



Ascension Wisconsin IRB

Mentor Researcher User Manual

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1. Introduction

This manual provides essential information that Researchers need to use the online IRB submission system, called Mentor. This manual includes a description of the Mentor system and step-by-step explanation of common uses.

Mentor is an electronic IRB submission and document management system. All submissions to the IRB are submitted using Mentor. Mentor is online and available from any device with internet access. IRB submission forms and templates, including consent form templates, are located on the IRB Info page in Mentor.

1.1. Mentor System User Support

To access text, click on this red question mark icon: 

You will see this icon and other red colored icons or text through Mentor. You can interact with the red items for more information – usually you hover over them or click them.

You can contact IRB staff anytime during normal business hours for assistance using Mentor or to schedule a training session. Refer to the [IRB website](#) for current contact information and IRB office hours.

2. Research Privileging and Requesting a Mentor Account

Before an individual can be added to a protocol in Mentor, they must complete the following. There are two steps in creating an account, creating the account and completing the user profile; the user profile is used as documentation for research privileging. Below are additional details for completing this process, which is also described on the Researcher Account Activation [page](#).

2.1. Create a User Account in Mentor

You must have a Mentor account before you can access Mentor. Additionally, before staff can be added to a study, they must also have an account.

To Create a New Mentor Account:

- Request an account [here](#).
- Follow the instructions and submit the form.
- You will get an email to confirm your email address and set your password.

You can only set up an account online using this method if you use an email address from Ascension Wisconsin or common research affiliates (email addresses such as Gmail won't work). If you do not meet these criteria you complete [this form](#) and IRB staff will set up the account and you will be notified when complete.

2.2. Complete the User Profile

Once you have a Mentor account, there may be additional steps you need to complete before submitting a project through Mentor.

Your User Profile will depend on the kinds of projects that you will submit for review. There are instructions and links on the Researcher Account Activation [page](#).

	Mentor Account	CV/ Resume	CITI Training	Conflict of Interest Disclosure	HUD User Form	Advisor Account
Involved in the conduct of human subject research	X	X	X	X*		
Humanitarian Use Devices (HUD)	X	X**	X		X**	
Only non-human subject research proposals (like Quality Improvement projects and Emergency or Expanded Access to an investigational product.)	X					
Students, residents and fellows conducting research	X	X	X	X		X

* Only if you are working on funded research.

** Physician users only (not administrative support/coordinators)

To upload required documents:

- Log into Mentor
- Go to the IRB tab across the top
- Click on My Training Certificate along the left
- Use the grey upload button to upload the CV
- Note: CITI does not need to be uploaded separately if you are affiliated with Ascension in CITI and use the same email for CITI and Mentor. This information will automatically populate from CITI into your Mentor account. If you use a different email or if you completed CITI for another institution, upload the completion certificate.

3. Access to Mentor and User Roles

3.1. User Roles

The role titles in Mentor are based on the privileges each role has in the system. The role assignment or titles of research personnel in Mentor may be different from that on the Site Delegation of Authority Log or other study documentation.

The Mentor Protocol application requires individuals to be identified as one of the following roles:

- PI: This is the Principal Investigator. All approval notices, expiration reminders and other announcements and notifications from Mentor will be sent to the PI.
- External PI: The designation should be used when the PI is someone external to Ascension Wisconsin with no formal affiliation to the institution. This person would have the research personnel role of Co-I or Sub-I. If added as an External PI in Mentor, they will not be able to access Mentor at all; if they require access, they could request a Mentor user account.
- Sub-I: The Sub-Investigator (Sub-I) role in Mentor should include all Sub-I's and Co-I's as defined above. Persons assigned to this role will have access to view all information in Mentor, but will not receive notifications and are not able to submit and manage protocols (including but not limited to continuing reviews or amendments).
- Research Coordinator: Principal Investigators may designate one or more other Mentor users as Research Coordinators. Research coordinators are authorized

to submit and manage protocols on behalf of their PI. If there is one or more coordinators listed, there should be at least one “primary” coordinator marked. They will also receive all approval notices, expiration reminders and other announcements and notifications from Mentor that are sent to the PI.

- Research Associate: Any other study staff should be identified in Mentor as a research associate. Research associates have access to view all information in Mentor, but will not receive notifications and are not able to submit and manage protocols.

3.2. Logging in

You will get an automated email from Mentor when your account is created. The email will include instructions to set an account password.

- Go to the Mentor [website](#). (This link is also found on the IRB [website](#)).
- The Institution ID is ASCENSION. Click the box below that field so the Institution ID is filled in every time you visit the Mentor site.
- The User ID field is your email address. This is the email you submitted when you opened the account. For most Ascension associates and employed physicians this will be the Ascension email address.
- Enter the password that you chose when you logged in for the first time.



Institution ID

Remember my Institution ID

User

Password

Login

[Forgot Password](#)

[Request a New Account.](#)

[View IRB SOPs and Guidance or Forms and Templates.](#)

3.3. Resetting your password

Go to the Mentor [website](#) and choose the "Forgot Password" link just below the login fields. Follow the instructions in the reset your password section above.

4. General Tips & How-Tos

4.1. Navigation and Important Pages


Mentor Home Page

You will be taken to this page when you first log in. IRB news and updates will be posted on this page. Click the “IRB” tab along the top navigation bar to get to the IRB forms and other functions. See the [Bookmarks Section](#) for how to customize your shortcuts. After navigating to the IRB tab, you will see page options along the left-hand column:

IRB Info Page

After clicking the IRB tab, you will be taken to the IRB Info page.

Context Menu

Throughout Mentor, you will see a red page icon , called the context Menu. You can left click on this menu for a list of available actions.

My Protocols Page

From this page you can:

- Create a new protocol

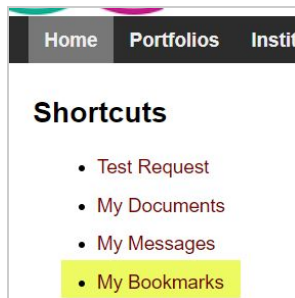
- See all studies that you are listed on and filter by type of study, or your study role.
 - Click the study title (red link) to go to the study page.
 - Quickly see the study status, if revisions have been requested and the date the next annual review is due.


Protocol Main Page

Each protocol has a main page that lists the general information about the protocol. These fields are completed at the time of initial submission. You can also see the documents submitted with the initial approval and a link to the IRB Application Sections.

4.2. Bookmarked Pages

The Mentor Home page includes a “My Bookmarks” link so that you can have quick access to pages that you commonly use. You can also set the link to display in this Shortcuts list on the homepage.



You can also click the red “B”  icon at the top right corner of any page in Mentor to bookmark it.

4.3. Designating a Research Coordinator

Research Coordinators identified in Mentor are able to create, complete and request the PI signature to submit new protocols, Continuing Reports, Amendments or other protocol-related reports to the IRB on behalf of the PI (as well as submit modifications requested by the IRB). However, the PI must designate a coordinator in order for the Research Coordinator field to appear on the PI’s protocol summary. Only the names of Research Coordinators who are designated to the PI will be able to be selected on that PI’s studies. If the PI is unable to do this, contact the IRB office.

To designate a Research Coordinator the PI must:

- Log into Mentor and go to “Research Coordinators” on the left navigation bar.
- Click the “Designate a New Research Coordinator” button.
- Start typing the coordinator’s last name. If the coordinator has a Mentor account, their name will appear. Choose the name and click “Designate”. If the coordinator does not have a Mentor account yet, they must request one before they can be added.
- The Research Coordinator’s name will now appear on the PI’s “Research Coordinator” page.

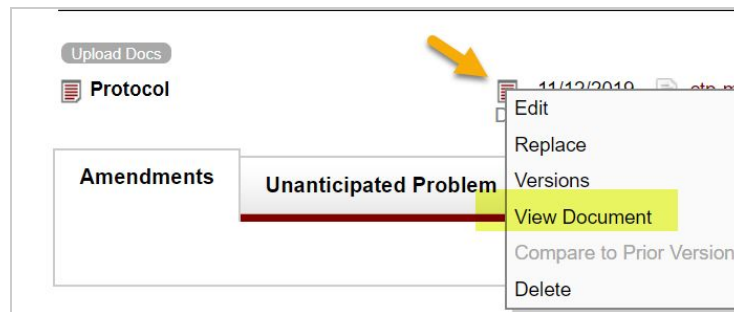
The designated Research Coordinator's name will also show up as an option in the "Research Coordinator" field when creating a new protocol for that PI. Selecting a Research Coordinator in the protocol assigns the coordinator to a specific study.

4.4. Viewing Documents in Mentor Viewer

You have the option to view documents online, rather than to download and open them.

To view a document:

- Left click the context menu.
- Select "View Document" and the document will open up in a window using the document viewer. There are limited search and comment features available in this view.



4.5. Electronic Signatures

The PI's Signature is required for most submissions to the IRB. Mentor uses electronic signatures to accomplish this task.

The report will NOT be submitted to the IRB until electronically signed by the PI.

If the PI completes a submission in Mentor, they can sign it immediately when completing the report.

If another person completes the submission in Mentor, they will request the signature from the PI, who will complete the signature as follows:

- The PI will receive an email notification from Mentor indicating that a signature is required.
- The email will come from Mentor and be titled: Request Electronic Signatures for [submission type] - IRB ID: [###].
- The PI must click the link in the email to review the submission and sign. No login is required.
- The PI will be taken to the submission, no login required.
- The PI can review the IRB application sections/ submission forms describing the report and any documents that are uploaded.
- The PI must click the "Sign Electronically" button to complete the submission.
- Once signed, the protocol or report is automatically submitted to the IRB.

5. File Management and Communication

5.1. Uploading Documents

The PI or coordinator can upload supporting documents before the protocol or report is submitted to the IRB, or if the IRB returns the submission to request revisions.

To upload a document, click the “Upload” button or option and browse to the file saved on your computer or Drive. Many file types can be uploaded, including Google, Office, pdf, video, and audio files.

Depending on the submission, there may be multiple ways to upload a document.

“Upload Docs” button


You will see an button to “Upload Docs” on a new protocol submission, at the top of the main protocol page:



And elsewhere in submissions and reports you may see a smaller button:



Once you click the “Upload Docs” button, you can select to upload a single file or multiple files at the same time. You will also be prompted to choose the file type and have the option to rename the file.



Context Menu (red page icon)

You can left click on the red context menu to the left of any file type and select “upload” to choose a single file to upload in that file type.



During the IRB application or report details form

You may be prompted to upload certain supporting documents as you complete the IRB application or other report details forms in Mentor.

5.2. Editing, Replacing or Deleting Documents

Before any submission is approved by the IRB, the PI or coordinator is able to click on the context menu (red page icon) next to the file name to edit, replace or delete the document. Once the submission is sent to the IRB, the study team may not have all options available.

To do this:

- Left click on the context menu (red page icon) to the left of the file name link.
- Choose the option.
 - Edit= rename or change file type
 - Replace= submit a new version of a document already uploaded to Mentor to track versions.
 - If the “Replace” option is not available, upload a new document in that same file type (use context menu next to gray status bar for the report and select “Upload Document”)
 - Delete= remove the document from Mentor
 - If the “Delete” option is not available, please contact the IRB office
- Follow the instructions on each step to complete the selection.

5.3. Mentor Messages

The study team, IRB staff and IRB members can all send messages through Mentor.

To send or view messages:

- There is a “Messages” link in red font at the top right corner of every submission section.
- On the “Messages” page, you will be able to create a new message, view or respond to any past messages.
- Use the context menu (red page icon to the left of the message time/date stamp) to create a Reply.

When a new message is sent, the recipient selected receives the message via their email account. You can respond via email, and all messages are stored in the appropriate section in Mentor for documentation. However, DO NOT include attachments to Mentor messages as they are not sent. You must upload any documents directly into Mentor.

Mentor messages remain part of the submission record and are printable.

5.4. Responding to Revisions requested by the IRB

The IRB office staff and/or IRB may request revisions or clarifications. This can happen in pre-review or after the IRB review is completed in order to secure approval. Revisions or requests for clarification are requested by the IRB or office via Mentor (and revisions are submitted by the study team through Mentor too).

Pre-Review Requests for Revisions

If the IRB office does a pre-review of the submission and needs clarification or revisions, you will receive an email notification via Mentor.

The notification will outline the pre-review requirements and suggestions.

In addition to the notification, there will be an indicator in the upper left of the main protocol page (for initial reviews) or report section (for all other reports) tab that indicates that there are revisions that need to be submitted for review.

Submit Revisions for Review

To complete the pre-review request for revisions:

- Locate the study on the “My Protocols” page and click on the study title. This takes you to the Protocol Summary page.
 - If the submission is a Continuing Review, Amendment, Safety Update, etc., scroll down to the bottom of the page and click on the appropriate tab. Locate the report you are working on (most recent will be on the top).
- Address each request by uploading [new/revised documents](#) or revising the content in the submission (IRB Application sections, Amendment or Continuing Report Details, Safety report, etc.), depending on the request
- Respond to any comments or clarification using the [Message](#) function (for example, providing justification for not making revisions or confirming staff training requirements have been completed)
- Once all requested revisions are made and/or uploaded in Mentor, the PI or coordinator must click the yellow highlighted box “Submit Revisions for Review”. This checkbox is always at the top left of the applicable report section tab.

Note: If this box is not checked, the revisions are never submitted to the IRB.

- The IRB staff are notified of the completed revisions; no additional notification to the IRB is required.
- You may also receive automated reminders from Mentor about once a week until the revisions are submitted.

IRB Review Completed with determination of “Approved Pending Revisions” - Responding to requests for revisions or clarification

The PI and Research Coordinator(s) will receive an email notification with the IRB determination of “Approved Pending Modifications” if there are minor questions or requests for revision after the review is complete.

To complete the request for revisions:

- Locate the study on the “My Protocols” page and click on the study title. This takes you to the Protocol Summary page.
 - If the submission is a Continuing Review, Amendment, Safety Update, etc., scroll down to the bottom of the page and click on the appropriate tab. Locate the report you are working on (most recent will be on the top).
- Address each request by uploading [new documents](#) or revising the content in the submission (IRB Application sections, Amendment or Continuing Report Details, Safety report, etc.), depending on the request

- Respond to any comments or provide clarification using the [Message](#) function (for example, providing justification for not making revisions or confirming staff training requirements have been completed)
- There will not be a “Submit Revisions” button - please send a [Message](#) in that report to notify the IRB that the revisions are complete and ready for their final review

6. Submission Types

All Protocol information, reports, and related documents are entered directly into Mentor and signed electronically by the PI.

Make sure to have the materials completed as outlined in [IRB Submission Guide for Full Board or Expedited IRB Review](#) or [Exempt studies](#). These guides and other IRB forms are located on the IRB Info page in Mentor. There is more information available on the [IRB Submissions](#) website.

6.1. Creating a New Protocol in Mentor

Initiate the Protocol in Mentor

- Go to the “My Protocols” page and click on the “Create New Protocol” button.
- A protocol summary page titled “Create IRB Protocol” will open as a pop-up window. Complete the questions. The red asterisks are required fields. (Information entered in this pop-up window can be edited later via the Protocol Page, prior to submitting the new protocol to the IRB for review.)
 - **Research Personnel** - Researchers must have a Mentor eIRB account in order to be added to a study. To request an account go to the Mentor eIRB page on the IRB website. Once a Mentor account is set up, you can type the last name of the individual and Mentor will populate the field.
 - Principal Investigator: Choose the PI name from the drop-down menu.
 - Research Coordinator: If the PI has designated research coordinators, a “Research Coordinator” field will appear. Choose the Research Coordinator’s name from the drop-down menu. The Research Coordinator will be copied on all eIRB correspondence sent to the PI. Instructions for designating a Coordinator are on the IRB website.
 - Sub-I: Type the first few letters of the individual’s last name. Choose the name from the list and click “Add”. These people will have view only privileges.
 - External PIs: Do not add research collaborators at other sites unless they are engaged in the conduct of the research at the institution. If you have a question about engagement contact the IRB staff at IRB@ascension.org or 414-465-3059.
 - Research Associate: Type the first few letters of the individual’s last name. Choose the name from the list and click “Add”. These individuals will have “view only” privileges.
 - **Protocol Title:** Enter the protocol title.
 - **Regulatory Oversight:** Check the box(es) as appropriate for the study. If you are unsure, IRB staff will update as needed.

- **Sponsor Information:** Select the Sponsor Funding Source type and, if appropriate, enter the study Sponsor/Funding Source (agency) and Protocol/Grant ID.
- **Review Type:** Different questions appear based on the review type you select. The IRB will confirm the review type following receipt of the submission.
 - Full Review: Studies greater than minimal risk
 - Exemption Requested: Human subject research that meets the an exemption category or projects that are not research or do not include human subjects
 - Expedited Review Requested: Studies that are no greater than minimal risk
 - Delegate to an External IRB: Studies requesting another IRB complete the review
 - Humanitarian Use Device Request: HUD protocols
 - Emergency Use: Emergency use of an investigational product
 - Complete review type specific questions Different questions appear based on the review type you select.
- **Consent/HIPAA:** Choose the appropriate status of the consent process and/or HIPAA access/use for the study
- **Location of Research** - check any/all locations of research for the study
- **Vulnerable Subjects** - check any/all vulnerable populations that will be included in the protocol
- **Enrollment Goal** - provide the local site enrollment goal for the protocol
- Protocol Categories - check the appropriate category for the protocol
- **Searchable Keywords** - for future use, you may choose to enter keywords to search for this protocol
- **Message to the IRB** -optional to include a note to the IRB office/Board.
- Click “Save” when the summary is complete.
- After saving, an “Upload Documents” button will appear on the top of the protocol summary.
- Once saved, you will then be taken to the Protocol Main Page, where you can upload any additional documents and complete the IRB Application Sections.

Enter the Details of the Protocol in Mentor

- “Upload Docs” button - choose a file type from the drop-down menu (protocol, consent form, FDA correspondence, questionnaire, advertisement, etc.). Click “choose file” to locate the document on your device and upload. Repeat this activity to attach and save all applicable items. The uploaded documents will automatically appear at the bottom of the protocol main page under a header that matches the chosen file type name.
- “Application Sections” - this required activity is marked with a green arrow. Complete the electronic IRB Application sections as it applies to the study. Red asterisks are required questions.

Submit the Protocol in Mentor

- “Request Signature” button - this button on the protocol main page will be activated once all required questions and elements have been completed in Mentor. If it is grayed out, look for an unanswered required question.
 - The PI will be sent the email notification to provide an electronic signature in Mentor.
 - If you are the PI, you do not need to request the signature, you can simply complete your [electronic signature](#).

- Once the PI provides the electronic signature, the protocol is submitted automatically. The IRB staff is notified of the submission and will contact you with any questions.

6.2. Continuing or Final Reports

Click on "My Protocols" and choose the study. Scroll down to the bottom of the page and click on the "Cont. Reviews" tab.

Initiate the Continuing or Final Report in Mentor

- "Complete & Submit" button - this button will open a pop-up window. Answer the questions. Upload documents as appropriate.
 - Enter the number of subjects in the categories since the last IRB review. All of the numbers entered for all other categories should add up to the number entered for "Total # Provided consent (considered enrolled by IRB) to date." If this is the first year you are creating the Continuing Review electronically, the column for "Prior Year" will be blank. All future years will pre-populate the Prior Year column for reference.
 - **For HUDs:** Enter the number of patients treated in the "Total # Provided Consent" box only. This number should be for the life of the HUD.
 - Upload documents as appropriate. (You have the ability to upload these documents later, as well.)
 - Click "Submit Report" to create and begin the Continuing or Final Report - ***THIS WILL NOT SUBMIT THE CONTINUING REVIEW TO THE IRB.***
 - After this you will be returned to the Cont. Reports tab to fill in the required **Continuing Report Details** electronic form, upload documents, and request the PI electronic signature prior to submission.

Enter the Details

- Click the red font "Continuing Review Details" link and complete all required questions.
 - You can go back into this link and edit each response using the "Edit Answer" button.
 - You can use the "Back" link at the top right of any page to return to the main protocol page.
- Upload any remaining documents, if any.
- You can print the complete report using the "print to pdf" button on the details/survey page or on the main report page.

Submit the Continuing or Final Report in Mentor

- "Request Signature" button - this button on the Cont. Report page will be activated once all required questions and elements have been completed in Mentor. If it is grayed out, look for an unanswered required question. The PI will be sent the email notification to provide an electronic signature in Mentor. (If you are the PI, you can sign it right from the report page.)
- Once the PI provides the electronic signature, the Cont. Review is submitted automatically. The IRB staff is notified of the submission and will contact you with any questions.

- Your submission is complete. An IRB staff member will contact you with any questions.

6.3. Amendments

Click on "My Protocols" and choose the study. Scroll down to the bottom of the page and click on the "Amendments" tab, then click the "Create New Amendment."

Initiate the Amendment in Mentor

- "Create New Amendment" button - this button will open a pop-up window. Choose the Amendment Type(s); more than one type can be selected if appropriate.
 - Choose the IRB Application Sections that will need to be updated to reflect the new revisions being requested in this amendment.
 - Click "Create Amendment".
- After this you will be returned to the Amendment page to fill in the required **Amendment Details** electronic form, update the IRB Application Sections if any, upload documents if any, and request the PI electronic signature prior to submission.

Enter the Details

- Click the red font "Amendment Details" link and complete all required questions.
 - If more than one Amendment Type was selected, you must complete multiple details forms (more than one link will appear).
 - You can go back into this link and edit each response using the "Edit Answer" button.
 - You can use the "Back" link at the top right of any page to return to the main protocol page.
- Click the red font "Application Sections" - update information in the questions shown.
 - **NOTE:** If the currently-approved IRB Application is in paper, these electronic Application Section responses will be blank. The responses must be entered to reflect the study as a whole, seamlessly and not just the new revisions included in the amendment.
 - When you choose to change the Application Sections after they have been populated in prior submissions, you will insert changes into the previously saved text seamlessly (adding/deleting where necessary) and must use **Track Changes**.
 - All changes you make to the Application Sections will be stored in Mentor upon approval of the amendment.
 - You can go back into this link and edit each response using the "Edit Answer" button.
- Upload applicable documents, if any.
- You can print the complete details/survey using the "print to pdf" button on the survey page or on the main report page.

Submit the Amendment in Mentor

- "Request Signature" button - this button on the Amendment page will be activated once all required questions and elements have been completed in

Mentor. If it is grayed out, look for an unanswered required question. The PI will be sent the email notification to provide an electronic signature in Mentor. (If you are the PI, you can sign it right from the report page.)

- Once the PI provides the electronic signature, the Amendment is submitted automatically. The IRB staff is notified of the submission and will contact you with any questions.

6.4. Reportable Events

Click on "My Protocols" and choose the study. Scroll down to the bottom of the page and click on the appropriate reportable event tab:

- "Unanticipated Problem" - Click the button "New Unanticipated Problem"
- "Noncompliance" - Click button "New Significant Deviation or Noncompliance"
- "Safety Report" - Click button "New Safety Info from Sponsor, FDA, DSMB"

Initiate the Reportable Event in Mentor

- "New..." button - this button will open a pop-up window (specific names shown above). Enter the date of the event and a brief comment if desired. The full report should not be entered in the comments box in this pop-up; there are questions later that will address the report details.
- Click "Save."
- After this you will be returned to the report page to fill in the required electronic survey/form, upload supporting documents if any, and request the PI electronic signature prior to submission.

Enter the Details

- Click the red font link and complete all required questions. The name of this survey link will differ based on the reportable event type (e.g. Significant Deviation or Noncompliance Survey).
 - Some questions will ask for additional explanation or file uploads, depending on your answer.
 - You can go back into this link and edit each response using the "Edit Answer" button.
 - You can use the "Back" link at the top right of any page to return to the main protocol page.
- Upload supporting documents, if any.
- You can print the complete details/survey using the "print to pdf" button on the survey page or on the main report page.

Submit the Reportable Event in Mentor


- "Request Signature" button - this button on the report page will be activated once all required questions and elements have been completed in Mentor. If it is grayed out, look for an unanswered required question. The PI will be sent the email notification to provide an electronic signature in Mentor. (If you are the PI, you can sign it right from the report page.)
- Once the PI provides the electronic signature, the reportable event is submitted automatically. The IRB staff is notified of the submission and will contact you with any questions.

6.5. Acknowledgement of Other Materials via Administrative Review

If the study team or study Sponsor wants to inform the IRB about something that does not meet the criteria of other standard review submission types, you can use the “Administrative Review” request in Mentor. *Specifically, do not submit Continuing Reviews, Adverse Events, Amendments, Safety Reports or Reportable Events using this form.*

Click on "My Protocols" and choose the study. Scroll down to the bottom of the page and click on the “Administrative Review” tab.

Initiate and Submit the Administrative Review request in Mentor

- “New Item” button - this button will open a pop-up window.
- Upload the file to be reviewed and acknowledged by the IRB.
- Include a brief description of the submission.
- Click “Save.”
- After this you will be returned to the main protocol page.
- To upload additional documents, go to the collapsed bar beneath the Administrative Review tab and click the double-arrows. This will open the collapsed portion to display the submitted Administrative Review request.
-  Click on the context menu (red page) icon to upload additional documents related to the administrative review.
- The PI electronic signature is not required for this submission type.
- The IRB is notified immediately when the “Save” button is chosen.
- You can print the complete details/survey using the “print to pdf” button on the survey page or on the main report page.

6.6. Humanitarian Use Devices (HUD)

After completing and organizing materials as outlined in the [HUD Instructions & Application Form](#), you are ready to create the study in Mentor eIRB. Go to the “My Protocols” page and click the “Create New Protocol” button.

Initiate the New HUD Protocol in Mentor

- Follow the instructions above for [Creating a New Protocol](#) in Mentor.
- Special HUD-specific Comments:
 - Select the Review Type as “Humanitarian Use Device”
 - Adding Physicians to a HUD: Physicians must have a Mentor eIRB account in order to be added to a new HUD protocol, as well as meet other requirements described above to [complete the user profile](#).
 - You can upload the HUD product brochure and Patient Information Booklet (or consent, if applicable) in the initial pop-up window or later from the main protocol page.

Enter the New HUD Protocol Details

- Follow the instructions above for [Creating a New Protocol](#) in Mentor.

Submit the New HUD Protocol in Mentor

- “Request Signature” button - this button on the protocol page will be activated once all required questions and elements have been completed in Mentor. If it is grayed out, look for an unanswered required question. The PI will be sent the

email notification to provide an electronic signature in Mentor. (If you are the PI, you can sign it right from the report page.)

- Once the PI provides the electronic signature, the new protocol is submitted automatically. The IRB staff is notified of the submission and will contact you with any questions.

Humanitarian Use Device – Continuing Review

- Follow the instructions above for [Continuing or Final Reports](#) in Mentor.

6.7. Request to Defer to NCI CIRB or other Single IRB Reliance Request

If you are requesting to rely on an external IRB (including NCI CIRB), you should create a new protocol to do so.

Go to the “My Protocols” page and click the “Create New Protocol” button.

Initiate the Reliance Request Protocol in Mentor

- Follow the instructions above for [Creating a New Protocol](#) in Mentor.
- Special Reliance Request-specific Comments:
 - Select the Review Type as “Delegate to External IRB”
 - If you are requesting for our IRB to be the single IRB of record, select the appropriate review type and then you will be required to provide a response in the IRB Application Section “IRB Reliance on an External IRB” to provide more information.

Enter the Reliance Request Protocol Details

- Follow the instructions above for [Creating a New Protocol](#) in Mentor.

Submit the Reliance Request Protocol in Mentor

- “Request Signature” button - this button on the protocol page will be activated once all required questions and elements have been completed in Mentor. If it is grayed out, look for an unanswered required question. The PI will be sent the email notification to provide an electronic signature in Mentor. (If you are the PI, you can sign it right from the report page.)
- Once the PI provides the electronic signature, the new protocol is submitted automatically. The IRB staff is notified of the submission and will contact you with any questions.

Post-Approval of IRB Reliance Request on NCI CIRB Protocols

- All post approval submissions are completed in Mentor as described in the applicable sections throughout this guide.
For studies deferred to an external IBR, see other IRB SOPs and guidance to determine when submissions to the Ascension WI IRB are required.