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.

![Special Review Window](image)

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.

![Attachments Window](image-url)
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.
Coeus Lite How To - Submit Standard Submissions

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 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