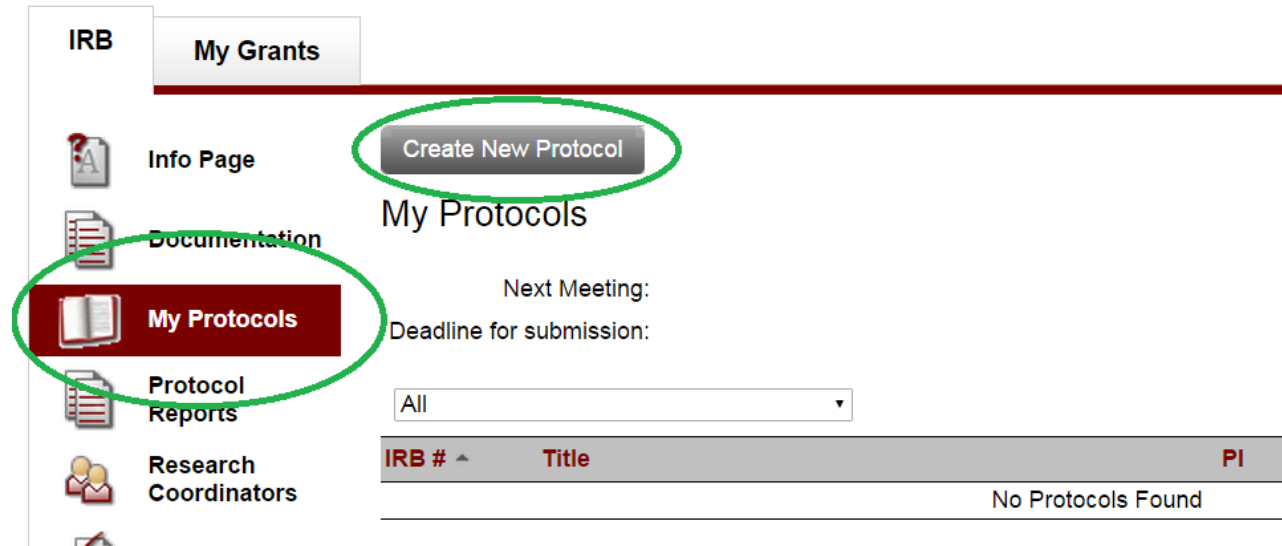


How do I submit a new protocol?

To submit a new protocol, click on the My Protocols item on the left navigation menu on the IRB tab.

Then click the “Create New Protocol” button:



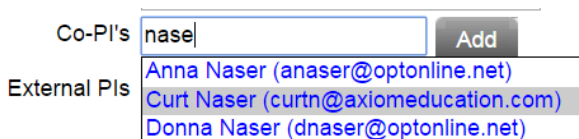
In some instances of Mentor, clicking the Create New Protocol button will initiate a pre-protocol survey. This survey is designed to assist the PI in determining the proper level of review (exempt, expedited, full board). Other instances do not use this survey and you will be taken directly to the protocol submission form.

The contents of the protocol submission form will vary depending on configuration of your instance of Mentor IRB. In general, the following fields will most likely always appear:

PI	<input type="text" value="Sample Investigator"/>
Co-PI's	<input type="text"/> <input type="button" value="Add"/>
External PIs	<input type="text"/>
Research Associates	<input type="text"/> <input type="button" value="Add"/>
* Protocol Title	<input type="text"/>
* Start Date	<input type="text"/> <input type="button" value="Clear"/>
End Date	<input type="text"/> <input type="button" value="Clear"/>
Funding Source	<input type="text"/>
Review Type	<input type="text" value="Full Review"/>
Waiver of Informed Consent	<input type="text" value="Not Requested"/>
Waiver of Documentation of Informed Consent	<input type="text" value="Not Requested"/>
Number Of Subjects	<input type="text"/>
* Upload Protocol Description	<input type="button" value="Choose File"/> No file chosen
Upload Consent Form	<input type="button" value="Choose File"/> No file chosen
Message to IRB Chair	<input type="text"/>

Complete the protocol submission form. Only the red starred items are actually required. Keep in mind that you can always edit your protocol after you initially save it.

Note the fields that have the “Add” button. These fields are used to find the names of other Mentor users who will be working on your protocol. To use these fields, type in the first letters of the person’s last name. As you type, a list will popup below the text input box. Continue typing to narrow the list down. Then select the desired name from the list:

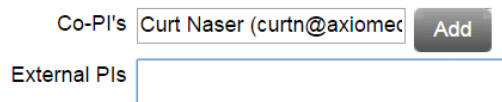


Co-PI's

External PIs

- Anna Naser (anaser@optonline.net)
- Curt Naser (curtn@axiomeducation.com)
- Donna Naser (dnaser@optonline.net)

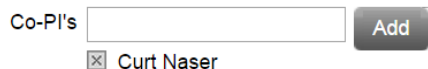
Note: You must select the name from the popup list. Typing in the name in the text box will not work.



Co-PI's

External PIs

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



Co-PI's

☒ Curt Naser

When you select the Review Level, depending on your institution’s setup, additional questions may appear below. These may include exemption or expedited review categories as well as custom defined questions by your institution.

There are generally two file upload buttons on the initial submission form. After you save your protocol, you can upload additional files by using the Upload Docs button that appears at the top of the view protocol page. We limit the number of files you can upload on the initial submission form to ensure that all the information is recorded.

The View Protocol Page:

Messages (0) | Back

Info Page Edit Research Coordinators Copy Upload Docs Print / Zip

Documentation

My Protocols

Protocol Reports

Research Coordinators

Reviewer

PI Documentation

Meetings

IRB Members

My New Protocol

Submit Protocol for Review

Protocol ID 10

PI Sample Investigator

PI Type Faculty

Department

Submitted By Sample Investigator

Co-PI's Curt Naser

External P.I.'s

Approval Status New - Full Review

Date Received

Date Approved

Proposed Start Date 11/25/2014

End Date

Date Closed

Funding Source

IRB Review Fee

Consent Waived Not Requested

Waiver of Documentation of Informed Consent Not Requested

Protocol Description 11/18/2014 Test.docx

Pre-Protocol Questionnaire 11/18/2014 Pre-Protocol Questionnaire.pdf

Annual Reports Amendments Adverse Events Protocol Deviations DSMB Reports

Note the “Submit Protocol for Review” button. This button does not appear for all institutions using Mentor IRB as it is a setup option. If you see this button, then your protocol is not formally submitted to the IRB until you click it. Your protocol is visible to the IRB, the chair and the administrator, so if you have questions and would like them to look at it before you formally submit, they will be able to see the record and any uploaded files.

Also note the “Upload Docs” button. This opens a form with a menu to select the specific type of document you wish to upload. The list of file types is in part defined by each institution:

Upload Documents

* File type Additional Documentation

* File Additional Documentation

Rename File to

Consent Form

Notifications

Protocol Description

Recruitment Materials

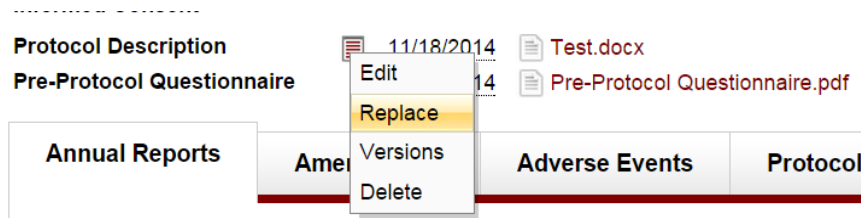
Revised Consent Form

Revised Protocol

Save Cancel

The file button is hidden behind the menu. The “Rename File to” allows you to rename your file on upload. You can upload multiple files to each file type listed, but you can only upload one file at a time.

Another option for uploading files to protocols is to use the “Replace” function. This is handy for doing revisions to protocols or consent forms. Click the Context Menu on the file you wish to replace on the View Protocol page. The Context Menu is the small maroon page icon to the left of the file date:



Select “Replace” and Mentor will open a file upload form. Just upload the new file and it will replace the existing file, rather than listing the new file below the existing file. The original file is maintained in a “version control” system in Mentor. Just click the “Versions” option on the Context Menu to download a prior version of the file. You can also “Rollback” to the original version or any subsequent version of the file.

Note the Annual Reports and other tabs at the bottom of the protocol (labels on these tabs will vary by client institutional setup). There is no annual report listed on a new protocol since it hasn’t yet been approved. Likewise, you cannot amend a new protocol, so these tabs don’t become active until after the protocol is approved.