

Institutional Review Board

EXTERNAL INVESTIGATOR MANUAL

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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.

Request Mentor User Account

* Form Code

* First Name

* Last Name

* Email Address

* Phone Number

* Institution Name

* User Type

* Please Enter Text from the image

S E C V L O A I

Submit

[If you already have a Mentor account please click here to login.](#)

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.

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

View Supported Browsers

Login Bloom's Taxonomy Calculator Visit Our Website

Institution ID

Remember my Institution ID

User

Password

Login

Forgot Password

ADA SITE COMPLIANCE ACCESSIBILITY POLICY

TrustedSite CERTIFIED SECURE

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.

IRB

Info Page **Create New Study**

Resources

My Studies

(1) Pending Signatures

Researcher Studies

Research coordinators

Reviewer

PI Documentation

Meetings

My Studies

PI Documentation No Certificate

Next Meeting: 06/26/2023

Deadline for Submission: 06/19/2023

Clear search filters

IRB ID Status I am the PI or Research staff

Submitted

IRB #	Title	PI	Approved	C.R. Due	Tracking Status
2	Test	PI Test			With Assigned Reviewers
4	PI Test Study	PI Test	06/12/23	05/28/24	Completed

Page 1 of 1

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.

Pre-Submission Survey

FDAType: Multiple Choice

Does your research involve evaluation of either a drug or medical device and/or US FDA oversight?

Options: 1. No

2. Yes, I understand that the IDPH IRB does not review such studies, but is willing to enter a reliance agreement with another institutional IRB registered with the US FDA to review such research.

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.

Select Responsible IndividualCancel

Select Responsible Individual

Select your Responsible Individual by typing the first letters of their last name in the Lookup field below. Then select their name from the pop-up list.

Responsible Individual

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.

Create IRB Study

Next Meeting 08/01/2023
Deadline for Submission for Full IRB Review 07/28/2023

External PI/Researcher J F
Responsible Individual Jane Fornoff
Co-PIs **Add** (Type first letters of last name and select from popup list, then click "Add")
External Sub-Investigators
Research staff **Add** (Type first letters of last name and select from popup list, then click "Add")

* Study Title

* Proposed Start Date [Clear Acceptable Formats](#)
Proposed End Date [Clear Acceptable Formats](#)

? * Risk Level -Select-

Data Types Collected Secondary Data Analysis (analysis of data that already exists)
 Surveys/Questionnaire/Psychometric Testing
 Interviews/Oral History/Focus Groups
 Observational/Ethnographic Research
 Audio/Video-Recording and/or Photographs
 Deception/Incomplete Disclosure of Research Purpose or Procedure
 Specimen Collection and/or Analysis, Including Genetic Analysis
 Other

* Data Use Agreement -Select-

Funding Source
Grant Number

* Review Type Not Human Subjects Research Determination

Waiver of Informed Consent Not Requested

Waiver of Documentation of Informed Consent Not Requested

Vulnerable Subjects Healthy volunteers
 Controls
 Elderly
 Minors (under age 18)

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.

IRB

Info Page Edit Research coordinators Upload Docs Link Print / Zip Link Messages (0) | Back

Resources

My Studies 1 Signatures Missing Required Questions Not Answered Submit Study for Review

Researcher Studies

Research coordinators Required signatures missing. Submit button will be enabled after all required signatures are present.

Reviewer Tracking Status: No Status Recorded

PI Documentation [Click here to Complete the Application Sections](#)

Meetings

Admin	
Study ID	12
PI	PI Test (Training Certificates) Sign Electronically
Type	IDPH Researcher
Department	
PI Institution	
External Sub-Investigators	
Review Type	Exemption
Approval Status	Exemption Requested Withdraw Study from Review
Submitted By	(4) Secondary Research Uses of Data or Specimens
Date Received	PI Test
Date of Completion	
Date Approved	
Final Approval Date	
Proposed Start Date	07/31/2023
Proposed End Date	
Date Closed	
Risk Level	Minimal Risk
Data Types Collected	Secondary Data Analysis (analysis of data that already exists)
Data Use Agreement	This study requires a fully executed Data Use Agreement (DUA)
Funding Source	
Grant Number	
Consent Waived	Not Requested

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.

IRB

Info Page Edit Research coordinators **Upload Docs** Link Print / Zip Link Messages (0) | Back

Resources IDPH Test Study

My Studies 1 Signatures Missing
Required Questions Not Answered
Submit Study for Review

Researcher Studies

Research coordinators Required signatures missing. Submit button will be enabled after all required signatures are present.

Reviewer Tracking Status: No Status Recorded

Click here to Complete the Application Sections




PI Documentation Admin Study ID 12
PI IDPH Researcher PI Test (Training Certificates) Sign Electronically


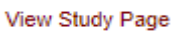
Meetings Type IDPH Researcher
Department
PI Institution
External Sub-Investigators
Review Type Exemption
Approval Status Exemption Requested Withdraw Study from Review
(4) Secondary Research Uses of Data or Specimens
PI Test

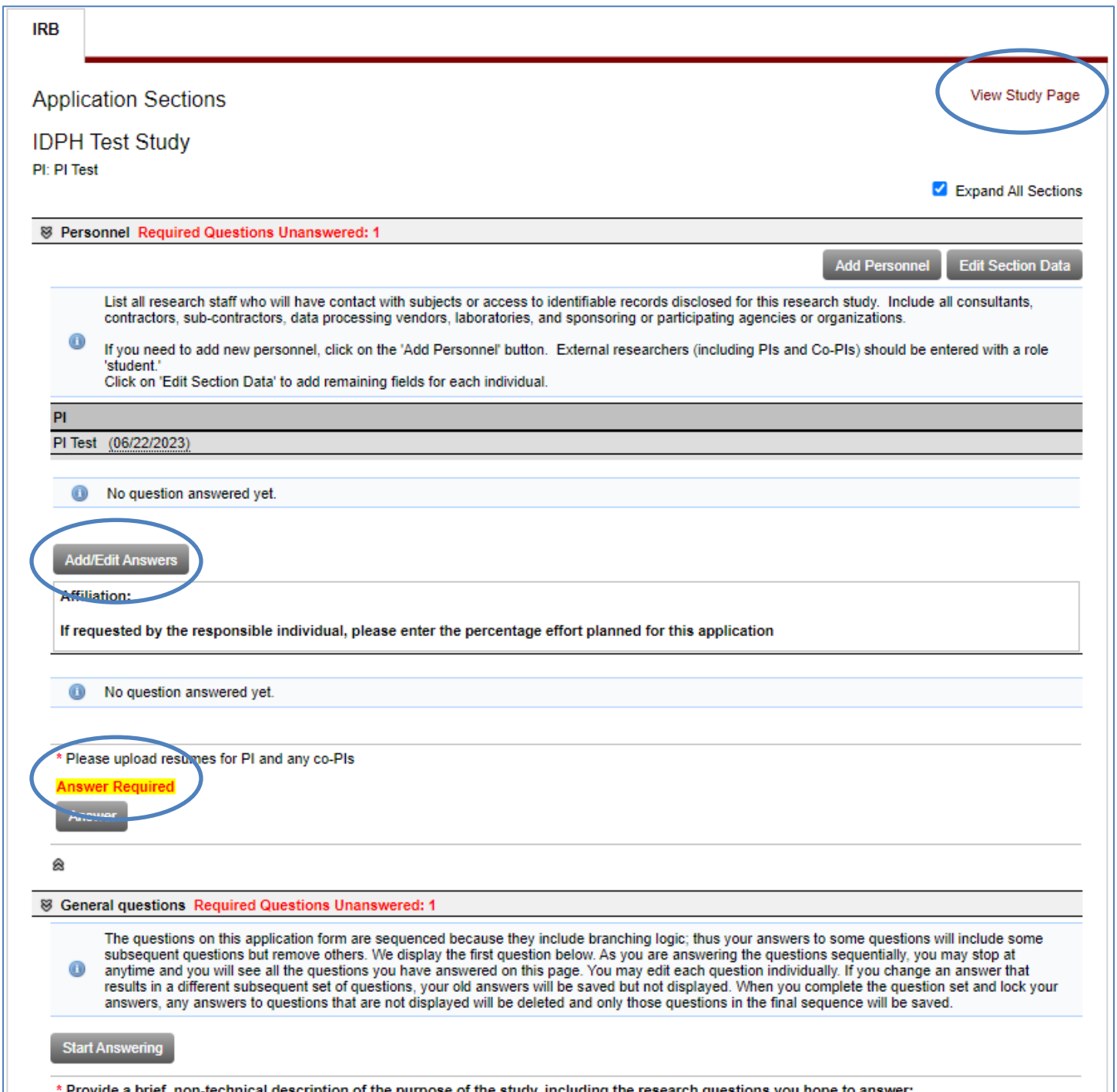
Submitted By
Date Received
Date of Completion
Date Approved
Final Approval Date
Proposed Start Date 07/31/2023

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

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

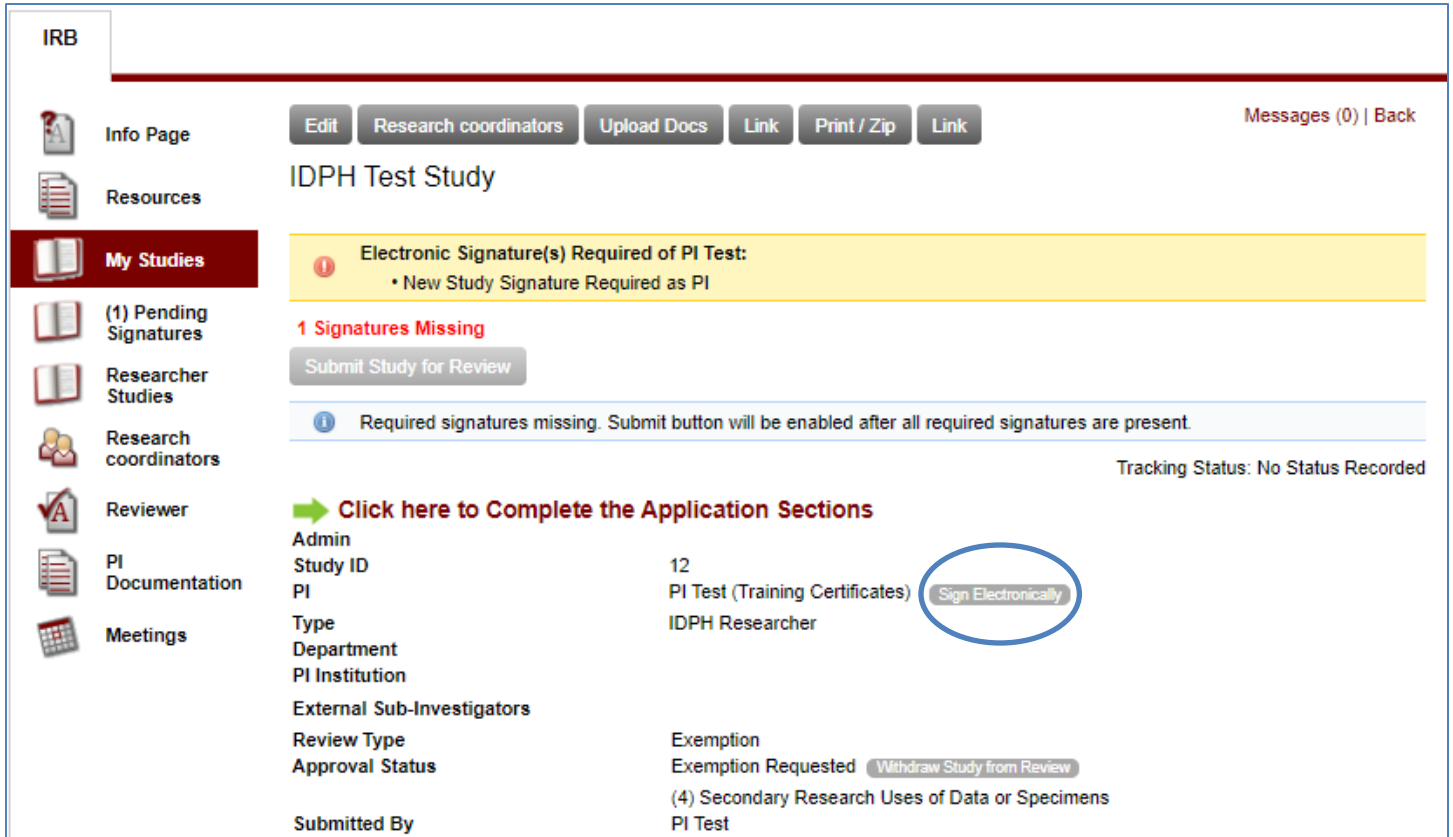
The IRB Application Sections page will open. You will need to answer questions in all the displayed sections. To expand or minimize sections, click on the double arrows ( and  or  respectively.)

Select  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 .


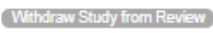


The screenshot shows the IRB Application Sections page for 'IDPH Test Study'. The page is titled 'IRB' and 'Application Sections'. A 'View Study Page' button is circled in blue in the top right corner. Below the title, there is a 'PI: PI Test' label and an 'Expand All Sections' checkbox which is checked. A section header 'Personnel' is followed by 'Required Questions Unanswered: 1'. There are two buttons: 'Add Personnel' and 'Edit Section Data'. Below this is a text box with instructions: 'List all research staff who will have contact with subjects or access to identifiable records disclosed for this research study. Include all consultants, contractors, sub-contractors, data processing vendors, laboratories, and sponsoring or participating agencies or organizations.' An information icon (i) is present. Below the text box is a table with one row: 'PI' and 'PI Test (06/22/2023)'. Below the table is a message: 'No question answered yet.' Below this is a circled 'Add/Edit Answers' button. Below the button is a text box labeled 'Affiliation:' with the instruction: 'If requested by the responsible individual, please enter the percentage effort planned for this application'. Below this is another 'No question answered yet.' message. Below that is a circled '* Please upload resumes for PI and any co-PIs' message, followed by a circled 'Answer Required' label and a 'Submit' button. Below this is a collapse icon. A section header 'General questions' is followed by 'Required Questions Unanswered: 1'. Below this is a text box with instructions: 'The questions on this application form are sequenced because they include branching logic; thus your answers to some questions will include some subsequent questions but remove others. We display the first question below. As you are answering the questions sequentially, you may stop at anytime and you will see all the questions you have answered on this page. You may edit each question individually. If you change an answer that results in a different subsequent set of questions, your old answers will be saved but not displayed. When you complete the question set and lock your answers, any answers to questions that are not displayed will be deleted and only those questions in the final sequence will be saved.' An information icon (i) is present. Below the text box is a 'Start Answering' button. At the bottom, there is a circled '* Provide a brief, non-technical description of the purpose of the study, including the research questions you hope to answer:'.

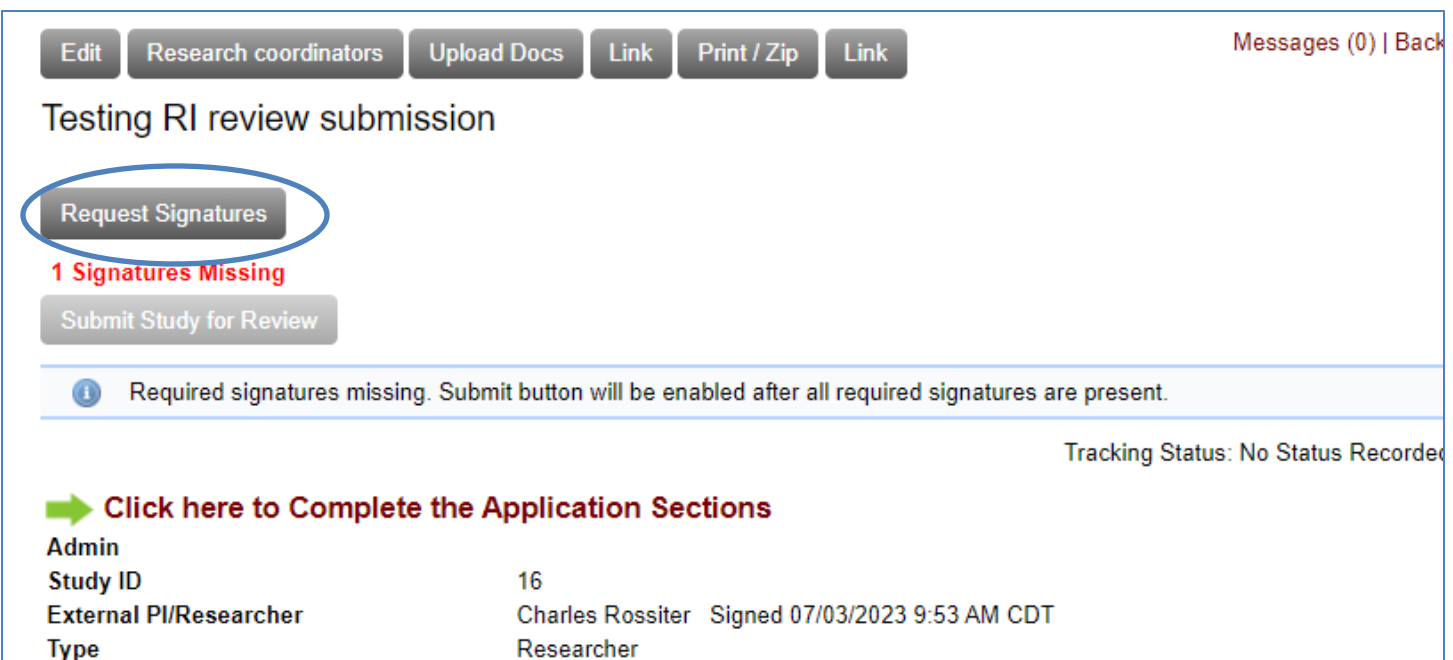
The study submission must next be Electronically Signed for submission to the Responsible Individual for review. Next to the PI's name you will see . Select this button to sign the application.



The screenshot shows the IRB system interface for a study titled "IDPH Test Study". The left sidebar contains navigation options: Info Page, Resources, My Studies (selected), (1) Pending Signatures, Researcher Studies, Research coordinators, Reviewer, PI Documentation, and Meetings. The main content area includes a yellow warning banner: "Electronic Signature(s) Required of PI Test: • New Study Signature Required as PI". Below this is a red text notification: "1 Signatures Missing" and a grey "Submit Study for Review" button. A blue information banner states: "Required signatures missing. Submit button will be enabled after all required signatures are present." The tracking status is "No Status Recorded". A green arrow points to a link: "Click here to Complete the Application Sections". Below this is a table of study details:

Admin	
Study ID	12
PI	PI Test (Training Certificates) 
Type	IDPH Researcher
Department	
PI Institution	
External Sub-Investigators	
Review Type	Exemption
Approval Status	Exemption Requested 
Submitted By	(4) Secondary Research Uses of Data or Specimens PI Test

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



The screenshot shows the IRB system interface for a study titled "Testing RI review submission". The top navigation bar includes buttons for Edit, Research coordinators, Upload Docs, Link, Print / Zip, and Link. The tracking status is "Messages (0) | Back". The main content area includes a grey "Request Signatures" button circled in blue, a red text notification: "1 Signatures Missing", and a grey "Submit Study for Review" button. A blue information banner states: "Required signatures missing. Submit button will be enabled after all required signatures are present." The tracking status is "No Status Recorded". A green arrow points to a link: "Click here to Complete the Application Sections". Below this is a table of study details:

Admin	
Study ID	16
External PI/Researcher	Charles Rossiter Signed 07/03/2023 9:53 AM CDT
Type	Researcher

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.

IRB

Home IRB

Info Page Create New Study

Resources

My Studies

Research coordinators

PI Documentation

Meetings

My Studies

PI Documentation No Certificate

Next Meeting: 08/01/2023

Deadline for Submission for Full IRB Review: 07/28/2023


Clear search filters

IRB ID Status All I am the PI

Submitted All

IRB #	Title	PI	Approved	C.R. Due	Tracking Status
15	This is only a test study	Charles Rossiter			

Page 1 of 1 First Prev Next Last

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.**”

IRB

Info Page Edit Research coordinators Upload Docs Link Print / Zip Link

Resources

My Studies

Researcher Studies

Research coordinators


Reviewer

PI Documentation

Test for Requesting Revisions

All Electronic Signatures Recorded

Tracking Status: Submitted to the IRB

 **Click here to Complete the Application Sections**

Admin

Study ID 17

External PI/Researcher Researcher Test (Training Certificates) Signed 07/07/2023 11:19 AM CDT

Type Researcher

Responsible Individual Signed 07/07/2023 11:23 AM CDT RI Test (Training Certificates) 07/06/2023

Responsible Individual Acceptance Status Not Yet Accepted

Messages (1) | Back

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

IRB

Application Sections [View Study Page](#)

This is only a test study
PI: Charles Rossiter
Responsible Individual: Amanda Bennett

Expand All Sections
 Revisions Required Questions

» Personnel	Date Last Updated: 06/30/2023 1:44 PM CDT
» General questions	Date Last Updated: 06/30/2023 1:47 PM CDT
» Risks & Benefits	Date Last Updated: 06/30/2023 1:48 PM CDT
» Data Sources Revisions Required: 1	Date Last Updated: 06/30/2023 1:50 PM CDT
» Waiver of Informed Consent	Date Last Updated: 06/30/2023 1:50 PM CDT
» Pregnant Women	Date Last Updated: 06/30/2023 1:50 PM CDT
» Data Protection and Records Retention Revisions Required: 1	Date Last Updated: 06/30/2023 1:51 PM CDT
» Study results	Date Last Updated: 06/30/2023 1:51 PM CDT

[View Study Page](#)

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.

» Data Protection and Records Retention **Revisions Required: 1** Date Last Updated: 06/30/2023 1:51 PM CDT

i You have answered all questions in this Survey.

*** Will direct participant identifiers be recorded?**
(names; Social Security numbers; patient, hospital, laboratory or claim numbers; addresses; telephone numbers; email addresses; locator information; etc.)

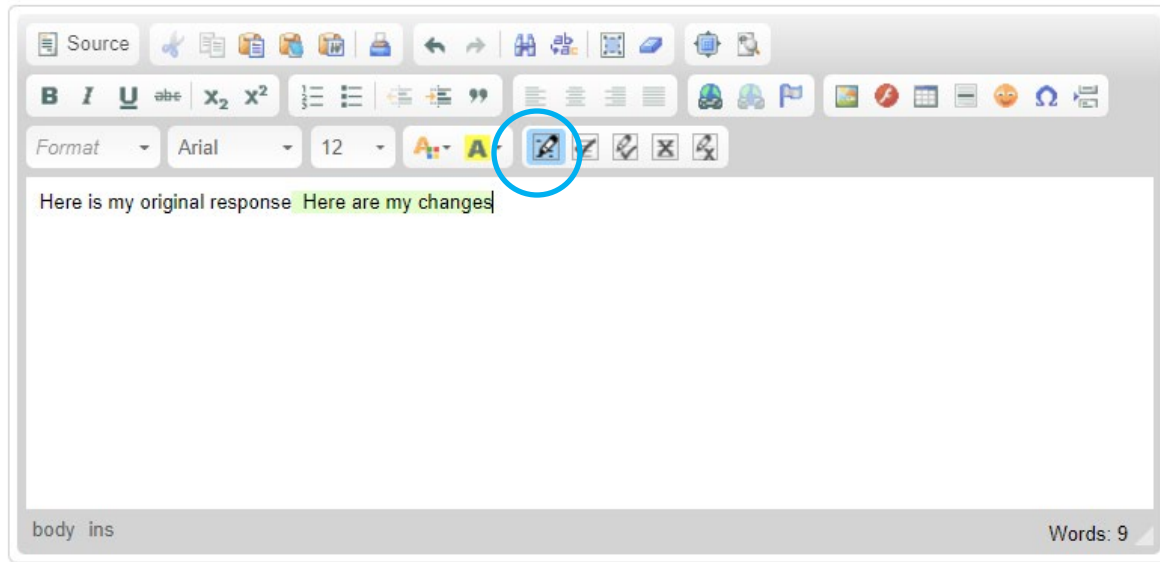
Answer: Yes
 ✓ No

Submit Revisions for Review


Edit Answer

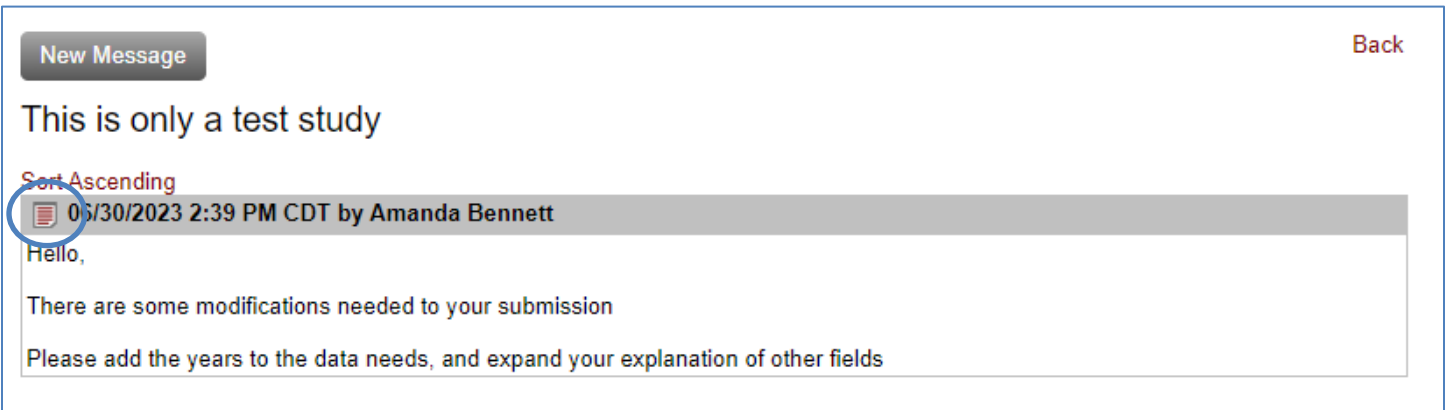
»

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



Save Answers Save Answers & Close Cancel

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.”

The screenshot shows the IRB application interface. On the left is a navigation menu with items: IRB, Info Page, Resources, My Studies (highlighted), Research coordinators, PJ Documentation, and Meetings. The main content area displays 'This is only a test study' and 'All Electronic Signatures Recorded'. A checkbox labeled 'Submit Revisions for Review' is highlighted in yellow and circled in blue. Below it is a green arrow pointing to the text 'Click here to Complete the Application Sections'. At the bottom, there is a table with columns: Admin, Study ID, External PI/Researcher, Type, and Responsible Individual. The table contains two rows of data.

Admin	Study ID	External PI/Researcher	Type	Responsible Individual
	15	Charles Rossiter	Signed 06/30/2023 1:51 PM CDT	Researcher
		Signed 06/30/2023 4:04 PM CDT	Amanda Bennett	06/29/2023

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

The screenshot shows the IRB application interface with two main sections. The 'Publications' section has a message: 'Please list any publications or presentations arising from this study that have used IDPH data. Upload the article itself, or a document containing the title, authors, and date of publication or presentation.' Below this is a 'New Item' button. The 'Cont Reviews' section has three tabs: 'Amendments', 'Adverse Events', and 'Deviations'. Below the tabs is a table with columns: Year, Status, Due Date, Date Received, Date Approved, and Submitted By. The table contains one row of data.

Year	Status	Due Date	Date Received	Date Approved	Submitted By
1	Due	06/27/2023			

Below the table are buttons for 'Continuation Form' and 'Submit', and a 'Print Messages (1)' link.

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](#)

Submit New Item for Publications

i Please list any 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.

Date [Clear Acceptable Formats](#)

Publications Type

- Peer-reviewed journal article
- Other journal article
- Conference presentation
- Conference poster
- Other

Upload File No file chosen
Allowed Extensions: doc, docx, pdf, xls, xlsx, ppt, pptx, jpg, png

Description

Rename File to

Leave blank to use original file name

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.

The screenshot shows the Sitero Mentor IRB interface. On the left sidebar, the 'My Studies' menu item is highlighted with a blue circle. The main content area displays a table of studies. The row for IRB # 12, titled 'IDPH Test Study', is also circled in blue. The table has the following data:

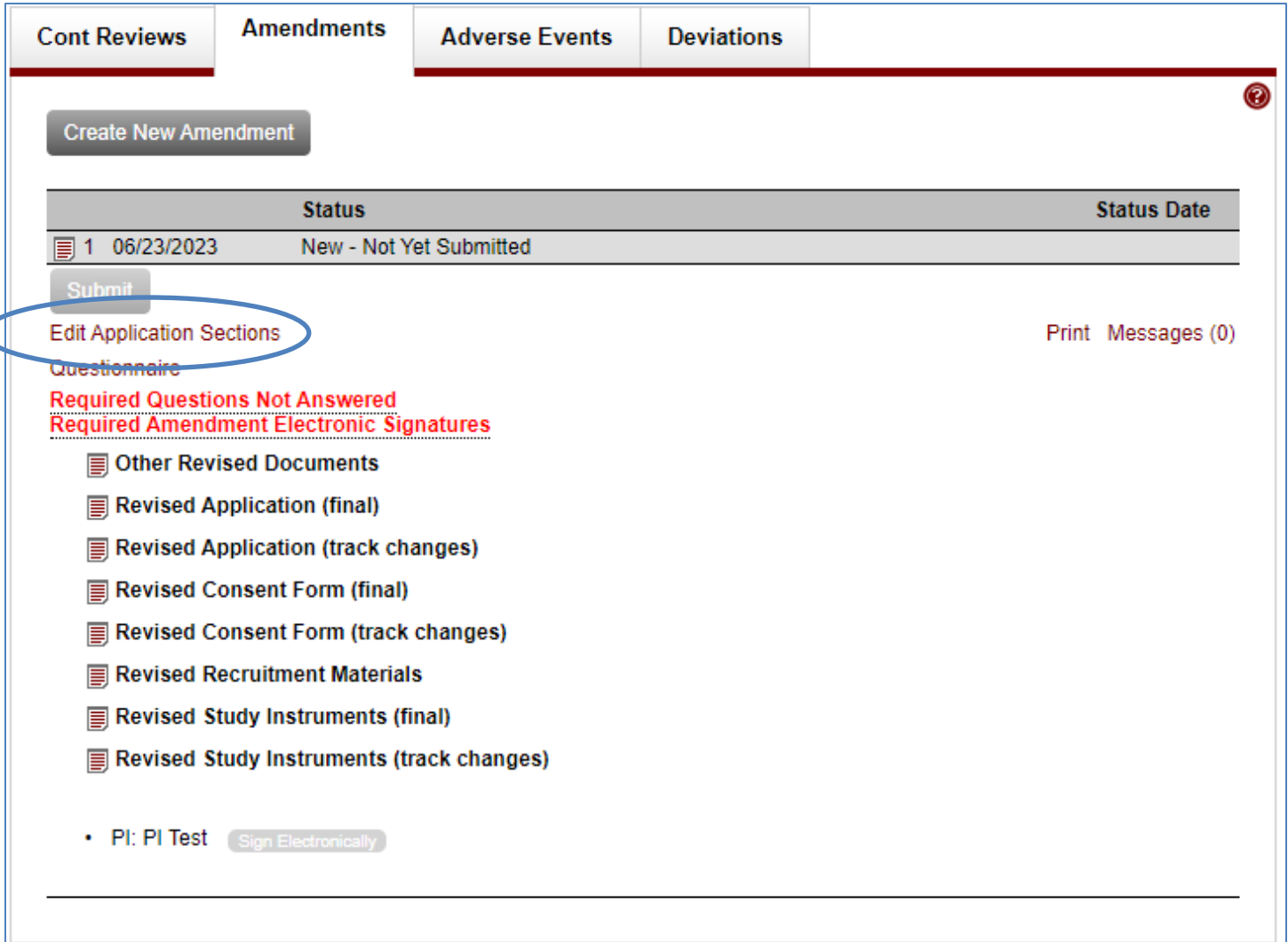
IRB #	Title	PI	Approved	C.R. Due	Tracking Status
2	Test	PI Test			With Assigned Reviewers
4	PI Test Study	PI Test	06/12/23	05/28/24	Completed
12	IDPH Test Study	PI Test	06/23/23	05/11/24	Completed

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.

The screenshot shows the bottom of the View Study screen. The 'Amendments' tab is selected and highlighted. Below the tabs, there is a gray button labeled 'Create New Amendment'.

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 screenshot shows the 'Amendments' tab selected in a navigation bar. Below the navigation bar is a 'Create New Amendment' button. A table lists amendments with columns for 'Status' and 'Status Date'. The first row shows an amendment dated 06/23/2023 with a status of 'New - Not Yet Submitted'. Below the table is a 'Submit' button and a link for 'Edit Application Sections', which is circled in blue. To the right of this link is a 'Print Messages (0)' link. Below these are links for 'Questionnaire', 'Required Questions Not Answered', and 'Required Amendment Electronic Signatures'. A list of document types for revision follows, each with a list icon: 'Other Revised Documents', 'Revised Application (final)', 'Revised Application (track changes)', 'Revised Consent Form (final)', 'Revised Consent Form (track changes)', 'Revised Recruitment Materials', 'Revised Study Instruments (final)', and 'Revised Study Instruments (track changes)'. At the bottom, there is a list item 'PI: PI Test' with a 'Sign Electronically' button.

	Status	Status Date
1	06/23/2023	New - Not Yet Submitted

Submit

[Edit Application Sections](#) [Print Messages \(0\)](#)

[Questionnaire](#)

[Required Questions Not Answered](#)

[Required Amendment Electronic Signatures](#)

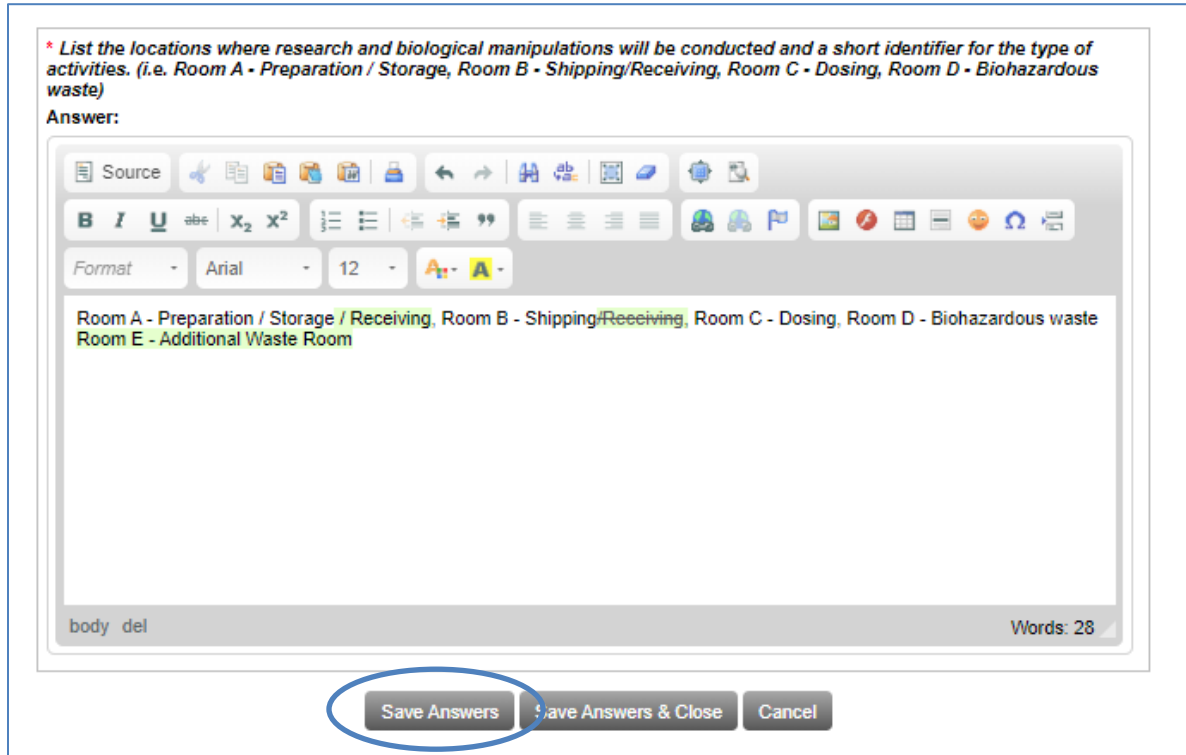
- [Other Revised Documents](#)
- [Revised Application \(final\)](#)
- [Revised Application \(track changes\)](#)
- [Revised Consent Form \(final\)](#)
- [Revised Consent Form \(track changes\)](#)
- [Revised Recruitment Materials](#)
- [Revised Study Instruments \(final\)](#)
- [Revised Study Instruments \(track changes\)](#)

• PI: PI Test [Sign Electronically](#)

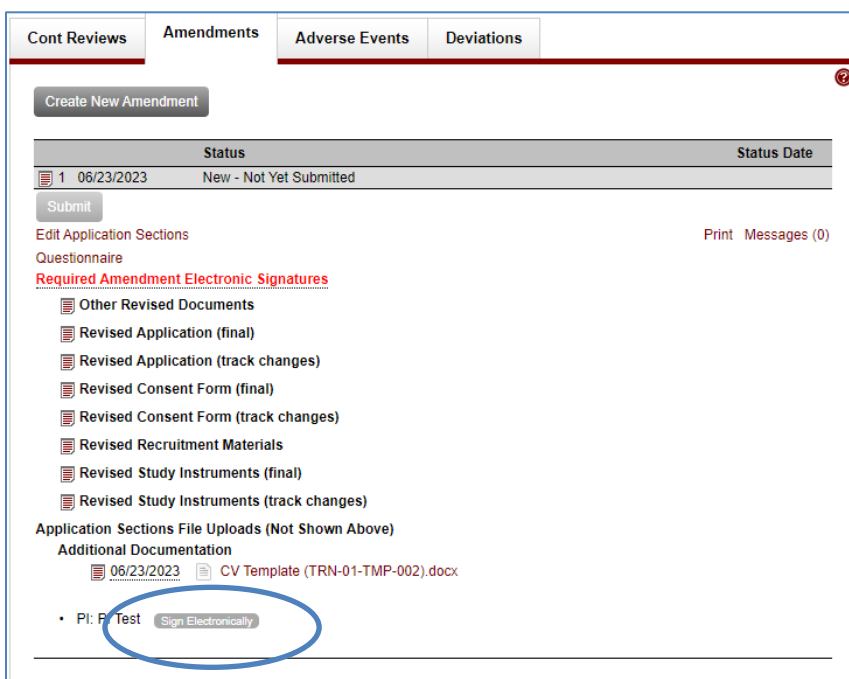
The IRB Application Sections: Amendment Page will automatically open. Begin amending the application by selecting the [Add/Edit Answers](#) where you want to make changes.

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.

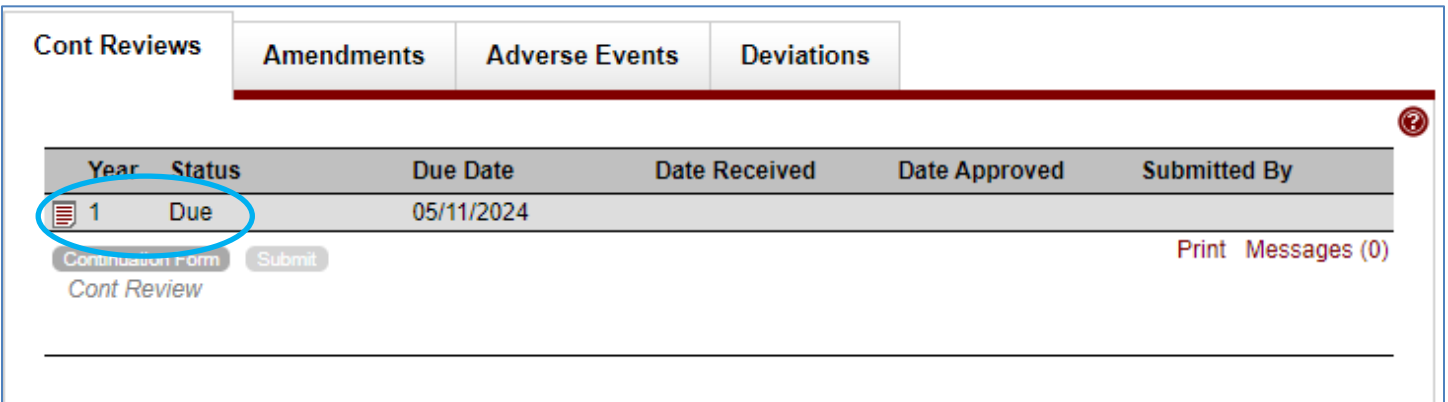
You must await the approval of your amendment by the IRB before implementing the requested changes. You will be notified by email if the IRB has questions, requests revisions, or approves the amendment.

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

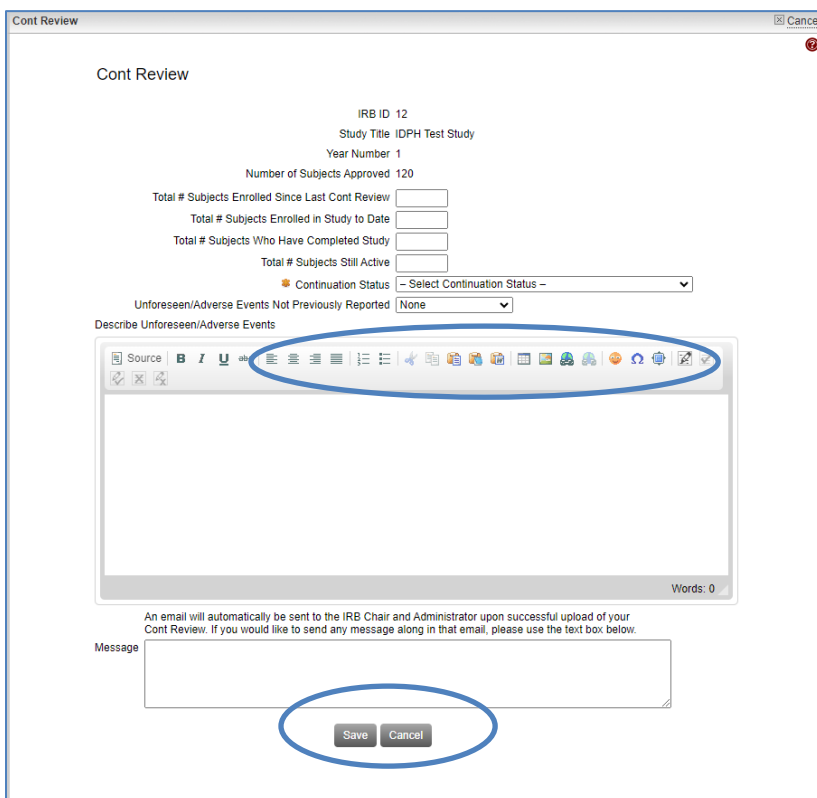


Year	Status	Due Date	Date Received	Date Approved	Submitted By
1	Due	05/11/2024			

[Continuation Form](#) [Submit](#) [Print Messages \(0\)](#)

Cont Review

the appropriate option from the dropdown menu.



Cont Review

IRB ID 12
Study Title IDPH Test Study
Year Number 1
Number of Subjects Approved 120

Total # Subjects Enrolled Since Last Cont Review
Total # Subjects Enrolled in Study to Date
Total # Subjects Who Have Completed Study
Total # Subjects Still Active

Continuation Status

Unforeseen/Adverse Events Not Previously Reported

Describe Unforeseen/Adverse Events

Words: 0

An email will automatically be sent to the IRB Chair and Administrator upon successful upload of your Cont Review. If you would like to send any message along in that email, please use the text box below.

Message

[Save](#) [Cancel](#)

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.

Cont Reviews Amendments Adverse Events Deviations

Year	Status	Due Date	Date Received	Date Approved	Submitted By
1	Due	05/11/2024			

Continuation Form Submit Print Messages (0)

Missing: Signatures
Cont Review

Close Study Requested

- PI: PI Test Sign Electronically

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 image shows two side-by-side screenshots of the Sitero Mentor IRB interface. The left screenshot displays the 'Adverse Events' tab, which includes a blue information icon and the text 'Use this tab to report possible or actual harms to participants in your research study.' Below this is a 'New Adverse Event' button circled in blue. A table below the button shows columns for 'Event / Date', 'Status / Comments / Files', and 'Submitted By', with the message 'No Adverse Events Found' below it. The right screenshot displays the 'Protocol Deviations' tab, with a 'New Protocol Deviation' button circled in blue. A table below the button shows columns for 'Status', 'Protocol Deviations File/Comments', and 'Submitted By', with the message 'No Protocol Deviations Found' below it.

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

Adverse Event

Use this tab to report possible or actual harms to participants in your research study.

Report Date: 06/23/2023 Clear Acceptable Formats

Reported from Another Site

Attach A File: Choose File No file chosen
Allowed Extensions: doc, docx, pdf, xls, xlsx, ppt, pptx, jpg, png

Rename File to:

Leave blank to use original file name

Relation to Study Procedures: Related

Requires Changes to Study or Consent Form

Requires Urgent IRB Review

Comments:

Complete Questionnaire After Saving This Form.

Save
Cancel

New Protocol Deviation

Protocol Title: IBC Test Submission

Date: 06/15/2023 Clear Acceptable Formats

Protocol Deviation Report: Choose File No file chosen

Rename File to:

Leave blank to use original file name

Comments:

Save
Cancel

aaaaaaaaa

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.

Adverse Events

Use this tab to report possible or actual harms to participants in your research study.

New Adverse Event

Event / Date	Status / Comments / Files	Submitted By
1. 06/23/2023	New Adverse Event Reported	Mentor Admin

Adverse Event Questionnaire ✓ Print Messages (0)

✓ Related

06/23/2023	New Adverse Event Reported	Mentor Admin
06/23/2023	QIS-01-TMP-005 (Template for Template).docx	Mentor Admin

Additional Documentation

- PI: PI Test Sign Electronically

Protocol Deviations

New Protocol Deviation

Status	Protocol Deviations	File/Comments	Submitted By
1. New	06/15/2023	No file	PI Test

Type: Deviation Print Messages (0)

06/15/2023

Additional Documentation

- PI: PI Test Sign Electronically

No Site Assigned Tracking Status: Submitted to IBC Coordinator

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.