

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.

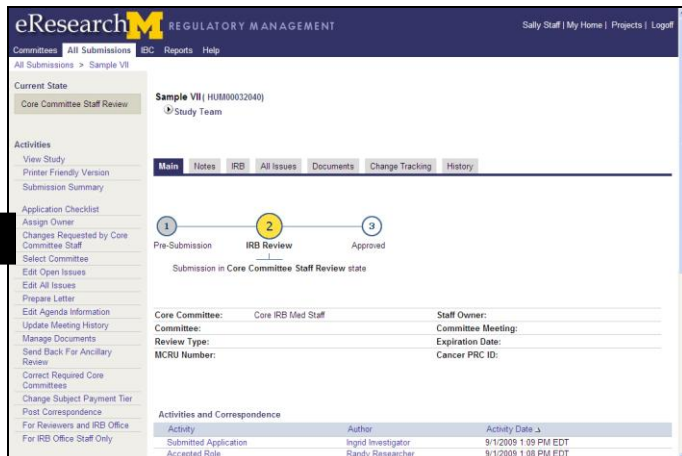
Refer to the table of contents below for the topics covered in Module 3.

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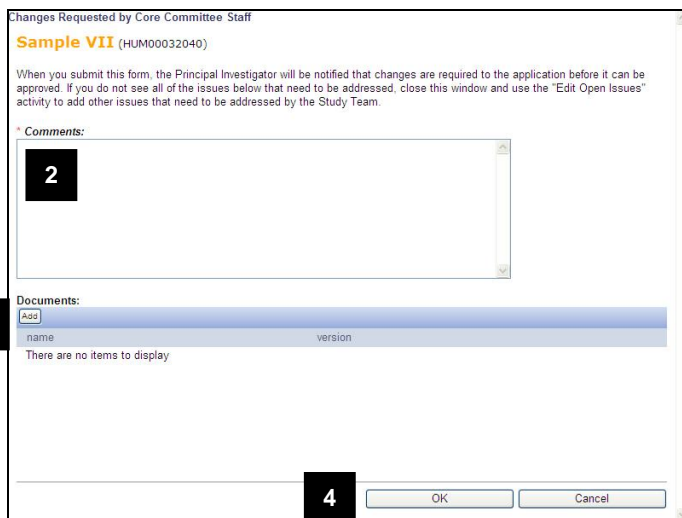
Requesting Changes from the Study Team

eResearch Study Workspace



1. Select **Changes Requested by Core Committee Staff**.

Change Request Window

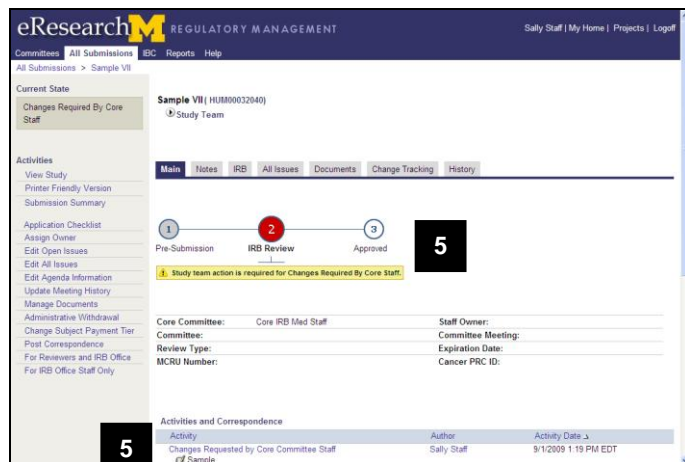


2. Enter your **Comments** to the study team in the box.

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**.

eResearch Study Workspace



The screenshot shows the eResearch Study Workspace interface. The top navigation bar includes links for Committees, All Submissions, ISC, Reports, and Help. The main content area displays the current state of the application, which is 'Sample VII (HUM00032040)' and is owned by the 'Study Team'. The status is 'Changes Required By Core Staff'. A progress bar shows the application is in the 'IRB Review' stage (indicated by a red circle with the number 2), with previous stages being 'Pre-Submission' (1) and 'Approved' (3). A yellow box highlights the message: 'Study team action is required for Changes Required By Core Staff.' Below the progress bar, there are fields for 'Core Committee' (Core IRB Med Staff), 'Staff Owner' (Committee Meeting), 'Committee' (Committee Meeting), 'Expiration Date', 'Review Type', 'MCRU Number', and 'Cancer PRC ID'. At the bottom, there is a table titled 'Activities and Correspondence' with columns for Activity, Author, and Activity Date. The table shows one activity: 'Changes Requested by Core Committee Staff' by 'Sally Staff' on '9/1/2009 1:19 PM EDT'. A black box with the number 5 is overlaid on the bottom left of the screenshot.

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.

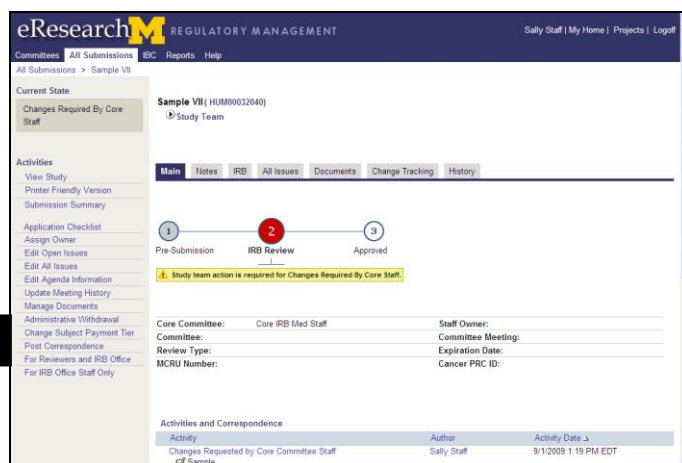
Note: Issues marked as publish are published to the study team and require a response.

Posting Correspondence

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**.

Post Correspondence Window

Post Correspondence
Sample VII (HUM00032040)

Comments and documents are posted to the Study Workspace.

Comments and documents are visible to anyone with access to the study and cannot be deleted. This includes:

- Study Team Members
- Committee Staff
- Committee Members
- Technical Staff
- Regulatory parties

Comments:

2

Revised documents that were originally uploaded in the application should NOT be uploaded here: these documents should be uploaded to the appropriate section of the application. Post Correspondence is a communication tool only, and will not update or submit your application.

For more information on working with documents, see Help.

Attach documents here:

Add

name	version
There are no items to display	

To send a notification of this posted correspondence, you **MUST** check a recipient below.

Study Team Member	Role on Study
<input type="checkbox"/> Randy Researcher (University of Michigan)	Co-Investigator
<input type="checkbox"/> Ingrid Investigator (University of Michigan)	PI

Required Core Committees

☐ IRBMED

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OK Cancel

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.

eResearch Study Workspace

eResearchM REGULATORY MANAGEMENT

Sally Staff | My Home | Projects | Logout

Committees All Submissions ISC Reports Help

All Submissions > Sample VII

Current State

Changes Required By Core Staff

Sample VII (HUM00032040)

Study Team

Main Notes IRB All Issues Documents Change Tracking History

1 Pre-Submission 2 IRB Review 3 Approved

4 Study team action is required for Changes Required By Core Staff.

Core Committee:	Core IRB Med Staff	Staff Owner:	
Committee:		Committee Meeting:	
Review Type:		Expiration Date:	
MCRU Number:		Cancer PRC ID:	

Activities and Correspondence

Activity	Author	Activity Date
Posted Correspondence	Sally Staff	9/1/2009 2:16 PM EDT
Notes and Ideas		
Changes Requested by Core Committee Staff	Sally Staff	9/1/2009 1:19 PM EDT
Sample		
Submitted Application	Ingrid Investigator	9/1/2009 1:09 PM EDT
Accepted Role	Randy Researcher	9/1/2009 1:08 PM EDT

Outstanding Issues

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6. An activity appears under the **Activities and 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.

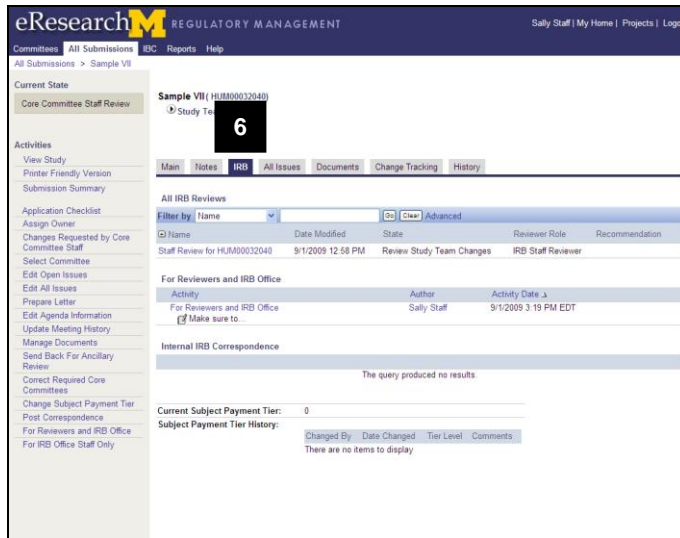
eResearch Study Workspace

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

Comment Window

- Enter your **Comments**.
- Use the **Add** button to attach documents, if needed.
- If needed, click the **Add** button to select who should receive email notification of the correspondence.
- Click **OK**.

eResearch Study Workspace



The screenshot shows the eResearch Study Workspace interface. The top navigation bar includes 'Committees', 'All Submissions', 'IRB', 'Reports', and 'Help'. The user is logged in as 'Sally Staff | My Home | Projects | Logout'. The left sidebar contains a 'Current State' section with 'Core Committee Staff Review' selected, and an 'Activities' section with various options like 'View Study', 'Printer Friendly Version', 'Submission Summary', 'Application Checklist', 'Assign Owner', 'Changes Requested by Core Committee Staff', 'Select Committee', 'Edit Open Issues', 'Edit All Issues', 'Prepare Letter', 'Edit Agenda Information', 'Update Meeting History', 'Manage Documents', 'Send Back For Ancillary Review', 'Correct Required Core Committee', 'Change Subject Payment Tier', 'Post Correspondence', 'For Reviewers and IRB Office', and 'For IRB Office Staff Only'. The main content area shows the 'IRB' tab for 'Sample VII (HUM00032040)'. The 'IRB' tab is active, and the 'All IRB Reviews' section displays a table with columns: 'Name', 'Date Modified', 'State', 'Reviewer Role', and 'Recommendation'. The table contains one entry: 'Staff Review for HUM00032040' with a date of '9/1/2009 12:58 PM', state of 'Review Study Team Changes', and reviewer role of 'IRB Staff Reviewer'. Below this, the 'For Reviewers and IRB Office' section shows a table with columns: 'Activity', 'Author', and 'Activity Date'. The table contains one entry: 'For Reviewers and IRB Office' with author 'Sally Staff' and activity date '9/1/2009 3:19 PM EDT'. The 'Internal IRB Correspondence' section shows a message: 'The query produced no results.' The 'Current Subject Payment Tier' is 0. The 'Subject Payment Tier History' section shows a table with columns: 'Changed By', 'Date Changed', 'Tier Level', and 'Comments'. The table contains one entry: 'There are no items to display'.

6. Comments for reviewers and staff display under the **IRB** tab.

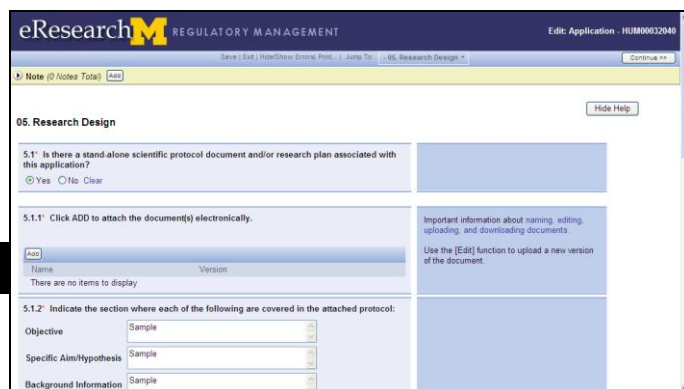
Note: Reviewer can also view For Review and IRB office correspondence under the IRB tab in the review workspace.

Uploading Information

Important Information

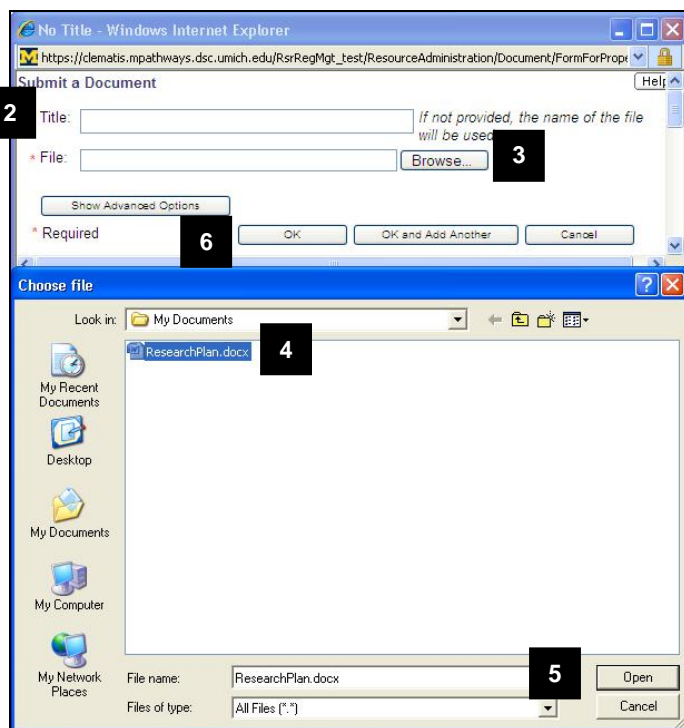
- Supporting documents can be uploaded to certain sections of the eResearch study application.
- An **Add** button appears in these sections.

eResearch Study Application



- Click the **Add** button to attach supporting documents to the study.

Adding Supporting Documents



- 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.

- Use the **Browse** button to locate the document on your computer.
- Select the file to upload.
- Click **Open**.
- 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.

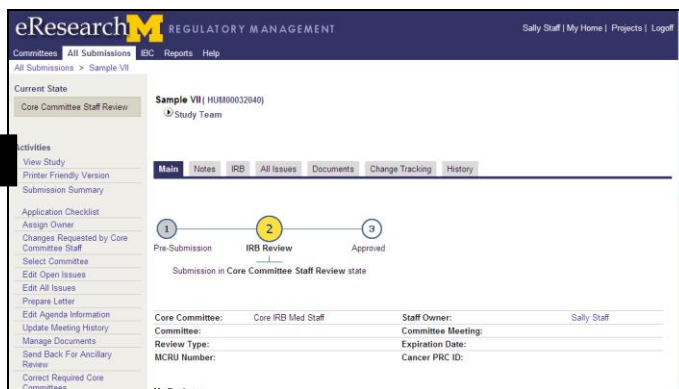
Core Committee Staff Home Page



- Once the study team submits the requested contingencies, the submission will display in the Core Staff owner's **Inbox**.
- Click on the **Submission ID** in the Inbox.

Note: The state of the staff review displays **Review Study Team Changes**.

Core Committee Staff Review



- Click **View Study** to determine if the contingencies have been met.

Note: The Change Tracking tab displays changes made to the submission.

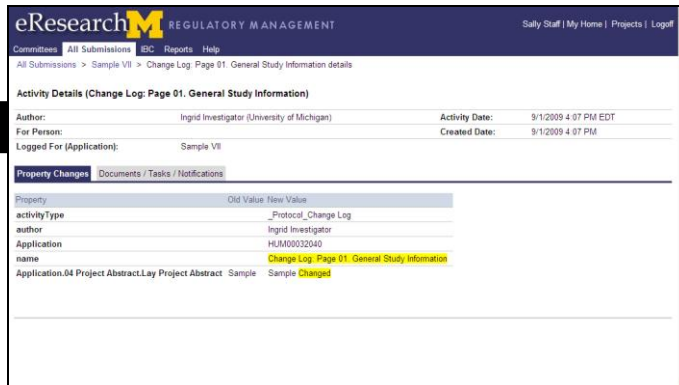
Change Log Activity Details Page



- Click the **Change Tracking** tab to review the changes made to the submission.

Activity Details

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eResearchM REGULATORY MANAGEMENT Sally Staff | My Home | Projects | Logout

Committees All Submissions EIC Reports Help

All Submissions > Sample VII > Change Log: Page 01. General Study Information details

Activity Details (Change Log: Page 01. General Study Information)

Author:	Ingrid Investigator (University of Michigan)	Activity Date:	9/1/2009 4:07 PM EDT
For Person:	Ingrid Investigator	Created Date:	9/1/2009 4:07 PM
Logged For (Application):	Sample VII		

Property Changes Documents / Tasks / Notifications

Property	Old Value	New Value
activityType		_Protocol_Change Log
author		Ingrid Investigator
application		HJM00032040
name		Change Log: Page 01. General Study Information
Application.04 Project Abstract.Lay Project Abstract Sample		Sample Changed

5. The **Activity Details** displays the author, activity date, etc. and all property and documents / tasks / notification changes.