Coeus Lite – How to submit amendments

Coeus Lite Amendments

Coeus Lite website
- 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
Create An Amendment

Click New Amendment

- In the protocol screen, click New Amendment
  - This is located towards the bottom of the left hand column

Best practices

- Avoid clicking New Renewal with Amendment as this will force you to complete a renewal along with your amendment
- Coeus Lite will only process one modification at a time, so if you submit another, the system will not process, nor will your HRP coordinator review, until the immediate amendment has been approved
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Amendment Summary

- After you click New Amendment, the Amendment Summary box will appear
  - Type what you are modifying
    - If adding or removing personnel, mention that researcher’s name in the text box
  - Anything that you are modifying that corresponds to an area in the left hand column matches with the click boxes below the Amendment Summary box
    - So for my amendment, I am adding a site
    - Adding a site requires a change in the protocol
    - A new protocol means I have to upload a new attachment
    - So the click box I want is Add/Modify Attachments

- Click Save
  - When Coeus Lite saves, your protocol number gets additional, post approval identifiers
    - For amendments, your protocol number will have an A followed by the number of amendment that this is
    - Protocol status (by protocol number) is Amendment in Progress
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Make Your Changes

- In the left hand column, select whatever area you need to change
- For my amendment, I would click Attachments to upload the protocol

Best practices

- Any revision to an already approved documents requires
  - A tracked version of the new document compared to the original
  - A clean version with accepted changes
- Forgetting to attach either document will result in your amendment being rejected

To attach new documents

- Click Add New Document

Document type

- Always select HRP-213 Modification to Approved Human Research Form when uploading any document for a modification regardless of what it is
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My revised protocol is attached in two versions

- Clean
- Tracked

Amendment application

When you are done modifying your protocol, either through attaching new documents and or editing the left hand column areas, your next step is to complete the application.

- The application is at the bottom of the left hand column, in the Forms sections
  - HRP 213 Modification of Approved Research
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Amendment application

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

You will receive a pop up knowing questionnaire is completed
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
  - Modification of Approved Protocols
- Review Type
  - To be determined
- Type Qualifier
  - Standard
- Once you click Submit, Coeus Lite will ask you to confirm
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**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>1710065674A002 (Routing in Progress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator:</td>
<td>Rivollo, Ralph J.</td>
</tr>
<tr>
<td>Title:</td>
<td>Test Protocol #4</td>
</tr>
</tbody>
</table>

**General Protocol Information**

- *Indicates Mandatory Fields

**Protocol Details**

- Type: Standard
- Title: Test Protocol #4
- Description: 
- Application Date: 10/06/2017
- Approval Date: 10/16/2017
- Reference Num 1: 
- Reference Num 2: 

- To check the approval status
  - You can click Approval Routing to see where your submission stands

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

Amendments only need the principal investor to approve

- Principal investigator will receive an email alerting them that they have an approval waiting

Once the principal investigator approves, HRP will received your request and begin the review process.