

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.

The screenshot shows the Coeus Lite login interface. At the top left is the Drexel University logo. The page title is 'Coeus Web'. Below this is a 'Coeus Login' section. On the left side of this section, there is a white box containing the text 'Use of this CoeusLite™ requires a username and password.' Below this text are two input fields labeled 'USERNAME' and 'PASSWORD'. Underneath these fields are two buttons: 'Login' and 'Reset'. On the right side of the login section, there is a large graphic with the word 'COEUS' in large, stylized letters. Below the graphic, it says 'Drexel University - Office of Research Compliance Administration'. At the bottom left of the page, it says '© 2006, MIT'. At the bottom right, it says 'CoeusLite Version 4.5.1 P3'.

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

The screenshot shows the CoeusLite web application interface. At the top, the user is identified as 'User: Storino, Cheryl L'. The navigation menu includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My COI', 'My IRB Protocols' (circled in red), 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The main content area is titled 'Welcome to CoeusLite' and lists the following primary features:

- My Protocols** - Allows Principal Investigators to prepare and submit protocol applications and review detailed information associated with their existing protocols.
- My Proposals** - Allows Users to view and prepare grant applications and route their applications for Institutional Approval. Institution Administrators can see and approve grant applications. Institute Approvers can view, approve, or reject proposals for correction. OSP Authorized Administrators can submit applications to Grants.gov.
- COI Disclosure** - Allows individuals to provide data and required updates on entities in which they hold interest.
- Inbox** - List of Resolved and Unresolved messages from Coeus application with active links to Coeus Lite proposals listed by title and number.

The right sidebar contains a 'Change Password' section and a 'Coeus Mission' section with the text: 'To create, maintain and support the most robust electronic solution to manage all components of sponsored projects from proposal development through award closeout while fostering best practices by joining innovative technology with the knowledge base of a national consortium of research stakeholders.'

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 to
- 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

The screenshot displays the CoeusLite web application interface. At the top, the user is identified as 'User: Storino, Cheryl L' with a 'Current Locks' link. The navigation bar includes links for 'Coeus Home', 'My Negotiations', 'My Proposals', 'My COI', 'My IRB Protocols' (highlighted), 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. Below this, a secondary menu shows 'All Protocols', 'Pending Protocols', 'Pending PI Action' (highlighted), 'Amendments & Renewals', 'Create New Protocol', 'Protocol Search', 'All My Reviews', and 'Schedules'. The main content area is titled 'List of Pending PI Action Protocols' and contains three expandable sections: 'List of Specific Minor Revisions Required Protocols', 'List of Substantive Revisions Required Protocols', and 'List of Expiring Protocols'. Each section currently displays 'No rows found with current selection criteria'. The footer of the page includes '© 2006, MIT' and 'Coeuslite Version 4.5.1_P3'.

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

The screenshot displays the CoeusLite web application interface. At the top, the user is identified as 'User: Storino, Cheryl L' and 'Current Locks' are shown. The navigation bar includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The main menu on the left lists various options, with 'General Info' selected and marked with a red checkmark. The main content area is titled 'Create New Protocol' and contains sections for 'General Protocol Information' and 'Protocol Details'. The 'Protocol Details' section includes fields for 'Type', 'Title', 'Description', 'Application Date' (set to 04/06/2016), 'Reference Num 1', and 'Reference Num 2'. A 'Save' button is located at the bottom of the form.

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.

The screenshot shows the 'Create New Protocol' form in the CoeusLite system. The 'General Info' tab is highlighted with a red circle. The form fields are as follows:

- Type:** Standard (dropdown menu)
- Title:** (text input field)
- Description:** (text input field)
- Application Date:** 04/06/2016 (calendar icon)
- Reference Num 1:** (text input field)
- Reference Num 2:** (text input field)
- FDA Application No:** (text input field)
- Save** button

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 screenshot displays the CoeusLite interface for editing a protocol record. The 'Protocol #' field is circled in red, showing the value '1604004038 (Pending/In Progress)'. The form is divided into sections: 'General Protocol Information' and 'Protocol Details'. The 'Protocol Details' section includes fields for Type (Standard), Title (Title of the Protocol), Description (Description or Purpose of the Research Project), Application Date (04/06/2016), Reference Num 1 (alphanumeric), Reference Num 2 (alphanumeric), and FDA Application No (IND or IDE No). A 'Save' button is located at the bottom of the form.

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.

Coeus Lite How To - Submit Standard Submissions

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.

The screenshot displays the Coeus Lite web application interface. The top navigation bar includes the Coeus Lite logo and the user name "User: Storino, Cheryl L." with a "Current Locks" link. The main navigation menu is located below the header and includes "Coeus Home", "My Negotiations", "My Proposals", "My Awards", "My COI", "My IRB Protocols" (highlighted with a red circle), "My IACUC Protocols", "Inbox", "My ARRA", and "Logout". The left sidebar contains a list of menu items: "General info", "Organization" (with a right-pointing arrow), "Investigators / Study Personnel", "Correspondents", "Areas of Research", "Funding Source", "Subjects", "Special Review", "Other Identifiers", "Notes", "Others", "Attachments", and "Other Attachments". The main content area shows the "Protocol Organization" window for protocol # 1604004038 (Pending/In Progress). It includes fields for "Investigator:", "Title:", "Expiration Date:", and "Last Approval Date:". Below these fields is the "Add Organization" section with "Type:" and "Organization:" dropdown menus, both set to "----Please Select----", and a "Search" button. A "Save" button is also present. At the bottom, there is a "List of Protocol Organizations" section showing details for "Performing Organization" (Drexel University) with its address: "3201 Arch Street, Suite 100, Philadelphia, PA - 19104-2875, USA".

Investigators/ Study Personnel

The screenshot displays the CoeusLite interface. At the top, the user is identified as 'User: Storino, Cheryl L' with a 'Current Locks' link. The navigation bar includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. Below this, a secondary navigation bar lists 'All Protocols', 'Pending Protocols', 'Pending PI Action', 'Amendments & Renewals', 'Create New Protocol', 'Protocol Search', 'All My Reviews', and 'Schedules'. The left-hand menu is expanded to show 'General Info', 'Organization', 'Investigators / Study Personnel' (circled in red), 'Correspondents', 'Areas of Research', 'Funding Source', 'Subjects', 'Special Review', 'Other Identifiers', 'Notes', 'Others', 'Attachments', and 'Other Attachments'. The main content area shows protocol details for '1604004038 (Pending/In Progress)'. A red message states: '* The PI information is not saved yet. Click the Save button to save the PI information'. Below this is a link 'Add Investigators / Study Personnel Details' (circled in red) and a table titled 'List of Investigators / Study Personnel:'. The table has columns for 'Person Name', 'Department', 'Lead Unit', 'Role', 'Affiliate', and 'Training'. There are also links for 'COI Disclosure Status' and 'Send Notification'.

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 screenshot shows the CoeusLite interface. The top navigation bar includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The user is identified as 'User: Storino, Cheryl L.' with 'Current Locks' visible. The main content area shows a search window for 'Employee search' (highlighted with a red circle). The search results for 'Storino, Cheryl L.' are displayed, including fields for Name, Email (cheryl.l.storino@drexel.edu), Phone ((215) 255-7868), Mobile, Fax, Unit (7101), Protocol Role (Principal Investigator), and Person Role. There are 'Save' and 'Cancel' buttons. Below the search results is a table titled 'List of Investigators / Study Personnel:' with columns for Person Name, Department, Lead Unit, Role, Affiliate, and Training.

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

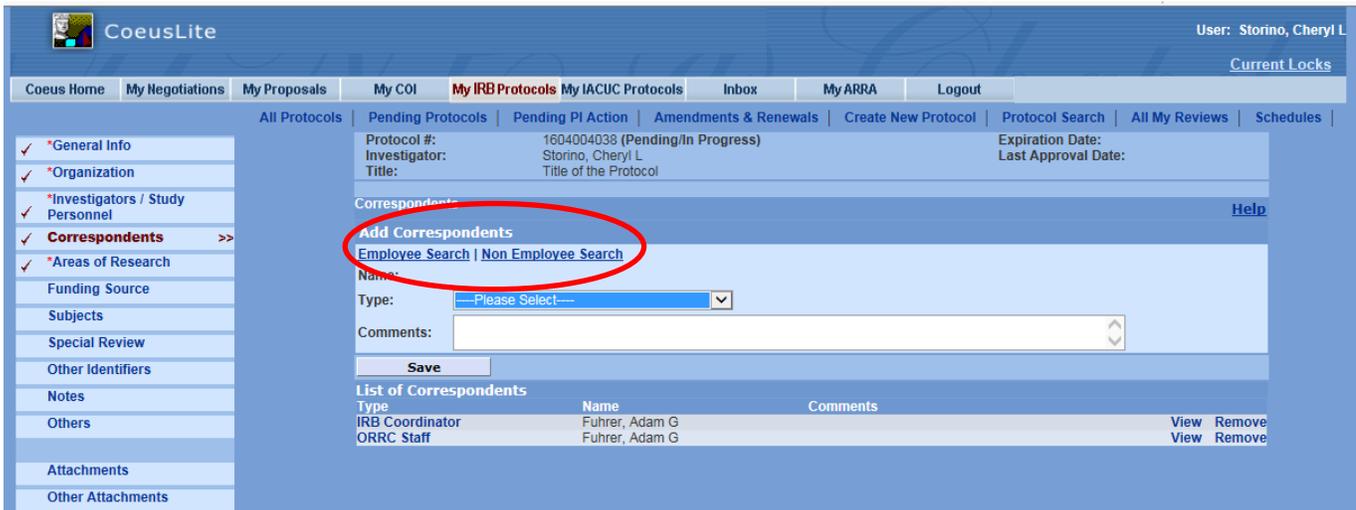
- Are NOT needed IF you can find your researcher in the personnel table (Employee search)
- Are NEEDED if you cannot find your researcher in the personnel table (Employee search)
 - Upload both documents in the Attachments tab

Coeus Lite How To - Submit Standard Submissions

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.



The screenshot shows the CoeusLite interface. The left sidebar has a menu with 'Correspondents' selected. The main content area shows protocol details for '1604004038 (Pending/In Progress)'. The 'Correspondents' section is active, with 'Add Correspondents' circled in red. Below it is a form with a 'Type' dropdown menu (currently showing '---Please Select---') and a 'Comments' text area. A 'Save' button is located below the form. At the bottom, there is a table titled 'List of Correspondents' with the following data:

Type	Name	Comments		
IRB Coordinator	Fuhrer, Adam G		View	Remove
ORRC Staff	Fuhrer, Adam G		View	Remove

- **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.

The screenshot shows the CoeusLite interface. On the left, the 'Funding Source' menu item is highlighted with a red circle. The main content area displays the 'Add Funding Source' form. The 'Type' field is a dropdown menu with a red circle around it, and the 'Number/Code' field is also circled in red. Below the form is a table titled 'List of Funding Source' with columns for 'Type', 'Number/Code', and 'Name/Title'.

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.

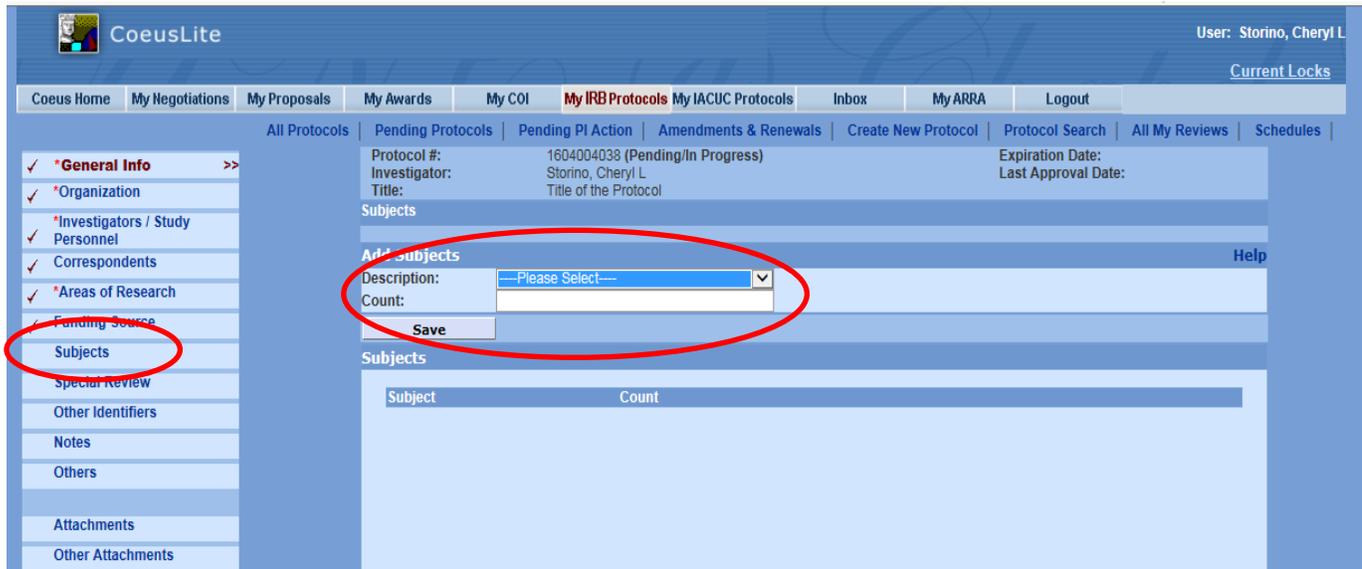
When searching the asterisk (*) can be used before, after or around a unit name. Click **Search**.

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

Coeus Lite How To - Submit Standard Submissions

Subjects

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



The screenshot displays the CoeusLite interface. The top navigation bar includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The user is identified as 'Storino, Cheryl L'. The main content area shows protocol details for protocol # 1604004038 (Pending/In Progress), with investigator 'Storino, Cheryl L' and title 'Title of the Protocol'. Below this, there is a section for adding subjects with a dropdown menu for 'Description' and a text field for 'Count'. The 'Subjects' menu item in the left-hand pane is circled in red.

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.

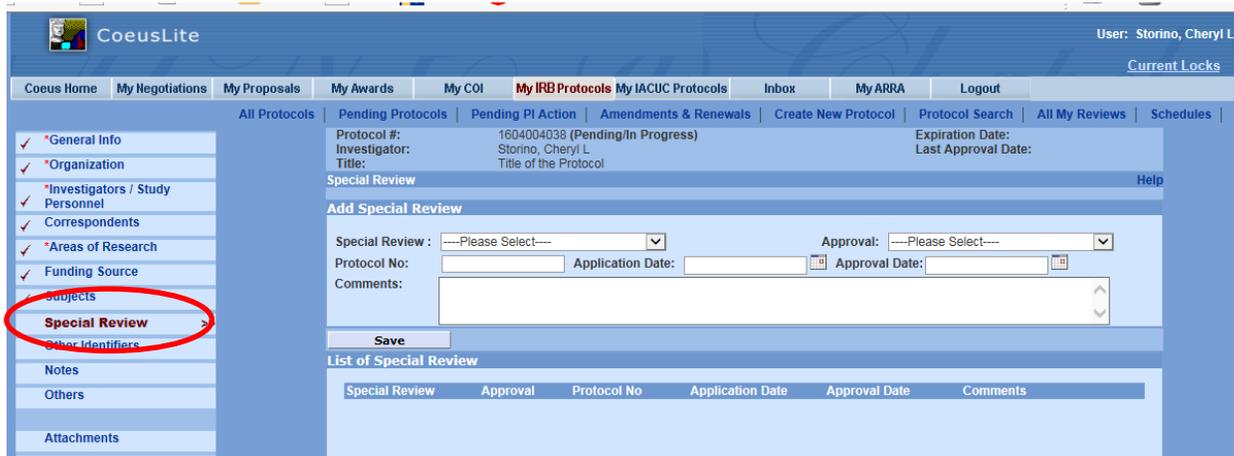
Common subject categories

- 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.



The screenshot shows the CoeusLite interface. The user is logged in as 'Storino, Cheryl L'. The navigation menu on the left includes 'Special Review', which is circled in red. The main content area displays the 'Add Special Review' form. The form includes a dropdown menu for 'Special Review' (set to '---Please Select---'), an 'Approval' dropdown (set to '---Please Select---'), and input fields for 'Protocol No.', 'Application Date', and 'Approval Date'. A 'Comments' text area is also present. Below the form is a 'Save' button and a 'List of Special Review' table with columns for 'Special Review', 'Approval', 'Protocol No', 'Application Date', 'Approval Date', and 'Comments'.

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

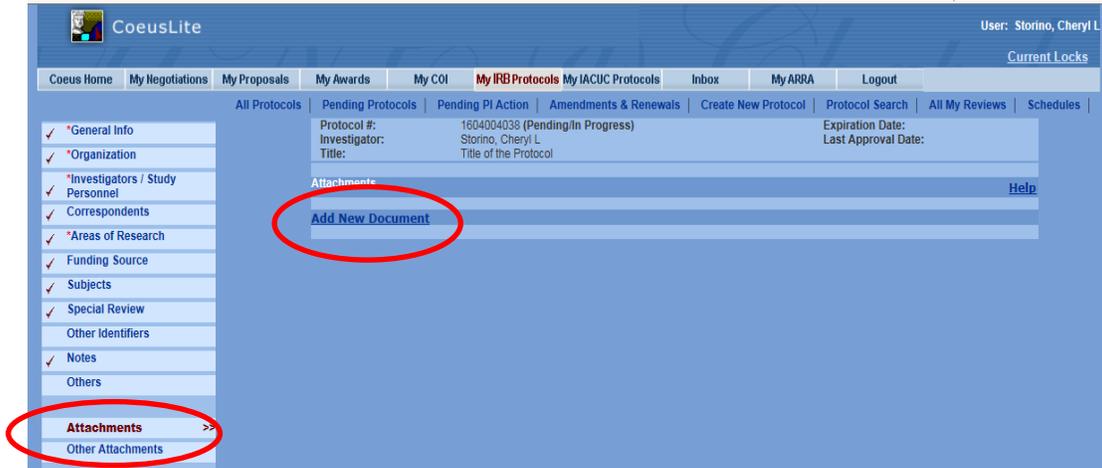
The **Notes** window is for any comments regarding this specific submission to the HRP Office

Coeus Lite How To - Submit Standard Submissions

Attachments

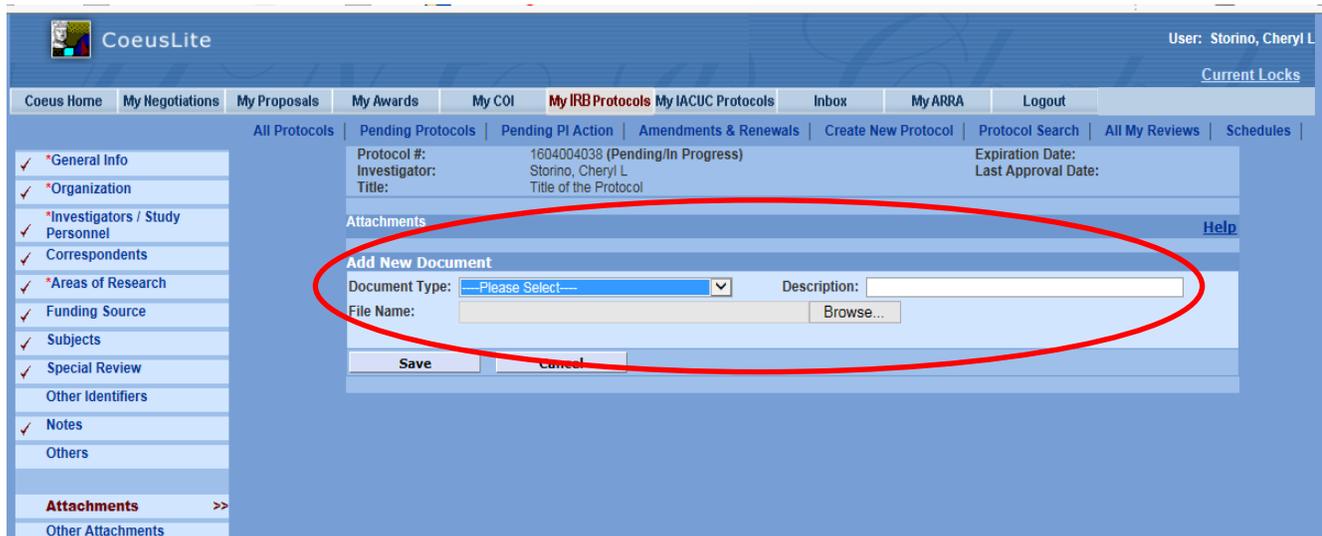
Once all data fields required for the protocol record are complete, it is time to upload the documents that the researcher must send to the HRP for review and approval.

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.



Coeus Lite How To - Submit Standard Submissions

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).



The screenshot shows the CoeusLite interface for a user named Cheryll L. Storino. The main navigation bar includes options like 'My IRB Protocols' and 'My IACUC Protocols'. The left sidebar lists various protocol-related categories. The central area displays details for a protocol with ID 1604004038. Below this, the 'Attachments' section is active, showing the 'Add New Document' form. This form is circled in red and contains the following elements: a 'Document Type' dropdown menu currently set to 'Please Select...', a 'Description' text input field, a 'File Name' text input field with a 'Browse...' button, and 'Save' and 'Cancel' buttons.

- **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

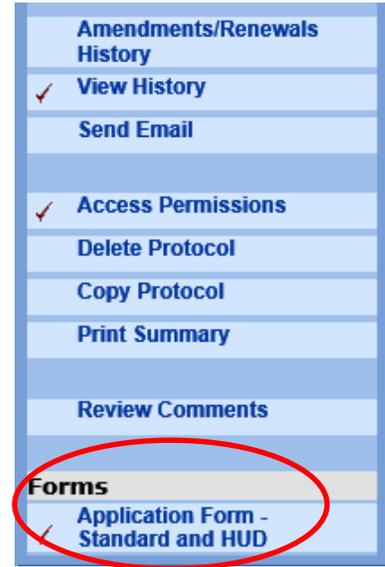
Select the appropriate application form from the left hand column in the Forms tab to complete the required electronic questionnaire.

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

A screenshot of the 'Application Form - Standard and HUD' questionnaire. The form has a blue header with the title and navigation links: 'Previous', 'Modify', and 'Start Over'. Below the header are nine numbered questions, each with radio button options and a 'More' link to the right. Question 1: 'How many subjects do you plan to enroll?' with a text input field containing '100'. Question 2: 'Is informed consent needed for this study?' with 'Yes' and 'No' radio buttons. Question 3: 'Has everyone involved in the study completed the appropriate trainings? Note: Standard and HUD Submissions: Ensure required CITI and DU trainings are completed and not expired before submitting the protocol to the IRB.' with 'Yes' and 'No' radio buttons. Question 4: 'Does anyone on this...' with 'Yes' and 'No' radio buttons. Question 5: 'Is/are external site(s)...' with 'Yes' and 'No' radio buttons. Question 6: 'Are unapproved dru...' with 'Yes' and 'No' radio buttons. Question 7: 'Are approved drugs planned for use in this study?' with 'Yes' and 'No' radio buttons. Question 8: 'Are investigational devices being evaluated for safety and effectiveness in this study?' with 'Yes' and 'No' radio buttons. Question 9: 'Is a Humanitarian Use Device (HUD) being used?' with 'Yes' and 'No' radio buttons. A 'Print' button is at the bottom left. A modal popup titled 'Message from webpage' is centered over the form, featuring a yellow warning triangle icon, the text 'Questionnaire Completed for protocol 1710005676', and an 'OK' button.

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 steps approve the protocol within Coeus Lite, after receiving an email from the platform requesting their review and approval.

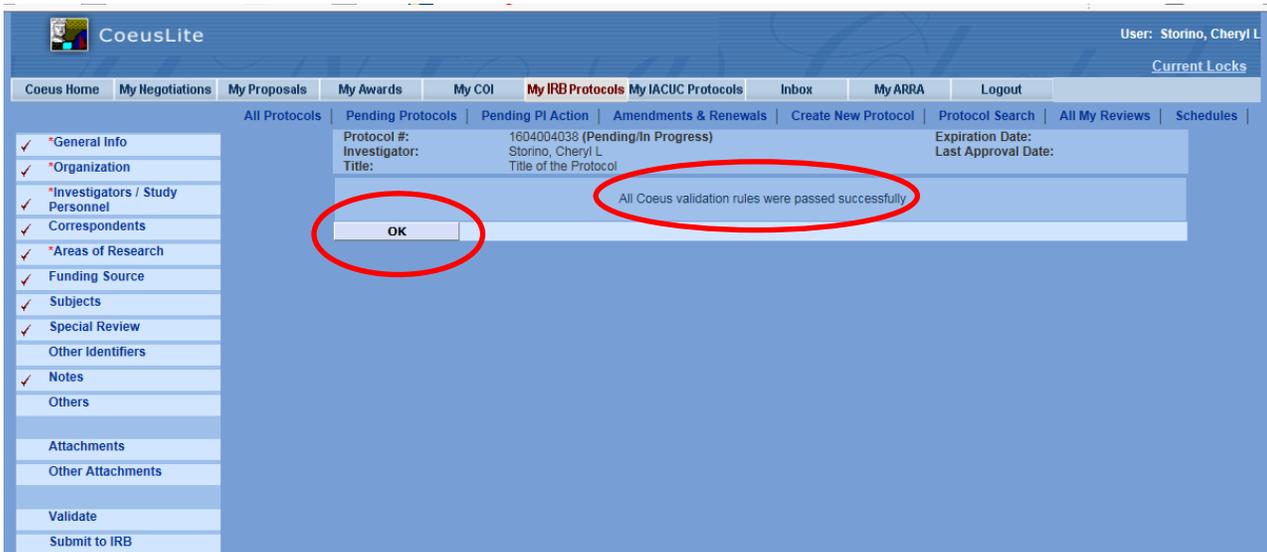
After the protocol has all approvals, Coeus Lite will route your submission to the HRP Office.

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**.

The screenshot displays the Coeus Lite user interface. At the top, the user is identified as 'User: Storino, Cheryl L'. The navigation menu includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The 'My IRB Protocols' section is active, showing a list of protocols with tabs for 'All Protocols', 'Pending Protocols', 'Pending PI Action', 'Amendments & Renewals', 'Create New Protocol', 'Protocol Search', 'All My Reviews', and 'Schedules'. The left-hand navigation pane lists various protocol components, with 'Submit to IRB' at the bottom circled in red. The main content area displays details for a specific protocol: 'Protocol #: 1604004038 (Pending/In Progress)', 'Investigator: Storino, Cheryl L', and 'Title: Title of the Protocol'. Below this, a 'Protocol Actions' section indicates that the user can perform the following actions: 'Submit For Review' (circled in red) and 'Submit to IRB for Review'.

Coeus Lite How To - Submit Standard Submissions

Validation will be requested. Select OK and OK again.



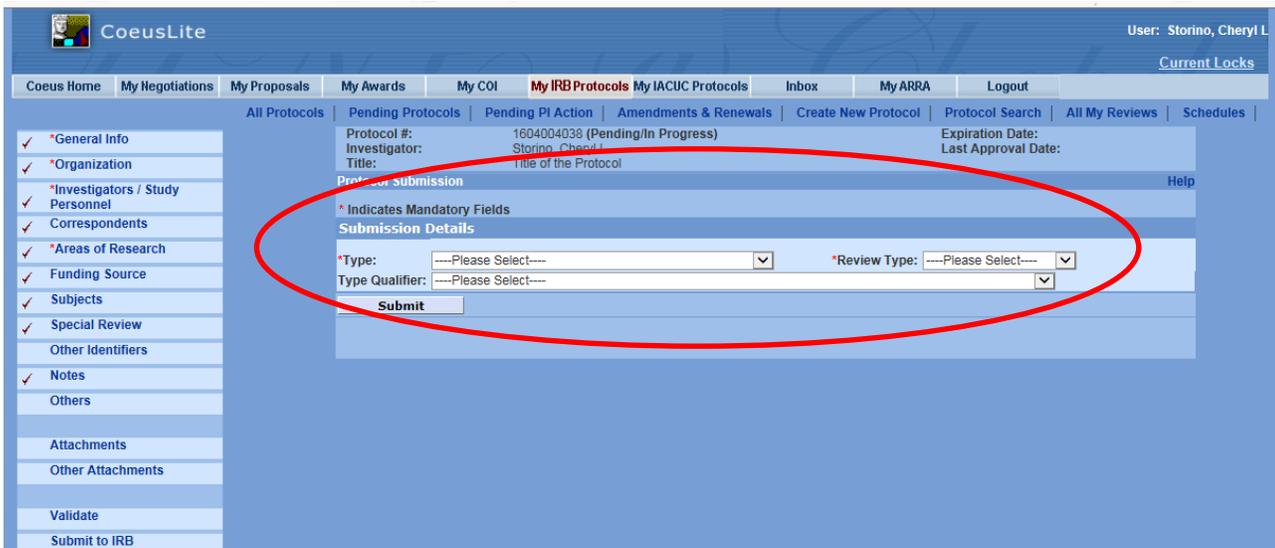
The screenshot shows the CoeusLite web application interface. The user is logged in as 'Storino, Cheryl L'. The navigation menu includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The main content area displays details for a protocol with ID 1604004038 (Pending/In Progress). The investigator is 'Storino, Cheryl L'. A message states 'All Coeus validation rules were passed successfully'. An 'OK' button is visible below the message.

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 screenshot shows the CoeusLite web application interface. The user is logged in as 'Storino, Cheryl L'. The navigation menu includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The main content area displays details for a protocol with ID 1604004038 (Pending/In Progress). The investigator is 'Storino, Cheryl L'. The 'Protocol Submission' section is highlighted with a red oval. It contains a 'Submit' button and a 'Submission Details' section with three dropdown menus: '*Type: ----Please Select----', '*Review Type: ----Please Select----', and 'Type Qualifier: ----Please Select----'.

The Protocol Is Now Submitted For Approvals

The screenshot shows the CoeusLite interface. The user is logged in as 'Fuhrer, Adam G'. The navigation menu includes 'Coeus Home', 'My Negotiations', 'My Proposals', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. The 'My IRB Protocols' section is active, showing a list of protocols. The selected protocol is '1710005680 (Routing In Progress)'. The form details include:

Protocol #:	1710005680 (Routing In Progress)	Expiration Date:	
Investigator:	Skinner, Karen B	Last Approval Date:	
Title:	10 October 2017	Meeting Date:	

General Protocol Information

* Indicates Mandatory Fields

Protocol Details

*Type: Standard

*Title: 10 October 2017

Description: 10 October 2017

*Application Date: 10/10/2017

Reference Num 1:

Reference Num 2:

FDA Application No:

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

The screenshot shows the CoeusLite interface with a navigation menu and a table of pending protocols. The user is identified as 'Fuhrer, Adam G'.

Protocol Number	Title	Status	Creation Date
1710005705	Title	Routing In Progress	24/October/2017
1710005704	Protocol Test #8	Routing In Progress	23/October/2017
1710005703	Protocol Test #7	Routing In Progress	20/October/2017
1710005700	18 October 2017	Routing In Progress	18/October/2017

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.

The screenshot shows a vertical menu with various options. The 'Approval Routing' option at the bottom is circled in red.

- ✓ ***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**

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 **AND 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