

# Coeus Lite Continuing Reviews

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

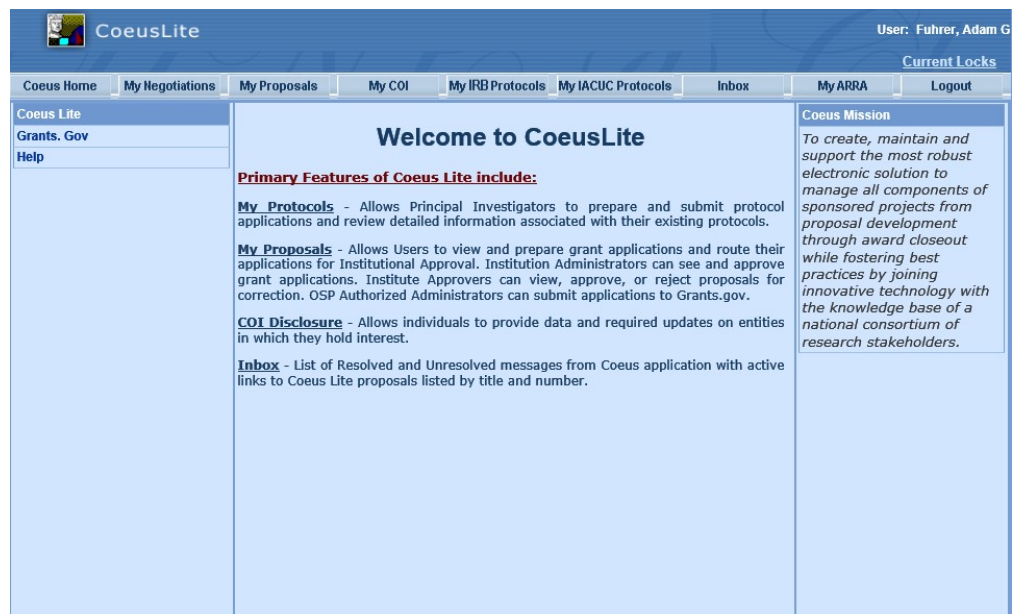
Login Information

- 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		
1710005688	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

Search window details:

- URL: https://coeus.drexel.edu/?type=Protocol&search=true&searchName=ALL\_PROTOCOL\_SEARCH&SUBHEADER\_ID - Inte...
- Message: Please enter search criteria of the form \*value\* or \*value or value\* in any of search fields.
- Protocol No.: \*1710005674\*
- Protocol Type: [Dropdown]
- Protocol Status: [Dropdown]
- Investigator: [Text Field]
- Buttons: Search, Cancel

## CREATING A CONTINUING REVIEW OR FINAL REPORT (HRP 212)

Use this submission type to request a renewal (continuing review) or to close a protocol (final report) for a currently approved research protocol.

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**.

Protocol Number	Title	Status	Approval Date	Expiration Date
1606004506A001	Title of the Protocol II	Submitted to IRB	20/June/2016	18/June/2017
1606004506	Title of the Protocol II	Active - Open to Enrollment	20/June/2016	19/June/2017
1605004503	Standard Submission Test	Pending/In Progress		
1605004502	Case Report Case Study Test	Pending/In Progress		
1605004500	Title of the Protocol	Pending/In Progress		
1605004495	test protocol case study/ case report	Routing In Progress		
1605004493	Testing Case Study / Case Report Questionnaire 05-24-16	Pending/In Progress		

Or you can select **Protocol Search** and search by using the base protocol number. A partial entry may be made, with an asterisk used as a wildcard when placed before or after the partial entry.

- Ex. \*0123\*

Click **Search**

Protocol Search - Internet Explorer

https://coeus.irttest.drexel.edu/coeus//protocolSearch.do?type=Protocol&search=true&searchName=ALL\_PROT

Please enter search criteria of the form \*value\* or \*value or value\* in any of search fields.

Protocol No: *1234*	Protocol Type: [v]
Title: [ ]	Protocol Status: [v]
Expiration Date: [ ]	Investigator: [ ]
Funding Source: [ ]	

Search Cancel

## Renewal/Final Report Application

### Letter of Reliance Approved Protocols

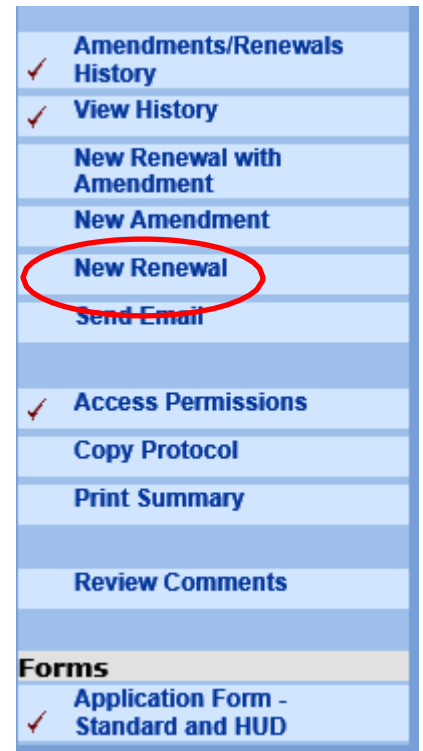
- When Drexel University is not the IRB of Record, an electronic HRP-212 is not required to be submitted until study closure. Principal investigators need only provide the Drexel University HRP with a copy of the approved renewal documents (including the continuing review approval letter) provided by the IRB of Record.

Click the **New Renewal** button from the column on the left-hand side.

The **Renewal** summary window opens.

The **Renewal Summary** box is to include the type of continuing review request you are submitting for review and approval:

- Active and Open to Enrollment
  - Continue for Data Analysis Only
  - Continue for Follow Up of Subjects Only
- AND INCLUDE**
- Progress report of what has happened with study since last approval



**Renewal Summary:**

In January 2017, after IRB approval, the co-investigator contacted principals, teachers and students at Delanco Elementary, Holy Cross High School and University of Scranton to ask them to identify teachers in the core content areas who made innovations to their instruction. Principals from two of the three schools and the Director of Technology and Innovation responded with the names of 60 teachers. In April 2017, the researcher invited all 60 teachers to participate in the first phase of the research study by completing the demographics and background, innovation and mindset questionnaire via a link to [Qualtrics](#). Those 45 teachers who completed the questionnaire were invited to participate in phase two of the research study: interviews. In August 2017, 21 teachers participated in either focus group or individual interviews. Data collection and data analysis has concluded.

Click **Save**. The Renewal has been created.

Note an R00x suffix is applied to the protocol number. This refers to the sequential number of renewals for that particular protocol. The R suffix is dropped once the renewal is approved by the IRB.

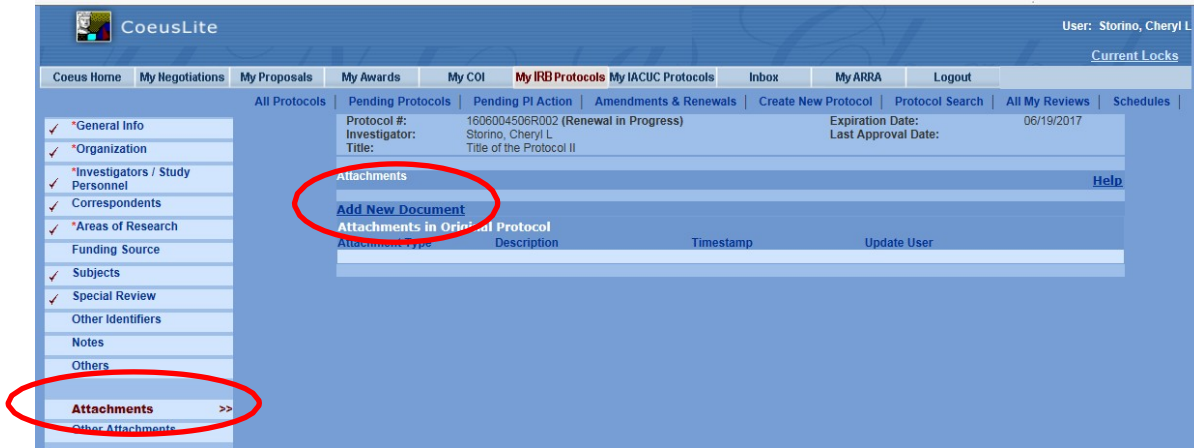
Protocol #:	1710005674R001 (Renewal in Progress)	Expiration Date:	10/15/2018
Investigator:	Rivello, Ralph J	Last Approval Date:	
Title:	Test Protocol #4		
Protocol Organization			Help



## Uploading A Document For Review

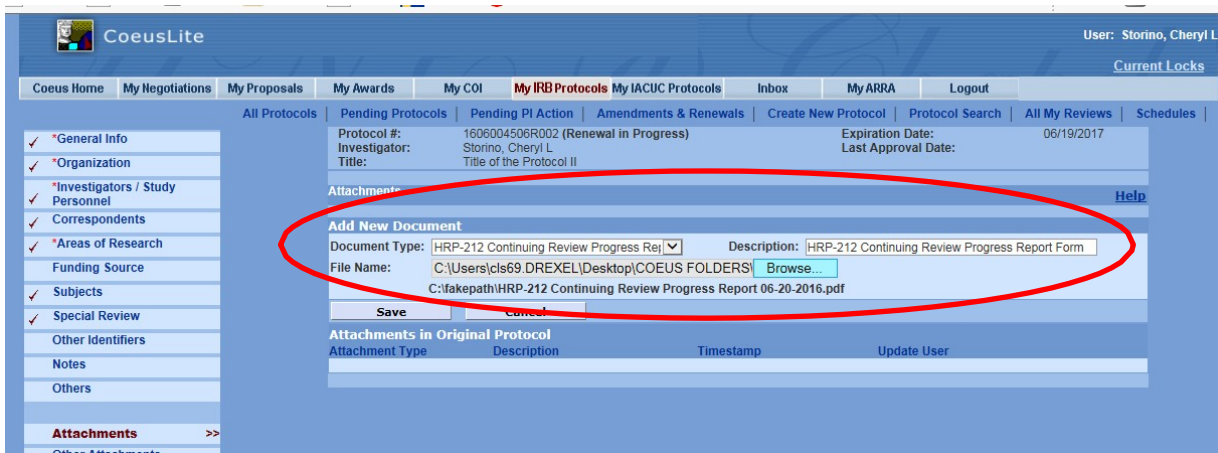
Select the **Attachments** tab from the left hand column. This opens the **Attachments** window to upload the required **clean copies (unstamped) of all previously stamped approval documents** (consent forms, advertisements/brochures, surveys, data collection tools, etc.)

- Clean copies are not required if the protocol is permanently closed to enrollment.



Click **Add New Document** to upload a new document. From the **Document Type** drop down box, select **HRP- 212 Continuing Review Progress Report Form**. Use the **Description** to indicate the document. For example, HRP 502 Consent Form (unstamped).

- **For any document attached with your renewal/final report,** you must select **HRP-212 Continuing Review Progress Report Form** regardless of the actual document



## Renewal/Final Report Application

The renewal/final report application is at the bottom of the left hand column, in the Forms sections

- HRP 212, Continuing Review/Final Report

## Application

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

<a href="#">Validate</a>
<a href="#">Submit to IRB</a>
<a href="#">Amendments/Renewals History</a>
<a href="#">View History</a>
<a href="#">Send Email</a>
<a href="#">Access Permissions</a>
<a href="#">Copy Protocol</a>
<a href="#">Print Summary</a>
<a href="#">Review Comments</a>
<b>Forms</b>
<a href="#">Application Form - Standard and HUD</a>
<a href="#">HRP 212, Continuing Review/ Final Report</a>

HRP 212, Continuing Review/ Final Report  
Amendment/Renewal Questionnaire


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

1) Has the study been updated in ClinicalTrials.Gov? [More](#)  
 Yes  No

2) Is this submission a Continuing Review ? [More](#)  
 Yes  No

All must be applicable for a final report ; Research permanently closed to enrollment at this organization ; All subjects enrolled at this organization completed all-research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data ; No additional identifiable private information about the subjects is being obtained by this organization's investigator ; Analysis of private identifiable information at this organization is complete. (This is applicable even if a statistical center at another organization) [More](#)

Message from webpage

4)  Questionnaire Completed for protocol 1710005674R001

6)

7) number of subjects enrolled since last approval? [More](#)

8) Total number of subjects enrolled study wide? This is applicable when the PI is enrolling or receiving data from multiple subsites. [More](#)

9) Total number of subjects approved for enrollment? [More](#)

10) I acknowledge the following information must be completed for enrolled subjects of a vulnerable population at the investigators site(s). [More](#)  
 Yes  No

## Submit to IRB

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

A vertical navigation menu with a blue background and white text. The menu items are: \*General Info (with a checkmark), \*Organization (with a checkmark), \*Investigators / Study Personnel (with a checkmark), Correspondents (with a checkmark), \*Areas of Research (with a checkmark), Funding Source (with a checkmark), Subjects (with a checkmark), Special Review (with a checkmark), Other Identifiers (with a checkmark), Notes, Others, Attachments (with a checkmark), Other Attachments, Validate, and Submit to IRB (circled in red).

## Protocol Submission Window

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

The Protocol Submission window displays the following information:

Protocol #:	1710005674R001 (Renewal 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: CONTINUING REVIEW (dropdown) \*Review Type: To be determined (dropdown)

Type Qualifier: Standard (dropdown)

**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 #: 1710005674R00 (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
    - Approval Routing will only show after you Submit to IRB
- If you are the principal investigator
  - You can click Approval Routing to approve
    - Options are
      - Approve
      - Reject

Renewals/final report need the principal investor and department chair or program director to approve

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

Once the principal investigator and department chair or program director 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