COEUS LITE eIRB
TRAINING MANUAL
For Department’s Protocol Submissions

Drexel University
Version March 2017
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GETTING STARTED: CREATING A NEW IRB PROTOCOL

Web Based Application -

URL:  https://coeus.drexel.edu/coeus/userAuthAction.do

or Enter through Office of Research Website by googling:  Office of Research COEUS Lite /  http://drexel.edu/research/resources/coeus/coeusLite/

Log into the Coeus application by entering your username and password.

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

- **Installing** the AnyConnect VPN Client (#install)
- **Launching** the AnyConnect VPN client from the Windows Start Menu (#Launching)
- **Disconnecting** from the VPN Service (#Disconnect)

### Installation Instructions for the Cisco AnyConnect VPN client for Windows

1. Visit [https://vpn.drexel.edu](https://vpn.drexel.edu)

2. Select the group "Drexel VPN" (usually the default option). Enter your Drexel User-id and password. Click Login.

3. Click **Start AnyConnect** to begin the installation of the client and connect to the VPN service.
4. You are now connected through the VPN. To disconnect and to connect future sessions, see the next.

**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 User-id 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.

*Disconnect via the Taskbar*

Right-click on the icon and select "Disconnect".

*Disconnect via the AnyConnect Client*

*Open the AnyConnect Client from the Taskbar*

Select "Disconnect".
VPN FOR MAC OS X

CISCO ANYCONNECT VPN CLIENT FOR MAC

- Installing the AnyConnect VPN Client
- Launching the AnyConnect VPN Client from the Applications Folder
- Disconnecting the AnyConnect VPN Client

Installation Instructions for the Cisco AnyConnect VPN Client for Mac OSX

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

2. Select the group "Drexel VPN" (usually the default option). Enter your Drexel User-id and password. Click Login.

   Note: For most users the Drexel User-id is your initials, followed by two to four numbers.

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

4. Once connected, you will see the Connection Established verification screen.
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 User-id and password. Make sure DrexelVPN is selected for the Group.
3. Once connected, you will see a confirmation screen.

4. **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.


New Information

When using the COEUS Submission System, the following documents and applications are now electronic and will be completed in COEUS (the hard copies available on HRPP’s website are not needed when submitting through COEUS):

- HRP-211 Application for Initial Review
- HRP-212 Continuing Review Progress Report Form
- HRP-213 Modification of Approved Research Form
- HRP-214 Reportable New Information Form

- Letter of Determination Application
- Case Reports and Case Studies Application

These documents are located on the left-hand side column (towards the bottom).

Example: The HRP 211 is required to be completed for a: Standard and HUD Submission.

The questionnaire can be opened by clicking once on the name. According to your answers, the questionnaire will only prompt additional questions applicable to your responses.
After logging in, the Welcome to Coeus eIRB window will launch. Click My IRB Protocols.

To create a new protocol, click Create New Protocol.

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.
TO CREATE A NEW PROTOCOL

Utilizing the screens outlined below, you will enter pertinent information to create and prepare an initial protocol submission.

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. For protocols being reviewed by another institution, select “External Review”.

**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.

**Reference Num 1:** WIRB Applicants will type “WIRB”
NCI Applicants will type “NCI Central IRB”
Northeast ALS Applicants will type “NEALS”
Columbia Univ CIRB Applicants will type “Columbia Central IRB”
All others will type “DU”
**Reference Num 2:** Clinicaltrials.gov NCT Number (if applicable); if not yet registered, email [HRPP@drexel.edu](mailto:HRPP@drexel.edu) the NCT Number upon registration.

**Expiration Date:** The date is automatically populated with the date the IRB approves the initial submission and each renewal/continuing review.

**FDA Application No.:** 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.

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

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**
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 DU, and 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. If the DU member does not appear in the search, contact coeus-help@drexel.edu and request the individual be added to COEUS.

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

Non-Employee Search

Use the Non-Employee Search to look up the names of individuals who are not associated with Drexel University. If a non-affiliated person is not available in the Non-Employee Search, contact the HRP at hrpp@drexel.edu for assistance.

The **Person Search Result** window opens. The **Person Search Result** displays all investigators with the same last name (or other search criterion).
Select the investigator by clicking on the appropriate name. The selected name, unit and contact information populate fields in the **Investigator/Study Personnel Details** window.

Note that the unit leading the research (lead unit) must also be designated and the field will automatically default to the home organization of the Principal Investigator. This can be over-written by the user by conducting a unit search. When searching the asterick (*) can be used before, after or around a unit name. Click Search.

*Note:* 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. Indicate the Person Role by typing in the appropriate information, e.g., Consultant, co-investigator, Research Assistant, etc. The field may be utilized to identify those investigators and study personnel who serve as consent personnel or another capacity or role pertinent to the research. This is only a required field when a person has been assigned the Study Personnel role.
3. Select the individual’s affiliation with Drexel by selecting from the Affiliation drop down box. Choices are Faculty, Staff, Affiliate or External Collaborator.

The **Contact Information** brought in for each person is the information that is listed in the university Banner system. Investigators and Correspondents must change their source information with Drexel’s Human Resources if they want the appropriate contact information to appear in this window.
This screen is populated with the names of persons who should receive notice of the IRB 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 **Non Employee Search** to find and add correspondents, as described in the Investigator section.

*It is mandatory to add at least the Clinical Research Coordinator’s name (person handling the administrative duties.)*

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

**Additional Information to Add**

List the name of the administrator who will receive the communication so that you the investigator need not manually send a copy of the IRB Approval outside of the system.

Also add personnel from other institutions that are involved in the research study who may wish to receive notifications of renewal reminders, approvals, expired protocols, etc. These may include the Human Subject Protection
Administrator at a collaborating institution or Drexel’s Research Affiliate organizations.
Note, however, that these persons must be set up as Coeus Users with Drexel University in order to access information such as IRB approval letters from the system.

AREAS OF RESEARCH

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 IRB to perform congruency reviews between sponsor proposals and the IRB protocols.

The entries made in this field are critical for ensuring that the IRB 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 research has been approved by the IRB and the project funding will not be released until IRB approval and congruency have been verified with Drexel’s Office of Research Administration.

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.

Select **Unit** to denote when the research is funded by departments within Drexel.

Select **Proposal Development Transmittal or Institute Proposal** when the protocol is fully or partially funded by an *external* entity.

Click **Search**. The **Search** Window will open.

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

**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 following are **Required** to be Selected and Completed:

- Select the appropriate Gender(s) and add the total DU Subject Count – Click Save
- Select the “Age Range From” – Enter age in the count field (Ex: 18) – Click Save
- Select the “Age Range To” – Enter age in the count field (Ex: 60) – Click Save
- Select the types of Data Collection (if applicable) – Click Save
- Identify and Select All Descriptions that are applicable

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

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

**SPECIAL REVIEW**
The **Special Review** screen is used by the researcher to note and track other protocol-related information that must be acted on by the Drexel IRB. Financial conflict of interest disclosure (form 2) and radiation safety review are examples, as they must either be approved or acknowledged by the Drexel IRB.

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.

**NOTE*** **Remember to upload** pertinent documents with your protocol submission.

Enter the **Application Date** and **Approval Date** using the following information when applicable:

**Application Date:** Click on the calendar icon and select the application date for the Special Review type. (Option type: mm/dd/yyyy format.)

**Approval Date:** Click on the calendar icon and select the approval date where appropriate. (Option type: mm/dd/yyyy format.)
The **Comments** field allows for alphanumeric entry. The Comments Section is associated with each individual review.

If Tenet Facilities are being used, select Tenet from the dropdown list and in the Comments Section place the facility name/dpt and floor being used at Tenet.

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

**Note:** All New Biosafety and Radiation Safety applications are required to be submitted directly to the appropriate biosafety and radiation officer before submitting a copy to the IRB with this submission.

**OTHER IDENTIFIERS**

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

**NOTES**

The **Notes** window is for **HRP Use Only**.

**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 IRB 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 IRB (the *document’s title* should be saved the exact same way as the description field instructions). For protocols being reviewed by another institution, select “External Review Documents” and upload the file.
**Description Field:** Do not use the following invalid characters in document titles or in any free text field: / @ # $ % ^ & *

**Description Field:** type in the specific HRP Document Number and Title. Example: “HRP 503 Protocol”, “HRP 502 Consent Document” when uploading the HRP 201 Contact Information Form and the Financial Interest Disclosure Form, include the HRP Document Number, Title and Individual’s Last Name:

“HRP 201 – Last Name”
“FIDForm Page 1– Last Name”
“FIDForm Page 2 – Last Name”

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

Highlight the document you wish to upload to the IRB 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.

Repeat as necessary until all documents required by the IRB for review are uploaded into the application.

**Note:** The research team member is encouraged to account for each document to ensure a thorough submission by double checking the documents that have been uploaded into the application. They are listed below the SAVE button for easy reference.

A PreReview will be performed by the HRP Office before directing to the IRB for review. All incomplete submissions will be returned to the PI.
OTHER ATTACHMENTS

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

### HRP-211 APPLICATION FOR INITIAL REVIEW

Select the **HRP-211 Application for Initial Review** form from the left hand column to complete the required electronic questionnaire.

<table>
<thead>
<tr>
<th>Access Permissions</th>
<th>Delete Protocol</th>
<th>Copy Protocol</th>
<th>Print Summary</th>
<th>Review Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Forms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRP 214 Internal Part I - For HRP IRB Staff Use</td>
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<tr>
<td>HRP 214 Internal Part II - For HRP IRB Staff Use</td>
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<tr>
<td><strong>HRP-211 Application Form Supplement</strong></td>
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<tr>
<td>Letter of Determination</td>
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<tr>
<td>Case Study Case Report Questions</td>
<td></td>
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</tr>
</tbody>
</table>

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### SUBMIT TO IRB

Once the protocol record 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.

Note: The protocol will be routed to the PI’s department for review and electronic signature by the Principal Investigator, the Department Chair or his/her designee, and Dean if applicable. The first “stop” after the approval routing is complete, will be to the IRB Regulatory Reviewer.
To commence 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 to IRB**. The **Withdraw Submission** feature cannot be used until the protocol has already been received by the IRB.

**Validation** will be requested. Select OK

Do You Want to Submit the Protocol for IRB Review – Select OK
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.

Click the **Submit** button to submit to the IRB.

The user will receive a message asking whether or not they wish to submit the protocol. Click **OK**.

**THE PROTOCOL IS NOW SUBMITTED TO THE APPROVAL ROUTING QUEUE**
Once the protocol has been electronically approved by all appropriate reviewers, the IRB 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, 2016 but the Submission Deadline is July 18, 2016. Thus an investigator “pushes” the submit button on July 17th, thinking it will be received by the IRB in time for the meeting on the 18th. However, via the electronic routing, it is waiting for the departmental Chair’s review and signature and doesn’t get approved by the Chair until July 19th. This causes the protocol to miss the deadline submission date. Thus, the protocol is 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.

- Open Coeus eIRB. Note that the user’s list of protocols defaults to the Pending Protocols after clicking My IRB Protocols.

- Select the pink icon next to the protocol status to launch a summary of the protocol status.

CHECKING ON STATUS IN ROUTING

To view the status of an initial protocol, or when appropriate an amendment, that is being routed to the department chair for signature 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.

**REVIEWING REVISIONS REQUIRED BY THE IRB**

Investigators are notified when revisions are required by the IRB so that approval of the protocol submission may be eventually granted. Investigators can view these requests for revisions through the Coeus eIRB system.

After signing into the Coeus Web page, click on **My IRB Protocols**. The list of protocols defaults to those that are **Pending Protocols**. Protocols requiring revisions are assigned a Status noted as either **Specific Minor Revisions Required** or **Substantive Revisions Required**.

Investigators may also view protocols requiring action by clicking on **Pending PI Action**.
In either screen, click on the protocol to open the protocol record and then click the View History in the left hand column. This will permit the investigator to view the actions with the IRB.

Note the Specific Minor Revisions Required in the Description field. Click View to see the quick comments from the IRB.

**RESPONDING TO THE IRB WHEN REVISIONS ARE REQUESTED**

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

In other cases however, changes are required to the protocol documents that were previously sent into the IRB for its initial review. As an example, the IRB may 1) require specific word changes to Consent Documents or 2) require that the investigator change interventions or procedures in the protocol. In the case of example #1; modifications to the originally submitted consent document must be made and re-uploaded into the system for review by the IRB. Similarly, in the case
of 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 IRB.

To upload the investigator’s letter of response, 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. Example: HRP 502 Revised Consent Form Version ___

Use Browse to upload the document from your computer files. Click Save.

Note, the investigator can Modify or Remove the response document if changes are required prior to submitting it to the IRB.

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

Choose Type: Response to Pending Conditions
Choose Review Type: “To Be Determined”

Click Submit

NOTIFY IRB

The Notify IRB functionality is used when a member of the research team needs to notify the IRB of a specific research activity or event.

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

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. Be sure to include the date of the incident.

The **Action Date** will default to today’s date.

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.**

Select the **HRP 214 Reportable New Information-Research Team** form from the left hand column to complete the required electronic modification questionnaire.
Click **Complete Submission** from the left hand column to submit the Notify IRB item to the IRB for formal review.

Click OK to complete the submission.

**THE HRP 214 IS NOW SUBMITTED TO THE IRB**
CREATING AN AMENDMENT TO A CURRENTLY APPROVED PROTOCOL

Click on My IRB Protocols.

Click on All Protocols to see the full listing of protocols that are already approved. Select and click the protocol you wish to work with. Note the protocols and related information can be sorted by clicking on any one of the column headings. Example: Statuses may be sorted in ascending/descending alphabetical order by clicking on the column heading Status.

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, after or around the partial entry. Ex. *0123* Click Search.
Click on **New Amendment** on the left-hand side column. This launches the **Amendment Summary** window.

You must provide a brief but detailed summary of the amendment in the Amendment Summary Window provided.

Click on **All** the applicable checkboxes for those items being changed. Note that clicking on the box opens up the protocol record for the information to be edited in that tab. Example: Selecting “General Info” will allow you to revise any field in the General Info Window (Title, Description, Ref Number 1 and 2, FDA Application No)

![General Protocol Information](image)

Always include the selection of: “**Add/Modify Attachments.**” Click **Save**.

![Select the appropriate tab](image)

Select the **appropriate tab** in the left-hand side column, to change the requested information in the protocol record. The window for the tab chosen will open,
allowing for selection and/or entry of items to be added or removed. Save when complete. Repeat for each tab as applicable.

Note an A00x suffix is applied to the protocol number. This refers to the sequential number of amendments for that particular protocol. The A suffix is dropped once an amendment is approved by the IRB. This means that the changes proposed in the Amendment have been incorporated into the Protocol you can still submit other amendments or renewals by searching and selecting the base protocol number.

UPLOADING/ATTACHING A NEW DOCUMENT FOR REVIEW BY THE IRB
Select the **Attachments** tab from the left hand column when attaching required documents with your Amendment submission.

Be sure to include the mandatory **Cover Letter and all appropriate documents** to ensure a complete submission.

*Note:* All HRP Documents are available on our website: [http://drexel.edu/research/human-research/humanSubjects/irb/applications/](http://drexel.edu/research/human-research/humanSubjects/irb/applications/)

Click **Add a New Document** to upload a new document, for example, adding a new consent document because a new population has been added to the project. Select the appropriate **Document Type** from the drop down box. Enter the name of the document into the **Description** field. It is required to use the Official Document Name referred to by the research team (Add a date and last name for clarity purposes):

Examples:
HRP-502 Template Consent dtd 07-04-2016
HRP 201 – Last Name
FIDForm Page 1– Last Name
FIDForm Page 2 – Last Name

Click **Browse** to upload the new version from the user’s computer files or travel drive.
Click **Save**. Repeat as needed.

Select the **HRP 213 Modification of Approved Research** form from the left hand column to complete the required electronic modification questionnaire.

Click **Submit to IRB** from the left hand column to submit the amendment to the IRB for formal review.

Click **Submit for Review**.

All **Coeus Validation Rules** were passed successfully – Click **OK**.

Do you want to **Submit** the protocol for Review – Click **OK**.

**Submission Details** will generate. Select the **Type “Modification of Approved Protocol”** and Review Type **“To be determined”**.

Click **Submit**.
THE PROTOCOL IS NOW SUBMITTED TO THE APPROVAL ROUTING QUEUE

Once the protocol has been electronically approved by the Principal Investigator, the IRB will assign the modification application appropriately. If the protocol is required to be reviewed at a convened meeting, the on-line submission deadline dates will be used.
Once the appropriate reviews and approval(s) are received, the protocol’s **Status** will be updated to **Submitted to IRB**.

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**CHECKING THE STATUS OF THE AMENDMENT SUBMISSION**

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

- Open Coeus eIRB. Note that the user’s list of protocols defaults to the **Pending Protocols** after clicking **My IRB Protocols** (be sure to select the protocol with its suffix A00X).

- Select the pink icon next to the protocol status to launch a summary of the protocol status.

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**CHECKING ON STATUS IN ROUTING**
To view the status of an amendment protocol, that is being routed to the principal investigator for signature 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.
CREATE A RENEWAL OR REAPPROVAL

Use this submission type to request reapproval or renewal 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, after or around the partial entry. *Ex. *0123* * Click Search.

![Protocol Search Screenshot]

![List of All Protocols Screenshot]
Double click on the protocol you wish to work with. This will open up the protocol 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
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.*
UPLOADING A NEW DOCUMENT FOR REVIEW BY THE IRB

Select the **Attachments** tab from the left hand column. This opens the Attachments window to upload the required **Summary Report and 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.

*Note:* All HRP Documents are available on our website: http://drexel.edu/research/human-research/humanSubjects/irb/applications/

**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 IRB with a copy of the approved renewal documents (including the continuing review approval letter) provided by the IRB of Record.

Click **Add a New Document** to upload a new document. Select the appropriate **Document Type** from the drop down box. Enter the name of the document into the
**Description** field. It is required to use the Official Document Name referred to by the research team (You should add a date and last name for clarity purposes):

Examples:
HRP-502 Template Consent dtd 07-04-2016
HRP 201 – Last Name
FIDForm Page 1– Last Name
FIDForm Page 2 – Last Name

Click **Browse** to upload the new version from the user’s computer files or travel drive.

Click **Save.** Repeat as needed.

Select the HRP 212 Continuing Review Progress Report form from the left

Click **Submit to IRB** from the left hand column to submit the renewal to the IRB for formal review.
Click **Submit for Review**.

All **Coeus Validation Rules** were passed successfully – Click **OK**.

Do you want to **Submit** the protocol for Review – Click **OK**.

**Submission Details** will generate. Select the Type “**Continuing Review**” and Review Type “**To be determined**”.

Click **Submit**.

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**THE PROTOCOL IS NOW SUBMITTED TO THE APPROVAL ROUTING QUEUE**

Once the protocol has been electronically approved by the Principal Investigator and the Department Chair, the IRB will assign the Renewal Application appropriately. If the protocol is required to be reviewed at a convened meeting, the on-line submission deadline dates will be used.
Once the appropriate reviews and approval(s) are received, the protocol’s **Status** will be updated to **Submitted to IRB**.
CHECKING THE STATUS OF THE RENEWAL SUBMISSION

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

- Open Coeus eIRB. Note that the user’s list of protocols defaults to the Pending Protocols after clicking My IRB Protocols (be sure to select the protocol with its suffix R00X).

- Select the pink icon next to the protocol status to launch a summary of the protocol status.

CHECKING ON STATUS IN ROUTING

To view the status of a renewal protocol, that is being routed to the principal investigator and department chair for signature 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.
REQUEST TO CLOSE

Use this submission type to request a study closure 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.

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, after or around the partial entry. Ex. *0123* Click Search.

Double click on the protocol you wish to work with. This will open up the protocol record. Click the Submit to IRB button from the column on the left-hand side.

The Submit to IRB window opens. Select the action, Request to Close.

The Request to Close box is to be completed.
It is required to attach the HRP-212 Continuing Review Progress Report, Final Summary of Research Memo, and any other applicable documents for review - the Description Field needs to read the official name of the HRP Document. (LOR’s do not require an HRP-212 when DU is not the IRB of Record).

Click **Save**.

Click **Save Submission Details** to save the details.

**THE PROTOCOL IS NOW SUBMITTED TO THE APPROVAL ROUTING QUEUE**
Once the protocol has been electronically approved by the Principal Investigator and the Department Chair, the IRB will assign the Request for Closure Application appropriately. If the protocol is required to be reviewed at a convened meeting, the on-line submission deadline dates will be used.

Once the appropriate reviews and approval(s) are received, the protocol’s Status will be updated to **Submitted to IRB.**