Using eResearch

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.

I. Logging into eResearch
II. Using the eResearch Home Workspace
III. Reviewing a new study application
   - Print an application
   - Request changes from study team
   - View submitted changes
   - Approve study
IV. Reviewing an amendment
V. Reviewing an adverse event
VI. Reviewing a continuing review

Details
The following pages provide details about the changes listed above.
I. Logging into eResearch

Navigation
The eResearch application is accessed at https://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/unnames.
- 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.

eResearch Home Page

2. Click the log in link.
3. Click in the **login** field and type your **uniqname**.

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

5. Click **Login** or press **Enter**.

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

1. Your **Home Workspace** contains all eResearch study submissions that are associated to you. The submissions are organized by status (Applications in Progress, Approved Studies, and Archived Studies), and can be accessed by clicking the appropriate tab for each category. Submissions that require some action appear under **My 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 the **My Home** link from any page in eResearch to return to your **Home Workspace**.

4. Click the **Logoff** link to exit eResearch.
III. 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 My Inbox tab.

eResearch Home Workspace

1. My 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.

   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**.
III. 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.

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

2. Click Printer-Friendly Version.
3. **Click Print.**

4. **Click Print** to print the application.
III. 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

1. Select Changes Requested by Ancillary Committee.

2. Enter your Comments to the study team in the box.

3. Use the Add button to attach documents, if needed.
Submit a Document Window

4. Enter a title for the document you are uploading.
5. Use the Browse button to locate the document on your computer.
6. Click the desired document file to select it.
7. Click Open.
8. Click OK.

Change Request Window

9. Click the checkbox for your committee.
10. Click OK.
11. The **Correspondence** tab is updated to reflect your request for changes.
III. 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**.

**eResearch Study Workspace**

2. When the study team has completed the requested changes, you will see a comment in the **Correspondence** tab.

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

eResearch Study Workspace

1. Click Issue Ancillary Committee Approval from My Activities.

Ancillary Committee Approval Window

2. Check the box next to the Committee you represent to indicate your approval.

3. Click OK.
IV. 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 My Inbox tab.

1. Click the Name of the amendment you would like to review.

2. Click Edit/Review Amendment Cover Sheet to view the amendment cover sheet.
Amendment Instructions

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

eResearch Amendment Workspace

4. Click **Edit/Review Application Forms** 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.
Amendment Audit Trail Window

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.

Amendment Approval Window

9. Check the box next to the Committee you represent to indicate your approval.

10. Click OK.
V. 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 Applications in Progress tab.

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

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**.
VI. 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 Applications in Progress tab.

eResearch Home Workspace

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

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**.