

eCompliance

IRB Study Submission Guide

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Logging In

The IRB system is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

To log in:

1. If you do not see the form shown to the right, click the **Login** link located at the top right corner of your screen.
2. Type the user name and password you received into the boxes.

Login as
 User Name:
 Password:
 Remember me

★ **Tips:** Press the Tab key after typing your user name to move to the Password box. If you do not know your user name or password, contact the IRB for assistance. (See [Contacting Support on page 15.](#))

3. Click **Login** (or press Enter).

Automatically Logging In

You can set the IRB system to log you in automatically when you access the IRB web site.

★ **Important!** Do not enable autologin if you are using a shared or public computer. Autologin could cause a security breach by allowing others to take actions as though they were you.

To turn on autologin:

1. The next time you log in, check the **Remember me** box before clicking Login.

Login as
 User Name:
 Password:
 Remember me

To turn off autologin:

1. Click the **Logoff** link in the upper right corner.
2. Click **Clear Autologin**.

Logoff successful.

Creating a New Study

You can prepare a new study for IRB review by entering information into a series of online forms. The number of forms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information.

The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study. For differences, see [Submitting Continuing Reviews and New Information on page 13](#).

Before you begin, gather files and information about your study such as:

- Supporting information files (for a list, see [Checklist of Information to Attach on page 14](#))
- Financial interest status for each of your study team members
- Contact information and IRB oversight information for external sites involved in the study

★ **Tip:** If you regularly create studies with a similar set of team members, you can save time by defining the default team members to be added to each study you create. For instructions, see the online help.

Similarly, you can save time by defining the default list of ancillary reviewers to be added to each study you create. For instructions, see the online help.

To create a new study for review:

1. From My Inbox, click **Create New Study**.

Note: If you do not see the Create New Study button, click the **My Inbox** link (upper right).

Your Name **My Inbox** Logoff

2. Fill in the applicable boxes and answer the questions.

★ **Tip:** When you create a study, you are assigned to be the primary contact who receives all communications from the IRB on behalf of the study team. (The principal investigator you specified also receives the communications.) You can change the primary contact later as described in [Changing the Primary Contact on page 9](#).

3. Click **Continue** to move to the next form.

★ **Tip:** A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, see the tips in the online help. If you do not answer a required question initially, you must return and answer it before you can submit the study for review.

4. When you reach the final page, click **Finish** to exit the study.

You can continue to edit the study until you submit it for review. See [Editing a Study on page 5](#).

★ **Important!** The study has not been submitted for review yet. For instructions, see [Submitting the Study for Review on page 7](#).

Finding More Information

To find this...	...look for this...	...and click...
More information about a question or form.		Click the question mark icon next to the question or form title.
The full online help system, with search and table of contents.	Shortcuts <hr/> My Inbox <hr/> Reports <hr/> Help <hr/> Study Submission Guide	Click the Help link in the Shortcuts area on the left.
The online help contains additional procedures and information for all users.		
Document templates, checklists, and IRB procedures.		Click IRB and then IRB library in the upper left corner.

Editing a Study

You can continue to make changes to a study until you submit it for IRB review. You can also make changes if the IRB requests clarifications (except during committee review) or modifications.

To edit a study:

1. From My Inbox, click the name of the study to open it.

Note: If the study does not appear in your inbox, see [Accessing a Study on page 10](#).

2. Click **Edit Study** on the left.
3. Make changes as appropriate.
4. Exit the study.



- ★ **Tip:** Choose one of these ways to exit:
- Click the **Exit** link. If prompted to save the study, click **Yes**.
 - Click **Continue** on each form, and then click the **Finish** button on the final form.

Checking the Study for Errors

Checking the study for errors and omissions helps you include all the relevant information, which is critical for receiving a timely review of your study.

Using these types of error checking helps you supply all the information the IRB needs:

- **Automatic system error checking** identifies any omitted answers to required questions on the form when you click Continue. A red asterisk (*) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions that cause more forms to be added to your study.
- **Visually inspecting the forms** to see what you may have missed, especially:
 - Questions that are relevant to your study but are not required for all studies
 - Documents that should be attached (see [Checklist of Information to Attach on page 14](#))
 To perform a visual inspection, open the study and look through the forms in order. To open the study, see [Editing a Study on page 5](#).
- **Using the Hide/Show Errors option** to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts to submit the study. However, if you are filling out the forms on behalf of the PI, it is best to check the study for errors before the PI attempts to submit it, using the steps below.

To use Hide/Show Errors to find and correct errors:

1. Open the study, as explained in [Editing a Study on page 5](#).
2. From the top navigation area, click **Hide/Show Errors**.



The Error/Warning Messages pane appears at the bottom of the window, listing all the current errors and where to find them.

Error/Warning Messages			Refresh
Message	Field Name	Jump To	
⊖ This is a required field.	Is Study Under IND	Drugs	
⊖ This is a required field.	Devices	Devices	
⊖ This is a required field.	Device Type	Devices	

3. For one of the errors listed, click the link in the Jump To column to go to the form containing the error.
4. Click **Continue** to identify the specific questions on the form with errors.
5. Fill in the missing information.
6. Click **Refresh** in the Error/Warning Messages pane to update the list of errors.
7. Continue correcting errors until no errors are listed.

Submitting the Study for Review

After entering all required information into the forms and attaching files, the principal investigator must submit the study for IRB review.

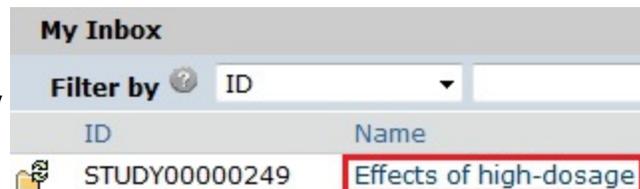
★ Tips:

- Make sure you attach all applicable information to the study, as identified in [Checklist of Information to Attach on page 14](#).
- Check for missing information before attempting to submit the study, as described in [Checking the Study for Errors on page 6](#). Any errors or omissions not corrected are shown when attempting to submit the study and must be corrected before you can submit it for review.
- Identify any person or organization outside the IRB who needs to review the study. Add them to the list of ancillary reviewers by clicking Manage Ancillary Reviews. For instructions, see the online help.

★ **Important!** Only the principal investigator can complete the following steps.

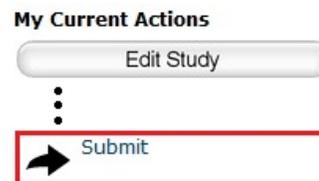
To submit the study for IRB review:

1. Log in to the system.
2. Make sure you are in My Inbox.
Note: If you do not see My Inbox, click the **My Inbox** link (top right part of the page).
3. Click the name of the study to open it.



★ **Tip:** If the study does not appear in the list, perhaps it was already submitted, or it does not include you as a study team member. To find the study, try clicking **IRB** in the top left navigation area. If you do not see it in that list, see [Accessing a Study on page 10](#) for more ideas.

4. Click **Submit** from the My Current Actions list on the left.



★ **Tip:** If any errors or warnings are shown, click the link in the Jump To column to go to the form containing the problem. For more information, see [Checking the Study for Errors on page 6](#). When all errors are corrected, try submitting the study by clicking Submit again.

5. Click **OK** to agree to the statement presented on the screen.
6. When prompted, log in again to verify your identity as the study's PI.
7. Click **Submit**.

What to Expect After Submitting

Submitting information to the IRB initiates a series of activities that may include:

- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Any of these may lead to a request for the investigator to take further action, such as providing clarifications or modifying the study. **Whenever you need to act, you receive an e-mail notification, and the study appears in My Inbox when you log in to the IRB system.**

★ **Important!** Make sure the appropriate person is listed as the primary contact to receive the e-mail and see the study in My Inbox (along with the PI, who always receives these). By default, the person who created the study is the primary contact. See [Changing the Primary Contact on page 9](#).

Checking the Status of Your Study

You can see a diagram showing the state of your study within the IRB review process by opening the study. For example:



You can easily open your study from one of the following lists (depending on its status):

- My Inbox
- IRB In-Review Studies
- IRB Active Studies

For instructions about opening your study from these lists, see [Accessing a Study on page 10](#).

Changing the Primary Contact

The study's primary contact for receiving communications from the IRB can be changed at any time. For example, it may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently.

Notes:

- To change the primary contact, you must be a member of the study team or the IRB coordinator assigned to the study.
- By default, the person who created the study in the system is the primary contact.
- The PI continues to receive notifications regardless of the primary contact assignment.

To change the primary contact:

1. Open the study by clicking the study's name. (For instructions about finding the study, see [Accessing a Study on page 10.](#))
2. Click **Assign Primary Contact** from the My Current Actions list on the left. A new window opens.
3. Click **Clear** to remove the current contact.
4. Begin typing the name of the new contact. A list of matching names appears.
5. Select the correct name using the mouse or down arrow key.
6. Click **OK**.

My Current Actions

View Study



 Assign Primary Contact

Note: If the primary contact is also engaged in the research, make sure the list of team members within the study includes the person.

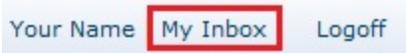
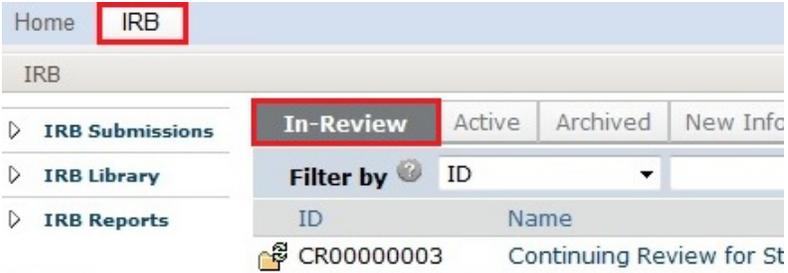
Accessing a Study

You may want to open a specific study to view or update its contents, submit it for review, review it, or take other actions on the study.

Note: Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

To open a study, click its name when you find it in a list of studies.

To find a list that includes the study, try these suggestions:

Check this list..	For...	How to find this list
My Inbox	<p>Studies assigned to you for action, such as a study you are:</p> <ul style="list-style-type: none"> ■ Preparing to submit ■ Assigned to review 	<p>Click the My Inbox link in the top right navigation header.</p> 
IRB In-Review tab	<p>Studies the IRB has not reviewed or for which it has not communicated a decision</p>	<p>Click IRB in the top left navigation area and select the In-Review tab.</p> 
IRB Active tab	<p>Studies approved by the IRB and currently in progress</p>	<p>Click IRB in the top left navigation area and select the Active tab.</p>
IRB All Submissions tab	<p>All studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view</p>	<p>Click IRB in the top left navigation area and select the All Submissions tab.</p> <p>Tip: Try filtering this list by the study name or principal investigator. Next to Filter by, select Name or Investigator. Then type the beginning of the name and click Go.</p>
IRB New Information Reports tab	<p>Reportable new information (RNI) submissions, possibly related to one or more studies</p>	<p>Click IRB in the top left navigation area and select the New Information Reports tab.</p>

Responding to a Request for Clarifications or Modifications

At any stage during the review process, the IRB may request clarifications to the study content. Similarly, the official IRB determination may be that the study requires changes before research can begin.

Both situations require the study staff to take similar actions. In either case, the PI and the study's primary contact receive an e-mail, and the study appears in My Inbox for each member of the study team.

To view the details of the request and respond with the changes:

1. From My Inbox, click the name of the study to open it.
2. Locate the details of the request, as described here:

For clarification requested: In the Activity column under Clarification Requested, read the request details.

History	Project Contacts	Documents	IRB Assignment Details	Reviews	Snapshots
Filter by	ID		Go	Clear	Advanced
Activity				Author	
Clarification Requested				Lee, Mabel	

This study is not detailed enough about the risk involved and how participants will be in consent process. A HHS-approved consent form is required to make sure we are meeting more detail about the drug dosages and indicate who will administer them. You study drugs. Please add that person, and give us all the details, so w... [read more](#)

If applicable, click the **read more** link to display the remaining text.

For modifications required: Click the letter link near the top of the page on the right side. The letter contains the modification requirement details.

Analgesic remedies for amputees

Principal investigator: Martha Mears

Submission type: Initial Study

Primary contact: Carmen Alverado

IRB coordinator: Lisa Jones

Letter: [Correspondence for IRB297.pdf](#)

3. Edit the study to incorporate changes as needed. For instructions, see [Editing a Study on page 5](#).

Notes:

- In most cases, you can update all aspects of the study, including adding or removing attached documents.
 - If clarifications were requested during committee review, you cannot edit the study, and you see the View Study button instead. In that case, respond to the reviewer by commenting in the Submit Changes form, as described in the next step.
4. Click **Submit Changes** to return the study to the reviewers.

Notes:

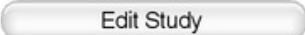
- The Submit Changes form gives you space to type a point-by-point response to the requests and to attach a file. However, any permanent study information should be incorporated into the study itself.
- If clarifications were requested during committee review, you may be asked to make permanent changes to the study after the review is complete.

5. Click **OK**.

The study returns to the review process.

Submitting Continuing Reviews and New Information

The table below summarizes how to get started submitting each type of information to the IRB.

To submit this type of information...	...start here...	...and click this button	Notes
Continuing review updates for an active study	From the Active tab, click the study name (see Accessing a Study on page 10)		You can submit a continuing review and a modification at the same time. The first form prompts you to identify the type of information to submit. To request study closure, submit a CR. Based on the research milestones completed, the study may be closed.
Modifications to an active study			
Request to close study			
New information or an adverse event report	For new information about a particular study, start from the Active tab and click the study name (see Accessing a Study on page 10)		Report new information as soon as you become aware of it. The form identifies the types of information you must report.
	For information affecting multiple studies, start in My Inbox		
New study for review	My Inbox		See Creating a New Study on page 4 .
Updates to a new study that hasn't been submitted for IRB review yet	Within the study (see Accessing a Study on page 10)		See Editing a Study on page 5 .

Checklist of Information to Attach

Be prepared to attach several files to your study. While editing the study, several forms provide places to attach related files. In some cases, a template file is provided, such as for the protocol.

When attaching each file, name it as you want it to appear on the IRB approval letter.

Attach the information listed below (if relevant to your study) to the location identified.

Protocol: (Basic Information page)

- Investigator protocol
- Complete sponsor protocol
- HHS (Department of Health and Human Services) protocol

Funding information: (Funding Sources page, with each source)

- Grant applications

Drug details: (Drugs page, with each drug, or on main Drugs page if not specific to one drug)

- Package insert
- Investigator brochure
- Verification of each IND number (one of these):
 - Sponsor protocol with the IND number
 - Communication from the FDA or sponsor with the IND number

Device details: (Devices page, with each device, or on main Devices page if not specific to one device)

- Product labeling/device instructions
- Investigator brochure
- Verification of each IDE or HDE number (one of these):
 - Sponsor protocol with the IDE / HDE number
 - Communication from the FDA or sponsor with the IDE / HDE number

Recruitment and consent details: (Recruitment Materials page)

- Consent documents:
 - Consent forms
 - HHS-approved consent document
 - For non-written consent, a script of the information provided orally to the subjects
- All material to be seen or heard by subjects, such as:
 - Evaluation instruments and surveys
 - Advertisements, including printed, audio, and video
 - Recruitment materials and scripts
 - Foreign-language versions of materials for subjects

All other relevant documents: (Supporting Documents page)

- Conflict of Interest Committee's determination for each financial interest related to the research
- Completed checklist of meeting Department of Energy requirements

Contacting Support

For additional answers to your questions, feel free to use the following resources:

Resource	How to access it
Documentation	See Finding More Information on page 5
Training materials on the website	http://research.ku.edu/ecompliance
IRB support staff	E-mail: hscl@ku.edu Phone: (785) 864-7429

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