COEUS LITE IRB SUBMISSION SYSTEM MANUAL APPENDIX UPDATEDAUGUST 24,2016

Creating an Amendment to a Currently Approved Protocol	2
Modifying Attachments	
Uploading a New Document for Review by the IRB	
Questionnaires	
Deleting a Pending protocol	8
Withdrawing a Submission	10
Create Renewal	11
Reviewing Revisions Required by the IRB	13
Responding to the IRB When Revisions Are Requested	
Modifications to Previously Uploaded Documents	
Other Protocol Actions	19
Closing your study	

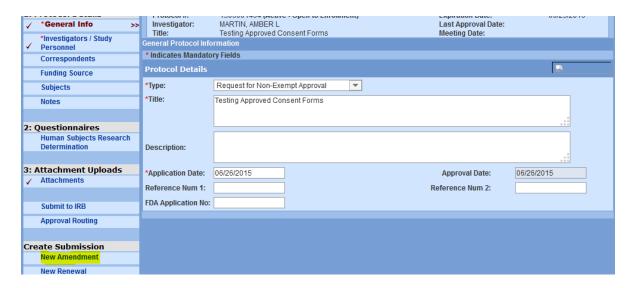
CREATING AN AMENDMENT TO A CURRENTLY APPROVED PROTOCOL

Click on My IRB Protocols.

Click on **All Protocols** to see the full listing of protocols and their current statuses. Select approved protocol you wish to work with. Note the protocols and related information can be sorted by clicking on any one of the column headings. Example: Statuses may be sorted in ascending/descending alphabetical order by clicking on the column heading Status.



Click on **New Amendment** in the column on the left-hand side. This will open the **Amendment Summary** window.





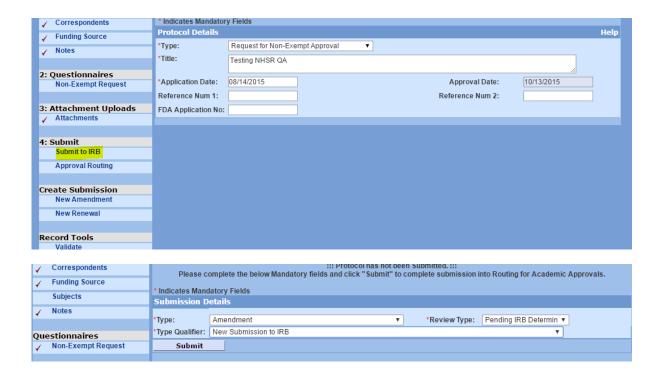
You must provide a brief but detailed summary of the amendment in the window. For example, be sure to note the names of new individuals being added to the research team and who they are replacing. Click on all the applicable checkboxes for those items being changed. Note that clicking on the box opens up the protocol record for the information to be edited in that tab.

Click on **Save** when complete. Note an A00x suffix is applied to the protocol number. This refers to the sequential number of amendments for that particular protocol. The A suffix is dropped once an amendment is approved by the IRB. This means that the changes proposed in the Amendment have been incorporated into the Protocol you can still submit other amendments or renewals by searching and selecting the base protocol number.

To change the information in the protocol record, click on the applicable tab in the column on the left-hand side. The window for the tab chosen will open, allowing for selection and/or entry of items to be added or removed. **Save** when complete.



Click **Submit to IRB** and select Amendment as the submission Select submit to route your request to the IRB for formal review.



MODIFYING ATTACHMENTS

Be sure to have clicked on the **Attachments** box on the **Amendment Summary** screen. Click **Save**.



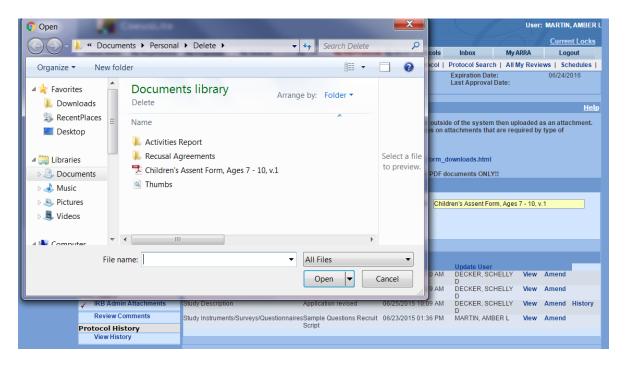
Select the **Attachments** tab from the left hand column to modify a document that has previously been uploaded into Coeus IRB. To modify a previously uploaded document click **Amend** located to the right of the document listing.



Note that the name of the **Document Type** and the **Description** remains the same, as this is the document that the user is modifying. (See grayed out text in image above.) Update your version number (eg: v.1, v.2, v.3, etc.) and click **Choose File** to select and upload the modified version of the document from the user's computer files or flash drive.

UPLOADING A NEW DOCUMENT FOR REVIEW BY THE IRB

Click **Add a New Document** to upload a new document, for example, adding a new consent document because a new population has been added to the project. Select the appropriate **Document Type** from the drop down box. Enter the name of the document into the **Description** field with version control (eg: v.1, v.2, etc.). Be sure to use the name that the document is commonly referred to by the research team. You may also want to add a date for clarity purposes. Click **Choose File** to upload the new version from the user's computer files or flash drive.



Click Save.

Click **Submit to IRB** from the left hand column to submit the amendment to the IRB for formal review.

QUESTIONNAIRES

There will not be any questionnaires to complete for this submission. Instead, please complete and upload the Amendment to Approved Study Form, and if appropriate the Personnel Amendment Table, found on the Forms & Templates page of the Purdue IRB Website.

SUBMIT TO IRB

Once the protocol record is complete and all documents required by the IRB for review have been uploaded, then the researcher is ready to submit the protocol.

To commence the submission process, click the **Submit to IRB** menu item from the column on the left-hand side. This will indicate the types of actions that can be performed on the protocol. For new applications, researchers can only **Submit to IRB**. The **Withdraw Submission** feature cannot be used until the protocol has already been received by the IRB.

Click on <u>Submit for Review</u> to submit the amendment. This function permits the user to identify the type of submission being sent to the IRB for review and approval.

To Submit to the IRB: Select the submission **Type** from the drop down box. Be sure to select **Initial Application** for a new protocol. Select a **Review Type** from the drop down box.

Note

Federal guidance requires that someone other than the investigator determine whether or not a research study is exempt, therefore the only option to choose is Pending IRB Determination. Additionally, federal regulation and/or your institutions policy require the IRB office to determine the appropriate review type for each protocol. The IRB will override the selection to ensure compliance with federal regulations and institution policy regarding the appropriate review type when approved.

Select the **Type Qualifier** drop down box. For amendment submissions it should always be **Amendment**.

Click the **Submit** button to submit for review.

The user will receive a message asking whether or not they wish to submit the protocol. Click **OK**.

NOTE: CoeusLite is a dual submission system. After you have submitted through CoeusLite, the Principal Investigator will receive an email notification from Coeus-System@lists.purdue.edu asking for their approval. The Principal Investigator must follow the approval steps in order for the protocol submission to be routed to the HRPP-IRB.

DELETING A PENDING PROTOCOL

A protocol or amendment submission is considered as pending until the time a user submits the amendment to the IRB. Protocols can be deleted before they are submitted. Once submitted they cannot be deleted.

To delete a protocol, click on **Pending Protocols** from the main IRB menu. Then click **Status** to bring up the alphabetical listing of protocols by status. Search for the protocol you wish to delete.

Click on **Delete Protocol** from the left hand column.

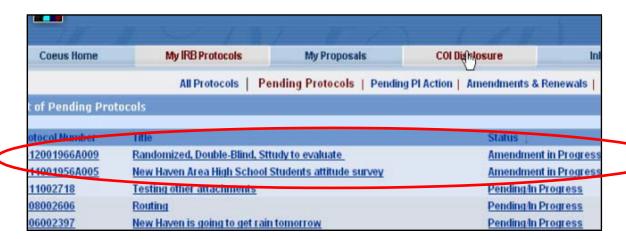


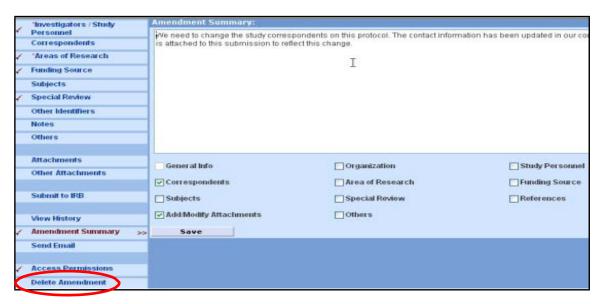
The user will be prompted with a message that asks whether or not you wish to delete the protocol. Click **OK** to say yes. Click **Cancel** to say no and continue working.



To delete an Amendment in Progress:

Bring up the **Amendment Summary** by double clicking the protocol Amendment number.



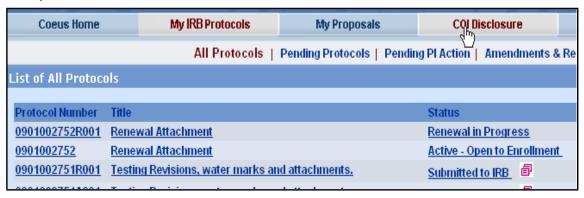


Click on **Delete Amendment** from the left hand column to delete the amendment summary. The user will be prompted with a message that asks whether or not you wish to remove the amendment. Click **OK** to say yes. Click **Cancel** to say no and continue working on the amendment.

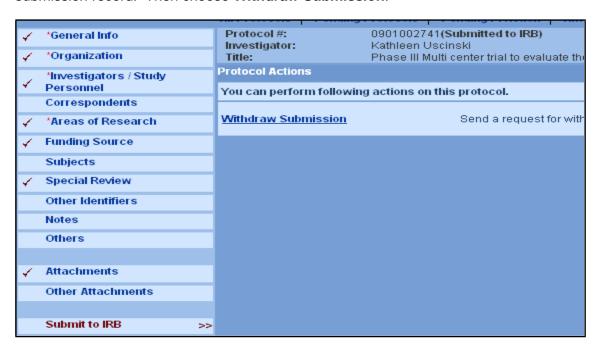
WITHDRAWING A SUBMISSION

The user can withdraw an initial protocol, an amendment or any other submission up until the time the protocol submission status is **In Agenda**. "In Agenda" means that the IRB is reviewing the protocol.

To choose the submission the user wishes to withdraw, search for the protocol submission by clicking on **All Protocols**, then searching the **Status** equal to **Submitted to IRB**. Double click on the submission (Renewal, amendment, renewal/amendment or Initial).



To withdraw a submission, choose the **Submit to IRB** from the left hand menu of the submission record. Then choose **Withdraw Submission**.



CREATE RENEWAL

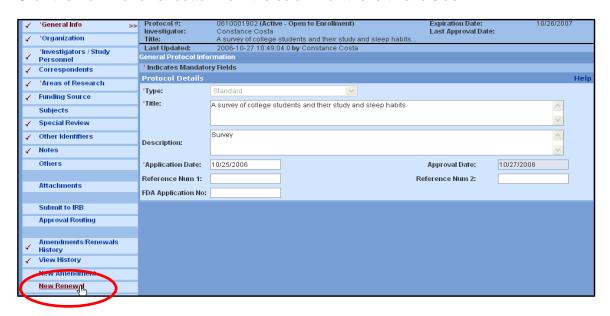
Use this submission type to request renewal for a currently approved research protocol. If you need to make changes to the currently approved protocol, consent document(s) or other protocol documents then you must use the **Amendment** submission.

Click on My IRB Protocols.

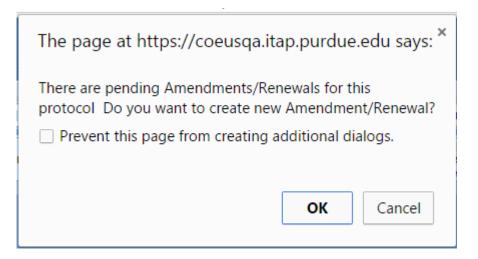
Click on **All Protocols** to see the full listing of protocols that are already approved. Select the protocol you wish to work with. The information can be sorted by clicking on any one of the column headings. Example: Expiration dates may be sorted in ascending/descending order by clicking on the column heading **Expiration Date**.



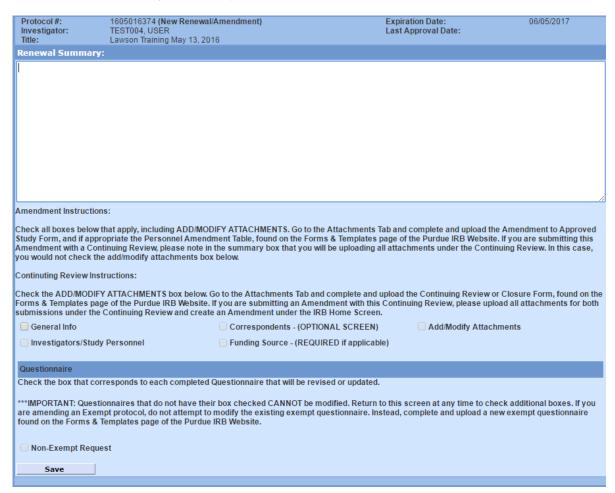
Double click on the protocol you wish to work with. This will open up the protocol record. Click the **New Renewal** button from the column on the left-hand side.



If there are pending renewals for the protocol, a window will pop up to indicate that these submissions already exist and inquire if you want to create a new renewal. Click **OK** to continue or click **Cancel**. (**Note: Cancel means no.**)



The Renewal summary window opens.



Type your comments in the **Renewal Summary** box. For example: "Research is progressing as planned.

Save when complete. Your renewal has been created.

To upload the required attachments, make sure that the **Add/Modify Attachments** box is checked in the Renewal Summary tab. Then select **Attachments** from the left hand column tab to upload. Select the appropriate from the **Document Type drop** down box. Type in the **Description** of the document. Then use **Choose File** to upload the completed documents from your computer files. Click **Save**.

Click **Submit to IRB** to submit your request for renewal to the IRB for formal review.

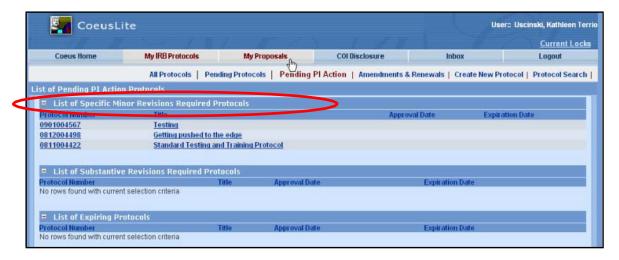
REVIEWING REVISIONS REQUIRED BY THE IRB

Investigators are notified when revisions are required by the IRB so that approval of the protocol submission may be eventually granted. Investigators can view these requests for revisions through the Coeus IRB system.

After signing into the Coeus Web page, click on **My IRB Protocols**. Select the **Pending Protocols** tab. Protocols requiring revisions are assigned a **Status** noted as either **Specific Minor Revisions Required** or **Substantive Revisions Required**.

1508016304A001	Testing NHSR QA	Amendment in Progress	10/22/2015
1506016211	Aviation Rumble Strips	Substantive Revisions Required	06/24/2015
1506016210A004	"Political Football: Race, College Football, and a Deca	Amendment in Progress	10/09/2015
1506016210A003	"Political Football: Race, College Football, and a Deca	Amendment in Progress	10/09/2015
1506016210A002	"Political Football: Race, College Football, and a Deca	Amendment in Progress	09/22/2015
1506016208	Autonomic Indices of Speech Perception in Infancy	Submitted to IRB	07/23/2015
1506016205	Analyses of Restricted Use Data from the National Longi	Substantive Revisions Required	07/08/2015
1506016200	Sentence production training for individuals with aphasia	Substantive Revisions Required	06/22/2015
1506016176	Preservice Teacher Education: Lessons in Lesson Planning	Substantive Revisions Required	06/15/2015
1506016173	Web Based Cyber Forensics Training for Law Enforcement	Specific Minor Revisions Required	06/15/2015
1506016137	Exploring Organizational Structures in Healthcare: A Fe	Specific Minor Revisions Required	06/01/2015
1505016087A002	Child-Parent attachment relationships in early childhoo	Submitted to IRB	07/17/2015
1502015787	Terrorism, Counterterrorism and Tourism.	Specific Minor Revisions Required	02/23/2015
4040447744004	Adaptive Video Cadina		07/47/2045

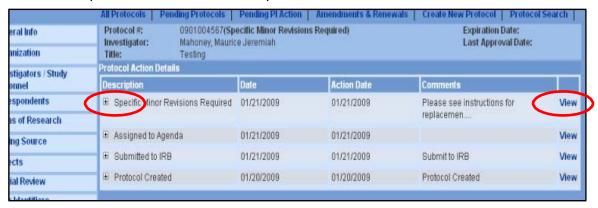
Investigators may also view protocols requiring action by clicking on **Pending PI Action** tab.



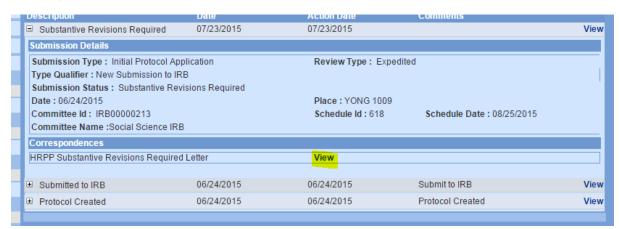
In either screen, click on the protocol to open the protocol record and then click the **View History** in the left hand column. This will permit the investigator to view the actions and correspondence with the IRB.



Note the Specific Minor Revisions Required in the **Description** field. Click **View** to see the quick comments from the IRB. To see the full correspondence click open the + next to the Specific Minor Revisions Required.



This screen provides submission details related to the IRB review. Note the name of the IRB Committee and the Committee date of review (Schedule Date) are listed on this screen. Click on **View** on the line that notes **Specific Minor Revisions Letter** under the **Correspondences** section to view the actual letter.



RESPONDING TO THE IRB WHEN REVISIONS ARE REQUESTED

The investigator is required to provide a written response to the IRB addressing each of the revisions requested by the IRB. In some cases only a response (memo or letter) from the investigator needs to be uploaded into the system and sent to the IRB as it sufficiently addresses the IRB's request for clarification.

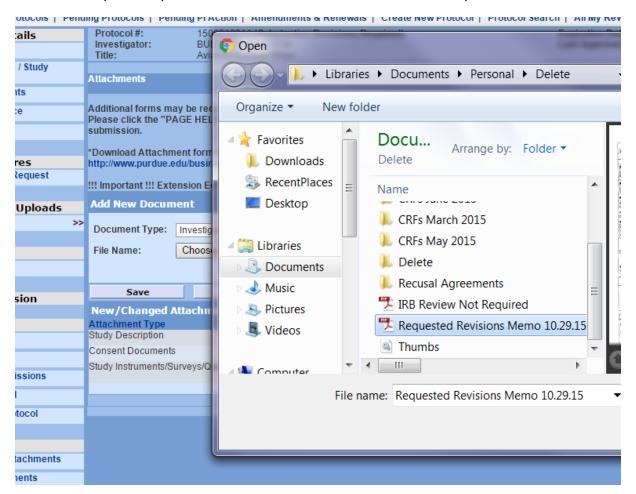
In other cases however, changes are required to the protocol documents that were previously sent into the IRB for its initial review. As an example, the IRB may 1) require specific word changes to Consent Documents or 2) require that the investigator change interventions or procedures in the protocol. In the case of example #1; modifications to the originally submitted consent document must be made and re-uploaded into the system for review by the IRB. Similarly, in the case of example #2, the questionnaire and perhaps the consent document would require modification and a re-upload into the system for re-review by the IRB.

While the comprehensive changes required of the investigator are noted in the IRB's response, an IRB may request that some changes, such as those requested in consent documents, are noted in a track-changed Word version of the document that is returned to the investigator by the IRB at the time it issued the Revision request. In this case, the investigator must be sure to review all the changes requested by the IRB and then upload a new version of that document both in Word.

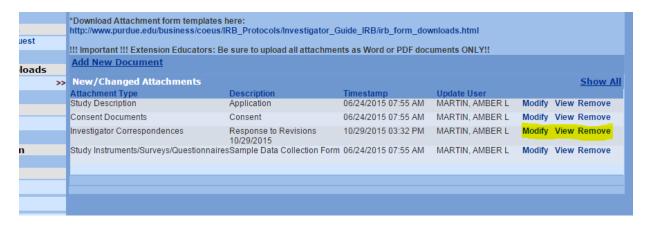
Note

Final approval markings are automatically applied to all Adobe (pdf) protocol-related documents when the IRB approves the protocol.

To upload the investigator's letter of response, Click on **Attachments** from the left hand column. Select **Add New Document** and use the drop down box to select the **Document Type** and under **Description** you can indicate that it is a response and the date. Example: Response to SMR of 10/29/2015. **Choose File** to upload the document.



Click Save.

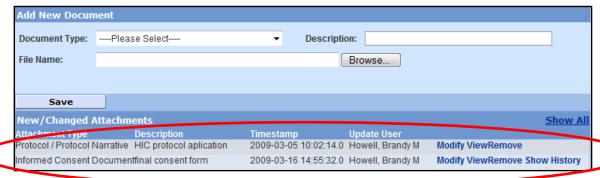


Note, the investigator can **Modify** or **Remove** the response document if changes are required prior to submitting it to the IRB.

MODIFICATIONS TO PREVIOUSLY UPLOADED DOCUMENTS

To view changes requested by the IRB that have been inserted into the documents already uploaded into the system and/or to modify documents previously submitted, select **Attachments** from the left hand column.





Note

The version of the document edited by the IRB (IRB User in this example is Howell) is the only version viewable as it was the last one edited in this example.

To see the version originally submitted by the investigator or the history of this particular document, click **Show History.** This will bring up all versions of the same document that were either previously submitted by the investigator or edited by the IRB.

New/Changed Attachments Show A						
Attachment Type	Description	Timestamp	Update User			
Protocol / Protocol Narrative	HIC protocol aplication	2009-03-05 10:02:14.0	Howell, Brandy M	Modify ViewRemove		
Informed Consent Documen	tfinal consent form	2009-03-16 14:55:32.0	Howell, Brandy M	Modify ViewRemove Hide History		
Informed Consent Documen	tconsent	2009-03-05 10:01:21.0	Howell, Brandy M	View		
Informed Consent Documen	tconsent_track	2009-03-09 09:39:06.0	mml37	View		

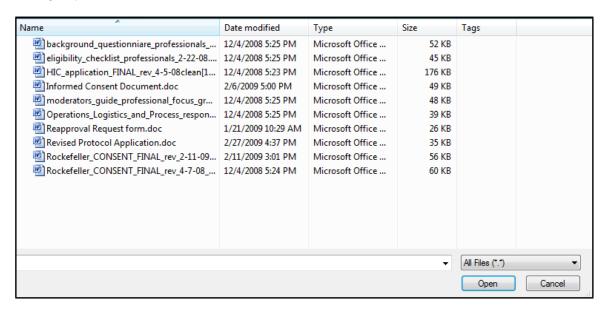
Note

The screen opens to permit investigators to add additional documents. However, the user must modify the currently uploaded document in order to re-upload it as the new version or revised version. This will also help to ensure that the IRB and PI acknowledge the editing history of each document. In other words, prior to uploading a new version of a document requiring revisions, the investigator first must modify the previous version. Do not forget to include version control with all of your uploaded documents. (eg: v.1, v.2, etc.)

To modify the document(s) requested by the IRB click **Modify**.

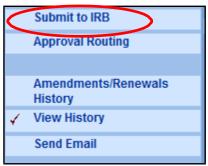
Prior to uploading a modified version of a document for submitting back to the IRB, the investigator will need to review the IRB edited version. This will help to ensure that the investigator has reviewed all revisions requested by the IRB. The investigator may accept all changes or may make additional changes. **The changed version should be saved to the investigator's computer files.** The investigator may choose to rename the document or add a date to help with identification. Using the **Modify** feature will ensure that any changes in title are still associated with the same document and will be recorded in the history.

Choose file to browse your computer and choose the version of the document with the changes you made. Click **Save**.



The document that has been modified now displays, replacing the document from the IRB.

When all attachments and the response are uploaded, then the response can be submitted back to the IRB. To do so, select **Submit to the IRB** from the left hand column.



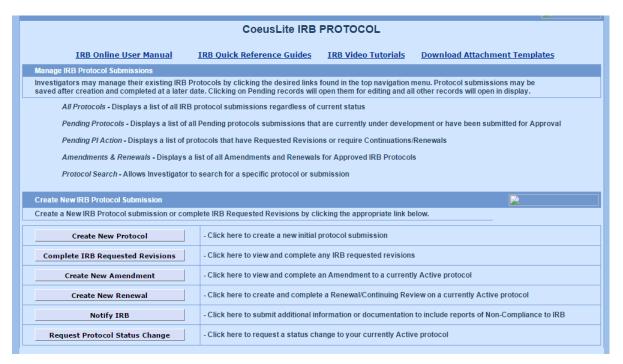
Click Submit for Review.



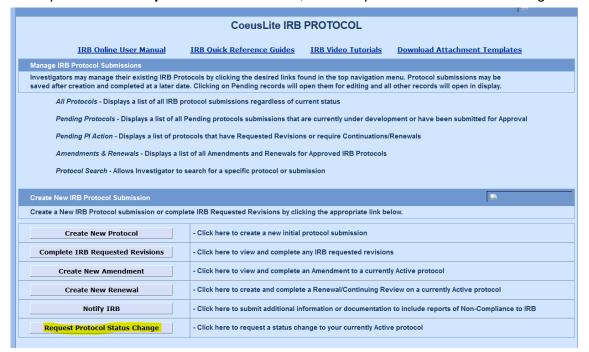
Choose the Type: Initial Submission, Renewal or Amendment. For Review Type, choose Pending IRB Determination.
For Type Qualifier, choose Revisions Requested by IRB Click Submit.

OTHER PROTOCOL ACTIONS

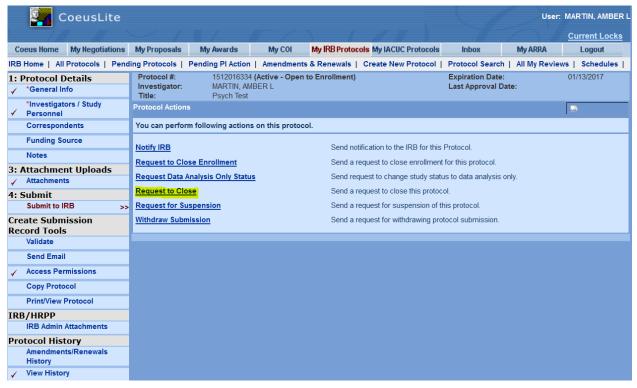
Depending upon the status of a protocol, the investigator is able to take certain actions on the protocol. This is done by clicking on the **My IRB Protocols** tab at the top of the page. This will open the list of actions:



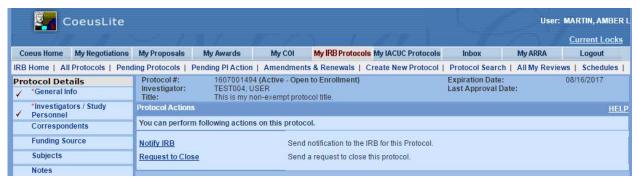
To request to close a protocol to enrollment, click Request Protocol Status Change.



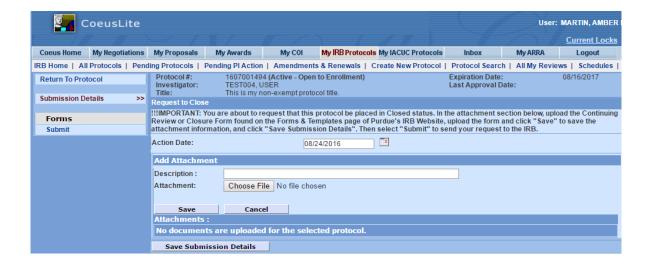
Select the study you wish to close. Select Request to Close.



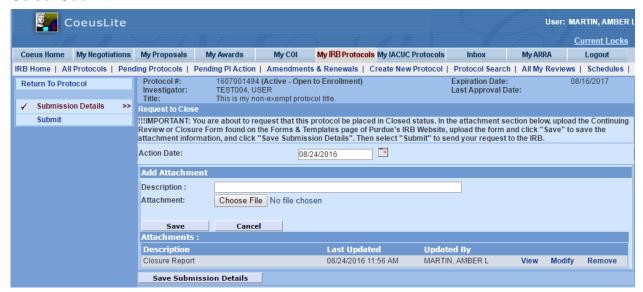
Save Submission Details.



Select Closure Request and follow the instructions.



Select Submit.



Select OK.

