

Work Instructions

TITLE:	Reviews – Full and Expedited SRC (New Protocols, Continuing Reviews, Amendments)		
EFFECTIVE DATE:	05/30/2019	REVIEWED BY:	OHRS

SYNOPSIS

These work instructions indicate how to navigate to and perform SRC reviewer assignments for expedited and full New Protocols, Continuing Reviews and Amendments.

Step 1: Selecting a Workspace and identifying assignments

1. Upon logging in to the system, scroll down to the “**All Tasks**” menu. The “**All Task**” menu is where you’ll be able to view and access your reviewer assignments.
2. Review your “**All Tasks**” menu; if you have a reviewer assignment, the “**Task Type**” will indicate “**Reviewer Assignment.**” The “**Description**” of the task will indicate your role as the reviewer, whether your reviewing for the full or expedited SRC and the type of submission (i.e., new protocol, amendment, continuing review, etc.). The “**All Tasks**” menu can be sorted by any of the column names to help organize and prioritize your reviewer assignments.

Step 2: Navigating submissions and performing reviews

1. Click the paper and pencil edit icon in the “**Click to Open**” column next to any of your reviewer assignments from your “**All Tasks**” menu referenced above.
2. Navigate to the “**General Information**” tab. Review the study staff list under “**Study Personnel**” to see if you are listed as a member of the study staff. If you are a member of the study staff or are otherwise conflicted and cannot perform the review, contact a member of OHRS immediately so they can reassign the reviewer.
3. Navigate to the “**Reviewer Checklist and Comments**” tab.
4. Under “**Reviewer Check List,**” click the paper and pencil edit icon in the “**View/Edit**” column in your review assignment row.
5. This will bring you to your reviewer checklist that you must complete in order to perform your review. Once you’re finished with each section, advance through the form to the next section by selecting the “**Save and Continue to Next Section**” button in the top right-hand corner.
6. In the first section of the checklist, review each submission document by clicking on their hyperlinked name.
 - a. To make comments directly on submission application forms, click the conversation icon on the right-hand side of the screen next to each individual section of the form; when you do this, a free text box will appear. Add your comments and click the “**Save Comment**” button. To get back to the reviewer checklist, click the “**Back**” button in the top right-hand corner.
 - b. When reviewing submission documents other than application forms (i.e., protocol documents, diaries, IDB’s, etc.), click the hyperlinked name of the document.
 - a. In the new page, find and click the document icon.
 - b. To add comments directly to these submission documents, click the “**Add Comment**” button on the top right-hand side of the document.
 - c. Enter your comments in the free text box that appears and click “**Save.**”
 - d. Click “**Back**” when finished.
7. Once you arrive at the “**Reviewer Checklist**” section of the form, provide your determination for each prompt and indicate any comments or conditions related to each area as follows:

- a. To add a comment or condition click either the “**Add Multiple Conditions**” or “**Add a New Condition**” button.
 - b. Indicate a “**Condition Type.**” The system provides three “**Condition Types,**” but please utilize only two of the following options:
 - i. **Conditions That Must Be Addressed** = These are conditions that the study team must reply to secure approval of the submission
 - ii. **Comments** = These are informational only and do not require any action on behalf of the study team
 1. **Please Note:** If you are reviewing an expedited submission and are going to refer the submission to the full board for review, do not use the “**Conditions That Must Be Addressed**” option.
 - c. Select the appropriate “**Condition Category**” based on your role as a reviewer.
 - d. Enter your comment or condition in the “**Condition Content**” free text field and click “**Save the Condition.**”
8. Once you reach the “**Comment and Condition Review**” section, review any comments or conditions you made throughout your review process. Additionally, under the “**Form Comment/Condition Review**” sub-section, if you made any comments directly to any submission forms, indicate whether those comment are “**Major**” (a condition that must be addressed) or “**Minor**” (a comment only) by selecting the appropriate radio buttons associated with each comment.
- a. **Please Note:** If you are reviewing an expedited submission and are going to refer the submission to the full board for review, do not mark any comments as “**Major.**”
9. Once your review is complete, select the “**Yes**” radio button in the “**Review Complete**” section of the form. Click “**Exit Form**” when prompted.
10. Once you have completed the assignment, it should no longer appear in your task list. Review of the submission is complete.

Reviewing Responses to Conditions

1. When assigned a review of responses to conditions, you will have a “**Task Type**” in your “**All tasks**” queue with the “**Description**” of “**(Your Name) has been assigned as the reviewer on a submission response form.**”
2. Click the paper and pencil edit icon in the “**Click to Open**” column.
3. Navigate to the “**Condition**” tab.
 1. Select “**Acknowledged**” or “**Returned**” for each condition in the “**Review Action**” column. If any of the responses indicate that a document was updated, you can navigate to the “**Submission Components**” tab and review the updated document. Once you review the document, return to the “**Condition**” tab to continue with your review of responses.
 2. Click “**Save Condition**” when finished acknowledging or returning any responses.
 - i. If you “**Returned**” any conditions, they will now appear under “**Conditions to be Sent for Response.**” Select the paper and pencil edit icon in the “**Edit**” column under “**Conditions to be Sent for Response.**”
 - ii. In the open text field under “**Condition Content,**” delete the text that is pre-populated from the previous condition and revise to indicate what issues remain with the condition.
 - iii. Click “**Save the Condition.**”
 - iv. Once the system brings you back to the “**Condition**” tab, click “**Save Condition.**”
4. Navigate to the “**Review Checklist and Comments**” tab.
5. Click “**Yes**” for “**Completed?**”
6. Click “**Save the Review Status.**”
7. Review of the responses to conditions is now complete.