Module 2: Reviewing Online Submissions

Module 2 Objective:
Covers how to review applications for human subject research in eResearch.

Refer to the table of contents below for the topics covered in Module 2.

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Applications are submitted for review in eResearch. Reviewing online submissions will be covered later in this document.

The actions listed below are some of actions that can be performed from My Activities on the workspace:

- **Assign Owner**: Changes the owner of the submission.
- **Changes Request by Core Committee Staff**: Notifies the PI that changes to the application are required before they can be approved.
- **Select Committee**: Selects the committee that will be responsible for reviewing the application.
  
  **Note**: This only applies to IRBMED, PRC, and GCRC.
- **Edit Identified Issues**: Used to add, change, and delete the outstanding issues for the submission.
- **Prepare Letter**: Used to prepare the submission outcome letter.
  
  **Note**: This function is used to prepare any of the letters.
- **Edit Agenda Information**: Used to add staff notes to the agenda and edit conflict of interest information.
- **Manage Documents**: Used to add and/or delete documents that appear under the documents tab in the application workspace.
- **Send Back to Ancillary Review**: Moves the application back to Ancillary Committee Review.
- **Correct Required Core Committees**: Used to send the application to a different IRB.
- **Post Correspondence**: Used to post comments and documents to the study workspace.
- **For Reviewers and IRB/PRC/GCRC Office**: Used to post comments and documents to the study workspace where they can be viewed and/or downloaded by all Core Office Staff, Committee members and Reviewers (comments are not viewable by study team members).
- **For IRB/PRC/GCRC Office Staff Only**: Used to post comments and documents to the study workspace where they can be viewed and/or downloaded by IRB/PRC/GCRC Office Staff only (not viewable by Study Team Member or Committee Members).
1. Verify that [Core Committee Staff] is displayed on the home workspace.

2. Click the [Unassigned] tab.

   **Note:** All unassigned submissions will appear.

3. All Unassigned submissions are now displayed.

4. Click on the Submission ID to access the study.

**Important Workspace Information!**

- You must go to the Submission ID to open the study, not the Review Name.
- Clicking on the Submission ID takes you directly to the Submission Workspace.
- All Core Staff reviewing, assigning, approving, etc. is performed from the Submission ID area.
- Submission State displays the current state of the Submission.
- Staff Notes displays both the auto-generated and staff edited information about the submission.
Assign Owner

Select Person

5. Click Assign Owner.

6. Click Select... to assign the Primary Owner.

7. Type the first three letters of the last name and click Go.

8. Select the staff member.

9. Click OK.

Notes:

- Individuals are added to the Select Person list once they log into eResearch for the first time and have been given the role of IRB staff. If the staff member you are attempting to add does not appear in this list, ask the individual to log into eResearch or use the New User activity in the study workspace and then request IRB staff access for that person by contacting the MAIS Help Desk.

- Secondary Core Staff Owner and Other Core Staff Owners can be added following the above procedure. However, every staff owner works within the same Staff Reviewer Checklist.

10. Click OK on the Assign Owner screen.
11. Verify the name of the owner now assigned to the study.

12. Click **My Home** to return to your **Home Workspace**.

13. If you selected yourself as the owner, the study now appears in your **Inbox**.
Important Information

- Applications can be assigned for review in eResearch in one of four ways:
  - **Not Regulated Determination** – The submission does not require IRB approval. A letter is prepared and sent to the study team, and the submission is stored in the Exempt & Not Regulated section of eResearch. (See page 25)
  - **Exempt Determination** – IRB Staff determines that the submission is exempt from review. (See page 22)
  - **Expedite Review** – The submission requires review by a selected committee member only. The committee is selected and a designated reviewer is assigned. The submission is not scheduled for a review meeting. (See page 13)
  - **Single Member Review** – Adverse Event
  - **Full Committee** – The submission requires review by the full IRB committee. A committee is selected and primary and secondary reviewers are assigned. You can also assign additional reviewers as needed. The submission is scheduled for review at a meeting. Meeting decisions are recorded in eResearch by the Core Staff. (See page 28)

Reviewing Online Submissions involves two major components:

- Complete Staff Reviewer Checklist
- Process Review Decision (review types listed above)
Staff Reviewer Checklist

Important Information:

Reviewing a submission requires two major components:

- Complete Staff Reviewer Checklist
- Process the review decision

This procedure details how to complete the Staff Reviewer Checklist. The last section of the Staff Reviewer Checklist differs based on whether you select:

- Not Regulated Determination
- Exempt Determination
- Expedite Review
- Single Member Review
- Full Committee

**eResearch Home Workspace**

1. Select the submission to review by its Submission ID.

**Important Workspace Information!**

- You must go to the **Submission ID** to open the study, **not** the Review Name.
- Clicking on the Submission ID takes you directly to the **Submission Workspace**.
- All Core Staff reviewing, assigning, approving, etc. is performed from the Submission Workspace.
- **Submission State** displays the current state of the Submission.
- **Staff Notes** displays the last action that was performed on the submission.
2. Verify the current state is **Core Committee Staff Review**.

3. The following information is displayed:
   - **Submission Information** – This area displays information such as the Study Team Member, Core Committee, Staff Owner, Committee Information and Required Ancillary Approvals.
   - **My Reviews** – This section shows the submission name, reviewer role, status and recommendation.
   - **Tabs** – This area displays Correspondence, Notes, IRB, All Issues, Documents, Change Tracking, and History tabs.

4. At My Reviews, click on **Click here to edit review** to open the Staff Reviewer Checklist (Staff Review page).

5. If desired, click **Print Version of the Submission** to open the submission.

6. The **Printable Version of the Submission** opens in a separate window which can be referenced when completing the Staff Reviewer Checklist.

**Note:** The submission can be moved around and resized within the eResearch window.
7. Verify the **Section** of the submission that needs to be reviewed.
   **Note:** You can click on the section number to go directly to that section of the Smartform.

8. Read the **Reviewer Checklist Item** (question and sub-set question needed for review).

9. Click **Condition Met** if the condition in the Reviewer Checklist item has been met.
   **Note:** At the end of the checklist, you can auto populate any responses in the Condition Met column that have not been completed.

10. Enter **Comments** for reference at a later date.
    **Note:** When a condition is not met, a comment is required and will be converted to an identified issue upon submission of the Reviewer Checklist.

11. Enter additional identified issues for the study team in **Additional Issues**.

12. Enter notes in the **Notepad** for your reference.
    **Note:** This information is not communicated to office staff or the study team.

13. Click **Add** to include **Supporting Review Documents**, if desired.
14. Enter a title for the uploaded document.  
   **Note:** Entering a title is optional. If you do not enter a title, the filename becomes the title of the document.

15. Click the **Browse** button to locate the document on your computer.

16. Select the file to upload.

17. Click **Open**.

18. Click **OK** to return to the Reviewer Checklist.

19. Select the **Review Recommendation** based how you would like the application reviewed.

   What you select here determines what options appear on the Submit Review page.

   Review options include:
   - **Not Regulated Determination**  
     Refer to steps 22-25.
   - **Exempt Determination**  
     Refer to steps 26-27.
   - **Request Change or Clarification**  
     Will not send the project team any communication about changes required. If you would like to communicate requested changes with the project team, you need to complete a separate activity. See the **Requesting Changes from the Study Team procedure** for more information.
   - **Assign to Expedited Review**  
     Refer to steps 28-30.
   - **Assign to Full Committee**  
     Refer to steps 31-33.

20. Select the **Check here...** box if you would like to auto populate any Condition Met responses that were not completed. Checklist items with comments will be populated with No and items without comments will be populated with Yes.

21. Click **Continue**.
Submit Review - Not Regulated Determination

STEPS FOR NOT REGULATED REVIEW ONLY

22. Choose the correct Not Regulated Category.
   
   Note: Multiple categories may apply to the study. Select as many that apply.

23. Click Continue.

24. Check Click here if you are ready to submit this review.
   
   Note: If you are not ready to submit the review, click on Save to save your work and then Exit.

25. Click Finish.
   
   Note: Although you have finished the Reviewer Checklist, you must now process your Not Regulate Review decision. See page 25 for the steps required to process your decision.

Submit Review – Exempt Determination

STEPS FOR EXEMPT DETERMINATION ONLY

26. Check on the Exempt Category applicable to the submission.

27. Click Continue.
   
   Note: Although you have finished the Reviewer Checklist, you must now process your Exempt Review decision. See page 22 for the steps required to process your decision.
Submit Review – Expedite

STEPS FOR EXPEDITE REVIEW ONLY

28. When a condition is not met, the associated comment will be converted to an Identified Issue upon submission of the review.

29. Check Click here if you are ready to submit this review.

30. Click Finish.

Note: Although you have finished the Reviewer Checklist, you must now assign the reviewer.

Submit Review – Full Committee

STEPS FOR FULL COMMITTEE REVIEW ONLY

31. When a condition is not met, the associated comment will be converted to an Identified Issue upon submission of the review.

32. Check Click here if you are ready to submit this review.

33. Click Finish.

Note: Although you have finished the Reviewer Checklist, you must now process your Full Committee Review decision. See page 28 for the steps required to process your decision.
Important Information:

Expedite Review requires review by a selected committee member only. The committee is selected and a designated reviewer is assigned. The submission is not scheduled for a review meeting.

To complete an Expedite Review, you must:

- **STEP 1:** Select the Submission that needs review.
- **STEP 2:** Select Committee (IRBMED, PRC, or GCRC only).
- **STEP 3:** Select Expedite Activity.
- **STEP 4:** Assign Reviewer.
- **STEP 5:** Validate the Review (record review decision) which includes:
  - Select Reviewer Determination
  - Process Decision
  - Finalize Documents

⚠ Prior to assigning the expedite reviewer, staff should complete the Staff Reviewer Checklist.

**STEP 1 - Select the Submission**

eResearch Home Workspace

1. Select the submission that needs to be reviewed.

   **Note:** You must select the application by its submission ID and not its Project Name.
2. Verify that the current state is Core Committee Staff Review.

3. Multiple functions can be performed from My Activities. See the My Activities section for detailed information.

STEP 2 - Select Committee (IRBMED, PRC, or GCRC Only)

1. If you are from IRBMED, PRC, or GCRC click Select Committee to assign the submission to a committee.

2. Select the committee that will be responsible for reviewing the application.

   **Note:** Select the committee on which the expedited reviewer sits.

3. Click OK to save your committee selection and return to the Study Workspace.
### STEP 3 - Expedite Submission Activity

1. Click **Expedite** to assign the reviewer.

   **Note:** If you are from IRBMED, PRC, or GCRC, Expedite is not an option until you select your committee.

### STEP 4 - Assign Reviewer

**Select Expedited Staff Primary Reviewer**

1. Click **Select** to assign the primary Reviewer.
2. Type the first three letters of the last name and click **Go**.
3. Select the Committee member.
4. Click **OK** to assign the reviewer and return to the Core Staff Expedited Review page.
5. Enter **Inbox Staff Notes**, if applicable.

6. Enter **Comments for Reviewers**, if applicable.

7. If you are from an IRB, choose an **Expedited Category**.

8. Click **OK** to assign to the reviewer.
9. Verify that the study state changed to **In Expedited Review** status.

**Note:** The Expedite activity no longer appears as an option under my activities.

If you need to assign a different reviewer, use the **Reassign Expedited Reviewer** button under My Activities.

**Note:** If you want to change from Expedite review to a Full Committee review use the **Unassign Expedited Reviewer** button to remove the reviewer.

**Note:** You cannot validate the review (record your review recommendation) until:

- Your assigned reviewer completes the Committee Member Reviewer Checklist

and

- the study state changes to **Validate Expedited Decision** status.

### STEP 5 - Validate Review (Record Review Results)

**Note:** Validate Expedited Decision can only take place after the expediting review has been submitted by the expedited Reviewer (Committee Reviewer checklist complete).

1. Verify the current state is **Validate Expedited Decision**.

2. Click **Record Expedited Decision**.
3. Select **Review Determination**.

4. For IRB only, choose **Approval Period**.
## Indicate Expedited Category

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Clinical studies of drugs and medical devices for which there is no reasonable expectation of risk to the subjects and no.origination or participation in the testing process, 21 CFR 50.6</td>
<td>21 CFR 50.6(c)(1)</td>
</tr>
<tr>
<td>C2</td>
<td>Medical procedures that are not hazardous to the subjects, 21 CFR 50.6</td>
<td>21 CFR 50.6(c)(2)</td>
</tr>
<tr>
<td>C3</td>
<td>Research on behavior or communication whose principal purpose is educational, 21 CFR 50.6</td>
<td>21 CFR 50.6(c)(3)</td>
</tr>
<tr>
<td>C4</td>
<td>Research for which the subjects are volunteers who are not members of the general population and whose participation is not directed by personal or family relationships to a person involved in the conduct of the research, 21 CFR 50.6</td>
<td>21 CFR 50.6(c)(4)</td>
</tr>
</tbody>
</table>

5. Verify **Expedited Category**, if needed.

6. If the reviewer has determined this submission is exempt, verify the **Exemption Category**.

7. Click OK.
Approve Expedited Decision

8. If the reviewer has approved, click Approve.

9. Optional, select the Reviews to be published.

10. Choose the Approval Template from the drop-down menu.

11. Review the Approval Letter.

   Tip: Verify that the correct committee, correct signature and correct approval date is displayed.

12. Click OK.

Study Workspace – Approved Study

13. Verify the current state is Approved.

14. Click Finalize Documents.
Finalize Documents

15. Select the Consent Form documents and/or Recruitment materials to finalize.

16. Verify the dates and edit, if necessary.

17. Click OK to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.

Submission Approval Complete

18. The Submission has been approved for research.
**Exempt Determination**

**Important Information:**

**Exempt Determination** denotes that the submission is exempt from Federal Regulation. The submission is not scheduled for a review meeting.

To complete an Exempt Determination, you must:

- **STEP 1:** Select the Submission that needs review.
- **STEP 2:** Select Committee (IRBMED only).
- **STEP 3:** Select Exempt Determination Activity to process the review decision.

⚠️ **Prior** to completing the exempt review; staff need to complete the **Staff Reviewer Checklist**.

### STEP 1 - Select the Submission

**eResearch Home Workspace**

1. Select the submission that needs to be reviewed.

   **Note:** You must select the application by its submission ID and not its Project Name.

**Study Workspace**

2. Verify the current state is **Core Committee Staff Review**.

3. Multiple functions can be performed from **My Activities**. See the **Review Activities** section for detailed information.
STEP 2 - Select Committee (IRBMED)

1. If you are from IRBMED, click Select Committee to assign the submission to a committee.
2. Select the committee that will be responsible for reviewing the application.
3. Click OK to save your committee selection and return to the Study Workspace.

STEP 3 – Exempt Determination Activity

1. Click Exempt Determination.
2. View the Approval Letter.
3. Click OK.

Note: If the submission needs to be reviewed, follow expedite or full committee step-by-step instructions.
4. Verify the current state is **Exempt Approved – Initial**.

   **Note:** The submission is now approved.

5. Click **Finalize Documents**.

6. Select the documents to finalize.

7. Verify the dates and edit, if necessary.

8. Click **OK** to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.
Not Regulated

Important Information:

A Not Regulated submission does not require IRB approval. A letter is prepared and sent to the study team, and the submission is stored in the Exempt & Not Regulated section of eResearch.

To complete a Not Regulated Review, you must:

- **STEP 1:** Select the Submission that needs review.
- **STEP 2:** Select Committee (IRBMED only).
- **STEP 3:** Select Not Regulated Determination Review Activity to process the review decision.

⚠️ Prior to completing the Not Regulated review; staff need to complete the Staff Reviewer Checklist.

**STEP 1 - Select the Submission**

**eResearch Home Workspace**

1. Select the submission that needs to be reviewed.

   **Note:** You must select the application by its submission ID and not its Project Name.

**Study Workspace**

2. Verify the current state is Core Committee Staff Review.

3. Multiple functions can be performed from My Activities. See the Review Activities section for detailed information.
STEP 2 - Select Committee (IRBMED)

4. If you are from IRBMED, click **Select Committee** to assign the submission to a committee.
5. Select the committee that will be responsible for reviewing the application.
6. Click **OK** to save your committee selection and return to the Study Workspace.

STEP 3 – Not Regulated Determination Activity

1. Click **Not Regulated Determination**.
2. Review the approval letter.
3. Click **OK**.

**Note:** If the submission needs to be reviewed, follow expedite or full committee step-by-step instructions.
4. Verify the current state is Not Regulated.
Full Committee Review & Adverse Event Review

Full Committee-- The submission requires review by the full IRB committee. A committee is selected and primary and secondary reviewers, if needed, are assigned. You can also assign additional reviewers as needed. The submission is scheduled for review at an IRB meeting. Meeting decisions are recorded in eResearch by the Core Staff.

To complete a Full Committee Review, you must:

- **STEP 1:** Select the Submission that needs review.
- **STEP 2:** Select Committee (IRBMED, PRC, or GCRC only).
- **STEP 3:** Select Full Committee Activity to process the review decision.
- **STEP 4:** Assign Reviewer.
- **STEP 5:** Validate the Review (record review decision) which includes:
  - Record Discussion Elements
  - Record Committee Decision
  - Validate Committee Decision
  - Approval Letter
  - Finalize Documents

**Note:** The steps for a Full Committee Adverse Event & Full Committee review only differ in that Adverse Event/ORIO is the Agenda Item Type for a Full Committee Adverse Event.

⚠️ Prior to completing the full committee review or adverse event review, staff should complete the **Staff Reviewer Checklist**.

**STEP 1 – Select the Submission**

eResearch Home Workspace

1. Select the submission or adverse event that needs a full committee review.

**Note:** You must select the application by its submission ID or adverse event ID and not its Name.
Core Committee Staff Review

2. Verify the current state is Core Committee Staff Review.

3. Multiple functions can be performed from My Activities. See the My Activities section for detailed information.

STEP 2 – Select Committee (IRBMED, PRC, or GCRC Only)

Select Committee

1. If you are from IRBMED, PRC, or GCRC, click Select Committee to assign the submission to a committee.

2. Select the committee that will be responsible for reviewing the application.

3. Click OK to save your committee selection and return to the Study Workspace.
1. Click **Full Committee** to process the review decision.

**Note:** If you are from IRBMED, PRC, or GCRC, Full Committee is not an option until you select your committee.
STEP 4 – Assign Reviewer – Assign to Full Committee

1. Select the **Agenda Item Type**. Options include:
   - New Study
   - Deferred Study
   - Deferred – Pending Clarification
   - Continuing Issues
   - Amendment
   - Adverse Event / ORIO
     **Note:** selected for adverse events
   - Reactivation Request
   - Scheduled Continuing Review
   - Final Reports
   - HIPPA Requirement
   - Discussion Items
   - Resubmission
   - Previous Meeting
   - IBC Registration
   - Unanticipated Problem Review

2. Add **Inbox Staff Notes**, if applicable.

3. Use **Reviewer Selection** to select Primary, Secondary, Regulatory, Scientific, and Other Reviewers, if applicable.
   **Note:** If desired, Staff can assign Reviewers and not assign a meeting, or assign a meeting and not assign Reviewers.

4. Choose the **Meeting Date**.

5. Enter **Comments for Reviewers**, if applicable.

6. If you are from IRB, select **Review Study Team Changes** if the study was previously deferred.
   **Note:** This will make the review appear in the committee members’ inbox.

7. Click **OK** to submit the review to the full committee.
STEP 5 – Validate the Review (Record Review Decision)

Full Committee Review

1. Verify the current state is Full Committee.

2. The following new actions can be performed from My Activities:
   - **Full Committee**: Used to add, delete, and/or modify agenda item type, inbox staff notes, reviewers, meeting date and conflicted committee members.
   - **Record Committee Decision**: Used to record the results of the meeting (does not send the PI any correspondence).
   - **Record Elements of Discussion**: Used to record both the draft and final elements of discussion and to add any related documents.
   - **Remove from Agenda**: Removes the submission from the meeting agenda it is currently assigned to.

   **Note**: The Reviewer Checklist will remain with the currently assigned Reviewer(s) unless you delete the Reviewer in the Full Committee or Expedite activity.

3. Click **Record Elements of Discussion**.
Record Elements of Discussion

1. Enter Draft Elements of Discussion.
2. Optional – enter Final Elements of Discussion.
3. Add Related Documents, if applicable.
4. Click OK.

Study Workspace

5. Click Record Committee Decision.
9. Enter **Time of Vote**.

10. Choose **Motion**.
    - Approved
    - Approved with Contingencies
    - Action Deferred Pending Study Team
    - Exempt Determination
    - Action Deferred Pending Core Committee
    - Not Regulated Determination
    - Disapproved
    - Disapproved Final
    - Tabled

**Note:** This example assumes the motion is approved. For more information about the various motion types, see Module 6: Validating Decisions.

11. If applicable, select the **Committee Member** for **Motion Made** and **Motion Seconded**.

12. Enter **Total Votes**, **Yes Votes**, **Abstained Votes**, **Abstained Members** and **No Votes**.

13. Add **Known Conflicted Committee Members** and **Members Out of Room**, if applicable.

14. IRB Only: Select the length in months of the **Approval Period** for the study.

15. Adverse Event full committee review only, answer if the board considered this submission for an unanticipated problem.

16. Click **OK**.
17. Verify the current state is **Validate Committee Decision**.

18. If the motion was approved, click **Approve**.

19. If desired, select the **Reviews** to be published.

20. Verify **Approval Letter** contents.

   **Tip:** Verify that the correct committee, correct signature and correct approval date is displayed.

21. Click **OK**.
22. Verify the current state is **Approved**.
23. Click **Finalize Documents**.
24. Select the **Consent Form** documents and/or **Recruitment** materials to finalize.
25. Verify the dates and edit, if necessary.
26. Click **OK** to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.
To complete an Adverse Event – Single Member Review, you must:

- **STEP 1:** Select the Submission that needs review.
- **STEP 2:** Select Single Member Review Activity and Assign Reviewer.
- **STEP 3:** Validate the Review (record review decision) which includes:
  - Record Decision
  - Approve Decision

**STEP 1 - Select the Submission**

**eResearch Home Workspace**

1. Select the adverse event that needs a single member review.

   **Note:** You must select the application by its submission ID and not its Name.

   **Note:** If your adverse event needs a full committee review, follow the Full Committee Review & Adverse Event procedure.
STEP 2 - Select the Single Member Review Activity & Assign Reviewer

Study Workspace

1. Verify that the current state is Core Committee Staff Review.
2. Click on Single Member Review
Select Single Member Review

3. Select the Primary Reviewer.

4. Enter Inbox Staff Notes and Comments for Reviewers, if applicable.

5. Click OK.

Study Workspace

6. Verify that the current state changed to **In Single Member Review**.

**Note:** The Single Member Review activity no longer appears as an option under my activities.

If you need to assign a different reviewer, use the **Unassign Expedited Reviewer** or **Reassign Expedited Reviewer** buttons under My Activities.

**Note:** You cannot validate the review (record your review recommendation) until:

- Your assigned reviewer completes the Committee Member Reviewer Checklist

and

- the study state changes to **Validate Single Member Review Decision**.
STEP 3 - Validate

Record Single Member Review Decision

7. Verify that the current state is **Validate Single Member Review Decision**.
8. Click **Record Single Member Review Decision**.

Single Member Review Motion

9. Choose the appropriate **Single Member Review Motion**.
10. Click **OK**.
Approve Single Member Review Decision

11. Click **Approve**.

12. Optional, select the **Reviews** to be published.

13. Choose the **Approval Template**.

14. Review the **Approval Letter**.
   
   **Tip:** Verify that the correct committee, correct signature and correct approval date are displayed

15. Click **OK**.