COEUS LITE IRB SUBMISSION SYSTEM MANUAL APPENDIX

UPDATED MARCH 31, 2016

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.

	Coeus Home	My Negotiations	My Proposals	My Awards	My COI	My IRB Protocols	My IACUC Protocols	Inbox	My ARRA	Logout

IRB Home | **All Protocols** | Pending Protocols | Pending PI Action | Amendments & Renewals | Create New Protocol | Protocol Search | All My Reviews | Schedules |

List of All Protocols

Protocol Number	Title	Status ↓	Approval Date	Expiration Date
1409001366	Cat 6 Testing 9.19.2014	Submitted to IRB		
1402001214	What do people think?	Submitted to IRB		
1307001183R003	Disappearing Summary Link Test	Submitted to IRB	07/18/2013	07/17/2014
1307001183A001	Disappearing Summary Link Test	Submitted to IRB	07/18/2013	07/17/2014
1506001464	Testing Approved Consent Forms	Active - Open to Enrollment	06/26/2015	06/25/2016
1504001441	New Expedited App Test	Active - Open to Enrollment	04/03/2015	04/02/2016
1402001213	Finding out what people do	Active - Open to Enrollment	01/29/2015	01/28/2016
1407001330A003	testing one...two...	Amendment in Progress	08/01/2014	
1407001330A002	testing one...two...	Amendment in Progress	08/01/2014	
1307001186A003	test	Amendment in Progress	07/26/2013	07/25/2014
1504001442	Exempt Trial Test	Exempt	04/03/2015	
1407001330	testing one...two...	Exempt	08/01/2014	
1205000876	Lite test	Exempt	11/05/2013	

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

	Protocol #:	1506001464 (Active - Open to Enrollment)	Expiration Date:	06/25/2016
✓ *General Info >>	Investigator:	MARTIN, AMBER L	Last Approval Date:	
*Investigators / Study Personnel	Title:	Testing Approved Consent Forms	Meeting Date:	

General Protocol Information

* Indicates Mandatory Fields

Protocol Details

*Type: Request for Non-Exempt Approval

*Title: Testing Approved Consent Forms

Description:

*Application Date: 06/26/2015   Approval Date: 06/26/2015

Reference Num 1:   Reference Num 2:

FDA Application No:

Left-hand navigation:
- ✓ *General Info >>
- *Investigators / Study Personnel
- Correspondents
- Funding Source
- Subjects
- Notes
- **2: Questionnaires**
  - Human Subjects Research Determination
- **3: Attachment Uploads**
  - ✓ Attachments
- Submit to IRB
- Approval Routing
- **Create Submission**
  - New Amendment
  - New Renewal

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.

Select the General Info Tab. This will bring up the IRB Amendment Questionnaire. You must complete the Amendment Questionnaire before submitting to the IRB.

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 the 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.) Click Choose File to select and upload the modified version of the document from the user's computer files or travel 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. 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 travel drive.
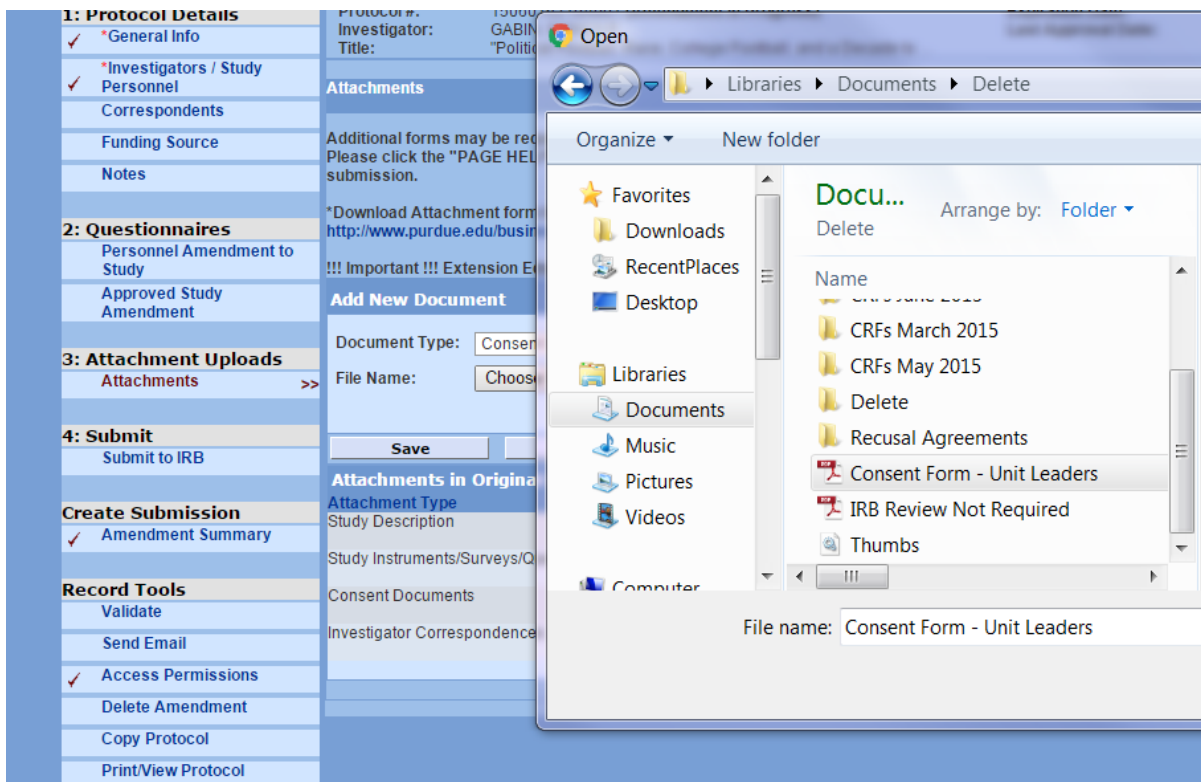
Click **Save.**

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

QUESTIONNAIRES

You will be required to complete a protocol questionnaire(s) prior to submitting an amendment. Questionnaires will be listed in the left-hand menu bar under the heading "**2: Questionnaires**".

2: Questionnaires
- ✓ **Non-Exempt Request**
- **Personnel Amendment to Study**
- **Approved Study Amendment**

To fill out a questionnaire, click on the title of the questionnaire and the questions will appear. Answer the questions and click **Save & Proceed**. The next set of questions are displayed. Continue until you complete the questionnaire. You will get a message when you are complete.

Questionnaire Completed for protocol 1602016340A001

OK

A check mark is now displayed in front of the Questionnaire:

2: Questionnaires
- ✓ **Non-Exempt Request**
- **Personnel Amendment to Study**
- ✓ **Approved Study Amendment** >>

To modify an answered Questionnaire, click on the Questionnaire. Select Modify or start over when the questions are displayed, and fill out and save the questions again.

SUBMIT TO IRB

Once the protocol record is complete, all documents required by the IRB for review have been uploaded and all appropriate questionnaires have been completed, 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 **Submit for Review** 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.
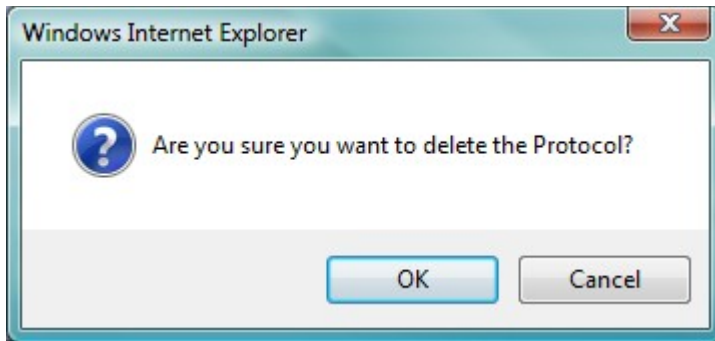
To delete an Amendment in Progress:

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).

Coeus Home	My IRB Protocols	My Proposals	COI Disclosure

All Protocols | Pending Protocols | Pending PI Action | Amendments & Re

List of All Protocols

Protocol Number	Title	Status
0901002752R001	Renewal Attachment	Renewal in Progress
0901002752	Renewal Attachment	Active - Open to Enrollment
0901002751R001	Testing Revisions, water marks and attachments.	Submitted to IRB

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

✓ *General Info	**Protocol #:** 0901002741**(Submitted to IRB)**
✓ *Organization	**Investigator:** Kathleen Uscinski
	Title: Phase III Multi center trial to evaluate th
✓ *Investigators / Study Personnel	**Protocol Actions**
Correspondents	You can perform following actions on this protocol.
✓ *Areas of Research	**Withdraw Submission** Send a request for with
✓ Funding Source	
Subjects	
✓ Special Review	
Other Identifiers	
Notes	
Others	
✓ Attachments	
Other Attachments	
Submit to IRB >>	

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 **Renewal** submission.*
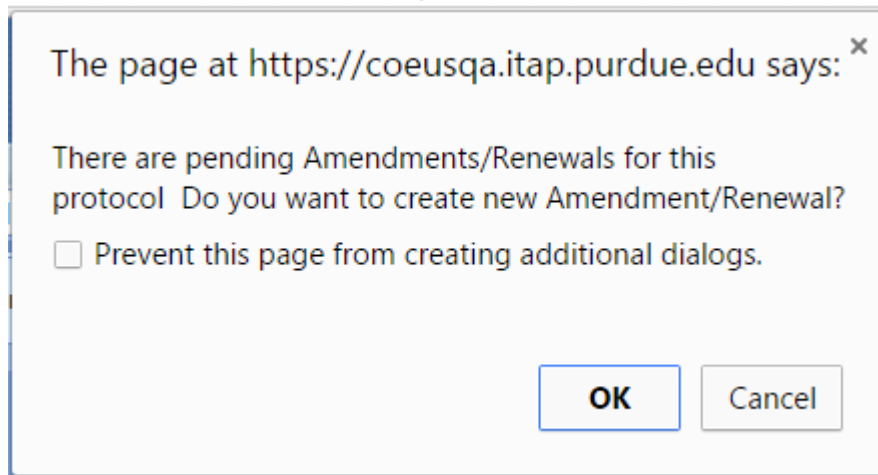
Click on **My IRB Protocols**.

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.**

	All Protocols	Pending Protocols	Pending PI Action	Amendments & Renewals	Create New Protocol	Protocol Sear
List of All Protocols					
Protocol Number	**Title ↑**	**Status**		**Approval Date**	**Expiration Date**
0806002372	Under dog teams upsets top seeds for the championship.	Submitted to IRB			
0806002411	Title of the Protocol	Pending/In Progress			
0708002108A003	Title of Study	Submitted to IRB			
0708002108	Title of Study	Active - Data Analysis Only		2007/09/17	2008/09/16
0806002410	Title of Protocol	Pending/In Progress			
0806002383	Title of Protocol	Submitted to IRB			
0806002379	The Beach Boys	Submitted to IRB			
0611001953	Testing Protocol on November 9, 2006	Submitted to IRB			
0806002373	Testing Protocol - Connie - 6/02/08	Active - Open to Enrollment		2008/06/18	2009/06/17
0804002320	Testing glucose inhibitors ot define triggers of Type I ...	Submitted to IRB			
0611001957	Testing 2 on Nov 9	Pending/In Progress			
0610001943	Test protocol on Tuesday, October 21, 2006	Active - Closed to Enrollment		2006/11/01	2007/10/31
0608001818R001	Test protocol created in CousLite	Submitted to IRB			
0611001950	Test -Connie-Nov 1, 2006	Submitted to IRB			
0611001945	Test -Connie-Nov 1, 2006	Submitted to IRB			
0610001899	Survey of High School Students	Closed Administratively for lack of response			
0610001892	Psychiatric Protocol	Active - Closed to Enrollment		2006/10/25	2007/10/25
0806002385	Protocol submission for review	Pending/In Progress			
0707002054	Protocol One	Pending/In Progress			
0610001913	Protocol One	Submitted to IRB			

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.

✓ '**General Info** >>	Protocol #:	0610001902 (Active - Open to Enrollment)		Expiration Date:	10/26/2007
✓ '**Organization**	Investigator:	Constance Costa		Last Approval Date:	
✓ '**Investigators / Study Personnel**	Title:	A survey of college students and their study and sleep habits...			
	Last Updated:	2006-10-27 10:49:04.0 by Constance Costa			
✓ **Correspondents**	**General Protocol Information**				
✓ '**Areas of Research**	' Indicates Mandatory Fields				
✓ **Funding Source**	**Protocol Details**				Help
Subjects	'**Type:** Standard ⌄				
✓ **Special Review**	'**Title:** A survey of college students and their study and sleep habits				
✓ **Other Identifiers**					
✓ **Notes**	**Description:** Survey				
Others	'**Application Date:** 10/25/2006		Approval Date:	10/27/2006	
	Reference Num 1:		Reference Num 2:		
Attachments	**FDA Application No:**				
Submit to IRB					
Approval Routing					
✓ **Amendments/Renewals History**					
✓ **View History**					
~~**New Amendment**~~					
New Renewal					

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 page at https://coeusqa.itap.purdue.edu says: ✕

There are pending Amendments/Renewals for this protocol Do you want to create new Amendment/Renewal?

☐ Prevent this page from creating additional dialogs.

OK   Cancel

The **Renewal** summary window opens.

Protocol #:	0910003223(New Renewal)	Expiration Date:	10/08/2010
Investigator:	Flach, Jennifer	Last Approval Date:	
Title:	new protocol for testing 4.3.6		

Renewal Summary:

☐ General Info   ☐ Organization   ☐ Study Personnel

☐ Correspondents   ☐ Area of Research   ☐ Funding Source

☐ Subjects   ☐ Special Review   ☐ References

☐ Add/Modify Attachments   ☐ Others

Save

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

Save when complete.   Renewal has been created. **Select the General Info Tab and select Save. This will bring up the IRB Continuing Review Questionnaire.**

Select the IRB Continuing Review Questionnaire and work your way through the questions until complete.
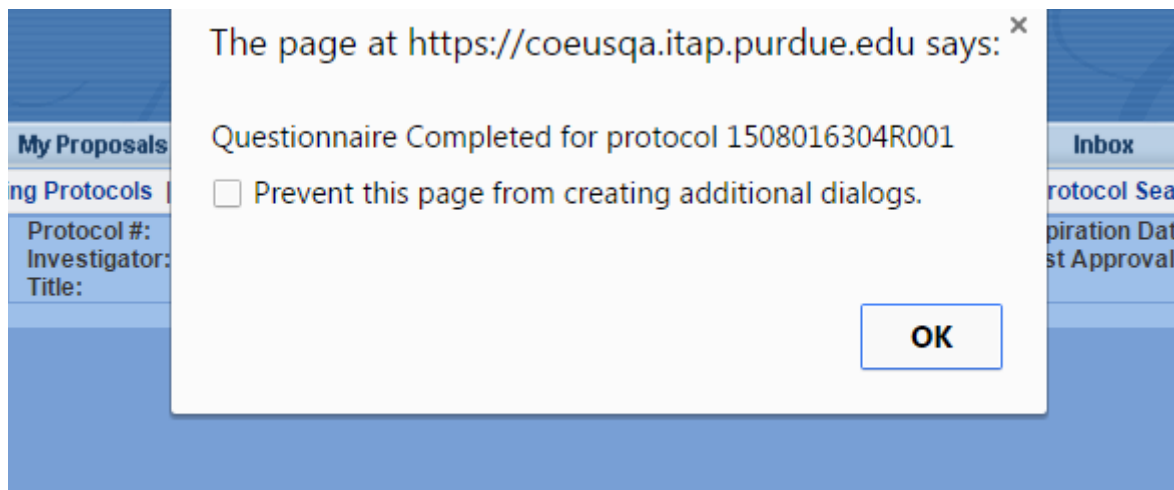
If you need to upload attachments, make sure that the **Add/Modify Attachments** box is checked in the Renewal Summary tab. Then select **Attachments** from the left hand column tab to upload. Select the appropriate from the **Document Type drop down box**. Type in the **Description** of the document. Then use **Browse** 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
1404014771A001	Adaptive Video Coding		07/17/2015

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.

Description	Date	Action Date	Comments	
⊟ Substantive Revisions Required	07/23/2015	07/23/2015		View

Submission Details

Submission Type : Initial Protocol Application   Review Type : Expedited
Type Qualifier : New Submission to IRB
Submission Status : Substantive Revisions Required
Date : 06/24/2015   Place : YONG 1009
Committee Id : IRB00000213   Schedule Id : 618   Schedule Date : 08/25/2015
Committee Name : Social Science IRB

Correspondences

HRPP Substantive Revisions Required Letter		View		
⊞ Submitted to IRB	06/24/2015	06/24/2015	Submit to IRB	View
⊞ Protocol Created	06/24/2015	06/24/2015	Protocol Created	View

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 01/23/2009. **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.

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.

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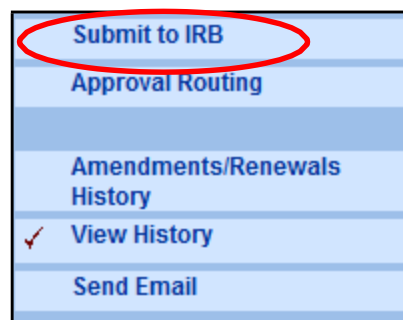
Click **Submit for Review**.
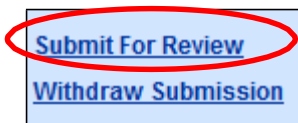
Choose the **Type**: **Initial Submission, Renewal or Amendment.**
For **Review Type**, choose **Pending IRB Determination**.
For **Type Qualifier**, choose **Revisions Requested by IRB**
Click **Submit.**

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:

CoeusLite IRB PROTOCOL

IRB Online User Manual   IRB Quick Reference Guides   IRB Video Tutorials   Download Attachment Templates

Manage IRB Protocol Submissions

Investigators may manage their existing IRB Protocols by clicking the desired links found in the top navigation menu. Protocol submissions may be saved after creation and completed at a later date. Clicking on Pending records will open them for editing and all other records will open in display.

All Protocols - Displays a list of all IRB protocol submissions regardless of current status

Pending Protocols - Displays a list of all Pending protocols submissions that are currently under development or have been submitted for Approval

Pending PI Action - Displays a list of protocols that have Requested Revisions or require Continuations/Renewals

Amendments & Renewals - Displays a list of all Amendments and Renewals for Approved IRB Protocols

Protocol Search - Allows Investigator to search for a specific protocol or submission

Create New IRB Protocol Submission

Create a New IRB Protocol submission or complete IRB Requested Revisions by clicking the appropriate link below.

Create New Protocol	- Click here to create a new initial protocol submission
Complete IRB Requested Revisions	- Click here to view and complete any IRB requested revisions
Create New Amendment	- Click here to view and complete an Amendment to a currently Active protocol
Create New Renewal	- Click here to create and complete a Renewal/Continuing Review on a currently Active protocol
Notify IRB	- Click here to submit additional information or documentation to include reports of Non-Compliance to IRB
Request Protocol Status Change	- Click here to request a status change to your currently Active protocol

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

CoeusLite IRB PROTOCOL

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Protocol Search - Allows Investigator to search for a specific protocol or submission

Create New IRB Protocol Submission

Create a New IRB Protocol submission or complete IRB Requested Revisions by clicking the appropriate link below.

Create New Protocol	- Click here to create a new initial protocol submission
Complete IRB Requested Revisions	- Click here to view and complete any IRB requested revisions
Create New Amendment	- Click here to view and complete an Amendment to a currently Active protocol
Create New Renewal	- Click here to create and complete a Renewal/Continuing Review on a currently Active protocol
Notify IRB	- Click here to submit additional information or documentation to include reports of Non-Compliance to IRB
Request Protocol Status Change	- Click here to request a status change to your currently Active protocol

Select the study you wish to close.

Select Request to Close.

Save Submission Details.

Select Closure Request.

Complete the Questionnaire.

Select Complete Submission.

Select OK.