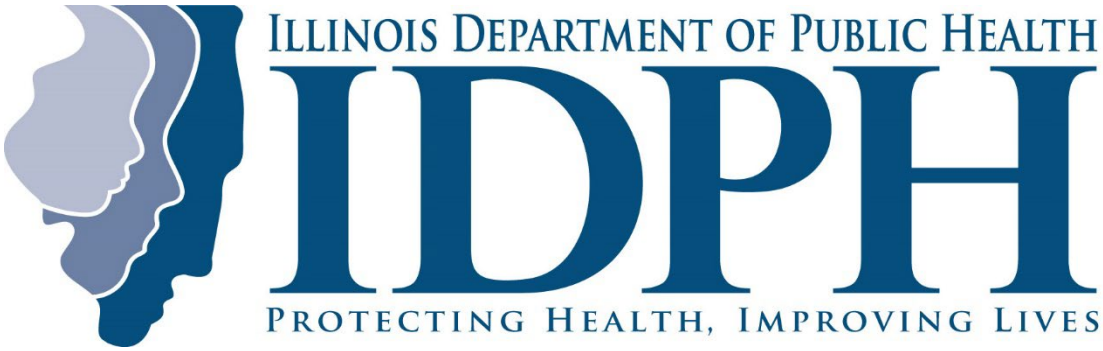


Institutional Review Board

EXTERNAL INVESTIGATOR MANUAL

TABLE OF CONTENTS

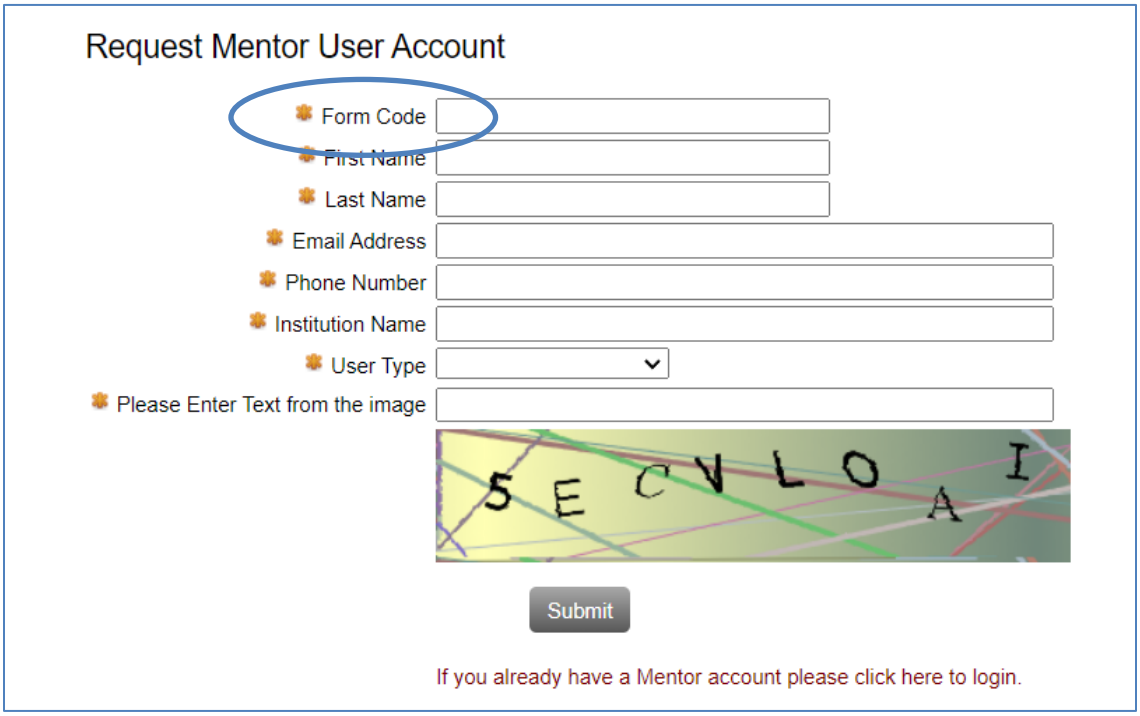
INTRODUCTION

The User Manual contains the essential information to use Sitero Mentor fully, including a description of the system functions and capabilities, contingencies and alternate modes of operation, and step-by-step procedures for system access and use.

Before submitting a study to the Illinois Department of Public Health (IDPH) Institutional Review Board (IRB), you must identify and talk to the person at IDPH responsible for the data you hope to receive (the Responsible Individual). This allows you to be certain the data you want are available and the Responsible Individual will be able to let you know the strengths and limitations of the data, changes in collection methods, and other characteristics that may impact your study. A list of Responsible Individuals is provided on the IDPH IRB website and also within Sitero Mentor, under Resources. If you cannot determine whom to contact, email dph.IRB@illinois.gov.

HOW TO OBTAIN ACCESS TO SITERO MENTOR

To submit an IRB application to the IDPH IRB, you will need to have access to the Sitero Mentor system. If you do not already have an account with IDPH Sitero Mentor, request a Form Code from the Responsible Individual or IRB administrative staff. You will use the Form Code to register at www.AxiomMentor.us/ILdph/NewAccount.



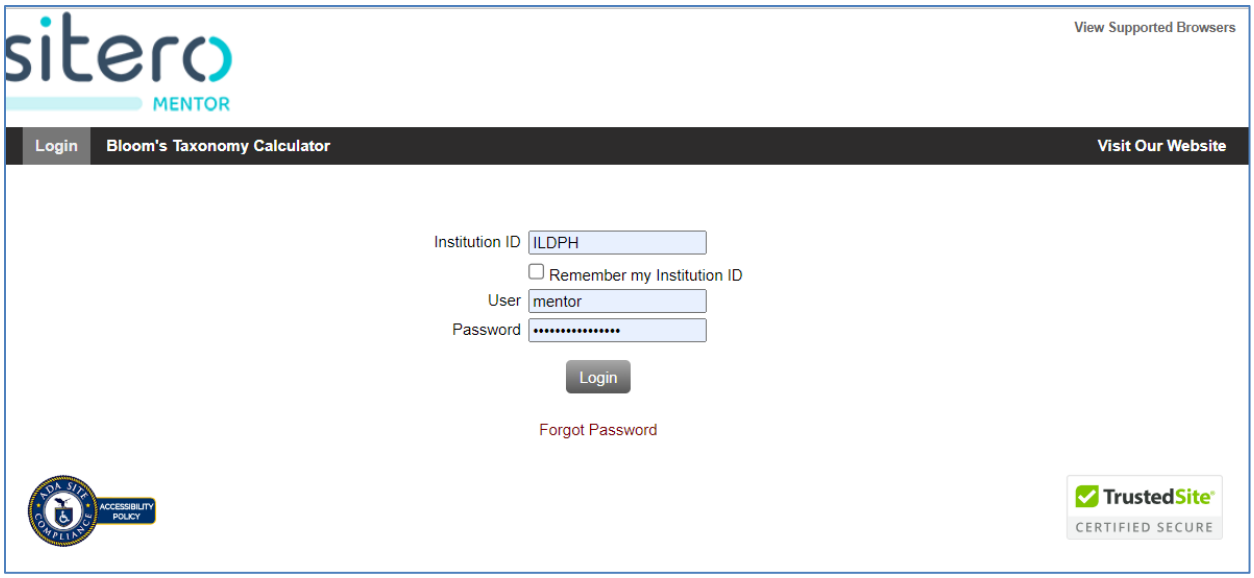
Once registered, an email will prompt you to reset your password. You will not be able to log into the system, however, until you receive notification that your account has been approved.

Make sure everyone involved with your study and who will have access to contact with subjects or identifiable records is also registered with the IDPH IRB. This includes consultants, contractors, sub-contractors, data processing vendors, laboratories, and sponsoring or participating agencies or organizations. Add information for each person yourself or share the web link and Form Code with each person.

HOW TO LOGIN TO SITERO MENTOR

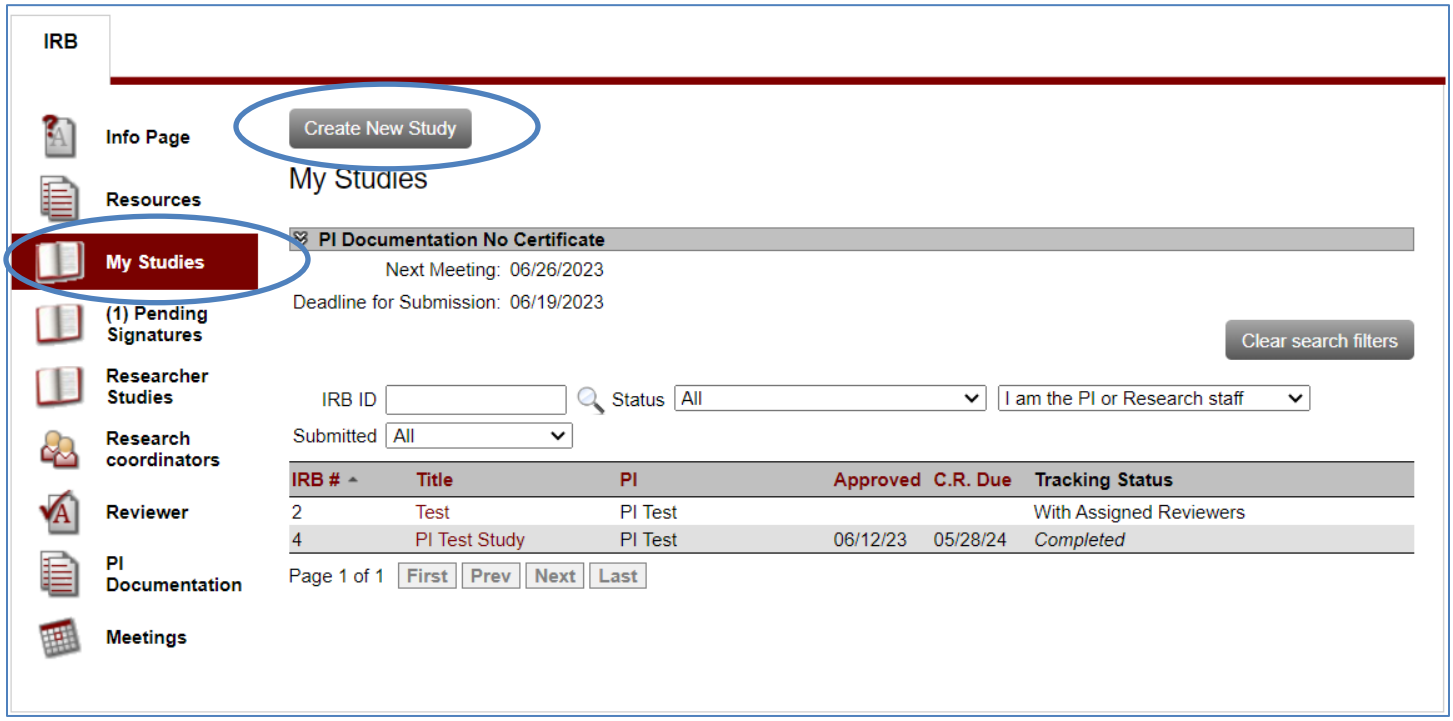
Open your browser and go to [www.AxiomMentor.us.](http://www.AxiomMentor.us)

Enter your Institution ID (**ILDPH)**, Username, and Password. Select Login.

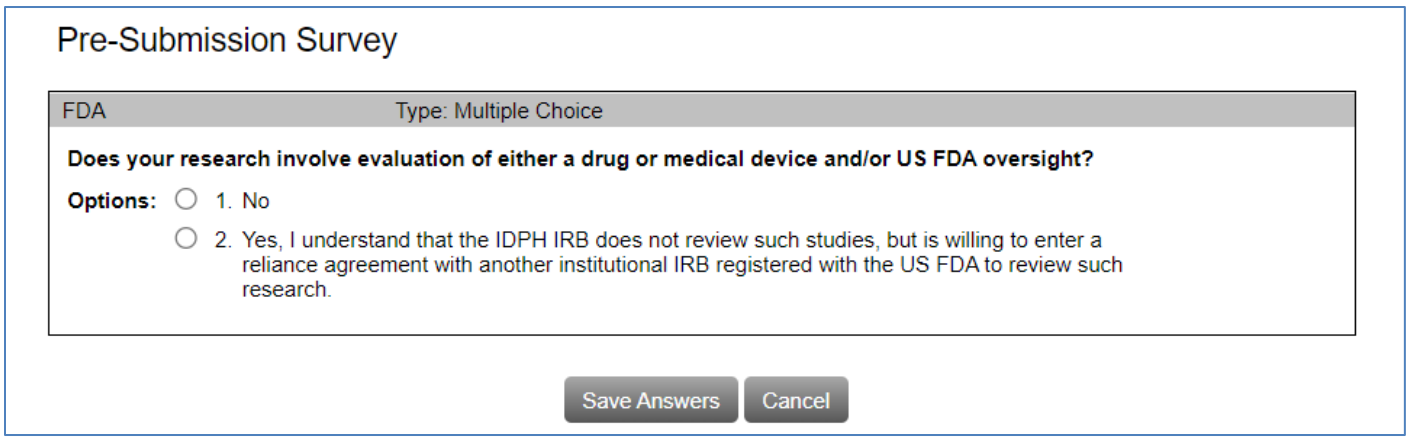


HOW TO SUBMIT A NEW STUDY

To submit a new study, click on the My Studies item on the left navigation menu on the IRB tab. Then select the “Create New Study” button.



The Pre-Submission Survey will appear and will help determine the review type needed for your study. The IRB may still select a different review type based on federal regulations and local policy and procedures.

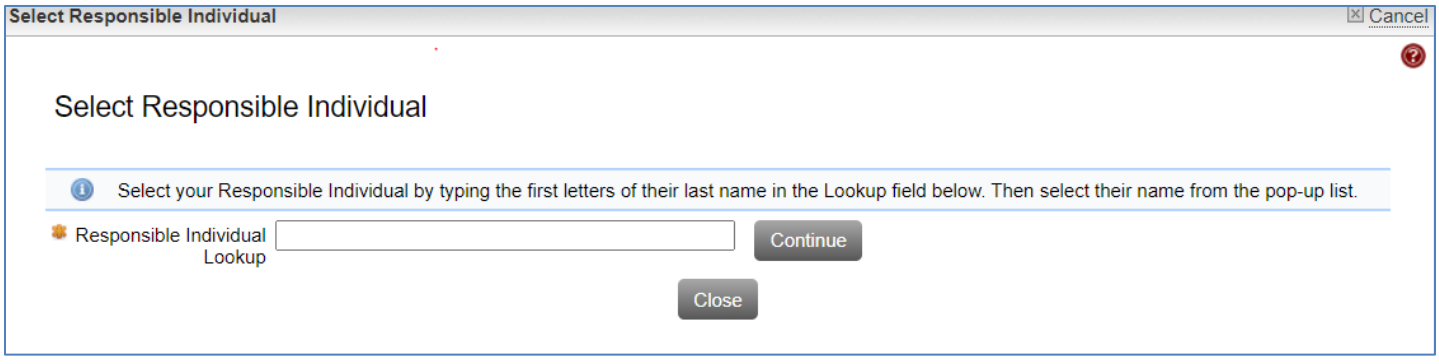


Once the survey has been completed, you will have determined that:

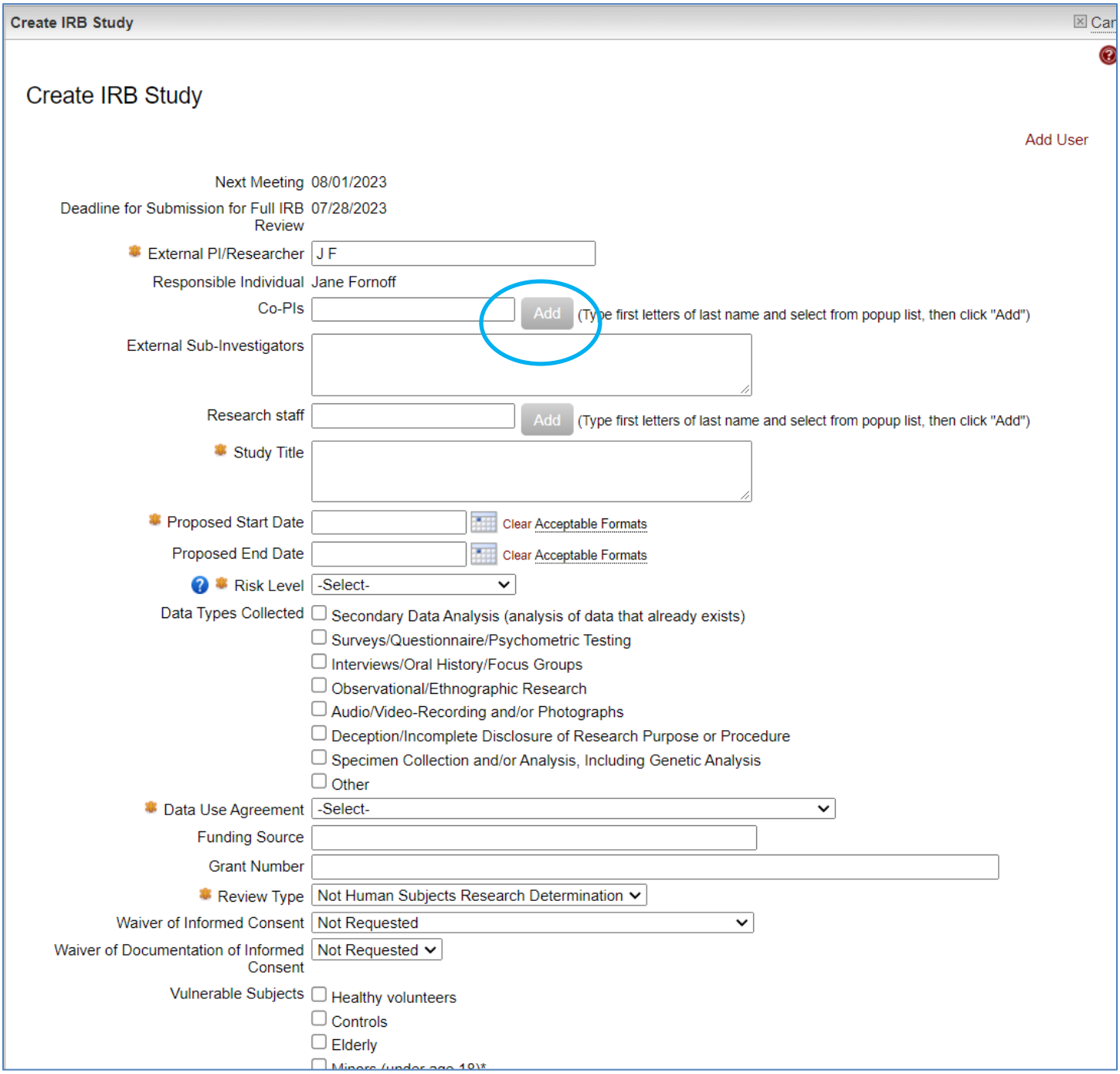
1) Your study needs IRB review > Complete the application
2) Your study does not need IRB review > Do not complete the application
3) You are still not sure > Discuss with IRB (dph.IRB@illinois.gov)

If you choose to complete the application, the first page will prompt you to select the Responsible Individual (RI). Type in the first letters of the RI's last name. A list will pop up below the text input box as you type. Continue typing to narrow the list down and select the desired name from the list. Once you have selected the RI, click on Continue.
Note: You must select the name from the popup list. Typing the name in the text box will not work.

Hopefully, you identified and talked to this person who is responsible for the data you want to receive. If not, select Close and talk to the RI before submitting your application. This will allow you to make sure the data you want are available. The RI will be able to let you know the strengths and limitations of the data, changes in collection methods, and other characteristics that may impact your study. A list of Responsible Individuals is provided on the IDPH IRB website and also within Sitero Mentor under Resources. If you cannot determine whom you need to contact, email dph.IRB@illinois.gov.



Once the Responsible Individual has been selected, the contents of the Create IRB Study screen will appear. Complete this form; the starred items are required. Keep in mind the study can always be edited at any time before submission to the IRB.



Note the fields that have the "Add" buttons; they are used to find the names of everyone involved with your study and who will have access to contact with subjects or access to identifiable records, including consultants, contractors, sub-contractors, data processing vendors, laboratories, and sponsoring or participating agencies or organizations. This will allow you and the IRB to assure their human subjects training is current for the duration of your study. If individuals are not already registered with the IDPH IRB, you can register them yourself or share the web link and Form Code with each person.

Add each person by typing in the first letters of the person's last name. A list will pop up below the text input box as you type. Continue typing to narrow the list down and select the desired name from the list.
Note: You must select the name from the popup list. Typing in the name in the text box will not work.

After selecting the name, click the Add button. The name will appear below the box and you can add additional names as needed. If you select the wrong name, click the "x" to the left of the name and the name will be removed.

Once the fields on the Create IRB Study form are completed, select save and you will be brought to the View Study Page.

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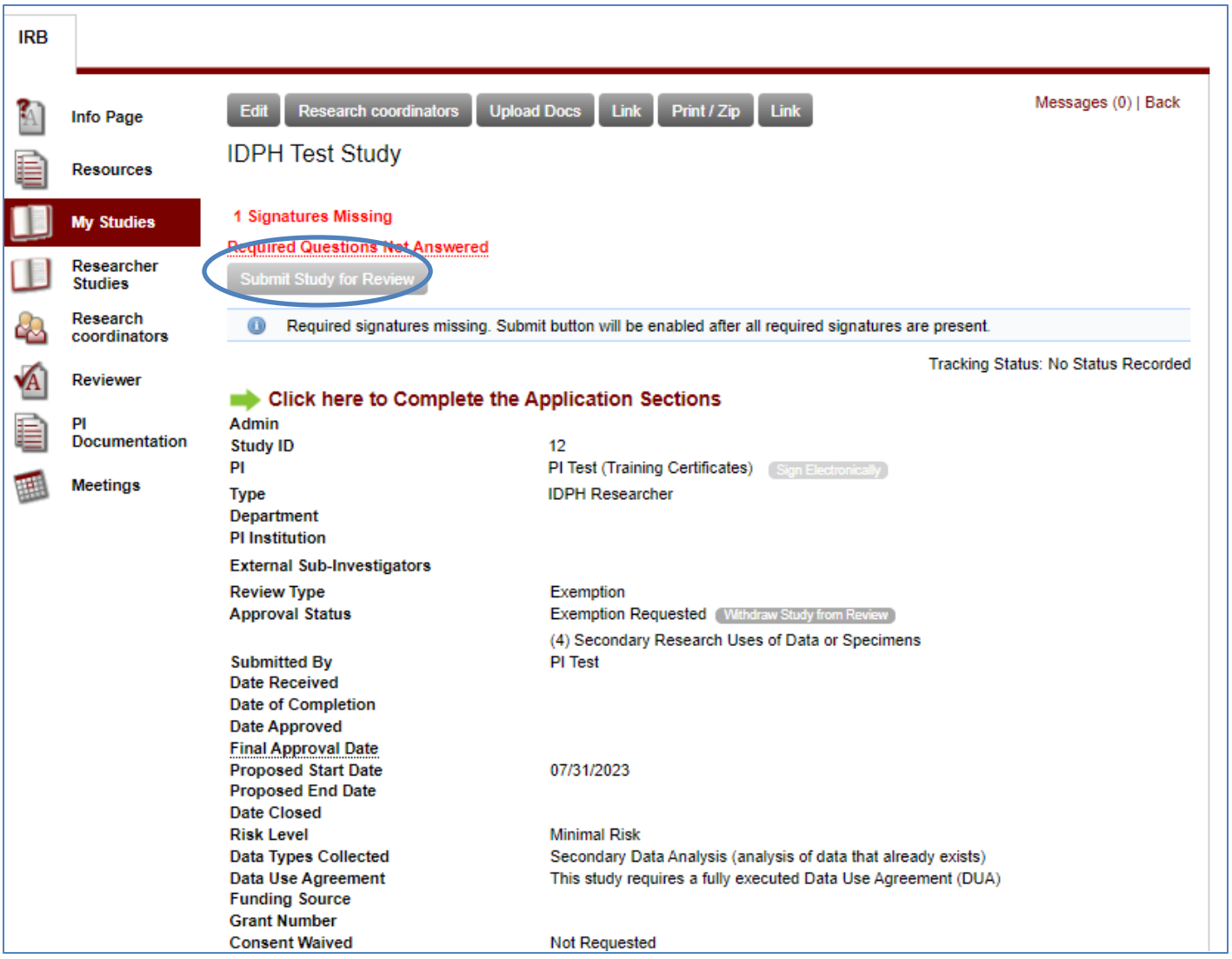


Be aware you will be required to upload some documents for your application before you can submit. Depending on your study, these may include:

PI and co-PI resumes
Study design and analysis plan
Application from any external IRB(s)
Approved forms and consents from any external IRB(s)
Decision documents from any external IRB(s)
Certificate of Confidentiality
List of variables and years requested for each IDPH data source
Data collection instruments (surveys/questionnaires)
Diagram or flow chart of any planned linkages
Letters of agreement from institutions or programs whose data will be linked with IDPH datasets
Contact protocols, letters, and scripts
Non-established surveys, questionnaires, or psychometric tests
Translations of any study materials

If there are other documents you would like to upload, click on the Upload Docs button.

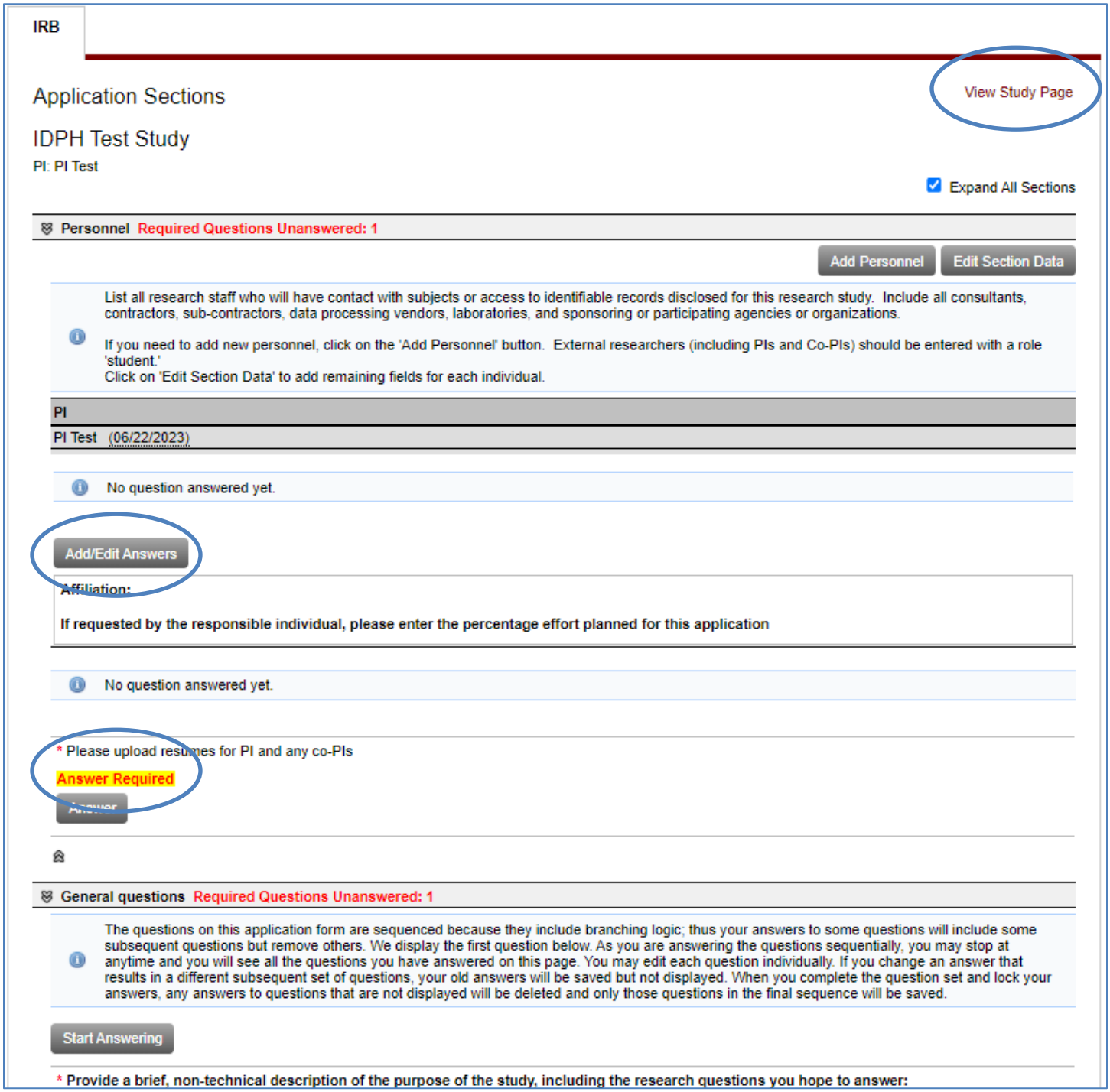
Note the "Submit Study for Review" button. If you see this button, then your study has not been formally submitted to the IRB. This will be done by the Responsible Individual when you are ready. Your study is visible to the IRB, the chair, and the administrator, so if you have questions and would like them to review it before submission, they will be able to see the study and any uploaded files.

To continue with your application, select the sentence that reads:

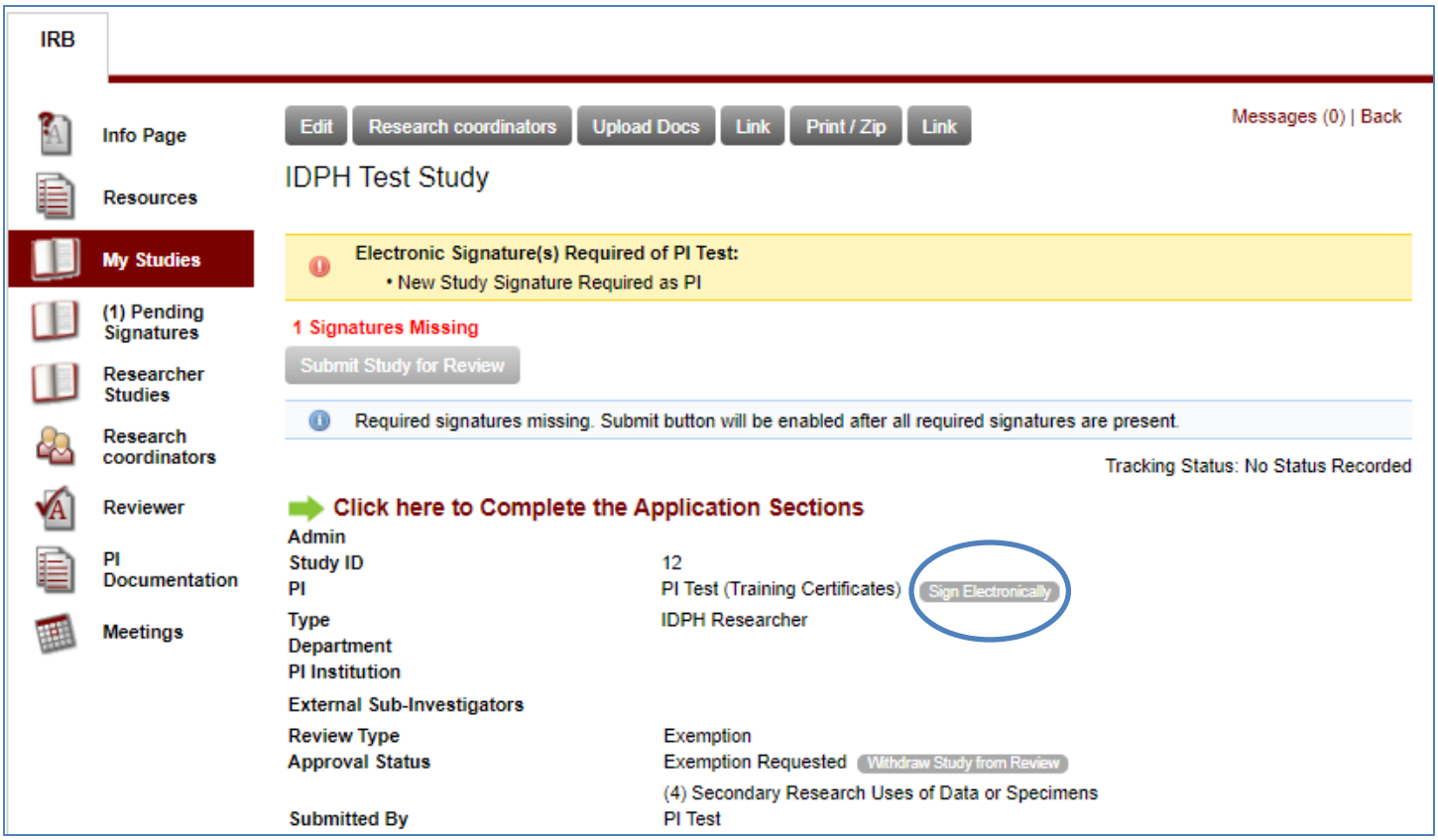
“ **Click Here to Complete the Application Sections.”**

The IRB Application Sections page will open. You will need to answer questions in all the displayed sections. To expand or minimize sections, click on the double arrows (and or respectively.)

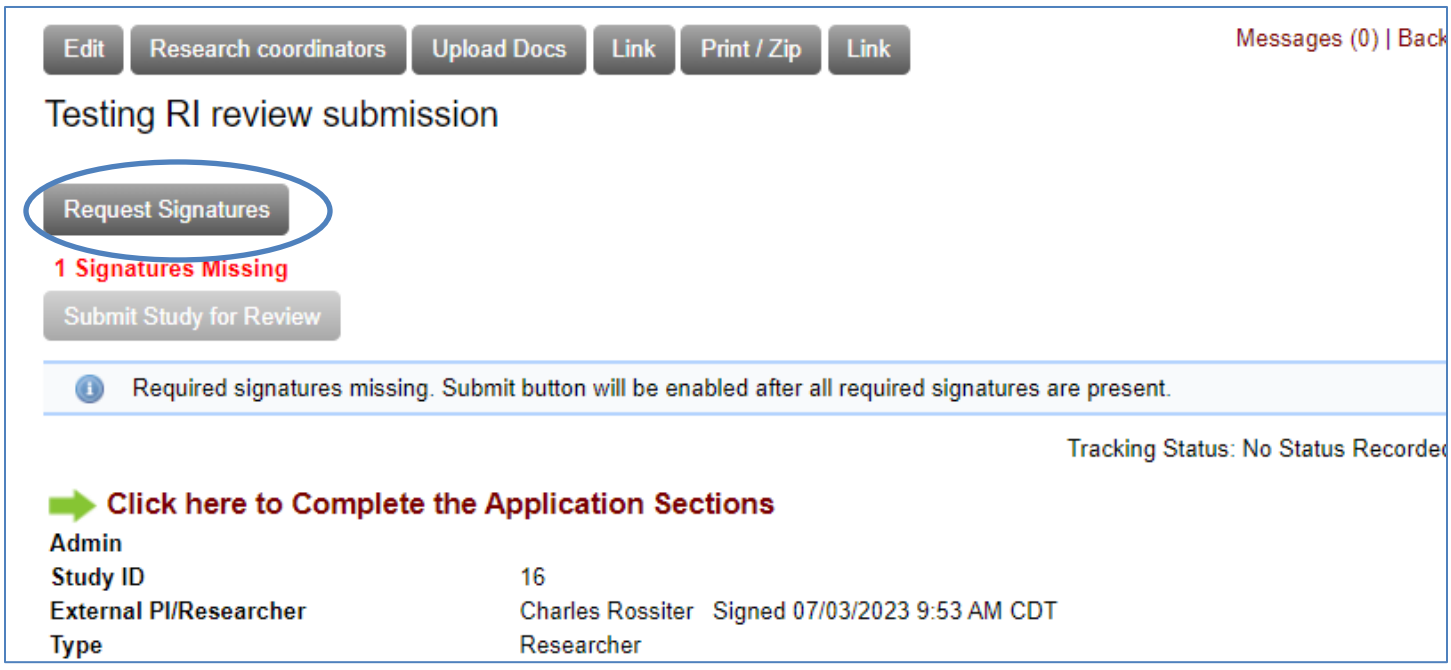
Select Add/Edit Answers and answer the questions in each section. Questions labelled “Answer Required” must be completed before the application can be submitted. You can leave the application at any point and return to it later. When all the Application sections are completed select View Study Page .



The study submission must next be Electronically Signed for submission to the Responsible Individual for review. Next to the PI's name you will see Sign Electronically. Select this button to sign the application.

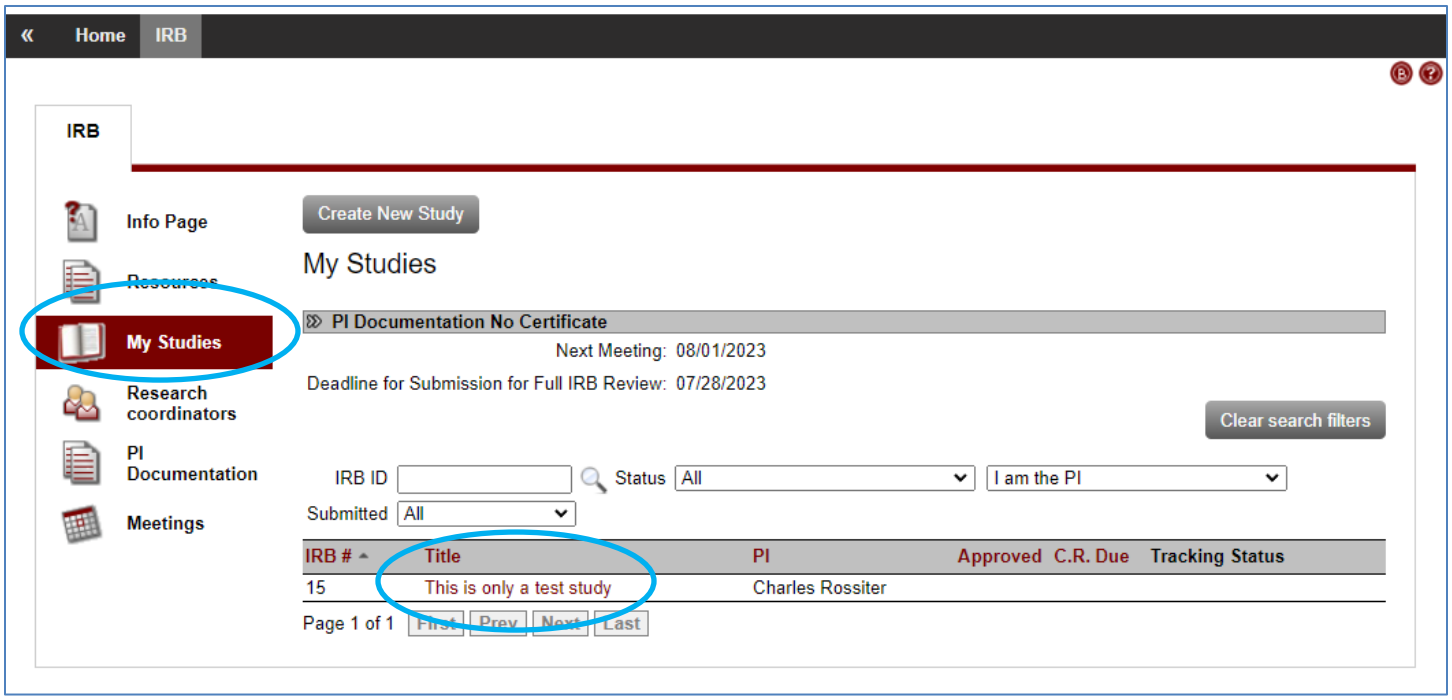


Finally, select Request Signatures to notify the Responsible Individual that your application is ready for review.



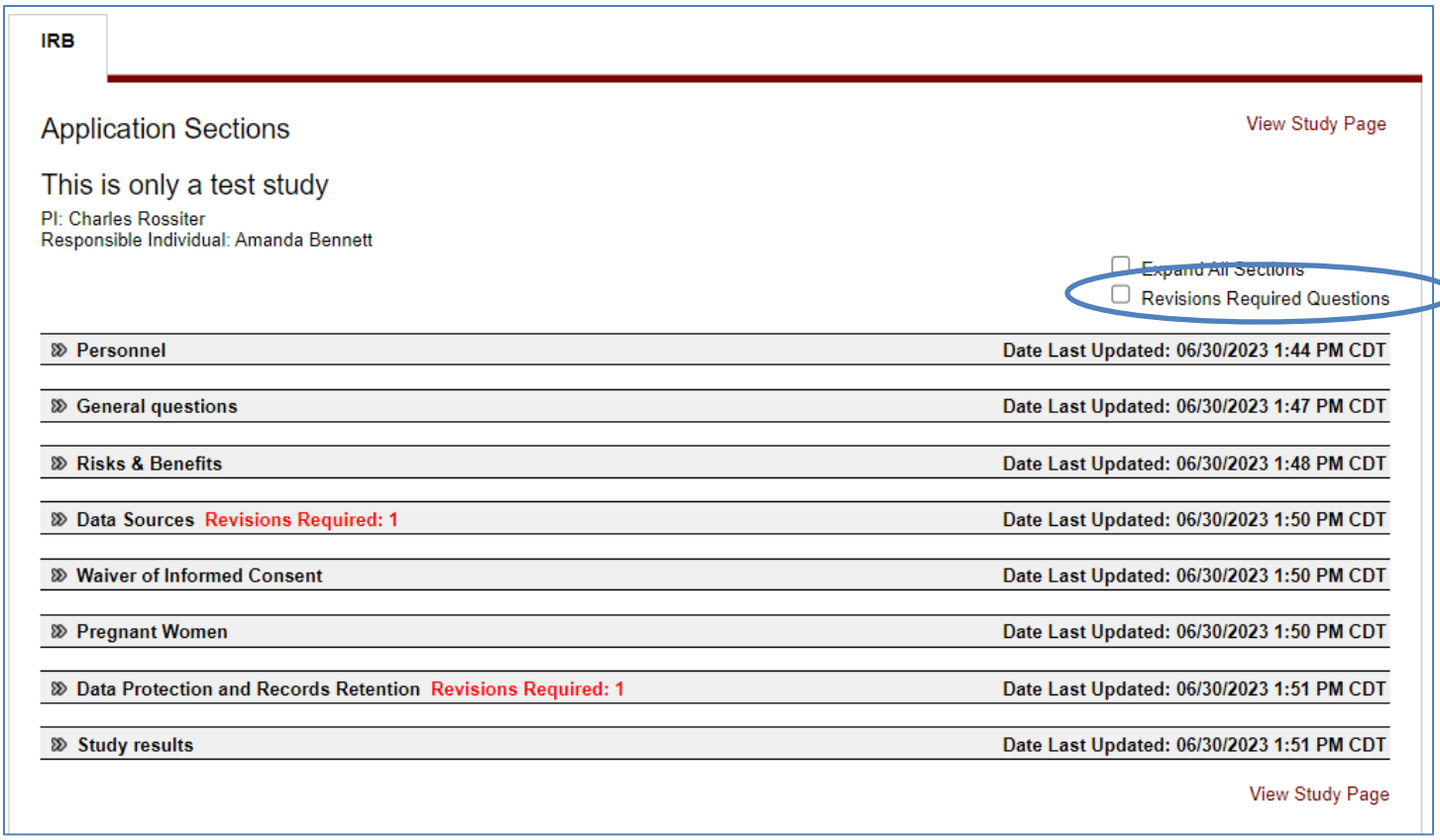
The Responsible Individual may have questions or comments about your study. The RI will flag the questions that need to be corrected and you will receive an email explaining the details. This will also be available in a message attached to your study (see below.)

To address the RI concerns, click on My Studies, and then on the title of the study.

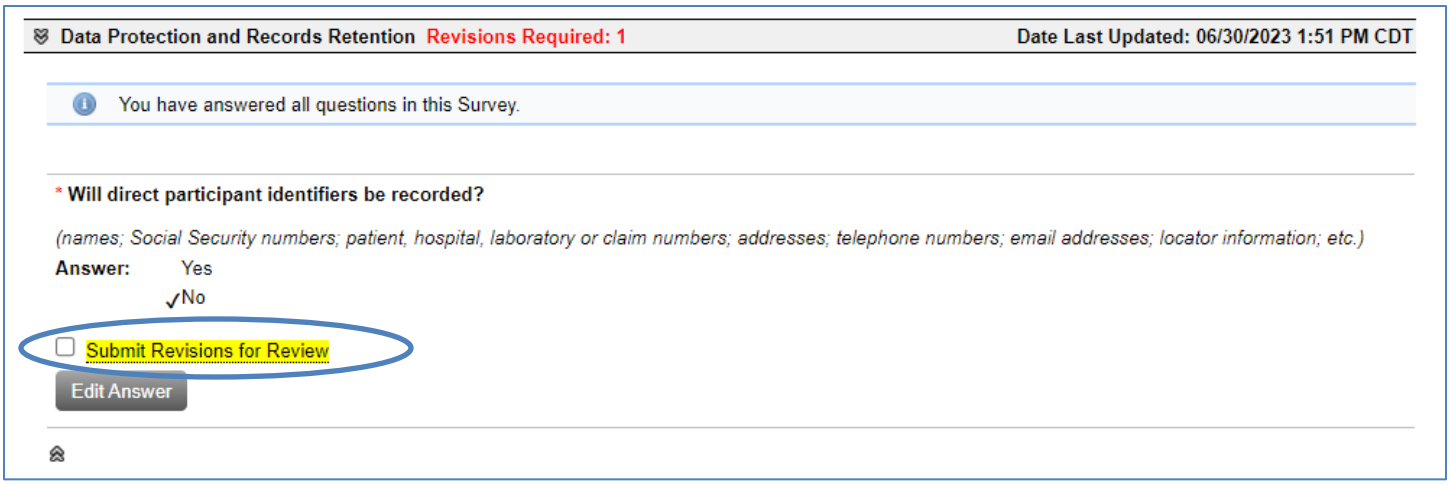


This will open the familiar View Study Page. You can now see that there is a message. This has the same content as the email you received notifying you about the RIs concerns. To make changes to your application, select the sentence that reads: " **Click Here to Complete the Application Sections."**

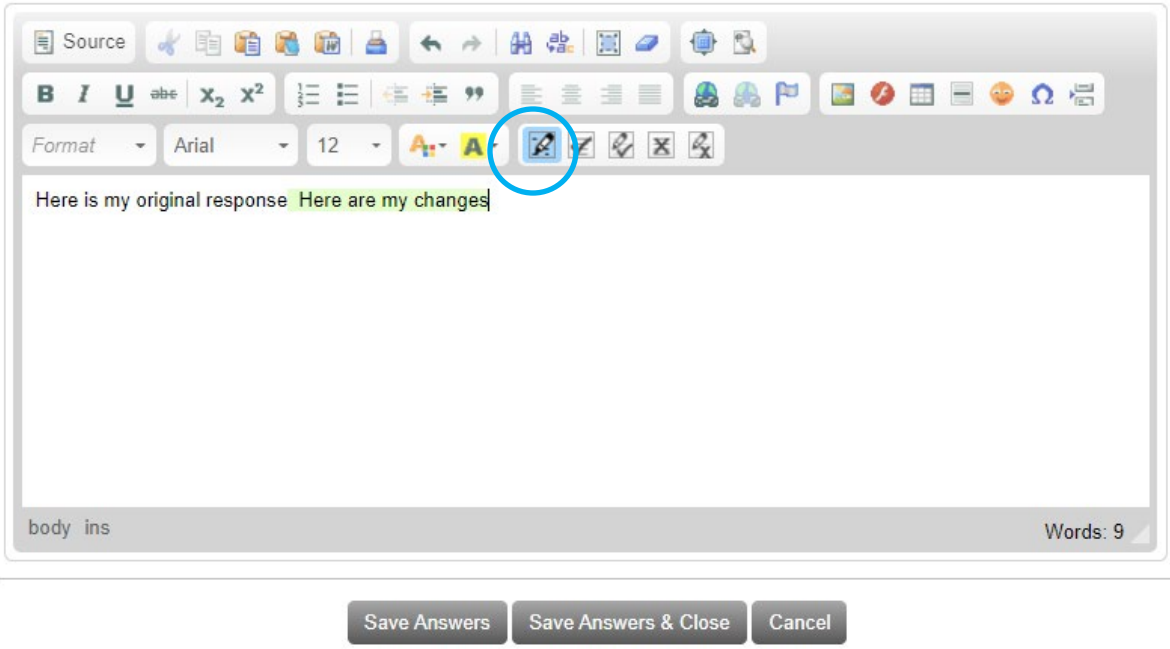
The next screen will show which sections need revisions. You can check the "Revisions Required Questions" box to open only those questions.



For each question, address the Responsible Individual's concerns. Select Edit Answer to change your response and then check "Submit Revisions for Review" once done.



It would be helpful to make sure track changes is on when responding to comments about questions with text responses.



If you want to discuss a request revision with the Responsible Individual, return to the View Study Page (View Study Page), click on Messages to view the message in Sitero Mentor, and reply by selecting . Alternatively, you can reply to the email message you received. More information about messaging can be found at the end of this manual.

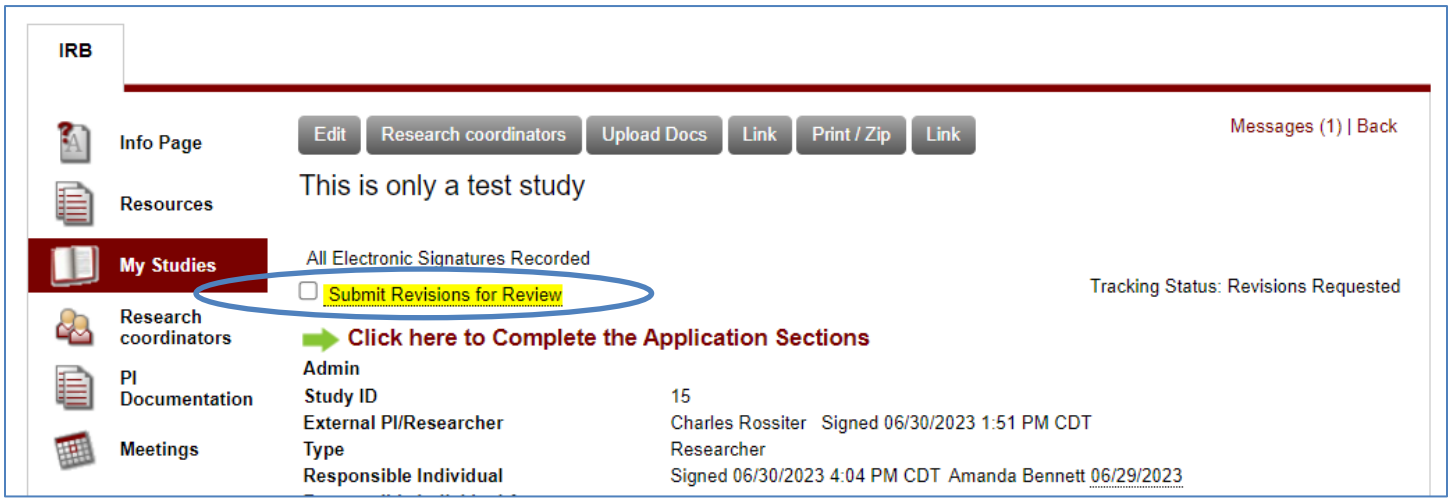
Once the needed revisions have been completed, reply to the Responsible Individual email message, letting the RI know you have responded and asking for signature. You will receive another email when the RI signs, notifying you that the study has been officially submitted for IRB review. At this time, you will no longer be able to modify your submission.

Notifications from the IRB with questions, revisions, or when your submission is approved will be received via email.

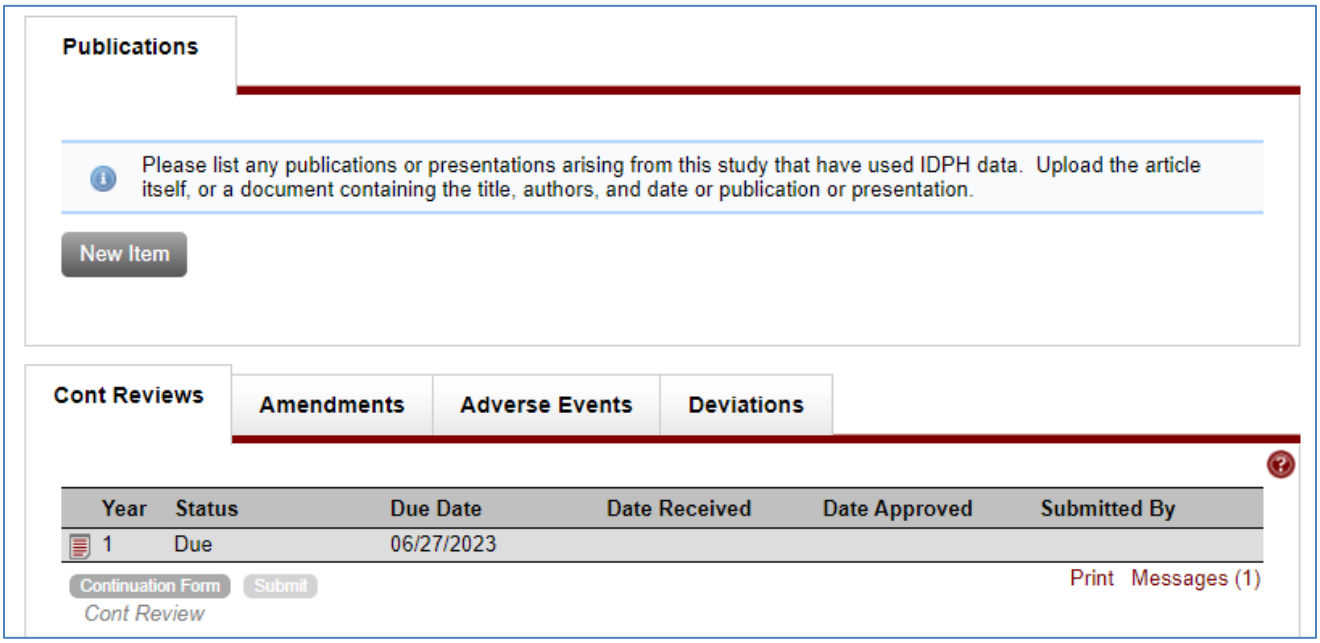
RESPONDING TO IRB REQUESTS FOR REVISIONS

When the IRB requests revisions, they will unlock your submission for you to make the required changes. Displayed at the top of the View Study page is a "Submit Revisions for Review" checkbox (highlighted in bright yellow). When you have completed the requested revisions, you **MUST** check this box. After this, you can no longer edit your re-submission.

Sitero Mentor then sends an automatic email notification back to the IRB stating that the requested revisions have been submitted. The study is now in the state of "Revisions Submitted."



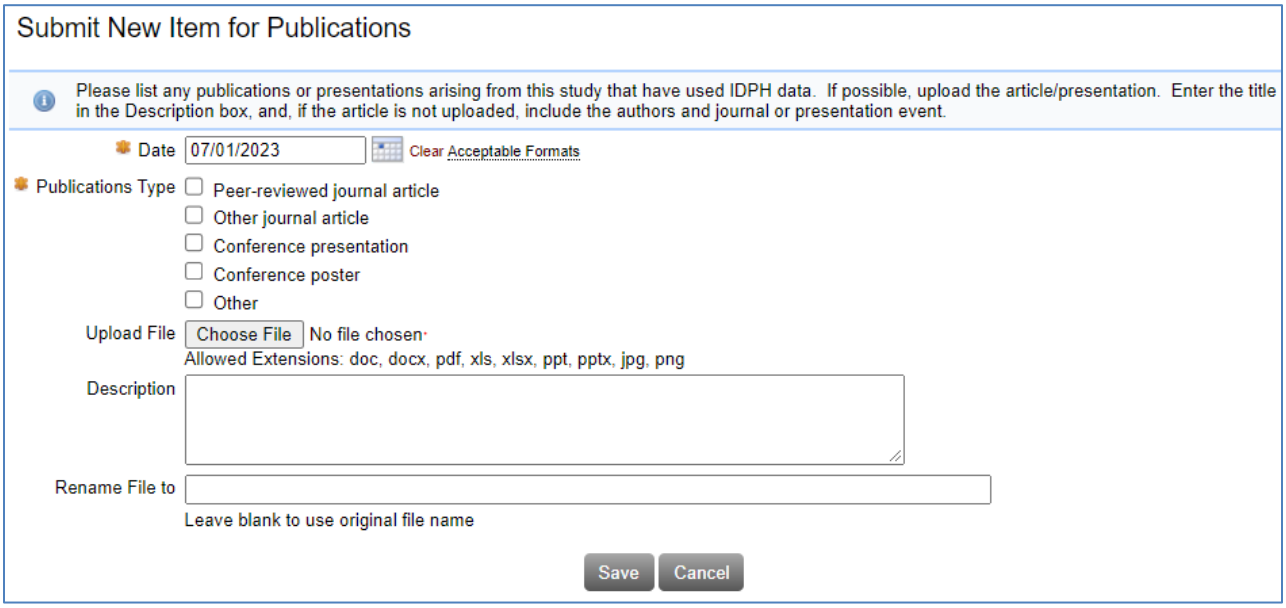
Once your application is approved, tabs at the bottom of the View Study Page are activated.



ENTERING PUBLICATIONS

Draft publications using IDPH data provided for your study should be sent to the Responsible Individual for review before being submitted for publication.

As presentations are made or articles are published, document them on the Publications tab. Click New Item



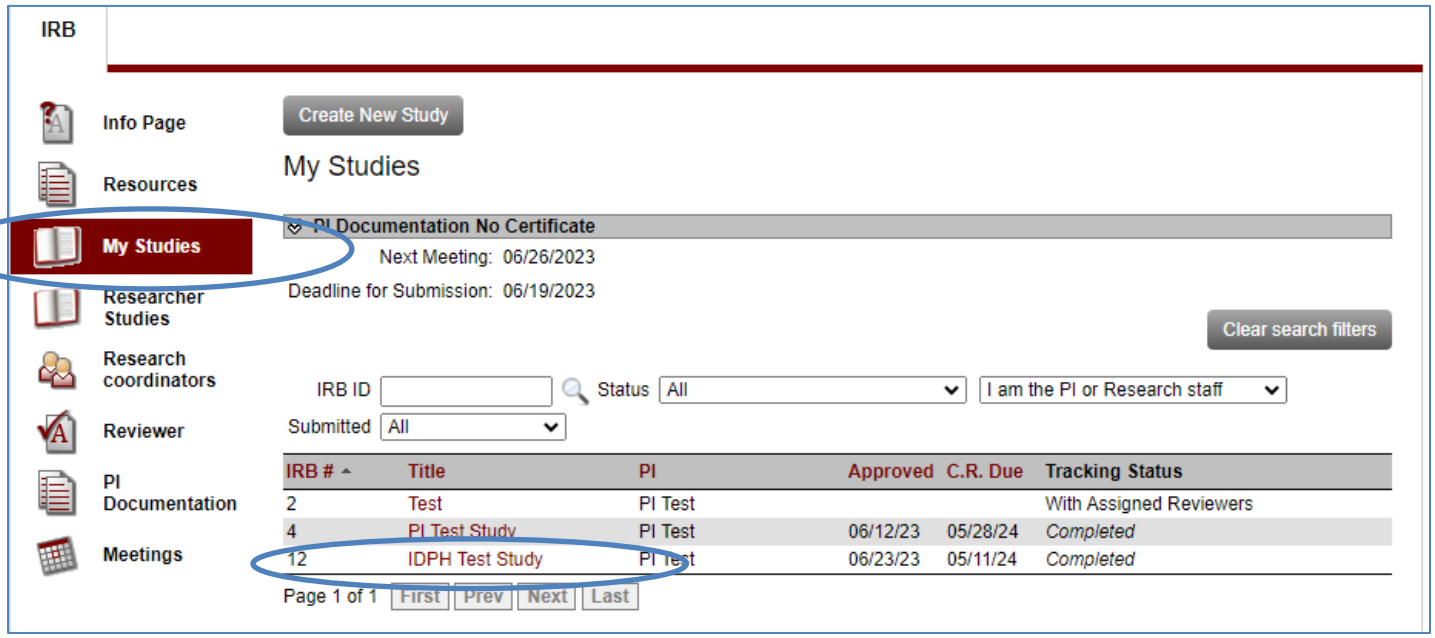
on

List publications or presentations arising from this study that have used IDPH data. If possible, upload the article/presentation. Enter the title in the Description box and, if the article is not uploaded, include the authors and journal or presentation event.

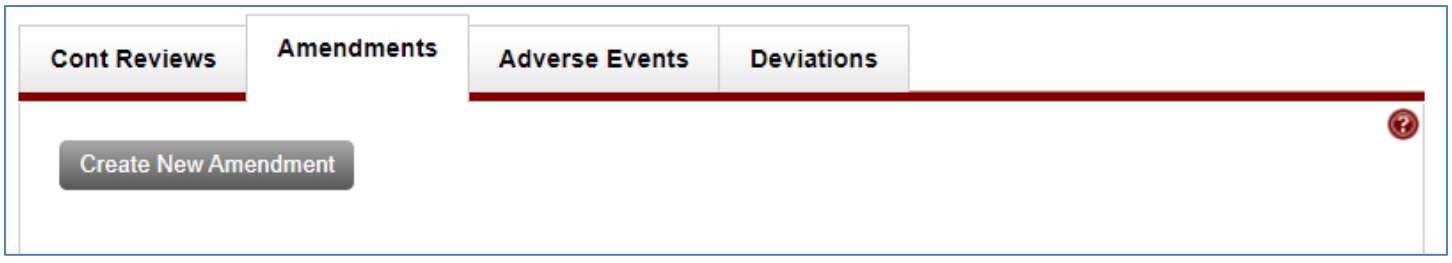
HOW TO SUBMIT AN AMENDMENT

From time to time, the PI may wish to modify a study protocol. There are various reasons for such modifications (additional staff, extending study period, scientific need, new risk information coming to light, protocol procedures not working as intended, etc.). When a study is modified, the PI is required to submit the amendment to the IRB for review.

To submit an amendment, log on to Sitero Mentor IRB. Under the IRB tab, click on My Studies and all your studies should be listed. Click on the study title you want to revise and the View Study screen will open.

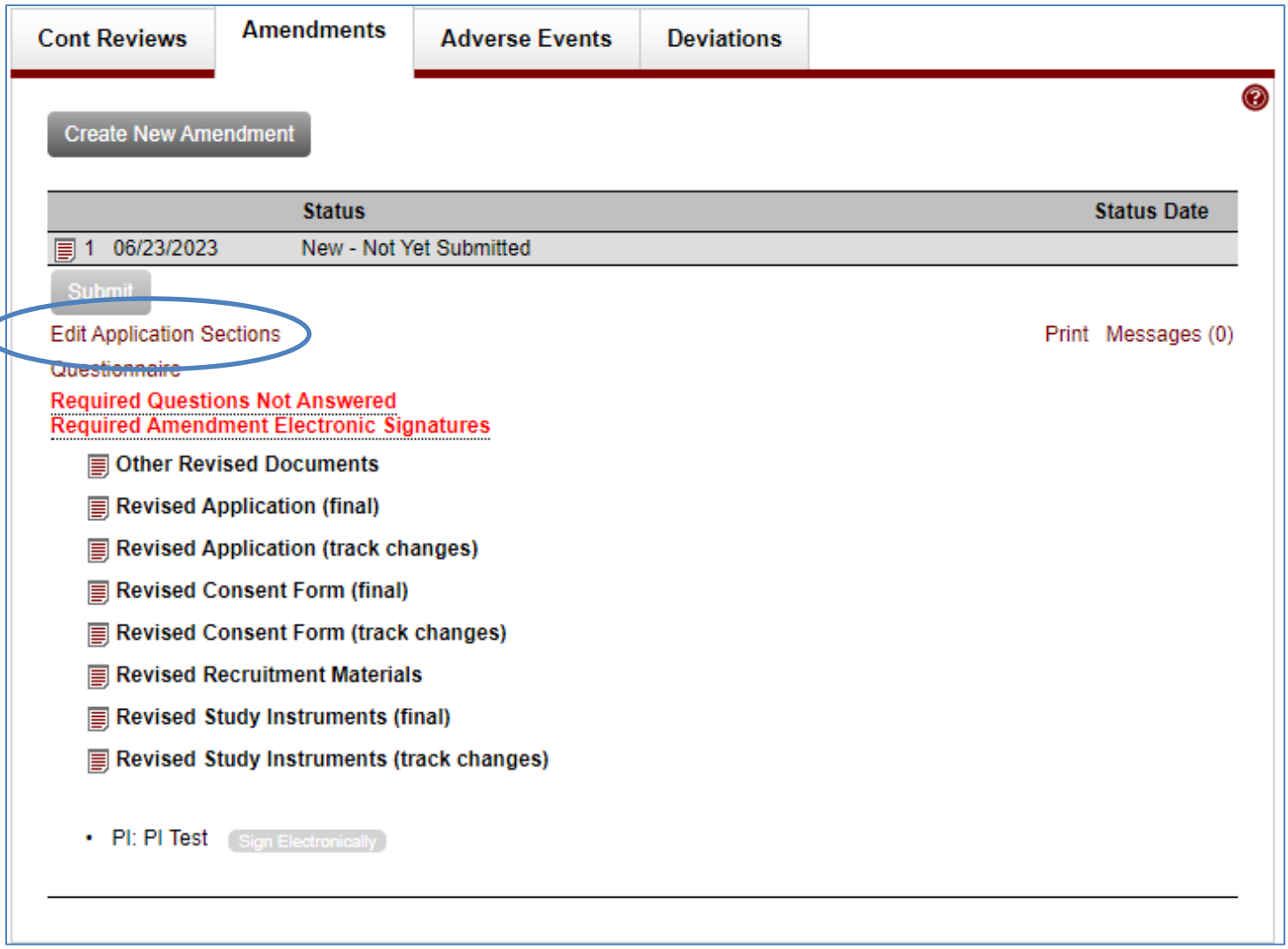


At the bottom of the View Study screen, there are several tabs: Continuing Reviews, Amendments, Adverse Events, and Deviations. Make sure you are on the Amendments tab. Click on the gray Upload New Amendment button.



On the Create New Amendment screen, select which sections of the IRB application you wish to revise and then select create amendment.

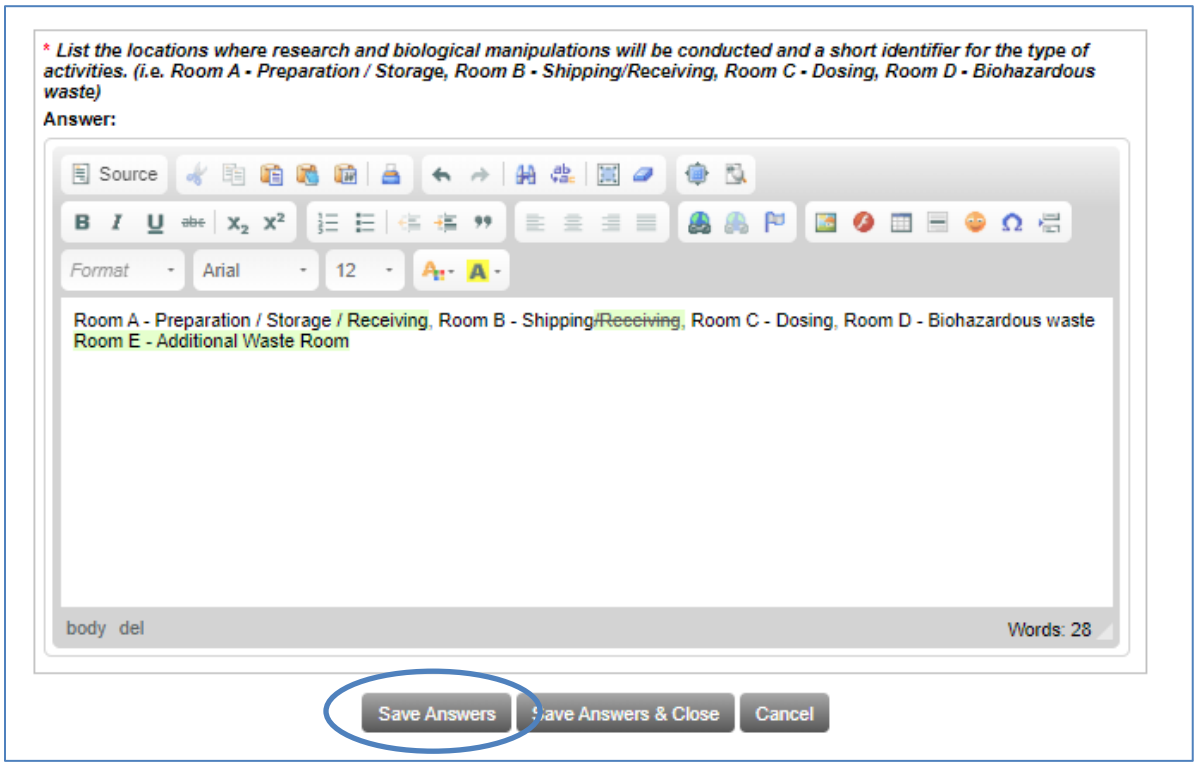
You will be brought back to the View Study Page and see the amendment now listed under the Amendments tab. Select Edit Application Sections to begin amending your IRB application.



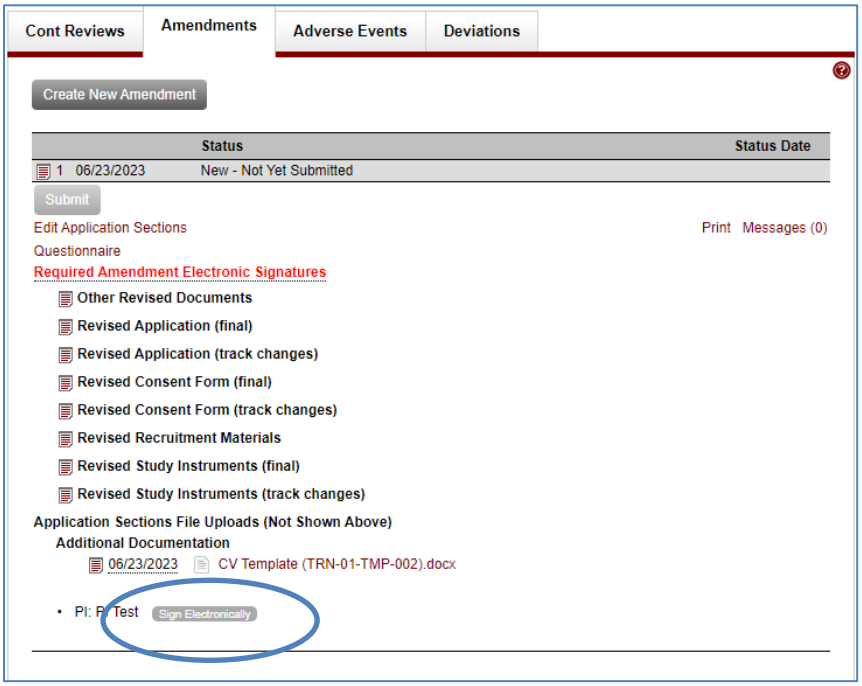
The IRB Application Sections: Amendment Page will automatically open. Begin amending the application by selecting the Add/Edit Answers where you want to make changes.

The Add/Edit Answers screen appears. Type in the additional information or delete other information. The changes will be highlighted.

Select “Save Answers” when completed. Do this in every section until you have amended the information relevant to the IRB.



Once completed, return to the View Study Page and electronically sign your submission like you did with the original submission.



Once signed, an email will automatically be sent to the IRB administrator upon successfully uploading the study amendment.

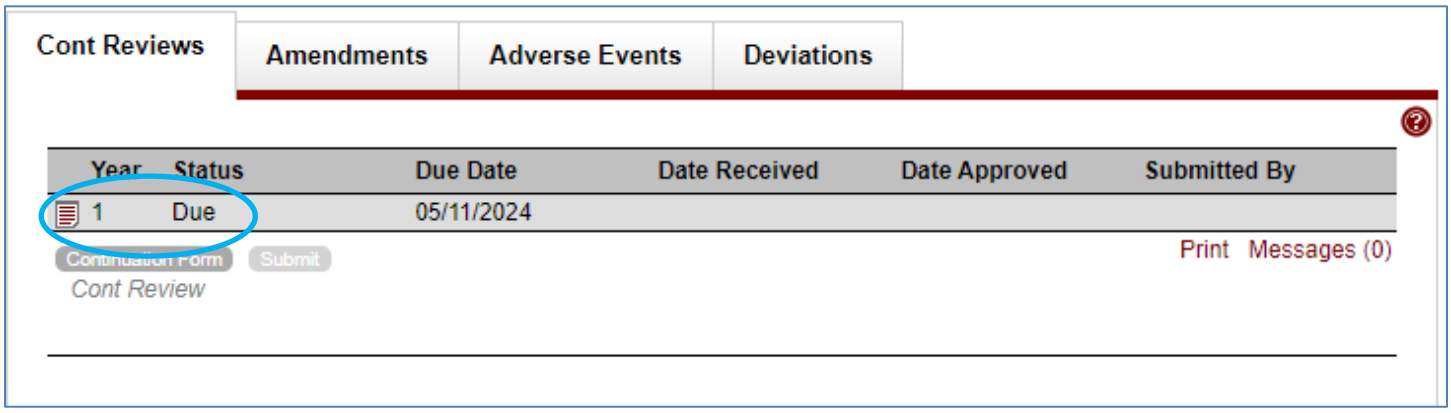
You must await the approval of your amendment by the IRB before implementing the requested changes. You will be notified by email if the IRB has questions, requests revisions, or approves the amendment.

HOW TO SUBMIT A CONTINUING REVIEW

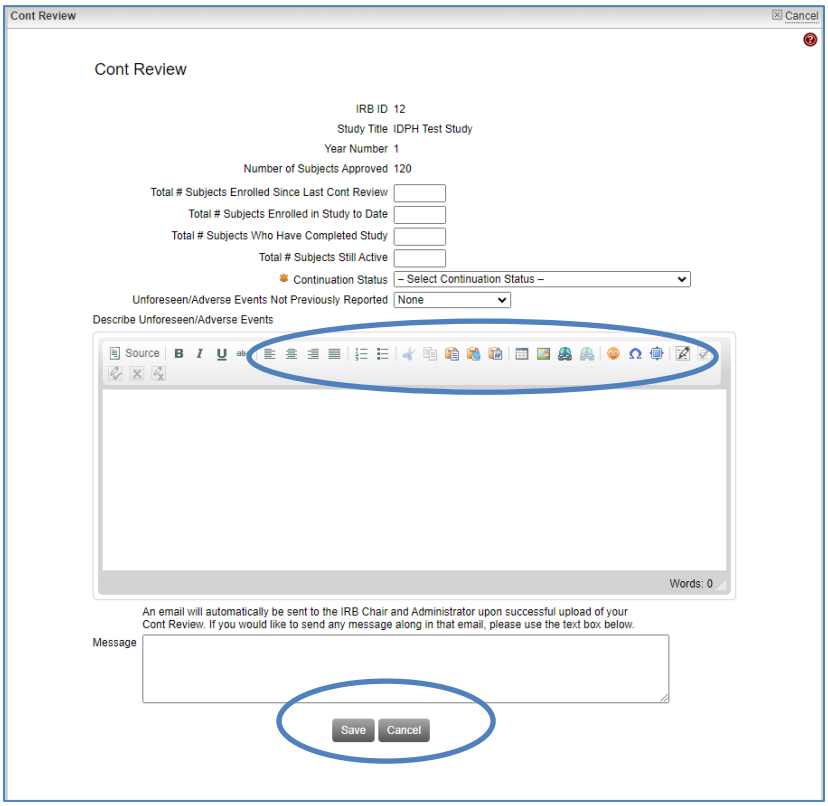
To submit a Continuing Review, log on to Sitero Mentor IRB. You will be reminded by an email from Sitero Mentor as the due date approaches. Under the IRB tab, click on My Studies and all your studies should be listed. Click on the study title you want to renew and the View Study screen will open.

At the bottom of the View Study screen are several tabs: Cont. Reviews, Amendments, etc. Make sure you are on the Cont. Reviews tab. Select the Continuation Form and the Cont. Review will appear.

Fill in the number of subjects and other pertinent information in the form. Under Continuation Status, select



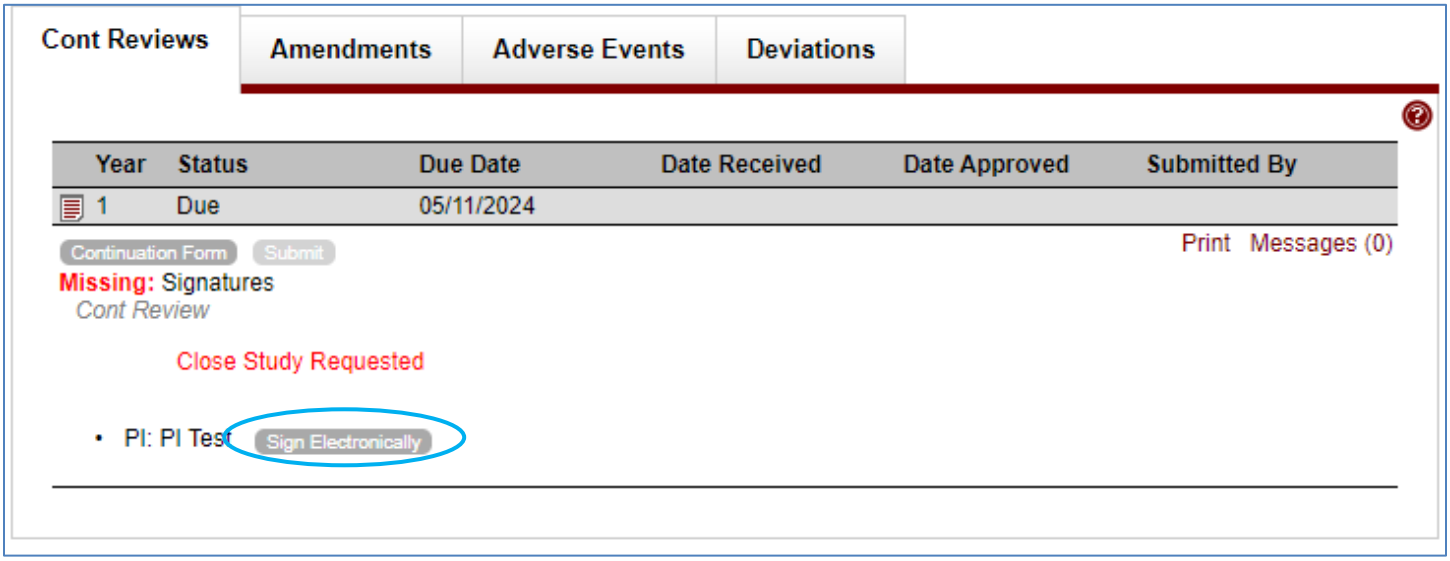
the appropriate option from the dropdown menu.



If you want to continue your study, select "Continue Study" in the Continuation Status field. Select "Close Study" in the Continuation Status field if you wish to terminate your study.

If there were adverse or unforeseen events, choose "Yes" from the Unforeseen / Adverse Events dropdown list and describe them in the first box. If you have other comments about the study, add them in the Additional Comments box. Once you have completed the Continuation, select "Save."

Return to the View Study Page and electronically sign your submission like you did your original submission.



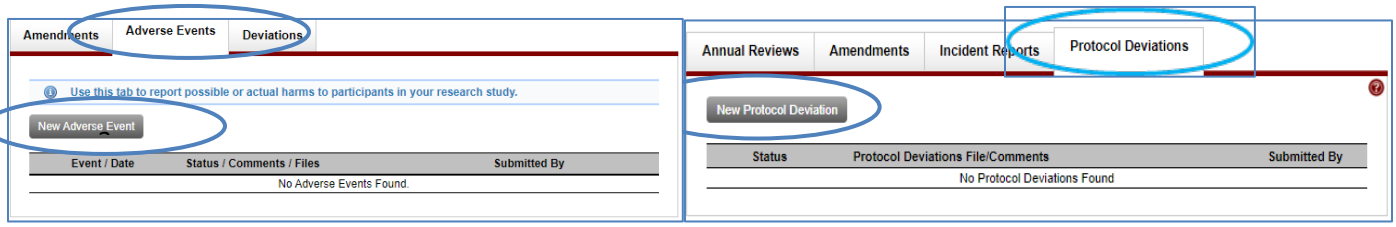
Once signed, an email will automatically be sent to the IRB administrator upon successfully completing the Continuation.

HOW TO SUBMIT ADVERSE EVENTS AND PROTOCOL DEVIATIONS

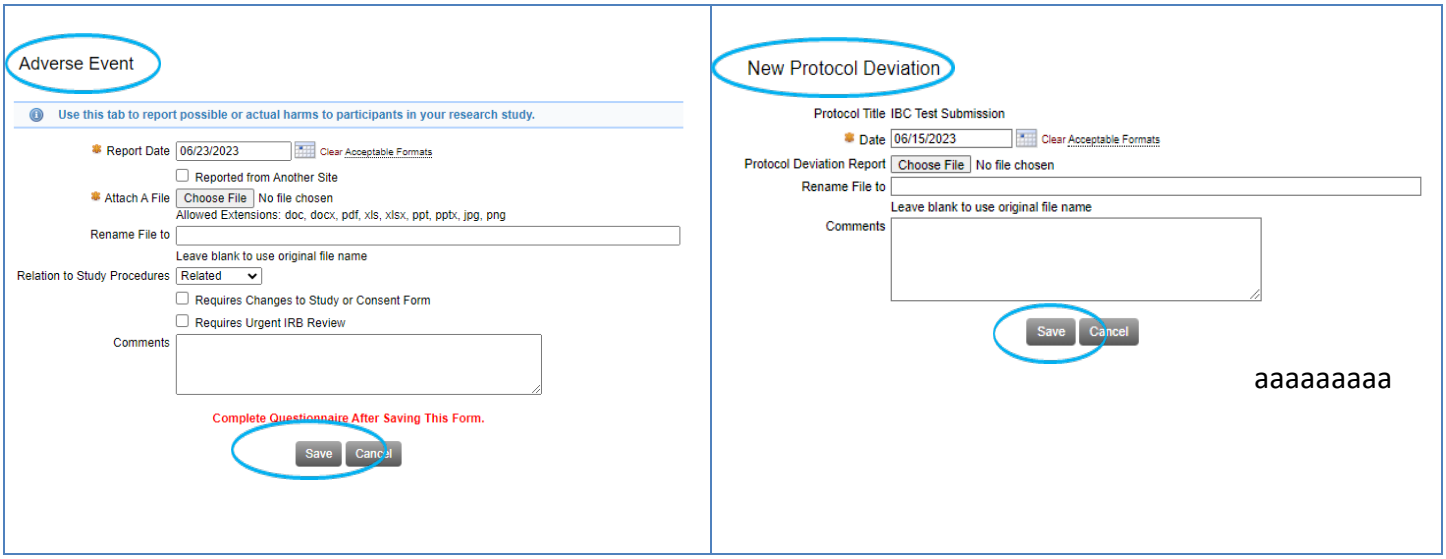
Submitting an adverse event or a protocol deviation is similar to submitting a continuation and/or amendment.

To submit an adverse event or a protocol deviation, log on to Sitero Mentor IRB. Under the IRB tab, click on My Studies and all your studies should be listed. Click on the study title you want to revise and the View Study screen will open.

At the bottom of the View Study screen, there are several tabs: Continuations, Adverse Events, etc. Make sure you are on the Adverse Events or Protocol Deviation tab. Click on the gray Upload New Amendment button. Select New Adverse Events or New Protocol Deviation.

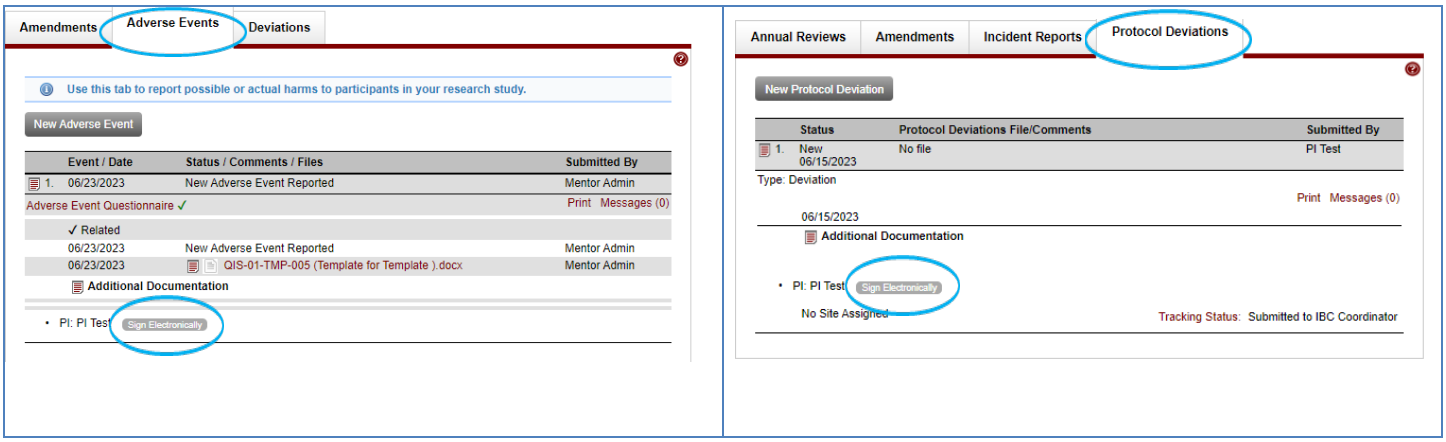


The screen requesting further information for an Adverse Event or New Protocol Deviation will appear next:



Complete the relevant questionnaire and select “Save.” For both an adverse event or protocol deviation you will be brought back to the View Study page.

You must select Sign Electronically for either submission to be submitted. Once submitted, the IRB will be in touch with questions, request revisions, or acknowledge submissions.



STUDY MESSAGES

Study Messages are emails sent from an individual study's messages page. Messages from this page are sent via email to the selected recipients. Replies to these emails from the recipients go back to the Sitero Mentor messages page, archived, and forwarded to the original recipient list. Thus, provided that the first message is sent from the Messages page, subsequent replies are archived on the Messages page.

Committee members can view all messages regardless of whether they were selected as email recipients of those messages. The archive of messages is part of the study's audit trail. The only exception to this is when a member is also a PI and the message is sent as an "IRB Only" message. In that case, Sitero Mentor will not display those IRB Only messages to the PI/member.

PIs also have access to the messages on the Messages page.

Default Recipients

When you click the New Message button on the Study Messages page, Sitero Mentor opens a message form. Sitero Mentor lists recipients on the righthand side, each with a check box, grouped by Study Personnel, Administrators, Reviewers, and Members. Study Personnel is only shown if the IRB Only switch is set to "No." The Reviewers group only includes the assigned reviewers on the current protocol who are automatically selected as recipients by default (you can always unselect any selected recipient by default). This form allows you to select who should, by default, be checked as a recipient when the New Message forms load.