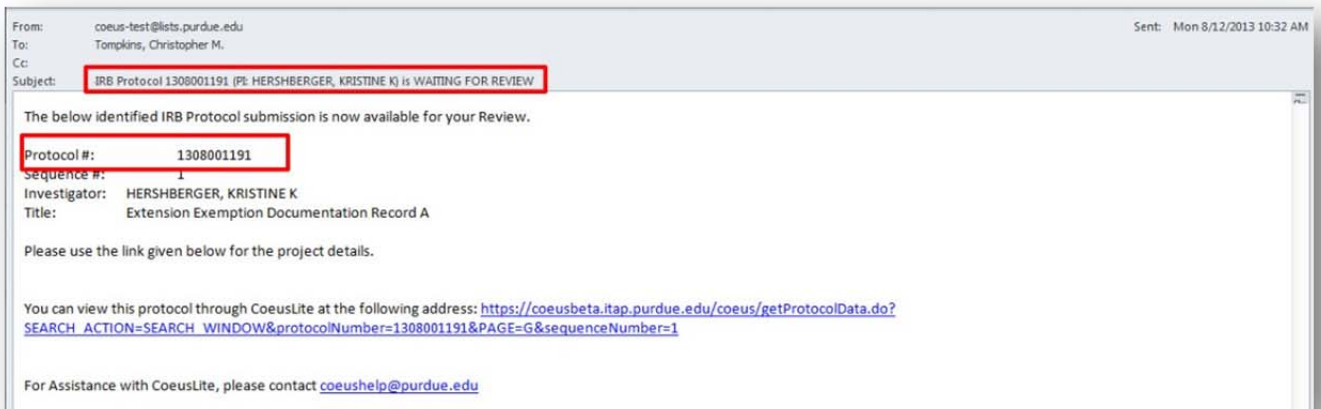


COEUS

Coeus Extension IRB Administrative Process – Administrative Review

The following processes apply to every Extension Educator Exemption request received by Extension Administration. The intake process should start once the system generated “Waiting for Review” email is received by Extension Administration:




NOTE: Notifications which state “*Waiting for Approval*” are for Routing only (Admin Intake). Once Approval/Routing has been satisfied and Reviewer has been assigned, “*Waiting for Review*” notification will be sent.



IRB Protocol Submission Module

To be completed in Coeus Premium IRB Protocol Submission Module by Extension Administrative Reviewer


Step 1: Open IRB Protocol Submission

1. Identify Protocol Submission Number from Notification Email – Submission number will be both in the email Subject line and in the body
2. Launch Coeus Premium and open the “IRB Protocol Submission” module by going to Maintain > IRB Protocol Submission –or– clicking the “IRB Protocol Submission”  icon.
3. IRB Protocol Search: The standard search window will open. Search by the Protocol number identified in the email notification and click “Find”

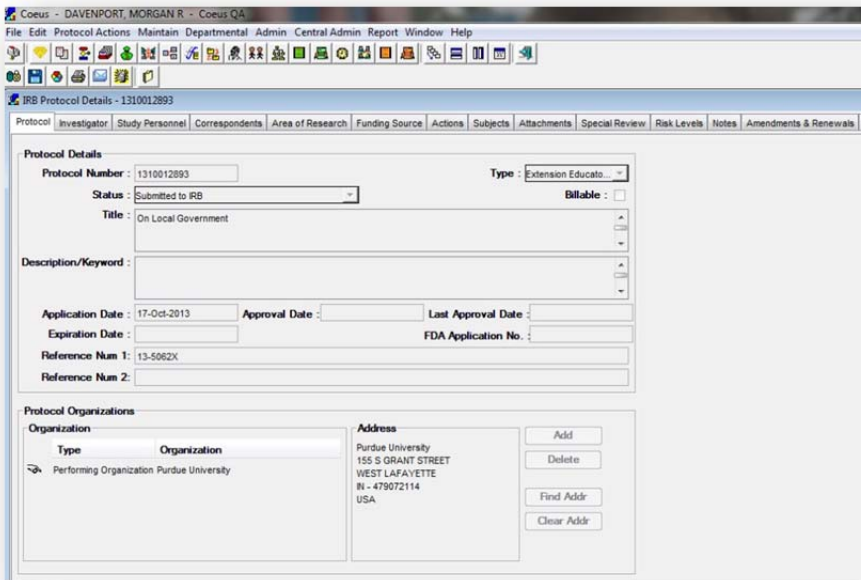
COEUS



NOTE:

- If the search window is accidentally closed, re-open by clicking the “IRB Protocol Submission Search”  icon in the top navigation.
- Search criteria may be abbreviated by using the asterisks key (*) as a wildcard. Example: Protocol 1201000385 can be searched by *385*

4. Select the submission with Submission Status = “Submitted to Committee”
5. Open record in Display by double clicking the listed result or going to Edit > Display IRB Protocol



Protocol Details

Protocol Number: 1310012893 Type: Extension Educato...

Status: Submitted to RB Billable:

Title: On Local Government

Description/Keyword:

Application Date: 17-Oct-2013 Approval Date: Last Approval Date: Expiration Date: FDA Application No.:

Reference Num 1: 13-5062X

Reference Num 2:

Protocol Organizations

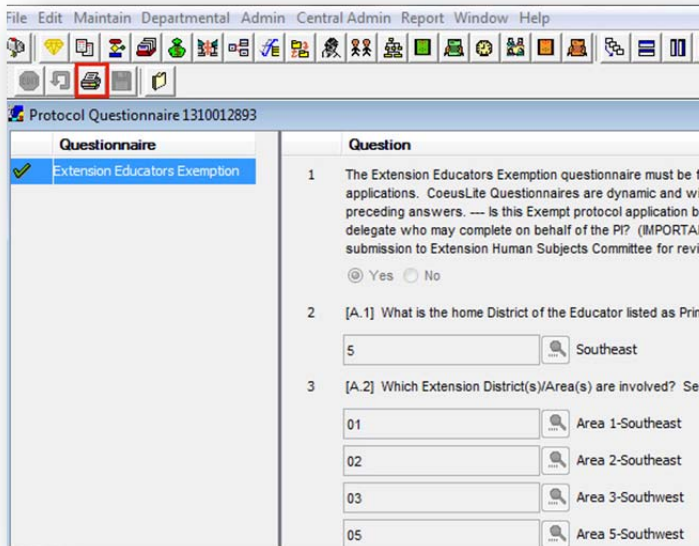
Type	Organization	Address
Performing Organization	Purdue University	Purdue University 155 S GRANT STREET WEST LAFAYETTE IN - 479072114 USA

Buttons: Add, Delete, Find Addr, Clear Addr

Step 2: Administrative Review


1. Review Questionnaire Content
 - a) Go to Edit>Questionnaire using task bar
 - b) Select Extension Educator Exemption Questionnaire from left hand column
 - c) To generate PDF of questionnaire, go to File>Print or select the “Print” icon on the second row of buttons (screen shot below)
 - d) When finished, close questionnaire

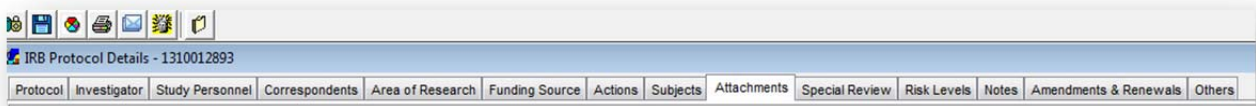
COEUS



2. Review Protocol Details

- Select and review information on each tab across the top of the screen
 - Specifically, Investigator, Study Personnel, Funding Source, & Attachments

 **Helpful Hint:** Use Notepad to record Review Comments to eliminate formatting issues associated with using copy/paste from other applications (such as Word).



Step 3: Open Protocol Submission Details



Submission details for Protocol 1308001191

Protocol Details
 Protocol ID : 1308001191
 Protocol Title : Extension Exemption Documentation Record A
 PI : HERSHBERGER, KRISTIN ApplicationDate : 12-Aug-2013

Submission Details :
 Submission Type : Initial Protocol Application Review Type : Exempt
 Type Qual : New Submission to IRB
 Submission Status : Submitted to Committee
 Date : 12-Aug-2013 Place :
 Committee Id : CES
 Committee Name : CES Human Subjects Advisory Committee Select Committee
 Schedule Id : Schedule Date : Select Schedule

Reviewers
Selected Reviewers

Review Complete	Name	Reviewer Type	Assigned Date	Due
<input type="checkbox"/>	TOMPKINS, CHRISTO...	Administrati...	08/12/2013	

Available Reviewers

- FERRIS, JONATHAN C
- BORDELON, BRUCE P
- MCKINLEY, STEVEN K
- VANDERGRAFF, DONNA J
- HUETTEMAN, JULIE K
- KIDWELL, CARLA A
- FHIEDS, BERRY A

Voting Details
 Vote Count : No : 0 Yes : 0 Abstainer : 0
 Comments :

Action Details

Description	Date	Action D...	Comments
Submitted to IRB	12-Aug-2013	12-Aug-2013	Submit to IRB

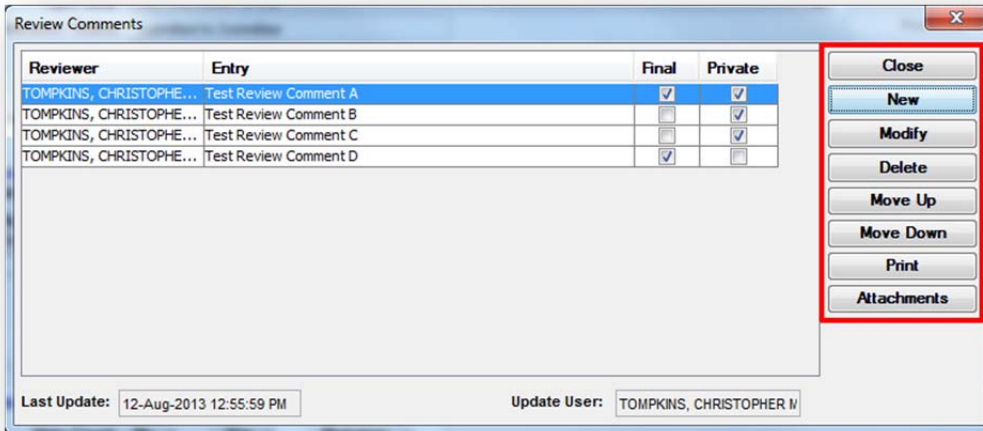
1. With protocol record still open from review, open Protocol Submission Details window:
 - a. Go to Edit > View Submission Details
2. Confirm/Revise Submission Details Fields
 - a. Submission Type:
 - b. Review Type:
 - c. Type Qual:
 - d. Committee:
3. Checklist
 - a. Click the "CheckList" button to the right of the Submission Details screen
 - b. Check the box next to the appropriate Exemption Category
 - c. Click "OK" to close Checklist window

NOTE: See Administrative Intake Guide for more details.

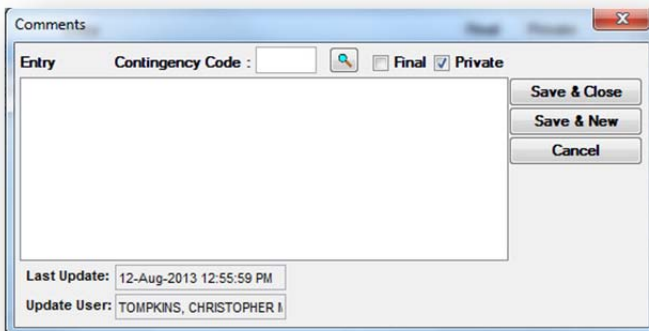
COEUS

Step 4: Review Comments & Attachments

IMPORTANT!!! Review Comments that are not marked "Private" WILL be both visible to an Investigator through CoeusLite and populate on any system generated correspondence document.



1. Open Review Comments window
 - a. From Submission List: Go to Edit > Review Comments
 - b. From Submission Details screen: Click the "Review Comments" button to the right of the screen



2. Add Review Comment
 - a. Click the "New" button to the right of window
 - b. Enter comment verbiage in "Entry" text box
 - c. Ensure Comment is appropriately marked "Final" and "Private" (*See note above)
 - d. Click "Save & New" to add additional comments –OR–
 - e. Click "Save & Close" to exit comment window
 - f. Click "Close" on Review Comments window to exit or continue with additional Comments




3. Modify Review Comment:

 NOTE: IRB Administrators may modify all Review Comments regardless if they had created them or not.

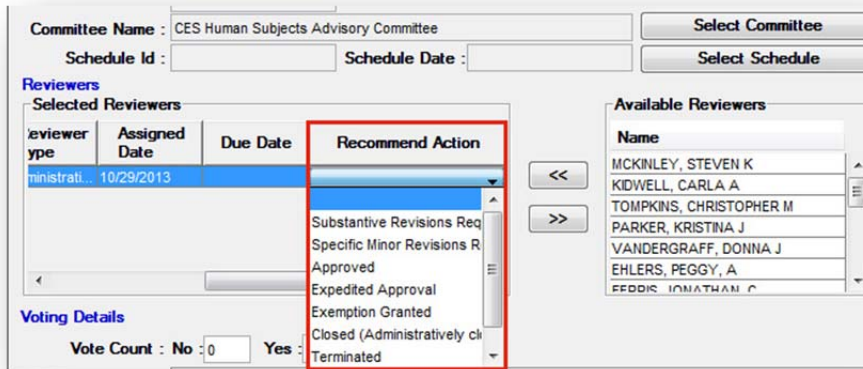
- a. Click the Comment to modify and highlight
- b. Click the “Modify” button to the right of window
- c. Make any desired changes to Comment text in Entry field
- d. Ensure Comment is appropriately marked “Final” and “Private”
- e. Click “Save & Close” to exit comment window
- f. Click “Close” on Review Comments window to exit or continue with additional Comments

4. Delete Review Comment:

- a. Click the Comment to modify and highlight
- b. Click the “Delete” button to the right of window
- c. Click “Yes” on confirmation window
- d. Click “Close” on Review Comments window to exit or continue with additional Comments

 NOTE: Review Attachments may only be VIEWED in Premium and must be uploaded or edited in CoeusLite.

Step 5: Enter Recommended Action



1. When you have determined your Recommended Action, enter it in Submission Details
 - a) Open Submission Details (Open record, go to Edit>View Submission Details –OR– from Protocol Submission List screen, go to Edit>Submission Details or select Submission Details button)
 - b) Scroll to the right of Selected Reviewers box until Recommended Action field is visible
 - c) Click in the field for drop-down to appear, select your Recommended Action

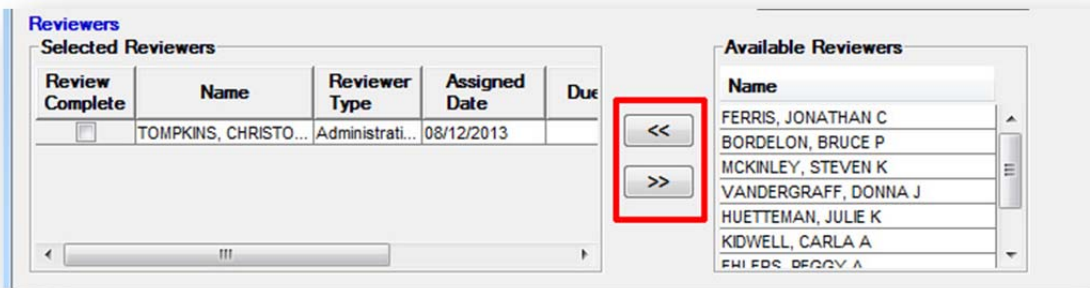
COEUS

- Applicable Actions for Extension:
 - Substantive Revisions Required
 - Specific Minor Revisions Required
 - Exemption Granted

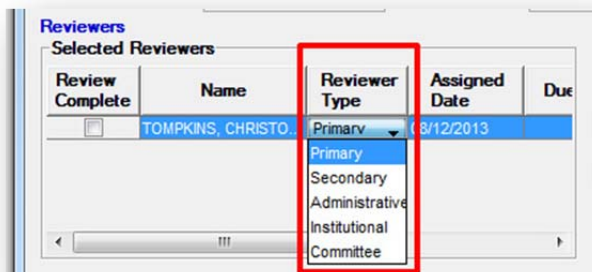
Step 6: Assign Reviewers (if Administrative Review is Exemption Granted or Specific Minor Revisions)

****If Recommended Action is Substantive Revisions Required, go to Step 7****


IMPORTANT!!! Extension Director should be initially added as a Reviewer with the "Administrator" Reviewer Type. Allow for Director to complete review, add comments, and Recommend Action prior to assigning Committee Member Reviewers.



1. Must be completed in Submission Details window
2. Assign Applicable Reviewers
 - a. Click the name of the Reviewer in the Available Reviewers list on the right
 - b. Click the left pointing double arrow icon to assign



- c. Update Reviewer Type to be "Primary"

 **NOTE:** Email notification will be automatically sent to assigned Reviewers when Submission Details are saved.

3. Click "OK" to save and close Submission Details window

COEUS

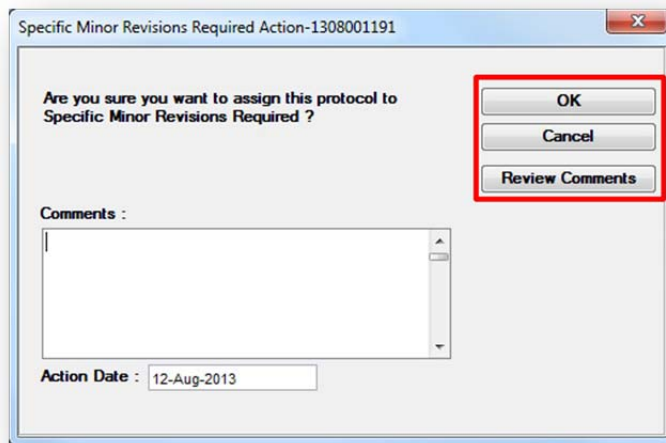
4. System generated email notification will automatically be sent to all Reviewers that were just assigned. Notifications will NOT be sent to reviewers that were already assigned.

Step 7: Request Revisions (if Administrative Review is Substantive Revisions)

1. Open Review Comments window
 - a. From Submission List: Go to Edit > Review Comments
 - b. From Submission Details screen: Click the "Review Comments" button to the right of the screen
2. Complete Comments Scrub (Only if Applicable)

IMPORTANT: Ensure that Comments to Investigator are worded correctly and NOT marked "Private". All internal Comments should be marked "Private".

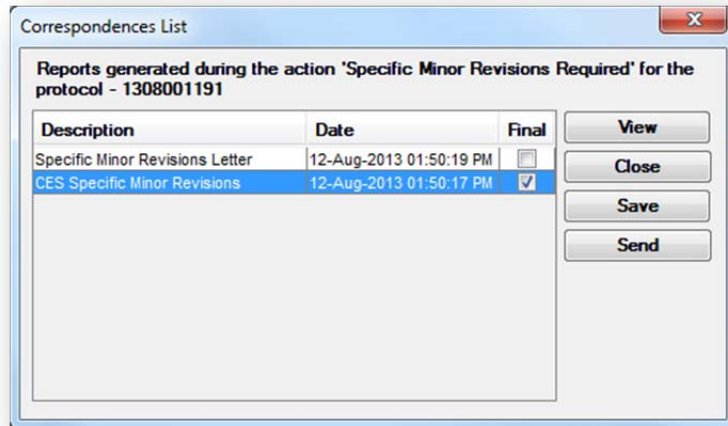
- a. Click the Comment to modify and highlight
 - b. Click the "Modify" button to the right of window
 - c. Make any desired changes to Comment text in Entry field
 - d. Ensure Comment is appropriately marked "Final" and "Private"
 - e. Click "Save & Close" to exit comment window
 - f. Click "Close" on Review Comments window to exit or continue with additional Comments
3. Revisions Requested Action
 - a. Make sure the correct submission is highlighted in the IRB Protocol Submission List
 - b. Go to: Actions > "Specific Minor Revisions Required" or "Substantive Revisions Required", new window will open



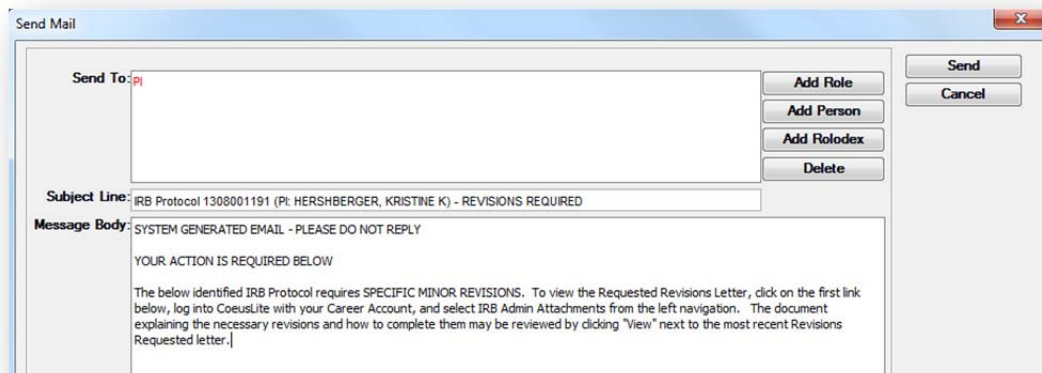
- c. Confirm Review Comments
 - Click "Review Comments"
 - Review all comments and confirm internal comments are marked "Private" and comments to be sent to PI are not

COEUS

- Click “Close” to return to Minor Revisions Required Action screen
 - d. Click “Ok” to finalize Revision Action
 - e. Correspondences List will open
- 4. Select Correspondence



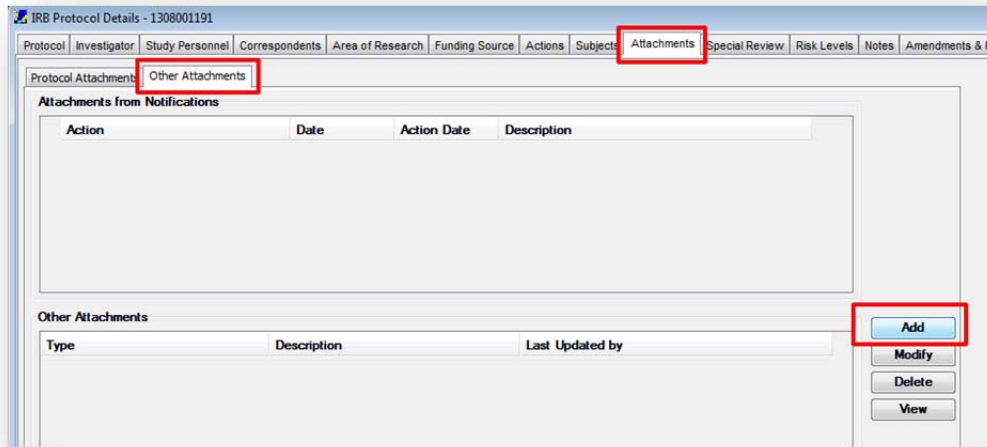
- a. Click checkbox next to appropriate Correspondence template
 - b. Click Save
 - c. Click “View” to open system generated Correspondence memo in separate browser window
 - d. Save Correspondence to desktop with appropriate naming convention
 - Protocol number_YYYY.MM.DD
 - e. Close (do **not** Send from Correspondences List window)
- 5. System Email Notification



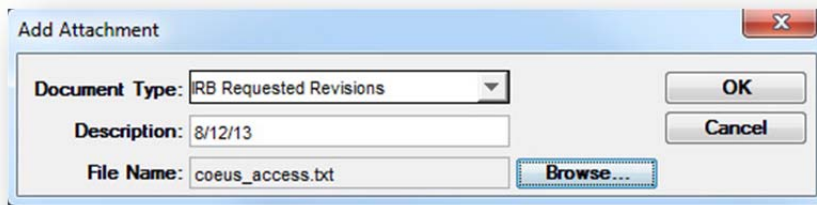
- a. Send Mail screen will automatically open
- b. Add Additional Recipients

COEUS

- Click “Add Person”
 - Complete standard Coeus Person Search
 - Click desired Recipient from results list and click “OK” to add them
- c. Click “Send” to email system notification to listed Recipients
6. Upload Correspondence



- a. Double click listed submission that Revisions were just requested for
- b. Click on the “Attachments” tab, then click the “Other Attachments” sub-tab
- c. Click the “Add” button in the bottom “Other Attachments” section
- d. “Add Attachments” window will open



- e. Document Type: select “IRB Requested Revisions”
- f. Description: enter identifying description per naming convention
 - Protocol number_YYYY.MM.DD
- g. Upload Attachment: complete standard Browse to upload Revisions Requested correspondence that had been saved to desktop (step 6.4.d)
- h. Click “OK” to save attachment
- i. Exit protocol Record