

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

1. Click on **My IRB Protocols**. The list of protocols defaults to those that are **Pending Protocols**. Protocols requiring revisions are assigned a **status** noted as either Specific Minor Revisions Required or Substantive Revisions Required.

Protocol Number	Title	Status	Creation Date
0901004582	ORIG Check	Pending In Progress	2009-01-23
0901004574	CHCS 1	Submitted to IRB	
0901004573	CHCS 2	Submitted to IRB	
0901004572	CHCS	Submitted to IRB	
0901004569	Testing	Submitted to IRB	
0901004568	Testing	Submitted to IRB	
0901004567	Testing	Specific Minor Revisions Required	2009-01-20
0901004562/0001	Research Participant Perception of Care Project I	Amendment In Progress	2009-01-21
0901004558	Testing Notify All in Notification	Pending In Progress	2009-01-16

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

Protocol Number	Title
0901004586	Follow-up of Extremely Low Birthweight Infants after nutritional couns...

2. In either screen, click on the protocol to open the protocol record and then click the **View History Tab** in the left hand column.

Amendments/Renewals History
<input checked="" type="checkbox"/> View History
Send Email

This will permit the investigator to view the actions and correspondence with the IRB. Note the “Specific Minor Revisions Required” in the **Description** field.

Description	Date	Action Date	Comments	View
Specific Minor Revisions Required	01/26/2009	01/26/2009	Please contact Ellen Bedard at the HIC...	View
Assigned to Agenda	01/26/2009	01/26/2009		View
Submitted to IRB	01/26/2009	01/26/2009	Submit to IRB	View
Protocol Created	01/26/2009	01/26/2009	Protocol Created	View

3. Click **View** to see the quick comments from the IRB.

Comments	View
Please contact Ellen Bedard at the HIC....	View

Comments - Windows Internet Explorer

Comments

Please contact Ellen Bedard at the HIC office should you have questions regarding the revisions requested of the IRB.

4. To see the full correspondence, Click on the **+** next to the Specific Minor Revisions Required. Note the name of the IRB Committee and the Committee date of review (Schedule Date) is listed on this screen.

Description	Date	Action Date	Comments	View
Specific Minor Revisions Required	01/26/2009	01/26/2009	Please contact Ellen Bedard at the HIC...	View

Submission Details	
Submission Type : Initial Application	Review Type : Full
Type Qualifier :	
Submission Status : Specific Minor Revisions Requested	
Date : 01/26/2009	Place : Room 205
Committee Id : 595	Schedule Id : 3252
Committee Name : Human Investigation Committee I	Schedule Date : 02/04/2009

Correspondences	
Specific Minor Revisions Letter	View

Description	Date	Action Date	Comments	View
Assigned to Agenda	01/26/2009	01/26/2009		View
Submitted to IRB	01/26/2009	01/26/2009	Submit to IRB	View
Protocol Created	01/26/2009	01/26/2009	Protocol Created	View

- Click on **View** on the line that notes **Specific Minor Revisions Letter** under the **Correspondences** section to view the actual letter.

The correspondence displays as a PDF.

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 the response (memo or letter) from the investigator needs to be uploaded into the system 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 re-review by the IRB. Similarly, in the case of example #2, the original protocol would require modification and a re-upload into the system for re-review by the IRB.

For full details on responding to the IRB, please see the comprehensive Coeus training manual that is available on the Coeus website:

<http://www.yale.edu/coeus/training.html>

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:

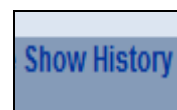
- Select **Attachments** from the left hand column.

The list of documents associated with the protocol displays:

New/Changed Attachments				Show All
Attachment Type	Description	Timestamp	Update User	
Informed Consent Document	Consent for Healthy Controls.pdf	2009-01-26 15:59:45.0	Ehrenkrantz, Richard Allan	Modify View Remove
Protocol / Protocol Narrative	HIC Application and Protocol	2009-01-26 15:51:44.0	Ehrenkrantz, Richard Allan	Modify View Remove
Informed Consent Document	Consent for Healthy Controls	2009-01-26 16:15:44.0	Howell, Brandy M	Modify View Remove Hide History
Informed Consent Document	Consent for Healthy Controls	2009-01-26 15:58:54.0	Ehrenkrantz, Richard Allan	View

The IRB coordinator's name will display next to any attachment that has been revised and changed by the IRB, so it's easy to recognize who made the changes. In this case, Brandy Howell made changes. You can view the attachment, save it on your computer and work on it.

- 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 All
Attachment Type	Description	Timestamp	Update User	
Informed Consent Document	Consent for Healthy Controls.pdf	2009-01-26 15:59:45.0	Ehrenkrantz, Richard Allan	Modify View Remove
Protocol / Protocol Narrative	HIC Application and Protocol	2009-01-26 15:51:44.0	Ehrenkrantz, Richard Allan	Modify View Remove
Informed Consent Document	Consent for Healthy Controls	2009-01-26 16:15:44.0	Howell, Brandy M	Modify View Remove Hide History
Informed Consent Document	Consent for Healthy Controls	2009-01-26 15:58:54.0	Ehrenkrantz, Richard Allan	View

Note: the screen opens to permit investigators to add additional documents. However, the user must download the modified version to his/her local drive and revise it prior to reuploading it. This will 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.

- In order to attach a modified version, the investigator will need to review the IRB edited version prior to uploading a modified version of a document for submitting back to the IRB. This will help to ensure that the investigator has reviewed all revisions requested by the IRB. The investigator may accept all changes or 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.

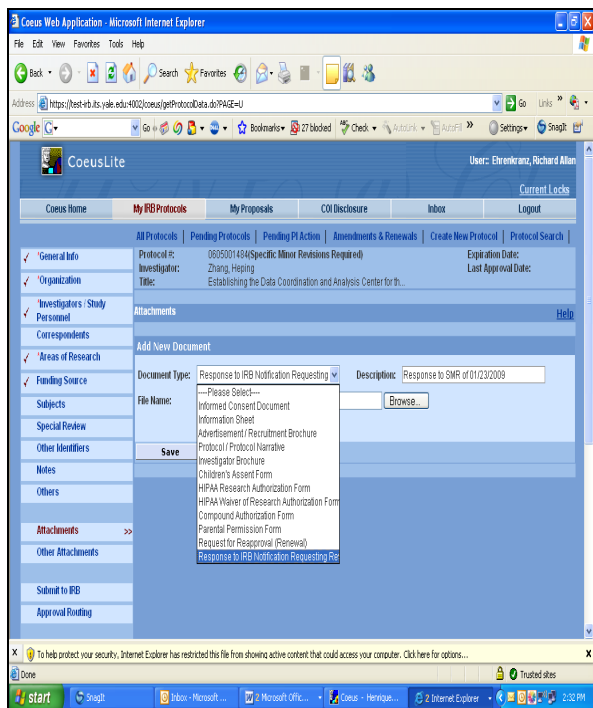
- Browse your computer and choose the version of the document with the changes you made. Click **Save**.

Name	Date modified	Type	Size
background_questi...	12/4/2008 4:25 PM	Microsoft Office ...	52 KB
eligibility_checklist_...	12/4/2008 4:25 PM	Microsoft Office ...	45 KB
HIC_application_FL...	12/4/2008 4:23 PM	Microsoft Office ...	176 KB
<input checked="" type="checkbox"/> Informed Consent ...	2/6/2009 4:00 PM	Microsoft Office ...	49 KB
moderators_guide_...	12/4/2008 4:25 PM	Microsoft Office ...	48 KB
Operations_Logistic...	12/4/2008 4:25 PM	Microsoft Office ...	39 KB
Reapproval Request...	1/21/2009 9:29 AM	Microsoft Office ...	26 KB
Rockefeller CONSE...	12/4/2008 4:24 PM	Microsoft Office ...	60 KB

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

New/Changed Attachments				Show All
Attachment Type	Description	Timestamp	Update User	
Informed Consent Document	Consent for Healthy Controls.pdf	2009-01-26 15:59:45.0	Ehrenkrantz, Richard Allan	Modify View Remove
Protocol / Protocol Narrative	HIC Application and Protocol	2009-01-26 15:51:44.0	Ehrenkrantz, Richard Allan	Modify View Remove
Informed Consent Document	Consent for Healthy Controls	2009-02-06 16:08:55.0	Hostetter, Margaret K	Modify View Remove Show History

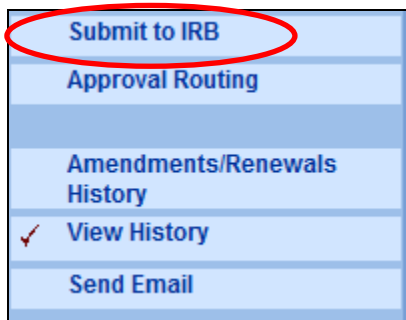
- Prior to submitting the changes to the IRB, the investigator must upload a memo or letter summarizing their response to the IRB's Request for Notifications. To do so, select **Add New Document**. Select that Document type that is Response to IRB Notification Requesting Revision. Then use Browse to upload the investigator's response.



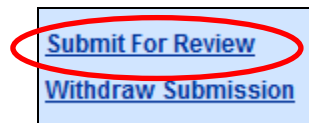
8. When all attachments and the response are uploaded, then the response can be submitted back to the IRB. To do so, select **Validate** from the left hand column.



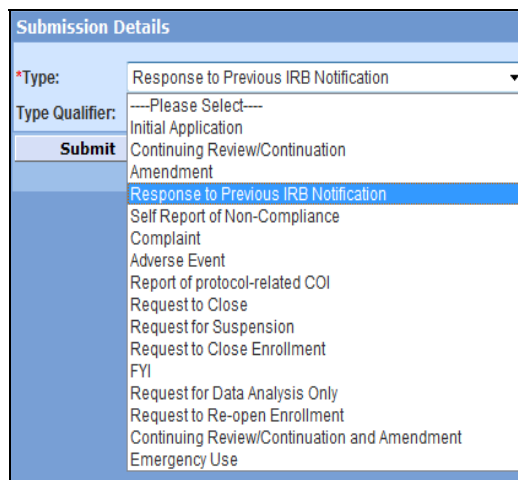
9. Once Validation Rules have been passed successfully, select **Submit to the IRB** from the left hand column.



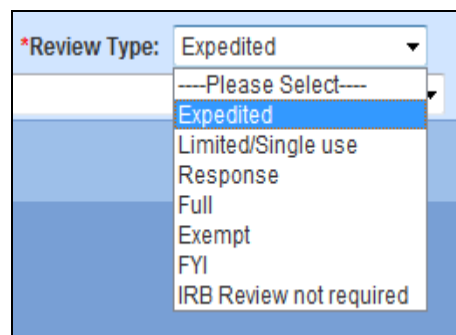
10. Click **Submit for Review**.



11. Choose Response to Previous IRB Notification as the **Type**.



For **Review Type**, choose Expedited, if the IRB has indicated Specific Minor Revisions, and checkoff checklist # 10



12. Click **Submit**.