**HOW-TO GUIDES: SCREEN-READER FRIENDLY**

This document houses Teachers College Institutional Review Board’s (TC IRB’s) How-To Guides in a screen-reader friendly format. To access the corresponding powerpoint slides, please visit tc.edu/irb. For questions or concerns, please reach out to [IRB@tc.edu](mailto:IRB@tc.edu).

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# How to Submit a New Protocol Using TC Mentor Institutional Review Board

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| Slide 1 |  | How to Submit a New Protocol Using TC Mentor Institutional Review Board |
| Slide 2 |  | Please navigate to <https://my.tc.columbia.edu/> and click the Faculty, Student, or Employee Resources tab. |
| Slide 3 |  | Navigate to the Mentor IRBbutton on the right-hand side of the screen.  Mentor IRB should open in a new page. |
| Slide 4 |  | 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. |
| Slide 5 |  | 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. |
| Slide 6 |  | **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 |
| Slide 7 |  | 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. |
| Slide 8 |  | 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.” |
| Slide 9 |  | 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 participant’s home, or in a public location, like a coffee shop. |
| Slide 10 |  | 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 IRB/Documentation.  Research conducted outside of the US is considered international research. |
| Slide 11 |  | **Categories that Require Full Review.**  Populations that typically require **Full Board Review** include adults not competent to consent, prisoners, pregnant women, and those who are 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. |
| Slide 12 |  | 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.” |
| Slide 13 |  | 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.  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. |
| Slide 14 |  | After completing the PI survey, you will upload the IRB Application ([available here](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/submitting-a-new-protocol/) or on Mentor IRB/Documentation) to “Upload Protocol Description.”  If working with human subjects, also upload a Consent Form.  Afteryou 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.  **For 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. |
| Slide 15 |  | 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.  **For 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.  **For 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.  **For faculty sponsors:** 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. |
| Slide 16 |  | 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](mailto:IRB@tc.edu).  Additionally, 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. |

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

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| Slide 1 |  | How to Submit an IRB Modification, Continuing Review, Protocol Deviation, and Adverse Event |
| Slide 2 |  | As the Principal Investigator (PI) of record for a 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. |
| Slide 3 |  | 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 are 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). |
| Slide 4 |  | Protocol Documentation, Continued.  **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 wellbeing, 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. |
| Slide 5 |  | Navigating to Your Protocol   * Please navigate to <https://my.tc.columbia.edu/> and click the **Faculty, Student, or Employee Resources** tab. |
| Slide 6 |  | Navigate to the **Mentor IRB** button on the right-hand side of the screen.  Mentor IRB should open in a new page. |
| Slide 7 |  | 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. |
| Slide 8 |  | 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. |
| Slide 9 |  | Submitting a Modification Continued.   * 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](mailto:IRB@tc.edu) when the response to revisions is submitted as the reviewer will not be notified when your response has been uploaded. |
| Slide 10 |  | Navigating the Continuing Review   * The **Continuing Review** tab will have a section for each year of review. * Click the context menu (*little red notebook icon*) for other options * Be mindful of due dates! * This section indicates data analysis only, no new participants were added since the last continuing review. * You should upload the last two signed consent forms. |
| Slide 11 |  | Submitting a 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. |
| Slide 12 |  | * Continue filling out the questionnaire as it pertains to your study. |
| Slide 13 |  | * 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. |
| Slide 14 |  | * 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. |
| Slide 15 |  | * Once you have completed the questionnaire, your answers will be submitted to the IRB for review. * Please allow 7-10 business days for review. |
| Slide 16 |  | Protocol Deviation   * **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 wellbeing, or the accuracy and reliability of the study data. |
| Slide 17 |  | 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. |
| Slide 18 |  | * 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. |

# How to Submit an IRB Modification for Studies Moved Online Due to COVID-19

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| Slide 1 |  | How to Submit an IRB Modification for Studies Moved Online Due to COVID-19  Teachers College, Columbia University |
| Slide 2 |  | Changes to Protocols Due to COVID-19   * Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. * Given the current COVID-19 coronavirus outbreak and the real or perceived risk of exposure, the risk/benefit ratio for research participation must be reassessed for each IRB protocol. * While pausing studies to minimize the risks of transmission of COVID-19 will often outweigh the harms to research programs, TC IRB will also consider possible harms to subjects should a study be paused or ceased. * Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. * Given the current COVID-19 coronavirus outbreak and the real or perceived risk of exposure, the risk/benefit ratio for research participation must be reassessed for each IRB protocol. * While pausing studies to minimize the risks of transmission of COVID-19 will often outweigh the harms to research programs, TC IRB will also consider possible harms to subjects should a study be paused or ceased. |
| Slide 3 |  | For protocols affected by COVID-19, researchers have several options available to them including:   * **Self-Determined Pause:** Researchers can choose to pause study activities at their discretion. * Pausing researcher work, does not require an IRB protocol submission. * **Study Activities Can be Moved Online:** In the event that all face-to-face study activities can be moved to online methods (e.g., conducting participant interviews via Skype or Zoom), PIs must submit a modification (details included on the next slide). * **Study Activities Cannot Be Moved Online:** In the event that online substitutes for face-to-face study activities are not practical or possible (e.g., administering of a drug trial), PIs can submit a modification with justification for continuing study activities in person. * **Some Methods Can Be Moved Online While Others Cannot:** In some cases, some study activities in a protocol may be transferred online, while other activities in the same protocol are not substitutable. * PIs must submit a modification designating a plan of action for all activities. * **TC IRB Determination:** Protocols are regularly reviewed by TC IRB on a case-by-case basis.   For those PIs who do not self-select to change their study activities to accommodate evolving COVID-19 conditions, TC IRB reserves the right to assess study activities for the protection of participants.   * In these circumstances, TC IRB will contact the PI’s directly about next steps. * “COVID-19-specific” modification guides are available at: https://www.tc.columbia.edu/institutional-review-board/updates/ |
| Slide 4 |  | Due to the spread of COVID-19, some research sites may have been shut down. In some cases, researchers may be able to move all face-to-face contact with research subjects online (e.g. Zoom or Skype interview). In these cases, researchers should submit a modification through TC Mentor IRB. If you are making these study changes due to COVID-19, submit a “COVID-19-specific” modification.  Once the “COVID-19-specific” modification has been submitted, researchers can immediately begin online study activities. TC IRB will review all modifications and send out acknowledgement letters. However, researchers do not need to wait for an acknowledgement letter before beginning online study activities. Researchers can begin online study activities before receiving this letter.  For all typical “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities. The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”) https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/ |
| Slide 5 |  | Navigating to Your Protocol  Please navigate to <https://my.tc.columbia.edu/> and click the **Faculty, Student, or Employee Resources** tab. |
| Slide 6 |  | Navigate to the **Mentor IRB** button on the right-hand side of the screen.  Mentor IRB should open in a new page. |
| Slide 7 |  | 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. |
| Slide 8 |  | Submitting a COVID-19 Modification   * To view modifications, scroll down to the bottom of your protocol and you will see a **Modification** tab. * Once in the tab, you can **Create a New Modification.**   When submitting a protocol, please be sure to follow the submission directions. |
| Slide 9 |  | For studies that cannot be moved online, please choose the first checkbox, **My Study Methods Cannot be Moved Online for Covid-19.**  Then click **Create Modification.** |
| Slide 10 |  | * You will be taken back to the **Modifications** tab. * Scroll down until you see the latest modification titled, “Moving to Online Methods in Response to Covid-19.” * PIs must fill out both the **Moving Study Online Questions** and the **Study Cannot be Moved Online or Paused Questions.** * Click on the first link to be taken to the survey. |
| Slide 11 |  | The link will take you to a short questionnaire. Please click on the **Add/Edit Answers** box and answer each question. |
| Slide 12 |  | * Once you are satisfied with your answers, click **Save Answer.** * You will be taken to the screen below. Click **Return to Protocol Page.** |
| Slide 13 |  | * You will be taken back to the **Modifications** tab. * Scroll down until you see the latest modification titled “Moving to Online Methods in Response to Covid-19.” * All modifications must be submitted with a Modification Memo. Click the red notebook icon to **Upload a Memo.** * The Modification Memo Template can be downloaded from Mentor IRB/Documentation/ 18\_Modification Memo Template |
| Slide 14 |  | Moving Face-to-Face Study Activities to Online Methods in Response to COVID-19: Once you have uploaded a “COVID-19-Specific” Modification, you may begin online study activities. You do not have to wait to receive an acknowledgement letter before beginning online study activities.  If you receive a Request for Revisions from an IRB reviewer, submit the revisions (along with the Request for Revisions Memo Template) 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” checkbox 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. |
| Slide 15 |  | For all **typical** “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities.  The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”) <https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/> |
| Slide 16 |  | Responsibilities of the Primary Investigator  As the PI of record for a 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. |
| Slide 17 |  | 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. |

# How to Submit an IRB Modification for Studies that Cannot be Paused and Only Some Activities Can Be Moved Online

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| Slide 1 |  | How to Submit an IRB Modification for Studies that Cannot be Paused and Only Some Activities Can Be Moved Online |
| Slide 2 |  | Changes to Protocols Due to COVID-19   * Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. * Given the current COVID-19 coronavirus outbreak and the real or perceived risk of exposure, the risk/benefit ratio for research participation must be reassessed for each IRB protocol. * While pausing studies to minimize the risks of transmission of COVID-19 will often outweigh the harms to research programs, TC IRB will also consider possible harms to subjects should a study be paused or ceased. |
| Slide 3 |  | For protocols affected by COVID-19, researchers have several options available to them including:   * **Self-Determined Pause:** Researchers can choose to pause study activities at their discretion. * Pausing researcher work, does not require an IRB protocol submission. * **Study Activities Can be Moved Online:** In the event that all face-to-face study activities can be moved to online methods (e.g., conducting participant interviews via Skype or Zoom), PIs must submit a modification (details included on the next slide). * **Study Activities Cannot Be Moved Online:** In the event that online substitutes for face-to-face study activities are not practical or possible (e.g., administering of a drug trial), PIs can submit a modification with justification for continuing study activities in person. * **Some Methods Can Be Moved Online While Others Cannot:** In some cases, some study activities in a protocol may be transferred online, while other activities in the same protocol are not substitutable. * PIs must submit a modification designating a plan of action for all activities. * **TC IRB Determination:** Protocols are regularly reviewed by TC IRB on a case-by-case basis.   For those PIs who do not self-select to change their study activities to accommodate evolving COVID-19 conditions, TC IRB reserves the right to assess study activities for the protection of participants.   * In these circumstances, TC IRB will contact the PI’s directly about next steps. * “COVID-19-specific” modification guides are available at: https://www.tc.columbia.edu/institutional-review-board/updates/ |
| Slide 4 |  | Moving Only Some (*not all*) Face-to-Face Study Activities to Online Methods in Response to COVID-19   * Due to the spread of COVID-19, some research sites may have been shut down. * In some cases, researchers may only be able to move part of their face-to-face contact with research subjects online (e.g. Zoom or Skype interview) while the rest of the activities must be continued in person (e.g., participants receiving cancer treatments as a drug trial). * **If you are making these study changes due to COVID-19, submit a “COVID-19-specific” modification.** * Researchers who are **unable** **to move all** face-to-face contacts to online platforms must submit a “COVID-19-specific” modification with a plan of action detailing which activities will be moved online, and which ones will stay in person. * Once the modification has been submitted, **researchers must wait for an acknowledgement letter before they can continue with the in-person study activities.** * For all typical “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities.   The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”) <https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/> |
| Slide 5 |  | Navigating to Your Protocol  Please navigate to <https://my.tc.columbia.edu/> and click the **Faculty, Student, or Employee Resources** tab. |
| Slide 6 |  | Navigate to the **Mentor IRB** button on the right-hand side of the screen.  Mentor IRB should open in a new page. |
| Slide 7 |  | 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. |
| Slide 8 |  | Submitting a COVID-19 Modification   * To view modifications, scroll down to the bottom of your protocol and you will see a **Modification** tab. * Once in the tab, you can **Create a New Modification.** * When submitting a protocol, please be sure to follow the submission directions. |
| Slide 9 |  | For study activities that cannot be moved fully online, please chose the first checkbox, **Moving to Online Methods in Response to Covid-19** AND the second checkbox, **My Study Methods Cannot be Moved Online for Covid-19.** Then click **Create Modification.**  These two selections signal to reviewers that some (not all) of your study activities will be online. **Reviewers will focus on risk assessment for the in-person activities.** |
| Slide 10 |  | You will be taken back to the **Modifications** tab.  Scroll down until you see the latest modification titled, “Moving to Online Methods in Response to Covid-19.”  PIs must fill out both the **Moving Study Online Questions** and the **Study Cannot be Moved Online or Paused Questions.**  Click on the first link to be taken to the survey. |
| Slide 11 |  | The **Moving Study Online Questions** link will take you to a short questionnaire.  Please click on the **Add/Edit Answers** box and answer each question. |
| Slide 12 |  | Once you are satisfied with your answers, click **Save Answer.**  You will be taken to the screen below. Click **Return to Protocol Page.** |
| Slide 13 |  | You will be taken back to the **Modifications** tab.  Scroll down until you see the latest modification titled “Moving to Online Methods in Response to Covid-19.”  Complete the second survey, **Study Cannot be Moved Online or Paused Questions.** |
| Slide 14 |  | The link will take you to a short questionnaire.  Please click on the **Answer** box to indicate which options apply to your study. |
| Slide 15 |  | Mark the appropriate option(s).  Make sure to explain your selection(s) in the answer box.  Researchers who mark the first option must explain how pausing the study will harm participants.  Once you are satisfied with you answer, click **Save Answer.**  You will be directed to **Return to Protocol Page,** where you can then upload a modification memo. |
| Slide 16 |  | Researchers who choose the second option OR a combination of both the first and second option will need to complete a second short answer explaining benefits to participants.  Once you are satisfied with you answers, click **Save Answer.**  You will be directed to **Return to Protocol Page,** where you can then upload a modification memo. |
| Slide 17 |  | You will be taken back to the **Modifications** tab.   * Scroll down until you see the latest modification titled, “Moving to Online Methods in Response to Covid-19.” * All modifications must be submitted with a Modification Memo. * Click the red notebook icon to **Upload** a Memo. * **Your memo must detail which study activities are being moved online, and which ones will be continued in person.** * The Modification Memo Template can be downloaded from Mentor IRB/Documentation/ 18\_Modification Memo Template. |
| Slide 18 |  | Changing Some (*not all*) Study Activities in Light of COVID-19 for: **Once you have uploaded a “COVID-19-Specific” Modification, TC IRB will review your study on a case-by-case basis.** Researchers must receive an acknowledgement letter before continuing with study activities.  If you receive a Request for Revisions from an IRB reviewer, submit the revisions (along with the Request for Revisions Memo Template) 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” checkbox** on the Modification record to submit your revisions. * Email [IRB@tc.edu](mailto:IRB@tc.edu) when the response to revisions is submitted as the reviewer will not be notified when your response has been uploaded. |
| Slide 19 |  | For all **typical** “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities.  The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”) <https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/> |
| Slide 20 |  | As the PI of record for a 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. |
| Slide 21 |  | 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. |

# How to Submit an IRB Modification for Studies Affected by COVID-19 that Cannot be Moved Online

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| Slide 1 |  | How to Submit an IRB Modification for Studies Affected by COVID-19 that Cannot be Moved Online |
| Slide 2 |  | Changes to Protocols Due to COVID-19   * Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. * Given the current COVID-19 coronavirus outbreak and the real or perceived risk of exposure, the risk/benefit ratio for research participation must be reassessed for each IRB protocol. * While pausing studies to minimize the risks of transmission of COVID-19 will often outweigh the harms to research programs, TC IRB will also consider possible harms to subjects should a study be paused or ceased. |
| Slide 3 |  | For protocols affected by COVID-19, researchers have several options available to them including:   * **Self-Determined Pause:** Researchers can choose to pause study activities at their discretion. * Pausing researcher work, does not require an IRB protocol submission. * **Study Activities Cannot Be Moved Online:** In the event that online substitutes for face-to-face study activities are not practical or possible (e.g., administering of a drug trial), PIs can submit a modification with justification for continuing study activities in person (details included on the next slide). * **Study Activities Can be Moved Online:** In the event that all face-to-face study activities can be moved to online methods (e.g., conducting participant interviews via Skype or Zoom), PIs must submit a modification. * **Some Methods Can Be Moved Online While Others Cannot:** In some cases, some study activities in a protocol may be transferred online, while other activities in the same protocol are not substitutable. * PIs must submit a modification designating a plan of action for all activities. * **TC IRB Determination:** Protocols are regularly reviewed by TC IRB on a case-by-case basis. * For those PIs who do not self-select to change their study activities to accommodate evolving COVID-19 conditions, TC IRB reserves the right to assess study activities for the protection participants. * In these circumstances, TC IRB will contact the PI’s directly about next steps. * “COVID-19-specific” modification guides are available at: https://www.tc.columbia.edu/institutional-review-board/updates/ |
| Slide 4 |  | Continuing Face-to-Face Study Activities in Light of COVID-19   * Due to the spread of COVID-19, some research sites may have been shut down. * In some cases, researchers may be able to move all face-to-face contact with research subjects online (e.g. Zoom or Skype interview). * In other cases, the study procedures will be such that online substitutes are not practical or even possible (e.g., participants receiving cancer treatments as a drug trial). * **If you are making these study changes due to COVID-19, submit a “COVID-19-specific” modification.** * Researchers who are **unable** to move face-to-face contacts to online platforms must submit a “COVID-19-specific” modification. * Once the modification has been submitted, **researchers must wait for an acknowledgement letter before they can continue with study activities in-person.** * For all typical “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities. * The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”) <https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/> |
| Slide 5 |  | Navigating to Your Protocol   * Please navigate to <https://my.tc.columbia.edu/> and click the **Faculty, Student, or Employee Resources** tab. |
| Slide 6 |  | * Navigate to the **Mentor IRB** button on the right-hand side of the screen. * Mentor IRB should open in a new page. |
| Slide 7 |  | 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. |
| Slide 8 |  | Submitting a COVID-19 Modification   * To view modifications, scroll down to the bottom of your protocol and you will see a **Modification** tab. * Once in the tab, you can **Create a New Modification.** * When submitting a protocol, please be sure to follow the submission directions. |
| Slide 9 |  | * For studies that cannot be moved online, please choose the first checkbox, **My Study Methods Cannot be Moved Online for Covid-19.** * Then click **Create Modification.** |
| Slide 10 |  | * You will be taken back to the **Modifications** tab. * Scroll down until you see the latest modification titled, “My Study Methods Cannot be Moved Online for Covid-19.” * PIs must fill out the **Study Cannot be Moved Online or Paused Questions.** * Click on the link to be taken to the survey. |
| Slide 11 |  | * The link will take you to a short questionnaire. * Please click on the **Answer** box to indicate which options apply to your study. |
| Slide 12 |  | * Mark the appropriate option(s). Make sure to explain your selection(s) in the answer box. * Researchers who mark the first option must explain how pausing the study will harm participants. * Once you are satisfied with you answer, click **Save Answer.** * You will be directed to **Return to Protocol Page,** where you can then upload a modification memo. |
| Slide 13 |  | * Researchers who choose the second option OR a combination of both the first and second option will need to complete a second short answer. * Once you are satisfied with you answers, click **Save Answer.** * You will be directed to **Return to Protocol Page,** where you can then upload a modification memo. |
| Slide 14 |  | * You will be taken back to the **Modifications** tab. * Scroll down until you see the latest modification titled, “My Study Methods Cannot be Moved Online for Covid-19.” * All modifications must be submitted with a Modification Memo. * Click the red notebook icon to **Upload** a Memo. * The Modification Memo Template can be downloaded from Mentor IRB/Documentation/ 18\_Modification Memo Template |
| Slide 15 |  | Continuing Face-to-Face Study Activities in Light of the COVID-19: **Once you have uploaded a “COVID-19-Specific” Modification, TC IRB will review your study on a case-by-case basis.** **Researchers must receive an acknowledgement letter before continuing with study activities.**   * If you receive a Request for Revisions from an IRB reviewer, submit the revisions (along with the Request for Revisions Memo Template) 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](mailto:IRB@tc.edu) when the response to revisions is submitted as the reviewer will not be notified when your response has been uploaded. |
| Slide 16 |  | For Typical Modifications (*not related to Covid-19*)   * For all **typical** “non-COVID-19-specific” modifications, researchers must wait for approval from TC IRB before beginning study activities. * The link below will guide you to the typical modification submission process (i.e., “non-COVID-19-specific”) <https://www.tc.columbia.edu/institutional-review-board/how-to-submit/modification/> |
| Slide 17 |  | 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. |
| Slide 18 |  | 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. |

# How to Terminate an IRB Protocol

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| Slide 1 |  | How to Terminate an IRB Protocol |
| Slide 2 |  | 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). |
| Slide 3 |  | Navigating to Your Protocol   * Please navigate to <https://my.tc.columbia.edu/> and click the **Faculty, Student, or Employee Resources** tab. |
| Slide 4 |  | * Navigate to the **Mentor IRB** button on the right-hand side of the screen. * Mentor IRB should open in a new page. |
| Slide 5 |  | * Navigate to **My Protocols** found on the left-hand sidebar of TC Mentor IRB. * Choose the study you would like to terminate. |
| Slide 6 |  | * 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.** |
| Slide 7 |  | 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. |
| Slide 8 |  | * Continue filling out the questionnaire as it pertains to your study. |
| Slide 9 |  | * 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. |
| Slide 10 |  | * 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. |
| Slide 11 |  | * Once you have completed the questionnaire, your answers will be submitted to the IRB for review. * Please allow 7-10 business days for review. |
| Slide 12 |  | 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. |
| Slide 13 |  | 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. |
| Slide 14 |  | 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. |