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.).
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.

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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.

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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.

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Submit Changes to Core Staff Window

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 **Add** if you wish to upload any documents pertaining to the changes.

10. Click **OK**.

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.

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