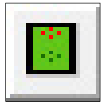
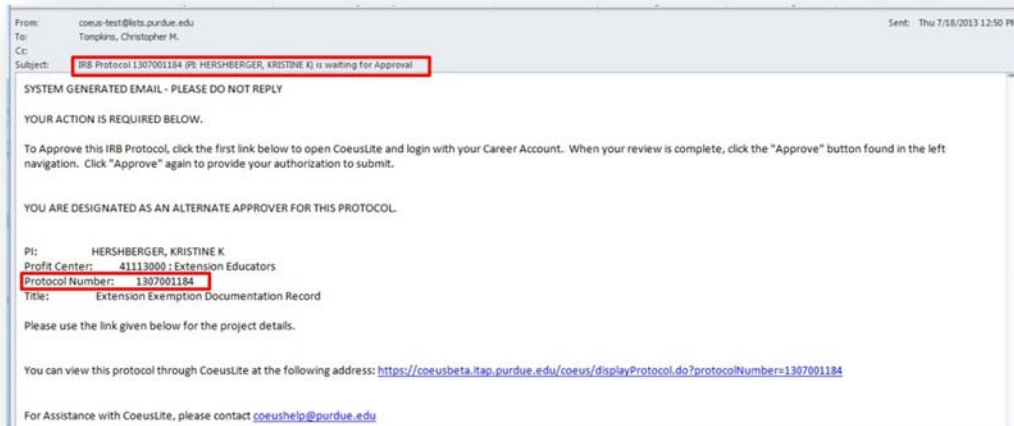


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Coeus Extension IRB Administrative Process – Submission Intake


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 Approval” email is received by Extension Administration:



IRB Protocol Module


To be completed in Coeus Premium IRB Protocol Module by Extension Admin Intake Staff

Step 1: Open IRB Protocol

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” module by going to Maintain > IRB Protocol –or- clicking the “IRB Protocol”  icon.
3. IRB Protocol Search: The standard search window will open. Search by the Protocol number identified in the email notification and click “Find”



NOTE:

- If the search window is accidentally closed, re-open by clicking the “IRB Protocol 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. Open record in Display by double clicking the listed result or going to Edit > Display IRB Protocol

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Step 2: Administrative Intake Review

Complete a review of the Submission content to ensure all required components are present and identify incorrect information when possible.


1. Check Questionnaire (Go to Edit>Questionnaire) to make sure #1 is marked “Yes”
 - a. If marked “No”— you will “Reject” in step 4.5
2. Check Attachments
 - a. Look for:
 - i. Survey
 - ii. Recruitment/Marketing document
 - b. If one is missing— you will “Reject” in step 4.5
 - i. In Routing/Rejection comments, state what is missing

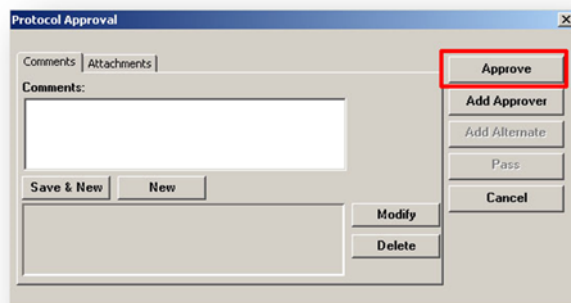
Step 3: CITI Training

1. Identify Protocol Personnel on both Investigators and Study Personnel tabs
2. Check Qualifications: List of current certification is here: X:\Shared\Human Subjects\CITI
3. Make note of Educators who require CITI but do not have it complete
4. CITI Training Review Comment will be entered in Step 5.7

Step 4: Protocol Routing & Approval

1. Open the Protocol Routing: Go to Protocol Actions > Approval/Rejection
2. Select the IRB: CES Admin Map
3. Confirm that “Waiting for Approval” is next to each listed name under *Sequential Step 1*
4. **APPROVE**

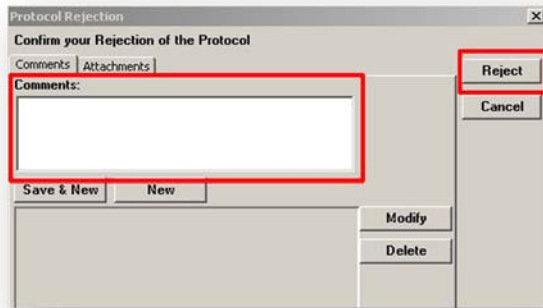
 NOTE: Approving protocol will acknowledge acceptance and move to IRB Protocol Submission module



- a. Click the “Approve” button, Protocol Approval window will open
 - b. Click the “Approve” button again.
- OR-

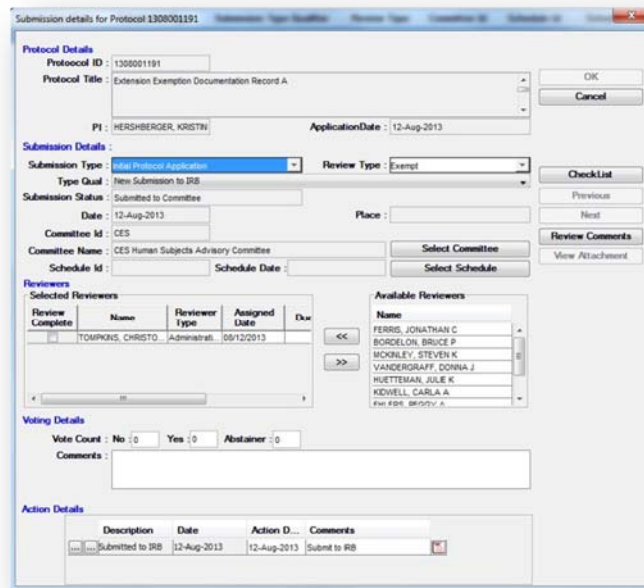


5. REJECT



- a. Click the "Reject" button, Protocol Rejection window will open
 - b. Enter DETAILED reasons for Rejection in Comments box (REQUIRED)
 - c. Click "Reject" again
6. Close Routing window if still open and close record to return back to IRB Protocol Search Results screen

Step 5: Open Protocol Submission Details (still in Protocol  Hands-off)



1. Open Protocol Submission Details window:
 - a. Go to Edit > View Submission Details

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- b. Submission Details window will open
2. Confirm/Revise Submission Type - Submission Types can usually be identified by the Protocol #.
 - a. Initial Protocol Application: will only have the base number. Ex: 1201000385
 - b. Amendment: will have the base number plus "A" suffix. Ex: 1201000385A003



NOTE: If CES Admin receives a submission with a suffix that begins with a "R" it is a Renewal Submission used by HRPP and was created incorrectly. Reject in Routing and comment back to Investigator.

3. Confirm Submission Type Qualifier - The Submission Type Qualifier should denote either the first time submission for review or submission of revisions
 - a. "New Submission to IRB" – first submission of a new protocol or amendment
 - b. "Revisions Requested by IRB" – any submission of revisions

*See next step to determine Submission of Revisions

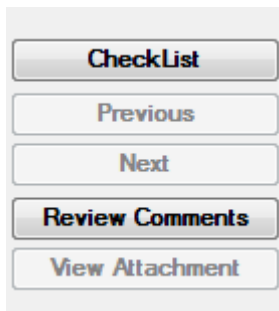
Determine Submission of Revisions - If the submission is a response to requested revisions, the "Previous" button will be available.

- a. Click the "Previous" button
- b. Look in the Action Details section at the bottom of the Submission Details screen
- c. If "Specific Minor Revisions Required" or "Substantive Revisions Required" is listed in the previous Details, submission should be Investigator submitted revisions

4. Update Review Type field

New Submission

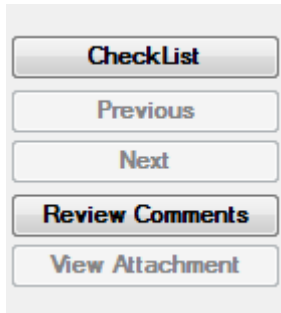
- a. Click the "Review Type" field to open dropdown
- b. Select "Exempt"
- c. Click Checklist and select first checkbox. Then click "OK" to close



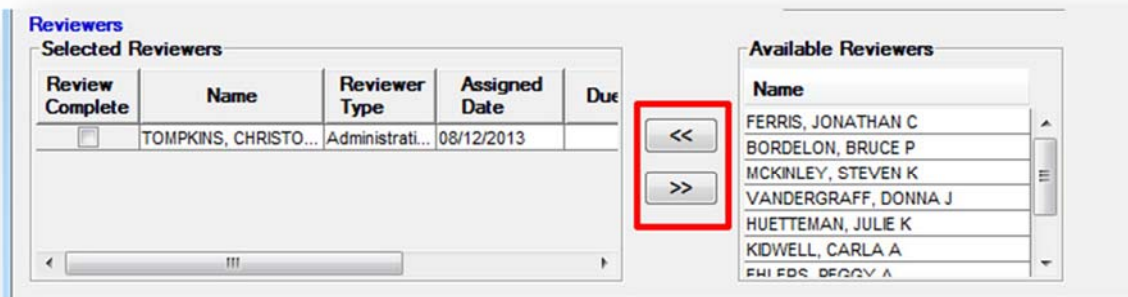
Amendment

- a. Click "Review Type" field to open dropdown
- b. Select "Expedited"
- c. Click Checklist and select number 16 (Amendment to Exempt Research resulting in continued Exempt status). Then Click "OK" to close


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5. Select/Save IRB Committee
 - a. Click the "Select Committee" button
 - b. Click "CES Human Subjects Advisory Committee" to highlight. Click "OK"
6. Assign Applicable Administrative Reviewer



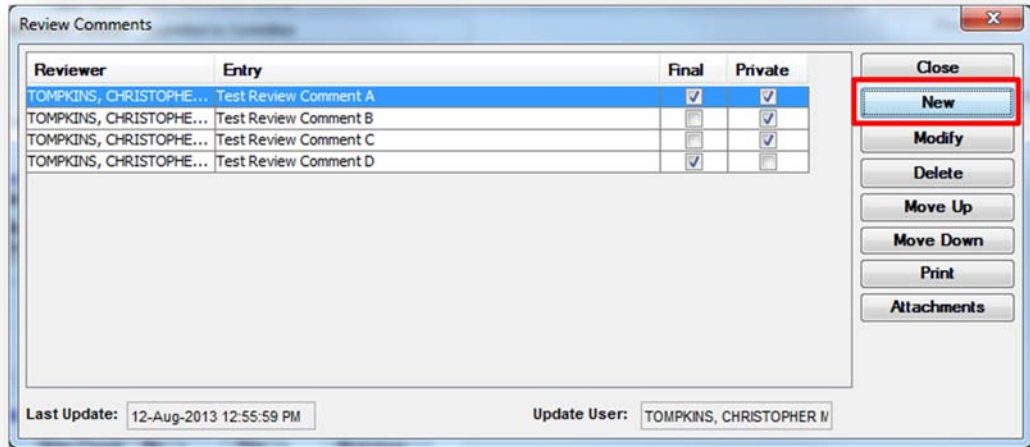
- c. Click the name of the Administrator in the Available Reviewers list on the right
- d. Click the left pointing double arrow icon to assign
- e. Update Reviewer Type to be "Administrative"

 **NOTE:** *Email notification will be automatically sent to assigned Administrative Reviewer once Submission Details are Saved.*

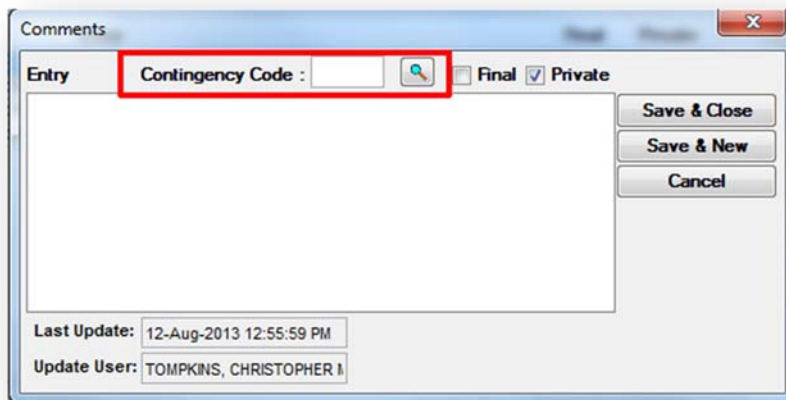
7. Enter CITI Training Comment

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- a. Click "Review Comments"



- b. On the Review Comments window, click "New"



- c. **If CITI COMPLETE:**
 - Manually enter "CITI certification is current"
- d. **If CITI INCOMPLETE:**
 - Manually enter "CITI certification is NOT current" and comments on training/qualifications discrepancies for all applicable Protocol Personnel in text box
 - Send CITI email via Outlook to Educator. Email template is located here: X:\Shared\Human Subjects\CITI
 - When Julie completes final review, she will check on CITI and confirm it is current. She will modify Marion's Review Comments and update with CITI completion date.
- e. Check both the Final and Private boxes

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- f. Click "Save & Close"
- g. Click "Close" on Review Comments window
8. Click "OK" to save and close Submission Details window
9. System generated email notification will automatically be sent to CES Administrative Reviewer


Miscellaneous Items

A. Running reports

1) To run monthly quick status report (in Protocol Hands-off):

- a) Complete "Protocol Search" using the following search criteria:
 - i. Unit: 41113000
 - ii. Protocol Status: "Routing in Progress" or "Pending in Progress"
 - iii. After updating Excel sheet, notify Julie so she can review

2) Clean-up, if needed



- a) To clean up/delete old records that are still "Pending" or created in error:
 - i. Open record in Protocol module 
 - ii. Go to Edit>Protocol Roles or second row>first icon
 - iii. Add yourself as "Aggregator" (Click, drag, and drop). If your name is not in Users list, select "Users" button on right and search.
 - iv. Click OK to close Protocol Roles window
 - v. Close/Exit record
 - vi. Make sure correct record is highlighted in IRB Protocol search results window
 - vii. Go to Edit>Delete IRB Protocol or second row>forth icon (eraser)
 - viii. Confirm that you want to delete the record

3) To see where protocol is in Routing & Approval process :

- a. Double click to open record
- b. Go to Actions>Approval/Rejection
- c. You can select the different stops on the map to get the details of who approved at each stop or which stop is waiting for approval
- d. You can also see previous route maps by selecting the "Show Previous Submission" button at the top of the current map. To go back even further, select the Previous button on the right.

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4) Submission Statuses

- a. Routing in Progress (Protocol module ) = Jennifer
- b. Pending (Submission module or Historic ) = Jennifer
- c. Submitted to Committee (Submission module) = Julie

5) Email Subjects

- a. Waiting for Approval = Jennifer & Julie receive; Jennifer takes action
- b. Waiting for Review = Jennifer has completed Admin check-in and assigned to Julie

5) Completing Administrative Corrections

 NOTE: Administrative Corrections may only be done when starting from Search Results list with submission highlighted. USE THESE SPARINGLY.

1. Select submission from results list
2. Go to: Edit > Administrative Correction
3. Enter Comment and click "OK"
4. Make necessary modifications/corrections
5. Save