



IRB Study Reviewer's Reference Guide

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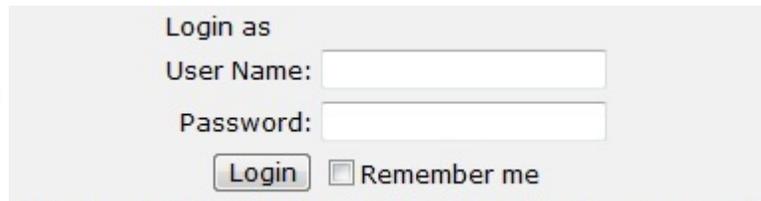
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Logging In

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 Error! Bookmark not defined.](#))

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.

Locating Your To-Do List

IRB studies that are assigned to you for action generally appear in My Inbox with a link to the study. You may also receive an e-mail with a link to the study. An e-mail indicates that you must take action or informs you of important changes, such as an IRB decision about your study.

Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study.

To access a study that does not appear in My Inbox, see [Accessing a Study on page 17](#).

Note for committee members: You can view the list of all submissions to be reviewed for a committee meeting as described in [Locating Meeting Agenda Items on page 5](#).

To access studies or other submissions assigned to you:

1. Click the **My Inbox** link in the top right navigation header.

Your Name **1** **My Inbox** Logoff

2. Identify the reason the study appears in My Inbox by looking at the State column.

My Inbox						
Filter by <input type="text" value="State"/> <input type="text" value="post"/> <input type="button" value="Go"/> <input type="button" value="Clear"/> <input type="button" value="Advanced"/>						
ID	Name	Date Created	Date Modified	State	Coordinator	
STUDY00000249	Effects of high-dosage vitamin D supplements in low-light environments	9/10/2012 2:22 PM	9/24/2012 1:35 PM	Post-Review	Orlando Max	

3. Open the study by clicking the link in the Name column.
The study workspace opens.

To view the details of the study, click **View Study** on the left. For instructions, see [Viewing the Study Details on page 10](#).

Understanding My Inbox

The list called My Inbox contains studies or other submissions that require you (or your team members) to take action. See the examples below to understand what you should and should not expect to appear in My Inbox.

Tip: Look at the State column in My Inbox, and see the explanation for that state in the table below.

Your role	In My Inbox		Not in My Inbox
	State	Explanation	
IRB committee member or occasional reviewer	Non-Committee Review	You have been designated as the reviewer for this exempt or expedited study. You must submit your final review before the IRB decision can be communicated to the study team. If you request clarifications, the study comes back to you to finish the review after the clarifications are made.	Studies assigned to other reviewers
	Committee Review	You may be part of the committee that will review this study. If so, review the study details in advance. You can request clarifications. Record your notes and recommendations in the system before the meeting as described in Preparing Comments for a Meeting on page 13 .	Studies assigned to other committees
Ancillary reviewer	One of several	You have been selected as a reviewer (either by name or representing a specific organization). The IRB can begin its review before you submit your review. The IRB may or may not wait for your input before completing its review of the study.	Studies not yet submitted for review

Locating Meeting Agenda Items

As a committee member, you can get a meeting agenda listing the studies and other submissions to be reviewed in an upcoming meeting. You can get the agenda in two forms:

- As a web page with links to the studies
- As a printable document

The procedures below describe how to access both forms of the agenda in two alternative ways:

- From an agenda notification e-mail you receive
- By navigating to the agenda within the IRB system

To access the agenda from an e-mail you receive:

1. Open the e-mail informing you about an IRB meeting agenda. The notification content should resemble this:

Notification of Meeting Agenda

To: Your Name

Link: [IRB Committee meeting on 10/31/2012 11:06 AM](#) Web Page

Title: IRB Committee meeting on 10/31/2012 11:06 AM Printable Document

Description: The agenda for this meeting has been generated or updated and is available at the follow link: [Agenda for IRB Committee meeting on 10/31/2012 11:06 AM\(0.01\)](#)

2. Click the appropriate link:
 - To access the meeting workspace web page containing links to the studies, click the link next to Link (shown above). The meeting workspace and its important links are shown below.
 - To open or save the printable document, click the link next to Description (shown above).
- Note:** The most up-to-date agenda is in the web page format.
3. If prompted, log in to the IRB system.

Tip: For more details about opening the document or using the web page, see the procedure below about navigating to the agenda.

To access the agenda by navigating to it:

1. Click **IRB** and then **Meetings** on the left.



2. From the list of meetings shown in the center of the page, click the name of the meeting to view. The meeting workspace displays the list of agenda items in the center of the page, resembling this:

IRB Committee 1

Meeting Date & Time: 10/31/2012 11:06 AM

Agenda: [Agenda for IRB Committee 1 meeting on 10/31/2012 11:06 AM\(0.01\)](#)

Minutes: Not yet created.

Report: Expedited Studies Approved in the last 45 days

Printable
Document

Agenda Items		Attendees	History
ID	Name		
 STUDY00000202	Comparison of calcium effects from supplements vs. foods on osteoporosis patients		
 STUDY00000206	Effectiveness of motivation techniques for long-term exercise habits		
 STUDY00000203	Effects of low-light environments on mood and behavioral disorders		
 STUDY00000190	Occupational choice influences - a survey		

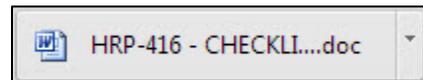
Links to Studies
on Agenda

3. Click the appropriate link:

- To access a study directly from the agenda items list, click the link to the study (shown above).
- To open or save the printable document, click the link in the page header next to Agenda (shown above). The agenda is in Microsoft Word format.

Tip: Microsoft® Word documents open differently in different web browsers. If the document does not open promptly:

- Click the Word icon if it is flashing at the bottom of your screen, and then click one of your open Word documents.
- Check the bottom of the browser window to see if the document icon and name is shown there. If so, click the name to open it.



Locating Checklists for Reviewers

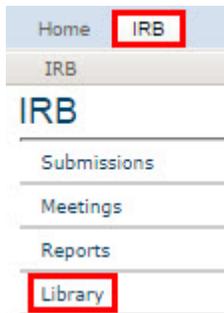
Several worksheets and checklists are provided in the system to guide your review process and document your decisions. They are intended for pre-reviewers, designated reviewers, and committee reviewers.

- **Worksheets** are for the reviewer's benefit only.
- **Checklists** must be completed and attached when submitting your review comments to document your decisions.

Tip: First identify the pertinent documents using the topical list in [Key Checklists and Worksheets on page 9](#). Then locate them using the procedure below.

To locate the worksheets and checklists:

1. Click **IRB** and then **Library** on the left.



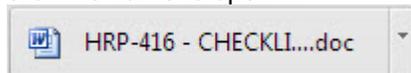
2. Click the **Worksheets** or **Checklists** tab, depending on the document you want to view.
3. Click a link to open or save the applicable document, which is in Microsoft Word format.

Tip: Microsoft® Word documents open differently in different web browsers. If the document does not open promptly:

Click the Word icon if it is flashing at the bottom of your screen, and then click one of your open Word documents.



Check the bottom of the browser window to see if the document icon and name is shown there. If so, click the name to open it.



Key Checklists and Worksheets

Many checklists and worksheets for reviewers are available in the IRB Library to provide reminders, guide decisions, and help document decision criteria.

Important! Checklist information is required by regulations to document the findings that justify your determinations. Fill out the pertinent checklists and attach them when you submit the review form. For committee reviews, attach your individual checklists as described in [Preparing Comments for a Meeting on page 13](#).

Worksheets also provide important guidance, but regulations do not require them to be retained.

The following table summarizes the pertinent checklists and worksheets, organized by the types of review decisions you must make.

Topic	Checklists (use and attach)	Worksheets (for reviewer's use)
Approval criteria		<ul style="list-style-type: none"> ▪ Criteria for Approval (HRP-314)
Level of review		<ul style="list-style-type: none"> ▪ Engagement (HRP-311) ▪ Exemption (HRP-312) ▪ Expedited (HRP-313)
Consent / recruitment	<ul style="list-style-type: none"> ▪ Waiver or Alteration of Consent (HRP-410) ▪ Waiver of Written Documentation of Consent (HRP-411) ▪ Waiver of Consent for Emergency Research (HRP-419) ▪ HIPAA Waiver of Authorization (HRP-441) 	
Special populations	<ul style="list-style-type: none"> ▪ Pregnant Women (HRP-412) ▪ Non-Viable Neonates (HRP-413) ▪ Neonates of Uncertain Viability (HRP-414) ▪ Prisoners (HRP-415) ▪ Children (HRP-416) ▪ Cognitively Impaired Adults (HRP-417) 	
Devices / drugs	<ul style="list-style-type: none"> ▪ Non-Significant Risk Device (FDA) (HRP-418) 	
Federal agencies / laws	<ul style="list-style-type: none"> ▪ HIPAA Waiver of Authorization (HRP-441) 	

Viewing the Study Details

As a reviewer or IRB staff member, you often need to view all the information submitted as part of the study.

To view the details of 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 17](#).
2. Click **View Study** on the left.

Tips:

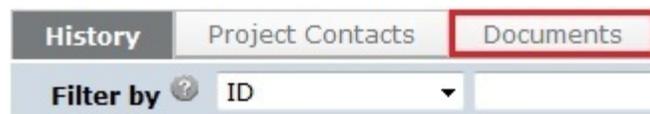
- For a continuing review or modification, click **View Modification / CR** instead.
 - For a new information report, click **View RNI** instead.
-

3. Use the Continue and Back buttons to view all of the forms.

Tip: Clicking Continue from the Supporting Documents page (the last page of the forms) exits the study.

To view the documents submitted as part of the study, you have these options:

- While viewing the details of the study (as instructed above), click the name of each document when you encounter it on the various forms. Documents are listed in tables throughout the forms.
- When you have opened the study workspace (as in step 1 above), you can view a list of all the attached documents in one place by clicking the Documents tab.



Tip: If the study team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document. When the IRB approves the documents, all tracked changes will be accepted and comments removed in the final versions.

To view the information entered for pre-review:

1. Open the study as instructed in step 1 above.
2. Click the **Reviews** tab.

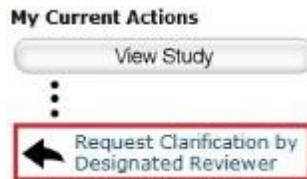
Tip: If the information entered for pre-review is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review information until the decision from designated or committee review is submitted.

Requesting Clarifications to a Study

If a study is confusing or needs additional information to receive IRB approval, you can request clarifications. Requesting clarifications sends the study back to the study team so they can edit it.

To request clarifications to a study:

1. From My Inbox, click the name of the study to open it.
2. Click **Request Clarification...** on the left.



3. In the Request Clarification form, provide detailed questions or requests for changes.
Note: You can also attach documents that explain, show the study text, or show screen captures of the problematic areas, or that show suggestions for resolving the problems.
4. Click **OK** to send the request to the study team.

Unless the study is in committee review, you will receive an e-mail notification when the study team submits their response to the clarification request.

Requests for clarifications are handled differently during committee review than during other types of review in that study team members are not solely in control of the submission:

- Committee members can continue to request clarifications after a request has been made. This allows multiple reviewers to communicate with the study team at once.
- Study team members cannot edit the study when the clarifications requested are from committee review, but they can submit comments back to the committee.
- The committee cannot record a decision for the submission when it is in the Clarification Requested state. The options are:
 - The IRB coordinator can remove the submission from the agenda before the meeting and reassign it to a later meeting.
 - At the time of the meeting, the committee chair or administrator can use the Convene Meeting activity to return all submissions still in the Clarification Requested state to the Committee Review state so their reviews can be recorded.

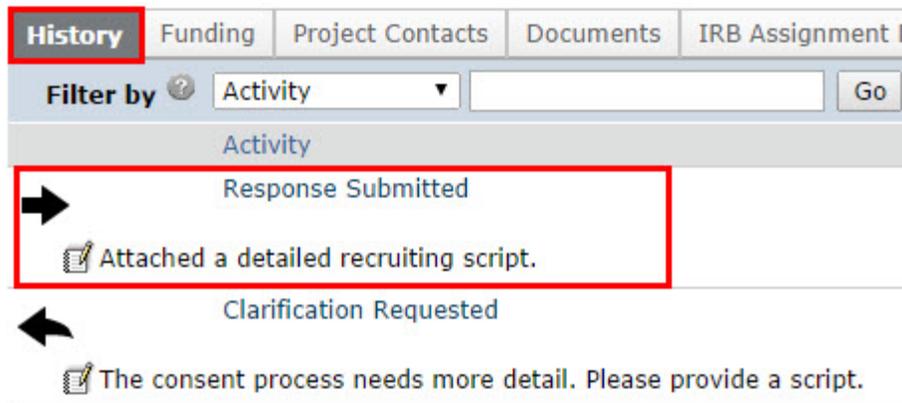
Viewing Changes to a Study

When a study changes based on reviewer requests, you may want to:

- View the response submitted for a particular request
- View the differences between two versions of a study

To view the response submitted for a clarification request:

1. From My Inbox, click the name of the study to open it.
2. Click the **History** tab.



3. Click the **Response Submitted** activity link to see any notes or documents added to the study.

To view the differences between two versions of a study:

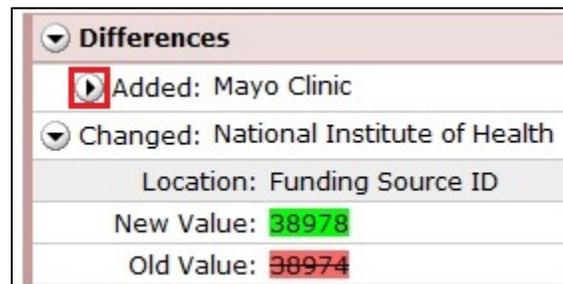
1. From My Inbox, click the name of the study to open it.
2. Click **View Differences** on the left.
3. Next to Show Changes, select a version to compare the current study to.



4. Look for red and green changes in the current form.

Click the  arrow to show the details. The changes since the version you selected appear as follows:

- Additions to text since that version are shown with green highlighting.
- Deletions to text show in a light red box below the current text.
- Additions and deletions of selectable items show the changes (such as old values) in a light red box after the current values that appear normally.



- Next to Changed Steps, click the  arrow (or use the drop-down list) to view each of the other forms that have changed.



- Exit the View Differences screen by clicking **Close** on the right.

Tip: If the study team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document. When the IRB approves the documents, all tracked changes will be accepted and comments removed in the final versions.

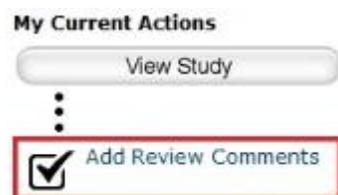
Preparing Comments for a Meeting

While reviewing a study, you can record your review comments within the IRB system. You can also upload required checklists and any review-related documents. This lets committee members view each other's comments before and during the meeting.

All of your comments and the files you attach will be purged from the system when the approval letter is sent. Your comments are never visible to the study team members.

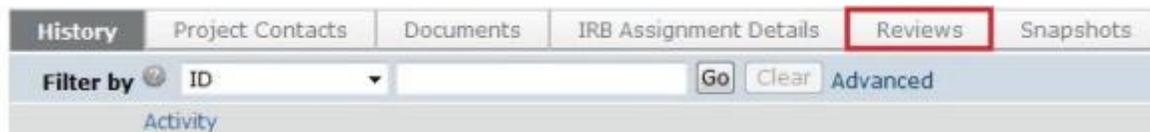
To record your review comments:

- Open the study. For details, see [Accessing a Study on page 17](#) or [Locating Meeting Agenda Items on page 5](#).
- Click **Add Review Comments** on the left.



- Type in notes, and upload any relevant reviewer checklists and other related documents.
- Click **OK**.

Note: Before and during the committee meeting, you can go to the study's Reviews tab as shown below to view your comments and comments from other reviewers.



Submitting a Review Decision

After reviewing a study or other submission, you must record the decision in the system. Recording the decision completes the review and moves the study forward in the IRB process.

Note for committee members: An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, record your comments and attach relevant files (such as reviewer checklists) as described in [Preparing Comments for a Meeting on page 13](#).

Tip: You can include comments when you record your decision. To avoid regulatory issues, it is best to phrase your comments as questions or requests for information. If you need the study team to answer a question before you can complete the review, request clarifications as described in [Requesting Clarifications to a Study on page 11](#).

There are several types of review, with procedures for each identified below:

- [Ancillary review](#)
- [Pre-review](#)
- [Designated review](#)
- [Committee review](#)

Note: The procedures below assume that the study team has completed any requested clarifications.

To open the study:

1. From My Inbox, click the name of the study to open it.
2. Choose the appropriate procedure below.

To complete an ancillary review:

1. Click **Submit Ancillary Review** on the left.



2. Select the review you are completing from the list.
3. Indicate whether you think the submission is acceptable as it is currently written.
4. (Optional) Add comments and attach documents related to the review.
5. Click **OK**.

The review comments are shown in the study.

To complete a pre-review:

1. Click **Submit Pre-Review** on the left.



2. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*).
3. (Optional) Attach documents related to the review, such as checklists.

4. If you are ready to move the study to the next stage of IRB review, answer Yes when asked if you are ready to submit this pre-review.
Otherwise, answer No, which enables you to return and perform Submit Pre-Review again to update the information.
5. Click **OK**.

Important! If you moved the review to the next stage, now you must assign the study to a committee meeting or a designated reviewer.

To complete a designated (or non-committee) review:

Tip: If the information entered for pre-review is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review information until the decision from designated or committee review is submitted. Make sure it is corrected before you submit your review decision.

1. Click **Submit Designated Review** on the left.



2. If true, check the box to indicate that you do not have a conflicting interest. (For more details about conflicting interests, click the  icon.)
3. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*).
4. (Optional) Add comments and attach documents related to the review.
5. If you have entered all the relevant information and are ready to submit the final IRB decision, answer Yes when asked if you are ready to submit this review.
Otherwise, answer No, which enables you to return and perform Submit Designated Review again to update the information.
6. Click **OK**.

If you submitted the final decision, the IRB can now officially communicate the decision to the study team.

To complete a committee review:

Important! An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, record your comments and attach relevant files (such as reviewer checklists) as described in [Preparing Comments for a Meeting on page 13](#).

Tip: If the information entered for pre-review is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review information until the decision from designated or committee review is submitted.

1. Click **Submit Committee Review** on the left.



2. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*).
3. (Optional) Add notes and attach documents related to the committee's review.
4. Click **OK**.

The IRB coordinator assigned to the study can now officially communicate the decision to the study team.

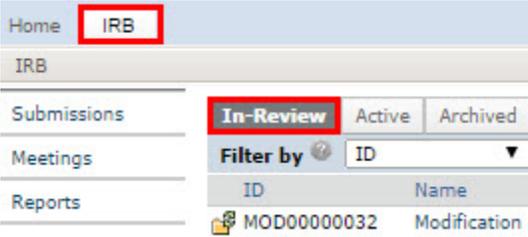
Accessing a Study

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.

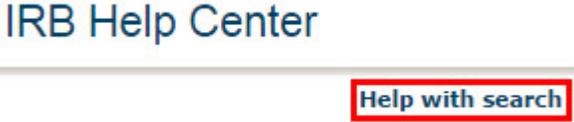
Note: Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

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: <ul style="list-style-type: none"> ▪ Preparing to submit ▪ Assigned to review 	 Click the My Inbox link in the top right navigation header.
IRB In-Review tab	Studies the IRB has not reviewed or for which it has not communicated a decision	Click IRB in the top left navigation area and select the In-Review tab. 
IRB Active tab	Studies approved by the IRB and currently in progress	Click IRB in the top left navigation area 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 left navigation area and select the All Submissions tab. <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	Reportable new information (RNI) submissions, possibly related to one or more studies	Click IRB in the top left navigation area and select the New Information Reports tab.

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click  next to the question or at the top of the form.
Help system	<p>The full online help system, with search and table of contents.</p> <p>The online help contains procedures and information for all users.</p>	<ol style="list-style-type: none"> Click the Help Center link on the left.  Then click Help with Search at the top of the page. 
IRB Study Submission Guide	Instructions for submitting a study for review.	<ol style="list-style-type: none"> Click the Help Center link on the left. On the Guides tab, click the name of the guide to open it.
IRB Study Reviewer's Guide	Instructions for reviewing an IRB submission.	
IRB Staff Administration Guide	An overview of the IRB review and administration process.	
IRB Library	Document templates, checklists, and IRB procedures.	Click the Library link on the left.

