Study Submission Guide

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Logging In

The eIRB 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 as an Ochsner employee:

1. To login as an Ochsner employee you need the following:

- An Ochsner employee ID
- To be logged into the Ochsner network either directly or through the VPN.

2. Simply click on the yellow highlighted box - Click Here for Ochsner Employee Login

To log in as an Non-Employee

1. To login as a non-employee you need the following:

- Username
- Password

2. Enter your username/password into the respective boxes

3. The first time you login or after a password reset you will need to set a new password

- Minimum 8 characters: 1 upper case, 1 lower case, number, or special character

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

Tips: Press the Tab key after typing your user name to move to the Password box.

If you do not see the login screen shown above, click the Login link located at the top right corner of your screen.

If you are an Ochsner Employee who will not be able to access the network you will need to contact the IRB to be issued a username and password.

If you do not know your user name or password, contact the IRB for assistance.

Auto Login

You can set the eIRB system to log you in automatically when you access the eIRB web site. This feature automatically stores your username and password similar to many other websites.

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 login, check the **Remember Me** box before logging in.

To turn off autologin:

1. Click the logoff link in the upper right corner
2. Click **Clear Autologin** (or **Clear All Autologin**)

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.

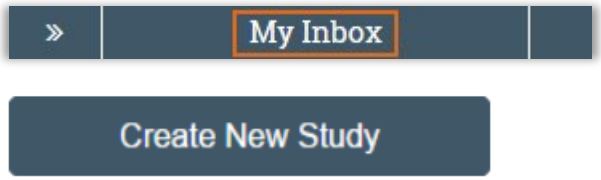
The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

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

- Supporting information files (for a list, see Required Documents)
- Study teams members and their study role (i.e., CRC, CRA, Sub-Investigator)

To create a new study for review:

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



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

Tips! Click next to the question or at the top of the form for help text.
A few more notes from the application:

- Basic Study Information
  - The default Principal Investigator is the creator of the study. You must update this field to move forward in the application.
  - Q5 pertains to use of an external IRB. Please, contact the Ochsner IRB to confirm we will accept the external IRB before selecting this option.
- Funding Source
  - If the study has no funding then please select Investigator.
- Study Scope
  - For study locations only select or enter locations in which the Ochsner study team is involved.
- If you answer 'yes' to ionizing radiation you will be required to fill in the tests that are greater than standard of care. This will trigger an automatic ancillary review by Radiation Safety upon submission. Be sure to consult with your PI about the answer to this question.

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

Tip: A red asterisk (*) precedes each question that requires an answer. 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.

Important! The study has not been submitted for review yet. For instructions, see Submitting the Study for Review.

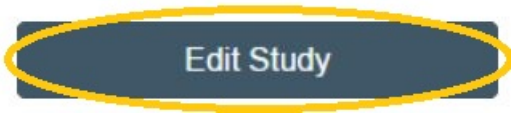
Editing a Study

You can continue to make changes to a study until you submit it for IRB review or if the IRB staff has requested changes.

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.

2. 

Click **Edit Study** on the left.
3. For all initial submissions documents should be clean, in final format. Do not submit tracked changes or draft documents as the IRB cannot review these.
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.

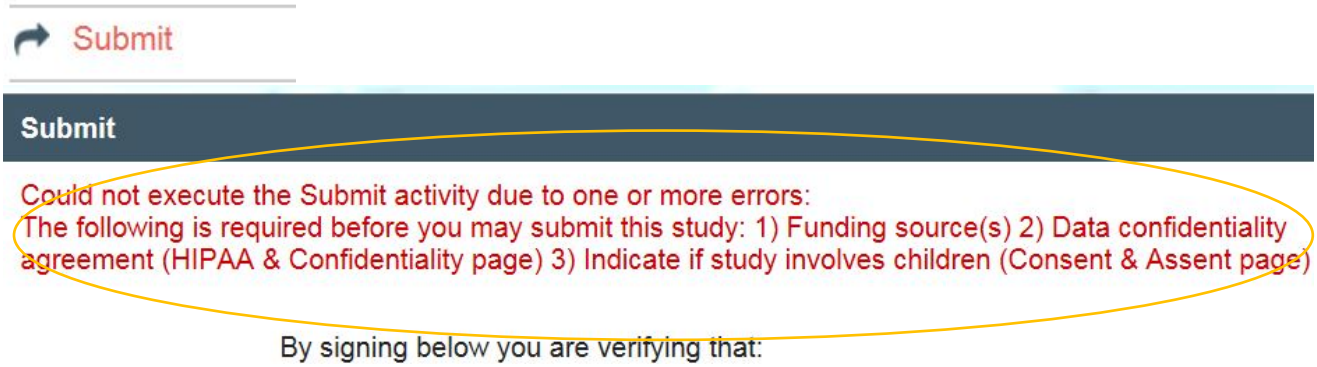
Checking the Study for Errors

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 via the 'Submit' activity** identifies omitted answers to required questions on the form when you click Continue. Keep in

mind the system does know if the information you've entered is correct only if information has been entered into the required fields/checkboxes.



- **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 Required Documents) To perform a visual inspection, open the study and look through the forms in order. To open the study, see Editing a Study.
- **Using the Hide/Show Errors option** has limited capability in eIRB and will not catch all errors. It is advised that you use the **'Submit'** activity instead.

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

1. Open the study, as explained in Editing a Study.
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.

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.

Financial Disclosures

All investigators, Principal Investigator and Sub-Investigators are required to submit a financial disclosure for each study on which they are listed prior to the study being submitted to the IRB.

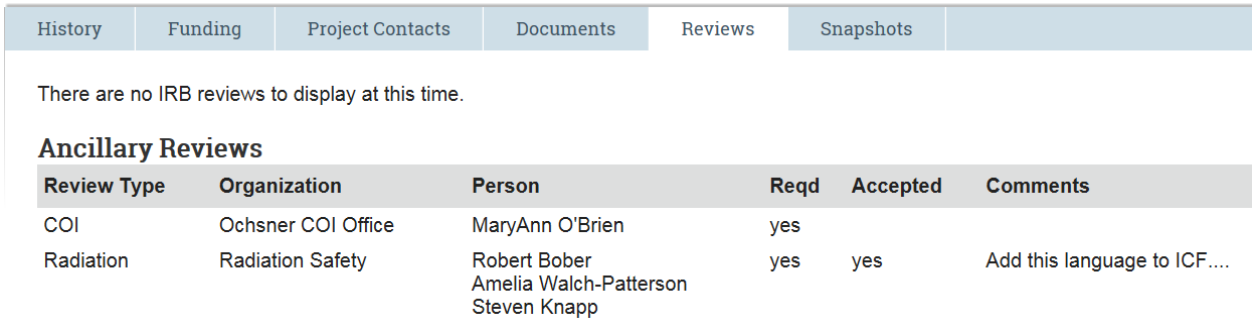
To request a disclosure and submit a disclosure:

1. 

Using the 'Request Financial Disclosure' activity on the left notify all investigators.
2. Investigators will receive an email with a link to the study that will take them directly into eIRB (after login) where they can use the 'Submit Financial Disclosure' activity.


3. Research Conflict of Interest (rCOI) is notified via email once a positive disclosure is made.
4. The IRB will not move forward with expedited or committee review until rCOI has completed their review and issued their approval in eIRB.

Note: You can review required ancillary reviews by going to the Reviews tab of the main study.



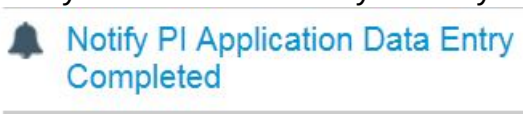
Submitting the Study for Review

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

Tips: PI proxies can be assigned one of two ways

- Study team member is identified as the Study Coordinator in the application
- The PI uses the 'Assign PI Proxy' activity to assign a proxy.

To notify the PI or submit as the PI Proxy:

1. Notify the PI that the study is ready for submission using the 

This notification will only go to the PI not the proxy.
2. The email notification will contain a link that will take the PI directly to the study where they can use the 

If accessing the study from My Inbox click the name of the study to open it.
Note: If the PI does not use the email link or the proxy is submitting, see Accessing a Study
3. Click **OK** to agree to the statement presented on the screen.
4. Click **Submit**.

What to Expect After Submitting

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

- Pre-review by an IRB staff member
- Ancillary review(s)
  - Radiation Safety
  - Biosafety
  - Compliance
  - Scientific
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Important! If your study requires an ancillary review you can view this and the response under the Reviews tab of the study.

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): For instructions about opening your study from these lists, see Accessing a Study.

At any point prior to approval the IRB, the reviewer or committee may request for the study team to take further action, such as providing clarifications or modifying the study. **Whenever the study team needs to act, the PI or their proxy receives an e-mail notification, and the study appears in My Inbox for the requested information or changes.**

Clarifications Requested by the IRB

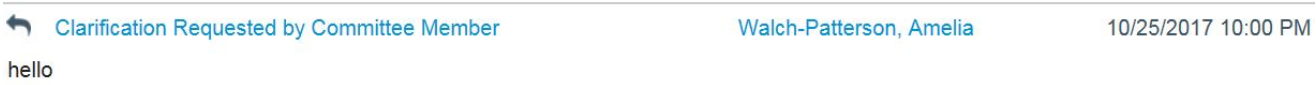
1. If clarifications are requested by the IRB you will receive an email notification with a link to the study. All changes must be made within the application see Editing a Study for how to access the application and make changes.
2. After making the requested changes the study must be re-submitted for IRB review by using the 

activity.

Note: Please do NOT upload documents for review in to the Submit Response activity!

Clarifications Requested by IRB Reviewers

1. If clarifications are requested by the IRB reviewer the PI/PI proxy will receive an email with a link to the study.
2. The clarification request can be found in the history log



3. No changes can be made to the application for these requests. You may provide clarifications using the 

activity only.

Post Review Modifications Required

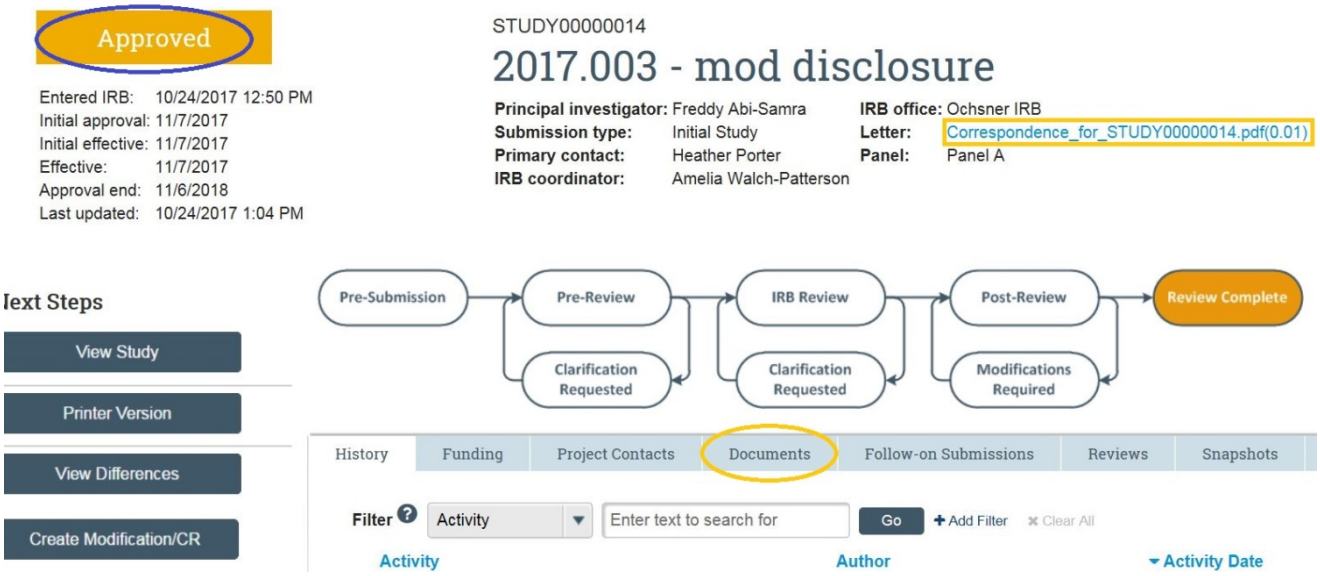
1. If modifications are required to secure approval the PI/PI proxy will receive an email with a link to the study.
2. A determination letter will be posted in the header of the study that contains details on the required changes to secure approval.

3. This will require that the application be edit and perhaps documents such as the protocol or ICF and the application resubmitted using the 'Submit Response' activity.

Note: Failure to respond promptly to any of the above requests slows the review and approval process for your submission. In some cases, your submission may be rescheduled for review at a later IRB meeting because the committee requires your response before making a decision.

Approved Study

Once a study is IRB approved the workspace changes.



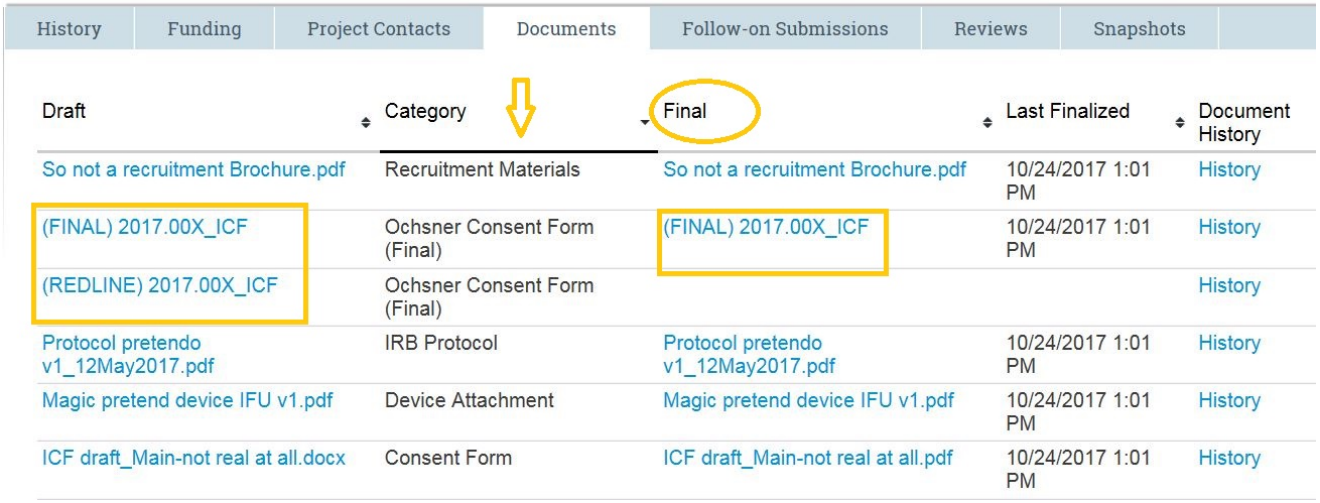
1. The application will no longer be editable. Any changes will require a Modification.
2. The approval letter is contained in the header.
3. All study documents including the consent form are listed on the documents tab.

Important! Approval letters will list the submitted documents as the file name from the submission. It is especially important that the document file name is correct to avoid errors.

Approved Documents

To access approved and draft documents click on the **Documents** tab. The columns are sortable.

All documents approved for use and conduct of the study will be listed in the Final column this includes the stamped, IRB approved consent form. Finalized documents are in pdf form and, if appropriate, contain the IRB stamp in the upper left corner.



History | Funding | Project Contacts | Documents | Follow-on Submissions | Reviews | Snapshots

Draft	Category	Final	Last Finalized	Document History
So not a recruitment Brochure.pdf	Recruitment Materials	So not a recruitment Brochure.pdf	10/24/2017 1:01 PM	History
(FINAL) 2017.00X_ICF	Ochsner Consent Form (Final)	(FINAL) 2017.00X_ICF	10/24/2017 1:01 PM	History
(REDLINE) 2017.00X_ICF	Ochsner Consent Form (Final)			History
Protocol pretendo v1_12May2017.pdf	IRB Protocol	Protocol pretendo v1_12May2017.pdf	10/24/2017 1:01 PM	History
Magic pretend device IFU v1.pdf	Device Attachment	Magic pretend device IFU v1.pdf	10/24/2017 1:01 PM	History
ICF draft_Main-not real at all.docx	Consent Form	ICF draft_Main-not real at all.pdf	10/24/2017 1:01 PM	History

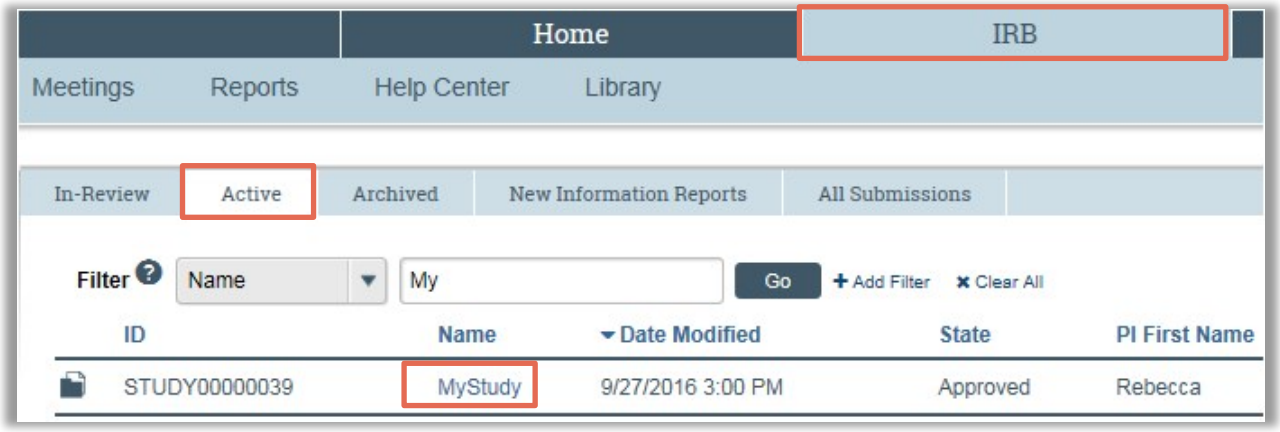
IMPORTANT! For each consent document there are 3 versions.

1. The IRB approved consent located in the Final column, category Ochsner Consent Form (Final).
2. The redline (tracked-changes) version of the ICF located in the Draft column, category Ochsner Consent (Final). This is not approved do not use for consenting subjects!!!
3. The word version that allows changes for Modifications located in the Draft column, category Ochsner Consent (Final).

Submitting a Modification

To change documents on an approved study:

1. Click **IRB** in the top navigator and select the **Active** tab.

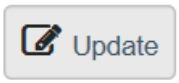


2. Click the name of the approved study.
3. This will take you into the approved study workspace and you will click the button to the left 

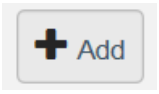
4. There are 2 cover pages that must be completed. On the 1st cover page it is advised that you click both boxes for the scope of the modification.

5. Click continue. Once you move past the 1st cover page you cannot edit your selections and will not have access to other parts of the study to modify if you did not check both boxes.
6. After the cover page the software takes you to a copy of your original application.
7. You can now make the appropriate changes for your modification.

IMPORTANT TIPS! Do NOT delete original study documents.

Use only the 

button to replace original documents.

The 

button should only be used for new documents.
The same convention of placing documents in the appropriate fields applies.

8. For revised documents a tracked changes version or a summary of changes is expected to accompany the submission.
9. For amended consent forms you will use the Draft version of the (FINAL) consent found on the **Documents** tab. See Approved Documents for how to access this document.

Submitting Continuing Reviews

To submit a continuing review:

1. Access the study from the Active tab as described in Accessing a Study.
2. Click on the 

button to the left.
3. Indicate the purpose of the submission as Continuing Review.
4. Follow the directions for each page and Finish.
5. Submit.

Note! DSMB reports can only be submitted through Reportable New Information. The question in the CR application serves only as a reminder to report the most current DSMB.

Study Closure

To submit a study closure:

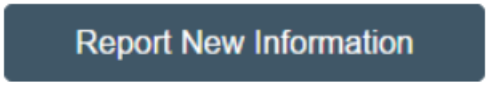
1. Access the study from the Active tab as described in Accessing a Study.
2. Click on the 

button to the left.
3. Indicate the purpose of the submission as Study Closure.
4. Click continue and complete the information.
5. Submit.

Note: If any RNI's are in pre-submission the Study Closure cannot be submitted. All RNI's must be submitted, but not yet processed in order for the study to be closed.

Reportable New Information

Events that meet reporting criteria should be submitted to the IRB in a timely manner.
To report a RNI

1. Access the study from the Active tab as described in Accessing a Study.
2. Click on the 

button to the left.
3. Give the information a name specific to the event(s).
4. Date aware refers to the date the study team became aware of the event, not necessarily the date of occurrence.
5. If applicable, select a category
6. Upload any pertinent documents.
7. Finish and Submit.
8. In most circumstances the IRB will review and return a letter of acknowledgement. If further action is required the IRB will contact you.

Tip: You can add related studies to the RNI submission to indicate that the information report applies to the studies. From the RNI submission, click **Add Related Submission** on the left.

Use the 

activity to the left.

Mod/CR/RNI Workspace

To access MODS, CRs, and RNI's for a study go the Follow-on Submissions tab of the main study workspace. You can view the Determination Letter from this space.

Submission Table

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)	Create Modification/CR	To request study closure, submit a CR.
Modifications to an active study			
Request to close study			
New information or an adverse event report	My Inbox	Report New Information	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	Create New Study	See Creating a New Study.
Updates to a new study that hasn't been submitted for IRB review yet	Within the study (see Accessing a Study on page 10)	Edit Study	See Editing a Study.

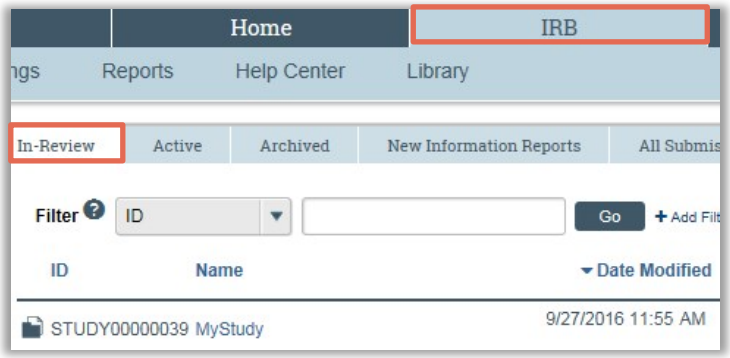
Accessing a Study

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	Studies assigned to you for action, such as a study you are: ▪ Preparing to submit ▪ Assigned to review	Click **My Inbox** in the top navigator. 
IRB In-Review tab	Studies the IRB has not reviewed or for which it has not communicated a decision	 Click **IRB** in the top navigator and select the **In-Review** tab.
IRB Active tab	Studies approved by the IRB and currently in progress	Click **IRB** in the top navigator and select the **Active** tab.
IRB All Submissions tab	All studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view	Click **IRB** in the top navigator and select the **All Submissions** tab. **Tip:** Try filtering this list by the study name or principal investigator. Next to Filter, select **Name** or **Investigator**. Then type the beginning of the name and click **Go**. For more information, see Filtering and Sorting Data.
IRB New Information Reports tab	Reportable new information (RNI) submissions, possibly related to one or more studies	Click **IRB** in the top navigator and select the **New Information Reports** tab.

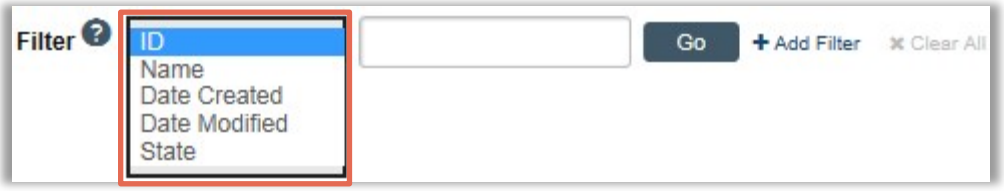
Filtering and Sorting Data

Many pages contain tables you can filter and sort to help you find the data you want.

- Filtering reduces the list to only the data that meets the criteria. You can also combine multiple filter criteria.
- Sorting displays the data in ascending or descending order by a particular column.

To filter data:

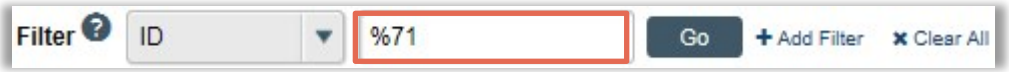
1. Select the column to filter by from the drop-down menu. The menu lists only the columns you can filter by. **Note:** To combine multiple filter criteria, such as, ID, name, **and** Date Created, use the add filters feature.



2. In the next box, type the beginning characters for the items you want to find. If you do not know the beginning characters, type a % symbol as a wildcard before the characters. Examples:

   o 71 shows all items beginning with 71 o

   %71 shows all items containing 71 in any position



Tip: For examples and a list of operators you can use, click the Help icon.

3. Click **Go** to apply the filter.

   The table shows only those rows that are an exact match.

Tip: If you do not see the expected items in the list, click **Clear All** in the Filter area to remove the filter.

To use multiple filters:

1. In the Filter area, click **Add Filter**.

2. Enter filter criteria as explained in the previous section.
3. Click **Go** to apply the filters.

The table shows only those rows that match all the filter criteria.

To sort data:

Click the column header you want to sort by. Click it a second time to reverse the sort order. The arrow indicates the column by which the data is sorted and the sort order, either ascending (up arrow) or descending (down arrow). **Note:** If the column header is not a link, you cannot sort by that column.

Guest List and Project Contacts

In eIRB you can add guests to studies. These users have read only access. The CRC Manager or Supervisor in the PI's department is automatically added. To view the Guest List and the study team use the Contacts tab from the study workspace.

History | Funding | Project Contacts | Documents | Follow-on Submissions | Reviews | Snapshots

Principal Investigator

Name	E-mail	Phone
Katrina Wade	katrina.wade@ochsner.org	504-213-0914

Study Team

Name	Roles	E-mail	Phone
Elsa Levenes	Study Coordinator	elsa.levenes@ochsner.org	24482
Spencer Jenkins	Other	spjenkins@ochsner.org	24483
Amanda Struckhoff	Study Coordinator	amanda.struckhoff@ochsner.org	504-915-0857
Heather Porter	Other	heather.porter@ochsner.org	32654
Christina Robinson	Other	chrrobinson@ochsner.org	5048423798
Jacob Estes	Sub-Investigator	jacob.estes@ochsner.org	504-842-4165
Andrew Lawton	Sub-Investigator	andrew.lawton@ochsner.org	504-842-3917
Richard Kline	Sub-Investigator	rkline@ochsner.org	

Other Study Team Member Information

Document	Description

Guests Who Can View This Submission

Name	E-mail	Phone
Gregory Johnstone	gregory.johnstone@ochsner.org	504-842-2932

To add a guest to the study:

1. Use the 

activity to the left.
2. Scroll down and use the selector to find other eIRB users.
   Note: The person must have an eIRB account to be found in the selector list
3. Click Ok.

Required Documents

Be prepared to attach several files to your study. It is extremely important to document management that documents are uploaded in the correct section or given the appropriate categorization. If editing a study or submitting a MOD the file name from the previous document will appear in the upload field delete this in order for the new file name to appear.

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)	
▪ Protocol	▪ Protocol Builder available
Funding information: (Funding Sources page, with each source**)**	
	▪ Grant applications
Drug details: (Drugs page, with each 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)	
▪ Product labeling/device instructions ▪ Investigator brochure	▪ Verification of each IDE or HDE number (one of these): o Sponsor protocol with the IDE / HDE number o Communication from the FDA or sponsor

	with the IDE / HDE number
Recruitment and Retention Materials	
Materials intended to recruit or retain subjects.	o Advertisements, including printed, audio, and video o Recruitment materials and scripts o Foreign-language versions of materials for subjects o Gifts o ID Cards
All other relevant documents: (Supporting Documents page)	
▪ Diaries ▪ Logs ▪ Questionnaires ▪ Email approvals	
Consent/Assent	
▪ Consents ▪ Assents	▪ Templates for Main, Addendum, and Registry found in the eIRB library under Templates ▪ Assent Signature Box 13-17y/o ▪ Assent statement 12y/o under

Contacting Support

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

Resource	How to access it
Documentation	eIRB library (login required)
Training materials on the web site	https://eIRB.ochsner.org
IRB support staff *vOct2017*	E-mail: irb@ochsner.org Phone: (504) 842-3535

NOTES: