IBC PI – Responding to Required Changes

Important Information
- There are times when the reviewer requests changes and/or updates to the Registration prior to approving the study.
- If changes and/or updates are needed, the Registration will appear in your Inbox.

Study Staff Home

1. Verify **Study Staff** is displayed on the home workspace.
2. Note that the **Inbox** is active.
   
   **Note:** The Inbox tab displays all submissions that currently require your action.
3. Click on the **Name** of the Registration to open the Registration workspace.

Changes Requested by IBC

4. The following tabs are active:
   - **Correspondence** – Shows all correspondence on the Registration, from initial submission, to Staff Review, to Committee Member Review.
   - **Documents** – Displays links to all documents that have been added to the Registration.
   - **Notes** – Displays all notes requiring a response that the Reviewer has made in the Registration.
   
   **Note:** In the Project Log, we can see that the reviewer is requesting a change prior to approval.
5. Click **Notes**.
Notes Tab

6. **Reviewer Notes** can be filtered by Type, Reviewer Last name or Reviewer First name or the last date the note was modified.

   **Note:** All **Response Required** notes require a response prior to submitting the changes to the IBC. The change request is listed directly under the Response Required field.

7. Click the **Jump To** link to go to the Registration page with a required change.

   **Note:** You can also click **Required Change** or **Response Required!** Click here to respond... to view the change requested by the Reviewer and respond to the request. However, you must edit the Registration to make the requested change.

8. Updated the Registration, as needed.

9. Click on **Response Required!** Click here to respond... to open the Respond to Reviewer Note window.

10. Choose whether you **Agree** or **Disagree** with the Reviewer recommendation.

11. Enter a **Response** to the Reviewer.

12. Click **OK**.

13. Click **Save**.

14. Click **Exit**.
Submit Changes to IBC

15. The Notes tab now displays your response to the request for change.

16. Click Submit Changes to IBC to submit the updated Registration for review.

Important Information: The system will generate an error if you do not respond to all Reviewer Checklist items and attempt to submit the Registration. The Registration cannot be submitted until all checklist items have been completed.

17. Summarize the changes made to the Registration.

18. Click OK.

IBC Committee Review

1. The Registration workspace is displayed.

2. The Correspondence tab shows all correspondence on the Registration.

Note: The Project Log shows that the changes have been successfully submitted to the IBC.