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 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
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 since last review.
5. These were the last two signed consent forms.

Select “Terminate,” rather than “Continue,” in the submission process to end a study.
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.
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.