Coeus Lite Continuing Reviews

Coeus Lite website
- [https://coeus.drexel.edu/coeus/userAuthAction.do](https://coeus.drexel.edu/coeus/userAuthAction.do)
- Note that you must be on the Drexel University network to use the platform – you can VPN in if you are not on the network

Login Information
- Username and password corresponds to other Drexel University credentials
  - Username example: abc123

My IRB Protocols
- Remember that all submissions needing HRP or IRB review and approval is submitted through the My IRB Protocols tab
Find Your Protocol

Principal Investigator or Co-Investigator

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

Study Personnel

- Click the Protocol Search tab
- In the search window, enter some identifier to find your protocol (such as protocol number, investigator, etc.)
  - Note that it is a best practice to use * when searching, so for my protocol, I typed *1710005674*
  - This allows Coeus Lite to search for any possible keyword combinations
CREATING A CONTINUING REVIEW OR FINAL REPORT (HRP 212)

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

Click on My IRB Protocols.

Click on All Protocols to see the full listing of protocols that are already approved. Select the protocol you wish to work with. The information can be sorted by clicking on any one of the column headings. Example: Expiration dates may be sorted in ascending/descending order by clicking on the column heading Expiration Date.

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

- Ex. *0123*

Click Search
Renewal/Final Report Application

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

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

The Renewal summary window opens.

The Renewal Summary box is to include the type of continuing review request you are submitting for review and approval:
• Active and Open to Enrollment
• Continue for Data Analysis Only
• Continue for Follow Up of Subjects Only
  AND INCLUDE
• Progress report of what has happened with study since last approval

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 Document For Review

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

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

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

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

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

Application

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

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

1) Has the study been updated in ClinicalTrials.Gov?
   • Yes  • No

2) Is this submission a Continuing Review?
   • Yes  • No

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

Message from webpage

Questionnaire Completed for protocol 1710005674R001

OK

7) Number of subjects enrolled since last approval?

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

9) Total number of subjects approved for enrollment?

16) I acknowledge the following information must be completed for enrolled subjects of a vulnerable population at the investigator's site(s).
   • Yes  • No
Submit to IRB

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

Protocol Submission Window

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

- You will know when your amendment has been submitted to the principal investigator for approval when your status changes to Routing in Progress

<table>
<thead>
<tr>
<th>Protocol #:</th>
<th>1710005874R002 (Routing in Progress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator:</td>
<td>Rwello, Ralph J</td>
</tr>
<tr>
<td>Title:</td>
<td>Test Protocol #4</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>10/15/2018</td>
</tr>
<tr>
<td>Last Approval Date:</td>
<td></td>
</tr>
<tr>
<td>Meeting Date:</td>
<td></td>
</tr>
</tbody>
</table>

- To check the approval status
  - You can click Approval Routing to see where your submission stands
    - Approval Routing will only show after you Submit to IRB

- If you are the principal investigator
  - You can click Approval Routing to approve
    - Options are
      - Approve
      - Reject

Renewals/final report need the principal investor and department chair or program director to approve
- Approver will receive an email alerting them that they have an approval waiting

Once the principal investigator and department chair or program director approves, HRP will received your request and begin the review process