

How to Submit a New Protocol using TC Mentor Institutional Review Board

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 lower half of the slide.



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

To submit a new protocol, click on the My Protocols sidebar on the left navigation menu on the IRB tab. Then click the “Create New Protocol” button:

The screenshot displays the IRB Admin interface. On the left sidebar, the 'My Protocols' menu item is highlighted with a red box. In the main content area, the 'Create New Protocol' button is also highlighted with a red box, and a red arrow points to it from the right. The interface includes tabs for 'IRB Admin' and 'IRB Setup', and a 'My Protocols' section with filters for 'All', 'I am the P.I. or an R.A.', and 'Submitted'. A table header is visible with columns for 'IRB #', 'Title', 'PI', 'Approved', and 'A.R. Due', and the message 'No Protocols Found' is displayed below it.

IRB Admin IRB Setup

Info Page **Create New Protocol**

Documentation My Protocols

Next Meeting: 05/22/2019
Deadline for Submission: 05/13/2019

All I am the P.I. or an R.A. Submitted All

IRB #	Title	PI	Approved	A.R. Due
No Protocols Found				

My Protocols

Protocol Reports

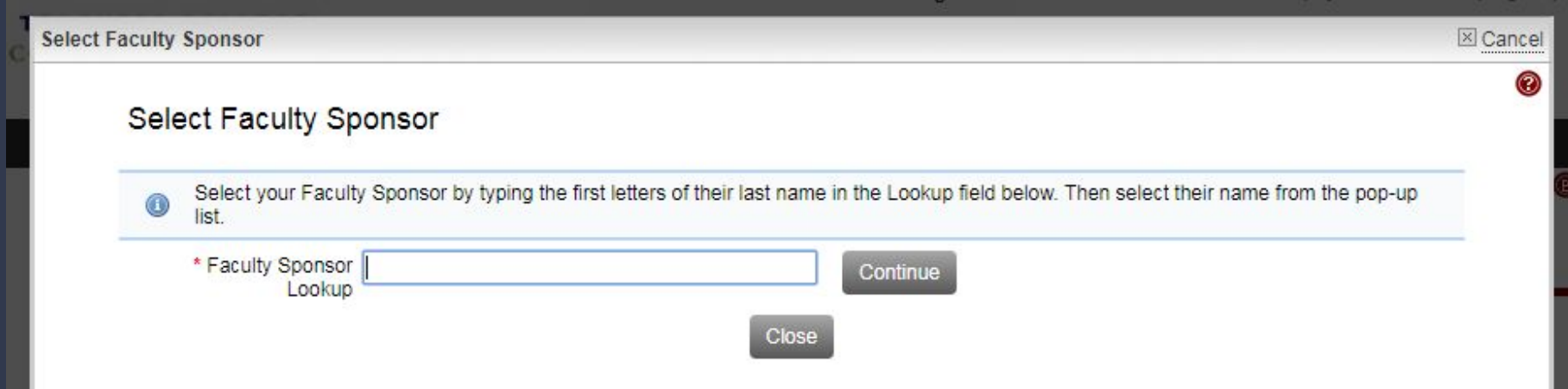
Student Protocols

Research Coordinators

Reviewer

****If you are a student, search for your Faculty Sponsor by Last Name**

As a student researcher, you should already have secured a Faculty Sponsor to support you in your research efforts. Prior to submitting your IRB protocol, the Faculty Sponsor will guide you in the drafting of any documents to be uploaded into Mentor IRB. After you save your protocol in Mentor, your Faculty Sponsor will automatically receive an email notice requesting they accept their Faculty Sponsorship role in Mentor. Please clearly communicate with your Faculty Sponsor about this process.



The screenshot shows a dialog box titled "Select Faculty Sponsor" with a "Cancel" button in the top right corner. The main heading is "Select Faculty Sponsor". Below this is an information box with an 'i' icon: "Select your Faculty Sponsor by typing the first letters of their last name in the Lookup field below. Then select their name from the pop-up list." Underneath is a text input field labeled "* Faculty Sponsor Lookup" with a "Continue" button to its right. At the bottom center is a "Close" button.

Next Meeting indicates the next time the Full Board will convene. Any protocols that fall within the Full Review category must be submitted by the **Deadline for Submission** in order to be reviewed at the next full board meeting. Full Board submission deadlines are also posted on TC IRB's website.

Expedited and Exempt categories are reviewed on a first-come-first-served basis.

- ❖ All Co-PIs, Research Coordinators, and Research Assistants should be registered in Mentor with their CITI Training on file prior to submission.
- ❖ **Start Date:** Projected date recruitment will begin
- ❖ **End Date:** Last day of data analysis

3 Protocol

Next Meeting 05/22/2019
Deadline for Submission 05/13/2019

Faculty Sponsor

Send Notification to Faculty Sponsor

Co-PI's

External PIs John Doe

Research Assistants

* Study Title Fostering Academic Help-Seeking for Engineering Students via Anonymous Questions

* Start Date

End Date

Funding Source

Grant Number

Review Type

Waiver of Informed Consent

Documentation of Informed Consent

Number of Subjects

Fred S. Keller School? No

May, 2019							
Today							
Wk	Sun	Mon	Tue	Wed	Thu	Fri	Sat
18				1	2	3	4
19	5	6	7	8	9	10	11
20	12	13	14	15	16	17	18
21	19	20	21	22	23	24	25
22	26	27	28	29	30	31	

* Start Date [Acceptable Formats](#)

End Date [Acceptable Formats](#)

Funding Source

Grant Number

Review Type **Full Review** ▼

Waiver of Informed Consent

Waiver of Documentation of Informed Consent **Not Requested** ▼

Number of Subjects

Fred S. Keller School? No

Yes

Full Review Questions

Study Collaboration

Does this research take place in NYC public schools? (if yes, please visit this link: [NYCDOE IRB](#))

Options: 1. Yes
 2. No

Does your research involve health care data subject to the requirements of HIPAA? (if yes, please visit this link: [NYCDOE IRB](#))

Options: 1. Yes
 2. No

This research will be conducted at or in collaboration with:

Options: 1. Grade school (K-12)
 2. University/college

Mentor automatically populates the **Review Type** as **Full Review**. Full Review is the highest risk review category. Please double check your review category in order to avoid resubmissions or review delays.

Visit:

<https://www.tc.columbia.edu/institutional-review-board/review-categories/> for more information on identifying the correct Review Category for your research.

Full Review Questions

Study Collaboration

Does this research take place in NYC public schools? (if yes, please visit this link: [NYCDOE IRB](#))

- Options: 1. Yes
 2. No

Does your research involve health care data subject to the requirements of HIPAA? (if yes, please submit a completed HIPAA form)

- Options: 1. Yes
 2. No

This research will be conducted at or in collaboration with:

- Options: 1. Grade school (K-12)
 2. University/college

- ❖ NYC DOE requires a **separate** IRB form to be submitted after receiving TC IRB approval.
- ❖ TC IRB will honor **consent, parent permission, and assent forms** that are based on the DOE IRB's templates.
- ❖ These DOE IRB templates are available on Mentor under "Documentation/DOE IRB Templates and Information"
- ❖ A HIPPA Form Template can be found on Mentor under "Documentation"

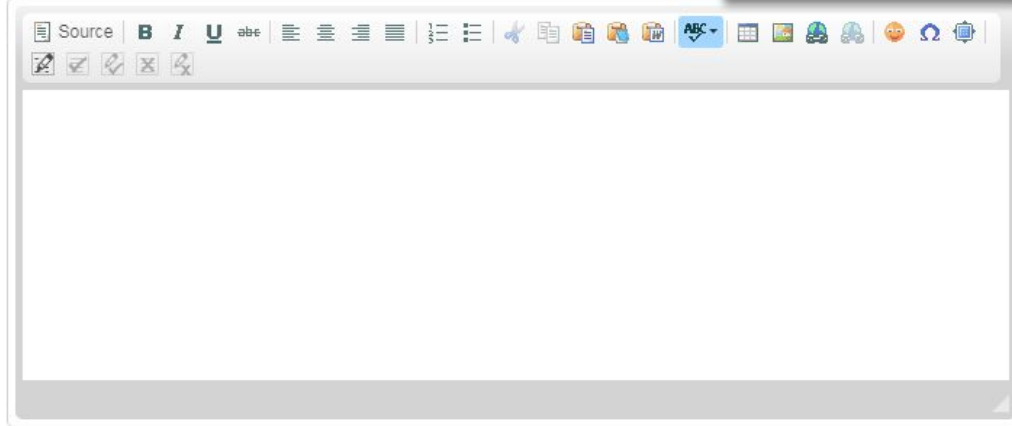
Create IRB Protocol

This research will be conducted at or in collaboration with:

- Options:
- 1. Grade school (K-12)
 - 2. University/college
 - 3. Medical facility
 - 4. Social service agency/NGO
 - 5. Government agency
 - 6. Private corporation
 - 7. Internet
 - 8. Other (describe below)

If you selected the "Other" option above, please describe:

Answer:



A screenshot of a rich text editor interface. The top toolbar includes options for Source, Bold (B), Italic (I), Underline (U), and text color (abc). There are also icons for bulleted and numbered lists, indentation, link, unlink, insert link, insert image, insert video, insert audio, insert table, and a dropdown menu labeled 'ABC'. Below the toolbar is a large, empty text area for entering the description.


- ❖ If your research is conducted only at TC, please check option (2).
- ❖ Any NYC DOE schools should be marked as option (1). TC IRB will accept DOE IRB templates (consent, assent forms, etc.), for your review.
- ❖ Examples of option (8) "Other" include research that occurs in a participants' home or public location, like a coffee shop.

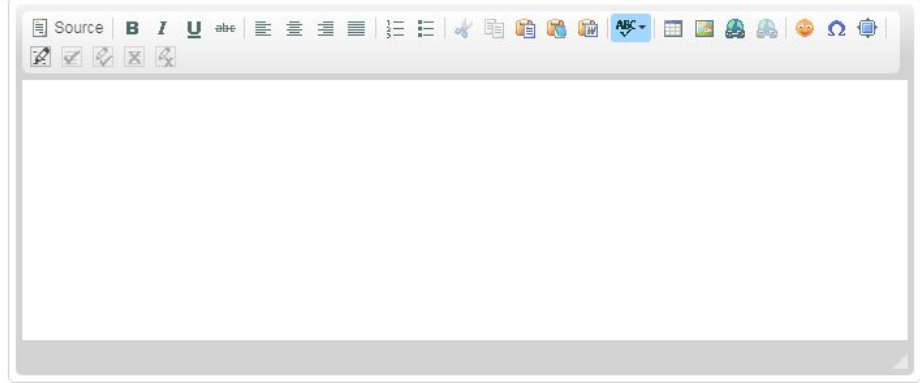
- ❖ Please be specific when listing research sites (i.e. Teachers College, Columbia University).
- ❖ Your IRB submission may also need a site permission form. This form is located in Mentor/Documentation.
- ❖ Research conducted outside of the US is considered international research.

Create IRB Protocol

List the schools, universities, corporations, government agencies, etc., with which you will work:

Answer:

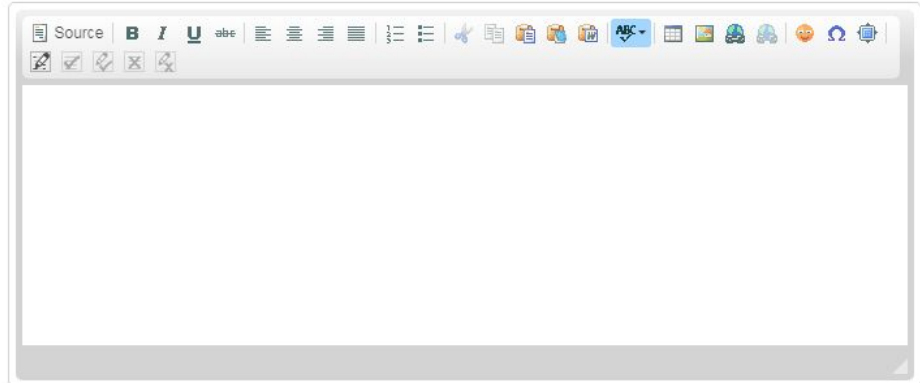
 Autosaved text exists for the editor box below. [View/Load Autosave](#)



A rich text editor interface with a toolbar containing icons for Source, Bold (B), Italic (I), Underline (U), text color (abc), bulleted list, numbered list, indent, outdent, link, unlink, insert link, insert image, insert video, insert audio, insert table, insert calendar, insert location, insert person, insert group, insert smiley, insert link, and insert document. Below the toolbar is a large, empty text area for input.

If this research takes place outside the U.S., state the location(s):

Answer:



A rich text editor interface with a toolbar containing icons for Source, Bold (B), Italic (I), Underline (U), text color (abc), bulleted list, numbered list, indent, outdent, link, unlink, insert link, insert image, insert video, insert audio, insert table, insert calendar, insert location, insert person, insert group, insert smiley, insert link, and insert document. Below the toolbar is a large, empty text area for input.

Create IRB Protocol

Cancel

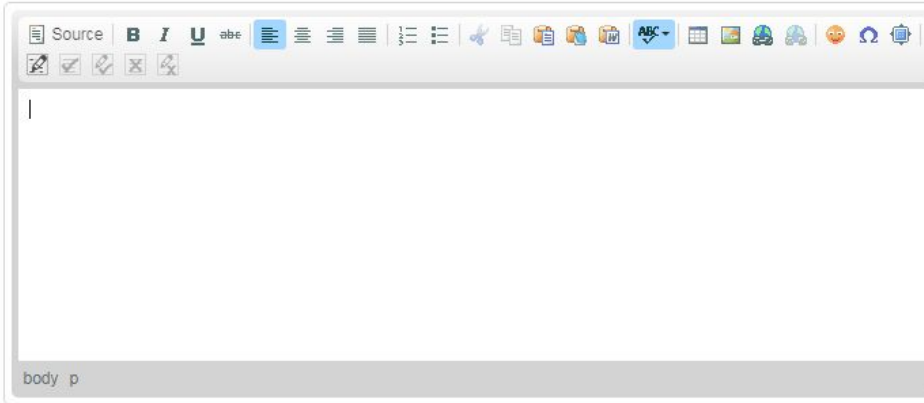
Subjects

Who will your potential subjects be? Please check the subject population(s) that will be involved in the research project.

- Options:
- 1. Adults (competent to consent)
 - 2. Adults (not competent to consent)
 - 3. Minors (under 18 years old)
 - 4. Prisoners
 - 5. Pregnant Women
 - 6. Developmentally disabled (please be specific about the population/s in the area below)
 - 7. Non-English speakers

If you selected above that your subjects will be developmentally disabled, please be specific about the population(s):

Answer:



The screenshot shows a rich text editor with a toolbar containing various icons for text formatting (bold, italic, underline), alignment, bulleted and numbered lists, indentation, link, unlink, insert table, insert image, insert video, insert audio, insert link, and insert document. Below the toolbar is a large text area with a vertical cursor at the beginning. At the bottom left of the text area, the text "body p" is visible.

Categories that Require Full Review

- ❖ Populations that typically require **Full Board Review** include adults not competent to consent, prisoners, pregnant women, and developmentally disabled

- ❖ Categories of research that are reviewed on a **case-by-case basis** depending on the type of engagement include minors and non-English speakers

Create IRB Protocol

Cancel

Additional Information on Subject Population (Individuals in the categories below may feel pressured to participate in a research study. If your study includes subjects in one or more of these categories, please address in your application how you will ensure that participation is truly voluntary.)

This subject population includes (check all that apply; additionally, if you will be working with your own students, read and submit this along with your application documents):

- Options:**
- 1. My current students (K-12)
 - 2. My current students (post-secondary)
 - 3. Students in my school/university (not currently enrolled in a class I am teaching)
 - 4. My clients/patients in a social service/medical setting
 - 5. Clients or patients at a facility where I am employed
 - 6. Individuals whom I supervise either directly or indirectly
 - 7. Teachers, students, or parents in a school or district in which I hold an executive position
 - 8. Other (please describe below)
 - 9. None of the above

If you selected the "Other" option above, please describe:

Answer:

The screenshot shows a rich text editor with a toolbar containing various icons for text formatting (bold, italic, underline, text color, background color, bulleted list, numbered list, indent, outdent, link, unlink, insert link, insert image, insert video, insert audio, insert table, insert code block, insert quote, insert table of contents, insert table of contents), a font color dropdown menu, and a background color dropdown menu. Below the toolbar is a large, empty text area for entering the answer.

- ❖ Please note that conducting research with your own students is inherently coercive. As such, this type of research requires an additional document.
- ❖ Visit Mentor/Documentation and download the "Working with Own Students in Research Template."

Create IRB Protocol

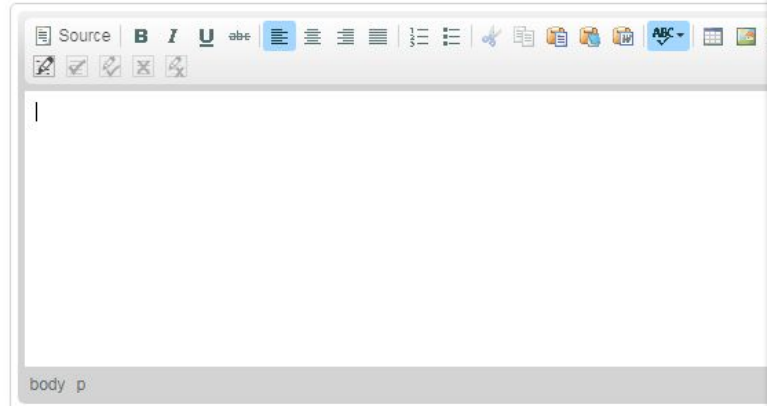
Does your study involve deception?

Options: 1. Yes
 2. No

Conflict of Interest

Describe any conflicts of interest you may have in regards to this study and/or the study subjects:

Answer:



A screenshot of a rich text editor interface. The toolbar includes icons for source, bold, italic, underline, text color, background color, bulleted list, numbered list, indent, outdent, link, unlink, insert image, insert video, insert audio, insert table, and a font color dropdown menu. The text area is currently empty with a vertical cursor at the beginning. The status bar at the bottom left shows 'body p'.

Studies involving deception will be reviewed at the **Full Board** level. Researchers should outline in the IRB application a debriefing statement concerning the planned deception.

Conflicts of interest (COIs) should be clearly outlined.

COIs may include:

- ❖ Maintaining a leadership or management role within a study site could pose a potential conflict of interest.
- ❖ Other conflicts of interest may include financial or other personal considerations which may compromise or impact a researcher's professional judgement in conducting ethical research.

Upload Protocol Description

Choose File

No file chosen

Allowed Extensions: doc, docx, pdf, rtf, xls, xlsx, ppt, pptx, mov, zip, jpg

Upload Consent Form

Choose File

No file chosen

Allowed Extensions: doc, docx, pdf, rtf, xls, xlsx, ppt, pptx, mov, zip, jpg

Message to IRB Chair

When you click on the "Save" button below, an e-mail will automatically be sent to the relevant individuals at the start of a new protocol. Please continue to check the website for updates regarding the status of your submission.

In addition to the questions you are answering online, you must upload the following two items that are part of the application (except in the case of Exempt 4 studies):

- IRB Application
- Consent, Assent, Participant's Rights, Investigator's Verification Documents

After you have submitted these documents, you will need to upload all additional materials. The IRB needs to review all materials used throughout a research study. As such, be sure to submit all study instruments (e.g., assessments, interview guides, surveys, etc.), recruitment materials (e.g., flyers, scripts for e-mails, scripts for announcements, text for online posts, etc.), all materials you will use throughout the study, approval letters from research sites, and the application checklist.

After completing the PI survey, you will upload the IRB Application ([available here](#) or on Mentor IRB/Documentation) to "Upload Protocol Description." If working with human subjects, also upload a Consent Form.

After you have clicked "Save," you will be taken to another screen where you can upload additional documents. **All documents should be uploaded separately.** Do not upload them as one packet.

Students: "Save" means that your faculty sponsor has received an email about the study. IRB will not review the study until the faculty sponsor has agreed to their role.

Finally...

When you are completely satisfied with your application and materials, and they are in final format (without tracked changes) click the **Submit Protocol for Review** button.

Students: You can only submit your study to the IRB *AFTER* your faculty sponsor has approved the protocol through the Mentor system. As such, you must log back in after you have received approval from your academic advisor to submit to the IRB.

Dissertation Studies: Please note that the IRB will only review *dissertation* studies after the proposal hearing has been passed. Pre-dissertation research, pilot studies, or exploratory studies will be reviewed on a regular basis.

Faculty Sponsor: Click on "Student Protocols" to approve protocols and modifications submitted by your advisees.

Remember, regardless of the type of study, no study involving human subjects can begin (including recruitment of subjects) without first having received IRB approval.

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.