Submitting Requested Changes

Reviewers may request the PI/Study Team make changes to a submission (e.g., Study Application, Amendment, Adverse Event/Other Reportable Information and Occurrence (AE/ORIO), Continuing Review, or IBC Registration). These submissions appear in the **Require Action by Study Team** list under the **My Inbox** tab of your Home Workspace.

The following procedure demonstrates submitting requested changes to Core Staff on a Study Application: the same steps can be applied for any reviewing body and submission type.

### Home Workspace

1. Click the **Name** of the submission to open the submission workspace (i.e., Study Workspace, Amendment Workspace, etc.).

### Study Workspace

Requested changes can be viewed in two locations: the **Activities and Correspondence** list and the **Outstanding Issues** table.

**Notes:**

- One or both of these sections may appear in the submission workspace depending on how changes were requested by the reviewer.

- The State of the submission is **Changes Required by Core Staff**. The reviewing body requesting the changes will be reflected in the State name.

2. Read the instructions/notes describing the requested changes, including any applicable section numbers.

3. Click **Edit Study**.

**Note:** The name of this activity will depend on the submission type (e.g., **Edit AE/ORIO**, etc.).
Study Application

4. Use the Jump to menu to navigate to the section(s) requiring changes.

5. Make the necessary changes (not shown).

Note: Remember to Save your changes before exiting or navigating to a different section.

Study Workspace

6. Click Submit Changes to Core Staff.

Note: The name of the activity may be different depending on the reviewing body that requested the changes.

Submit Changes to Core Staff Window

The system automatically validates that all required sections of the submission are complete before executing the activity. You must address any errors/warnings before continuing.

7. Click the appropriate radio button indicating the changes you made.

8. Enter any Comments for reviewers.

Note: Comments are required if you do not make all of the requested changes.

9. Click OK.

The State of the submission changes back to the previous “review” state (e.g., Core Committee Staff Review).