

Coeus Lite – How to submit amendments

Coeus Lite Amendments

Coeus Lite website

- <https://coeus.drexel.edu/coeus/userAuthAction.do>
- Note that you must be on the Drexel University network to use the platform – you can VPN in if you are not on the network

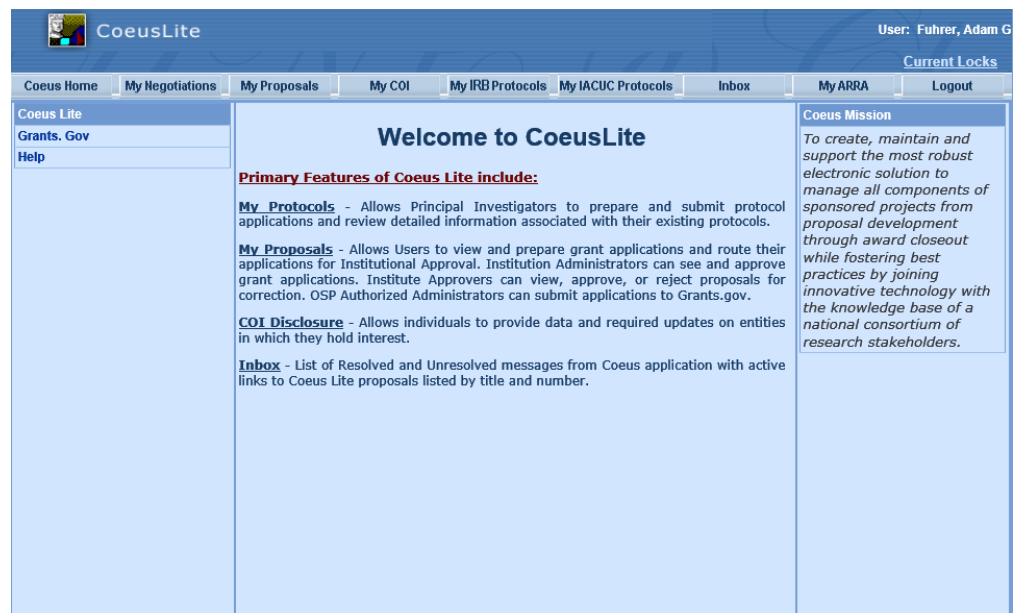
Login Information

- Username and password corresponds to other Drexel University credentials
 - Username example: abc123



My IRB Protocols

- Remember that all submissions needing HRP or IRB review and approval is submitted through the My IRB Protocols tab



Find Your Protocol

Principal Investigator or Co-Investigator

- Click All protocols tab
- Find protocol either through number or title

Protocol Number	Title	Status	Approval Date	Expiration Date
1710005707	African Born Women seeking HIV Care in Philadelphia: Qu...	Pending/In Progress		
1710005705	Post-operative pain management for routine general surg ...	Submitted to IRB		
1710005704	Adherence to PECARN criteria in trauma patients	Submitted to IRB		
1710005702	Weather influence on pediatric trauma	Submitted to IRB		
1710005700	Analysis of Post-Mortem Retrieved Devices and Tissues	Specific Minor Revisions Required		
1710005698	Reinforcing Nursing/Family Education on the American Ac ...	Pending/In Progress		
1710005696	10 year epidemiological review of train injuries in Pen ...	Submitted to IRB		
1710005695	A Qualitative Study of Black Male Engineering Achieveme ...	Routing In Progress		
1710005694	Letter of Reliance for Mind the Gap Intervention Pilot ...	Routing In Progress		
1710005690	Small round blue cell tumors: An educational review	Submitted to IRB		
1710005689	Pediatric disparities in treatment of concussion	Submitted to IRB		
1710005688	Clinical and Microbiological Outcomes Associated with V ...	Pending/In Progress		

Study Personnel

- Click the Protocol Search tab
- In the search window, enter some identifier to find your protocol (such as protocol number, investigator, etc.)
 - Note that it is a best practice to use * when searching, so for my protocol, I typed *1710005674*
 - This allows Coeus Lite to search for any possible keyword combinations

The screenshot shows the CoeusLite interface with the 'Protocol Search' window open. The search window has the following fields:

- Protocol No: *1710005674*
- Protocol Type: [Dropdown menu]
- Title: [Text input field]
- Protocol Status: [Dropdown menu]
- Expiration Date: [Text input field]
- Investigator: [Text input field]
- Funding Source: [Text input field]

Buttons for 'Search' and 'Cancel' are visible at the bottom of the search window. The background shows the 'List of All Protocols' table with various protocol entries.

Create An Amendment

Click New Amendment

- In the protocol screen, click New Amendment
 - This is located towards the bottom of the left hand column

Best practices

- Avoid clicking New Renewal with Amendment as this will force you to complete a renewal along with your amendment
- Coeus Lite will only process one modification at a time, so if you submit another, the system will not process, nor will your HRP coordinator review, until the immediate amendment has been approved

The screenshot displays the Coeus Lite system interface. On the left is a sidebar menu with various options, including 'General Info', 'Organization', 'Investigators / Study Personnel', 'Correspondents', 'Areas of Research', 'Funding Source', 'Subjects', 'Special Review', 'Other Identifiers', 'Notes', 'Others', 'Attachments', 'Other Attachments', 'Validate', 'Submit to IRB', 'Approval Routing', 'Amendments/Renewals History', 'View History', 'New Renewal with Amendment', 'New Amendment', 'New Renewal', 'Send Email', 'Access Permissions', 'Copy Protocol', 'Print Summary', 'Review Comments', and 'Forms'. The main content area shows protocol details for '1710005674 (Active - Open to Enrollment)'. The investigator is 'Riviello, Ralph J' and the title is 'Test Protocol #4'. The expiration date is '10/15/2018', the last approval date is '10/16/2017', and the meeting date is '10/16/2017'. The 'Protocol Details' section includes a dropdown for 'Type' (Standard), a text field for 'Title' (Test Protocol #4), and a text area for 'Description' (description.). The 'Application Date' is '10/06/2017' and the 'Approval Date' is '10/16/2017'. There are also fields for 'Reference Num 1', 'Reference Num 2', and 'FDA Application No.'. A 'Help' link is visible in the top right corner of the main content area.

Protocol #:	1710005674 (Active - Open to Enrollment)	Expiration Date:	10/15/2018
Investigator:	Riviello, Ralph J	Last Approval Date:	10/16/2017
Title:	Test Protocol #4	Meeting Date:	10/16/2017

General Protocol Information

* Indicates Mandatory Fields

Protocol Details [Help](#)

*Type: Standard

*Title: Test Protocol #4

Description: description.

*Application Date: 10/06/2017

Approval Date: 10/16/2017

Reference Num 1:

Reference Num 2:

FDA Application No:

Coeus Lite – How to submit amendments

Amendment Summary

- After you click New Amendment, the Amendment Summary box will appear
 - Type what you are modifying
 - If adding or removing personnel, mention that researcher`s name in the text box
- Anything that you are modifying that corresponds to an area in the left hand column matches with the click boxes below the Amendment Summary box
 - So for my amendment, I am adding a site
 - Adding a site requires a change in the protocol
 - A new protocol means I have to upload a new attachment
 - So the click box I want is Add/Modify Attachments

Protocol #: 1710005674 (New Amendment) Expiration Date: 10/15/2018
Investigator: Riviello, Ralph J Last Approval Date:
Title: Test Protocol #4

Amendment Summary:
Revising the protocol to include an additional site (University of Scranton) for subject recruitment

General Info Organization Study Personnel
 Correspondents Area of Research Funding Source
 Subjects Special Review References
 Add/Modify Attachments Others

Questionnaire
 Application Form - Standard and HUD

- Click Save
 - When Coeus Lite saves, your protocol number gets additional, post approval identifiers
 - For amendments, your protocol number will have an A followed by the number of amendment that this is
 - Protocol status (by protocol number) is Amendment in Progress

Protocol #: 1710005674A002 (Amendment in Progress) Expiration Date: 10/15/2018
Investigator: Riviello, Ralph J Last Approval Date:
Title: Test Protocol #4 Meeting Date:

General Protocol Information
* Indicates Mandatory Fields

Protocol Details [Help](#)

*Type: Standard
*Title: Test Protocol #4
Description: description.

*Application Date: 10/06/2017 Approval Date: 10/16/2017
Reference Num 1: Reference Num 2:
FDA Application No:

Make Your Changes

- In the left hand column, select whatever area you need to change
- For my amendment, I would click Attachments to upload the protocol

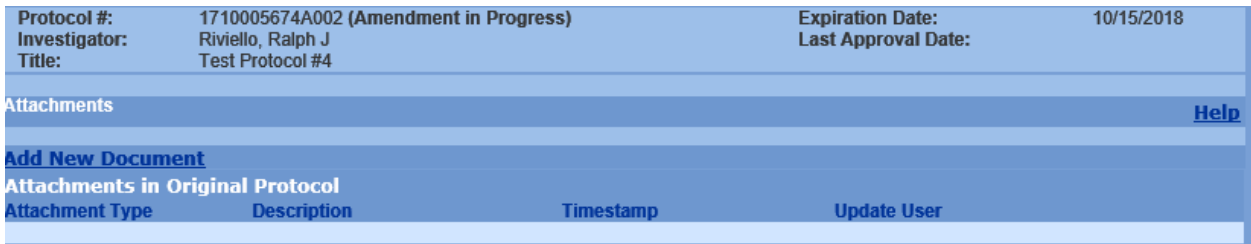
Best practices

- Any revision to an already approved documents requires
 - A tracked version of the new document compared to the original
 - A clean version with accepted changes
- Forgetting to attach either document will result in your amendment being rejected



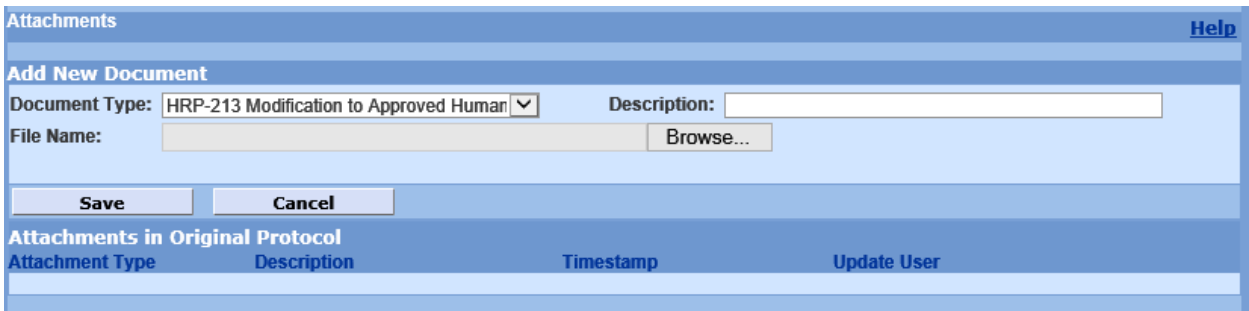
To attach new documents

- Click Add New Document



Document type

- Always select HRP-213 Modification to Approved Human Research Form when uploading any document for a modification regardless of what it is



Coeus Lite – How to submit amendments

My revised protocol is attached in two versions

- Clean
- Tracked

Protocol #:	1710005674A002 (Amendment in Progress)	Expiration Date:	10/15/2018
Investigator:	Riviello, Ralph J	Last Approval Date:	
Title:	Test Protocol #4		
Attachments Help			
Add New Document			
Document Type:	---Please Select---	Description:	<input type="text"/>
File Name:	<input type="text"/>	<input type="button" value="Browse..."/>	
<input type="button" value="Save"/>	<input type="button" value="Cancel"/>		
New/Changed Attachments Show All			
Attachment Type	Description	Timestamp	Update User
HRP-213 Modification to Approved Human Research Form	HRP 503 (clean)	10/12/2017 04:17 PM	Fuhrer, Adam G Modify View Remove
HRP-213 Modification to Approved Human Research Form	HRP 503 (tracked)	10/12/2017 04:18 PM	Fuhrer, Adam G Modify View Remove
Attachments in Original Protocol			
Attachment Type	Description	Timestamp	Update User

Amendment application

When you are done modifying your protocol, either through attaching new documents and or editing the left hand column areas, your next step is to complete the application.

- The application is at the bottom of the left hand column, in the Forms sections
 - HRP 213 Modification of Approved Research

Validate
Submit to IRB
View History
✓ Amendment Summary
Send Email
✓ Access Permissions
Delete Amendment
Copy Protocol
Print Summary
Review Comments
Forms
✓ Application Form - Standard and HUD
HRP 213 Modification of Approved Research

Coeus Lite – How to submit amendments

Amendment application

- Complete the application answering yes or no to the questions
 - Depending on your response, you may receive more questions for clarification

Protocol #:	1710005674A002 (Amendment in Progress)	Expiration Date:	10/15/2018
Investigator:	Riviello, Ralph J	Last Approval Date:	
Title:	Test Protocol #4		

**HRP 213 Modification of Approved Research
Amendment/Renewal Questionnaire**

[Previous](#) [Modify](#) [Start Over](#)

1) Are subjects currently enrolled? [More](#)
 Yes No

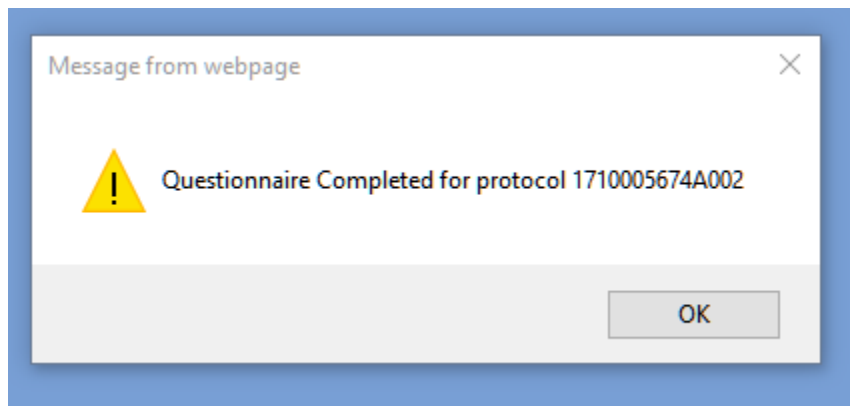
2) Is the protocol permanently closed to enrollment? [More](#)
 Yes No

3) Have all subjects completed all protocol-related interventions? [More](#)
 Yes No

4) Is the collection of private identifiable information completed? [More](#)
 Yes No

5) Will the current subjects be notified of these amendment changes? [More](#)
 Yes No

You will receive a pop up knowing questionnaire is completed



Coeus Lite – How to submit amendments

Submit to IRB

- To submit for approval routing
- Click Submit to IRB in left hand column
- Then
 - Submit for Review
 - Ok
 - OK

✓ *General Info
✓ *Organization
✓ *Investigators / Study Personnel
✓ <u>Correspondents</u>
✓ *Areas of Research
✓ Funding Source
✓ Subjects
✓ Special Review
✓ Other Identifiers
Notes
Others
✓ Attachments
Other Attachments
Validate
Submit to IRB

Protocol Submission Window

- Once submission is initiated, the last window is the Protocol Submission window
- Type
 - Modification of Approved Protocols
- Review Type
 - To be determined
- Type Qualifier
 - Standard
- Once you click Submit, Coeus Lite will ask you to confirm

Protocol #:	1710005674A002 (Amendment in Progress)	Expiration Date:	10/15/2018
Investigator:	Riviello, Ralph J	Last Approval Date:	
Title:	Test Protocol #4		
Protocol Submission Help			
* Indicates Mandatory Fields			
Submission Details			
*Type:	MODIFICATION OF APPROVED PROTOCOL	*Review Type:	To be determined
Type Qualifier:	Standard		
<input type="button" value="Submit"/>			

Approval Process

- You will know when your amendment has been submitted to the principal investigator for approval when your status changes to Routing in Progress

Protocol #:	1710005674A002 (Routing In Progress)	Expiration Date:	10/15/2018
Investigator:	Riviello, Ralph J	Last Approval Date:	
Title:	Test Protocol #4	Meeting Date:	
General Protocol Information			
* Indicates Mandatory Fields			
Protocol Details Help			
*Type:	Standard		
*Title:	Test Protocol #4		
Description:	description.		
*Application Date:	10/06/2017	Approval Date:	10/16/2017
Reference Num 1:		Reference Num 2:	
FDA Application No:			

- To check the approval status
 - You can click Approval Routing to see where your submission stands
- If you are the principal investigator
 - You can click Approval Routing to approve
 - Options are
 - Approve
 - Reject

Amendments only need the principal investor to approve

- Principal investigator will receive an email alerting them that they have an approval waiting

Once the principal investigator approves, HRP will received your request and begin the review process

✓	*General Info	>>
✓	*Organization	
✓	*Investigators / Study Personnel	
✓	Correspondents	
✓	*Areas of Research	
✓	Funding Source	
✓	Subjects	
✓	Special Review	
✓	Other Identifiers	
	Notes	
	Others	
✓	Attachments	
	Other Attachments	
	Validate	
	Approval Routing	