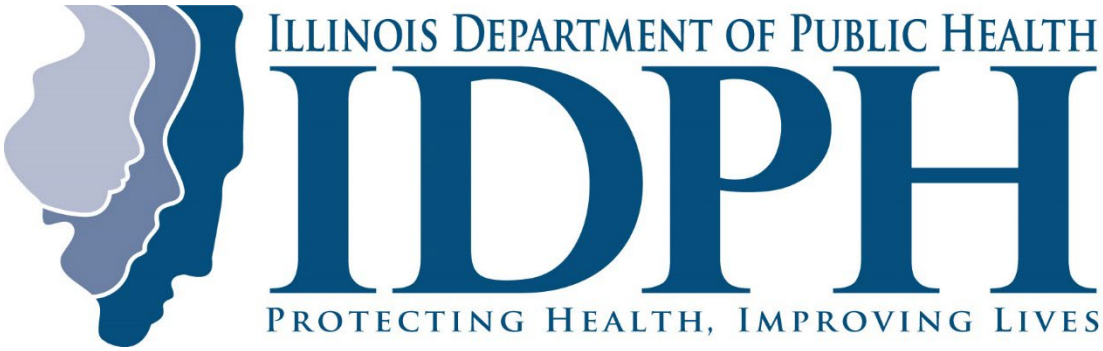


Institutional Review Board

EXTERNAL INVESTIGATOR MANUAL

TABLE OF CONTENTS

Introduction 2
How to Obtain Access to Mentor 2
How to Login to Mentor 3
Tips on Navigating in Mentor 3
Designating a Research Coordinator 4
Human Subject Protection Certification 5
Adding Human Subjects Protection Training Certification for Someone Else 5
How to Create a New Study Application 6
How to Complete a New Study Application 9
How to Submit a Completed Study Application 13
Responding to Questions from the Responsible Individual or IRB 14
Entering Publications 16
How to Submit an Amendment 17
How to Submit a Continuing Review 20
How to Submit Adverse Events 22
How to Submit Protocol Deviations 23
Study Messages 24

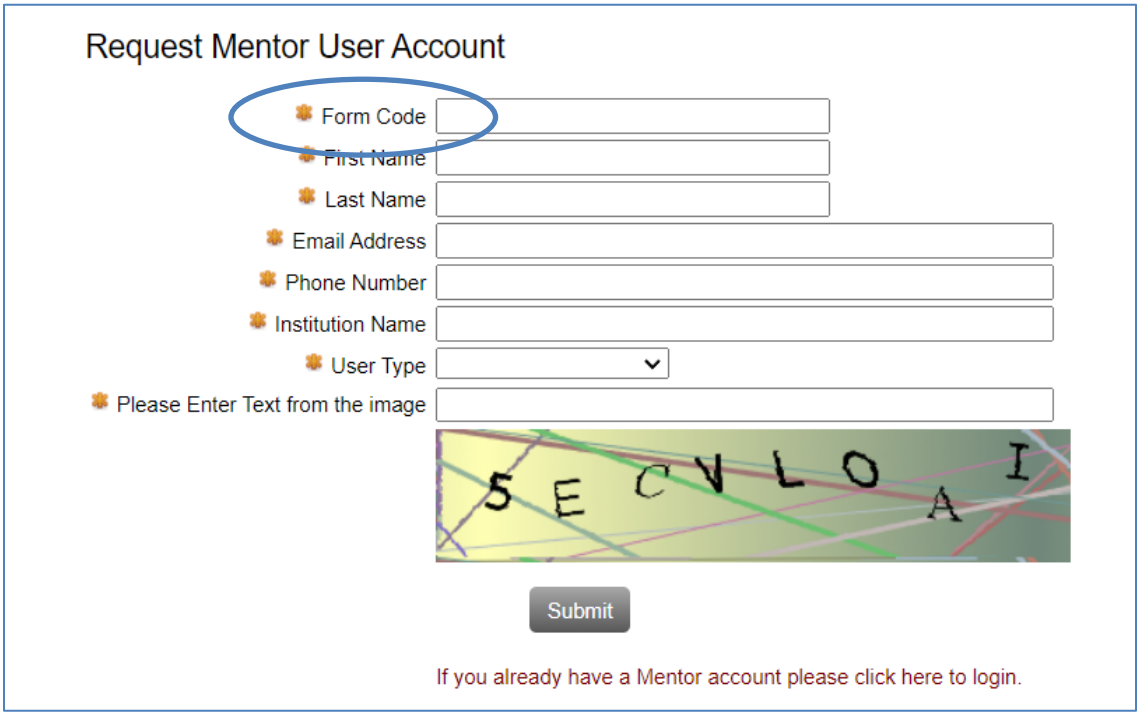
INTRODUCTION

The User Manual contains the essential information on how to use Mentor, including 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. 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 MENTOR

To submit an IRB application to the IDPH IRB, you must 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.



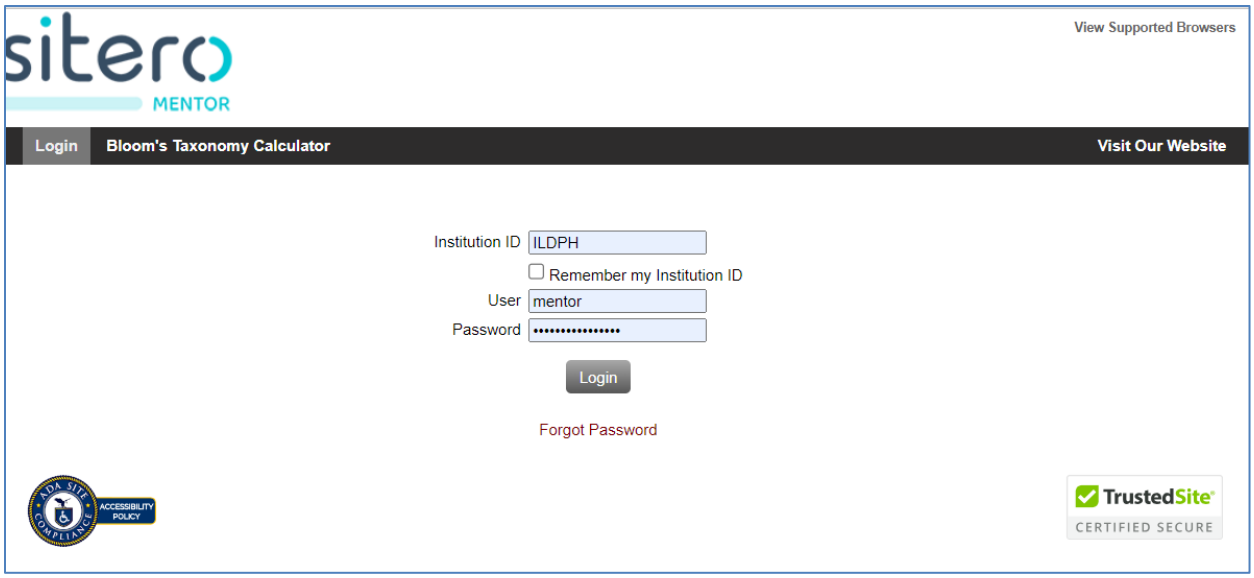
Once registered, an email will prompt you to reset your password. However, you will not be able to log into the system until you receive notification that your account has been approved.

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, as described on page 10, or share the web link and Form Code with each person.

HOW TO LOGIN TO MENTOR

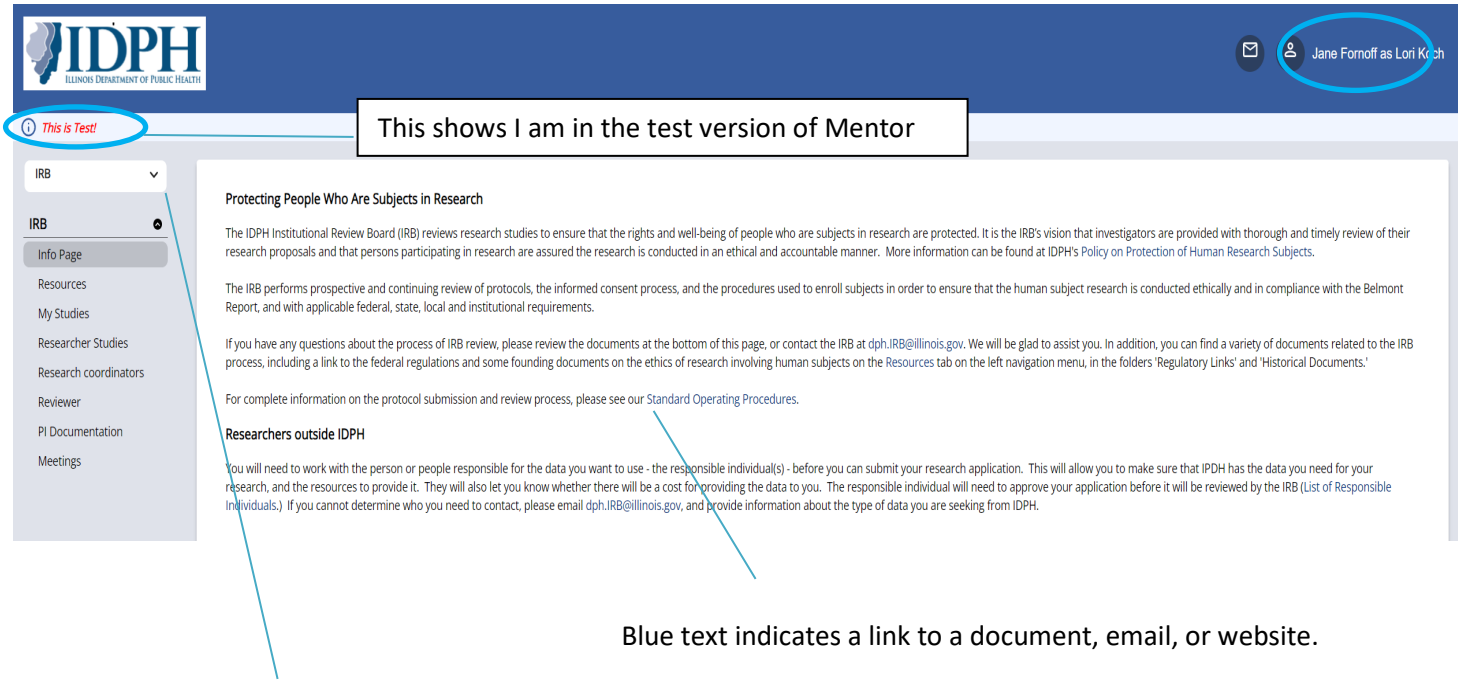
Open your browser and go to [www.AxiomMentor.us.](http://www.AxiomMentor.us)

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



TIPS ON NAVIGATING IN MENTOR

This is where you log out.



Blue text indicates a link to a document, email, or website.

You will likely spend most of your time on the IRB drop-down menu.

These are some of the icons you will see in Mentor.

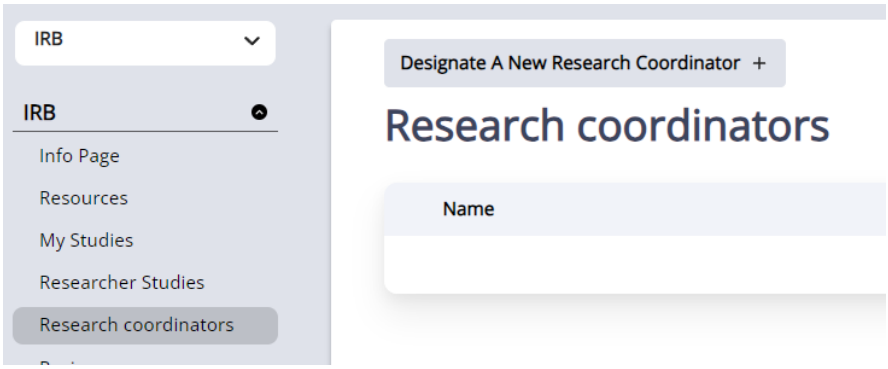
View Study Page	Takes you back to the current main study page.
Back	Takes you back to the previous screen.
⋮	Clicking here will give you a list of actions that can be taken.
	A document is attached. Click on the document name to open it.
	Clicking on the name next to it will take you to a new section.
	Clicking here will allow you to upload a document.
› or	Clicking here will open up a section.
⌄ or	Clicking here will close a section.
(0)	Indicates the number of messages associated with the study.
Docs ✓	Indicates that human subjects' protection documents have been uploaded and are within the three-year approval time frame. They will show in yellow as the expiration data gets closer or red if expired.
Pending	Indicates action is needed (not necessarily by you).

DESIGNATING A RESEARCH COORDINATOR

You can designate a research coordinator in Mentor, who will then be able to complete an application, add personnel, human subject protection training certificates and CVs, continuing reviews, amendments, adverse events, deviations, and publications on your behalf.

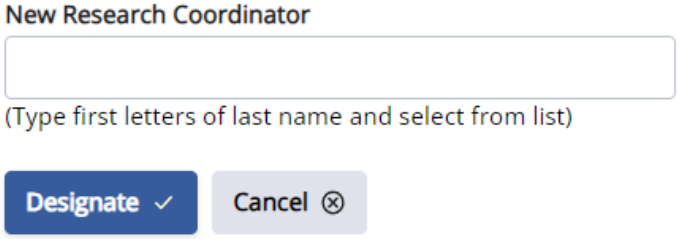
They will first need an account in Mentor, which can be obtained as described above in How to Obtain Access to Mentor.

To designate a research coordinator, select Research coordinators under the IRB menu on the left of the screen and then click Designate a New Research Coordinator.



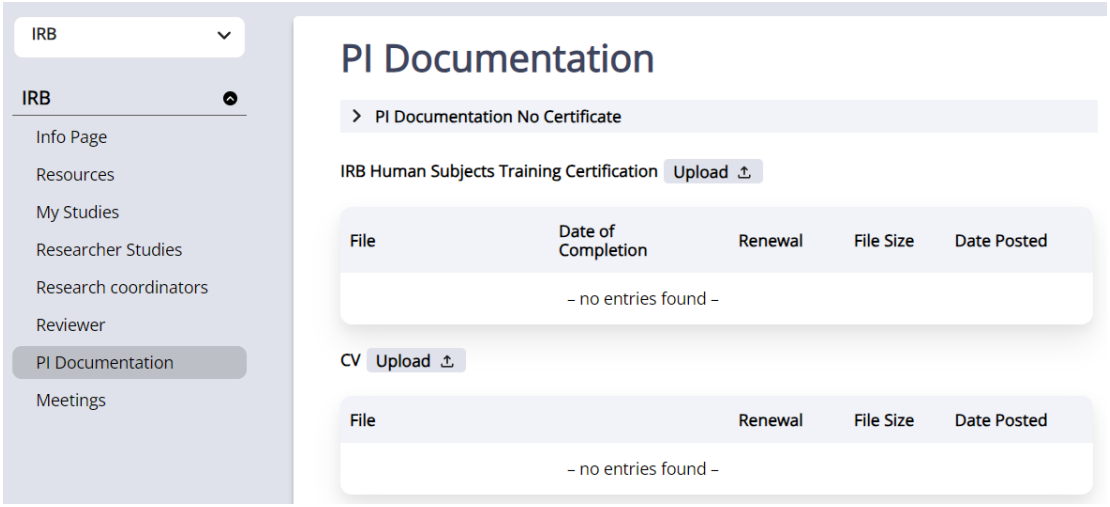
Search by last name and select it from the list. You must select the name from the popup list. Typing the name in the text box will not work.

Then click Designate.



HUMAN SUBJECT PROTECTION CERTIFICATION

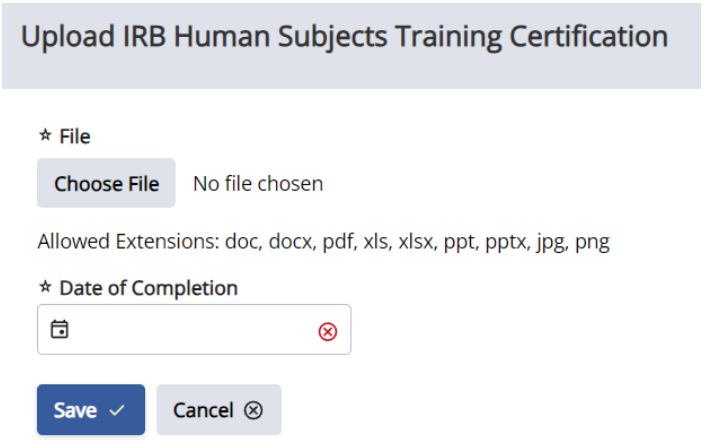
The IDPH IRB requires certification every three years. You can upload your human subject protection certification to Mentor. To upload a certificate, click the PI Documentation selection under the IRB menu and then the Upload button.



The screen on the right will open.

Choose the file and document the date of completion.

Click Save.



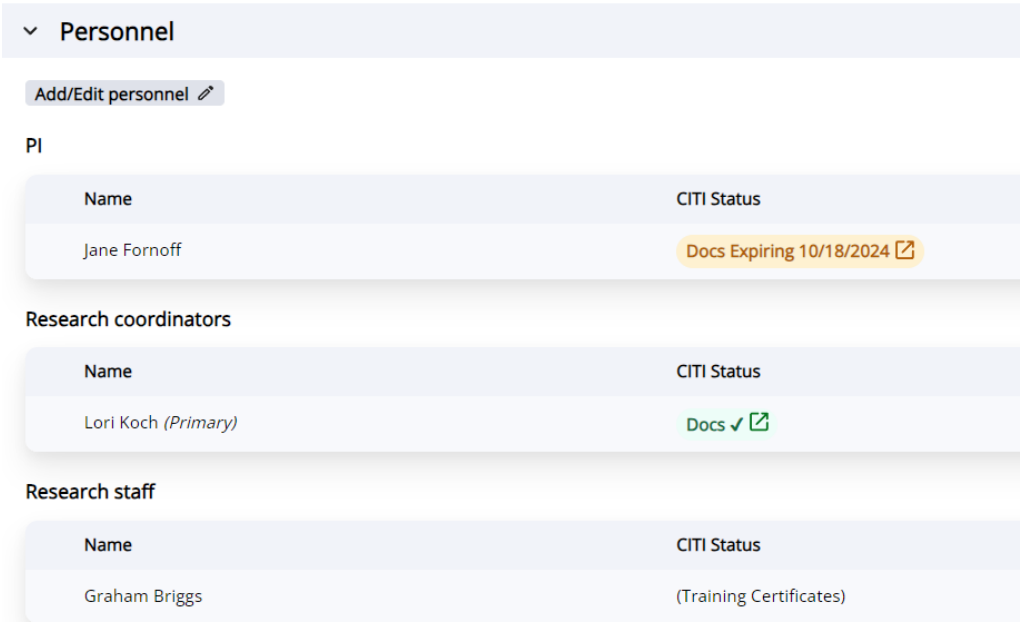
ADDING HUMAN SUBJECTS PROTECTION TRAINING CERTIFICATION FOR SOMEONE ELSE

If you are a PI, co-PI with editing rights, or a Research Coordinator and the personnel section for your study is complete, you can add human subjects' protection (HSP) training certificates for other people.

On the View Study screen, open the Personnel section by clicking on the > icon if it is not already opened.

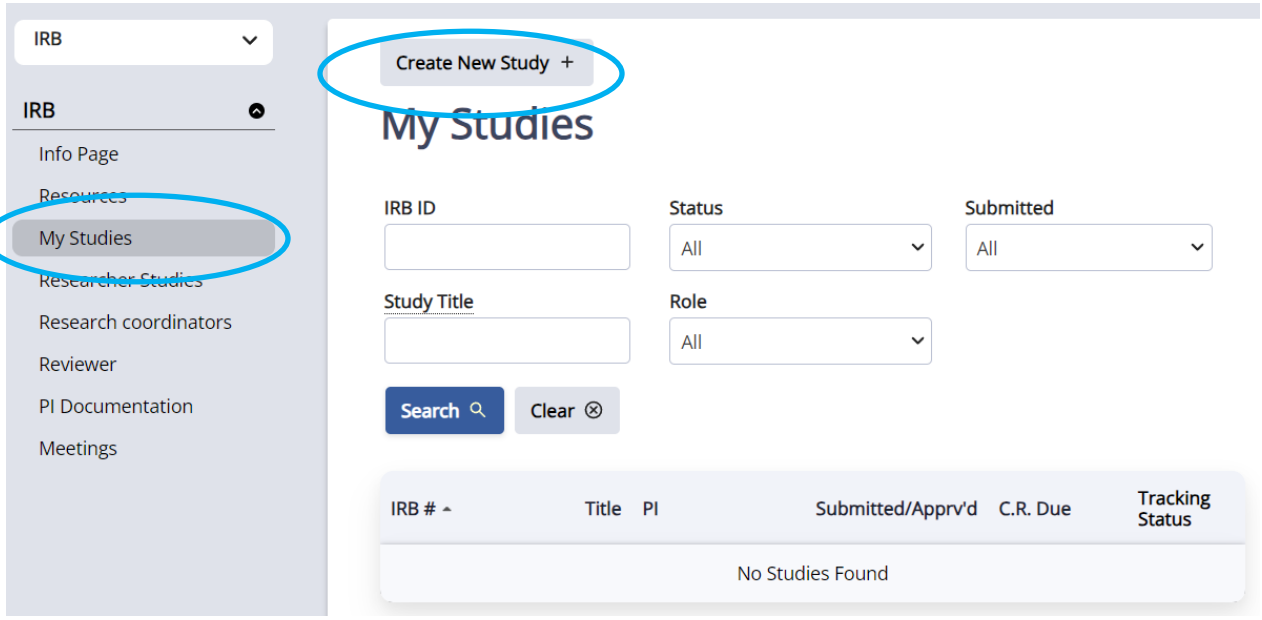
A CITI status with a green check indicates that uploaded HSP certificates are within the three-year approval time frame. They will show in yellow as the expiration date gets closer or red if expired. (Training Certificates) indicates that no certificates have been uploaded and approved.

To upload new certificates, click on the CITI status to open the upload screen described in the section aboveand complete in the same way.

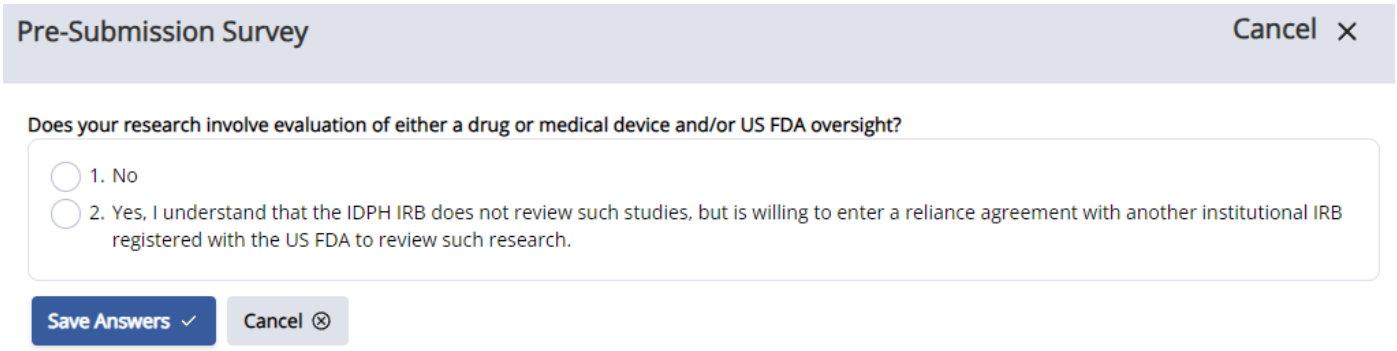


HOW TO CREATE A NEW STUDY APPLICATION

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 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.

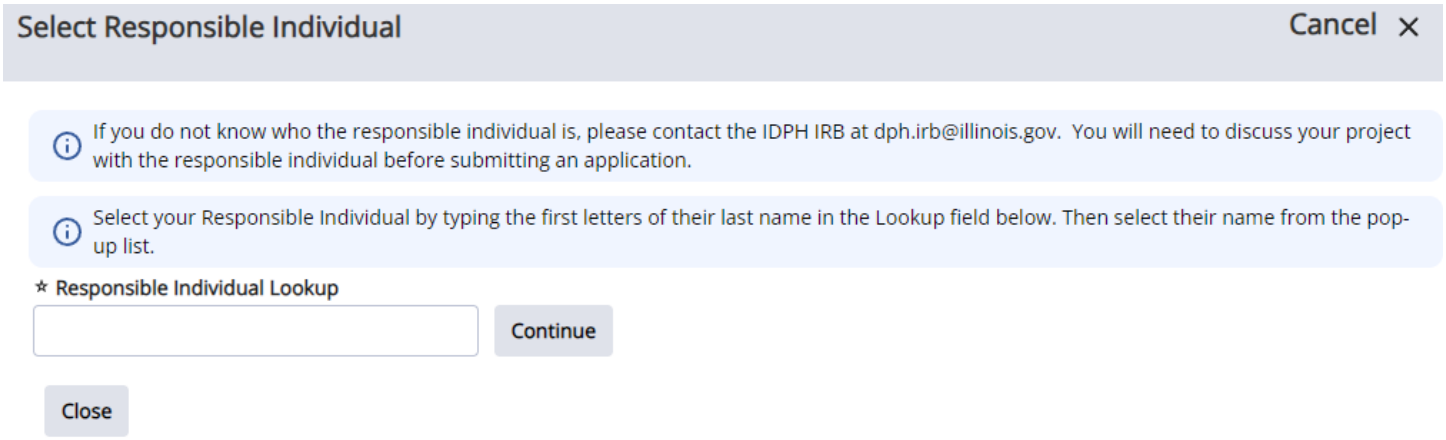


Once the survey has been completed, you will have determined that:

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)

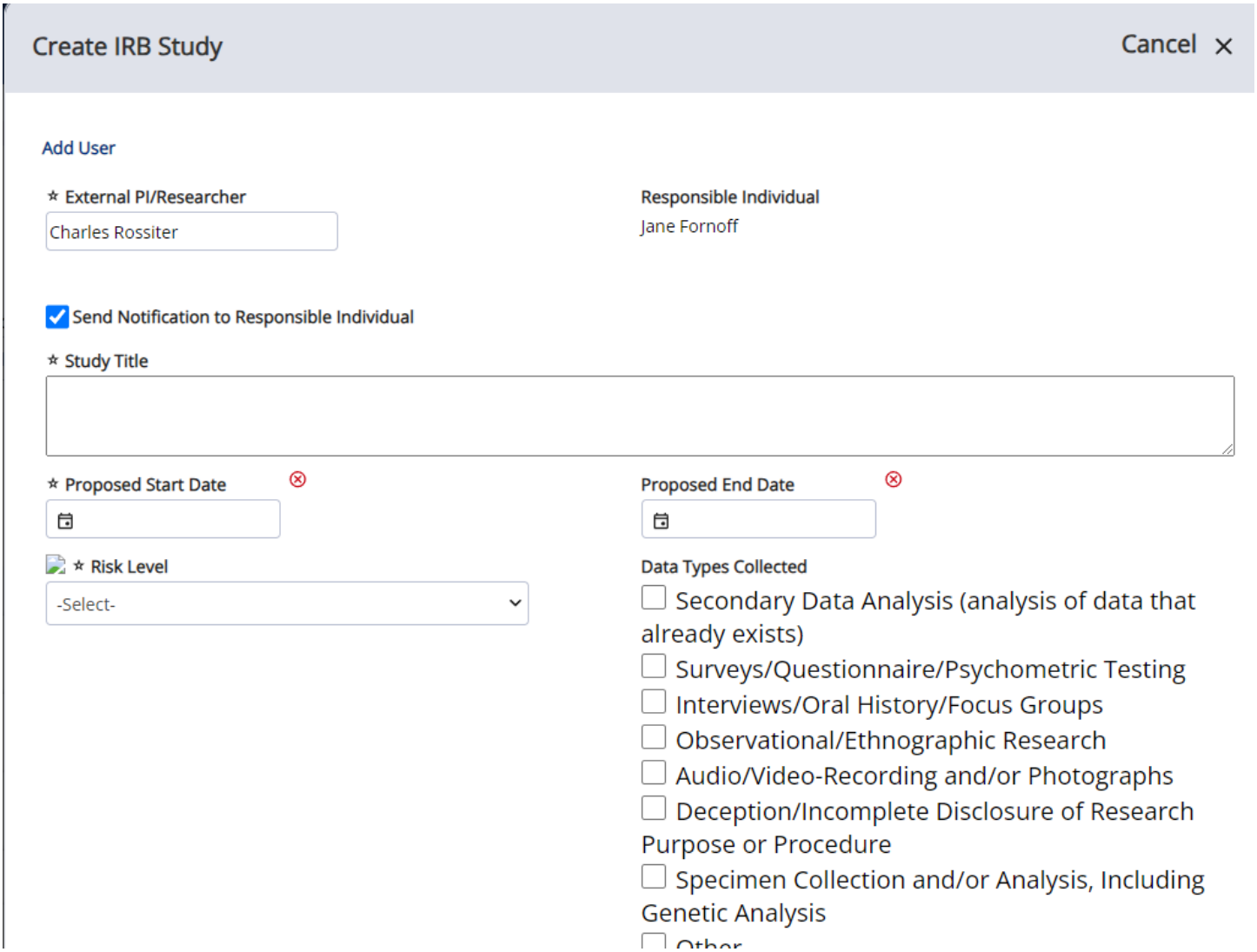
If you choose to complete the application, the first page will prompt you to select the Responsible Individual (RI). Type in the first letters of the RI's last name. A list will pop up below the text input box as you type. Continue typing to narrow the list down and select the desired name from the list. Once you have selected the RI, click Continue.

Note: You must select the name from the popup list. Typing the name in the text box will not work.

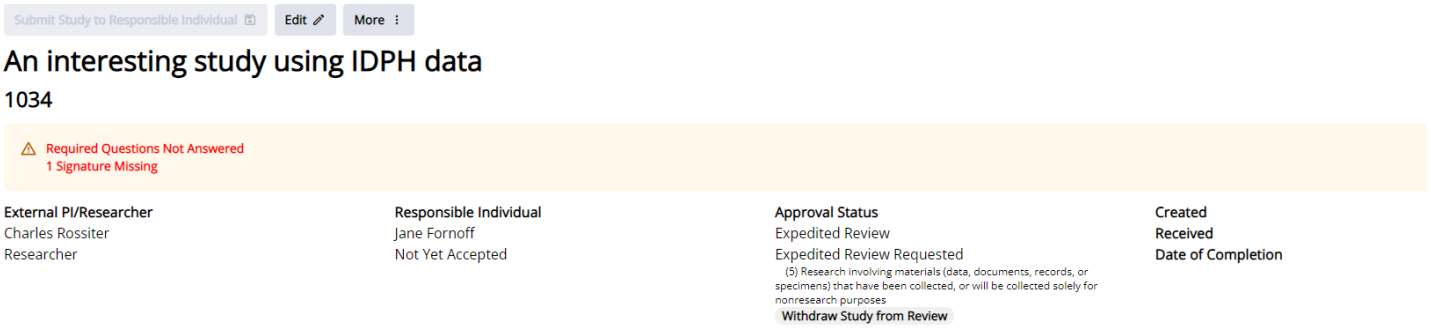


Hopefully, you identified and talked to the person who is responsible for the data you want to receive. If not, select Close and speak to the RI before submitting your application. This will allow you to make sure the data you want are available. The RI will be able to let you know the strengths and 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 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.



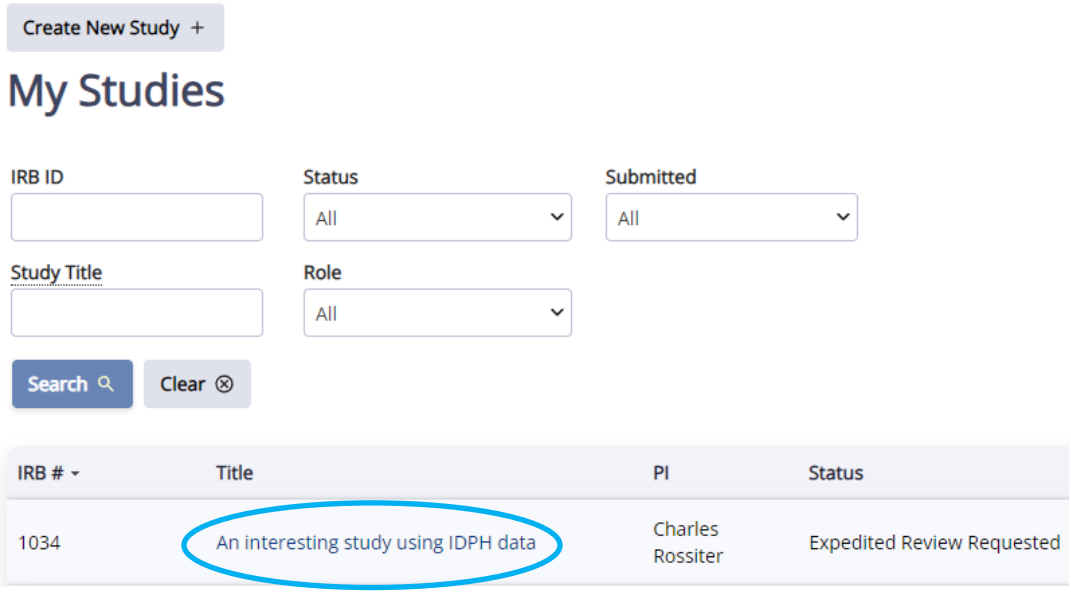
When you click on the **Save** button at the bottom of the screen, the initial study record will be created and you will be brought to the Study Page. You can then upload additional files, complete additional forms, and edit this form as needed.



You will see a couple of warnings in red telling you that the required questions have not been answered. That's fine because you will answer them next.

HOW TO COMPLETE A NEW STUDY APPLICATION

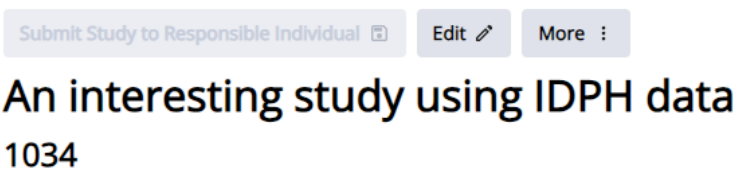
If you are not already on the Study Page, then under the IRB menu select My Studies. Your new study will have appeared. Click on the title to open the Study Page.



You should be aware that you will be required to upload some documents for your application before you can submit. It may help to have gathered everything before you begin. Depending on your study, these may include:

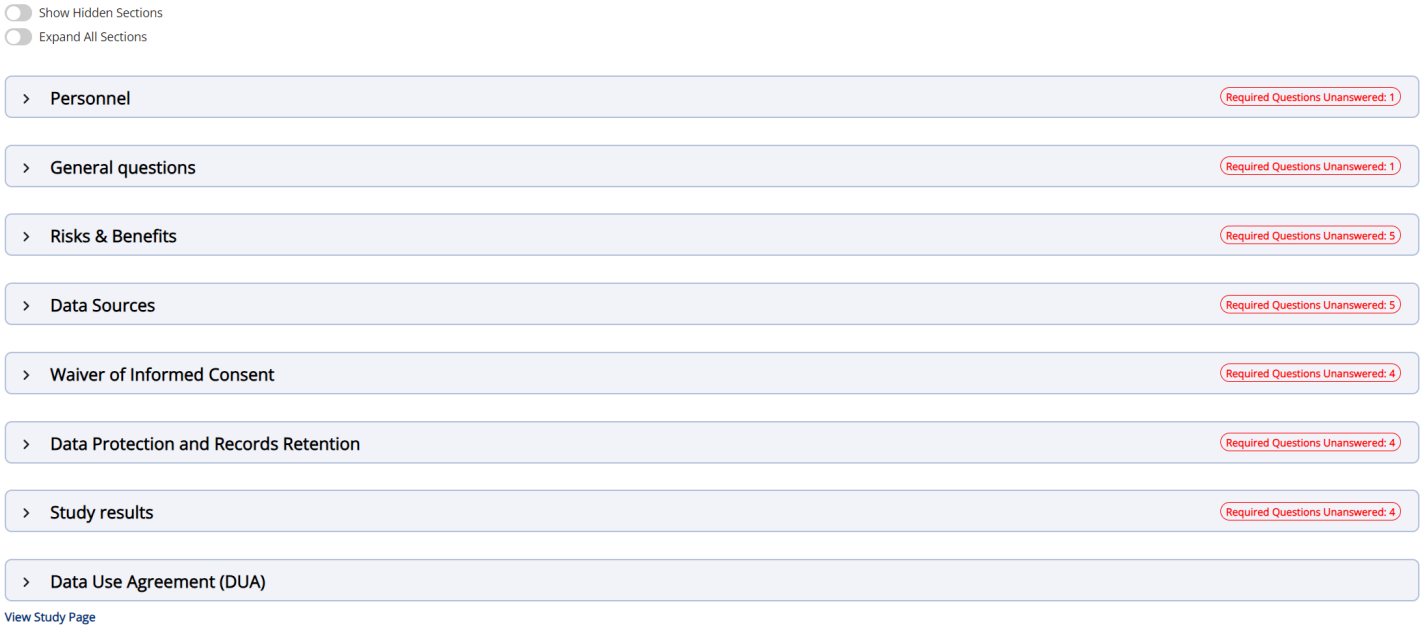
- PI and co-PI resumes
- Study design and analysis plan
- Application from any external IRB(s)
- Approved forms and consents from any external IRB(s)
- Decision documents from any external IRB(s)
- Certificate of Confidentiality
- List of variables and years requested for each IDPH data source
- Data 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 you want to change your responses to the questions you answered when creating the study proposal, click Edit at the top of the page just above the study title.



To add responses to the application, click this button.

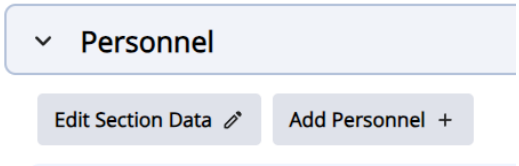
There will be several sections for which you need to answer questions.



<u>Personnel Section</u>

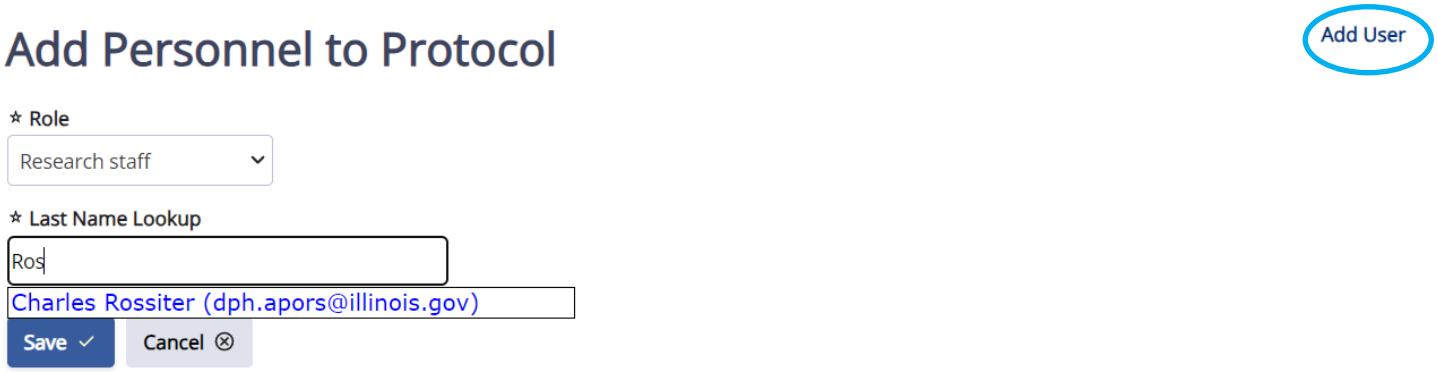
Study staff who will have contact with subjects or access to identifiable records disclosed for this research study should be registered with Mentor. This includes consultants, contractors, sub-contractors, data processing vendors, laboratories, and sponsoring or participating agencies or organizations. They should all be added to the list of study personnel. This will allow you and the IRB to assure their human subjects training is current for the duration of your study.

To add someone to the study, click **Add Personnel +** buttons. Select whether you are adding a PI, Co-PI, Research Coordinator, or Research staff.



(The Add/Edit personnel button on the View Study screen is really for editing personnel, so do not use it during the initial addition of personnel.)

Once the role is selected, look up their last name. 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 Save button. You should now see the name you added in the Personnel section. Repeat this process to add additional names as needed. If you select the wrong name, click the three dots to the left of the name and select Remove.

If individuals are not registered with the IDPH IRB, you can share the web link and Form Code with each person as described on page 2 or register them yourself using the **Add User** button on the top right of the screen. Do not assume that someone is not in the system. Always look them up first. Enter their email addresses as their usernames.

Complete this section by adding your resume and the resumes of co-PIs and listing any staff who are part of the study but will not have contact with subjects nor access to identifiable records disclosed for this study.

Data Use Agreement

The data use agreement (DUA) will not have been prepared yet during the submission process, so this section does not need to be completed.

Remaining Sections

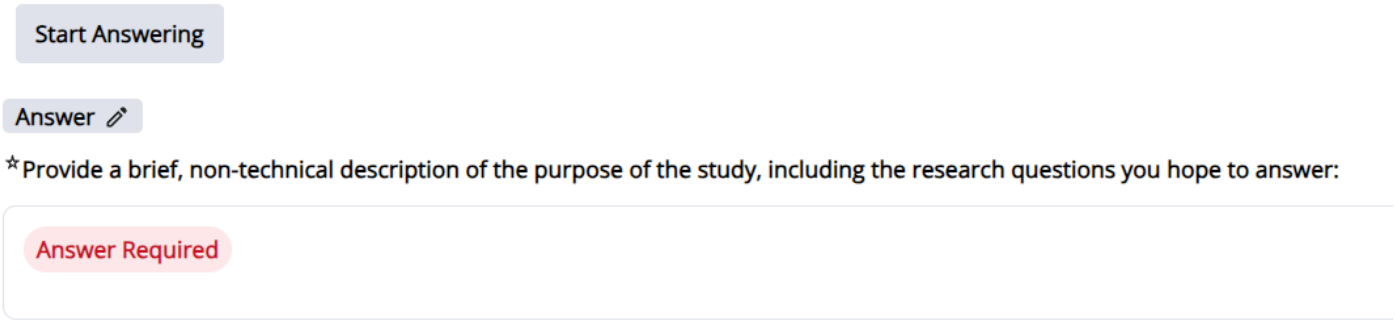
For each of the remaining sections, expand it, and answer each question. They do not have to be answered in the order they are listed. You will get different types of prompts, depending on the type of question you are answering. In each case, when you have responded, you will have three choices:

Save Answers will save your response and take you to the next question.
Save and Close will save your response and take you back to the application sections.
Cancel will not save your response and will take you back to the application sections.

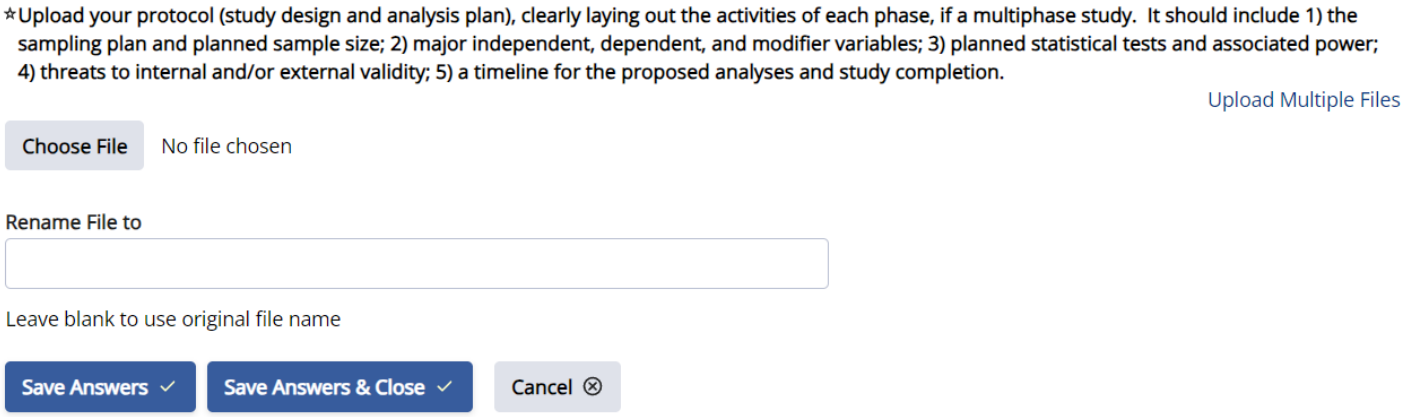
Text or Multiple-Choice Questions

Start Answering or **Continue Answering** will take you to the next question from where you last stopped.

The answer will take you to the specific question with which the button is associated.

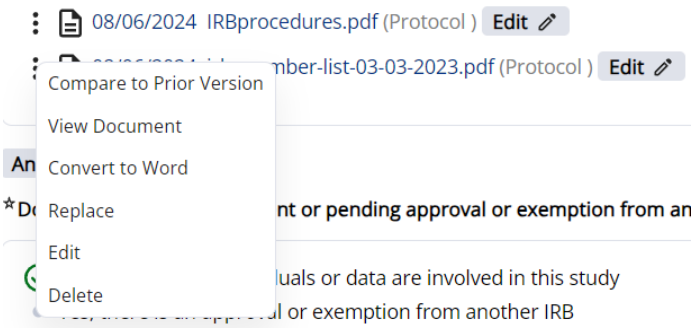


Upload file questions



You can upload files one at a time. It is helpful to rename the file if the name does not have a meaning that would be obvious to the IRB.

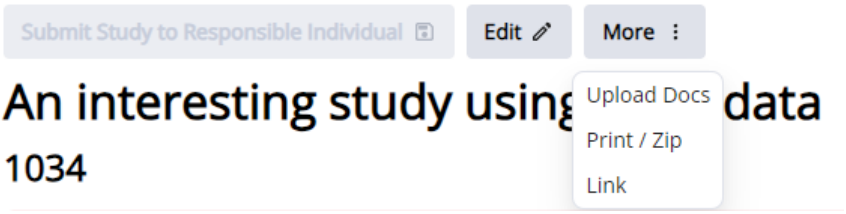
Alternatively, you upload multiple files simultaneously using the link in the top right corner. In this case, click the Upload Multiple Files button and select the files you want to upload. You cannot add them to the drag-and-drop area one at a time; they all must be added at once. You may select more than one file by holding the CTRL key down while you select each file. You cannot select multiple files from different folders on your computer, so all the files must be in the same folder to use this function.



Once the files are uploaded, clicking on the three dots to the left of the name gives several options for viewing, changing, or deleting the document.

Clicking on the associated **Edit** button changes the display name and allows the addition of a description, file version, and date.

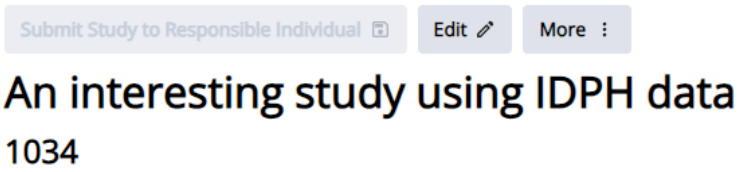
If you have documents you would like to upload that were not uploaded while completing the application, you can do so by clicking the **More** button and selecting Upload Docs.



HOW TO SUBMIT A COMPLETED STUDY APPLICATION

If you are not already on the View Study Page, select My Studies under the IRB menu. Your new study will be listed. Click on the title to open the View Study Page.

Note the "Submit Study to Responsible Individual" button at the top. If you see this button greyed out, your study has not been submitted to the RI. Your study is visible to the RI, IRB, the chair, and the administrator. If you have questions and would like someone to look at it before you formally submit, they will be able to see the application and any uploaded files. This button is unavailable for selection until all the Application questions are answered and you have signed the study.



Once you have answered all the questions, you should sign. On the View Study Page, click the **Sign Electronically** button on the same line as your name. (This button will be greyed out until all the questions are answered.) The Tracking Status will change to "Awaiting Responsible Individual Approval," and a signed date and time will appear. In due course, you will receive notification from the RI with questions, revisions, or when your submission is approved via email.

RESPONDING TO QUESTIONS FROM THE RESPONSIBLE INDIVIDUAL OR IRB

If the Responsible Individual (or later the IRB) has questions or comments about your study, you will receive an email notifying you. It will look like this, listing the questions you have been asked to revise.

Application Comments:

General questions

QUESTION:

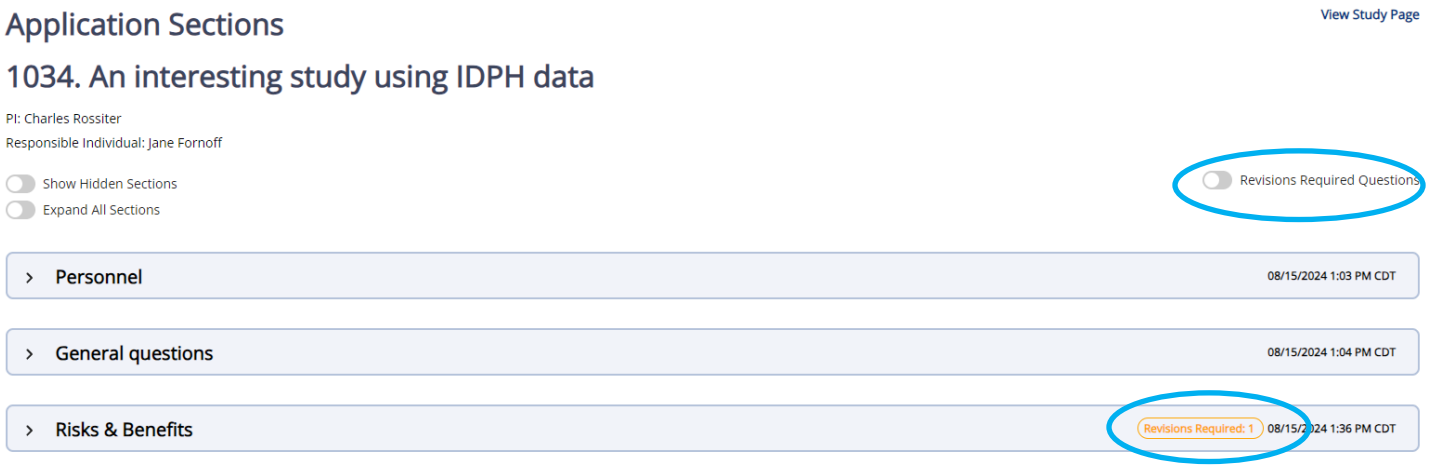
Provide a brief, non-technical description of the purpose of the study, including the research questions you hope to answer:

Data Protection and Records Retention

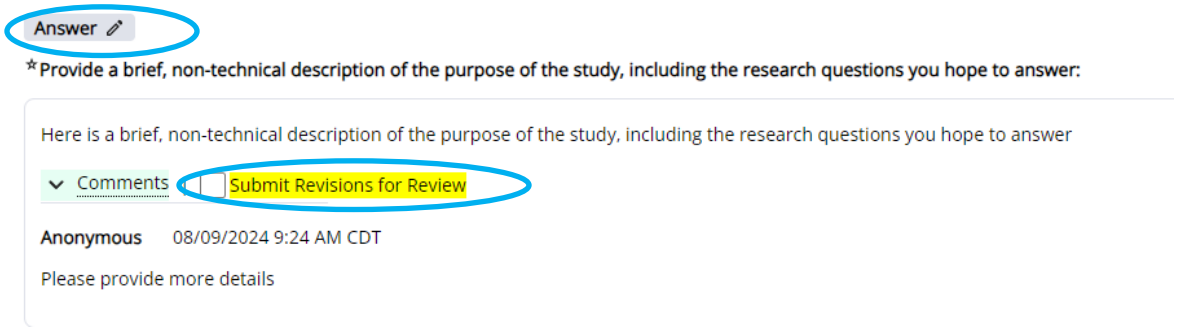
QUESTION:

Do you expect to maintain IDPH data or specimens beyond the completion of the study?

Go to the My Studies choice under the IRB drop-down menu and open your study by clicking on the title. To respond to questions, click on **Click here to Complete the Application Sections**. Each section will have an indicator showing whether revisions are requested for that section. You can open each section and respond. Alternatively, you can turn on the Revision Required Question button on the top right of the screen, and Mentor will open the questions requiring revision.



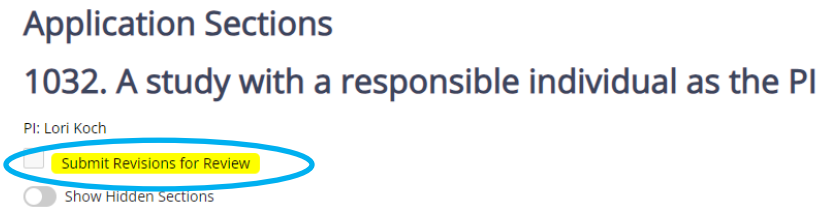
For each question, to see reviewers' comments, click **Comments**. To edit your response, click **Answer** above the question and address the reviewer's concerns. By default, track changes will be on. It is helpful to the reviewer to see the changes you have made. When finished, save your answer and check the **Submit Revisions for Review** box next to the question.



If you want to discuss a request revision with the Responsible Individual, return to the Study Page by clicking

View Study Page. Click on Messages to view the message in Mentor and reply by selecting **Send Now >**. Alternatively, you can reply to the email message you received. More information about messaging can be found at the end of this manual.

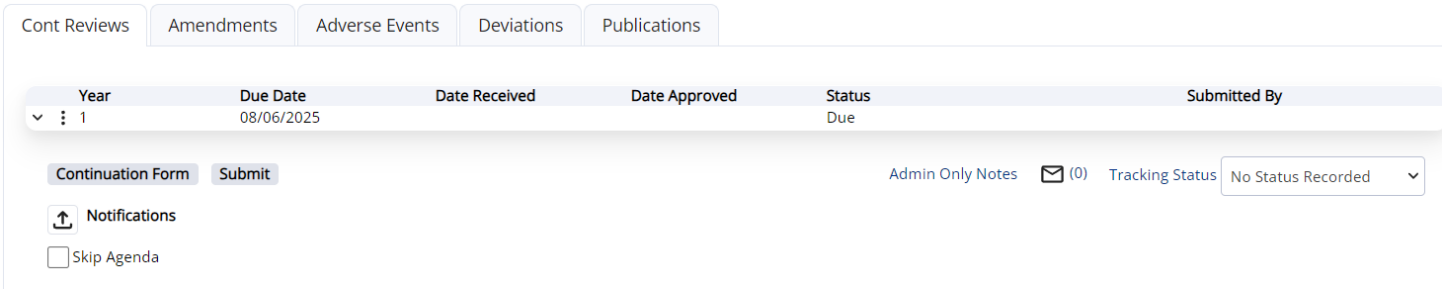
Once you have responded to all the questions, click on the **Submit Revisions for Review** at the top of the page (either on the Application page or the View Study Page.) This will resubmit your application to the RI (or IRB) and lock your application so you can no longer edit your re-submission.



Mentor then sends an automatic email notification back to the IRB stating that the requested revisions have been submitted. The tracking status now shows as "Revisions Submitted."

The Responsible Individual will review your changes and (if they answer the concerns) will submit them to the IRB. The IRB will review and ask for revisions and/or make a determination. You will be notified by email of the determination.

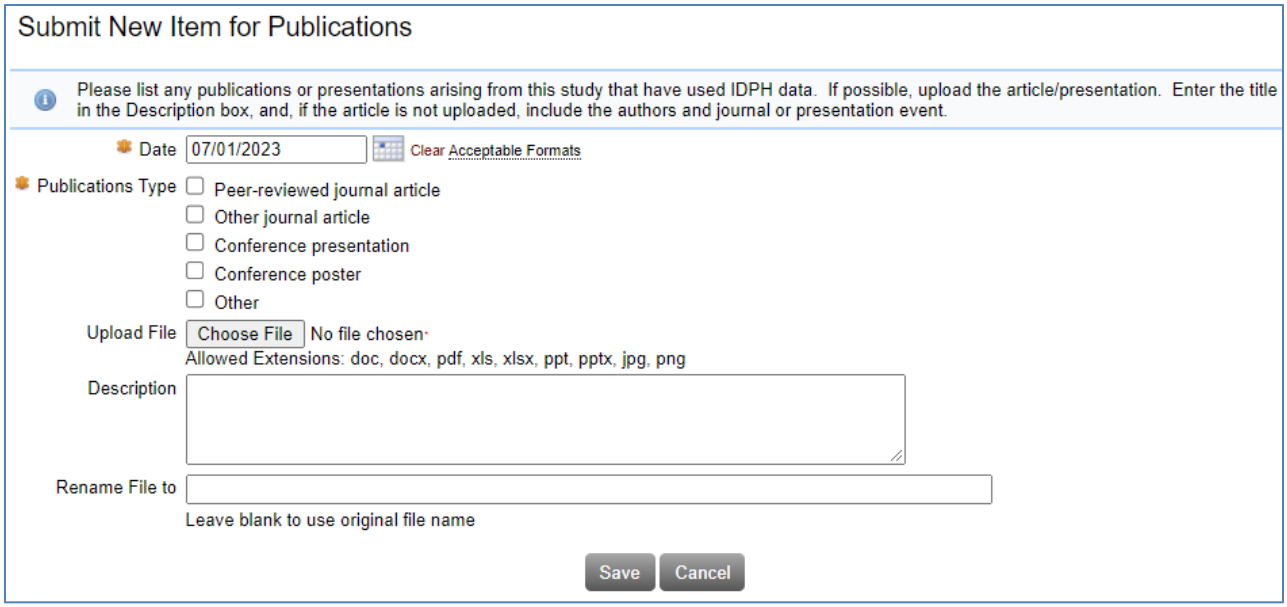
If your application is approved, tabs at the bottom of the Study Page are activated.



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.

Document them on the Publications tab as presentations are made or articles are published.
Click **New Publications**.

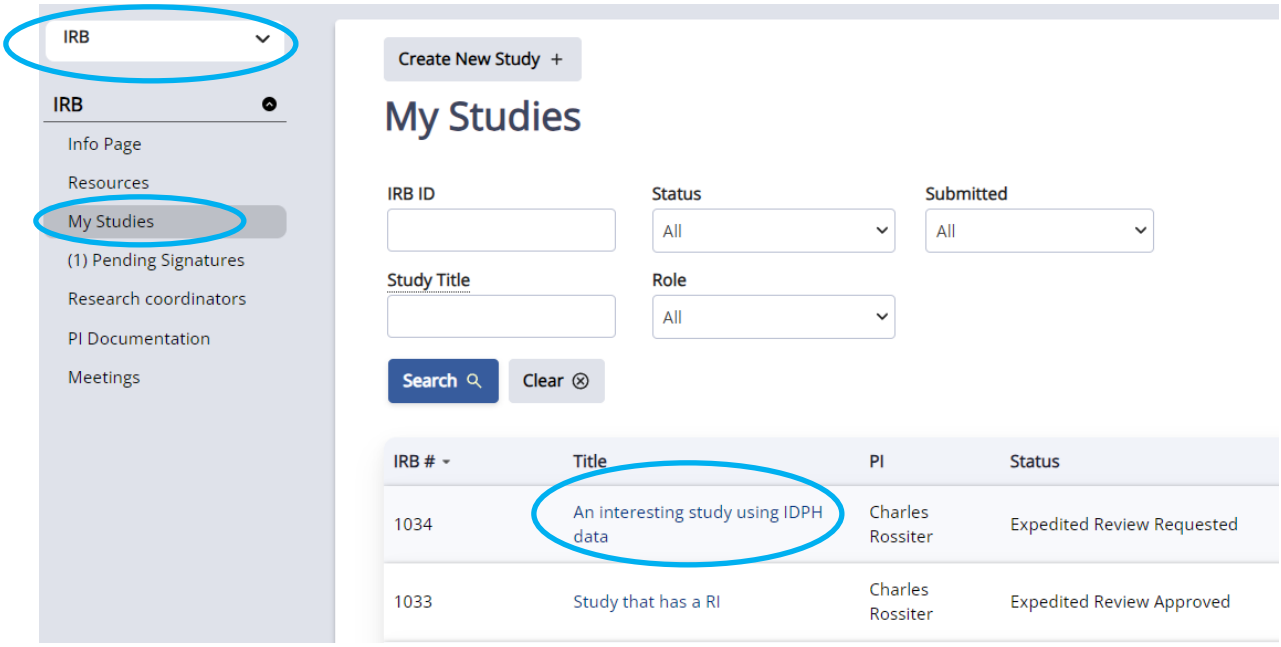


If possible, upload the article/presentation. Enter the title in the Description box, and if the article has uploaded, include the authors and journal or presentation event.

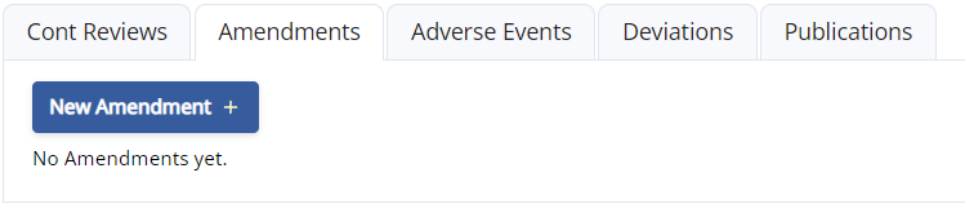
HOW TO SUBMIT AN AMENDMENT

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

To submit an amendment, log on to Mentor. Under the IRB Menu, click **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.



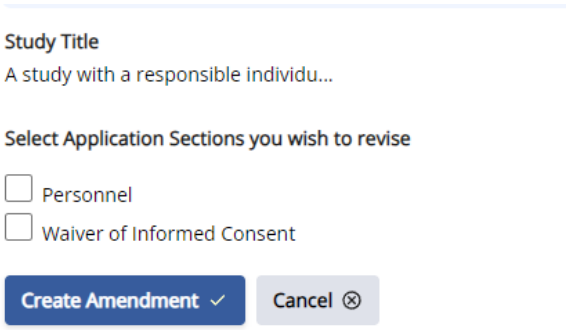
At the bottom of the View Study screen, there are several tabs: Continuing Reviews, Amendments, Adverse Events, and Deviations. Make sure you are on the Amendments tab. Click the **New Amendment** button.



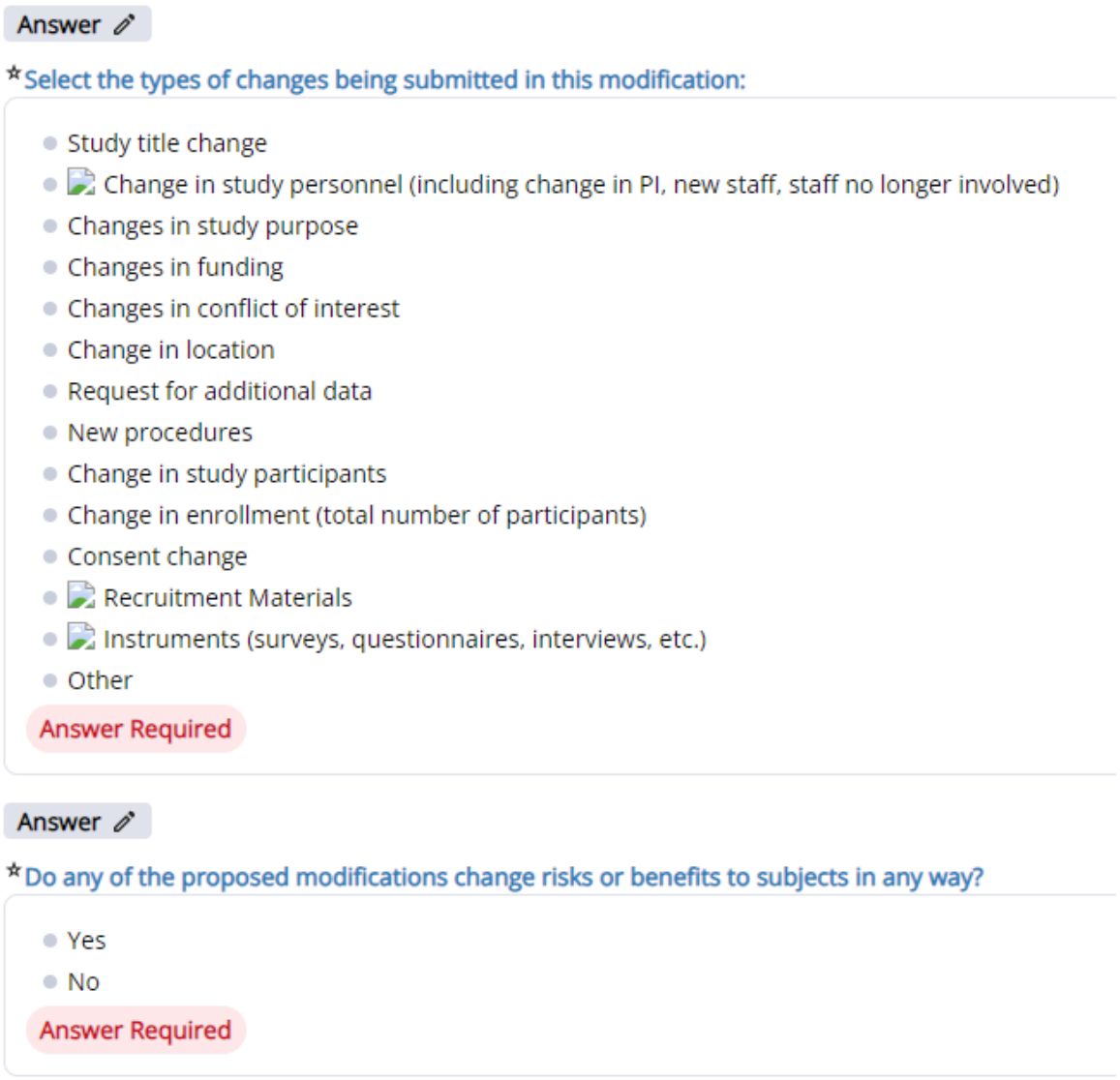
On the Create New Amendment screen, select which sections of the IRB application you wish to revise and then select Create Amendment.

You will be asked whether you want to amend specific sections, but these are not the only sections you can revise. Check the boxes next to the listed sections if you to revise them or leave them blank.

Then click the **Create Amendment** button. You will be asked for more details on the following screens.

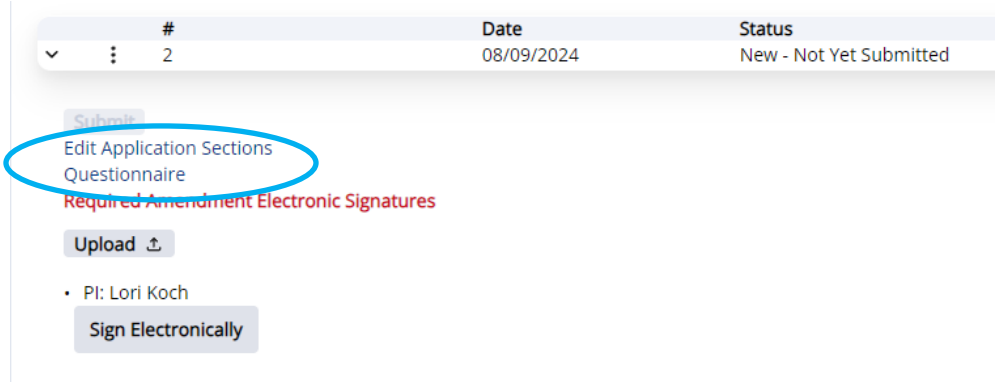


The next screen asks about the type of changes you are submitting. Click **Answer** and check all the applicable boxes. Then click **Save Answers** to go to the next question.



Once you have responded to all the questions, click **Return to Study Page**. Your amendment will now be listed on the amendments tab.

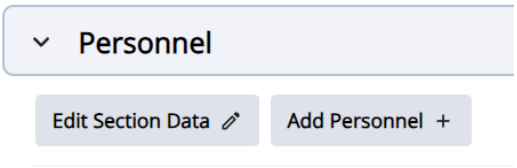
If you realize that you made a mistake in completing the screen above, click Questionnaire and edit your answers.



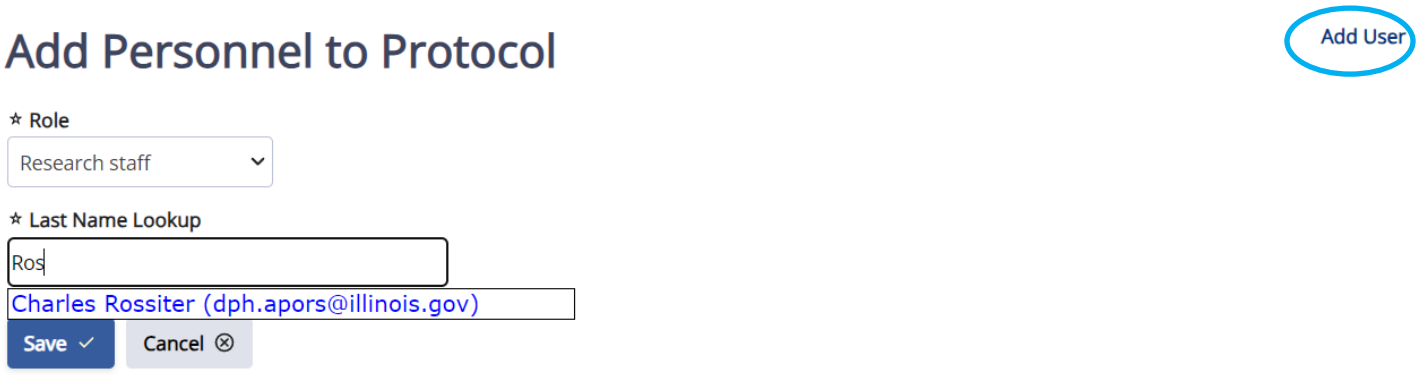
If you checked Personnel or Waiver of Informed Consent when you created the amendment, Select Edit Application Sections. This will show you the responses currently approved by the IDPH IRB.

Personnel Section

This section will show the people who are already associated with the study. To add someone to the study, click **Add Personnel +** buttons. Select whether you are adding a PI, Co-PI, Research Coordinator, or Research staff.



Once the role is selected, look up their last name. 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 Save button. You should now see the name you added in the Personnel section. Repeat this process to add additional names as needed.

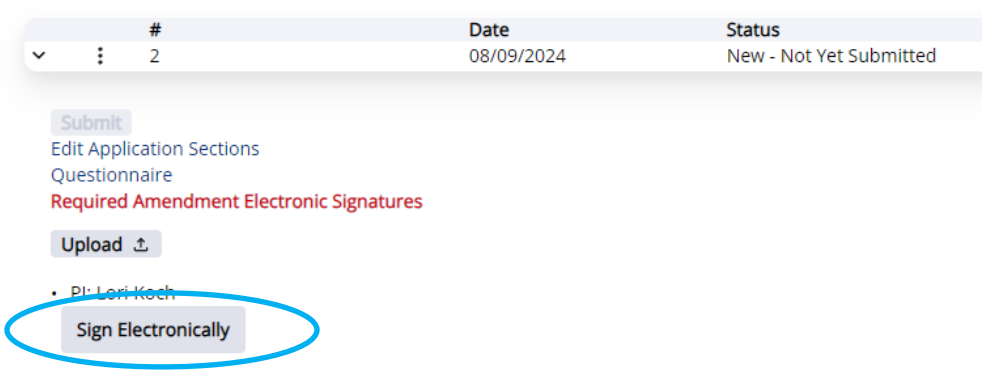
If you need to remove someone from the study, click the three dots to the left of the name and select Remove.

If an individual is not registered with the IDPH IRB, you can share the web link and Form Code with each person as described on page 2 or register them yourself using the **Add User** button at the top right of the screen. Do not assume that someone is not in the system. Always look them up first to avoid duplicating accounts.

Waiver of Informed Consent Section

If you are changing the waiver of informed consent, edit your original responses to the associated questions. Leave track changes on, to make the review as easy (and quick) as possible for IRB reviewers.

Once completed, return to the View Study Page. Make sure you have uploaded any necessary files and electronically signed your amendment. Once signed, an email will automatically be sent to the IRB Administrator.

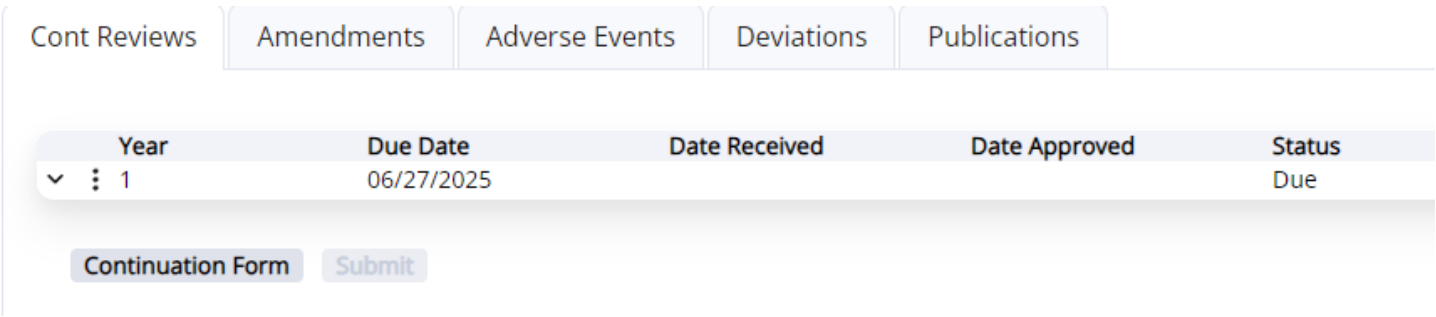


You must await the IRB's approval of your amendment before implementing the requested changes. If the IRB has questions, requests revisions, or approves the amendment, you will be notified by email.

HOW TO SUBMIT A CONTINUING REVIEW

You will be reminded by an email from Mentor as the due date approaches for submitting a continuing review report. To submit a Continuing Review, log on to Mentor. Click on My Studies under the IRB drop-down menu. All your studies should be listed. Click on the study title you want to renew and the View Study screen will open.

Make sure you are on the Cont Reviews tab at the bottom of the View Study screen. Then click the **Continuation Form** button.



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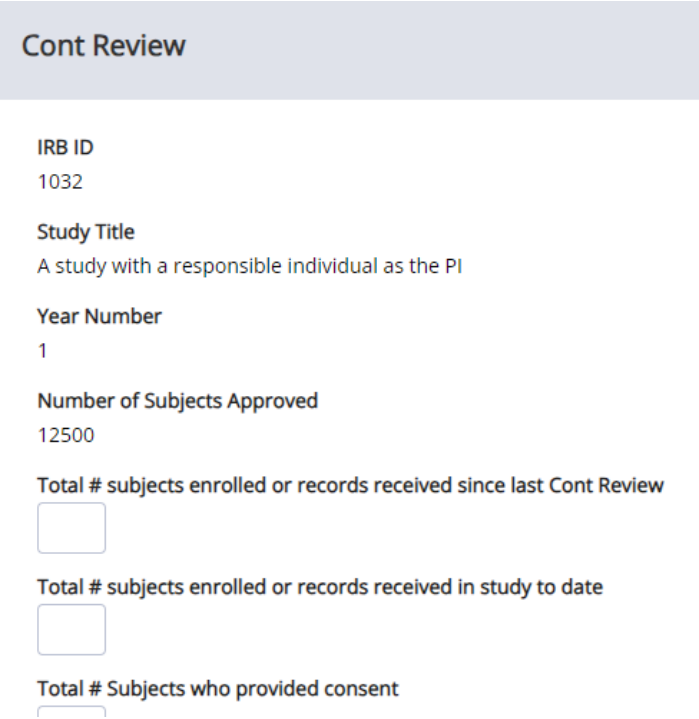
This will open the Continuation Form. Fill in the number of subjects and other pertinent information in the form. Under Continuation Status, select the appropriate option from the dropdown menu.



Complete the fields as appropriate. Enter 0 rather than leave a field blank when that is appropriate.

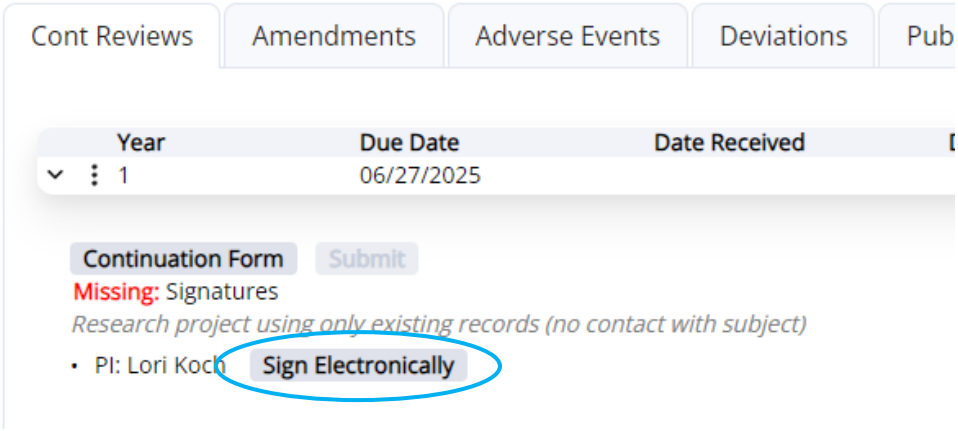
If you don't want to continue, select "Close Study" in the Continuation Status field; otherwise, choose an appropriate response.

If there were any adverse or unforeseen events, choose "Yes" from the Unforeseen / Adverse Events dropdown list and describe them.

If you want to send a message to the IRB, enter it in the message box. If not, then leave this box blank.

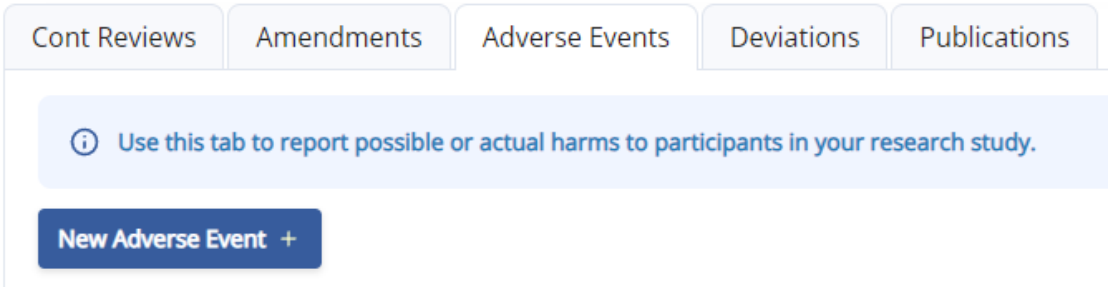
Once you have completed the Continuation Form, select "Save."

Once completed, return to the View Study Page and electronically sign your submission. The IRB administrator will automatically receive an email with your signature.

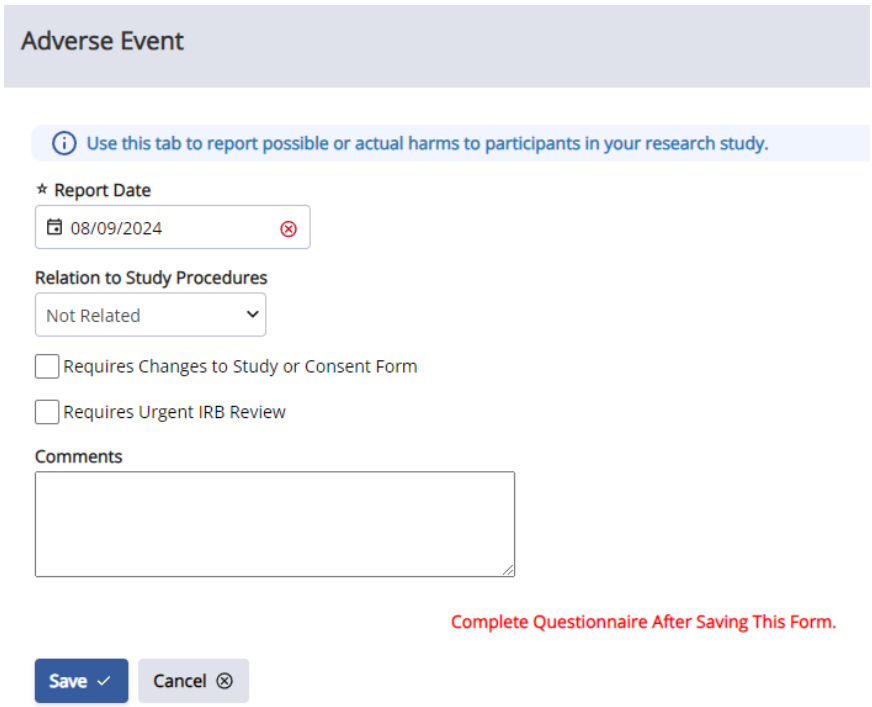


HOW TO SUBMIT ADVERSE EVENTS

Log on to Mentor. Click on My Studies under the IRB drop-down menu. All your studies should be listed. Click on the study title with the adverse event and the View Study screen will open. At the bottom of the View Study screen, select the Adverse Events tab. Click the **New Adverse Event +** button.



The screen requesting further information about the Adverse Event will appear next. Complete the fields and click **Save**. This will create the Adverse Event.



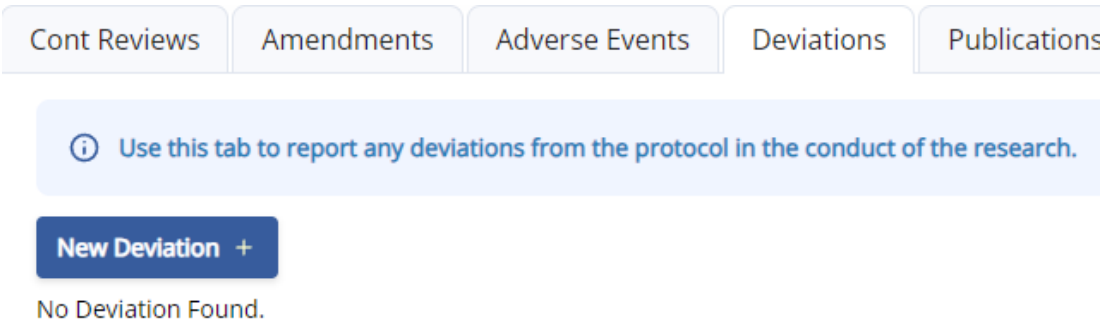
A questionnaire will appear next asking for details about the adverse event. Each question will need to be answered. Click **Answer** to begin responding and **Save Answers** to move on to the next question. At the end, you will be prompted to return to the Adverse Event Page.

To sign the adverse event, click on the date. This allows you to see your responses to the questions. Click on Sign Electronically. Once submitted, the IRB will contact you with questions or an acknowledgment of the submission.

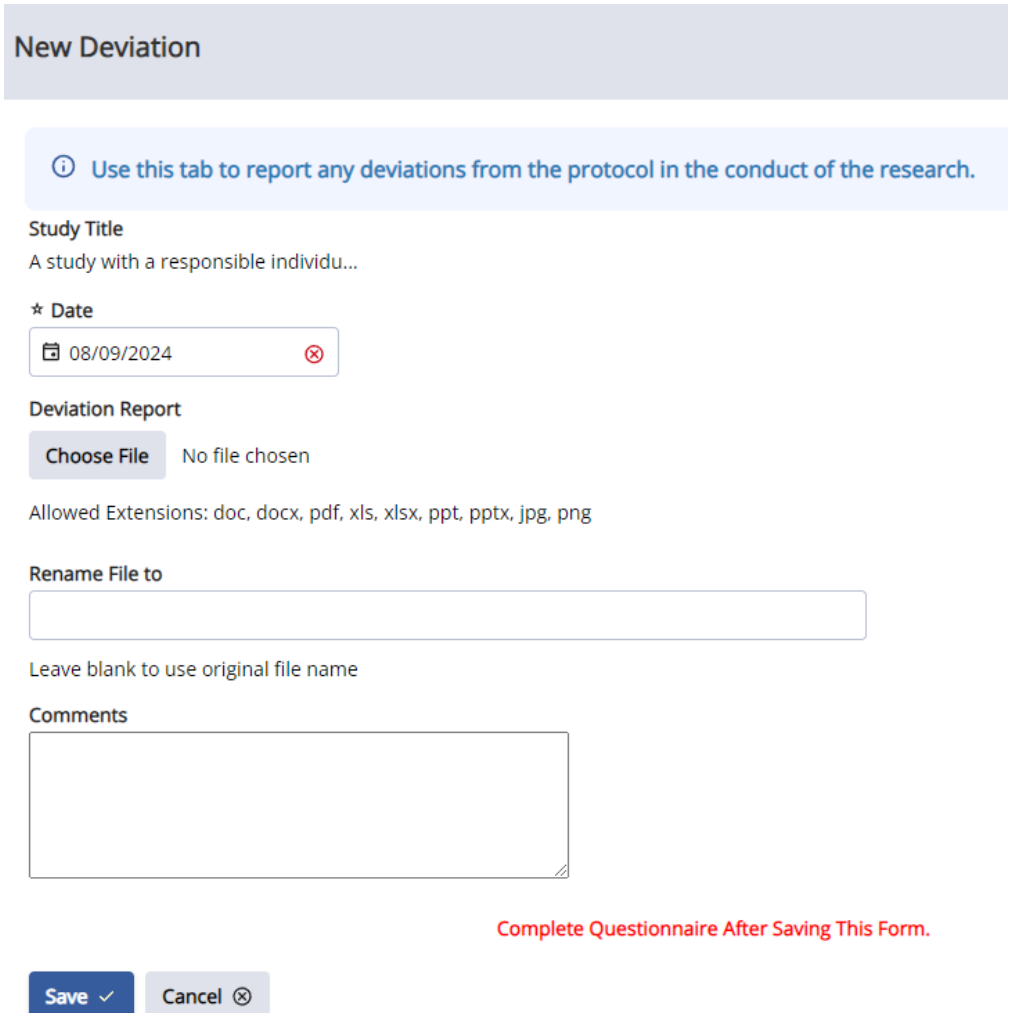
HOW TO SUBMIT PROTOCOL DEVIATIONS

Log on to Mentor IRB. Click on My Studies under the IRB drop-down menu. All your studies should be listed. Click on the study title with the protocol deviation and the View Study screen will open.

At the bottom of the View Study screen, select the Deviations tab. Click the **New Deviation +** button.

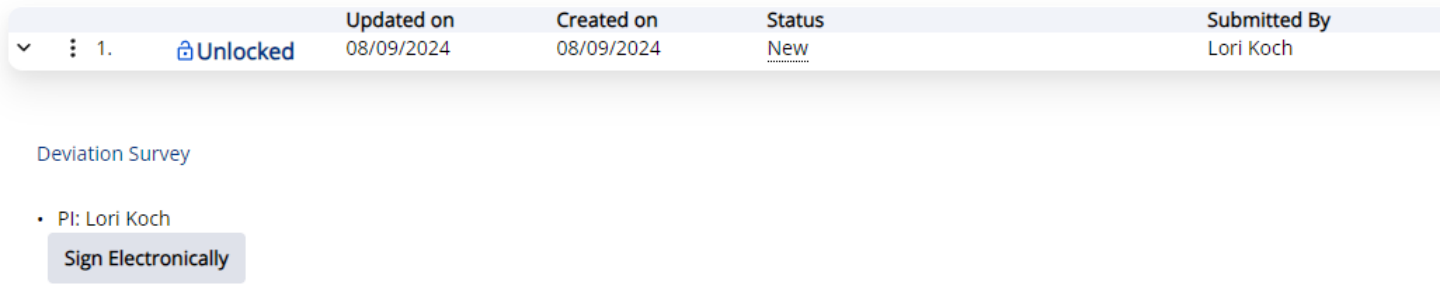


The screen requesting further information for the Deviation will appear next. Complete the fields and click **Save**. This will create the Deviation report. You have the choice of uploading a file with documentation but do not need to do so.



A questionnaire will appear next asking for details about the deviation. Each question will need to be answered. Click **Answer** to begin responding and **Save Answers** to move on to the next question. At the end, you will be prompted to return to the Deviation Page (tab).

To sign the Deviation, click the **Sign Electronically** button.



Once submitted the IRB will be in touch with questions or an acknowledgement of the submission.

STUDY MESSAGES

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

Click on one of the envelope icons to open the message page. From here you can:

- read old messages;
- reply to a message by clicking on the three dots, and selecting "reply to"; or
- create a new message by clicking on **New Message +**.

You can choose who receives the message by checking/unchecking the boxes next to the names and roles.

It is helpful to include a salutation so recipients know whether they are the primary target of the email or are simply being copied.