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I. Overview

This document provides a detailed description of the procedures Ancillary Committee Reviewer will use to review applications for human subject research in the eResearch system.
II. Logging into eResearch

Navigation

The eResearch application is accessed at http://eresearch.umich.edu.

Important Information

- For more information on how to obtain a uniqname and a UMICH Kerberos password, go to: www.itd.umich.edu/help/faq/unignames.
- For Study Team and Reviewer activities, eResearch supports the following system configurations:
  - Windows 2000 or Windows XP and Internet Explorer 5.5 or higher
  - Macintosh OSX and the Safari
- For optimal viewing, the recommended screen resolution size is 1024 x 768 or higher.

Signing Into eResearch and Authentication

Browser Home Page

1. Type https://eresearch.umich.edu into the Address field and press [Enter].
2. Click LOGIN.

UM Authentication Required Page

3. Click in the Login ID field and type your uniqname.

4. Tab to the Password field and type your UMICH Kerberos password.

5. Click Log In or press [Enter].

6. The eResearch application opens and displays your Home Workspace.
III. Using the eResearch Home Workspace

eResearch Home Workspace

1. Your **Home Workspace** contains all eResearch study submissions that are associated to you. The submissions are organized by status (Inbox, In Progress, Approved and Archived), and can be accessed by clicking the appropriate tab for each category. Submissions that require action appear under **Inbox**.

   **Note:** Confirm the **Ancillary Committee** role is selected to view your Ancillary Committee Member inbox.

2. Click the navigational arrows to display **Next** and **Previous** pages, if applicable.

3. Click **My Home** from any page in eResearch to return to your **Home Workspace**.

4. Click **Logoff** to exit eResearch.
IV. Reviewing a New Study Application

Important Information

- When a new research application is submitted that requires review by your committee, you will receive an email notification. This email will have a link to the application in eResearch.
- Once you log in to the eResearch system, the new submission will appear in your Home Workspace under the Inbox tab.

**eResearch Home Workspace**

1. **Inbox** displays all applications submitted to your committee for review.
2. View **Staff Notes**.
3. Click on the study name to access the Study Workspace.

**eResearch Study Workspace**

4. Select **Edit Inbox Staff Notes** to enter a staff note, if applicable.
   
   **Note**: Staff notes may be viewed and edited by all ancillary committee members.
5. Click the **View Study** button to display the study application.
6. Click **Continue >>** to proceed to the next page of the application.

7. Use the **Jump To** drop-down menu to go to a specific section of the application.

8. Click **Exit** to exit the application and return to the Study Workspace.
V. Print an Application

Important Information

- The printable version of the application includes only the completed application sections. Detail information is printed at the end of the document.

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**eResearch Home Workspace**

1. Click the name of the application to access the Study Workspace.

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**eResearch Study Workspace**

2. Click Printer-Friendly Version.
Print Window

3. Click **Print**.

Print Dialog Box

4. Click **Print** to print the application.
VI. Assign Ancillary Owner

eResearch Study Workspace

1. Select **Assign Ancillary Owner**.

Assign Ancillary Owner Window

2. Select a person from the **Current Ancillary Owner** for the appropriate ancillary is: drop-down Menu.

3. Click **OK**.
4. The owner is displayed on the Study Workspace.
VII. For Ancillary and IRB Office

eResearch Study Workspace

1. Select For Ancillary and IRB Office.

For Ancillary and IRB Office Window
2. Enter **Comments** to the recipients, if applicable.

3. Use the **Add** button to attach documents, if needed.

4. 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.

5. Use the **Browse...** button to locate the document on your computer.

6. Select the file to upload.

7. Click **Open**.

8. Click **OK**.
For Ancillary and IRB Office Window

9. Select the desired recipients.

10. Click **OK**.

**Note:** the correspondence will display on the Ancillary tab on the submission workspace.

VIII. Request Changes from the Study Team

**Important Information**

- If necessary, you may request that the study team make changes to the application prior to your approval.

eResearch Study Workspace

11. Select **Changes Requested by Ancillary Committee**.
12. Enter **Comments** to the study team, if applicable.

13. Use the **Add** button to attach documents, if needed.

14. 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.

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

16. Select the file to upload.

17. Click **Open**.

18. Click **OK**.
19. Click the checkbox for your committee.
20. Click OK.

21. The Activities and Correspondence section is updated to reflect your request for changes.
IX. View Submitted Changes

Important Information

- Once the study team completes the requested changes to the application and submits them for your review, you will receive an email notification. This email will have a web link to the application in eResearch.

**eResearch Home Workspace**

1. Click the name of the application to access the **Study Workspace**.
2. When the study team has completed the requested changes, a comment appears Activities and Correspondence section.

3. Click View Study or Change Tracking to view the application with the changes made by the study team.

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**X. Approve Study**

**eResearch Study Workspace**

1. Click Issue Ancillary Committee Approval from My Activities.
XI. Reviewing an Amendment

Important Information

- When an existing application for a research study is amended, review may be required by your committee. In such an event, you will receive an email notification. This email will have a web link to the amendment application in eResearch.

- Once you log in to the eResearch system, the new submission will appear in your **Home Workspace** under the **Inbox** tab.

**eResearch Home Workspace**
1. Click the **Name** of the amendment you would like to review.

2. Click **View Amendment Forms** to view the amendment cover sheet.

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**Amendment Instructions**
3. Click **Continue >>** to review the amendment information. Click **Finish** on the last page to return to the **Study Workspace**.

4. Click **View Study** to view the amended application.

5. Click **Amendment Audit Trail** to display a list of items that have been amended from the originally approved application.
6. Click **Change Log** to display more details about the change.

7. Click the **Page Link** to open the related section of the application form. **Note:** Click your browser **Back** button to return to the **Amendment Workspace**.

8. Click **Issue Ancillary Committee Approval** to approve the amendment.

9. Check the box next to the Committee you represent to indicate your **Electronic Approval**.

10. Click **OK**.
XII. Reviewing an Adverse Event

Important Information

⚠️ No action is required by the ancillary committees for adverse events.

- Adverse events submitted for research studies previously reviewed by your committee can be viewed under the **In Progress** tab.

**eResearch Home Workspace**

1. Click the **Name** of the adverse event you would like to review.

**eResearch Adverse Event Workspace**

2. Click **View Adverse Event**.
3. Click [Continue >>] to review the adverse event information. Click [Finish] on the last page to return to the Study Workspace.
XIII. Reviewing a Continuing Review

Important Information

⚠️ No action is required by the ancillary committees for Scheduled Continuing Reviews.

- Scheduled Continuing Reviews submitted for research studies previously reviewed by your committee can be viewed under the In Progress tab.

**eResearch Home Workspace**

1. Click the **Name** of the continuing review you would like to review.

**eResearch Continuing Review Workspace**

2. Click **View Continuing Review**.
Scheduled Continuing Review Window

3. Click **Continue >>** to review the continuing review information. Click **Finish** on the last page to return to the Study Workspace.