**Overview**

This document provides a detailed description of the procedures Principal Investigators and Study Coordinators will use to submit and manage applications for human subject research in the eResearch system.

Each activity is documented with screen shots of eResearch and the steps you need to take to perform the procedure. Additional Show Me training modules and registration for open lab sessions is available from the eResearch home page at [http://eresearch.umich.edu/](http://eresearch.umich.edu/)

Refer to the table of contents below for the specific topics covered in this self study guide.

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Automatic Notifications

eResearch automatically notifies Study Teams of an upcoming expiration at 90, 60, and 30 days prior to expiration. You can renew your study in eResearch by completing a Scheduled Continue Review. See the *Creating a Continuing Review step-by-step procedure* for more information.
Logging into eResearch

eResearch 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/uniqnames.
- For Study Team and Reviewer activities, eResearch supports the following system configurations:
  - Windows 2000 or Windows XP and Internet Explorer 6.0
  - Macintosh OSX and the Safari
- For optimal viewing, the recommended screen resolution size is 1024 x 768 or higher.

eResearch Home Page

1. Go to http://eresearch.umich.edu/.
2. Click Login.

U-M Authentication Required Page

3. Enter your Login ID (uniqname or Friend ID) and your Password.
   Note: If you a non U-M user, refer to the Obtaining a Friends Account step-by-step procedure for more information.
4. Click Log In.
5. The eResearch application opens and displays your **Home Workspace**.
Obtaining a Friends Account

Non-U-M personnel can obtain access to eResearch by requesting a Friends account. Friends accounts are issued by Information Technology Central Services (ITCS) and allow non-U-M personnel access to many campus systems, including eResearch.

Important Information
You must have a valid email address in order to obtain a Friends account.

eResearch Home Page
1. Go to http://eresearch.umich.edu/.
2. Click Login.

UM Authentication Required Page
3. Click create one now to create a Friend ID.
Obtaining a Friends Account
Step-by-Step Procedure

4. Click **Others** to view the full directions on How to Set Up a Friends Account.

   **Note:** The directions are summarized in the steps below.

5. Go to [https://friend.weblogin.umich.edu/friend/](https://friend.weblogin.umich.edu/friend/)

6. Enter your email address and click **Request**.

7. Review the message sent confirmation screen.

   **Notes:**
   - An email from friend-accounts@umich.edu will be sent to the address you entered.
   - Allow up to an hour to receive the email.
8. Click the **Create Friend Account** link in the email from friend-account@umich.edu.

9. Enter your **email address**.

10. Enter and re-enter your **password**.

11. Click **Set Password**.
Friend Account Created

12. Review your **Friend Account Created** confirmation.

eResearch Home Page


14. Click **Login**.

Cosign Login

15. Enter your **Login ID** (the email you used to request access) and your **Password**.

16. Click **Log In**.
17. Enter your contact information, filling in all fields marked with a red star (*).

18. Click Submit.

19. You now have access to eResearch and your Home Workspace is displayed.
Using the eResearch Home Workspace

1. **Verify** is displayed on the Home Workspace.  
   
   **Note:** If Study Staff is not displayed, click the **Study Team Member** link under My Roles.

2. The following tabs are available in your Home Workspace:
   - **My Inbox** - Displays items in your Inbox. It has the following sections:
     - **Ready to Submit**
     - **Need to Accept Role**
     - **Require Action by Study Team**
   
   **NOTES:**
   - **My Inbox** is active. When a tab is active it appears in blue.
   - Submissions will not appear in **My Inbox** unless you are required to make changes or take some other action on the Submission.
   - **My Inbox** sections can be sorted using the **Filter by** drop-down.
   - **In Progress** - Displays all of your Submissions that are currently in progress.
   - **Approved** - Displays all of your approved Applications & IBC Registrations.
   - **Exempt and Not Regulated** - Displays all exempt and not regulated Applications.
   - **Approaching Expiration** - Displays all of your Applications & IBC Registrations that are approaching expiration.
   - **Archived** - Displays all archived Applications.

3. Click **New Study** to create an application for a new study.

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

5. Click **Logoff** to exit eResearch.
Creating an Application for New Study

Important Information
Your browser must allow cookies, Javascript, Java applets and pop-ups (for the eresearch.umich.edu site).

eResearch Home Workspace

1. Click [New Study] to create a new eResearch study application.

Note: The system will not allow you to use [Continue >>] to move to the next page until you have completed all of the required fields.

Do not use your web browser to navigate between pages. You can lose data entries when using the web browser buttons.

eResearch Study Application

2. Complete all required fields marked with a red star (*).

3. Click [Continue >>] to save the current page and proceed to the next page.

4. Click [Save] to save the data entered without moving to a different page.
eResearch Study Application

5. The list allows you to jump directly to any section of the application, but it does so by ignoring the Smart Form logic.

**Note:** It is recommended that you use to navigate through the application initially, then use the list when you know what sections you must complete.

6. Click to view a list of required fields that are not completed.

7. Click to exit the application and return to the Study Workspace.

**Note:** Before exiting, your changes.

If you attempt to exit the page without saving your changes, you will be prompted to save the page.
Adding a Study Team Member

Important Information

- Applications for new research studies must be submitted by the Principal Investigator.
- In addition to the Principal Investigator, other study team members can be included on the application. Each Study Team Member can be granted rights to be included in future correspondence related to the study and/or granted edit rights to the application.
- Study team roles include:
  - Co-Investigator
  - Faculty Advisor
  - Study Coordinator / Project Manager
  - Staff
  - Consultant
  - Other
- Individuals with the roles of Co-Investigator and Faculty Advisor must open the application and accept their role before the application can be submitted. See the Accepting Your Role on the Study Team procedure for more information.

eResearch Study Application

Study Team Members are defined in section 1.3 of the eResearch application.

1. Click to add a new member to the team.
Adding a Study Team Member
Step-by-Step Procedure

1. **Study Team Detail Window**

   - **Click** to add the team member.
   - **Select Person Window**
     - **Type the first three letters of the last name and click [Go]**.
       **Note:** Use the percent sign (%) as a wildcard character to find a partial name.
     - **Select the team member.**
     - **Click [OK]**.
       **Note:** Individuals are added to the Select Person list once they log into eResearch for the first time. If the Study Team 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.

Last updated: 7/25/07
6. Select the Study Team Member’s role.

7. Choose whether this team member has rights to edit this study application.

8. Choose whether the team member should be included on future correspondence related to this study application.

9. Click **OK**.

10. The new team member has now been added to the application.

11. Click **Save**.

**Note:** Prior to submitting the application, Study Team Members named as Co-Investigators and Faculty Advisors must access the application and accept their assigned role.
Adding a Sponsor

This procedure demonstrates adding an External Sponsor. The same steps can be followed to add an Internal Sponsor.

eResearch Study Application

1. In Section 2, click Add.

2. Click Select... to open the Select a Sponsor window.
Select Sponsors Window

3. Search for the sponsor by **Acronym** or by entering a **Name**.

   **Note:** Use the percent sign (%) as a wildcard character to find a partial name.

4. Click **Find**.

5. Select the option next to the correct sponsor.

6. Click **OK**.

Sponsor Detail Window

7. The sponsor is added to the Sponsor Detail window.

8. Complete the rest of the Sponsor Detail window.

   **Note:** All fields marked with a red star (*) are required.

9. Click **OK**.
10. The sponsor is listed in Section 2.

11. Click **Save**.
Uploading/Adding a Document

Important Information

- Supporting documents can be uploaded to certain sections of the eResearch study application.
- Where documents can be uploaded, an Add button appears.

eResearch Study Application

1. Click Add to upload supporting documents to the study.

Adding Supporting Documents

2. Enter a title for the document you are uploading.
   **Note:** Since uploaded documents are listed in alphabetical order, you may find it helpful to use the following naming conventions:
   - Use a meaningful title.
   - Use a number to differentiate similar titles (e.g., Consent1, Consent2, Consent3).
   - Include version date.
   - Make sure the title you use for the uploaded document matches the file name of the document on your computer.

3. Click Browse to locate the document on your computer.

4. Select the file to upload.

5. Click Open.

6. Click OK.
   **Note:** The document has been added to the submission.
Editing a Document

Important Information

- After a document has been uploaded, you can change its title and/or replace the uploaded document.
- When you replace the uploaded document with a new document its version number will increment by one.
- Edit does not open the document to make changes.
- If you need a copy of the uploaded document, you can download the document and make necessary changes.

Download a Document

1. If you need a copy of the document to edit, right-click the name of the document. Skip to step 6 if you do not need to download a copy of the document.

Save Document

2. Click Save Target As…
3. Navigate to a location on your computer.
4. Click Save to save the document.
5. Make needed document changes.

Edit Document

6. Click [Edit].

Note: Edit does not open the document to make changes. See steps 1-5 above if you need to download a copy of the document to make changes to it.

Note: In this example the version number of the document is “0.01”. The version number of the document will change any time you change a document’s title or upload a new version of a document.
Submit a Document

7. If you need to change the document’s title, enter the new document title.

Note: Since uploaded documents are listed in alphabetical order, you may find it helpful to use the following naming conventions:
   - Use a meaningful title.
   - Use a number to differentiate similar titles (e.g., Consent1, Consent2, Consent3).
   - Include version date.
   - Make sure the title you use for the uploaded document matches the file name of the document on your computer.

8. If you need to replace the uploaded document with a new document, click **Browse...** to locate the document on your computer.

9. Select the file to upload.

10. Click **Open**.

11. Click **OK**.

   Note: The document has been added to the submission and replaced the original uploaded document.

12. Verify the document name and new version number.

   Note: In this example the version number changes from “0.01” to “0.02”.

13. If you would like to view the document’s revision history, click **View revision history**.
14. Click on the **Upload File** link if you would like to view one of the versions of the document.

15. Click **OK** to return to the **Submit a Document** page.
Deleting Supporting Documents

1. Select the document(s) you want to delete.
   
   **Note:** Make sure you select the correct document to delete. Once a document is deleted it cannot be recovered.

2. Click **Delete**.

Verification Window

3. Click **OK** to verify that you want to delete the document.

5. Notice that the document has been deleted.
Uploading Resumes, CVs, or Biographical Sketches for Others

Study Team members with rights to edit the study application can upload or update biographical information, such as a resume, CV, or biographical sketch, of other members in the study team. Often, this means that Study Coordinators can update these items for the Principle Investigator and Co-Investigators.

Important Information
Study Team Members can only update biographical information for others in question 1.3 of the study application.

### eResearch Study Application

1. In question 1.3, click the name of the person for whom you want to upload biographical information.

### Study Team Detail Window

2. In the Credentials area, click **Add**.

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3. Enter a title for the document you are uploading.
   **Note:** Entering a title is optional. If you do not enter a title, the filename becomes the title of the document.

4. Click **Browse** to locate the document on your computer.

5. Select the file to upload.

6. Click **Open**

7. Click **OK**

8. The document is added to the **Credentials** area.

9. Click **OK**
eResearch Study Application

10. Click **Save**.
Important Information

- Study Team Members can use the Post Correspondence activity in eResearch to communicate with others involved with the study.
- Messages posted using the **Post Correspondence** activity are permanent and visible to anyone with access to the Study Workspace (e.g., Study Team Members, Core Committee Staff, IRBs, Ancillary Committees, regulatory officials).

### eResearch Home Workspace

1. From your **Home Workspace**, click the name of the submission to access the **Study Workspace**.

### eResearch Study Workspace

2. Click **Post Correspondence**.
3. Enter your **Comments** to the Study Team.  
   **Note:** Post Correspondence is a communication tool only and will not update or submit your application.

4. Click **Add** to attach documents, if needed.  
   **Note:** Revised documents that were originally uploaded in the application should NOT be uploaded here. They should be uploaded to the appropriate section of the application.

5. Select the desired recipients of your correspondence.  
   **Note:** The selected recipients will receive an email notification of the correspondence.
Posting Notes for the Study Team

Important Information

- You can post notes for the Study Team directly in the section where the note is needed.

eResearch Home Workspace

1. From your **Home Workspace**, click the name of the submission to access the **Study Workspace**.

2. Click **Edit Study**.

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**Note:** eResearch Home Workspace and eResearch Study Workspace images are not included in the natural text representation. The text describes the steps to post notes in the Study Workspace and how to access it from the Home Workspace.
3. In the Notes area, click Add.

Note: This note is visible only to Study Team Members.

4. Add the note to the study team.

5. Click OK.

6. The note is added at the top of the section.

Note: Click the right arrow to display or the down arrow to hide the note(s).
7. You can also view all notes added by clicking the **Notes** tab in the Study Workspace.
1. From the **Need to Accept Role** section of **My Inbox**, click the name of the application or amendment to access the **Study Workspace**.

2. Click **Accept Role**.
Step-by-Step Procedure

3. Click the checkbox indicating acceptance of your role.
4. Upload or update your CV, resume or biological sketch.
5. Complete the Conflict of Interest section.
6. Click **OK**.
Error Checking

Important Information

- eResearch verifies that all required fields are completed on each page of the application whenever you click **Continue >>** to move to the next page.
- Prior to submitting the application, you can display a list of required fields that are not complete by using:
  - **Hide/Show Errors** from any section of the submission.
  - OR
  - **Error Check** from the end of the submission.

eResearch Study Application

1. To display a list of required fields that are not complete click:
   - **Hide/Show Errors** from any section of the application
   - OR

End of Application

- **Error Check** from the End of Application

**Note:** All required fields marked with a red star (*).
2. If you clicked **Hide/Show Errors** from any section of the application, you will see:

Required fields that are not completed appear in a window at the bottom of the application.

**Note:** Required fields that are not completed are displayed for the entire study application.

OR

3. Click the links to jump to the section of the application with fields that are not complete.

4. **Note:** You MUST click **Save** or **Continue >>** to save any changes you make.
Important Information
Prior to submitting the application, you can display a list application sections that are not complete by running the Application Checklist. You can then jump to incomplete sections and complete all required information.

eResearch Home Workspace
1. Click the name of the application to be submitted from Require Action by Study Team section of My Inbox.

eResearch Study Workspace
2. Click Application Checklist.
3. The Application Checklist Progress window displays the current progress status of each section of the application.

4. Click the name of an incomplete section to jump to that section within the application.

5. Make the necessary changes.

6. Click Save.
7. Keep the Application Checklist Progress window open to quickly navigate to incomplete sections within the application.

8. Click Close to close the application checklist and return to the Study Workspace.

### Application Checklist Progress Window

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>01. General Study Information</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>02. Sponsor Information</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>03. Performance Sites</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>04. Study Abstract</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>05. Research Design</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>06. Benefits and Risks</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>07. Special Considerations</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>08. Subject Detail</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>09. Subject Populations</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>10. Informed Consent</td>
<td>Incomplete</td>
<td></td>
</tr>
<tr>
<td>11. Confidentiality and Security</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>12. Exemption</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>13. Subject Payments Or Other Incentives</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>14. Health Care Treatments and Procedures</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>15. Drug, Biologics, Etc.</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>16. Devices</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>17. Placebo</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>18. Biological Specimens</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>19. Stem Cells</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>20. Genetic Analysis</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>21. Ionizing Radiation</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>22. Organ/Tissue/Cell Transfer</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>23. Gene Transfer</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>24. Secondary Data Analysis</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>25. Protected Health Information/HIPAA</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>26. Epidemiology</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>27. Deception Research</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>28. Internet/Email</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>29. Survey Research</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>30. International</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>31. Watching/Listening to Audiovisual Materials</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>32. Data Safety Monitoring Plan</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>33. Children</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>34. Neonates</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>35. Pregnant Woman and/or Fetuses</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>36. Lactating Woman</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>37. Women of Child Bearing Potential</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>38. Prisoners</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>39. Cognitively Impaired Adults</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>40. College Students</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>41. Subjects Vulnerable to Coercion</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>42. GOBC Information</td>
<td>Not Required</td>
<td></td>
</tr>
<tr>
<td>43. MADRC Information</td>
<td>Not Required</td>
<td></td>
</tr>
</tbody>
</table>
Notify Study Team Members to Accept Roles

Important Information

- Sends an email notification to selected study team members requesting them to accept their role.

eResearch Study Workspace

1. Prior to submitting a new study application, Co-Investigators and Faculty Advisors must accept their roles on the study.

- From the Study Workspace, click

![Notify Study Team Members to Accept Roles]

**Note:** The Study Workspace displays the following warning message in red, “Note: Not all Co-Is and/or Faculty Advisors have accepted their roles.”

OR

End of Application

1. From the End of Application, click

![Notify Study Team Members to Accept Roles]

**Note:** The End of Application displays a list of study team members who have not yet accepted their roles. Study team members must accept all of their roles before the study can progress.
2. Verify that the appropriate Study Team Members are selected.

**Note:** Study Team Members are selected by default. You can deselect any Study Team Members if needed.

3. If applicable, enter comments that you want included in the email notification.

4. Click **OK** to send the selected Study Team Members an email that requests that they accept their role.
Move to Ready to Submit Inbox

Important Information

- Using the Move to Ready to Submit Inbox Activity, a Study Team member can send an email to the selected study team members that the application is ready to submit and moves the application into the Ready to Submit section of the Inbox for all who have access to submit.
- The application must be complete before using the Move to Ready to Submit Inbox Activity.

eResearch Study Workspace

1. Prior to using this activity, Co-Investigators and Faculty Advisors must accept their roles on the study.
   - From the **Study Workspace**, click **Move to Ready to Submit Inbox**

End of Application

1. From the **End of Application**, click **Move to Ready to Submit Inbox**
Notify Study Team Members to Accept Role

1. Select the appropriate Study Team Members.
2. If applicable, enter comments that you want included in the email notification.
3. Click OK to send an email to selected study team members that the application is ready to submit and move the application into the Ready to Submit section of the Inbox for all who have access to submit.

Note: In the Study Workspace, “Ready to Submit” displays in red.
Submitting a Completed Application

Important Information

- New applications must be submitted by the Principal Investigator (PI).
- Prior to submitting a new study application, Co-Investigators and Faculty Advisors must accept their roles on the study.
- Prior to submitting a new study application, it is recommended that Study Teams:
  - Run or and complete all required fields on the application.
  - Run the Application Checklist and complete all required information.

**eResearch Home Workspace**

1. Click the name of the completed application to be submitted from Require Action by Study Team section of My Inbox.

**Note:** The completed application will appear in the Ready to Submit section of the My Inbox for the Principal Investigator if study staff flagged the application as ready to submit so it appears in this section of the PI’s inbox.

**eResearch Study Workspace**

2. Once all the required sections are complete, you are to submit the application using either option below:
   - From the Study Workspace, click Submit Application.

OR
• From the **End of Application**, click **Submit Application**.
3. Upload or update your CV, resume or biological sketch.

4. Complete the **Conflict of Interest** information.

5. Select the checkbox to indicate agreement with the **Investigator Assurances**.

6. Click **OK**.
Important Information

- Study applications can be printed from the Study Workspace or from within the application.
- The print version of the application includes only the required application sections. Detail information is printed at the end of the document.

eResearch Home Workspace

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

2. Click \[ Printer-Friendly Version \].

Note: You can also open the study application and click Print... to print specific pages of the application.
3. Click [Print] to print the application.

4. Click [Print] to print the application.
Tracking a Submitted Application

1. This example shows study applications that have been approved and appear in **Approved**.

   **Notes:**
   - Submissions only appear in **My Inbox** if an action is required by you.
   - All new submissions appear in **In Progress**.
   - Amendment, Continuing Review, and Adverse Event submissions appear in **In Progress** prior to approval. Once approved, these submissions can be viewed by accessing the parent study.
   - Exempt and Not Regulated applications appear in **Exempt and Not Regulated**.
   - Completed or withdrawn studies appear in **Archived**.

2. The **State** column displays the current state of the study.

3. Click the **Name** of the study to view more detail.
4. The status bar shows the progression the study application has made through the approval process.

5. The **Current State** of the study appears below the status bar.

6. Activities for each study appear in **Correspondence**.

**Note:** Items listed in Correspondence indicate actions that have already taken place. These buttons are not active function buttons.

7. The **Documents** tab displays all documents related to the study.

**Notes:**

- Documents appearing in: **Approved Documents** are consentee recruitment materials that have been finalized by Core Office Staff. **Supporting Documents uploaded by core staff** are other documents added to the application workspace by Core Office Staff.

- Links to documents included in the study application by the study team appear in **Supporting Documents in the Study**.
Submitting Requested Changes

Requested changes can be made to an Application, Amendment, AE/ORIO, Continuing Review, or IBC Request. This procedure shows example screen shots from an application.

**eResearch Home Workspace**

1. Submissions that require action appear in the **Require Action by Study Team** section of **My Inbox**.
2. The **State** column displays the current state of the study.
3. Click the **Name** of the study to view more detail.

**eResearch Study Workspace**

4. View the requested changes in the **Outstanding Issues** section of the **Correspondence** tab.

5. Click **Edit Study** to make the requested changes to the submission and save the changes or click on the blue text under Outstanding Issues to go directly to that section of the study.

- Click **Exit** to exit the submission and return to the **Study Workspace**.
6. When you have completed all required changes, click from the Study Workspace or the End of the Application.

7. Indicate the changes made in response to the identified issues.

8. Enter Comments, if applicable.

   **Note:** If all requested changes were not made, a comment is required.

9. Click OK.
10. A record of the submitted changes appears in [Correspondence].

11. Click [Change Tracking] to view the specific changes.

12. Click [Change Tracking] to view the details about each change.

**Note:** Click the page reference to go to the specific section of the study application.
13. The **Old Value** and **New Value** display the changed values for each property.

14. In the breadcrumb trail, click the name of the study to return to the **Study Workspace**.

   **Note:** The submission will appear in your **In Progress** tab of your Home Workspace.
Study Approvals and Submitting Contingencies

Important Information

- When the IRB meets to review applications, its decisions are recorded in eResearch and study teams are notified via email of the decision. The study team can view the status of the application at any time in eResearch.
- In some cases, submissions may be approved with contingencies. Study teams are required to submit additional information to satisfy the contingencies prior to full approval. Research cannot begin until final approval has been obtained.

eResearch Study Workspace

1. The study team is informed of pending contingencies via email notification. A link is provided to view this letter directly in eResearch. Any contingencies can be viewed in the Outstanding Issues section of the tab.

2. Click to make the requested changes to the study application and save the changes or click on the blue text under Outstanding Issues to go directly to that section of the study.
   - Click Exit in the Study Application to return to the Study Workspace.

3. Click Submit Contingencies from the End of the Application or Study Workspace to indicate that you have completed the request.
Submit Contingencies Window

4. Indicate the changes made in response to the identified issues.
5. Add Comments, if necessary.

Note: If all requested changes were not made, a comment is required.

6. Click OK.

7. The submission will appear in your In Progress tab of your Home Workspace.
Creating an Amendment

Important Information

- Amendments can be submitted on approved studies only.
- Only one amendment can be in process at a time for each study.

eResearch Home Workspace

1. Click **Approved** to display approved studies.
2. Click the **Name** of the study to view the approved study workspace.

Study Workspace

3. Click **New Amendment**.
Amendment Instructions

Click after reading the Amendment Instructions.

Note: If this amendment is in response to an adverse event (AE) or other reportable information and occurrence (ORIO) that has not yet been submitted for review, click the Back button and select New Adverse Event/ORIO. AE/ORIOs must be submitted prior to the initiation of the amendment in order for them to automatically display in the amendment cover sheet. This will allow the reviewer to consider the amendment in the context of the AE/ORIO report.

Amendment Cover Sheet

4. **Optional:** Enter a title for your amendment. Leave the original study number in the amendment title unless directed by the IRB to follow a specific naming convention.

   **Note:** Once approved, the amendment is accessed through the original study.

5. Complete the remaining fields on the form.

6. Click .
Amendment Copy Currently in Progress

Note: This screen informs you that the system is currently creating a copy of the approved application. The system will notify the study team members selected in section one via email when the amendment copy process is complete.

7. Verify that the check boxes are selected next to the names of the study team members who should receive email notification.

8. Click Finish.

Amend Currently Approved Application

Note: This screen will only appear if the amendment copy process has completed before step 9.

9. Click the Click here to make changes to the currently approved application link or Finish to navigate to the amendment workspace.

Amendment Workspace

Note: Click the link supplied in the email notification to navigate to the amendment workspace.

10. Click Edit/Review Study to make changes to the amendment.

Note: If the amendment includes changes to the study team members, please note that newly added Co-Investigators and Faculty Advisors will need to accept their role prior to submission.

11. After making all changes to the amended application, click Submit Amendment.

Note: Only the PI can submit an amendment.
Submit Amendment Window

12. Complete the **Conflict of Interest** form.

13. Select the checkbox to indicate that you will abide by the **Investigator Assurances**.

14. Click **OK**.

**Note:**

Track the progress of the amendment using your Home Workspace in **In Progress**.

Once the amendment is approved, the amendment is viewed under the Study. Use the **Amendments** tab in the Study Workspace to view the amendment.
Creating an Adverse Event / ORIO

Important Information

- Study teams are required to submit Adverse Events (AEs) and Other Reportable Information and Occurrences (ORIOs) via the eResearch system. ORIOs include audits, other reports, protocol deviations, protocol violations, facility/data accidents, and complaints (which includes lapses in approval).

eResearch Home Workspace

1. Click to display approved studies.
2. Click the Name of the study to view the approved study workspace.

3. On the Study Workspace, click New Adverse Event/ORIO.
4. Enter a title for your Adverse Event / ORIO

Note: To make tracking the adverse event easier, include the HUM # of the original study in the title. Once approved, the adverse event is accessed through the approved study workspace.

5. Select Adverse Events Report or Other Reportable Information and Occurrence (ORIO).

6. Click Continue >>.

7. Select the Type of Adverse Event or ORIO which you are reporting.

8. Indicate whether this report includes follow-up to previous reported events

9. Click Continue >>.
Previous Adverse Events

Note: If you select **Yes** to this question (1-1.2), you will be required to indicate the previous reported events which this report follows.

Adverse Event Form

10. Fill out the required fields in the form. For Adverse Events, you will be required to click **Add** and fill out the Adverse Event Detail form.
11. Fill out the required fields in the **Adverse Event Detail** form.

12. Click **OK**.

   **Note:** To report multiple adverse events of the same type within one form, click **OK and Add Another**.

13. Fill out the remaining fields in the **Adverse Event Form**.

14. Click **Continue >>**.
Adverse Event Form

15. Optional, enter the names of the documents in the box below as they should appear on the IRBMED approval, if the study sponsor requires that the IRBMED approval letter contain a list of supporting documents.

16. Click Continue >>.

17. Click Submit Adverse Event from the end of the submission or workspace.

Note: If you are not ready to submit the Adverse Event, you can still go back and edit it.

You can withdraw the Adverse Event after it has been submitted by clicking Withdraw Adverse Event from the Study Workspace.

Submit Adverse Event

18. Click OK.
Important Information

- Anyone with access to a study can run an Adverse Event Summary Report on it to see how many and what types of Adverse Events have occurred.

### eResearch Home Workspace

1. Click **Approved** to display approved studies.
2. Click the **Name** of the study to view the approved study workspace.

### eResearch Study Workspace

1. Click **AE/ORIO**.
2. Click on the **Summary: AE Summary Report** link.
3. The **Adverse Event Summary Report** opens. This report lists the number and types of all Adverse Events that have been submitted on the study.

   **Note:** The tables with “Total #” in the title include only those AEs that have been acknowledged while the other tables show all AEs that have been submitted and their state at the time the report is generated.
Creating a Continuing Review

Important Information

- Study teams receive an email reminder that their research application is due for a continuing review 30, 60, and 90 days prior to the study expiration date.
- Create a continuing review to renew or terminate your study.

eResearch Home Workspace

1. Click **Approved** to display approved studies.
2. Click the **Name** of the study to view the approved study workspace.

Study Workspace

3. Click **New Continuing Review**.
Continuing Review Form

Scheduled Continuing Review (SCR) or Termination

4. Enter a title for the continuing review.

Note: To make tracking the continuing review easier, include the HUM# of the original study in the title.

5. Click Continue >>

Continuing Review Form

6. Complete the required information on each page.

7. Click Continue to move to the next page of the continuing review form.

Submit SCR

8. Click Submit Scheduled Continuing Review from the End of Continuing Review or the Study Workspace.