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

Teachers College, Columbia University

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).

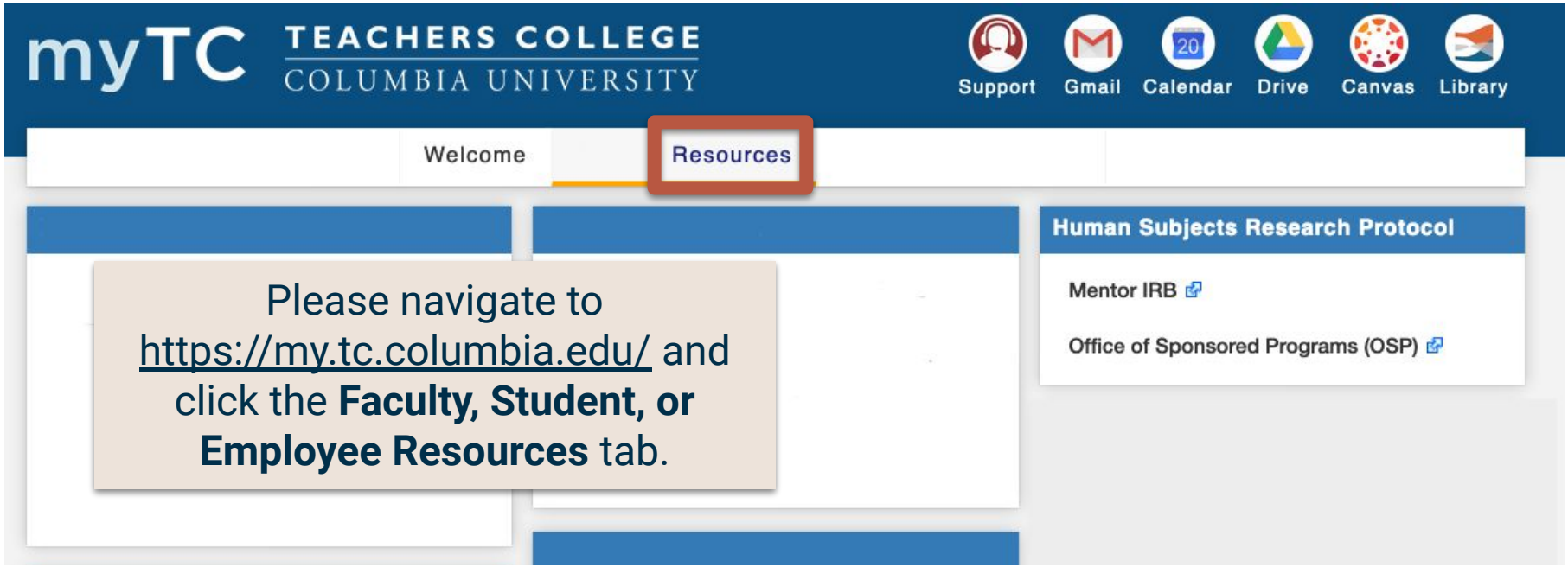
Protocol Documentation Continued

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

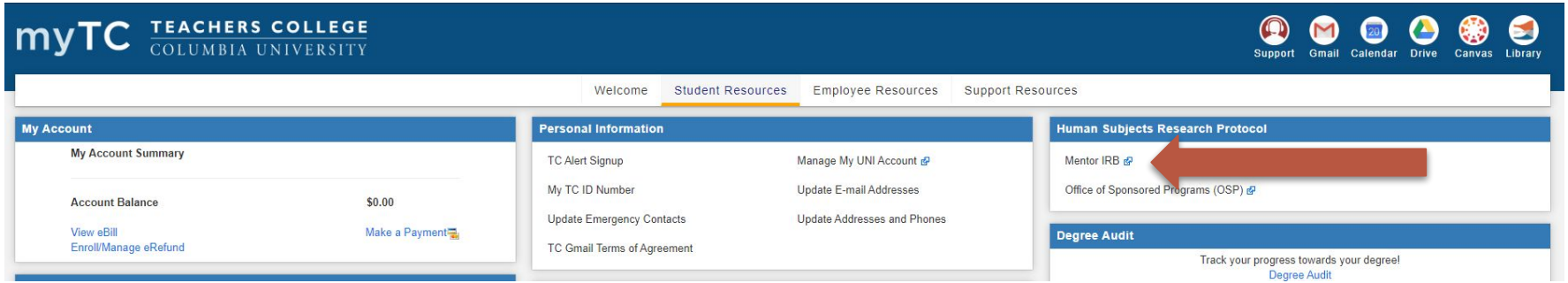
Protocol Deviations: A minor or administrative departure from the study design or procedure that has not been approved by the IRB and does not have a major impact on the subject's rights, safety or well being, or the accuracy and reliability of the study data. A common protocol deviation is when researchers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



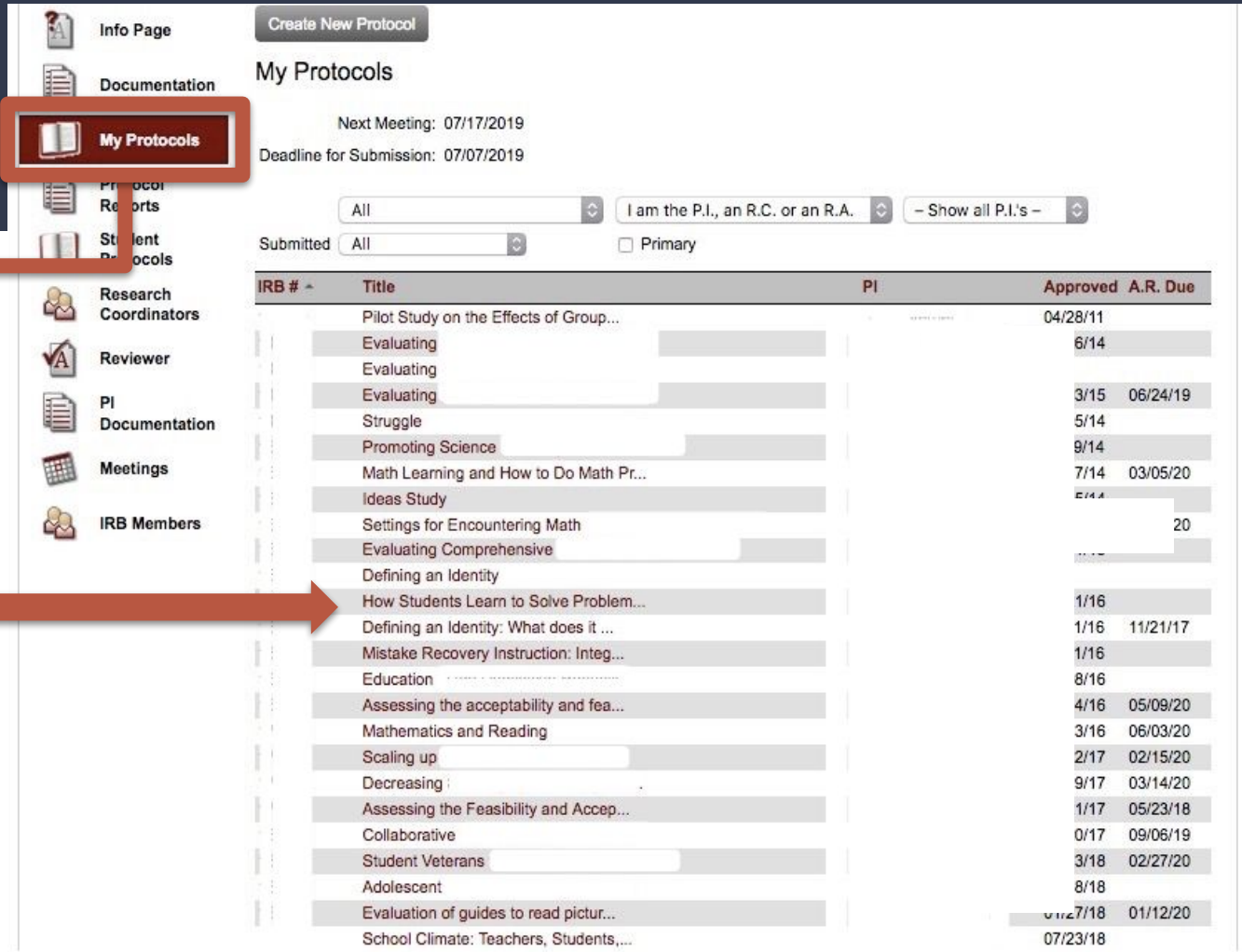
Navigate to the **Mentor IRB** button on the right hand side of the screen. Mentor IRB should open in a new page.



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.

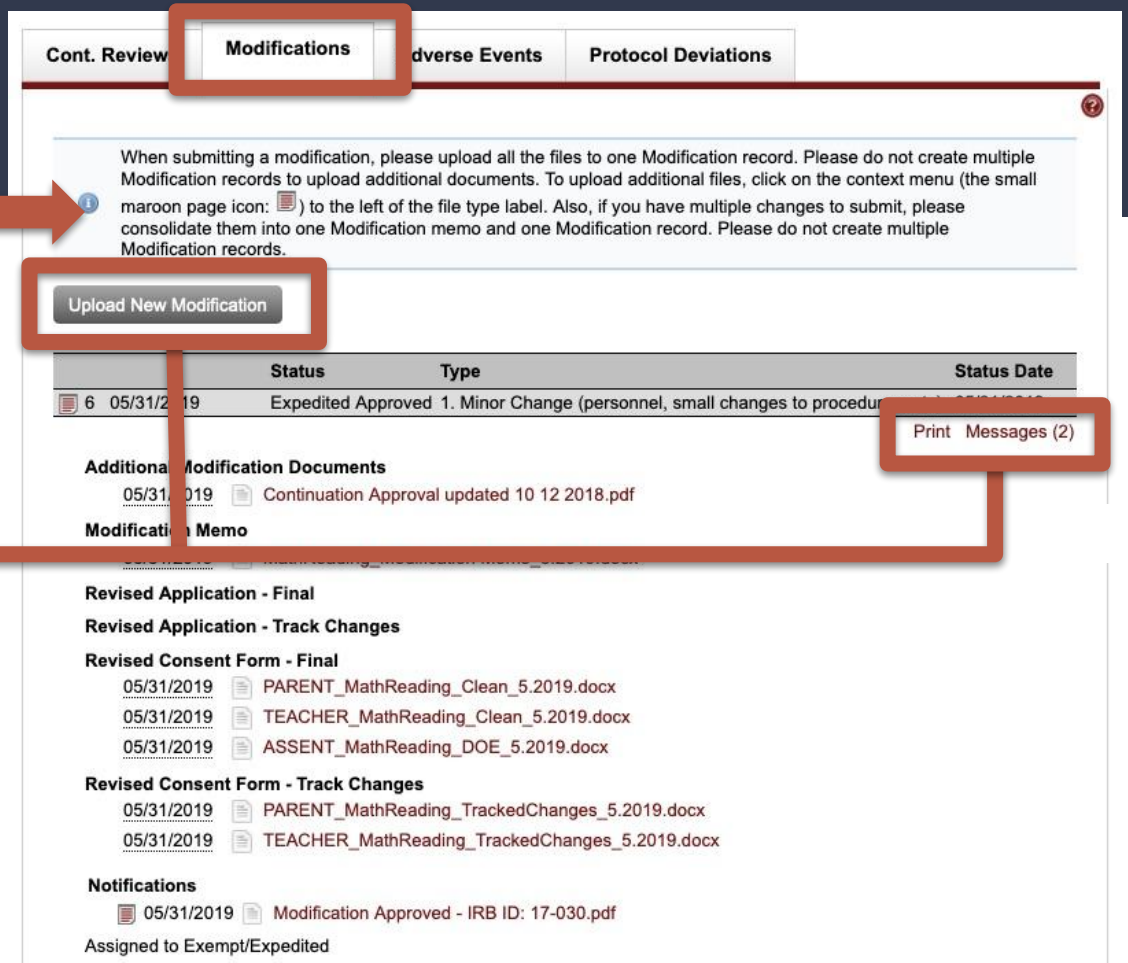


Submitting a Modification

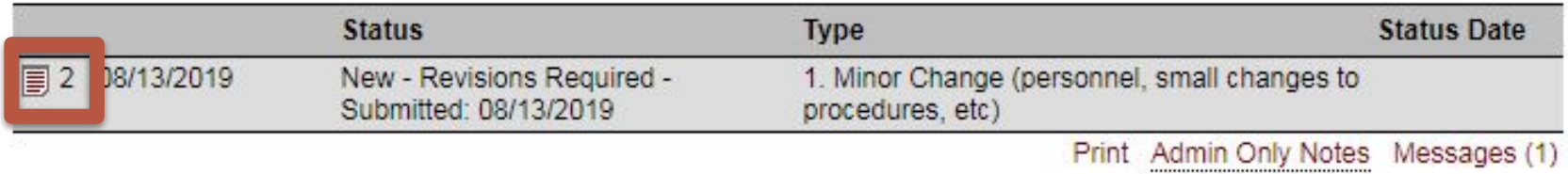
When submitting a protocol, please be sure to follow the submission directions.

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



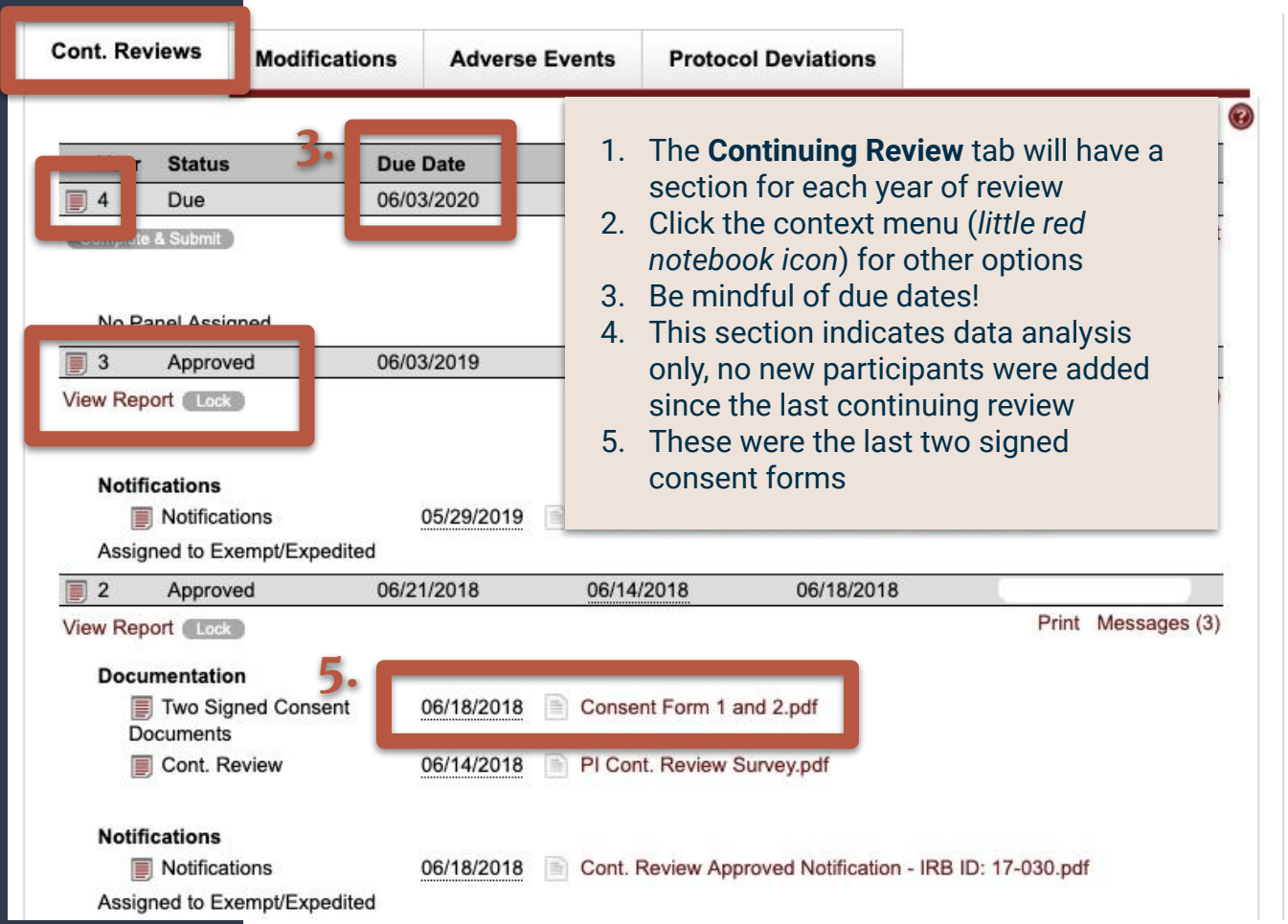
Submitting a Modification



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

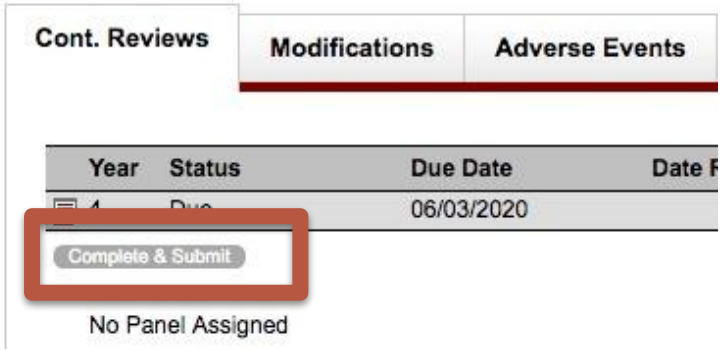
Revisions should be submitted to the current Modification record, using the Upload option on the appropriate file types listed on the Modification. You will find the Upload option on the **context menu** to the immediate left of each file type title. Please check the “Submit Revisions for Review” check box on the Modification record to submit your revisions. Email IRB@tc.edu when the response to revisions is submitted as the reviewer will not be notified when your response has been uploaded.

Navigating the Continuing Review

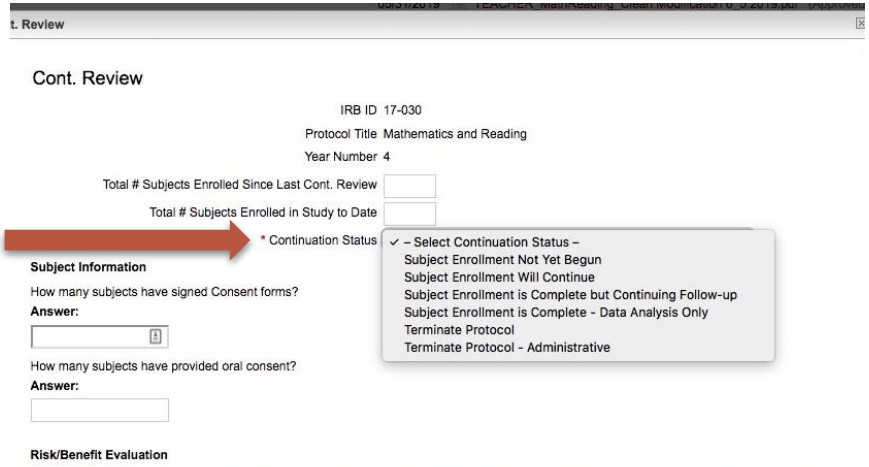


1. The **Continuing Review** tab will have a section for each year of review
2. Click the context menu (*little red notebook icon*) for other options
3. Be mindful of due dates!
4. This section indicates data analysis only, no new participants were added since the last continuing review
5. These were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

Submitting Continuing Review



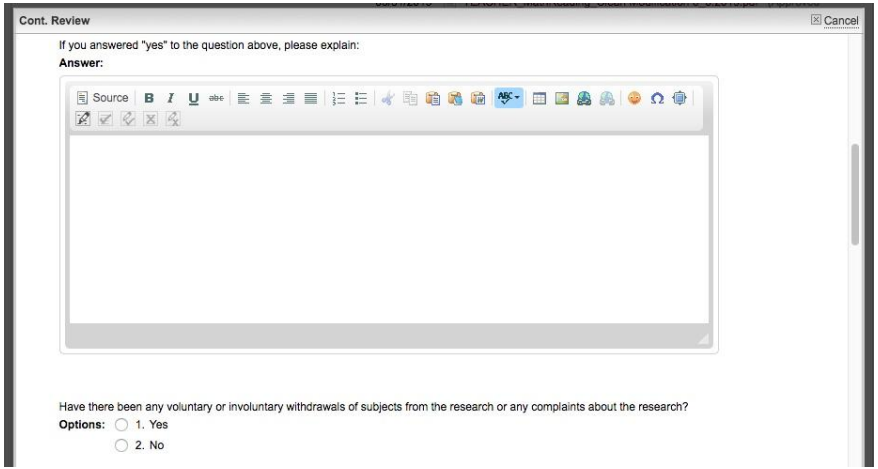
Once you are ready to submit a continuing review, click **Complete and Submit.**

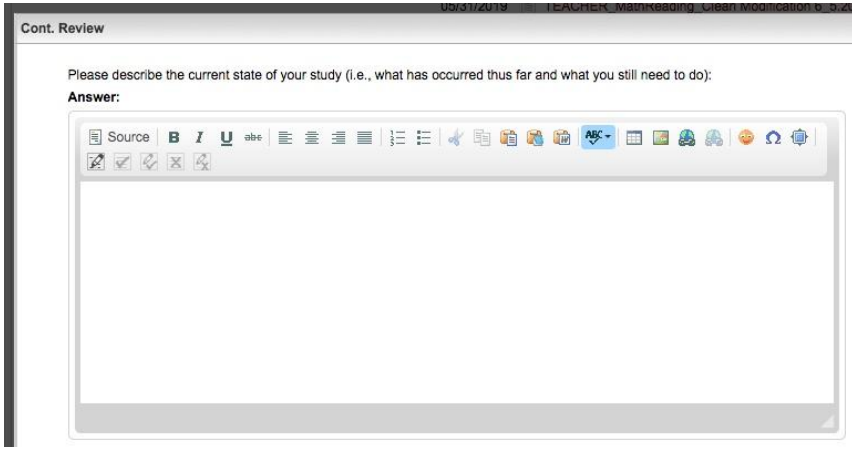


You will be prompted to complete the following questionnaire. Select the appropriate continuation status and fill out all relevant information. If you would like to terminate your protocol, select "**Terminate Protocol"** and visit https://www.tc.columbia.edu/institutional-review-board/how-to-submit/terminating-a-protocol/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

Submitting Continuing Review

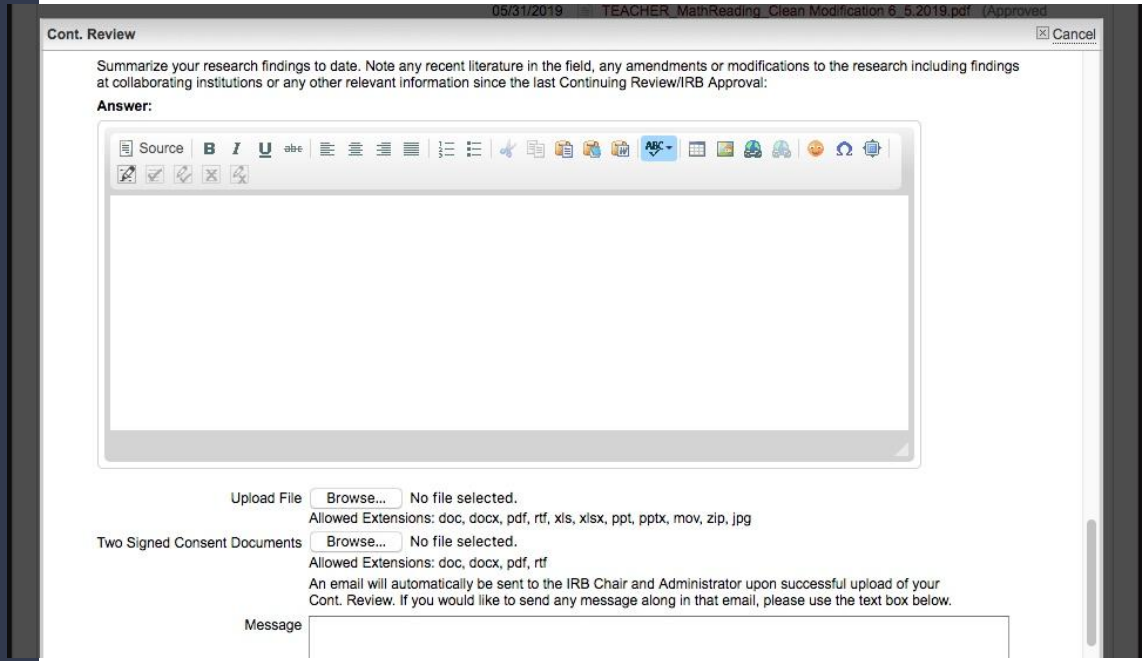
Continue filling out the questionnaire as it pertains to your study.



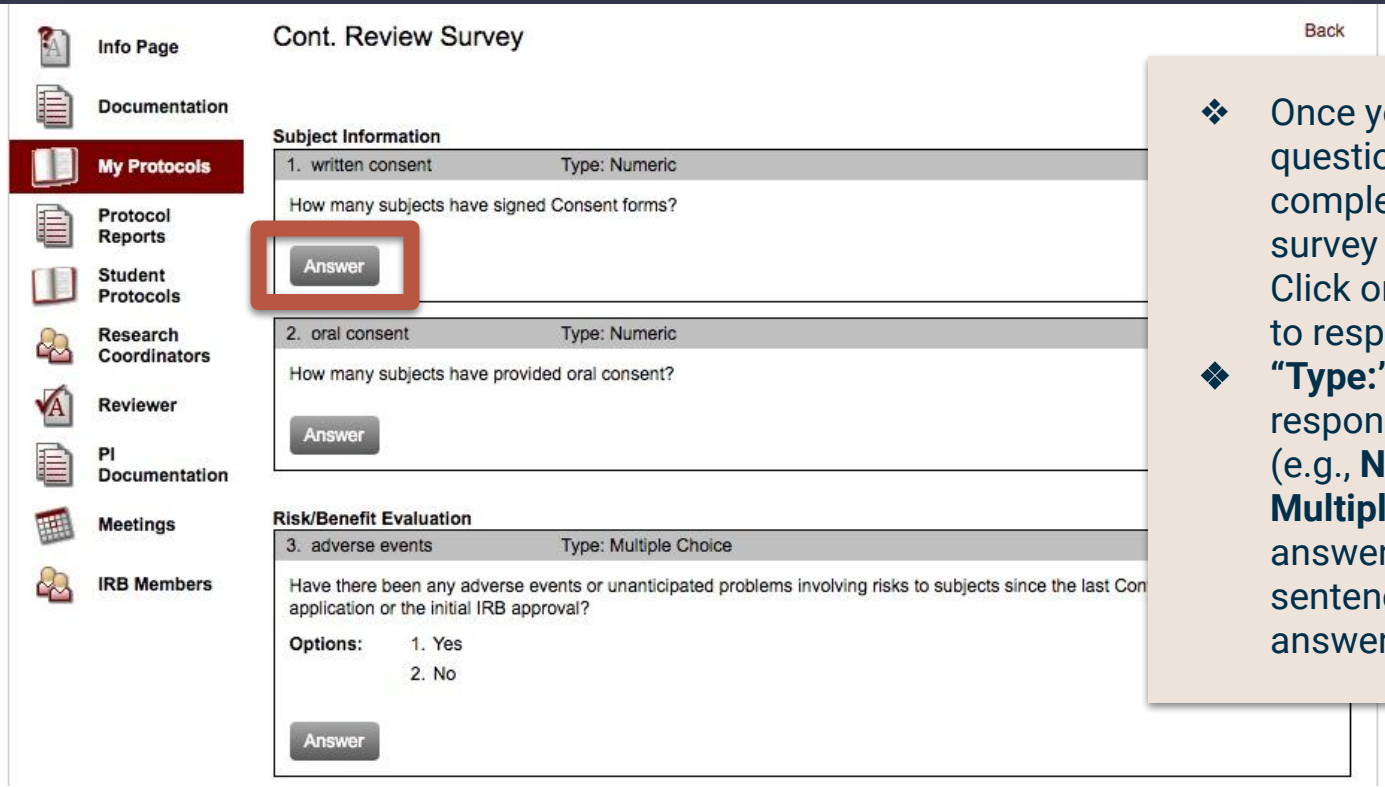


Submitting Continuing Review

- 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.

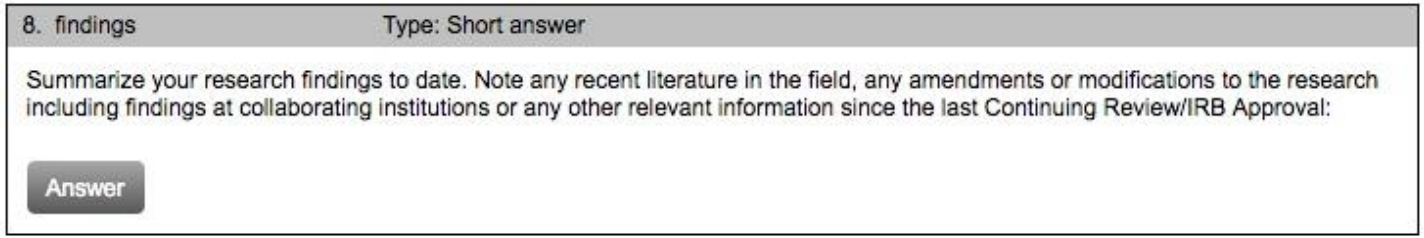


Submitting Continuing Review



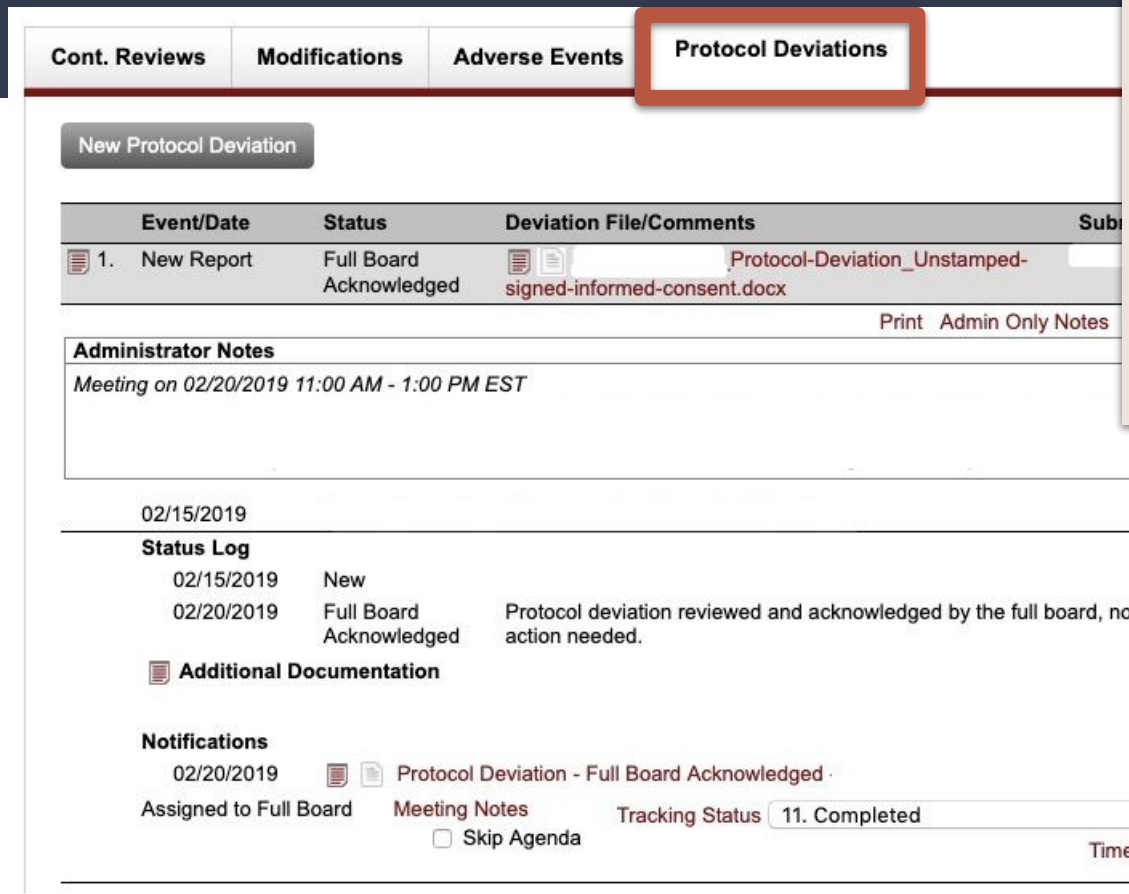
- Once you have finished the questionnaire, you will complete an 8 question survey about your research. Click on each **Answer** button to respond to each question.
- **"Type:"** indicates the response that should be given (e.g., **Numeric:** 1, 2 etc.; **Multiple Choice:** choose one answer; **Short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

Submitting Continuing Review



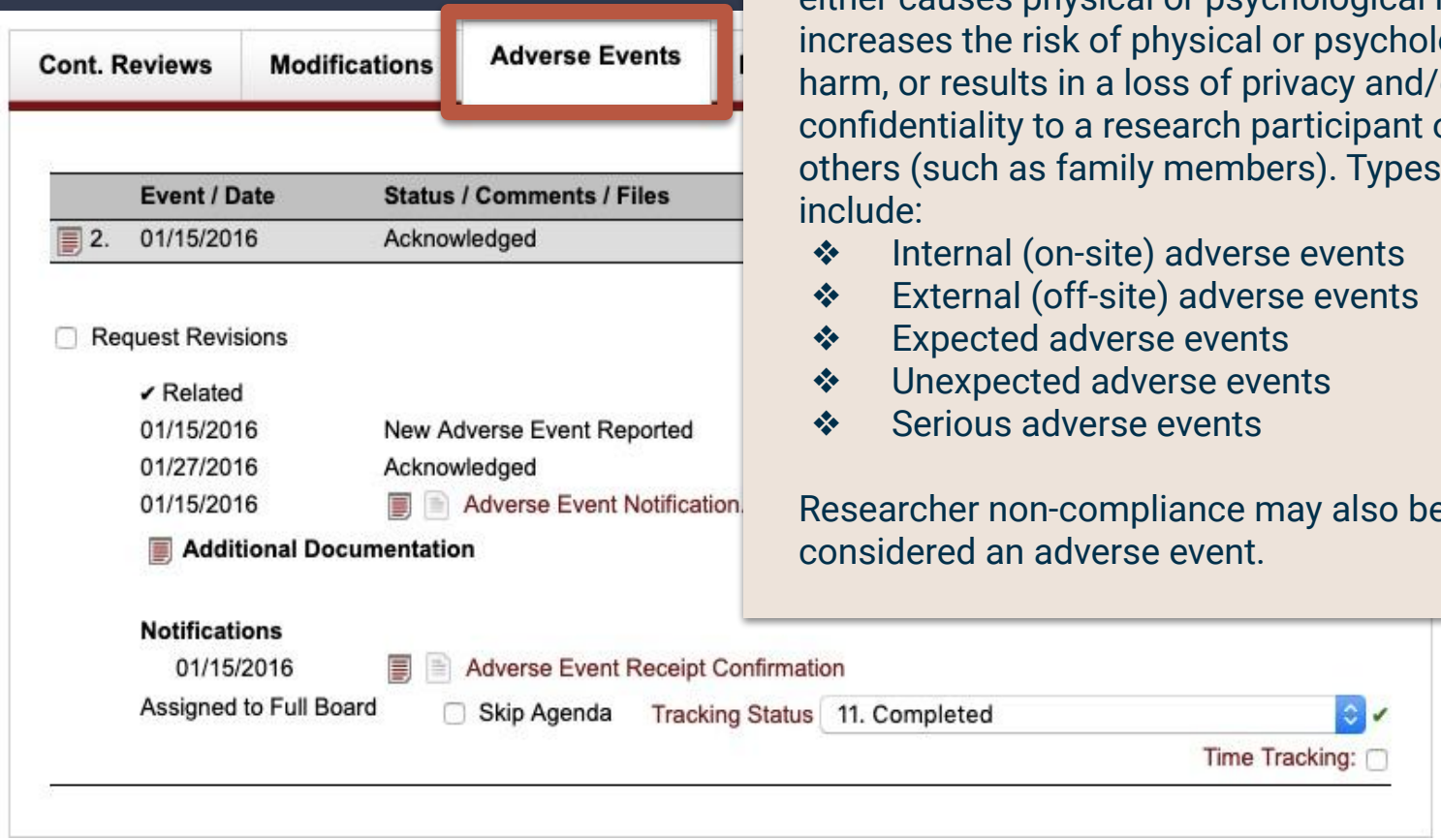
Once you have completed the questionnaire, your answers will be submitted to the IRB for review. Please allow 7-10 business days for review.

Protocol Deviation



A **Protocol Deviation** 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.

Adverse Events



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 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.