



**Institutional Review Board**

**EXTERNAL INVESTIGATOR MANUAL**

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## 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](mailto: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](http://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

SECVLOAI

Submit

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

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.

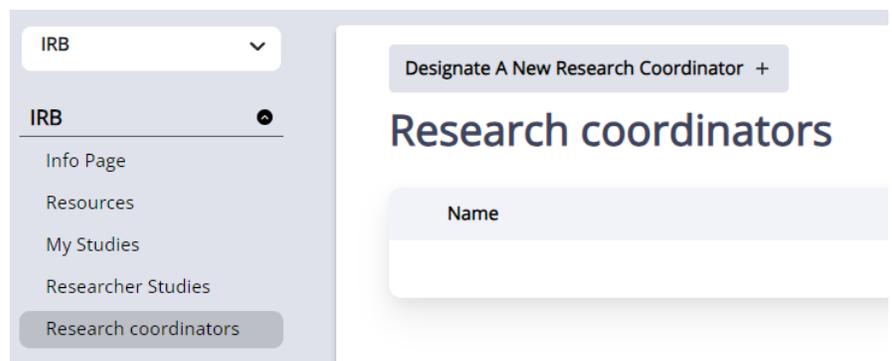
	Takes you back to the current main study page.
	Takes you back to the previous screen.
	Clicking here will give you a list of actions that can be taken.
	A document is attached. Click on the document name to open it.
	Clicking on the name next to it will take you to a new section.
	Clicking here will allow you to upload a document.
	Clicking here will open up a section.
	Clicking here will close a section.
	Indicates the number of messages associated with the study.
	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.
	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.

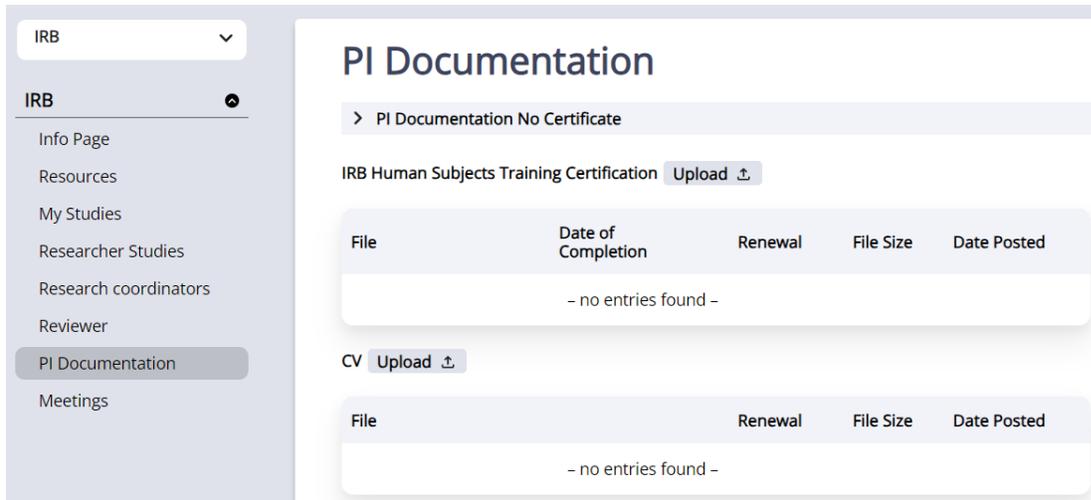
### New Research Coordinator

(Type first letters of last name and select from list)

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.

### Upload IRB Human Subjects Training Certification

★ File

No file chosen

Allowed Extensions: doc, docx, pdf, xls, xlsx, ppt, pptx, jpg, png

★ Date of Completion

✓

⊗

## 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 above and complete in the same way.

Personnel

Add/Edit personnel [↗](#)

PI

Name	CITI Status
Jane Fornoff	Docs Expiring 10/18/2024 <a href="#">↗</a>

Research coordinators

Name	CITI Status
Lori Koch (Primary)	Docs <a href="#">✓</a> <a href="#">↗</a>

Research staff

Name	CITI Status
Graham Briggs	(Training Certificates)

## 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 screenshot shows the IRB system interface. On the left, the navigation menu is visible with the 'My Studies' item highlighted. In the main content area, the 'Create New Study +' button is circled in blue. Below this, the 'My Studies' section contains search filters for IRB ID, Status, Submitted, Study Title, and Role. A 'Search' button and a 'Clear' button are also present. At the bottom, a table header is shown with columns for IRB #, Title, PI, Submitted/Approv'd, C.R. Due, and Tracking Status. The table currently displays 'No Studies Found'.

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.

## Pre-Submission Survey

Cancel ×

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

- 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.

Save Answers ✓

Cancel ⊗

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](mailto: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.

## Select Responsible Individual

Cancel ×

 If you do not know who the responsible individual is, please contact the IDPH IRB at [dph.irb@illinois.gov](mailto:dph.irb@illinois.gov). You will need to discuss your project with the responsible individual before submitting an application.

 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 Lookup

Continue

Close

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](mailto: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.

Create IRB Study
Cancel ×

**Add User**

★ External PI/Researcher

**Responsible Individual**

Jane Fornoff

Send Notification to Responsible Individual

★ Study Title

★ Proposed Start Date ⊗

Proposed End Date ⊗

★ Risk Level

**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

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.

Submit Study to Responsible Individual

### An interesting study using IDPH data

1034

⚠ Required Questions Not Answered  
1 Signature Missing

<p><b>External PI/Researcher</b> Charles Rossiter Researcher</p>	<p><b>Responsible Individual</b> Jane Fornoff Not Yet Accepted</p>	<p><b>Approval Status</b> Expedited Review Expedited Review Requested <small>(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes</small> <input type="button" value="Withdraw Study from Review"/></p>	<p><b>Created</b> Received <b>Date of Completion</b></p>
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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.

Create New Study +

### My Studies

IRB ID

Study Title

Status

Submitted

Role

Search

IRB #	Title	PI	Status
1034	An interesting study using IDPH data	Charles Rossiter	Expedited Review Requested

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.

Submit Study to Responsible Individual

**An interesting study using IDPH data**  
1034

To add responses to the application, click this button.

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

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

- Show Hidden Sections
- Expand All Sections

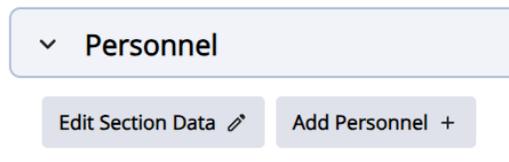
> Personnel	Required Questions Unanswered: 1
> General questions	Required Questions Unanswered: 1
> Risks & Benefits	Required Questions Unanswered: 5
> Data Sources	Required Questions Unanswered: 5
> Waiver of Informed Consent	Required Questions Unanswered: 4
> Data Protection and Records Retention	Required Questions Unanswered: 4
> Study results	Required Questions Unanswered: 4
> Data Use Agreement (DUA)	

[View Study Page](#)

### **Personnel Section**

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.



## Add Personnel to Protocol

★ Role  
Research staff ▼

★ Last Name Lookup  
Ros  
Charles Rossiter (dph.apors@illinois.gov)

Save ✓ Cancel ⊗

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.



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.

Submit Study to Responsible Individual Edit More

An interesting study using **data**  
1034

- Upload Docs
- Print / Zip
- Link

## 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.

Submit Study to Responsible Individual Edit More

An interesting study using IDPH data  
1034

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.

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

### Personnel

Add/Edit personnel

External PI/Researcher

Name	CITI Status	Signed Date	Date Added
Charles Rossiter			08/15/2024

## 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.

### Application Sections

[View Study Page](#)

#### 1034. An interesting study using IDPH data

PI: Charles Rossiter

Responsible Individual: Jane Fornoff

Show Hidden Sections

Expand All Sections

Revisions Required Questions

> Personnel	08/15/2024 1:03 PM CDT
> General questions	08/15/2024 1:04 PM CDT
> Risks & Benefits	Revisions Required: 1 08/15/2024 1:36 PM CDT

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.

**Answer**

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

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

▼ Comments **Submit Revisions for Review**

**Anonymous** 08/09/2024 9:24 AM CDT

Please provide more details

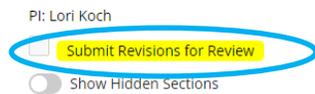
If you want to discuss a request revision with the Responsible Individual, return to the Study Page by clicking

**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.

## Application Sections

### 1032. A study with a responsible individual as the PI



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.

Cont Reviews | Amendments | Adverse Events | Deviations | Publications

Year	Due Date	Date Received	Date Approved	Status	Submitted By
1	08/06/2025			Due	

Continuation Form | Submit | Admin Only Notes | Tracking Status: No Status Recorded

Notifications

Skip Agenda

## 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**.

### 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**   [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

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.

The screenshot shows the 'My Studies' interface. On the left, the IRB menu is visible with 'My Studies' selected. The main content area includes a 'Create New Study +' button and search filters for IRB ID, Status, Submitted, Study Title, and Role. Below the filters is a table of studies:

IRB #	Title	PI	Status
1034	An interesting study using IDPH data	Charles Rossiter	Expedited Review Requested
1033	Study that has a RI	Charles Rossiter	Expedited Review Approved

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.

The screenshot shows the 'Amendments' tab selected. It features a 'New Amendment +' button and the text 'No Amendments yet.'

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.

Study Title  
A study with a responsible individu...

Select Application Sections you wish to revise

Personnel

Waiver of Informed Consent

**Create Amendment** ✓ **Cancel** ⊗

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.

Answer ✎

★ Select the types of changes being submitted in this modification:

- Study title change
-  Change in study personnel (including change in PI, new staff, staff no longer involved)
- Changes in study purpose
- Changes in funding
- Changes in conflict of interest
- Change in location
- Request for additional data
- New procedures
- Change in study participants
- Change in enrollment (total number of participants)
- Consent change
-  Recruitment Materials
-  Instruments (surveys, questionnaires, interviews, etc.)
- Other

Answer Required

Answer ✎

★ Do any of the proposed modifications change risks or benefits to subjects in any way?

- Yes
- No

Answer Required

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

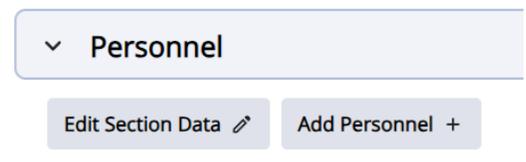
If you realize that you made a mistake in completing the screen above, click Questionnaire and edit your answers.



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.

## Add Personnel to Protocol



★ Role

Research staff

★ Last Name Lookup

Ros

Charles Rossiter (dph.apors@illinois.gov)

Save Cancel

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.

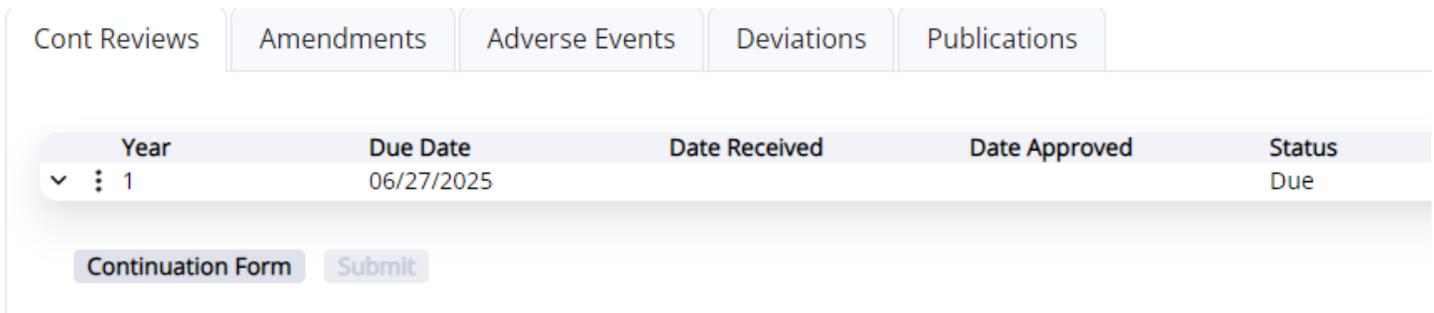


You must await the IRB's approval of your amendment before implementing the requested changes. If the IRB has questions, requests revisions, or approves the amendment, you will be notified by email.

### **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.



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.

**Cont Review**

IRB ID  
1032

Study Title  
A study with a responsible individual as the PI

Year Number  
1

Number of Subjects Approved  
12500

Total # subjects enrolled or records received since last Cont Review

Total # subjects enrolled or records received in study to date

Total # Subjects who provided consent

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.

Cont Reviews   Amendments   Adverse Events   Deviations   Pub

Year	Due Date	Date Received
1	06/27/2025	

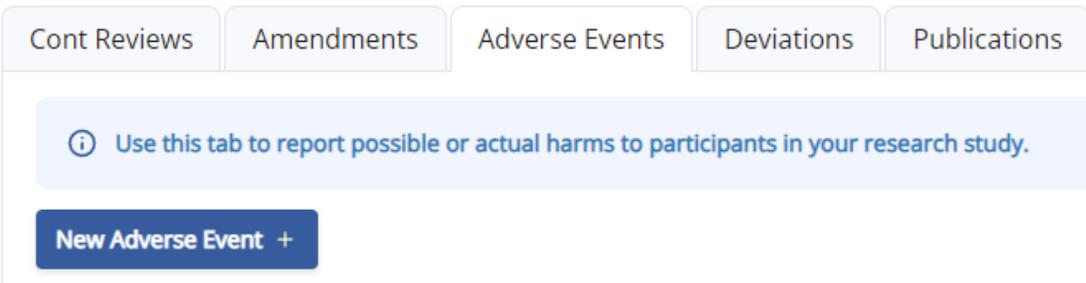
**Continuation Form**   [Submit](#)

**Missing:** Signatures  
*Research project using only existing records (no contact with subject)*

- PI: Lori Koch   [Sign Electronically](#)

## 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.

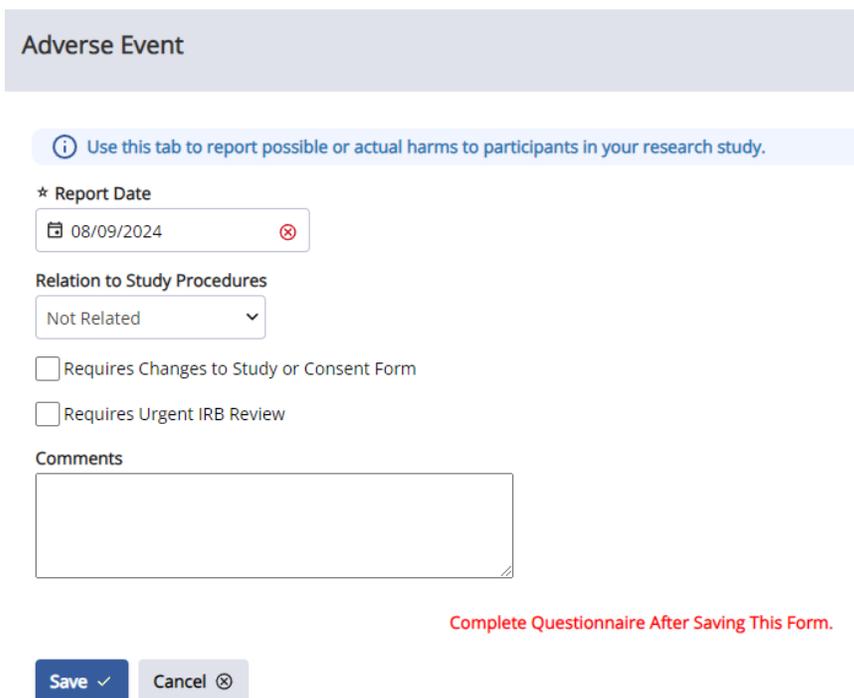


Cont Reviews   Amendments   Adverse Events   Deviations   Publications

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

**New Adverse Event +**

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



**Adverse Event**

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

\* Report Date  
08/09/2024

Relation to Study Procedures  
Not Related

Requires Changes to Study or Consent Form

Requires Urgent IRB Review

Comments

**Save**   **Cancel**

*Complete Questionnaire After Saving This Form.*

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.



**Signatures**

Request Signatures

Lori Koch - PI   Sign Electronically

## 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.



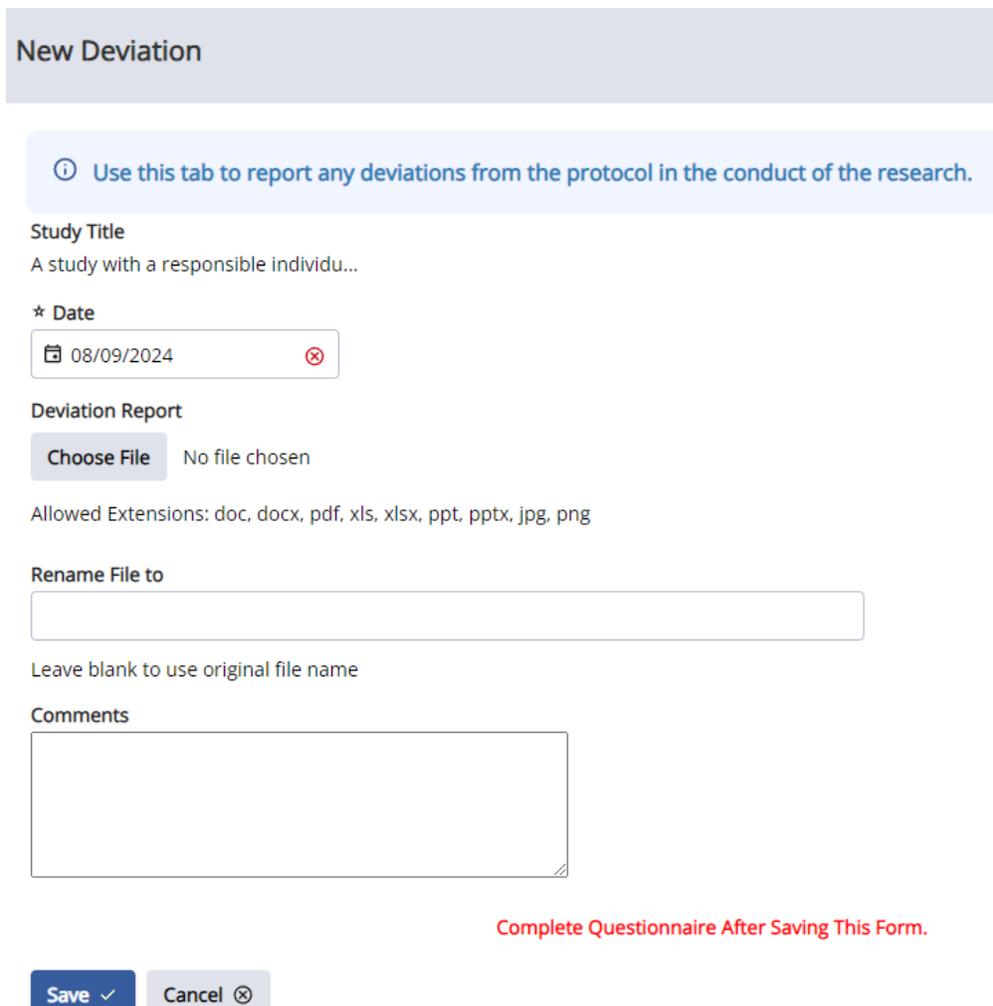
Cont Reviews   Amendments   Adverse Events   Deviations   Publications

**i** Use this tab to report any deviations from the protocol in the conduct of the research.

**New Deviation +**

No Deviation Found.

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.



### New Deviation

**i** Use this tab to report any deviations from the protocol in the conduct of the research.

**Study Title**  
A study with a responsible individu...

**\* Date**  
08/09/2024

**Deviation Report**  
**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

**Comments**

**Complete Questionnaire After Saving This Form.**

**Save** ✓   **Cancel** ⊗

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.

	Updated on	Created on	Status	Submitted By
1.  Unlocked	08/09/2024	08/09/2024	New	Lori Koch

Deviation Survey

- PI: Lori Koch

**Sign Electronically**

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 +**.

**New Message +**

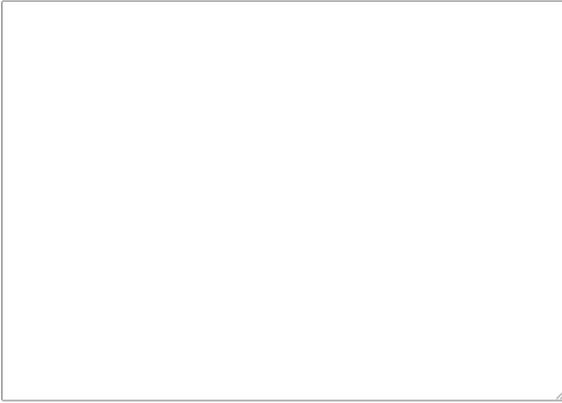
### A study with a responsible individual as the PI Deviation #1

Sort Ascending

**08/09/2024 1:31 PM CDT by Lori Koch**

Testing the title

Message



Save ✓ Cancel ⊗

Send Notification(s) to PI(s)

Lori Koch (PI)

Send Notification to IRB Member(s)

Jane Fornoff (Chair)

Harold Duckler (Administrator)

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.