Training and Support from the eResearch Homepage (www.eresearch.umich.edu)

The Regulatory Management links on the eResearch homepage contain information on:

**Training**
- Online Training, Step-by-Step Procedures, and Job Aids

**Support**
- Technical Support (navigation, connectivity, system errors)
  - Contact the ITS Service Center at 734-764-4357 (4-HELP) or 4HELP@umich.edu
- Regulatory Support (completing application questions, clarifications for materials, regulatory compliance)
  - Contact your IRB (http://research-compliance.umich.edu/u-m-irb-contacts)

**Regulatory Management Sandbox**
- The Sandbox is your place to “play” around with a copy of eResearch without fear of completing your real application incorrectly. You can upload documents, enter information, add study team members, etc. It is available anywhere you have an Internet connection. **Data entered in the Sandbox will not populate in the eResearch production system.**

---

**Log Into eResearch Regulatory Management.**

2. Click Regulatory Management Login. [Login]
3. Login using your Login ID (uniqname or Friend ID) and password.
   - If you are a non U-M user, refer to the information below to set up a Friend ID.

---

**Set Up a Friend ID/Friends Account (Non-U-M Users)**

2. Click Regulatory Management Login. [Login]
3. Click **create one now** to create a Friend ID.
4. Click the **Others** link to view the full directions on **How to Set Up a Friends Account**.
   - 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**.
   - You will receive further instructions via an email from friend-accounts@umich.edu.
   - Allow up to an hour to receive the email.
7. Click the **Create Friend Account** link in the email from friend-accounts@umich.edu.
8. Enter and confirm your **Password** on the web page that opens.
9. Click **Set Password**.
10. A **Friend Account Created** confirmation page displays and you will receive a confirmation email. You are now ready to login to eResearch using your Friend ID and password.

---

**Create a New Study**

1. From your Home Workspace, under Create New, click **Study**.
2. Enter the study information on the first page.
3. Click **Continue >>**.

---

**Add a Study Team Member**

Application question 1.3 allows you to add people to the Study Team.

1. Click **Add**.
2. Click **Select**.
   - A new window opens displaying all the people available to add to the team.
   - If the person you need to add does not display, see Help for more information.
3. Select the new Study Team Member.
4. Click **OK**.
5. Select the new Study Team Member’s function on the team.
6. Indicate if this person can edit the application or receive notifications of all study correspondence by selecting **Yes** to the appropriate questions.
7. Click **OK**.
8. Click **Save**.

---

**Add Documents**

Throughout the application, you can upload/add documents.

1. Click **Add**.
2. Enter a **Title** for the document you are uploading.
3. Click **Browse**... to locate the document on your computer.
4. Select the file to upload.
5. Click **Open**.
6. Click **OK**.
   - See Help for important information on naming your document.
Add Study Team Notes

When the application is in an editable state, Study Team Members can post Notes to other Study Team Members directly on the application. These Notes are visible only to Study Team Members.

1. Navigate to the application section where you want to add a Note.
2. In the Study Application, click Add.
3. Enter the Note.
4. Click OK.
   ⇒ The Note appears at the top of the section.
   ⇒ Click to see the Notes.

You can view all Notes in the Study Workspace in the Notes tab.

Post Correspondence

1. From the Study Workspace, click Post Correspondence.
2. Enter your message in the Comments field.
3. Attach supporting documents, if needed.
   ⇒ Do NOT add documents that were originally uploaded as part of the application. If a document that was included in the application needs to be revised, add it to the appropriate section of the application.
   ⇒ Post Correspondence is only a communication tool and will not update or submit your application.
4. Select the Study Team Members or Committees to receive email notification of the correspondence.
5. Click OK.

Hide/Show Errors

While inside an application:
1. Click Save.
2. Click Hide/Show Errors.
   ⇒ Required fields that are not completed are displayed in a window at the bottom of the application.
3. Click a link to jump to an incomplete section of the application.
4. When the section is complete, click Save before jumping to the next incomplete section.
5. Click Exit to return to the Study Workspace.

Print the Application

1. From the Study Workspace, click Printer Friendly Version.
2. Click Print.

Print a Section of an Application

1. From the Study Application section you want to print, click Print.  
2. Click Print.

Application Checklist

1. From the In Progress tab of your Home Workspace, click the Name of the study to be submitted.
   ⇒ The Study Workspace opens.
2. Click Application Checklist.
   ⇒ The Application Checklist displays the current status of each section in the application.
3. Click any section name to open that section in the main window.
4. Enter required information in the section.
5. Click Save.
6. Click Exit at the top of the Study Application to return to the Study Workspace.
7. To refresh the Application Checklist, click the Application Checklist button.

Submission Types

Submissions are identified by an automatically generated submission number.

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Submission # (example)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Application</td>
<td>HUM000000103</td>
</tr>
<tr>
<td>Amendment</td>
<td>Ame000000101</td>
</tr>
<tr>
<td>Scheduled Continuing Review / Termination</td>
<td>CR00000104</td>
</tr>
<tr>
<td>Adverse Event / ORIO</td>
<td>Adv00000102</td>
</tr>
</tbody>
</table>

Applications must be submitted by the PI

1. From the Study Workspace or End of Application, click Submit Application.
2. Upload or update your CV, resume, or biographical sketch.
3. Complete the Conflict of Interest information.
4. Select the checkbox indicating agreement with the Investigator Assurances.
5. Click OK.
Accept Role

Study Team members, with the exception of the PI and Administrative Staff, must accept their role before submitting the study application.

1. From the Need to Accept Role section of your Inbox, click the name of the application.
   ⇒ The Study Workspace opens.
2. Click Accept Role.
3. Click the checkbox to indicate you have read the application materials and accept the responsibilities associated with your role in the study.
4. Upload or update your CV, resume, or biographical sketch.
5. Complete the Conflict of Interest section.
6. Click OK.

Tips and Tricks

1. Save Often
   ⇒ Click Save on every page you enter data.
2. Do NOT use your web browser to navigate
   ⇒ You can lose data entries when using the web browser forward and back buttons.
   ⇒ Instead, only use Continue or the Jump to list (see below for more details).
3. Jump To list—Know where you’re going
   ⇒ The Jump To list allows you to directly access any section in the application.
   ⇒ The list changes based on your answers.
     ⇒ Current section (page) listed in red.
     ⇒ Required sections are listed in bold.
     ⇒ Sections not required are listed in italics.
   ⇒ It is recommended that you use the Continue button to navigate through the application initially because your response to some questions trigger additional required sections to open. Use the Jump To list when you know which sections you must complete.
4. Copy and Paste loses formatting
   ⇒ Information copied and pasted from documents on your computer into eResearch can lose some types of formatting, such as bolding, superscripts, and Greek characters.
   ⇒ To avoid losing this formatting, many sections requiring documentation allow you to upload the document and then refer to the section as a response to an application question.
5. Posted Correspondence is global
   ⇒ Any messages posted using the Post Correspondence activity are viewable by anyone with access to the study.
   ⇒ This includes Study Staff, IRB/IBC Office Staff, Reviewers, and Committee Members.

Post-Approval Activities

After your study is approved, the following can be reported/submitted through the approved Study Workspace:

Adverse Event / ORIO
⇒ Adverse Events (AEs) and Other Reportable Information and Occurrences (ORIOs) are associated with the initial Study Application. You can submit as many AEs and ORIOs as necessary.

Amendment
⇒ You may submit only one Amendment at a time, but you can incorporate multiple changes into one Amendment.

Continuing Review
⇒ Also known as Renewals/Terminations, Scheduled Continuing Review (SCRs) are used to renew or terminate a study. You may submit only one SCR at a time.
⇒ SCRs must be submitted separately from Amendments.

Edit Study Team Members
⇒ Used this activity to add, update, or delete study team members with the role of Administrative Staff.
⇒ All other study team members must be updated via an amendment.

See Approval Letter

From the Study workspace Main tab:

1. Click See Approval Letter, under Activities and Correspondence.

Study Documents

You can view the following Approved Documents from the Study workspace, Documents/Related Records tab:
- Finalized Documents
- Documents in the Study (links to application section))
- Supporting Documents

1. Click the document name to open it.
6. Submit Requested Changes
   ➔ Submitting requested changes is a two-step process:
     1) Make the requested changes to the study application.
     2) Use the Submit Changes activity to submit the requested changes from the application or the Study Workspace. Study Team members with edit rights can submit the changes.

7. Use percent sign (%) as a wildcard in searches and filters
   ➔ When searching or filtering lists in eResearch, use % as a wildcard character in your search.
   ➔ Wildcards let you specify parts of words for which you are searching.
   ➔ For example, searching for Dav% returns all instances of David, Davidson, Davis, etc.

8. Making changes to a submitted study application
   ➔ If changes need to be made to a submitted study application that has not been approved, use the Post Correspondence activity to ask the reviewing office to change the state of the application so the study team can make changes.
   ➔ This will allow you to edit the study application, make changes, and then resubmit the study application to the reviewing committee.

9. Making changes with an Amendment already in progress
   ➔ If changes need to be made to your study (such as adding a new Study Team Member) when an Amendment is in Progress, use the Post Correspondence activity to ask the reviewing office to change the state of the amendment so the study team can make changes.
   ➔ This will allow you to edit the amendment, make changes, and then resubmit the amendment to the reviewing committee.

---

### Study States

Track the study application through all committees with the progress bar.

The current State is always displayed in the Study Workspace.

**Note:** If approval is required from an ancillary committee, your progress bar will have four states. Ancillary committee review must be completed prior to IRB review.

Once an application is submitted for review, it cannot be edited by the Study Team unless changes are requested by the reviewing committee. See the list below for states in which the Study Team can edit the application.

<table>
<thead>
<tr>
<th>State of Submission</th>
<th>Editable by Study Team?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Submission</td>
<td>Yes</td>
</tr>
<tr>
<td>Cancer Center Program Director Review</td>
<td>No</td>
</tr>
<tr>
<td>Changes Required by CCPD - Pending Review</td>
<td>Yes</td>
</tr>
<tr>
<td>PRC Review Complete</td>
<td>Yes</td>
</tr>
<tr>
<td>Ancillary Committee Review</td>
<td>No</td>
</tr>
<tr>
<td>Changes Required by Ancillary Committee</td>
<td>Yes</td>
</tr>
<tr>
<td>Ancillary Disapproved</td>
<td>No</td>
</tr>
<tr>
<td>Core Committee Staff Review</td>
<td>No</td>
</tr>
<tr>
<td>Changes Required by Core Staff</td>
<td>Yes</td>
</tr>
<tr>
<td>In Exempt Review</td>
<td>No</td>
</tr>
<tr>
<td>Validate Exempt Decision</td>
<td>No</td>
</tr>
<tr>
<td>Exempt Approved - Initial</td>
<td>No</td>
</tr>
<tr>
<td>Exempt Approved - Transitional</td>
<td>No</td>
</tr>
<tr>
<td>In Expedited Review</td>
<td>No</td>
</tr>
<tr>
<td>Validate Expedite Decision</td>
<td>No</td>
</tr>
<tr>
<td>Full Committee</td>
<td>No</td>
</tr>
<tr>
<td>Validate Committee Decision</td>
<td>No</td>
</tr>
<tr>
<td>Contingencies Pending</td>
<td>Yes</td>
</tr>
<tr>
<td>Core Committee Staff Contingency Review</td>
<td>No</td>
</tr>
<tr>
<td>Designated Reviewer Contingency Review</td>
<td>No</td>
</tr>
<tr>
<td>Approved</td>
<td>No</td>
</tr>
<tr>
<td>Not Regulated</td>
<td>No</td>
</tr>
<tr>
<td>Disapproved</td>
<td>No</td>
</tr>
<tr>
<td>Disapproved Final</td>
<td>No</td>
</tr>
<tr>
<td>Terminated</td>
<td>No</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>No</td>
</tr>
<tr>
<td>Expired</td>
<td>No</td>
</tr>
<tr>
<td>Expired - Continuation In Progress</td>
<td>No</td>
</tr>
<tr>
<td>Exempt Approval Revoked</td>
<td>No</td>
</tr>
<tr>
<td>Full or Partial Suspension</td>
<td>No</td>
</tr>
<tr>
<td>Full or Partial Voluntary Hold</td>
<td>No</td>
</tr>
</tbody>
</table>