Coeus Lite

User Manual

–

Protocol Submissions

Drexel University

Version November 2017

TABLE OF CONTENTS

GETTING STARTED
(Login Information)

Coeus Lite is a web-based platform

On campus link: https://coeus.drexel.edu/coeus/userAuthAction.do

Off campus link (via Drexel VPN):
https://vpn.drexel.edu/+CSCO+0075676763663A2F2F70627268662E7165726B72792E727168++/coeus/userAuthAction.do

- Coeus Lite will only work if you are connected to Drexel University`s network. You must VPN (page 41) if you are not on campus.

Log into the Coeus Lite application by entering your credentials. Your username and password are the same associated with other Drexel University systems, such as DrexelOne.
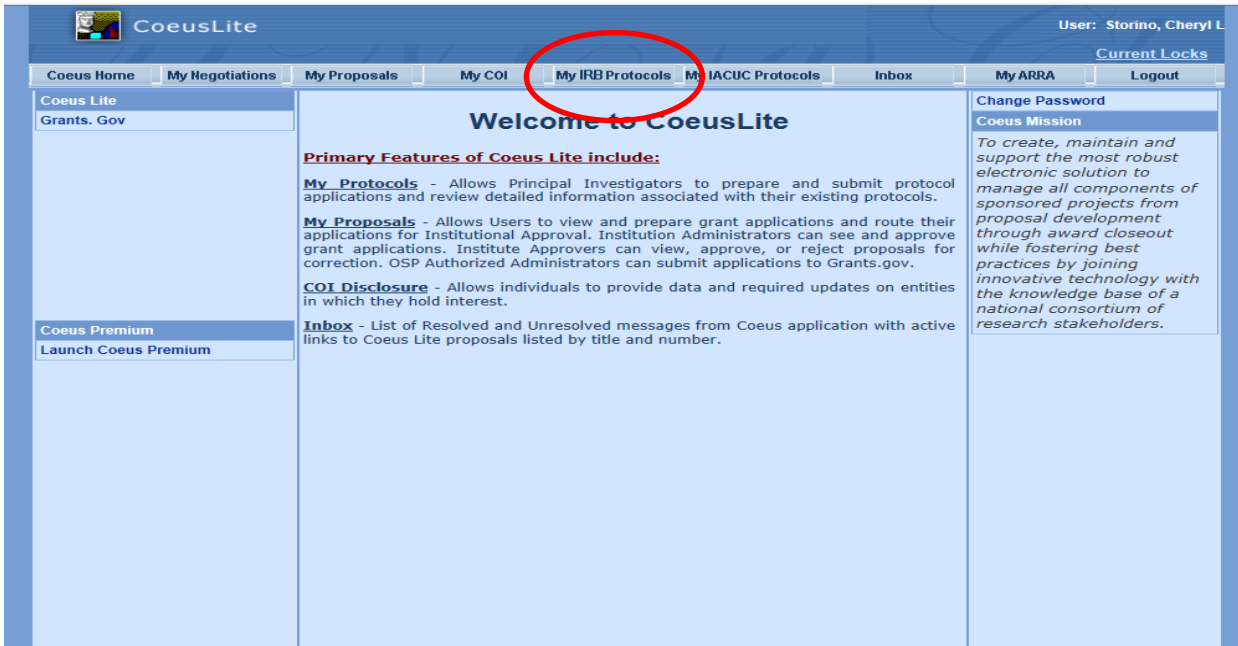
CREATING A NEW PROTOCOL

After logging in, the Welcome to Coeus Lite window will launch.

- Click My IRB Protocols
  - This is only for protocols reviewed by the Human Research Protection Office

Main View

- All Protocols
    - Lists all protocols that you are approved as either a principal investigator (PI) or co-investigator
- Pending Protocols
    - Lists all protocols that have outstanding items for those listed as a principal investigator or co-investigator
- Pending PI Action
    - Protocols needing some action by the respective PI
- Amendments & Renewals
    - Amendments (modifications) and renewals that the principal investigator or co-investigator is attached too
- Create New Protocol
    - Action to submit a new protocol to the HRP
- Protocol Search
    - Action to search for protocols you are on
    - Also used by researchers not listed as the principal investigator or co-investigator of a protocol
        - Listed as study personnel instead
- All My Reviews
    - Only available to HRP coordinators or IRB members
- Schedules
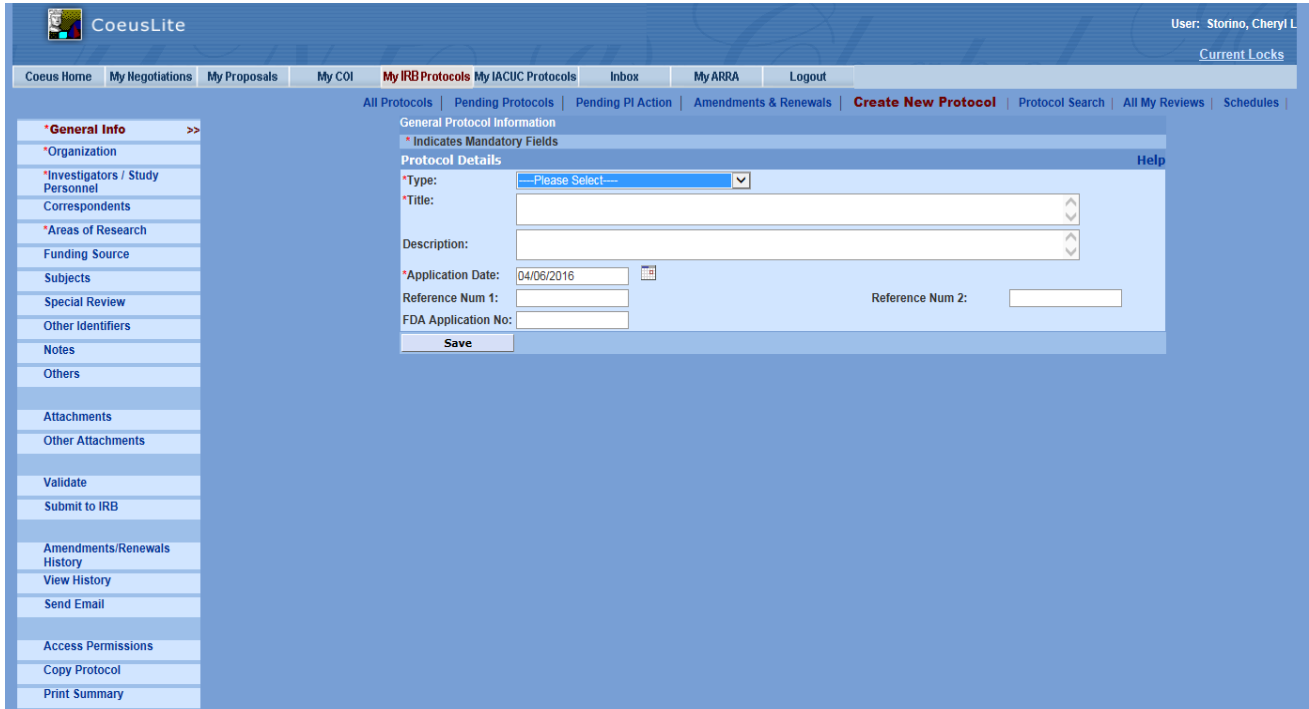   - Only available to HRP coordinators or IRB members

Side Bar: Maneuvering In And Entering Information Into The Protocol Screens

The menu items (General Info, Organization, etc.) located in the left-hand column in all the protocol screens serve as tools for entering and uploading the specific information required to create a protocol record and submit the protocol to the appropriate oversight authorities and the IRB.

The menu items noted with an asterisk * indicate that the field is mandatory.

Also note that as you work your way through the menu items, a red check √ mark will appear noting that the particular screen or "page" of the application is complete

and saved. It may also denote when some information may be assumed and has therefore been populated into the system. This auto-populated information can be over-written by the user and is described in this document.

Create A New Protocol

General Information tab

- **Type:** Select the appropriate protocol type from the drop down menu. The HRP staff will override your selection if the protocol is deemed to be other than the selection
- **Title:** Enter the title of the research protocol (mandatory)
- **Description:** Enter the description or purpose of the research project (mandatory)
- **Application Date:** Will default to today's date – the creation date of the protocol record
- **FDA Application Number:** Enter the alphanumeric information related to an Investigational New Drug (IND) or Investigational Devices (IDE or HDE) used in the protocol. Type pending if an IND or IDE number has yet to be received
- Used by HRP Office only
  - Reference Number 1
  - Reference Number 2

Click **Save** when all information is entered.

Types of applications

- Case Report / Case Study
- Emergency Use of a Device or Drug
- Humanitarian Use Device (HUD)
- Letter of Determination
- Letter of Reliance
- Standard (exempt, expedited and full levels of review)

- External
  - WIRB
  - NCI-CIRB
  - CU-CIRB
  - Shuman
- Student Project
  - Used for submissions counting as part of the curriculum

Protocol Number

- Saving generates and assigns the protocol number and a status of Pending/In Progress. (At this time the record is saved and the investigator may proceed with completing the submission or save until a later time to complete.)

The number assigned to the protocol is generated by the Coeus database. This number will automatically populate the protocol record when the General Information screen of the protocol record is first saved. Coeus generates and assigns protocol numbers that consist of ten digits. The first four digits represent the year and month the initial protocol record was created. The last six digits represent the sequential order in which the protocol record was created.

COEUS also assigns a suffix to continuing review and amendment submissions. The renewals and amendments are numbered consecutively, with an "R" indicating a renewal and an "A" representing an amendment.

- Ex. R001, R002, and A001, A002, etc.

Organization Tab (Coeus Lite will use standard information here unless you change it)

- In the column on the left-hand side of the screen, select **Organization**. This opens the **Protocol Organization** window
- The **Protocol Organization** defaults to Drexel University. If no other organizations require listing, no further action is needed.
  - This section is to record the principal investigator's affiliated organization.

To add additional or to change the Performing Organization:
- **Type:** Select "Performing Organization" from the drop down menu
- The **Organization** drop-down menu has the following listed to choose from
  - Hahnemann University Hospital
  - St. Christopher's Hospital for Children
  - The Academy of Natural Sciences of Drexel University
  - Volunteer Faculty Practice Site

To select other sites than listed in the drop-down menu
- Select Search.
- Type the name of the organization into the Name field.
  - A partial entry may be made, with an asterisk used as a wildcard when placed before, after or around the partial entry.   Ex. *St*Chris*
- Click **Save**
- Remove Organization as needed
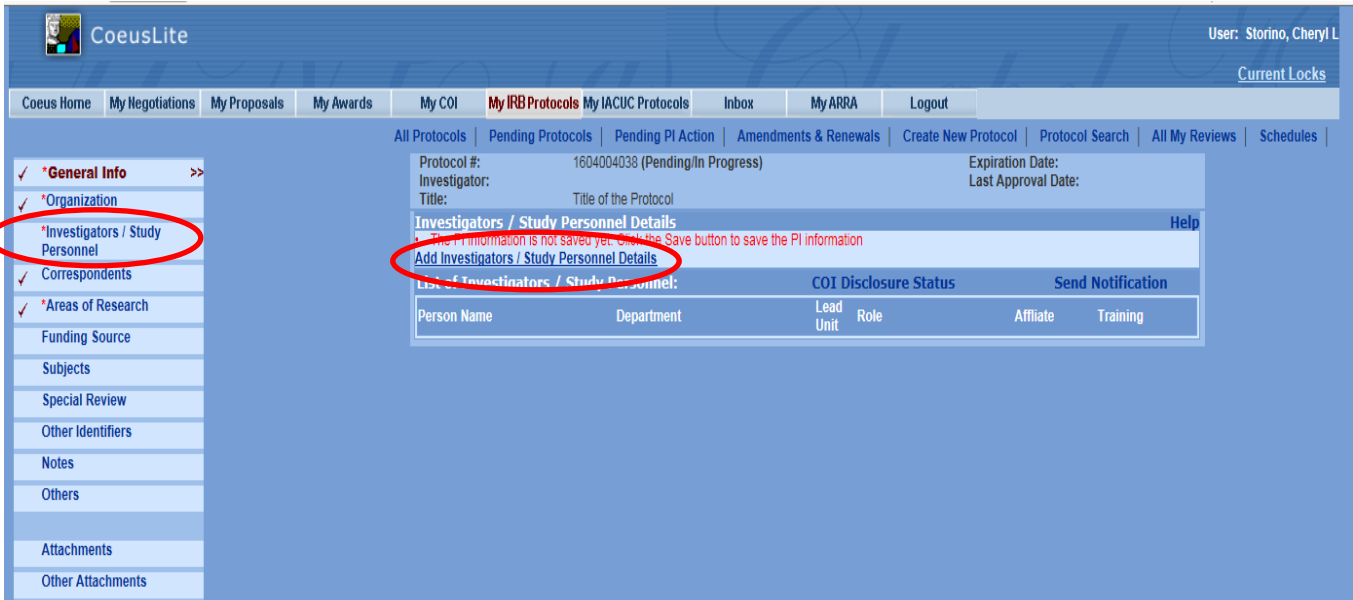
Note
This window is to record the principal investigator's affiliated organization. This field should not be used to list sub-recipient sites or other sites where the research is being conducted and subject to review and approval by a non-Drexel IRB.

Investigators/ Study Personnel

Click on **Investigators/Study Personnel** on the left-hand side column. This launches the **Investigators/Study Personnel Details** screen.

Select **Add Investigators/Study Personnel Details.** The default identifies the protocol creator as the Principal Investigator (PI) and provides an alert message that the PI information is not saved yet. The home unit of the protocol creator also defaults. If the creator is not the PI for the protocol or if a different unit will serve as the lead unit, do not save the information that defaulted.

Employee Search

To change the Principal Investigator or to find and add other investigators and study personnel, click on **Employee Search**. This will launch the Employee Search window.

To search, you can enter * and a partial last name of the individual followed by an asterisk (*). Example: *Fuhrer* will list all last names that begin or end with *Fuhrer*. Select the appropriate last and first name. Once you select, the employee name, unit number, and email address will be automatically populated.

The unit for each person is the person's home financial unit, or that unit from which the person is paid. It is ***critical* to ensure** that the unit brought in with the name of the principal investigator represents the unit of the department chair who will be reviewing and approving the research protocol via the routing feature. Electronic signatures from the unit heads designated by your school, college or department have already been entered into the system. It is your responsibility to make sure such signatures have been secured. Without the electronic signature, the Coeus system will not allow the submission and review process move onto the next step.

For each person added:
1. Enter the Protocol Role of the individual by clicking the drop down box. Choices are Principal Investigator, Co-Investigator or Study Personnel
2. For Study Personnel, indicate the Person Role by typing in the appropriate information, e.g., Consultant, co-investigator, Research Assistant, etc.
3. Select the individual's affiliation with Drexel by selecting from the Affiliation drop down box. Choices are Faculty, Staff, Affiliate or External Collaborator.
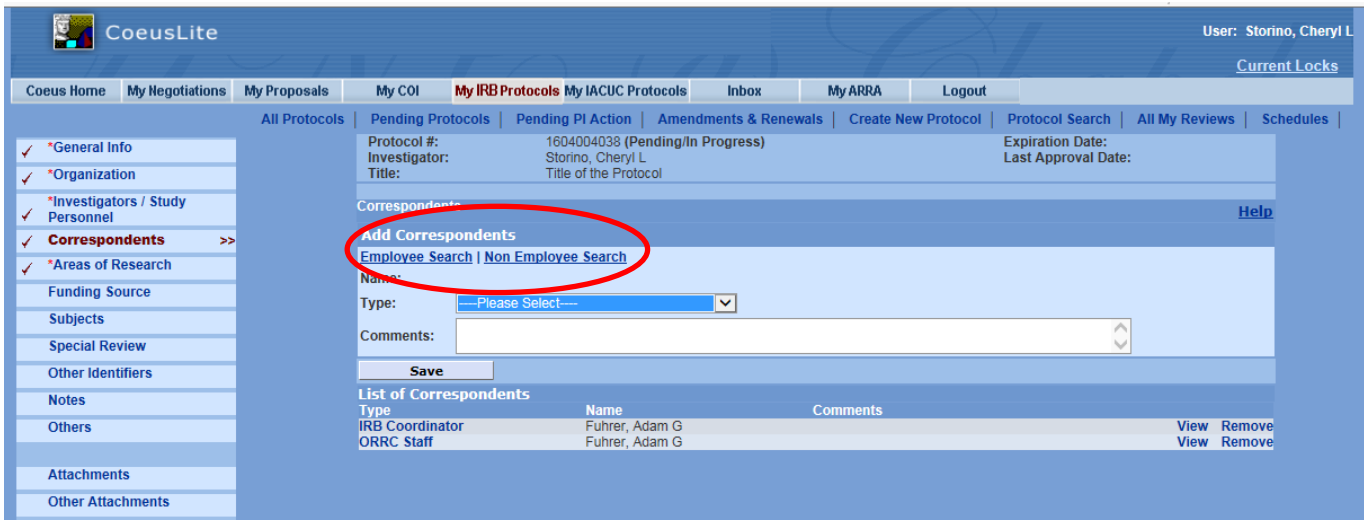
HRP 201 (Contact Information) and Financial Interest Disclosure Form
- Are NOT needed IF you can find your researcher in the personnel table (Employee search)
- Are NEEDED if you cannot find your researcher in the personnel table (Employee search)
  - Upload both documents in the Attachments tab

Correspondents (Coeus Lite will use standard information here unless you change it)

This screen is populated with the names of persons who should receive notice of the HRP correspondence that is sent to the investigator.

Click on the **Correspondents** button in the column on the left-hand side. This opens the **Correspondents** window. Add persons who should receive correspondence related to this protocol. Use the **Employee Search** or to find and add correspondents, as described in the Investigator/Study Personnel section.

- **Type:** Select the Type of correspondent from the drop down menu.
- **Save :** The selection is saved in the **List of Correspondents**. (Entries in the **Comments** section are optional.)

Areas Of Research (Coeus Lite will use standard information here unless you change it)
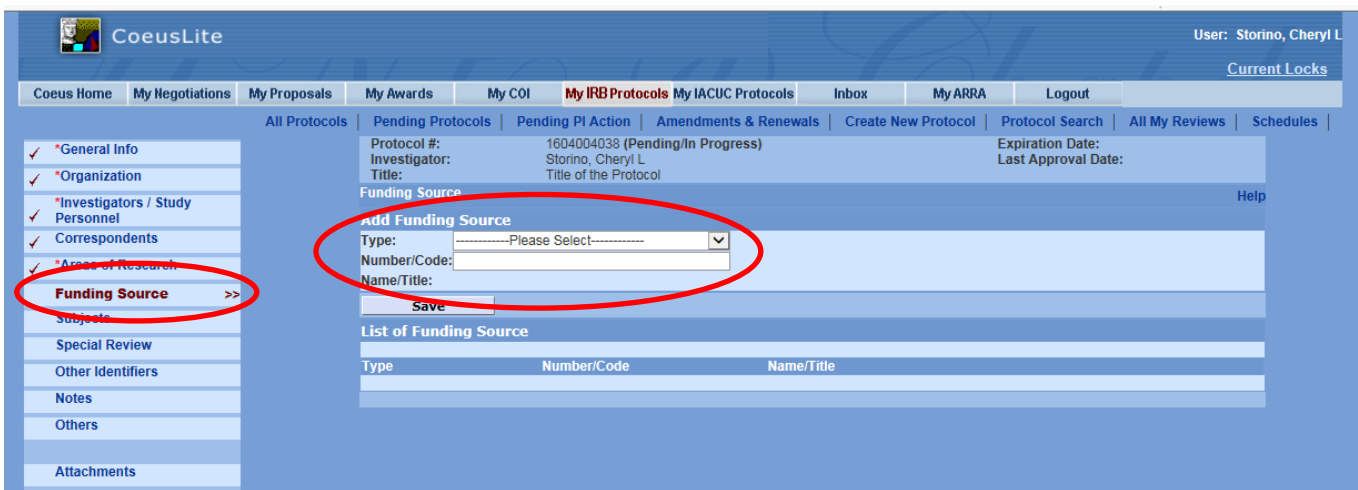
No Action is needed. The **Areas of Research** window defaults to All Research Areas. No other Areas of Research are to be added at this time.

Funding Source

Researchers must provide **all** sources of funding that support the conduct of the research project. Use this tab to provide the information necessary for the HRP to perform congruency reviews between sponsor proposals and the IRB protocols.

The entries made in this field are **critical** for ensuring that the HRP has the information it needs to perform the review required by federal regulation and University policy. Specifically, the University will not certify to the sponsor that the HRP has approved the research and the project funding will not be released until HRP approval and congruency have been verified with Drexel's Office of Research.

Select the **Funding Source** menu item from the column on the left-hand side of the screen.

To search for the funding source for the protocol, select **Type** from drop down menu.

- **Internal funding:** Select **Unit** to denote when the research is funded by departments within Drexel.
- **External funding:** Select **Proposal Development Transmittal** when the protocol is fully or partially funded by an _external_ entity.
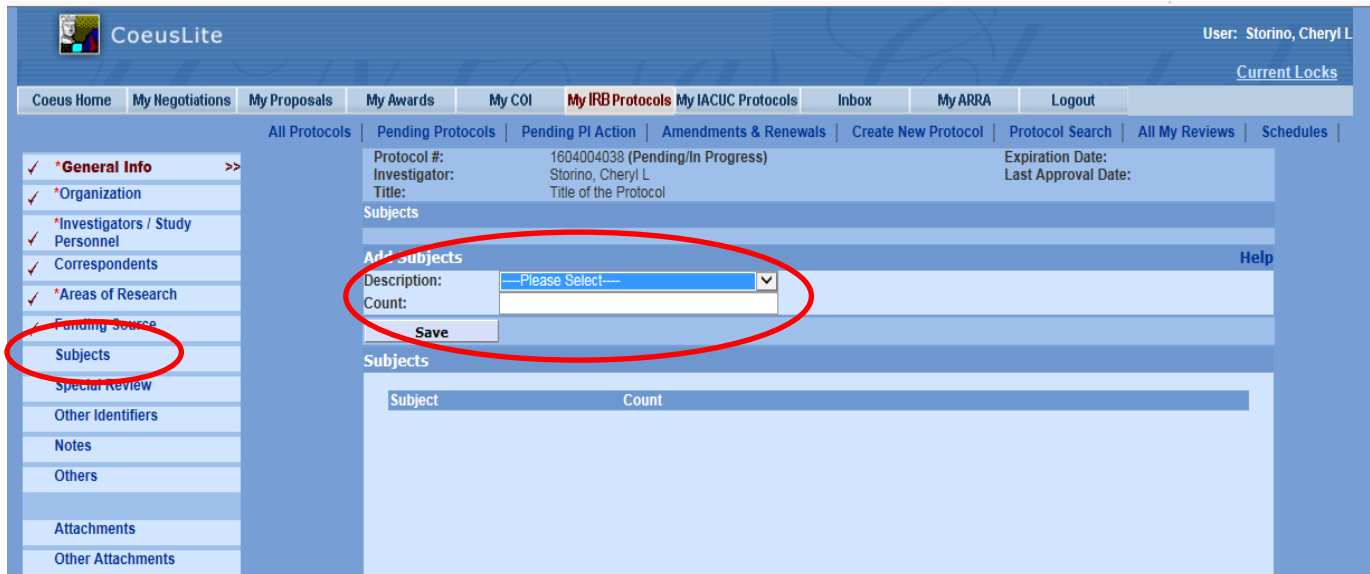
Click **Search.** The **Search** Window will open.

When searching the asterisk (*) can be used before, after or around a unit name. Click **Search**.

All protocols will have some type of funding, internal or external.

Subjects

Select the **Subjects** menu item from the column on the left-hand side.

Identify and select ALL that is applicable with the subject population from the drop down menu.

The subject populations appears in the **Subject** line.

The **Count** field should be populated with the number of persons targeted for enrollment at **Drexel University only.** The Subjects screen also helps to identify subject populations that may require special considerations and protections when participating in research.
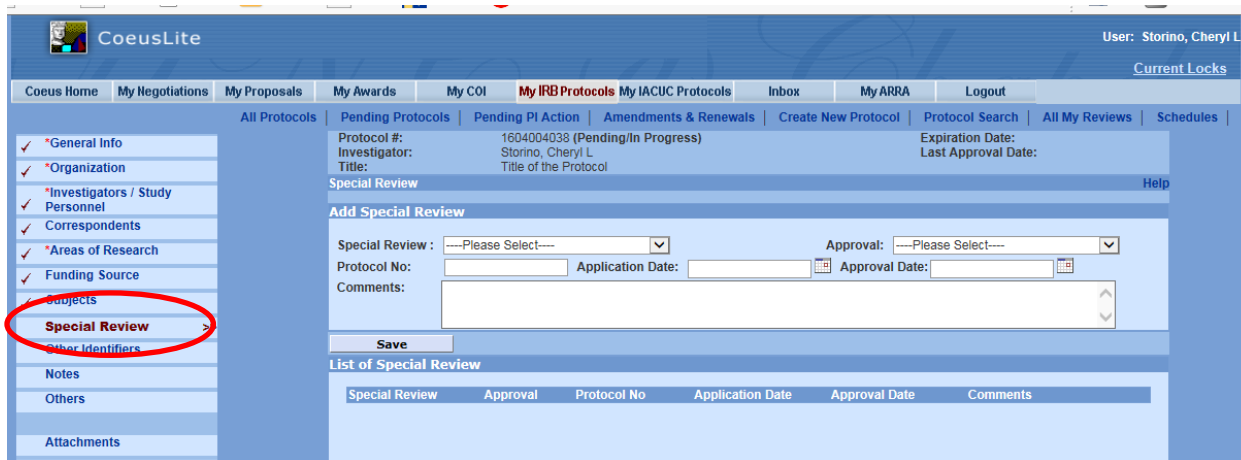
Common subject categories

- Children
- Decisionally Impaired
- Prisoner
- Pregnant Women
- Fetuses
- Students
- Adult
- Emancipated Minor
- Wards of State

- Children and Adults
- Female
- Male
- Medical Charts
- Other Records
- Surveys
- Privately Owned Data
- Publically Available Data

Special Review

The **Special Review** screen is to track other protocol related information that may include additional approvals outside the HRP review.

Click on the **Special Review** menu item from the column on the left-hand side. This opens the Special Review window.

Select the **Special Review** type from the drop down menu.

- **Approval:** Select the appropriate approval status from the drop down menu
- Remember to upload pertinent documents with your protocol submission

The **Comments** field can include additional notes to help in your Special Review approval, such as if Tenet Facilities are being used, place the facility name, department and floor being used at Hahnemann University Hospital.

Click on **Save** after each entry. All entries will be saved under the **List of Special Review.**

Other Identifiers
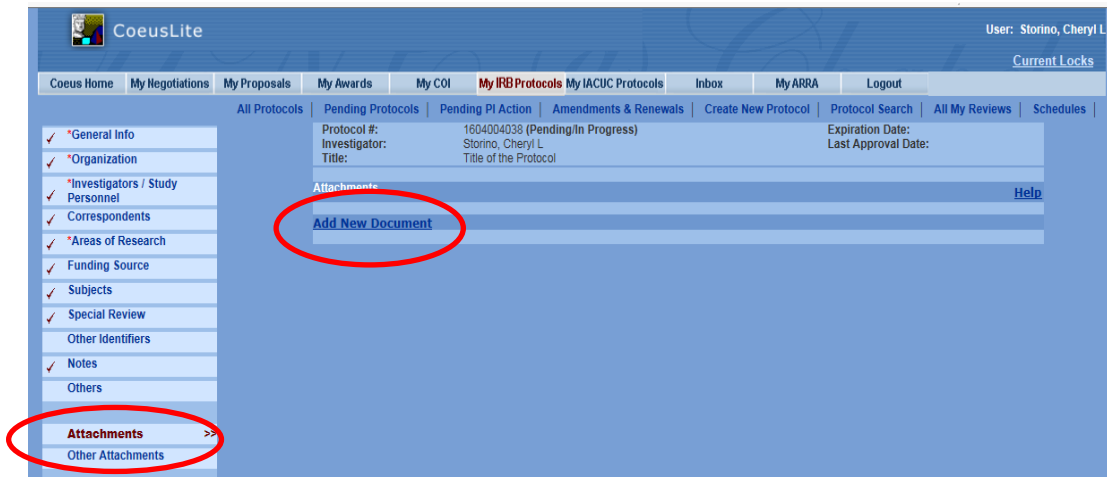The **Other Identifiers** window is not being utilized at this time.

Notes
The **Notes** window is for any comments regarding this specific submission to the HRP Office
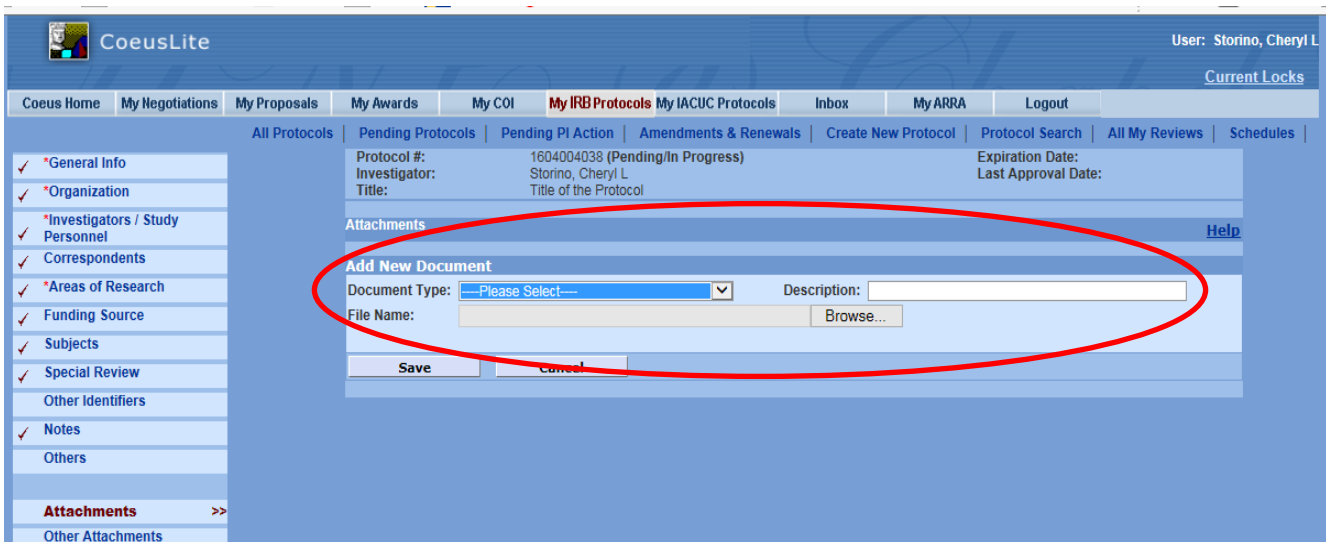
Attachments

Once all data fields required for the protocol record are complete, it is time to upload the documents that the researcher must send to the HRP for review and approval.

The **Attachments** menu item is used by the researcher to upload such protocol-related documents. Click on the **Attachments** menu item from the column on the left-hand side. This opens the **Attachments** window.

The researcher must select a **Document Type** from the drop down box for each item being uploaded for review by the HRP (the document's title should be saved the exact same way as the description field instructions).

- **Description Field:** Type in the specific HRP document number and title or general description of the document
- **Description Field:** Do not use the following invalid characters in document titles or in any free text field: **/ @ # $ % ^ & ***

Description field examples
- HRP 503 Protocol
- HRP 201 Contact Information Form – Researcher`s last name
- Data collection tools

Use the **Browse** button to search your system files for the appropriate document to be uploaded.

Highlight the document you wish to upload and click **Open** or double click the file to bring the document into the **File Name** field.

Click **Save** to build the list of attachments**.**

A pre-review will be performed by the HRP Office before directing to the IRB for review. All incomplete submissions will be returned to the research team.

Other Attachments

The Other Attachments window is not used during the initial protocol submission.
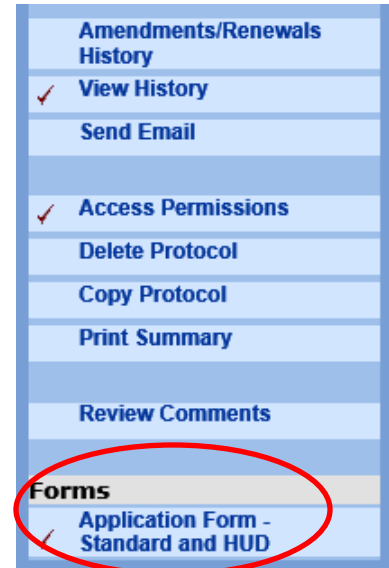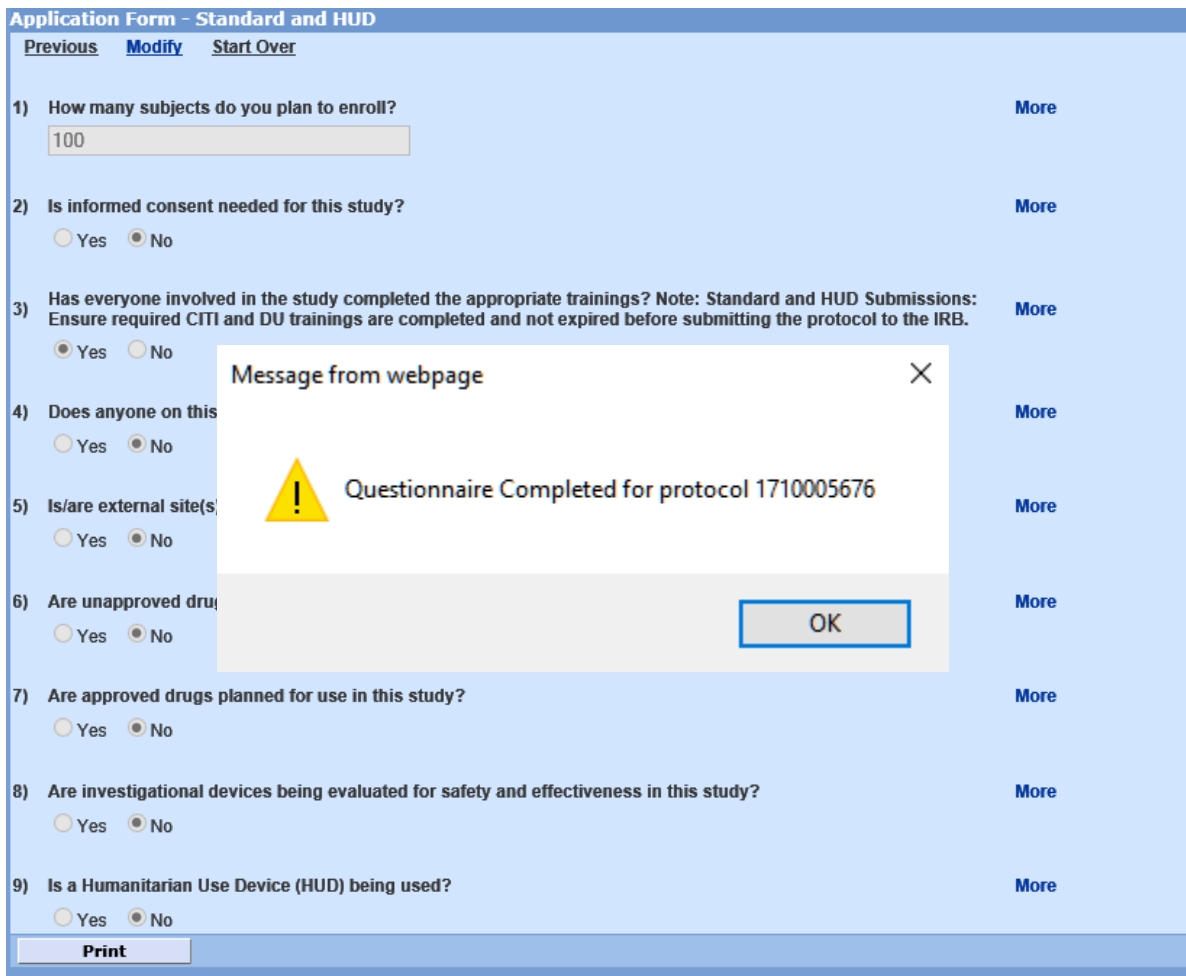
Application

Select the appropriate application form from the left hand column in the Forms tab to complete the required electronic questionnaire.

The electronic questionnaire you have to complete depends on the type of application selected in the General Info section.

All previous paper versions of our applications are now electronic questionnaires, including
- HRP 211 Application for Initial Review
- HRP 212 Continuing Review Progress Report
- HRP 213 Modification of Approved Research

Continue with the questionnaires until Coeus Lite returns a popup stating the application is complete
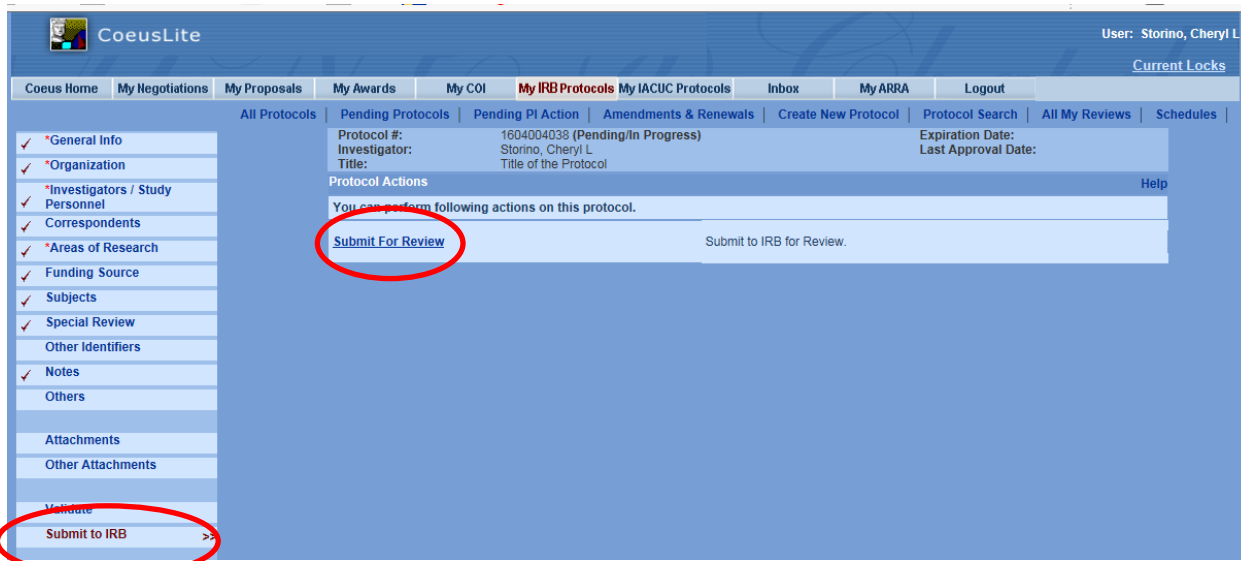
Submit To IRB

Once the primary protocol information 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.

Depending on the type of application, the protocol may be routed to the principal investigator, department chair or program director, and, for College of Medicine protocols, to the vice dean for research office. All stops approve the protocol within Coeus Lite, after receiving an email from the platform requesting their review and approval.
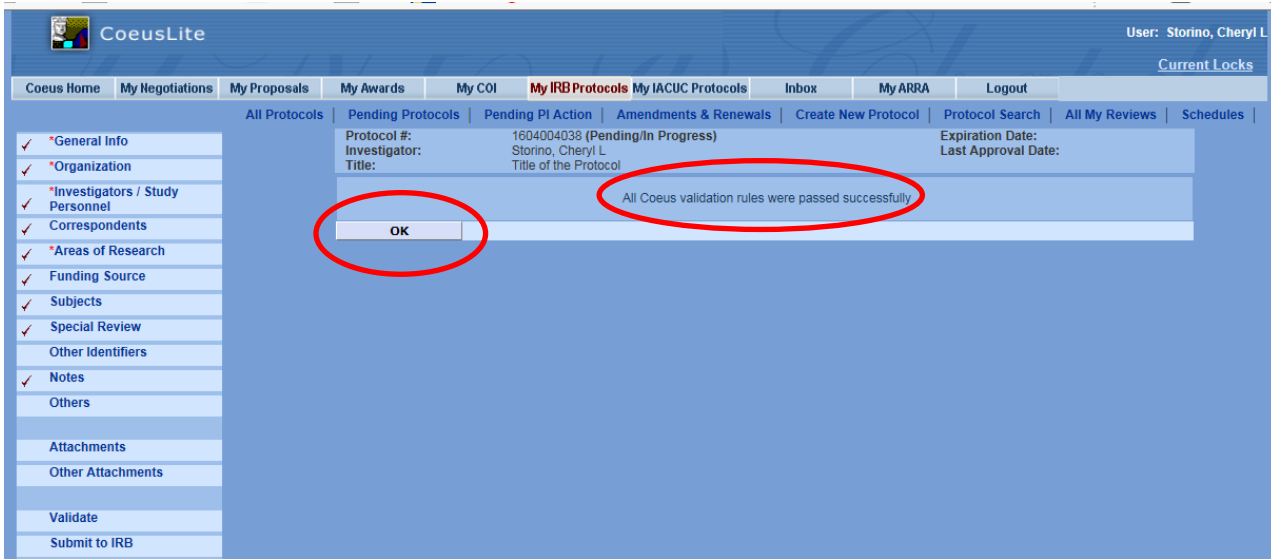
After the protocol has all approvals, Coeus Lite will route your submission to the HRP Office.

To begin 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 For Review**.

Validation will be requested. Select OK and OK again.
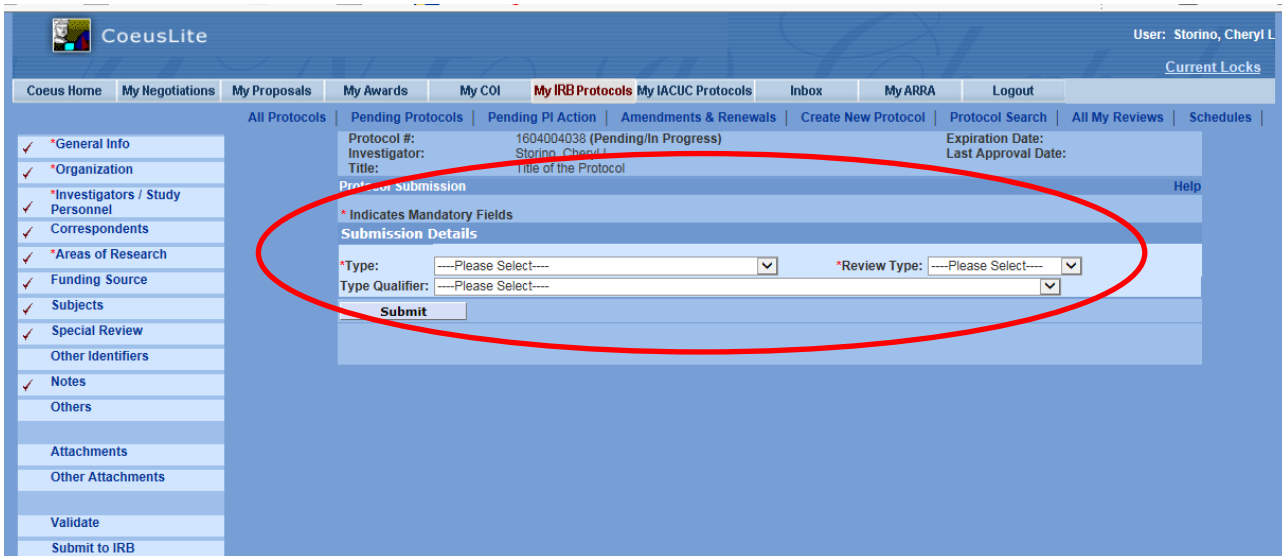
To Submit To The IRB

Select the submission **Type** from the drop down box. Be sure to select **Initial Protocol Application** for a new protocol. Select To Be Determined from the **Review Type** drop down box, and Standard from the **Type Qualifier** drop down box.
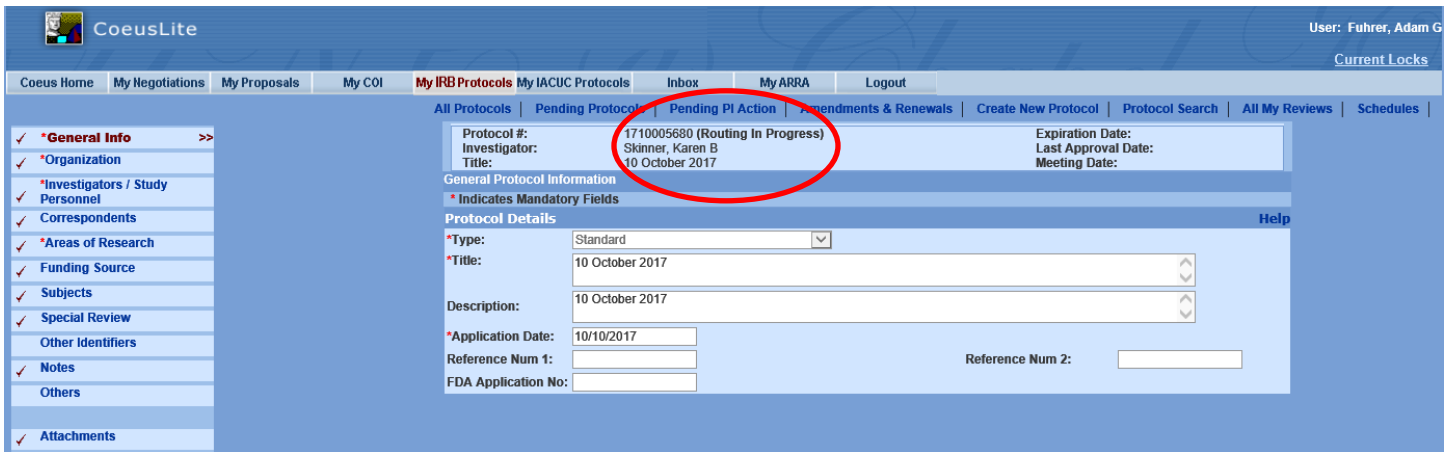
Click the **Submit** button to submit to the IRB.
The user will receive a message asking whether they wish to submit the protocol. Click **OK**.

The Protocol Is Now Submitted For Approvals

The protocol status will change from Pending/In Progress to **Routing In Progress**, which indicates that the protocol is routing for approvals.

Once the protocol has been electronically approved by all appropriate reviewers, the HRP Office will assign the initial protocol application appropriately.

If the protocol is required to be reviewed at a convened meeting, the on-line submission deadline dates will be used.

- Example: The IRB meeting may be scheduled for August 8, 2017 but the submission deadline is July 18, 2017. Thus an researcher submits the application on July 17th, thinking it will be received by the HRP in time for the meeting on the 18th. However, via the electronic routing, it is waiting for the departmental chair's review and signature, who doesn't approve until July 19th. This causes the protocol to miss the deadline submission date, and the protocol will now be scheduled for the next IRB meeting of September 12th.

Checking The Status Of The Initial Submission

Once the protocol is submitted, the user can view the status of the protocol in two ways.

From **My IRB Protocols**, click **All Protocols** to view the status of the protocols that you are listed as either the principal investigator or co-investigator of. The **Status** column will note where your submission current stands

From the **protocol`s main screen**, to view the status of an initial protocol, amendment or renewal that is being routed for approvals, click the **Approval Routing** menu item from the left hand column.

This will show all the routing steps that are involved in the review and approval of the submission based on the nature of the protocol and the home department of the principal investigator.

Common protocol statuses

- **Pending/In Progress:** Protocol is still in submission process **AND has not been submitted for approvals**
- **Amendment In Progress:** Protocol is still in submission process **AND has not been submitted for approvals**
- **Renewal In Progress:** Protocol is still in submission process A**ND has not been submitted for approvals**
- **Routing In Progress:** Protocol has been submitted for approvals
- **Submitted to IRB:** HRP has accepted your protocol for review
- **Active:** Protocol is approved for research activities
- **Exempt:** Protocol is approved for research activities (as exempt from IRB review)
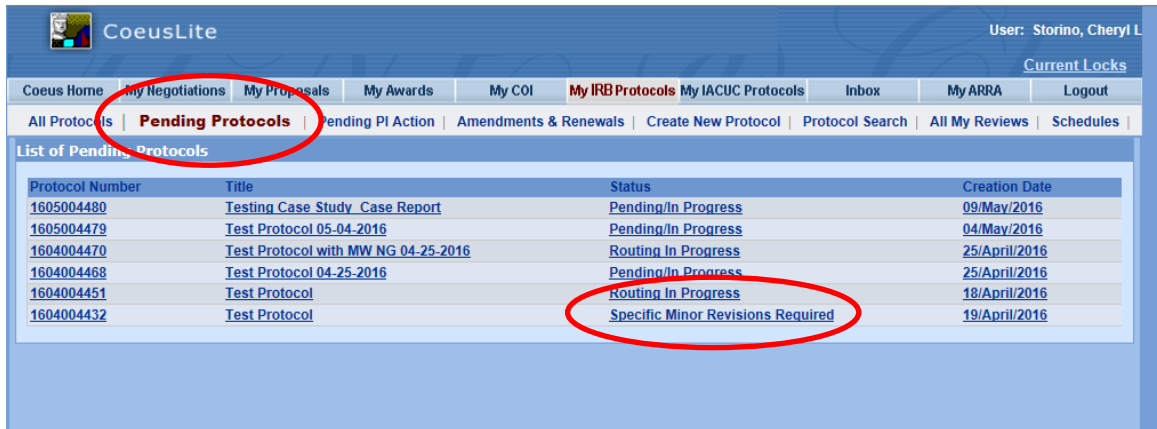- **Closed:** Protocol has been closed at the institution and all research activities have ended

REVIEWING REVISIONS REQUIRED BY THE IRB

The HRP Office will notify researchers when revisions are required so that approval of the protocol submission may be eventually granted. Researchers can view these requests for revisions through Coeus Lite.

From **My IRB Protocols,** those protocols with outstanding items are listed in the default view, in **Pending Protocols** tab. Protocols requiring revisions are assigned a Status noted as either **Specific Minor Revisions Required or Substantive Revisions Required.**

Responding To The IRB When Revisions Are Requested

The investigator is required to provide a written response to the HRP addressing each of the revisions requested. A memo or letter from the investigator needs to be uploaded into the system and sent to the HRP as it sufficiently addresses point-by-point the HRP`s request for clarification.

In other cases, however, changes are required to the protocol documents that were previously sent into the HRP for its initial review. As an example, the HRP may
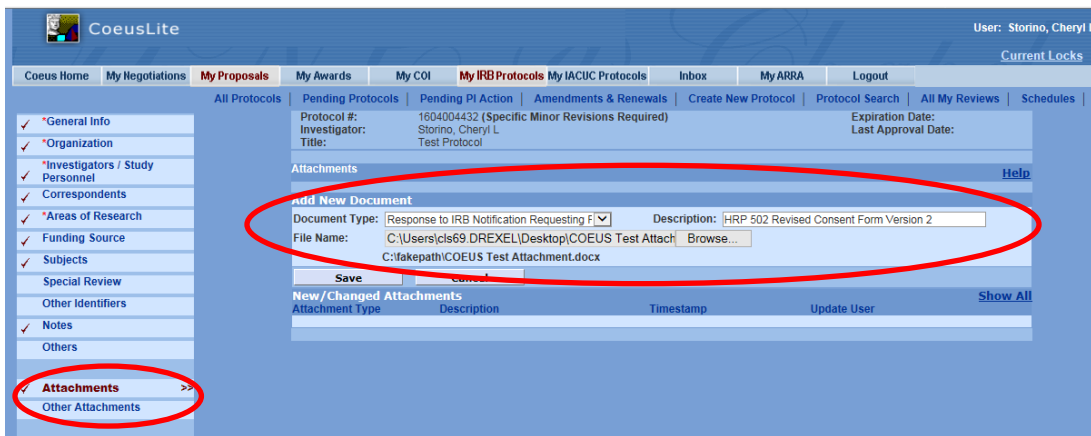- 1) Require specific word changes to consent documents
- 2) Require that the investigator change interventions or procedures in the protocol.

In example 1, modifications to the originally submitted consent document must be made and re-uploaded into the system for review by the HRP. Similarly, in example 2, the original protocol and perhaps the consent document would require modification and a re-upload into the system for re-review by the HRP.
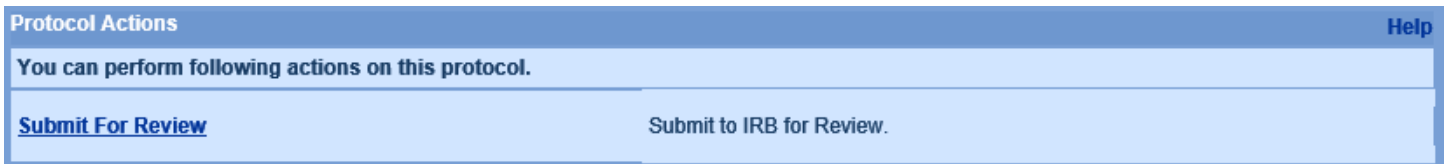
Attaching Revisions

To upload the research`s response letter, click on **Attachments** from the left hand column. From the **Document Type** drop down box, select **Response to IRB Notification Requesting Revisions**. Use the **Description** to indicate the response. For example, HRP 502 Revised Consent Form (tracked).

- **<u>For any response to pending conditions,</u>** you must select **Response to IRB Notification Requesting Revisions** as the **Document Type** regardless of the actual document
- You must upload clean and tracked (redline, highlighted) versions when revising any existing, already approved document
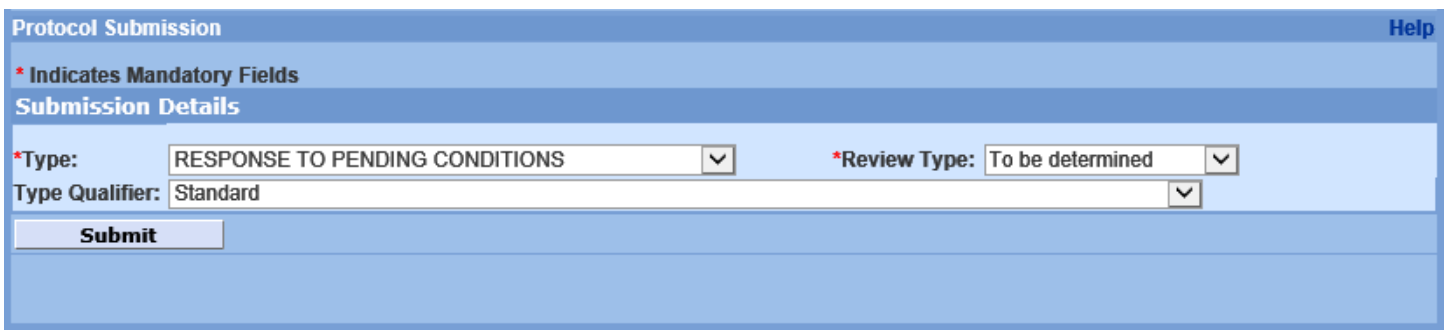

When all attachments and the response are uploaded, then the response can be submitted back to the HRP. To do so, select **Submit to the IRB** from the left hand column; then **Submit for Review**.

In the **Protocol Submission** window
- **Type:** Response to Pending Conditions
- **Review Type:** To be determined
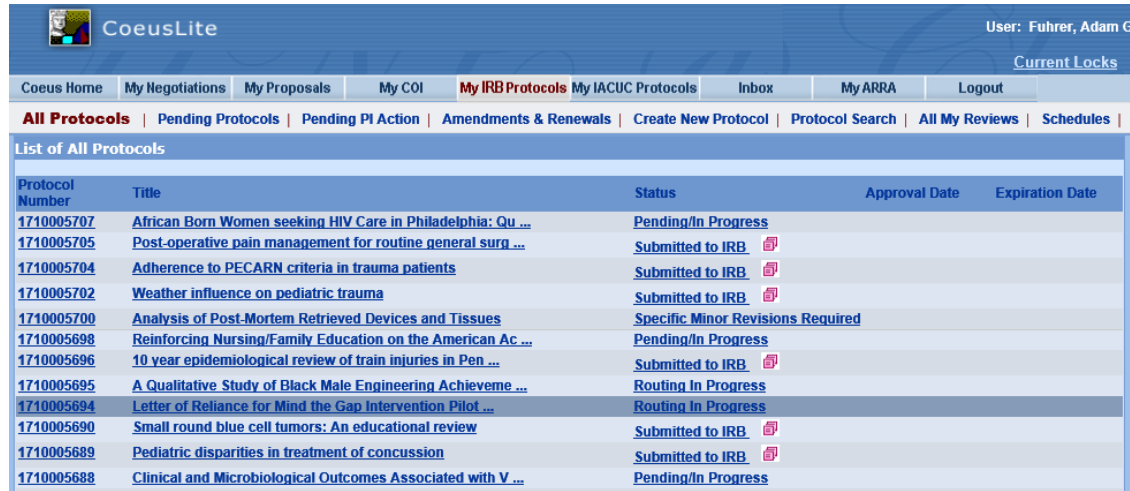- **Type Qualifier:** Standard

Click **Submit**

CREATING AN AMENDMENT TO A CURRENTLY APPROVED PROTOCOL
(HRP-213)

Find Your Protocol

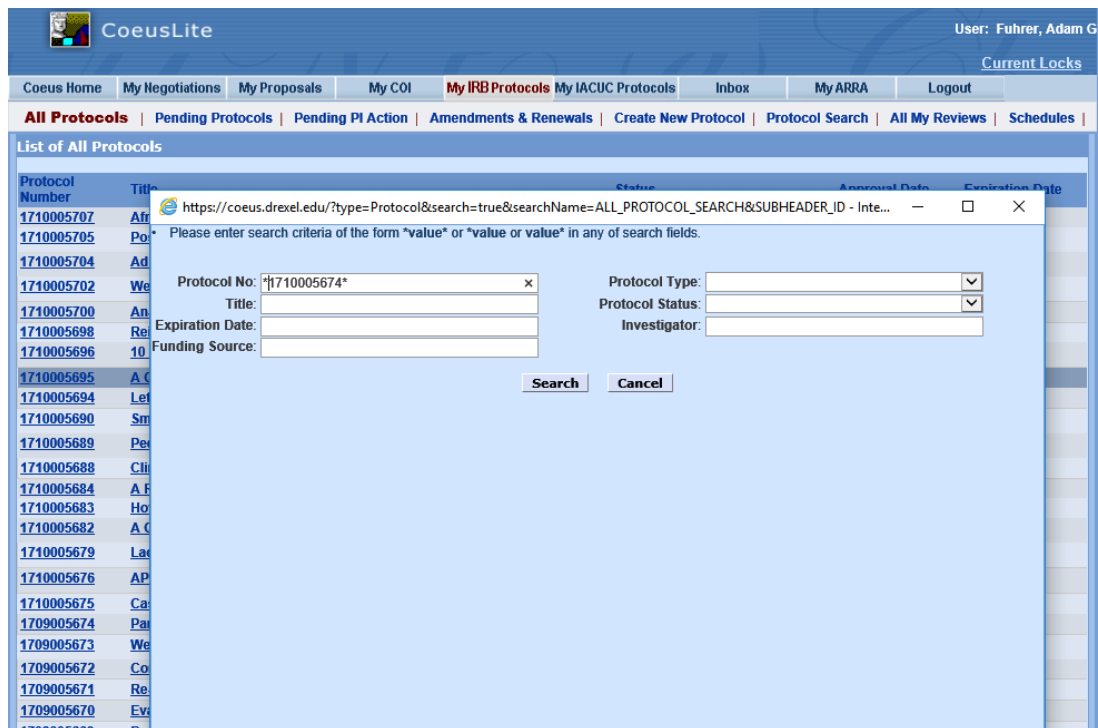Principal Investigator or Co-Investigator

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

Study Personnel

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

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

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

- 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

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
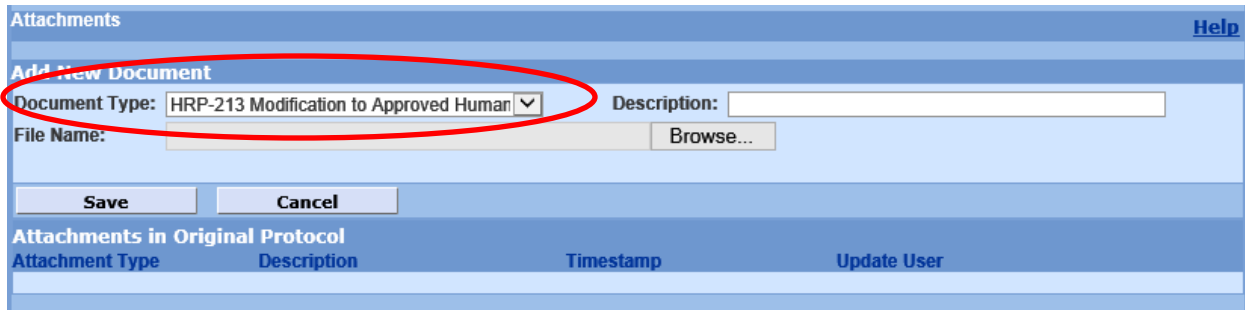
To attach new documents

- 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

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: [ ]

File Name: [ ] Browse...

[Save] [Cancel]

New/Changed Attachments   Show All

Attachment Type	Description	Timestamp	Update User			
HRP-213 Modification to Approved Human Research FormHRP 503 (clean)		10/12/2017 04:17 PM	Fuhrer, Adam G	Modify	View	Remove
HRP-213 Modification to Approved Human Research FormHRP 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

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
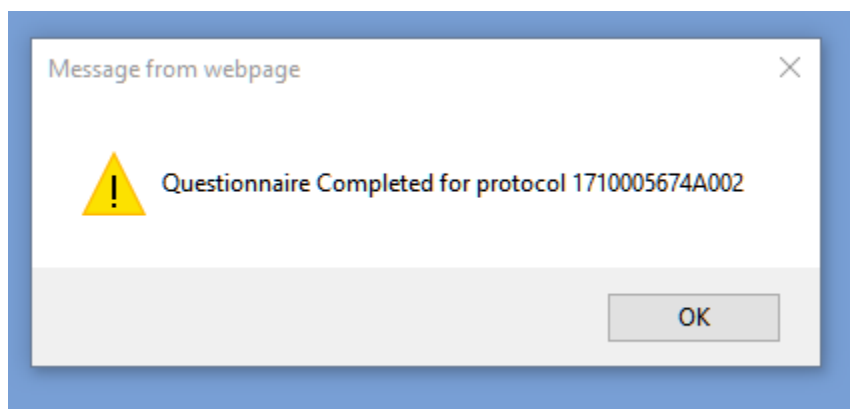   ○ Yes   ○ No

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

[Save & Proceed]   [Print]

You will receive a pop up knowing questionnaire is completed

Message from webpage   ✕

⚠ Questionnaire Completed for protocol 1710005674A002

[OK]

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
✓	Correspondents
✓	*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		

| 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

- 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

Amendments only need the principal investor to approve

- Principal investigator will receive an email alerting them that they have an approval waiting
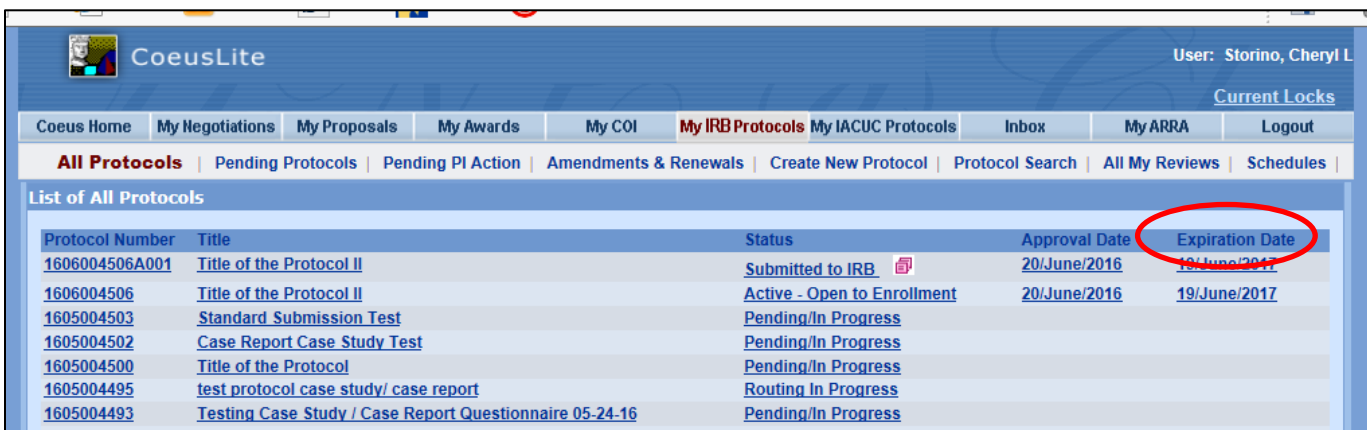
Once the principal investigator approves, HRP will received your request and begin the review process

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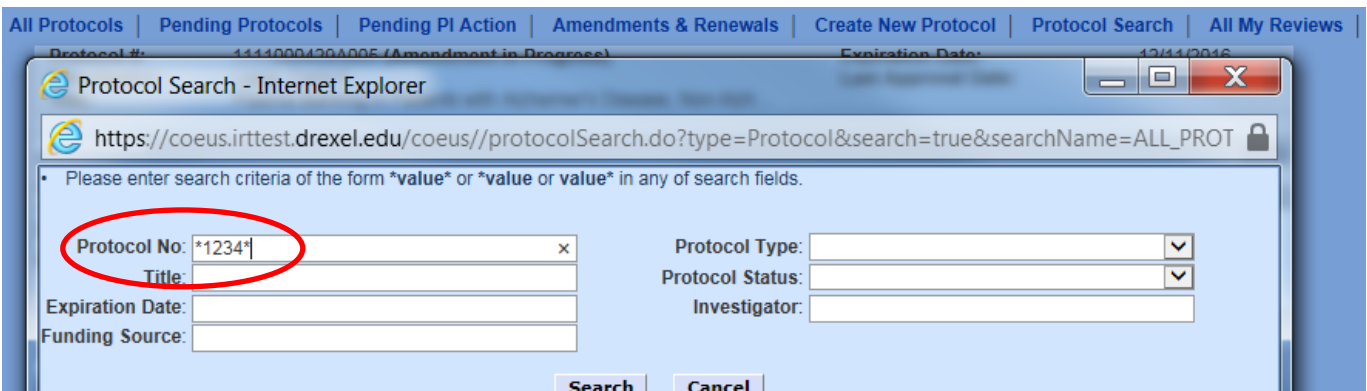
Or you can select **Protocol Search** and search by using the base protocol number. A partial entry may be made, with an asterisk used as a wildcard when placed before or after the partial entry.

- *Ex. *0123**

Click **Search**

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
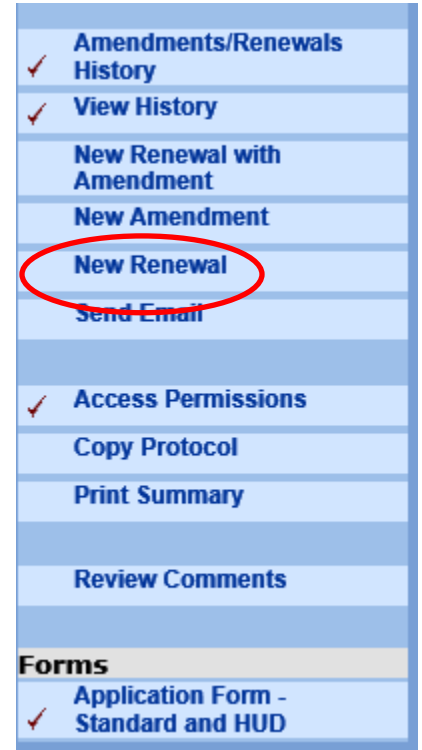
Renewal Summary:

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.

Save

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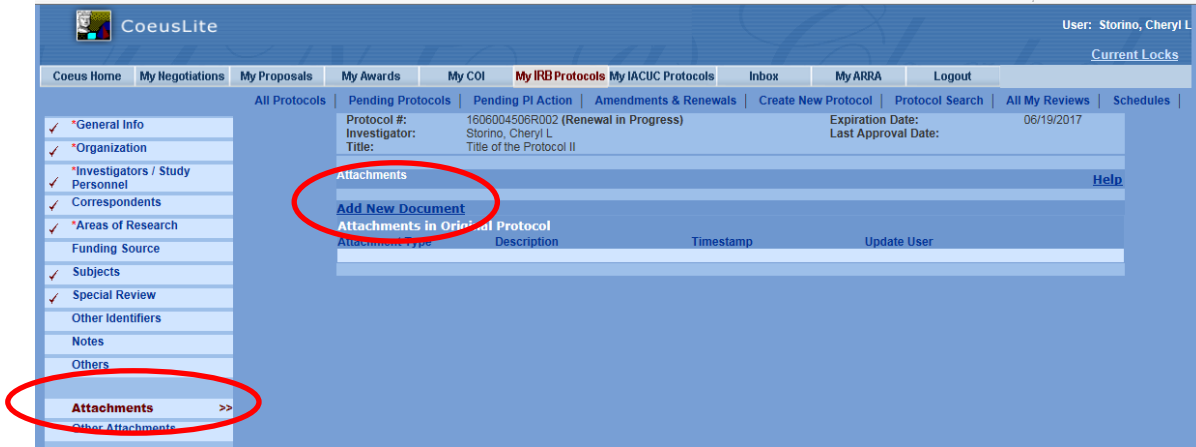
Click **Add New Document** to upload a new document. From the **Document Type** drop down box, select **HRP-212 Continuing Review Progress Report Form**. Use the **Description** to indicate the document. For example, HRP 502 Consent Form (unstamped).

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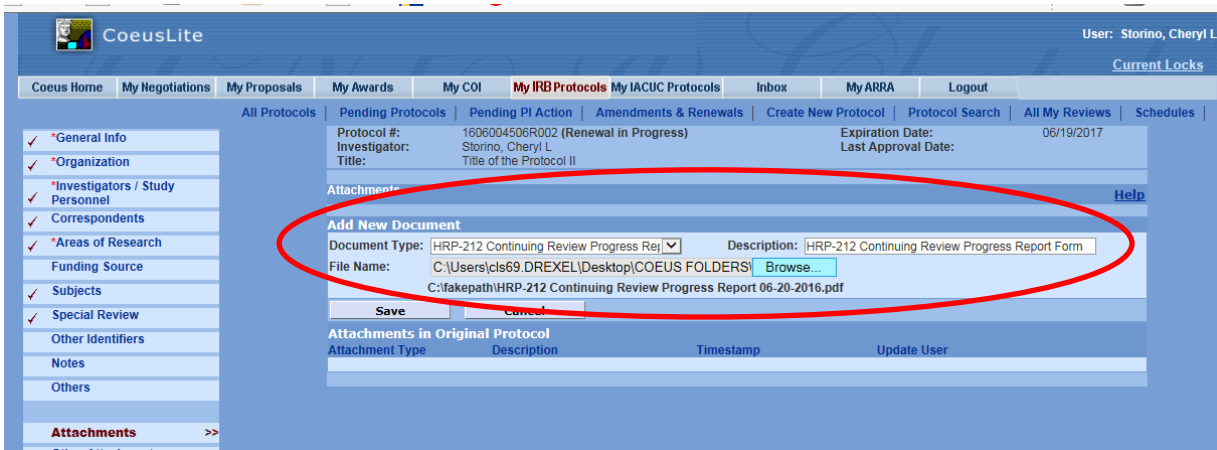
Renewal/Final Report Application

The renewal/final report application is at the bottom of the left hand column, in the Forms sections
- o HRP 212, Continuing Review/Final Report

Application

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

Submit to IRB

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

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

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

- 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

NOTIFY IRB
(HRP 214)

The **Notify IRB** functionality is used when a member of the research team needs to notify the HRP of a specific research activity or event, such as reportable new information (HRP 214).

Bring up the protocol that you wish to submit a report on by using the standard protocol search function.

Open up the protocol and select **Submit to IRB** from the left hand menu. This brings up the list of possible **Protocol Actions** that can be performed on the protocols. Select **Notify IRB**.

Using the drop down box, select the appropriate **Notification Type**: HRP-214 New Reportable Information.

Provide comments regarding the report in the open box.

Upload the cover memo and monitoring reports, DSMB reports or others as appropriate from your computer files. Using **Browse**, upload the document you wish to send to the IRB from your computer files. Click **Save** Click **Save Submission Details.**
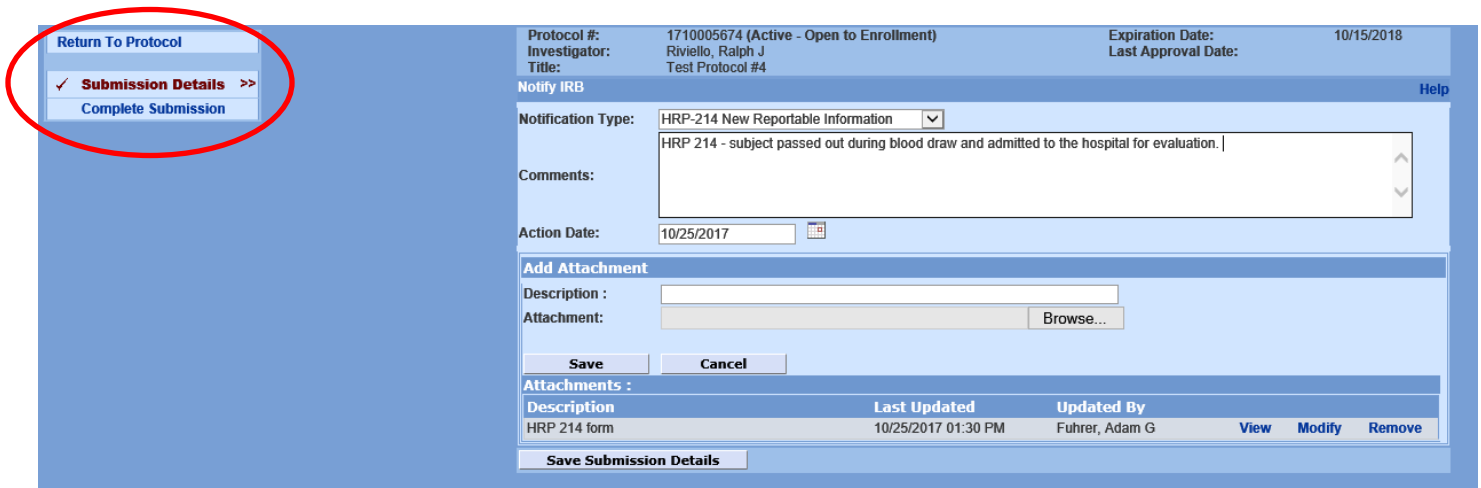
Click **Complete Submission** from the left hand column to submit the Notify IRB item to the HRP for formal review.

Click OK (to save the submission) and OK again (to submit the submission).

The HRP 214 is now submitted to the IRB.

CONNECTING OFF CAMPUS (VPN)

VPN Access For Windows

The Cisco AnyConnect VPN Client is available through the Drexel University AnyConnect VPN.

Installation Instructions for the Cisco AnyConnect VPN client for Windows

1. Visit https://vpn.drexel.edu/

2. Select the group "DrexelVPN" (usually the default option). Enter your Drexel University username (abc123) and password. Click Login.
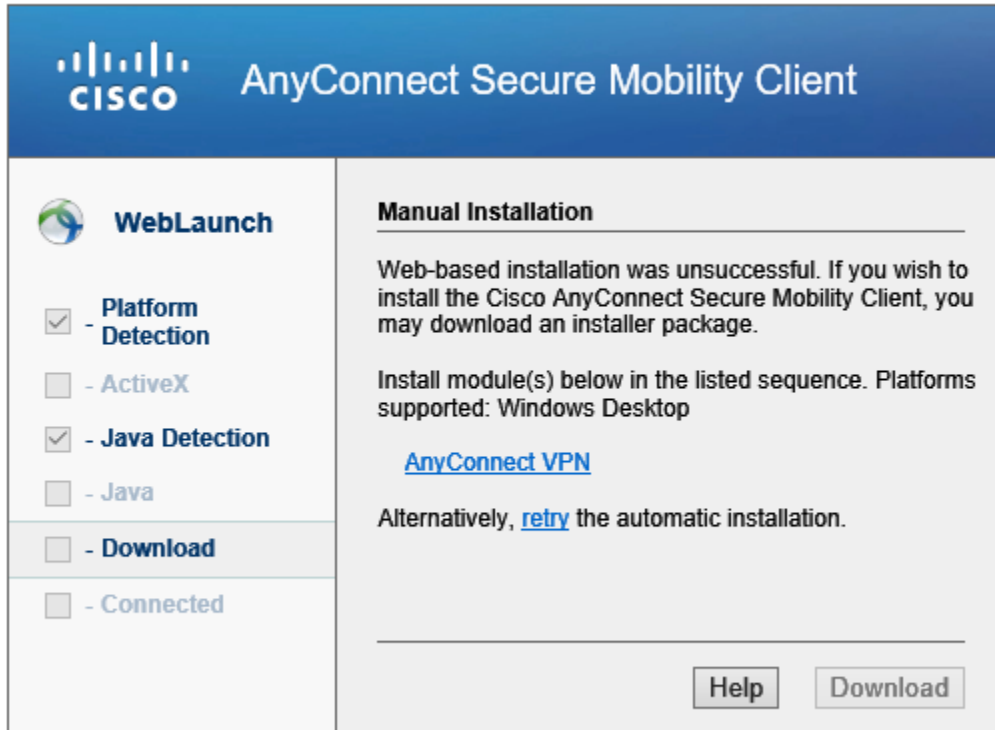

3. Click **Start AnyConnect** to begin the installation of the client and connect to the VPN service.

4. AnyConnect will try to install the client on your computer automatically. If unsuccessful, follow the prompts to install the package on your machine.

**Launching The AnyConnect Vpn Client From The Windows Start Menu**

Once installed you can launch the Cisco AnyConnect Client from the Start Menu.
Launch the program via the Start Menu by going to:

Start -> (All) Programs -> Cisco -> Cisco AnyConnect VPN Client -> Cisco AnyConnect Client (see image below)
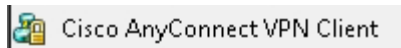
Select the group "Drexel VPN" (usually the default option). Enter your Drexel University username and password. Click Connect.
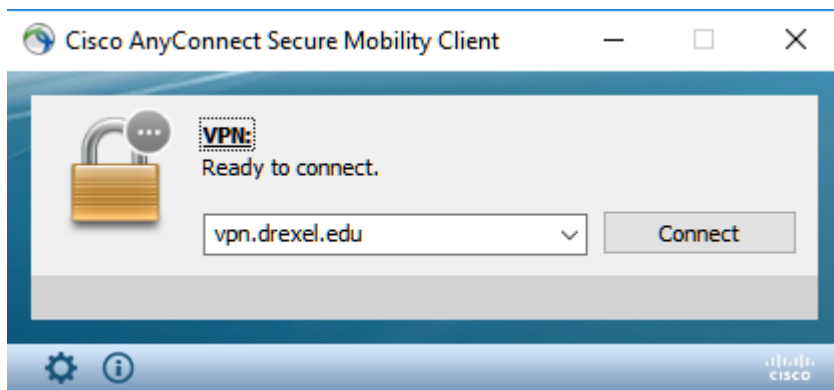
You will see the following icon in your system tray when you are successfully connected to the VPN service.
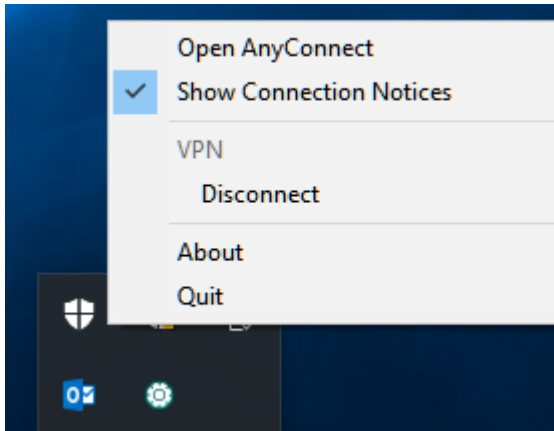
Disconnecting From The VPN Service

Best practices advise to always log out when you no longer need to access the internal Drexel network.
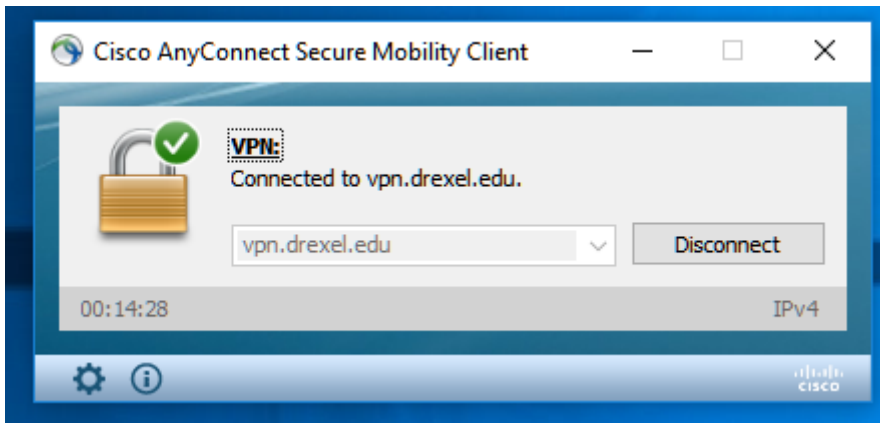
1. Disconnect via the Taskbar

    Right-click on the icon and select Disconnect

2. Disconnect via the AnyConnect Client

    Open the AnyConnect Client from the Taskbar (left click) and select Disconnect

VPN Access For Macintosh OS

The Cisco AnyConnect VPN Client is available through the Drexel University AnyConnect VPN.
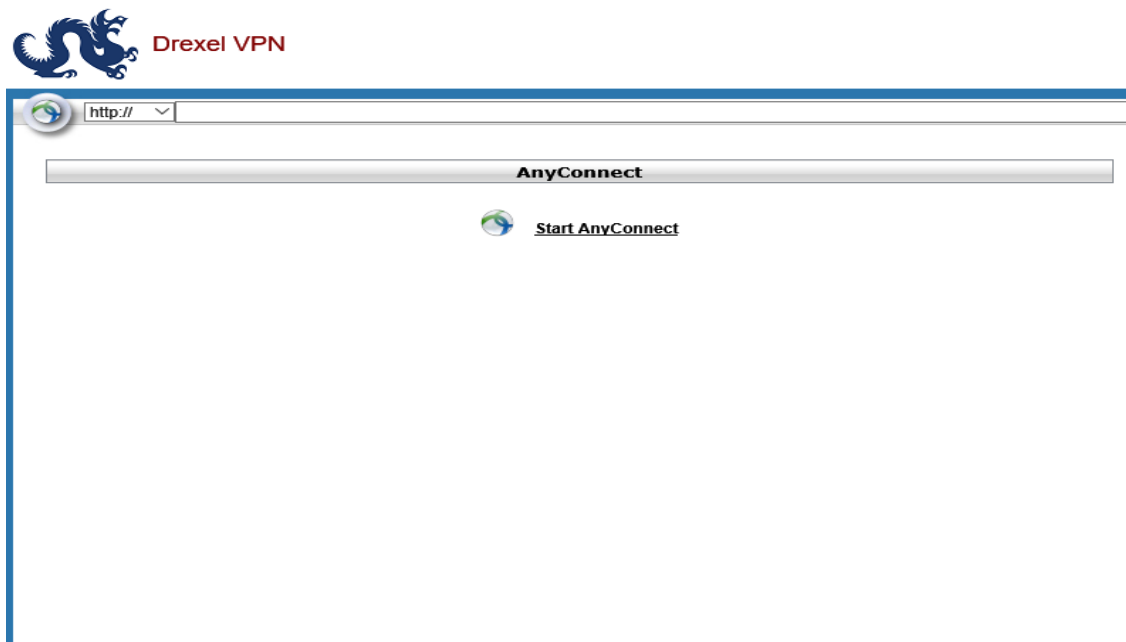
Installation Instructions for the Cisco AnyConnect VPN Client for Mac OSX

1. Visit https://vpn.drexel.edu/

2. Select the group "DrexelVPN" (usually the default option). Enter your Drexel University username (abc123) and password. Click Login.

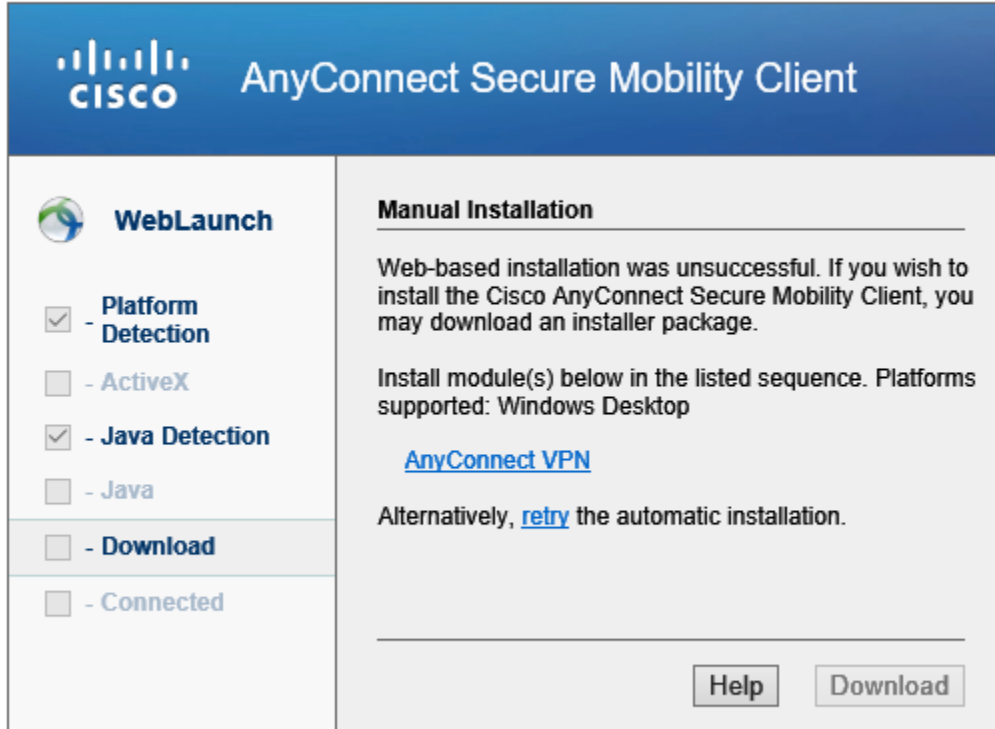3. Click **Start AnyConnect** to begin the installation of the client and connect to the VPN service.

4. AnyConnect will try to install the client on your computer automatically. If unsuccessful, follow the prompts to install the package on your machine.

Launching The AnyConnect VPN Client From The Applications Folder

1. Go to your Applications folder. Select the Cisco folder. Select the **AnyConnect Client** icon.
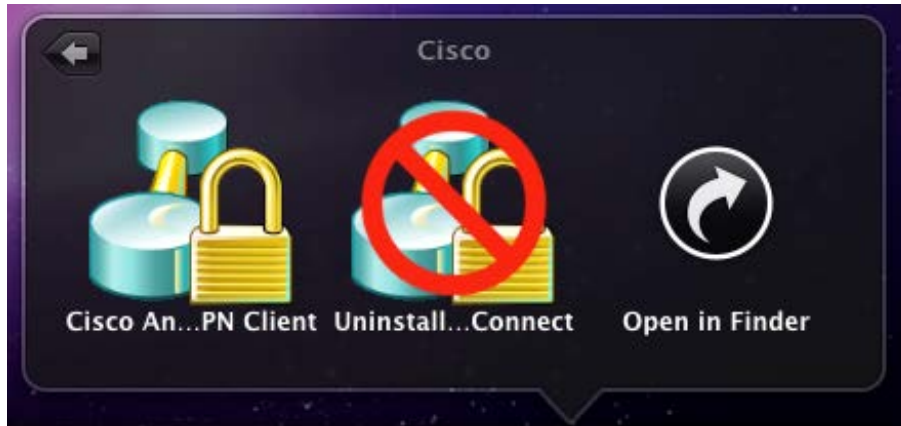
2. Enter your Drexel University username (abc123) and password. Make sure DrexelVPN is selected for the Group.

3. Once connected, you will see a confirmation screen.

Disconnecting The AnyConnect VPN Client

Always Log Out When Finished. Double click the AnyConnect icon on the dock to open the client dialog box (above). Click the Disconnect button. This will terminate the secure connection to the internal Drexel network.