Coeus Lite How To - Reviewing Revisions Required by the IRB

Reviewing Revisions Required by the IRB

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
Responding to Required Revisions

The HRP Office will notify researchers when revisions are required so that approval of the protocol submission may be eventually granted. Researchers can view these requests for revisions through Coeus Lite.

From My IRB Protocols, those protocols with outstanding items are listed in the default view, in Pending Protocols tab. Protocols requiring revisions are assigned a Status noted as either Specific Minor Revisions Required or Substantive Revisions Required.

Responding To The IRB When Revisions Are Requested

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

In other cases, however, changes are required to the protocol documents that were previously sent into the HRP for its initial review. As an example, the HRP may

- 1) Require specific word changes to consent documents
- 2) Require that the investigator change interventions or procedures in the protocol.

In example 1, revisions to the originally submitted consent document must be made and re-uploaded into the system for review by the HRP. Similarly, in example 2, the original protocol and perhaps the consent document would require revisions and a re-upload into the system for re-review by the HRP.
Attaching Revisions

To upload the research’s response letter, 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. For example, HRP 502 Revised Consent Form (tracked).

- **For any response to pending conditions**, you must select Response to IRB Notification Requesting Revisions as the Document Type regardless of the actual document.

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

In the Protocol Submission window
- **Type**: Response to Pending Conditions
- **Review Type**: To be determined
- **Type Qualifier**: Standard

Click Submit