Module 5: Managing Meetings

Module 5 Objective:
Covers how to manage meetings for human subject research in eResearch.

Refer to the table of contents below for the topics covered in Module 5.

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Scheduling a Meeting

**eResearch Home Workspace**

1. From your Home Workspace, click the name of the Committee.

**eResearch Committee Workspace**

2. Click New Meeting.

**New Meeting Window**

3. Enter the Name, Meeting Date, Location, and Start Time of the meeting.
4. Enter comments in the Notes section, if necessary.
5. Click OK.

**Note:** When creating multiple meetings (e.g., meetings for an entire year), always create the meetings in chronological order because meeting are sorted by the date they were created.
Important Information

Do not simply change the meeting date in the Full Committee activity to change a meeting. Follow the steps below to remove the submission from the meeting agenda first before change the meeting date.

1. If you need to change the meeting in which the submission will be reviewed, click **Remove from Agenda**.

2. Click **OK**.

3. Click **Full Committee** to select another meeting.
4. 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

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

6. 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.

7. Choose the **Meeting Date**.

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

9. 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.

10. Click **OK** to submit the review to the full committee.
1. From your Home Workspace, click the name of the **Committee**.

2. Click the name of the upcoming meeting with the agenda you wish to edit.
3. Click **Edit Discussion Items**.

4. Click **Add**.
5. Select the **Type** of discussion item.
6. Enter the **Discussion Item Title**.
7. Optionally, add a description, upload any supporting documents, or add any meeting notes.
8. Click **OK**.

9. The item is added to the Discussion Items.
10. Click **OK**.

11. Verify that the added discussion item appears under the **Agenda Discussion Items** for the meeting on the **Agenda** tab.
Prepare Report of Exempt/Expedited Reviews

eResearch Home Workspace

1. From your Home Workspace, click the name of the Committee.

eResearch Committee Workspace

2. Click the name of the upcoming meeting.

eResearch Meeting Workspace

3. Click Configure Review Reports.
4. Select the type of reviews you want to include in the report.

5. Enter the dates for the Beginning and Ending Dates of Approval Period to be included in the report.

6. Click OK.

7. Click View Expedited/Exempt Reviews to open the report.

**Note:** Use the Edit Discussion Items activity to add this item to the agenda.
eResearch Core Committee Staff – Self Study Guide

Add Meeting Minutes from Previous Meeting to Agenda

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eResearch Home Workspace

1. From your Home Workspace, click the name of the Committee.

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eResearch Committee Workspace

2. Click the name of the upcoming meeting in which the minutes will be reviewed.

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eResearch Meeting Workspace

3. Click Add Previous Meeting Minutes to Agenda.
4. Click the radio button next to the previous meeting with minutes to be reviewed in the upcoming meeting.

   **Note:** Previous meetings must be in the state of Meeting Concluded – Minutes Not Approved to appear on this window. (See the Conclude Meeting procedure for more information.) You can select minutes from more than one meeting.

5. Click OK.

   **Note:** This activity adds a link to the previous meeting workspace to the agenda for the upcoming meeting.

6. Verify that the previous meeting minutes were added to the meeting agenda.

7. Click the Items to Process tab.

8. Click the link on the agenda to open the meeting workspace for the previous meeting.
9. Click **View Printable Meeting Minutes** to view the minutes.
Preparing and Mailing Agendas

**eResearch Home Workspace**

1. From your Home Workspace, click the name of the Committee.

**eResearch Committee Workspace**

2. Click the name of the upcoming meeting with the agenda you wish to send.

**eResearch Meeting Workspace**

3. Click View Agenda by Submission Type to review a copy of the agenda.

   **Note:** You can also click View Agenda by Reviewer to view the agenda sorted by the reviewer.

4. Click Mail Out Agenda.
5. Click **OK**.

**Note:** The agenda will be sent to IRB staff and Committee Members.
Important Information

You can notify all Committee Members by sending out special notices.

**eResearch Home Workspace**

1. From your Home Workspace, click the name of the Committee.

**eResearch Committee Workspace**

2. Click the name of the upcoming meeting related to the message you wish to send.
3. Click **Send Special Notice**.

4. Enter the **Special Notice**.

5. Click **OK**.
   - The Special Notice is sent to all Committee Members.
1. Click the name of the upcoming meeting related to the attendees you need to update.

2. Click Edit Confirmed Attendees.
3. To add attendees as confirmed or declined, click **Add** in the appropriate section. Continue to Step 5.

4. To remove attendees as confirmed or declined, select the person and then click **Remove** in the appropriate section.

   **Note:** Committee Members who go in and accept or decline attendance themselves are automatically added to the list.

5. To continue adding a person, select the person from the list.

6. Click **OK**.
7. Click **OK**.

8. Attendees for the meeting are updated.
Conclude Meeting

eResearch Home Workspace

1. From your Home Workspace, click the name of the Committee.

   ![eResearch Home Workspace](image)

eResearch Committee Workspace

2. Click the name of the upcoming meeting with the agenda you wish to send.

   ![eResearch Committee Workspace](image)

eResearch Meeting Workspace

3. Click Meeting Concluded.

   ![eResearch Meeting Workspace](image)
4. Click **OK**.
Important Information
During the committee meeting, you record the elements of discussion in eResearch. You can access all the studies for the meeting from the Printable Agenda.

Meeting Printable Agenda

1. From the Meetings Printable Agenda, click the name of the study to open the Study Workspace.

2. From the Study Workspace, click Record Elements of Discussion.
3. Record ongoing discussion in the **Draft Elements of Discussion** area.

4. Cut and paste the appropriate discussion items into **Final Elements of Discussion**. 
   **Note:** Discussion items that are entered here appear in the minutes for the meeting.

5. **Add** related documents, if needed.

6. Click **OK**.
Record Committee Decision

Important Information

Once the submission is reviewed at the meeting, Core Staff record the decision in eResearch. The decision may include:

- Approved
- Approved with Contingencies
- Not Regulated Determination
- Exempt Determination
- Action Deferred Pending Study Team
- Disapproved
- Disapproved Final
- Tabled

See Module 6: Validating Decisions for more information about each of these specific decision and related actions required with each decision.

Study Workspace

1. Click Record Committee Decision from the Study Workspace.
2. Enter **Time of Vote**.

3. 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

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

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

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

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

8. Click **OK**.
Important Information: You can modify meeting minutes from a previous meeting using the Update Meeting History activity.

**eResearch Home Workspace**

1. From your Home Workspace, click the name of the **Submission** to be updated.

**eResearch Study Workspace**

2. Click **Update Meeting History**.
Update Meeting History Window

3. Click [Edit] next to the meeting to be updated.

1. Enter the **Time of the Vote**.
2. Select the **Motion** from the drop-down menu.
3. Select the **Motion Made** and the **Motion Seconded**.
4. Enter number of **Total Votes**, **Yes Votes**, **No Votes** and **Abstained Votes**.
5. Enter **Abstained Members**.
6. Enter **Members Out of Room**.
7. Enter **Draft Elements of the Discussion**.
8. Enter **Final Elements of the Discussion**.
9. Click **OK**.
**Approve Meeting Minutes**

**eResearch Home Workspace**

1. From your Home Workspace, click the name of the **Committee**.

**eResearch Committee Workspace**

2. Click the name of the past meeting with minutes to be approved.

**eResearch Meeting Workspace**

3. Click **Record Committee Decision**.
Record Committee Decision Window

4. Enter the Time of the Vote.
5. Select the Motion from the drop-down menu.
6. Select the Motion Made and the Motion Seconded.
7. Enter number of Total Votes, Yes Votes, No Votes and Abstained Votes.
8. Enter Abstained Members.
9. Enter Members Out of Room.
10. Enter Elements of the Discussion.
11. Click OK.