

## Training and Support on the eResearch Homepage

The eResearch homepage has links for:

### Training

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


### Support

- Technical Support (navigation, connectivity, system errors)
  - ⇒ Contact the MAIS Help Desk at 6-7000 (734-936-7000) or maishelpdesk@umich.edu
- Regulatory Support (completing application questions, clarifications for materials, regulatory compliance)
  - ⇒ Contact your IRB (www.irb.research.umich.edu)


### 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. 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

- Go to <http://eresearch.umich.edu/>.
- Click .
- Login using your Login ID (username 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)

- Go to <http://eresearch.umich.edu/>.
- Click .
- Click [create one now](#) to create a Friend ID.
- 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.
- Go to <https://friend.weblogin.umich.edu/friend/>
- 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.
- Click the **Create Friend Account** link in the email from friend-accounts@umich.edu.
- Enter and confirm your **Password** on the web page that opens.
- Click **Set Password**.
- 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

- From your Home Workspace, click **New Study**.
 
- Enter the study information on the first page.
- Click **Continue**.


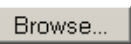
## Add a Study Team Member

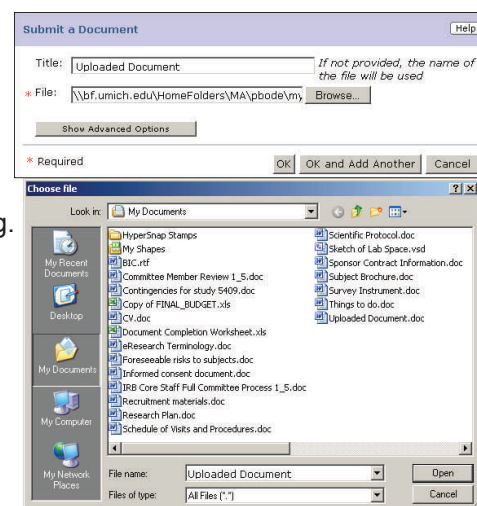
Application question 1.3 allows you to add people to the Study Team.

- Click **Add**.
- 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.
- Select the new Study Team Member.
- Click **OK**.
- Select the new Study Team Member's function on the team.
- Indicate if this person can edit the application or receive notifications of all study correspondence by selecting **Yes** to the appropriate questions.
- Click **OK**.
- Click **Save**.

## Add Documents

Throughout the application, you can upload/add documents.

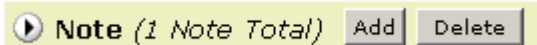
- Click .
- Enter a **Title** for the document you are uploading.
- Use  to locate the document on your computer.
- Select the file to upload.
- Click **Open**.
- Click **OK**.
  - ⇒ See Help for important information on naming your document.




## Add Study Team Notes

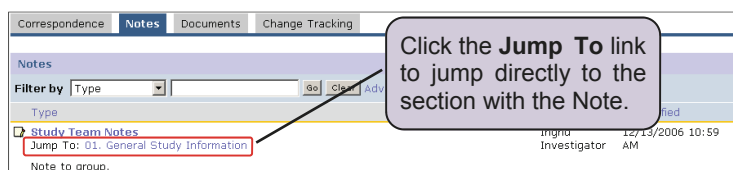
When the application is in an editable state, Study Team Members can post Notes to other Study Team Members directly on the application. These Notes are visible only to Study Team Members.

1. Navigate to the application section where you want to add a Note.
2. In the Study Application, click **Add**.



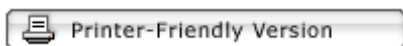
3. Enter the **Note**.
4. Click **OK**.
  - ⇒ The Note appears at the top of the section.
  - ⇒ Click  to see the Notes.

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



## Print the Application

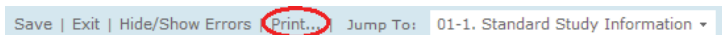
1. From the Study Workspace, click



2. Click **Print**.

## Print a Section of an Application

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



2. Click **Print**.

## 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**.

## Application Checklist

1. From **My Home**, click the title of the application to be submitted.
  - ⇒ The Study Workspace opens.
2. Click **Application Checklist**.



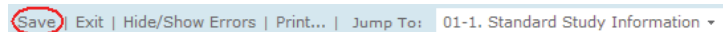
3. Click any section name to open that section in the main window.
4. Enter required information in the section.
5. Click **Save**.
6. Click **Exit** at the top of the Study Application to return to the Study Workspace.
7. To refresh the Application Checklist, click the **Application Checklist** button.

Section	Description	Progress
01. General Study Information		Complete
02. Sponsor Information		Complete
03. Performance Sites		Incomplete
04. Study Abstract		Complete
05. Research Design		Complete
06. Benefits and Risks		Complete
07. Special Considerations		Incomplete
08. Subject Detail		Complete
09. Subject Populations		Incomplete
10. Informed Consent		Complete
11. Confidentiality and Security		Complete
12. Exemption		Complete
13. Subject Payments Or Other Incentives		Complete
14. Health Care Treatments and Procedures		Complete

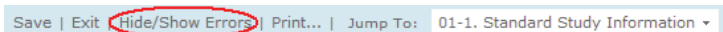
## Hide/Show Errors

While inside an application:

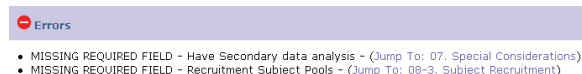
1. Click **Save**.



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 exit the form.


## Submit the Study

### Applications must be submitted by the PI

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

## Accept Role

If you are named as a Co-Investigator or Faculty Advisor on a study, you must accept your role in eResearch before the application can be submitted.

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. Select 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**.

## Post-Approval Activities

After your study is Approved, you will need to submit Adverse Events, Amendments, and Renewals via eResearch.

The following activities are available from the Study Workspace of an Approved study:

### New 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.

### New Amendment

- ⇒ You may submit only one Amendment at a time, but you can incorporate multiple changes into one Amendment.
- ⇒ Amendments must be submitted separately from SCRs.





### New 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.

## Submission Types

Submissions are identified by an icon, an abbreviation, and the submission number. These identifiers are automatically generated.

Submission types are as follows:

	HUM00000103	Study Application
	Ame00000101	Amendment
	CR00000104	Scheduled Continuing Review
	Adv00000102	Adverse Event or ORIO

## Tips and Tricks

Tips and Tricks for working in eResearch.

### 1. Informed Consent documents must contain merge fields

- ⇒ Finalized documents are stamped with the Application Number, IRB name, and the Approval Date by using special fields embedded in the Informed Consent documents.
- ⇒ When completing the application, you must include these fields in your attached Informed Consent document. Instructions and Microsoft Word templates for Informed Consent documents are available in eResearch forms via Help.

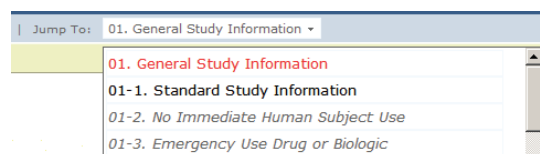
### 2. Save Often

- ⇒ Click save on every page you enter data.
- ⇒ If it will take a long time to complete a page, you will want to save periodically because your login times out after 2 hours of no system activity. As with all web-based tools, eResearch does not recognize typing as a system activity.

### 3. Do NOT use your web browser to navigate

- ⇒ You can lose data entries when using the web browser forward and back buttons.

### 3. Jump To list — Know where you're going



- ⇒ The **Jump To** list allows you to directly access any section in the application, but this suppresses the Smart Forms logic.
  - ⇒ Smart Forms logic routes you to only required questions when the questions are completed in a sequential order.
- ⇒ The **Jump To** list dynamically changes based on your answers.
  - ⇒ Current section (page) listed in **red**.
  - ⇒ Required sections are listed in **bold**.
  - ⇒ Not required sections are listed in *italics*.
- ⇒ It is recommended that you use the **Continue** button to navigate through the application initially. Use the **Jump To** list when you know which sections you must complete.

## Tips and Tricks

### 5. 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.

### 6. 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.

### 7. 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.

### 8. 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 you for which you are searching.
- ⇒ For example, searching for %mot% returns DeMott, Miyamoto, and Mott.

### 9. Making changes to a Submitted Study Application

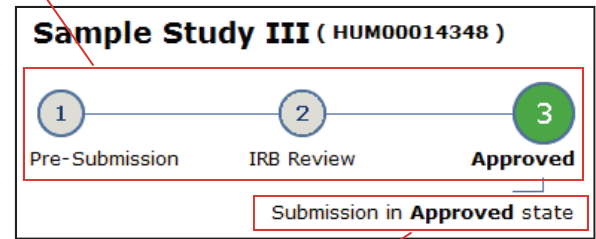
- ⇒ If changes need to be made to a submitted study application that has not been approved, use the Post Correspondence activity to ask the reviewing office to change the state of the application so the study team can make changes.
- ⇒ This will allow you to edit the study application, make changes,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

### 10. 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.

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