IRB Study Reviewer's Guide

August 2013

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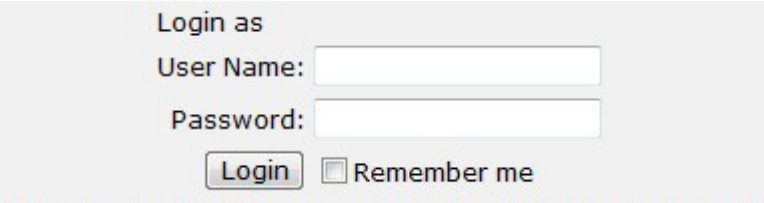
Logging In

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 your UGA MyID and password into the boxes.



> **Tips:** Press the Tab key after typing your UGA MyID into the user name box to move to the Password box.

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

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.

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

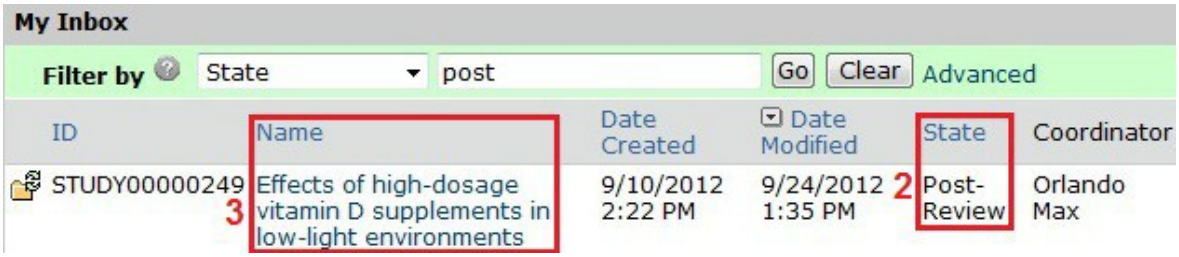
To access a study that does not appear in My Inbox, see Accessing a Study on page 14.

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 4.

To access studies or other submissions assigned to you:

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

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



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

To view the details of the study on a web-page by page format, click **View Study** on the left. For details, see Viewing the Study Details on page 9.

Understanding My Inbox

The list called My Inbox contains studies or other submissions that require you 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 study. You must complete and communicate your review to the IRB coordinator who is assigned to the study so that this information can be communicated to the study team. If you request clarifications, the response comes back to you to finish your review after the clarifications are made. Or, you can send your request via e-mail to the IRB Coordinator who will relay these to the study team. If the study qualifies for Expedited review, you should attach your completed checklists to a private comment for the IRB Coordinator and send the IRB coordinator an e-mail to notify him/her that your review is complete. If you recommend committee review, click on "Assign to Committee Review", add comments relevant to this recommendation via a private comment, then send the IRB coordinator an e-mail to notify him/her of your recommendation.	Studies assigned to other reviewers
	Committee Review	You may be part of the committee that will review this study. If so, please review the study details in advance. Primary Reviewers can request clarifications from the PI. Notes and recommendations can be entered in Click IRB by clicking on Add Review Comments and these can be viewed during the committee meeting.	Studies assigned to other committees

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:

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 **IRB Meetings** in the upper left corner.

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 the next page:

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) (Printable Document)

Minutes: Not yet created.
Report: Expedited Studies Approved in the last 45 days

(Links to Studies on Agenda)

Agenda Items | Attendees | History

ID	Name
STUDY00000202	Comparison of calcium effects from supplements vs. foods on osteoporosis patients
STUDY00000026	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

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** should be completed and attached to your review comments to document your decisions (for Expedited Reviews).

> **Tip:** First identify the pertinent documents using the topical list in Key Checklists and Worksheets on page 7. Then locate them using the procedure below.

To locate the worksheets and checklists:

1. Click **IRB** and then **IRB library** in the upper left corner.

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.
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> 
>

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!** Some checklist information is required by regulations to document the findings that justify your determinations. Fill out the pertinent checklists and attach them to private comments as you complete your review. For committee reviews, provide any completed checklists to the IRB coordinator.

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		• Criteria for Approval and Additional Considerations (HRP-314) • Additional Federal Criteria (HRP-318)
Type of review		• Pre-Review (HRP-308) • Review of Information Items (HRP-321) • Scientific or Scholarly Review (HRP-320)
Level of review	• Exempt Determination (UGA HRP-312) • Expedited Initial Review (UGA HRP-313)	• Human Research (HRP-310) • Engagement (HRP-311)
Consent / recruitment	• Waiver or Alteration of Consent (UGA HRP-410) • Waiver of Written Documentation of Consent (UGA HRP-411) • Consent Review Checklist (UGA HRP-410)	• Short Form of Consent (HRP-317) • Advertisements (HRP-315) • Payments (UGA HRP-316)
Special populations	• Pregnant Women (UGA HRP-412) • Non-Viable Neonates (UGA HRP-413) • Neonates of Uncertain Viability (UGA HRP-414) • Prisoners (UGA HRP-415) • Children (UGA HRP-416)	• Cognitively Impaired Adults (UGA HRP-417)
Devices / drugs	• Non-Significant Risk Device (FDA) (HRP-418)	• Drugs (HRP-306) • Devices (HRP-307) • Criteria for HUD Approval and • Additional Considerations (HRP-323) • Emergency Use (HRP-322)
Federal agencies / laws	• HIPAA Waiver of Authorization (UGA HRP-441)	• Additional Federal Criteria (HRP-318) • HIPAA Authorization (UGA HRP-330)

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 14.
2. Click **View Study** on the left. NOTE: It can be helpful to right-click View Study, then click "Open in New Tab" so that you can easily move between views using your browser without waiting for pages to re-load.

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

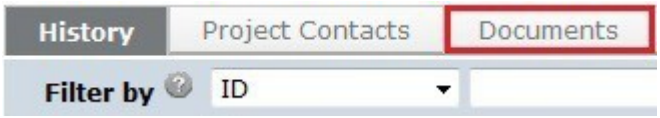
Use the Continue and Back buttons to view all of the forms, one page at a time.

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

3. Alternatively, click "Printer Version" to view a PDF of the entire submission as one continuous form/page.

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. As mentioned above, it may be helpful to right-click the Documents tab, then click "Open in New Tab" so that you can easily move between views using your browser without waiting for pages to re-load.



To view the information entered for pre-review:

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

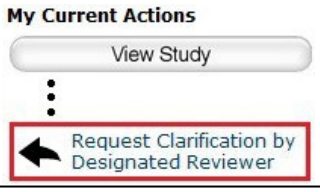
> **Tip:** If the information entered for pre-review is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review information until the decision from designated or committee review is submitted.

Requesting Clarifications to a Study

If a study is missing information, confusing, or needs additional information to receive IRB approval, you can request clarifications. Requesting clarifications assigns the study to the study team for revisions.

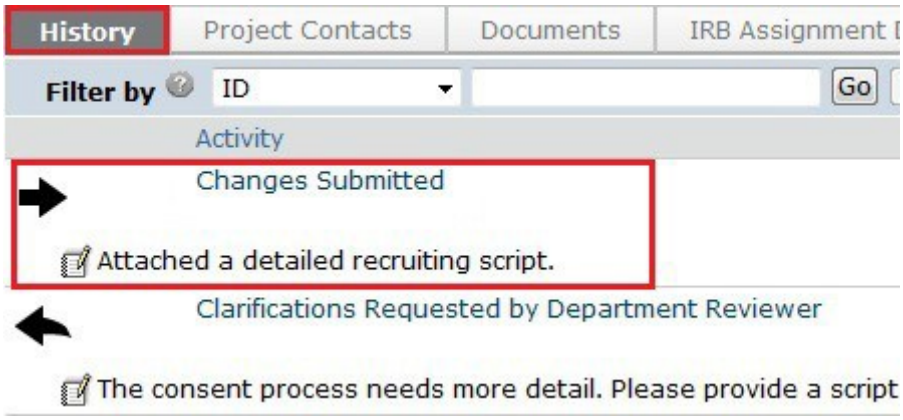
To request clarifications to a study:

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 receive an e-mail notification when the study team submits the clarifications for your review. In the Committee Review state (but before the committee meeting is in progress), you can submit additional requests, and other reviewers can also submit requests for changes. View the study's history log to identify when changes are made, as shown here.

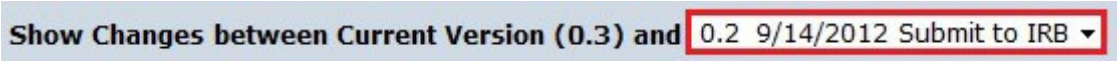


Viewing Changes to a Study

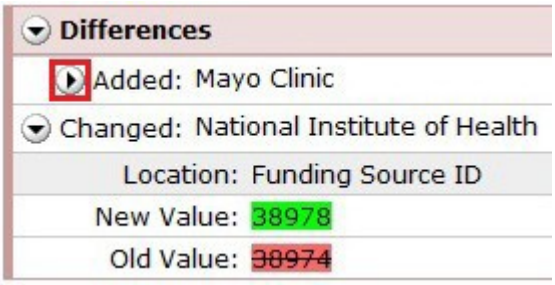
When a study changes based on reviewer requests, you may want to review just the specific changes. You can use the View Differences feature to identify all of the changes between two versions of a study.

To view the changes made to a study:

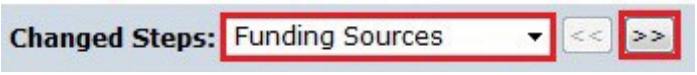
1. From My Inbox, click the name of the study to open it.
2. Click **View Differences** on the left. (Note: right-click on View Differences and "Open in New Tab" for easier viewing through your browser.
3. Next to Show Changes, select a version to compare the current study to.

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.

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

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

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.

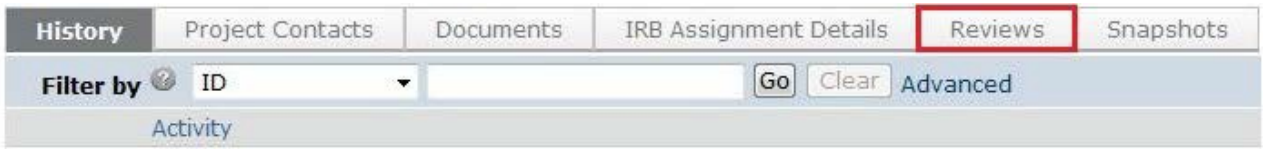
All of your comments and the files you attach will be purged from the system when the approval letter is sent. Your comments are never visible to the study team members.

To record your review comments:

1. Open the study. For details, see Accessing a Study on page 14 or Locating Meeting Agenda Items on page 4.
2. Click **Add Review Comments** on the left.

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

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, add recommendations, notes, comments, and relevant electronic files to the project record via Add Review Comments.

Tip: If you need the study team to answer a question before you can complete the review, the primary reviewer can request clarifications as described in Requesting Clarifications to a Study on page 10.

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:

> **Tip:** Only required ancillary reviewers can submit feedback within the IRB system. Optional reviewers can contact the IRB staff to provide feedback.

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

2. (Optional) Add comments and attach documents related to the review.
3. Click **OK**.

The study moves forward to IRB review.

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 (FOR IRB STAFF ONLY):

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 (FOR IRB STAFF ONLY):

> **Important!** An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, bring your recommendations, notes, comments, and relevant electronic files (such as reviewer checklists) to the committee meeting.

> **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 from the committee members and attach documents provided by reviewers.
4. Click **OK**.

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

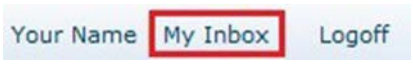
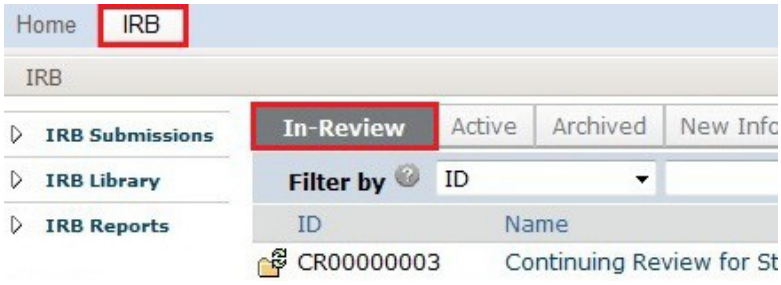
Accessing a Study

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.

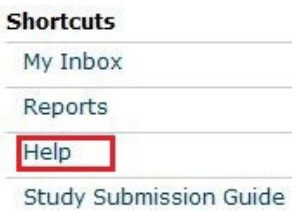
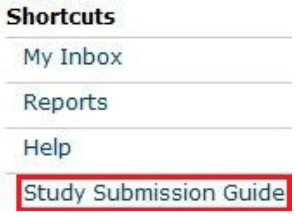
To open a study, click its name when you find it in a list of studies.

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: ▫ Preparing to submit ▫ Assigned to review	Click the **My Inbox** link in the top right navigation head 
IRB In- Review tab **Click IRB in the top left navigation area and select the In-Review tab.**	Studies the IRB has not reviewed or for which it has not communicated a decision	

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. **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**.
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

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. The online help contains additional procedures and information for all users.		Click the **Help** link in the Shortcuts area on the left.
Instructions for submitting a study for review.		Click the **Study Submission Guide** link in the Shortcuts area on the left.
Document templates, checklists, and IRB procedures.		Click **IRB** and then **IRB library** in the upper left corner.

Contacting Support

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

Resource	How to access it
Documentation	See above
Training materials on the web site	gear.ovpr.uga.edu >IRB >Training tab
IRB support staff	E-mail: IRB@uga.edu Phone: 706-542-3199

CLICK IRB TERMS

- **Pre-review** = The part of the review process after submission where HSO staff check for missing items and identify any overarching concerns that must be addressed in order for the IRB review process to begin. This process may involve one or more Requests for Clarification which require PI response (Submit Changes) in order to prepare the submission for review by a Designated Reviewer (for Expedited review) or by the Committee. In this state, ownership of the study is assigned to an IRB Coordinator/HSO Staff person.
- **Request for Clarification** = An activity where HSO Staff, Designated Reviewers, or Committee Members who are assigned to review a submission can request additional information or suggest/request revisions to materials.
    - During Pre-review, this activity transitions ownership from the IRB Coordinator/HSO Staff person to the PI so that the submission/materials can be edited.
    - During Non-Committee Review (Expedited or Exempt), this activity transitions ownership from the Designated Reviewer to the PI so that the submission/materials can be edited.
    - During Committee Review, this activity does not transfer ownership to the PI. The submission/materials are locked down until the Committee Review is submitted. However, the PI can respond by providing additional information and/or revised materials by clicking on Submit Changes. This information and/or material must be incorporated into the study via Edit Study after the Committee Review is submitted which transfers ownership to the PI. *If used during Committee Review to request for information/revision that is necessary in order for the IRB to make all of the determinations required for approval, the PI response must be received prior to or during the meeting or review of the submission must be deferred. To help minimize deferrals, allow sufficient time for the PI to respond and communicate the deadline clearly in the request.*
- **Private Comment** = There is no activity associated with adding a Private Comment. This is a mechanism for HSO Staff or Committee Members to add a permanent "note" on the submission record. The PI will not see this and no one (HSO Staff, PI, or Committee Member) will receive a notification that this has been added. Use should be limited to special parameters or items that are considered important to be viewable on the submission each time the submission is viewed. Note: Private Comments reside on the submission record and are not viewable on other submissions associated with a study.
- **Comment** = There is no activity associated with adding a Comment. This is a mechanism for HSO Staff, Committee Members, or Investigators to add a permanent "note" on the submission record. Anyone who has access to the study can see this. No one will receive a notification that this has been added. Use should be limited to special parameters or items that are considered important to be viewable on the submission each time the submission is viewed. Note: Comments reside on the submission record and are not viewable on other submissions associated with a study.
- **Review Comment** = There is no activity associated with adding a Review Comment. This is a mechanism for Committee Members to add their concerns/comments that they wish to be addressed in the meeting or by the investigators after the meeting. If any of these are requirements for approval, they will be summarized by HSO staff, submitted as the committee review, and relayed to the investigator via letter (official correspondence). Review comments are deleted by the system when Approval of the submission is granted.