Work Instructions

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

SYNOPSIS
These work instructions indicate how to perform reviews of new protocols, amendments and continuing reviews for the expedited IRB.

Related Documents:
• N/A

Step 1: Selecting a Workspace and identifying assignments

1. Review your "**All Tasks**" menu; if you have a reviewer assignment, the "**Task Type**" will indicate "**Reviewer Assignment.**" This task list includes a number of columns, and can be sorted by any of the column headers.
2. The task "**Description**" will indicate your role as the reviewer and what submission type you've been assigned to as a reviewer.

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 the "**All Tasks**" menu.
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**."
   a. **Please note:** This document, 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.
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 and complete your own reviewer checklist.
6. Navigate back to the OHRS Regulatory Review Checklist in iRIS and click the "**Back**" button to navigate back to the submission.
7. Under "**Reviewer Check List**," click the paper and pencil edit icon in the "**View/Edit**" column in your review assignment row. 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.
   a. In the first section of the checklist, review each submission document by clicking on their hyperlinked name.
   b. To make comments directly on submission application forms, click the conversation icon on the right-hand side of the screen; when you do this, an open text field 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.

DF/HCC
DANA-FARBER / HARVARD CANCER CENTER

    c. When reviewing submission documents other than submission forms (i.e., consent form, protocol documents, etc.), 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.

8. Following along with the OHRS regulatory review checklist, complete each section of your reviewer checklist indicating your determination for each prompt as necessary.

    a. **Please note:** The OHRS Regulatory Review Checklist is only a guide; the HRC could have made an error in their pre-review of the submission or you may disagree with their recommended outcomes, so be sure to review each section and make your determinations based on your independent review rather than relying solely on the information that's provided on the HRC's checklist. The only determination that should match the OHRS Regulatory Review Checklist for each submission is the "**Pre 2018**" or "**Post 2018**" Common Rule prompt as OHRS is checking this information as part of their pre-review of each submission and will provide the reviewer with the correct response.

9. Throughout the checklist, some sections will include a "**Conditions/Comments**" sub-section where you can include comments or conditions. To add a comment or condition click either the "**Add Multiple Conditions**" or "**Add a New Condition**" button.

    i. 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 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

            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.

    ii. Indicate "**Condition Category**" as either "**Consent**" if the comments are related to the consent or "**Other**."

    iii. Enter your comment or condition in the "**Condition Content**" free text field and click "**Save the Condition**."

10. Once you reach the "**Comment and Condition Review**" section, review any comments or conditions you made throughout your review process.

    a. Under the "**Form Comment/Condition Review**" 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.

        i. **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 of your form comments as "**Major**."

    b. Under the "**Checklist Comment/Condition Review**" section, edit any comments by selecting the paper and pencil edit icon in the "**Edit**" column. After making any changes, click "**Save the Condition**."

11. Continue navigating to the next section of the checklist. once your review is complete, select the "**Yes**" radio button in the "**Review Complete**" section of the form. Click "**Exit Form**" when prompted.

12. Once you have completed the assignment, it should no longer appear in your task list. Review of the submission is complete.

DF/HCC
DANA-FARBER / HARVARD CANCER CENTER

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.
   a. 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.
   b. Click "**Save Condition**."
      i. If you "**Returned**" any conditions, 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**."
4. Once the system brings you back to the "**Condition**" tab, click "**Save Condition**."
5. Navigate to the "**Review Checklist and Comments**" tab.
6. Click "**Yes**" under the "**Completed**?" column.
7. Click "**Save the Review Status**."

NCI CCC
A Comprehensive Cancer
Center Designated by the
National Cancer Institute