Module 6: Validating Decisions

Module 6 Objective:
Covers how Core Staff members process the decisions of the reviewers on each eResearch submission through a decision validation.

Refer to the table of contents below for the topics covered in Module 6.

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Validating Decisions Overview

Core Staff members are responsible for processing the decisions of the reviewers on each eResearch submission. This is done through a decision validation.

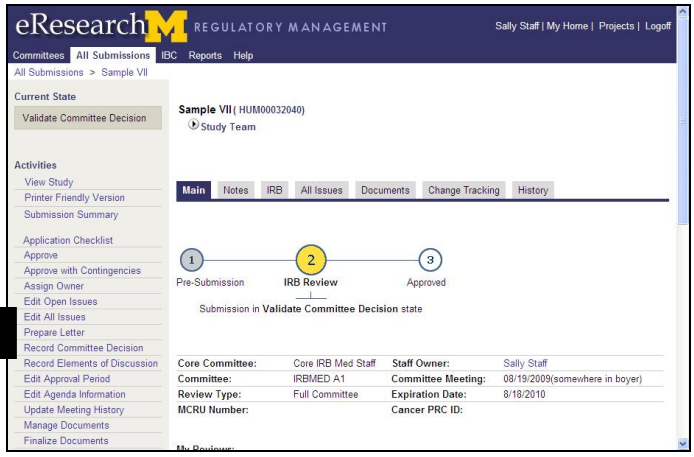
- **Validate Decision** – A validation activity is provided for each decision type, which changes the state of the submission to reflect the decision. Some decisions send a letter to the study team. The possible decision types include:
    - **Approve** – The Approval letter is sent to the study team. It includes the approval date and the expiration date. (See page 5)
    - **Approve with Contingencies** – The Approved with Contingencies letter is sent to the study team. This letter contains the contingencies that must be completed before the study team can begin their research. (See page 6)
    - **Disapprove** – The Disapproved letter is sent to the study team, informing them that the IRB has not approved the study. (See page 12)
    - **Action Deferred** – No letter is sent to the study team. (See page 13)
    - **Table** – No letter is sent to the study team. (See page 14)
    - You can prepare the letter to be sent to the study before you complete the Validate Decision activity. This letter can be saved for use during the Validate Decision activity. See page 3 for more information.

Preparing Letters Prior to Validating Review Decisions (Optional Step)

Important Information

Letter templates are provided in eResearch for communicating various decisions to the study team. These templates can be edited during the **Validate Decision** step. If extensive edits to the letter template are required, the Core Staff may use the **Prepare Letter** step to complete the edits prior to validating the decision.

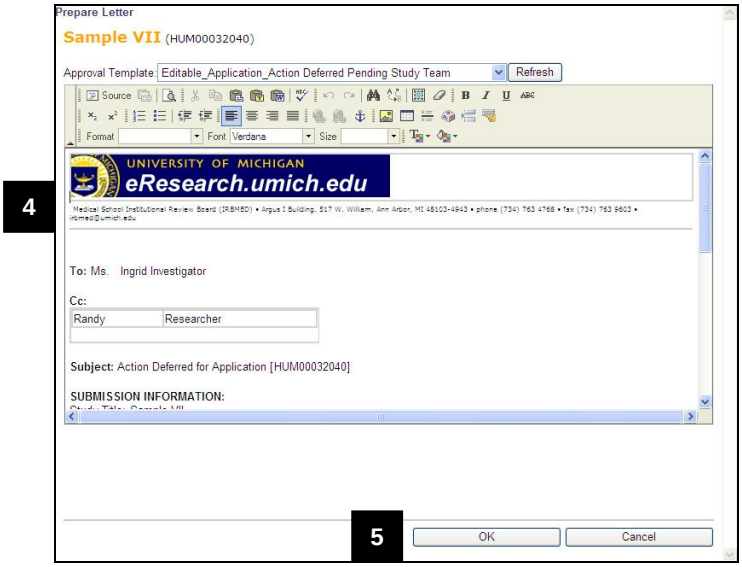
eResearch Study Workspace



1. From the Study Workspace, click **Prepare Letter**.

Prepare Letter Window

2. Select the appropriate **Approval Template** from the drop-down menu.
3. Click the down arrow to open the template editor toolbar.

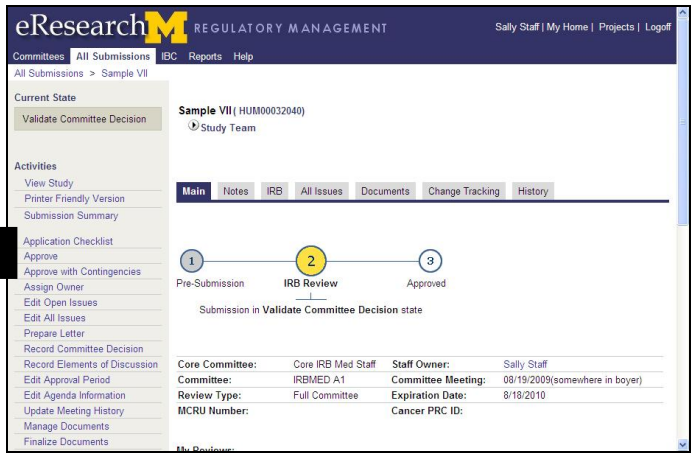


4. Edit the letter.
5. Click **OK**.

Note: This action does not send the letter to the study team.

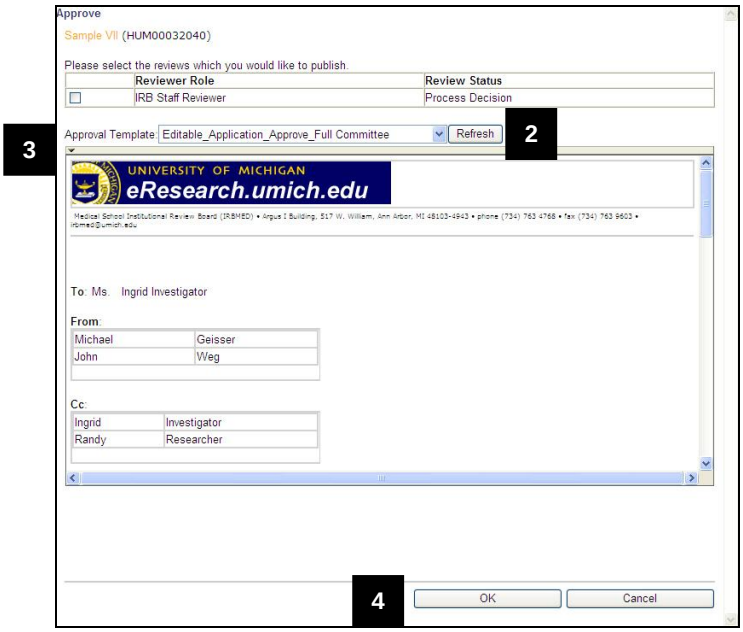
Approve

eResearch Study Workspace



1. Click **Approve**.

Approve Window



2. Select the appropriate letter template from the **Approval Template** drop-down menu.

Note: If you created a letter using the **Prepare Letter** step, select **Saved_Application** from the **Approval Template** drop-down menu to access the prepared letter.

3. Edit the letter, if necessary.
4. Click **OK**.

Note: This action sends the letter to the study team and changes the state of the submission to **Approved**.

Approve with Contingencies

Important Information

In the event a submission is approved with contingencies, extra steps are required to complete the approval process. The basic steps to approve a study that has contingencies are:

1. Edit the contingencies for the submission.
2. Issue an Approve with Contingencies decision, which sends a letter to the study team detailing the contingencies that must be met before the research can begin.
3. When the study team submits the required contingencies, defer the study to the designated reviewer to review the changes.
4. If the contingencies have been met, use the Edit Open Issues activity to enter a completion date for the contingencies.
5. Issue an Approval letter to the study team.

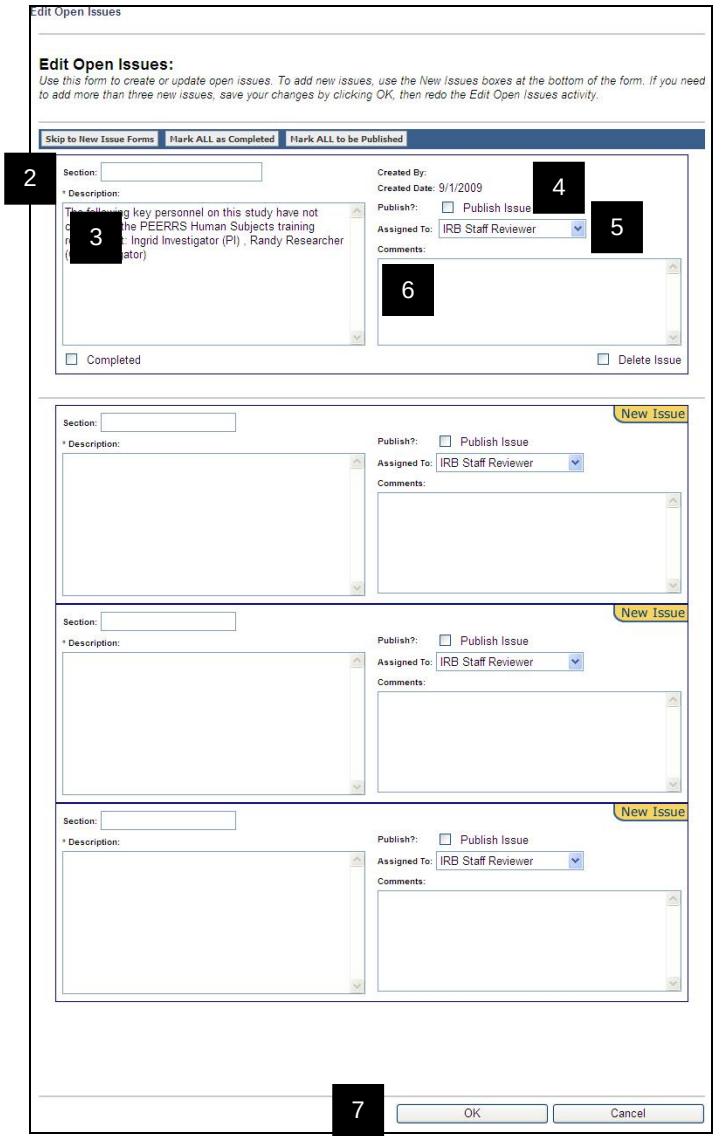
STEP 1 – Edit Contingencies

eResearch Study Workspace

1

1. Select **Edit Open Issues**.

Edit Contingencies Edit Window



For each issue:

2. Enter the **Section** that the issue is related to.
3. Enter a **Description** of the issue.
4. If the issue should be published, select **Publish Issue**.
5. If applicable, select which Reviewer is assigned to the issue.
6. If desired, enter **Comments**.
7. Click **OK** when you have entered all issues.

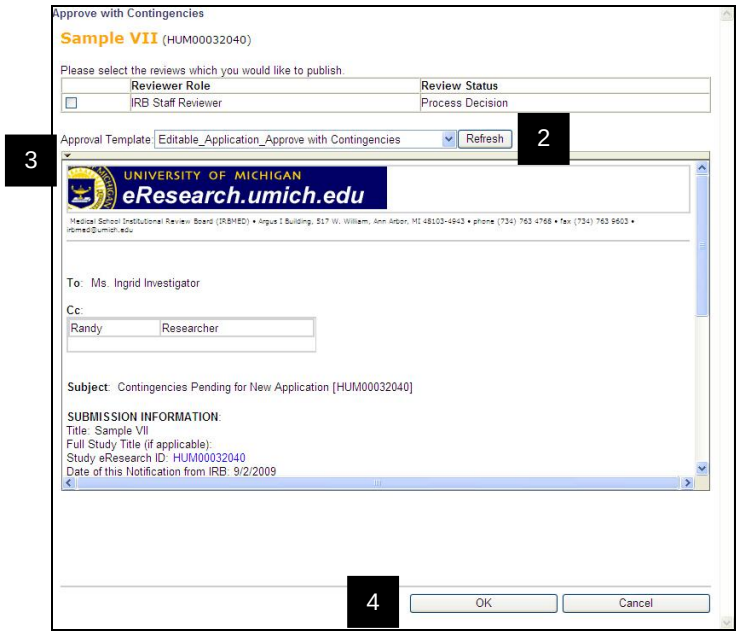
   Note: The issue(s) will appear under the issues tab in the Study Workspace.

STEP 2 – Send Approve with Contingencies Letter

eResearch Study Workspace

1. Click **Approve with Contingencies**.

Approve with Contingencies Window



2. Select the appropriate letter template from the **Approval Template** drop-down menu.

Note: If you created a letter using the **Prepare Letter** step, select **Saved_Application** from the **Approval Template** drop-down menu to access the prepared letter.

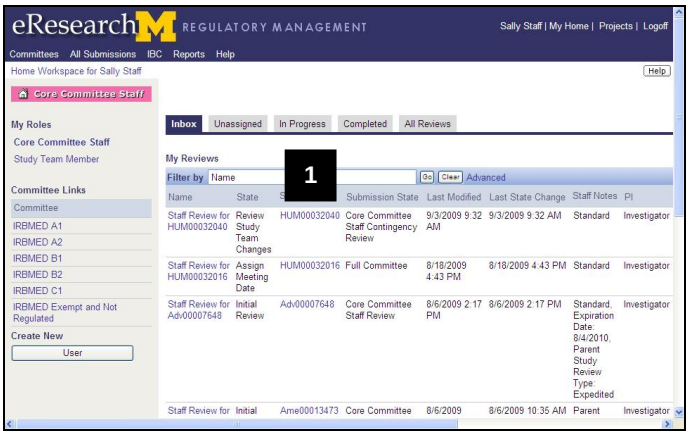
All issues marked as publish issue should appear on the approval letter.

3. Edit the letter, if necessary.
4. Click **OK**.

Note: This action sends the letter to the study team and changes the state of the submission to **Contingencies Pending**.

STEP 3 – Refer to Reviewer

eResearch Home Workspace



1. Once the study team submits the requested contingencies, the submission will display in the Core Staff owner's **Inbox**.

eResearch Study Workspace

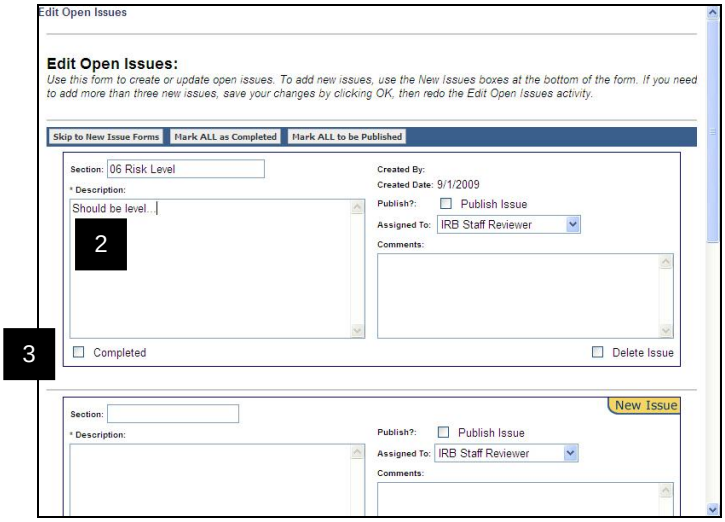
2. Click **View Study** to determine if the contingencies have been met.
3. If necessary, click **Refer to Designated Reviewer**.

STEP 4 – Enter Completion Date for Contingencies

eResearch Study Workspace

1. Select **Edit Open Issues**.

Edit Open Issues Window



For each issue:

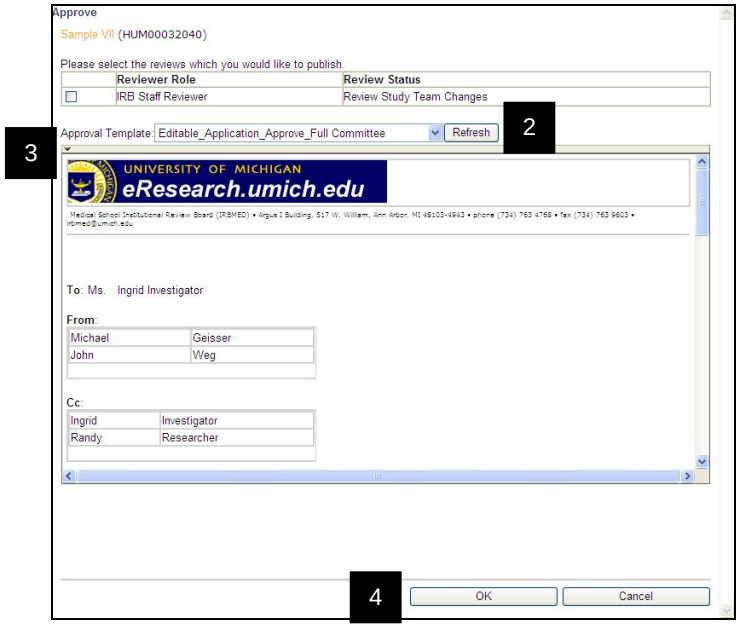
2. If applicable, update the information about the issue(s).
3. If the issue is complete, select **Completed**.
4. Click **OK**.

STEP 5 – Issue Approval Letter

eResearch Study Workspace

1. Click **Approve**.

Approve Window



2. Select the appropriate letter template from the **Approval Template** drop-down menu.

Note: If you created a letter using the **Prepare Letter** step, select **Saved_Application** from the **Approval Template** drop-down menu to access the prepared letter.

3. Edit the letter, if necessary.
4. Click **OK**.

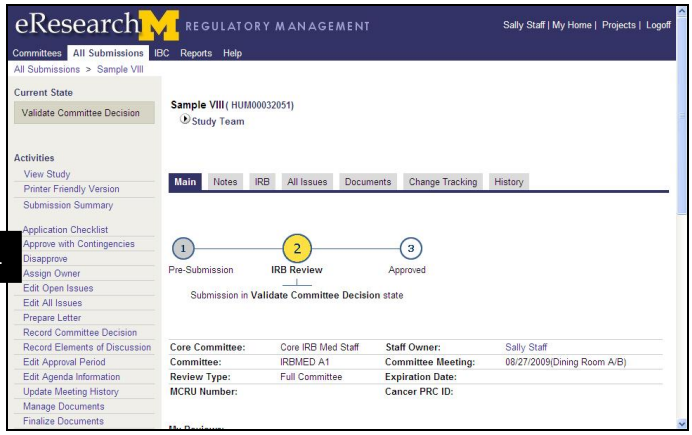
Note: This action sends the letter to the study team and changes the state of the submission to **Approve**.

Disapprove

Important Information:

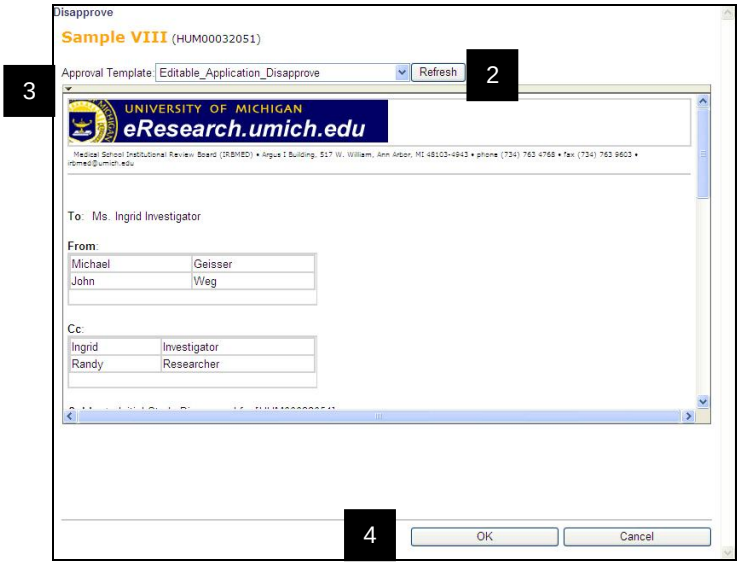
The PI has the right to rebut or decline the right to rebut when a study is disapproved.

eResearch Study Workspace



1. Click **Disapprove**.

Disapprove Window



2. Select the appropriate letter template from the **Approval Template** drop-down menu.

Note: If you created a letter using the **Prepare Letter** step, select **Saved_Application** from the **Approval Template** drop-down menu to access the prepared letter.

3. Edit the letter, if necessary.
4. Click **OK**.

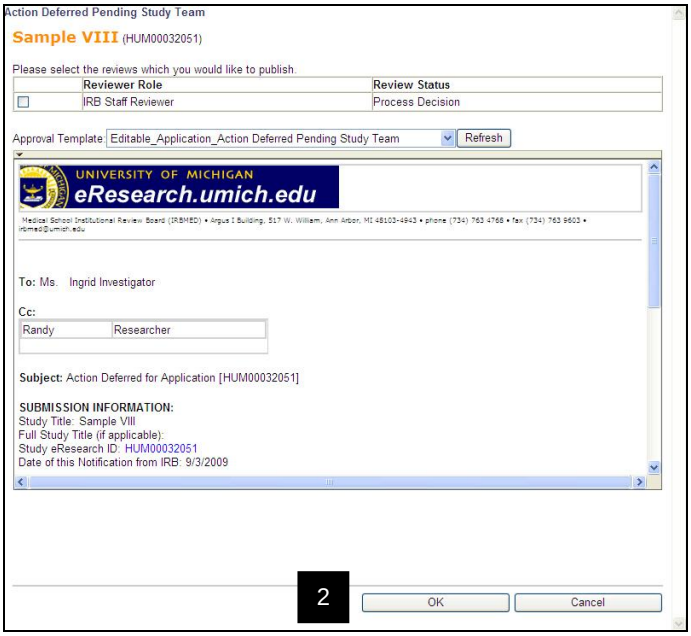
Note: This action sends the letter to the study team and changes the state of the submission to **Disapproved**.

Action Deferred

eResearch Study Workspace

1. Click **Action Deferred Pending Study Team**.

Action Deferred Window



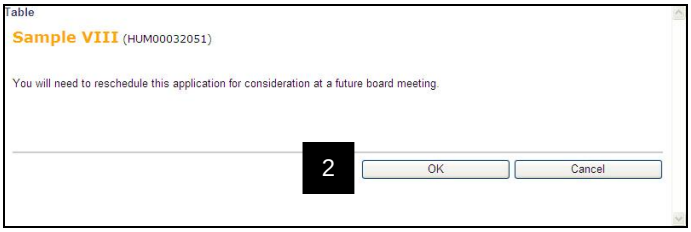
2. Click **OK**.
   - The study returns to the **Core Committee Staff Review** state.
   - See the Requesting Changes procedure for more information on requesting changes from the study team.
   - Once changes have been submitted, you must reassign the study to a new meeting for review.

Tabled

Approve Window

1. Click **Table**.

Approve Window



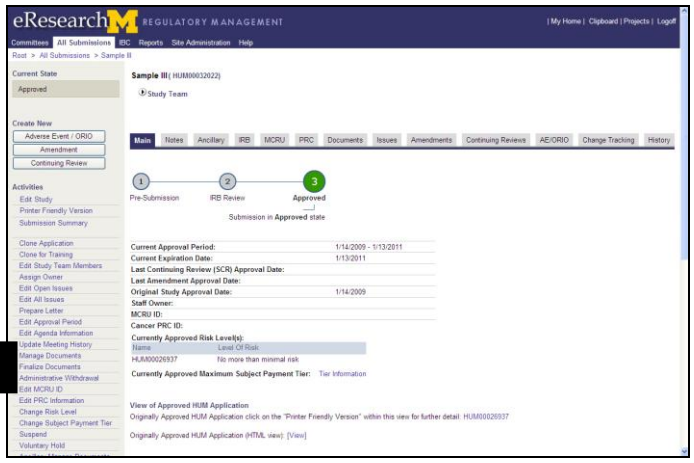
2. Click **OK**.
   - The study is tabled for the current meeting. You will need to select a new meeting where the study can be reviewed.

Finalizing Documents

Important

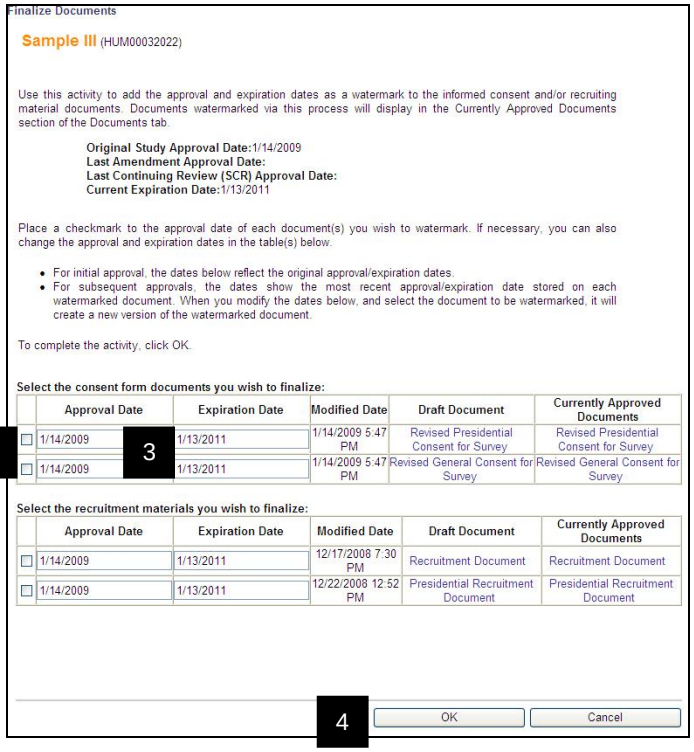
When the study is approved, Core Staff finalize the consent forms for the study. Finalizing the consent forms moves the documents into the Finalized Documents area and, if the documents were composed with the correct templates, watermarks the documents with the IRB Name, Study Number, Approval Date, and Expiration Date. Documents provided as Microsoft Word documents are also converted to PDF.

eResearch Study Workspace



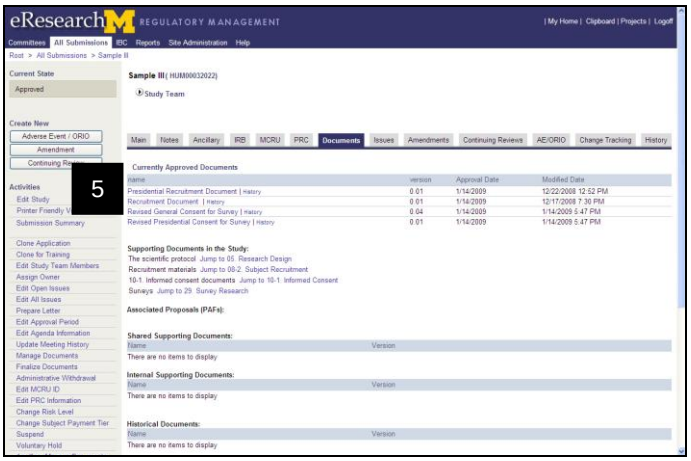
1. Click **Finalize Documents**.

Finalize Documents Window



2. Select the Consent Form documents and/or Recruitment materials to finalize.
3. Verify the dates and edit, if necessary.
4. Click **OK** to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.

Study Workspace



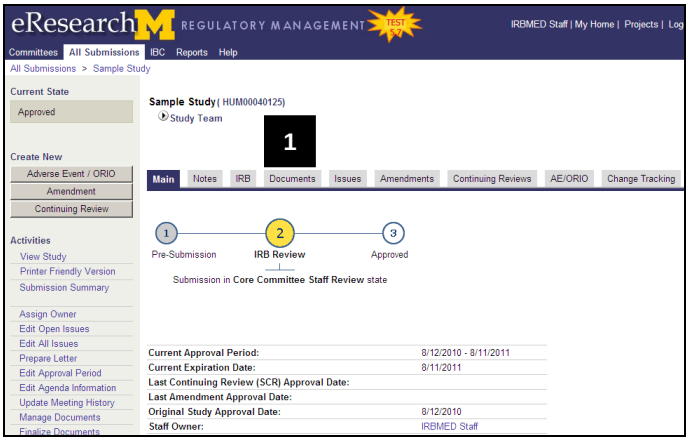
5. Finalized documents are moved to the **Currently Approved Documents** section on the **Documents** tab.

Manage Documents
(includes workaround for documents that fail Finalize Documents activity)

Important Information

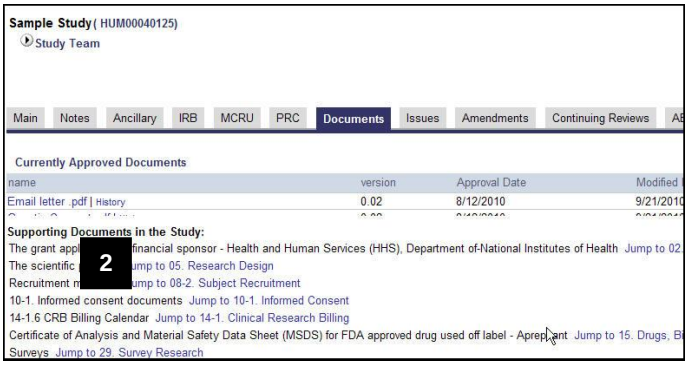
- If a document fails to finalize or it should not be stamped, this activity can be used to move documents to the Currently Approved section of the Documents Tab

eResearch Study Application



1. Click **Documents**.

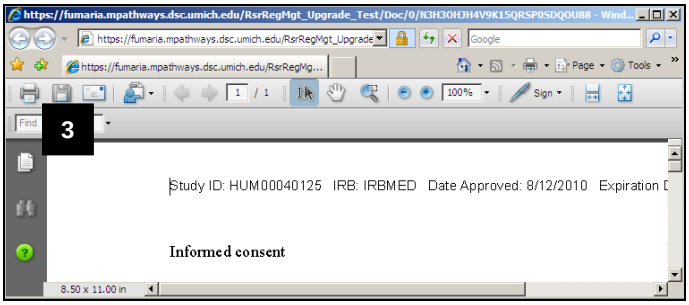
Documents



2. Click the link for the document(s) you want to download.

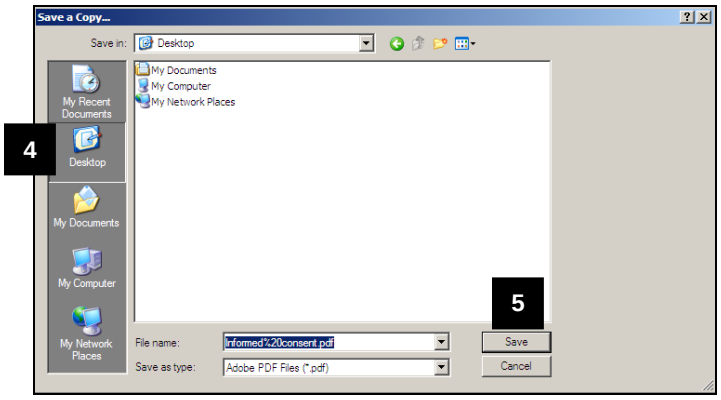
Note: This will take you to the section of the application where the document has been uploaded by the study team.

Document Sample



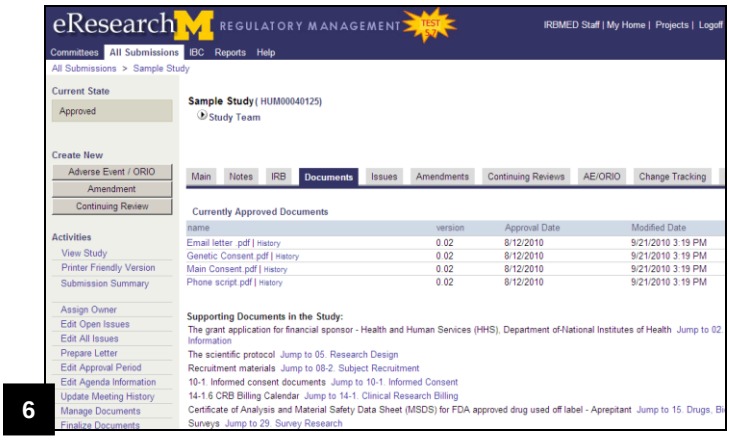
3. Enter the header or footer information into the document and select **Save** icon.

Save a Copy Window



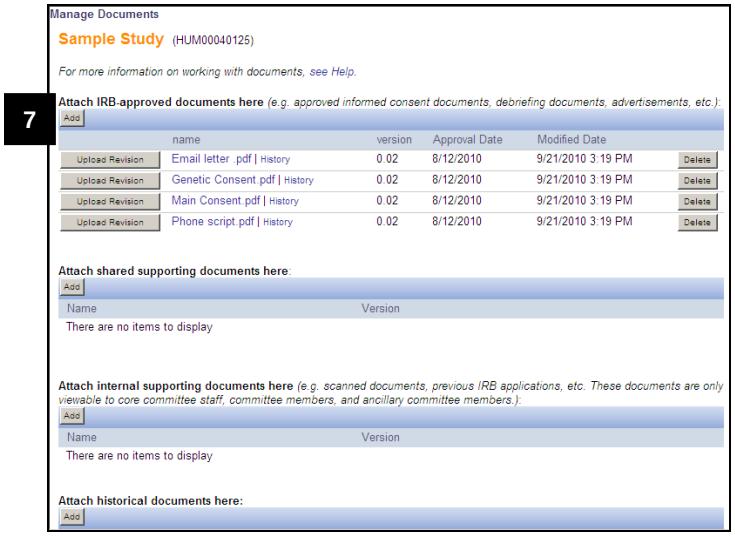
4. Click **Desktop**.
5. Click Save.

Documents



6. Click **Manage Documents**.

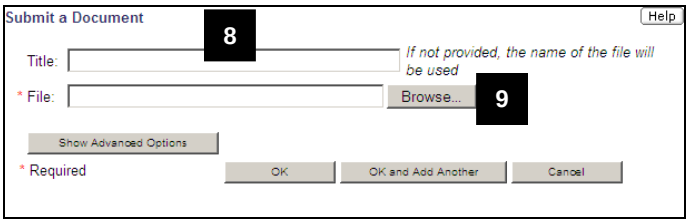
Manage Documents



7. Four categories of documents appear:
   - **IRB-approved**
   - **Shared Supporting**
   - **Internal Supporting**
   - **Historical**

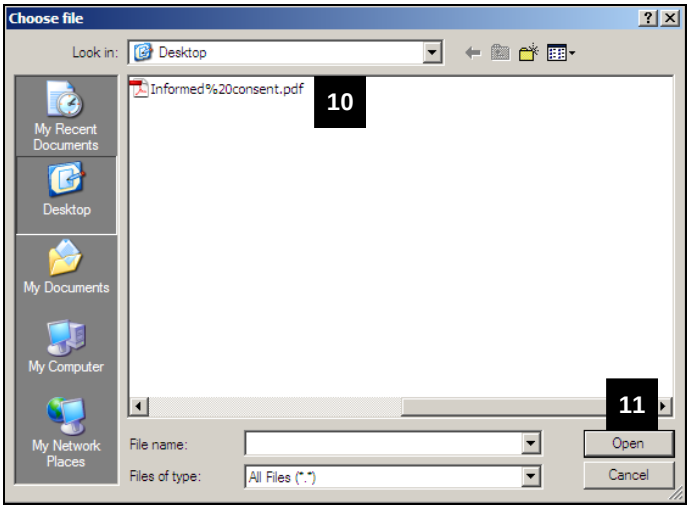
   Select the appropriate category and click Add.

Submit a Document



8. Type a title for your document in the **Title** field.
9. Click Browse...

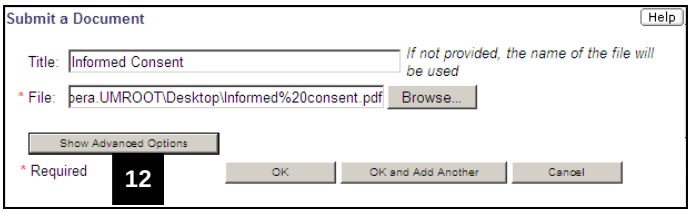
Choose File Window



10. Select file to upload.
11. Click Open

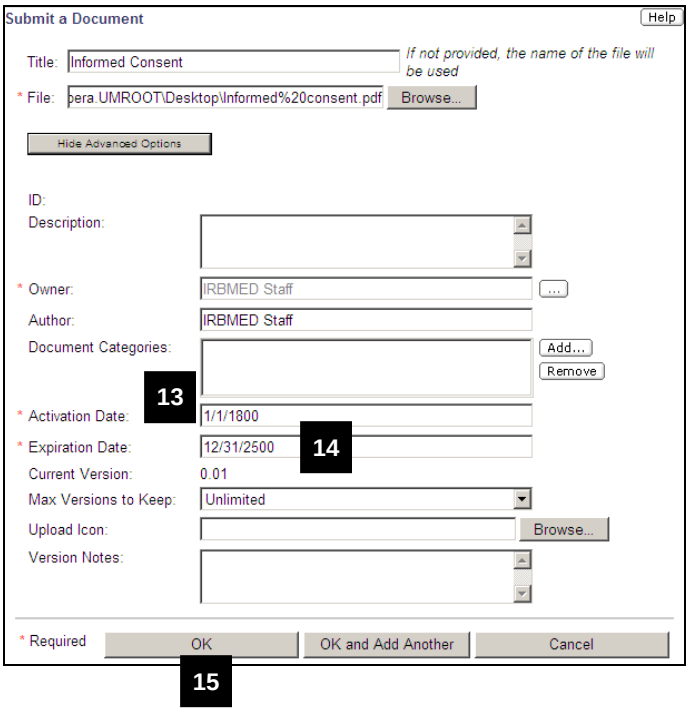
Note: The document will not automatically convert to a pdf. Ensure you have the document in your prefered format prior to uploading.

Submit a Document



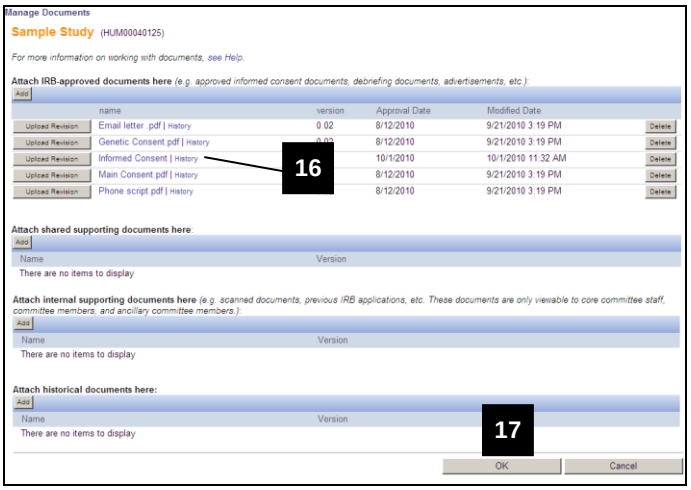
12. Click Show Advanced Options

Submit a Document



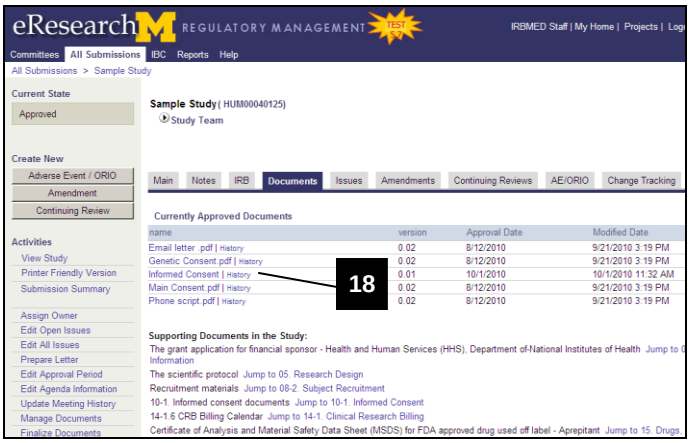
13. Type the document's Approval Date in the **Activation Date** field.
14. Type the document's Expiration Date in the **Expiration Date** field.
15. Click OK.

Manage Documents



16. Note your document appears in the list.
17. Click Add to upload another document, or click OK if you're finished uploading.

Documents



18. Note your document appears in the list under the **Documents** tab.