How to Terminate an IRB Protocol

Teachers College Institutional Review Board, Columbia University
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).
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.
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.
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**.
Terminating a Protocol

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:

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:
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.
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.)

### Subject Information

<table>
<thead>
<tr>
<th>Question</th>
<th>Type</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. written consent</td>
<td>Numeric</td>
<td></td>
</tr>
<tr>
<td>How many subjects have signed Consent forms?</td>
<td></td>
<td></td>
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<tr>
<td>2. oral consent</td>
<td>Numeric</td>
<td></td>
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<tr>
<td>How many subjects have provided oral consent?</td>
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</table>

### Risk/Benefit Evaluation

<table>
<thead>
<tr>
<th>Question</th>
<th>Type</th>
<th>Options</th>
<th>Response</th>
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</thead>
<tbody>
<tr>
<td>3. adverse events</td>
<td>Multiple Choice</td>
<td>1. Yes</td>
<td></td>
</tr>
<tr>
<td>Have there been any adverse events or unanticipated problems involving risks to subjects since the last application or the initial IRB approval?</td>
<td></td>
<td>2. No</td>
<td></td>
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Terminating a Protocol

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.