Core Staff Review – Adverse Event Single Member Review

eResearch Study Workspace

1. Verify **Core Committee Staff** is displayed on the home workspace.

2. Click the **Unassigned** tab.

   **Note:** All unassigned submissions will appear.

3. Click on the Adverse Event **Submission ID** to access the AE/ORIO.

   **Important Workspace Information!**
   - You must go to the **Submission ID** to open the study, *not* the Review Name.
   - Clicking on the **Submission ID** takes you directly to the **Submission Workspace**.
   - All Core Staff reviewing, assigning, approving, etc. is performed from the **Submission Workspace**.
   - **Submission State** displays the current state of the Submission.

   **Staff Notes** displays the last action that was performed on the submission.

Assign Owner

1. Verify the Current State is **Core Committee Staff Review**.

2. Click **Assign Owner**.
3. Click Select to assign the Primary Owner.
4. Type the first three letters of the last name and click Go.
5. Select the staff member.
6. Click OK.

Notes:
- Individuals are added to the Select Person list once they log into eResearch for the first time and have been given the role of IRB staff. If the staff member you are attempting to add does not appear in this list, ask the individual to log into eResearch or use the New User activity in the study workspace and then request access for that person.
- Secondary Core Staff Owner and Other Core Staff Owners can be added following the above procedure. However, every owner works within the same Reviewer Checklist.

7. Click OK on the Assign Owner screen.

1. Verify the current state is Core Committee Staff Review.
2. The following information is displayed:
   - Submission Information – This area displays information such as the Study Team Member, Core Committee, Staff Owner, Committee Information and Required Ancillary Approvals.
   - My Reviews – This section shows the submission name, reviewer role, state and recommendation.
   - Tabs – This area displays Correspondence, Notes, IRB, All Issues, Documents, Change Tracking, and History tabs.
3. At My Reviews, click on Click here to edit review.

Note: This takes you directly into the Revision Checklist.
4. If desired, click Print Version of the Submission to open the submission.

5. The Submission opens in a separate window.

Note: The submission can be moved around and resized within the eResearch window to allow for review of the submission and checklist simultaneously.

Reviewer Checklist

The column headings in the checklist are as follows:

1. Section identifies the section of the submission that needs to be reviewed.

Note: You can click on the section number to go directly to that section of the smartform.

2. Reviewer Checklist Item displays the question and sub-set question needed for review.

3. Click Condition Met if the condition in the Reviewer Checklist item has been met.

Note: At the end of the checklist, you can auto populate any responses in the Condition Met column that have not been completed. (See next section for details.)

4. Click Publish to Study Team to publish the identified issue to the study team.

Note: If this button is checked, all study team members can view the identified issue and corresponding comments once the review is submitted. If it is not checked, only committee members will have access to this data.

5. Comments can be added for reference at a later date.

Note: When a condition is not met, a comment is required and will be converted to an identified issue upon submission.

6. To be Reviewed by can be used if an issue needs to be reviewed by another reviewer. Use the drop down box to select the reviewer.
7. Notes can be added to **General Issues for Study Team and/or Staff**.
8. **Reviewer Notes** can be added and will only appear on the staff reviewers’ workspace.
9. Click on **Add** to include **Supporting Review Documents**, if desired.

10. Enter a title for the uploaded document. **Note:** Entering a title is optional. If you do not enter a title, the title becomes the filename of the document.
11. Use the **Browse** button to locate the document on your computer.
12. Select the file to upload.
13. Click **Open**.
14. Click **OK**.

15. Choose the desired **Reviewer Recommendation**.
16. Check the **Check here...** box if you would like to auto populate any Condition Met responses that were not completed. Checklist items with comments will be populated with No and items without comments will be populated with Yes.
17. Click **Continue**.
18. Check **Click here if you are ready to submit this review.**

19. Click **Finish.**

**Note:** You can edit and resubmit the checklist at any time until the determination for the submission is processed and the study team is notified.
Select Single Member Review

1. Verify that the current state is Core Committee Staff Review.
2. Click on Single Member Review
3. Select to assign the Primary Reviewer
4. Click OK.

Record Single Member Review Decision

1. Verify that the current state is Validate Single Member Review Decision.
2. Click Record Single Member Review Decision.
3. Choose the appropriate Single Member Review Motion.
4. Click OK.
1. Verify that the current state is **Validate Single Member Review Decision**.

2. Click on **Approve**

3. Optional, select the **Reviews** to be published

4. Choose the **Approval Template**.

5. Review the **Approval Letter**.
   
   **Tip:** Verify that the correct committee, correct signature and correct approval date are displayed

6. Click **OK**.