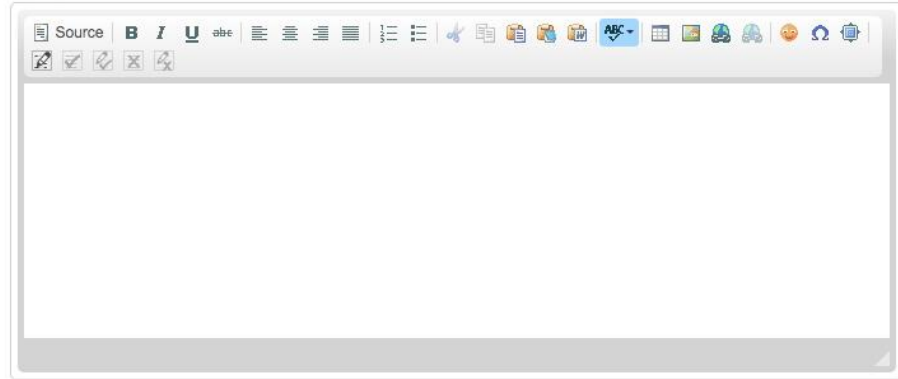
A rich text editor interface with a toolbar containing icons for source, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert link, insert image, insert video, insert audio, insert table, insert code, undo, redo, and print. The editor area is currently empty.

Terminating a Protocol

- ❖ All of your findings should be summarized in this section. Please include the overall findings.
- ❖ Upload all relevant documents, including the two most recent **signed** consent forms.

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:



The image shows a rich text editor window. The toolbar at the top includes options for Source, Bold (B), Italic (I), Underline (U), text color (abc), bulleted list, numbered list, decrease indent, increase indent, link, unlink, insert link, insert image, insert video, insert audio, insert table, insert form, insert signature, and insert document. Below the toolbar is a large, empty text area for entering the 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

Terminating a Protocol

Documentation

My Protocols

Protocol Reports

Student Protocols

Research Coordinators

Reviewer

PI Documentation

Meetings

IRB Members

Subject Information

1. written consent Type: Numeric

How many subjects have signed Consent forms?

Answer

2. oral consent Type: Numeric

How many subjects have provided oral consent?

Answer

Risk/Benefit Evaluation

3. adverse events Type: Multiple Choice

Have there been any adverse events or unanticipated problems involving risks to subjects since the 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).

Terminating a Protocol

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.

Investigator-Initiated Voluntary Protocol Suspension or Termination

Investigators may choose to voluntarily suspend or terminate some or all activities of an approved IRB protocol. If an investigator chooses to suspend or terminate their protocol, they should report to TC IRB and specify the reasons for suspension or termination. Reasons may include:

- ❖ The project is complete, and the investigators are no longer engaging in human subjects research
- ❖ Unanticipated problem(s) involving risk to participants or others
- ❖ Incident of serious and continuing non-compliance

Once an IRB protocol has been terminated, it cannot be reopened. In most cases, investigators will be required to submit a new protocol to TC IRB for review and approval.

IRB Protocol Administrative Closure

IRB staff may close a research protocol administratively for the following reasons:

- ❖ If an investigator has failed to submit the required continuing review materials
- ❖ The investigators are no longer engaging in human subjects research and are unable for some unforeseeable reason (e.g., illness, injury, etc.) to terminate the protocol on their own
- ❖ Unanticipated problem(s) involving risk to participants or others
- ❖ Incident of serious and continuing non-compliance

Administrative closures occur after the IRB approval period on a protocol expires. This action is taken to ensure that investigators do not mistakenly assume that their protocols remain active. Ideally, the investigator will alert TC IRB of any study terminations or suspensions.

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.