

## Work Instructions

<b>TITLE:</b>	<b>Reviews – Full Board IRB (New Protocols, Continuing Reviews, Amendments, AEs/OEs)</b>		
<b>EFFECTIVE DATE:</b>	<b>05/30/2019</b>	<b>REVIEWED BY:</b>	<b>OHRS</b>

### SYNOPSIS

These work instructions indicate how to perform reviews of new protocols, amendments, continuing Reviews and Events for the full IRB.

### 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 IRB 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 Submission Components and Performing Reviews

1. From your “**All Tasks**” menu, click the paper and pencil edit icon in the “**Click to Open**” column next to any of your reviewer assignments. The system will navigate you to the submission review record.
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. If you are able to perform the review, navigate to the “**Reviewer Checklist and Comments**” tab.
4. Under “**Reviewer Check List,**” click the book icon under “**View/Edit**” next to the “**OHRS Regulatory Review**” row.
5. Click the “**Print Friendly**” button in the top right-hand corner. Select the “**PDF Form**” radio button and click “**Apply Selection.**” The document will open as a PDF; keep the document open as a guide as you perform your review.
  - a. **Please note:** The OHRS Regulatory Review Checklist, which has been filled out by the responsible HRC will act as a reviewer guide, indicating what special determinations need to be made and any other submission specific information that the HRC would like to bring to the reviewer’s attention.
6. In iRIS, click the “**Back**” button to navigate back to the submission.
7. Navigate to the “**Submission Components**” tab where you can access and review submission documents.
8. **Reviewing Submission Documents Option 1:**
  - a. Each submission document can be reviewed individually by clicking on the hyperlinked name of the document.
  - b. Click the name of a submission document; the system will automatically open the document.
  - c. When reviewing submission application forms, you can make comments directly on the application by clicking any of the conversation icons on the right-hand side of each section; when you do this, a free text box will appear. Add your comments and click the “**Save Comment**” button. That section of the checklist will now turn green indicating that your comment was added successfully. When you’re

finished reviewing the document, click the “**Back**” button to get back to the other submission components.

- d. When reviewing submission documents such as the protocol and consent form, click the hyperlinked name of the document.
  - i. In the new page, find and click the document icon.
  - ii. To add comments, click the “**Add Comment**” button on the top right-hand side of the document.
  - iii. Enter your comments in the free text box that appears and click “**Save.**”
  - iv. Click “**Back**” when finished.

#### 9. **Reviewing Submission Documents Option 2:**

- a. Rather than reviewing submission documents individually, reviewers can create their own submission packet by click the select all button under “**Include in PDF Packet**” (image below.)



- b. Click the “**Include in PDF Packet**” button and the system will check each checkbox next to the submission documents. Click the “**Create PDF Packet**” button.
  - c. In the new dialogue box that appears, you can rearrange and reorder the submission documents if you prefer to see the submission documents in a particular order. Once you finish rearranging the documents, click the “**Generate PDF Packet**” button.
  - d. The system will automatically generate the PDF packet of all the submission documents.
10. Once you have reviewed the submission documents and have further issues with the submission, navigate to the “**Condition**” tab. If you have no further issues and do not need to add any further comments, skip to #13 below.

#### 11. **Adding Conditions Option 1:**

- a. Conditions and comments can be added one at a time by clicking the “**Add New**” button.
- b. The system will navigate you to a new page to add your condition or comment.
- c. Select a “**Condition Type.**” The system provides three “**Condition Type**” options, but please utilize only the following:
  - i. **Conditions That Must Be Addressed** = These are conditions that the study team must reply to in order to secure approval of the submission.
  - ii. **Comments** = These are informational only and do not require any action on behalf of the study team.
- d. Indicate “**Condition Category**” as either “**Consent**” if the comments are related to the consent or “**Other.**”
- e. Enter your comment or condition in the “**Condition Content**” free text field and click “**Save the Condition.**”

#### 12. **Adding Conditions Option 2:**

- a. Multiple conditions can be added at one time by clicking the “**Add Multiple**” button.
- b. The system will navigate you to a new page to add your condition.
- c. Select a “**Condition Type.**” The system provides three “**Condition Type**” options, but please utilize only the following:
  - iii. **Conditions That Must Be Addressed** = These are conditions that the study team must reply to in order to secure approval of the submission.
  - iv. **Comments** = These are informational only and do not require any action on behalf of the study team.
- d. Indicate “**Condition Category**” as either “**Consent**” if the comments are related to the consent or “**Other.**”
- e. Enter your comments or conditions in the “**Content**” free text field separating each condition or comment by hitting enter and starting a new line. Click “**Save the Condition**” when finished.

13. Once you're finished adding your comments and conditions, and are ready to complete your review, navigate to the **"Review Checklist and Comments"** tab. Click the **"Yes"** radio button under **"Completed?"** next to your review row. Click the **"Save the Review Status"** button. Review of the submission is now complete.