Module 3: Changes and Correspondence

Module 3 Objective:
Covers how to request application changes and communicate with study team, core staff and reviewers.

Important Points:
- eResearch provides multiple methods for Core Staff to communicate with study teams, including requesting changes to the submission, sending correspondence, and adding comments directly to the submission. All change requests, correspondence, and comments are tracked in the eResearch system for future reference.
- When requesting changes to a submission, use the Changes Requested by Core Committee Staff activity. This activity changes the state of the submission, transferring responsibility for the next action to be taken to the study team.
- Changes may also be initiated by Reviewers. If reviewers require additional information or changes from the study team, they have the option to Request Clarification/Change. Core Staff then request changes from the study team using the Changes Requested by Core Committee Staff activity.
- The Post Correspondence activity is used to communicate with all the individuals related to the study but does not change the state of the study. Note that all communications created with the Post Correspondence activity are visible to all eResearch users with access to the study.
- Core staff members can add comments viewable by Core Staff only, or by Core Staff and Reviewers only. These activities allow comments to be added to the submission with no change in the state.

Refer to the table of contents below for the topics covered in Module 3.

Table of Contents

Requesting Changes from the Study Team................................................................. 2
Posting Correspondence......................................................................................... 4
Adding Comments............................................................................................... 6
Uploading Information ......................................................................................... 8
Viewing Submitted Changes.................................................................................. 9
1. **Select Changes Requested by Core Committee Staff.**

2. Enter your **Comments** to the study team in the box.

   **Note:** If you created Issues for the study team in the application, verify that these appear above the **Comments**.

3. Use the **Add** button to attach documents, if needed.

4. Click **OK**.
5. The state of the application is changed and an activity is added to the **Correspondence** tab indicating the request for changes from the study team.

**Note:** A red circle appears on the status meter because study team action is required.

**Note:** Issues marked as publish are published to the study team and require a response.
Important Information

- The **Post Correspondence** activity can be used by anyone with access to the study to communicate with study team members and Core Staff. It does not change the state of the study.

- **Note:** All communication created through the **Post Correspondence** activity is visible to all eResearch users with access to the study.

**eResearch Study Workspace**

1. Click **Post Correspondence**.
2. Enter your Comments to the study team and/or Core Staff.

3. Add documents, if desired.

4. Select the desired recipients of the email notification.

5. Click OK.

Note: The team member and Core Committee Staff selected will receive an email notification of this correspondence.

6. An activity appears under the Correspondence tab indicating that a correspondence was posted.
Adding Comments For Reviewers & IRB Office Staff

Important Information

- The Add Comments activities allow comments to be added to the submission with no change in the state. Core staff members can add comments that are viewed by Core Staff only, or by Core Staff and Reviewers only.

eResearch Study Workspace

1. Click For Reviewers and IRB Office or For IRB Office Staff Only to add a comment.

Comment Window

2. Enter your Comments.
3. Use the Add button to attach documents, if needed.
4. If needed, click the Add button to select who should receive email notification of the correspondence.
5. Click OK.
6. Comments for reviewers and staff display under the IRB tab.

**Note:** Reviewer can also view For Review and IRB office correspondence under the IRB tab in the review workspace.
Uploading Information

Important Information

- Supporting documents can be uploaded to certain sections of the eResearch study application.
- An Add button appears in these sections.

eResearch Study Application

1. Click the Add button to attach supporting documents to the study.

Adding Supporting Documents

2. Enter a title for the document you are uploading or leave it blank.
   **Note:** Entering a title is optional. If you do not enter a title, the filename becomes the title of the document.
3. Use the Browse button to locate the document on your computer.
4. Select the file to upload.
5. Click Open.
6. Click OK.
**Viewing Submitted Changes**

**Important Information**
- When the study team completes the requested changes to the application and submits them for your review, you receive an email notification with a link to the application in eResearch.

**Core Committee Staff Home Page**

1. Once the study team submits the requested contingencies, the submission will display in the Core Staff owner’s **Inbox**.
2. Click on the **Submission ID** in the Inbox.
   **Note:** The state of the staff review displays **Review Study Team Changes**.

**Core Committee Staff Review**

3. Click **View Study** to determine if the contingencies have been met.
   **Note:** The Change Tracking tab displays changes made to the submission.

**Change Log Activity Details Page**

4. Click the **Change Tracking** tab to review the changes made to the submission.
5. The **Activity Details** displays the author, activity date, etc. and all property and documents / tasks / notification changes.