COEUS Lite

!!! Extension Educator IRB Exemption Use ONLY !!!!

HRPP IRB Protocol submissions should continue to utilize hardcopy process

Extension IRB Requested Revisions on Exemption Requests

Protocol submission revisions or requests for additional information will now be completed electronically within the Coeus system for the purpose of process consistency and tracking.

Open Record to be Revised

NOTE: The CoeusLite Launch Page may be found at: https://coeus.itap.purdue.edu/coeus/userAuthAction.do

1. PI will be notified by system generated email when Specific Minor or Substantive Revisions are required
2. Click the first embedded link found at the bottom of the email notification.
3. Log into CoeusLite
4. System will automatically open the appropriate record to be revised.
   -OR-
5. Log into CoeusLite
6. Click "My IRB Protocols"
7. Click the "Complete IRB Requested Revisions" button in bottom section of IRB Home page
8. Pop up window will open with all protocols that have requested revisions, click the protocol that you wish to complete revisions for.

Review Requested Revisions

Review Revision Memo - RECOMMENDED

1. Towards the bottom of the left navigation under the IRB/HRPP section, click "IRB Admin Attachments"
2. Select the appropriate Revisions Requested Letter and click the "View" link to open the document
3. Memo will open in separate browser window that can be saved to desktop or printed

Alternate Method: Review Comments

1. Click on "Review Comments" in the left navigation
2. Requested revisions or additional information will be itemized. Click "View" in each comment to expand
3. Comments from previous submissions are listed in the bottom "Review comments/Attachments from Past Submissions" section and can be ignored.

Complete Requested Revisions

NOTE: All revisions must be completed in the appropriate section of the Protocol record to ensure a complete and final protocol is approved.

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Revisions to section 1: Protocol Details

1. Click on the appropriate screen link in the Left Navigation as directed by Requested Revisions.
2. Make all appropriate changes to the identified data fields as requested.
3. Click "Save" at the bottom of each screen you have revised.

Revisions to section 2: Questionnaires

1. Go to section 2: Questionnaires and click the Field Ext Educator Exemption Questionnaire to revise.
2. Click "Modify" at top of completed Questionnaire
3. Click "Save & Proceed" until you get to first question needing revisions
4. Make all appropriate changes as requested.
5. Repeat steps 3 & 4 for all questions requiring revisions and then continue to "Save & Proceed" until Questionnaire Completion message is received.
6. Click "Ok".

Revisions to section 3: Attachments

1. IMPORTANT: Attachments uploaded into CoeusLite records CANNOT be modified within the system.
2. Go to section 3: Attachments, click the "Attachments" link.
3. Locate appropriate Form that needs revisions from the attachment list.
4. Click the "View" button next to the Attachment.
5. Save the previously submitted document to your desktop if it is not already saved.
6. Open the document from desktop and make all appropriate changes as requested. Be sure to HIGHLIGHT changed information.
7. When revisions are complete, go back to the Attachments screen in CoeusLite. Click the "Modify" link next to the Attachment to revise.
8. Complete the standard Browse/Upload to attach the revised document file and click "Save".
9. When all change are complete, Submit to IRB

Submit to IRB

NOTE: Submission for both Academic Approvals and IRB review will now be done electronically through the system. Only complete the "Submit to IRB" function when the protocol is complete and ready for review.

1. Click "Submit to IRB" in the left navigation
2. Click "Submit for Review"
3. Validation Checks will automatically run. "Errors" MUST be corrected prior to submission. "Warnings" may be corrected if desired.
4. Click "Ok" and complete the following fields:
    a. Type: Select the applicable value "New Protocol Application", "Continuing Review/Continuation", or "Revised Exemption"
    b. Review Type: select "Pending IRB Determination"
    c. Type Qualifier: Select "IRB Requested Revisions"
5. Click "Submit"
6. Click "OK" in confirmation window

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PI Approval

NOTE: The PI will be the first electronic Approval required. This allows for a designate to complete the record entry while ensuring the PI is aware and authorizes the submission.

If PI completed record and has "Submitted to IRB":

1. Click "Return to IRB Protocol"
2. Click "Approval Routing" in the left navigation
3. Click "Approve"
4. Enter Comments and/or Attachments if desired
5. Click "Approve" again to complete PI Approval

If Investigator Delegate completed record and has "Submitted to IRB:

1. Open record from "My IRB Protocols" or Email Notification
2. Click "Protocol Details" and review submission
3. Click "Approval Routing" in the left navigation
4. Click "Approve"
5. Enter Comments and/or Attachments if desired
6. Click "Approve" again to complete PI Approval