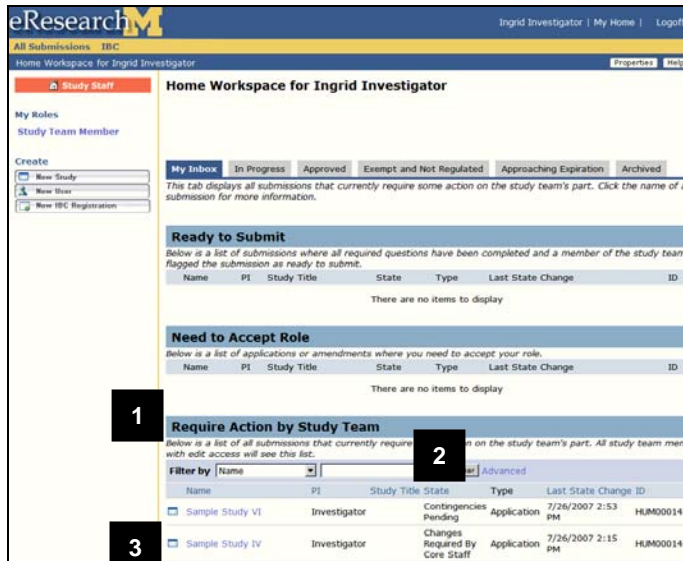


Submitting Requested Changes

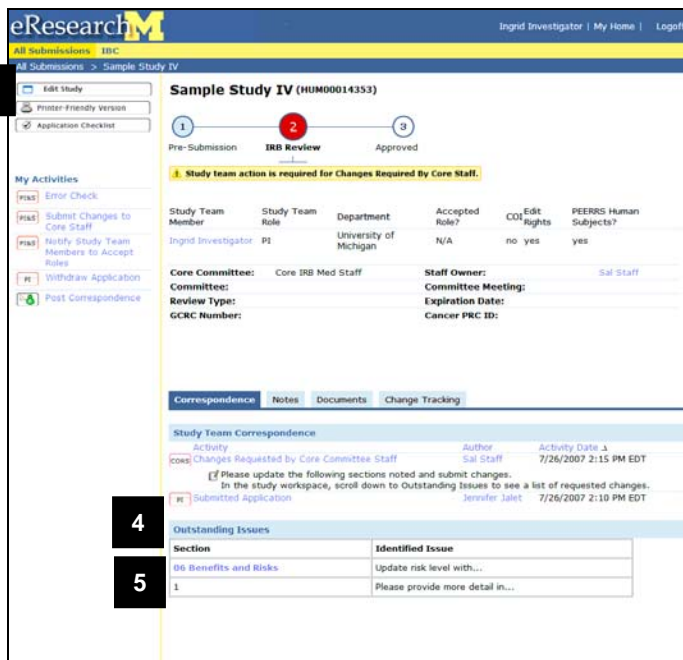
Requested changes can be made to an Application, Amendment, AE/ORIO, Continuing Review, or IBC Request. This procedure show example screen shots from an application.

eResearch Home Workspace



1. Submissions that require action appear in the **Require Action by Study Team** section of **My Inbox**.
2. The **State** column displays the current state of the study.
3. Click the **Name** of the study to view more detail.

eResearch Study Workspace



4. View the requested changes in the **Outstanding Issues** section of the **Correspondence** tab.
5. Click **Edit Study** to make the requested changes to the submission and save the changes or click on the blue text under Outstanding Issues to go directly to that section of the study.
 - Click **Exit** to exit the submission and return to the **Study Workspace**.

eResearch Study Workspace

- When you have completed all required changes, click



from the Study Workspace or the End of the Application.

Submit Changes to Core Staff

- Indicate the changes made in response to the **identified issues**.

- Enter **Comments**, if applicable.

Note: If all requested changes were not made, a comment is required.

- Click .

eResearch Study Workspace

Sample Study IV (HUM00014353)

Pre-Submission **IRB Review** Approved

Submission in Core Committee Staff Review state

Study Team Member	Study Team Role	Department	Accepted Role?	CO ₂ Edit Rights	PEERS Human Subjects?
Ingrid Investigator	PI	University of Michigan	N/A	no yes	yes

Core Committee: Core IRB Med Staff Staff Owner: Sal Staff

Committee Meeting: Committee Meeting:

Review Type: Expiration Date:

GRC Number: Cancer PRC ID:

10 Correspondence Notes Documents **11** Change Tracking

Study Team Correspondence

Activity	Author	Activity Date
Submitted Changes to Core Staff	Ingrid Investigator	7/30/2007 2:59 PM EDT
Changes Requested by Core Committee Staff	Sal Staff	7/26/2007 2:15 PM EDT

Please update the following sections noted and submit changes.
In the study workspace, scroll down to Outstanding Issues to see a list of requested changes.

Submitted Application Jennifer Jalec 7/26/2007 2:10 PM EDT

Outstanding Issues

- A record of the submitted changes appears in **Correspondence**.
- Click **Change Tracking** to view the specific changes.

Change Tracking Tab

Sample Study IV (HUM00014353)

Pre-Submission **IRB Review** Approved

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

Study Team Member	Study Team Role	Department	Accepted Role?	CO ₂ Edit Rights	PEERS Human Subjects?
Ingrid Investigator	PI	University of Michigan	N/A	no yes	yes

Core Committee: Core IRB Med Staff Staff Owner: Sal Staff

Committee Meeting: Committee Meeting:

Review Type: Expiration Date:

GRC Number: Cancer PRC ID:

Correspondence Notes Documents **12** Change Tracking

Activity Log

Activity	Author	Activity Date
Change Log: Page 08: Subject Description	Ingrid Investigator	11/20/2006 10:35 AM
Change Log: Page 09: Subject Description		

- Click **Change Tracking** to view the details about each change.
- Note:** Click the page reference to go to the specific section of the study application.

Change Log Activity Details Page

14

Activity Details (Change Log: Page 08, Subject Description)

13

Property	Old Value	New Value
activityType		_Protocol_Change Log
author		Ingrid Investigator
Application		HLN0005441
name		Change Log: Page 08, Subject Description
Application.11 Subjects.Inclusion Exclusion Criteria	Inclusion...	Inclusion show includes
Application.11 Subjects._attribute33_text	Inclusion...	Inclusion show includes

13. The **Old Value** and **New Value** display the changed values for each property.

14. In the breadcrumb trail, click the name of the study to return to the **Study Workspace**.

Note: The submission will appear in your **In Progress** tab of your Home Workspace.