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Navigation and Basic Tasks

When you first log in, you will be on the My Inbox page. This topic lists where to find submissions and the basic tasks you will perform.

Where do I find?

From the My Inbox page, you will find:

1. **Submissions** that require you to take action.
2. **Actions** you can perform, such as create a new study.
3. **Shortcuts** that provide access to other items such as all the submissions you can view.

What do I do?

4. Review the state of submissions in your inbox. The state gives a clue as to what to do next. For example, “Committee Review” means a study is scheduled or in-review by an IRB committee.

Open a Submission

5. From your inbox, click the submission name.
6. The submission workspace opens.

View History

7. From the submission workspace, click the **History** tab.
8. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.
9. Click the **Submissions** shortcut.

10. Click the tab to see submissions you can access:
   - **In-Review**: Submissions undergoing IRB review.
   - **Active**: All approved submissions as well as external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.
   - **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
   - **All Submissions**: All submissions, in any state.

**Filter Data**

Many pages contain tables that you can filter to show specific data.

11. Select the column to filter by.

12. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71

13. Click the Help icon for operators you can type in the text box.

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

15. To combine multiple filter criteria, click **Add Filter**.
Find Important Documents

If you are an IRB committee member or reviewer, you may want to access meeting agendas, worksheets, or checklists.

**Locate Meeting Agendas**

As a committee member, you can access a meeting agenda listing the studies and other submissions to be reviewed in an upcoming meeting from the agenda notification email or by navigating to it in the IRB system.

1. In the top navigator, click **IRB** and then **Meetings**.
2. From the list of meetings, click the name of the meeting.
   The meeting workspace displays the list of agenda items.
3. You may access submissions to be reviewed directly from the agenda items list by clicking the Study ID or Name. Click the agenda link for a printable agenda document.

**Locate Reviewer Checklists and Worksheets**

Several worksheets and checklists are provided in the system to guide your review process and document your decisions.

**Note:** Worksheets are for the reviewer’s benefit only, but checklists must be completed and attached when submitting review comments.

Checklists uploaded by an IRB coordinator will be most relevant to your review. To find these:

4. In the study workspace, click the **Reviews** tab.
5. Under Latest Pre-Review, click the link to download checklists relevant to your review.
You can also find a list of all worksheets and checklists in the IRB Library.

6. In the top navigator, click IRB and then Library.

7. Click the Worksheets or Checklists tab, depending on the document you want to view.

8. Click a link to open or save the applicable document, which is in Microsoft Word format.
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.

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:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Checklists (use and attach)</th>
<th>Worksheets (for reviewer’s use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval criteria</td>
<td>• Criteria for Approval and Additional Considerations (HRP-314)</td>
<td>• Pre-Review (HRP-308)</td>
</tr>
<tr>
<td></td>
<td>• Additional Federal Criteria (HRP-318)</td>
<td>• Review of Information Items (HRP-321)</td>
</tr>
<tr>
<td>Type of review</td>
<td></td>
<td>• Scientific or Scholarly Review (HRP-320)</td>
</tr>
<tr>
<td>Level of review</td>
<td>• Human Research (HRP-310)</td>
<td>• Consent/recruitment</td>
</tr>
<tr>
<td></td>
<td>• Engagement (HRP-311)</td>
<td>• Short Form of Consent (HRP-317)</td>
</tr>
<tr>
<td></td>
<td>• Exemption (HRP-312)</td>
<td>• Advertisements (HRP-315)</td>
</tr>
<tr>
<td></td>
<td>• Expedited (HRP-313)</td>
<td>• Payments (HRP-316)</td>
</tr>
<tr>
<td>Consent/recruitment</td>
<td>• Waiver or Alteration of Consent (HRP-410)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Waiver of Written Documentation of Consent (HRP-411)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Waiver of Consent for Emergency Research (HRP-419)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• HIPAA Waiver of Authorization (HRP-441)</td>
<td></td>
</tr>
<tr>
<td>Special populations</td>
<td>• Pregnant Women (HRP-412)</td>
<td>• Short Form of Consent (HRP-317)</td>
</tr>
<tr>
<td></td>
<td>• Non-Viable Neonates (HRP-413)</td>
<td>• Advertisements (HRP-315)</td>
</tr>
<tr>
<td></td>
<td>• Neonates of Uncertain Viability (HRP-414)</td>
<td>• Payments (HRP-316)</td>
</tr>
<tr>
<td></td>
<td>• Prisoners (HRP-415)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Children (HRP-416)</td>
<td></td>
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<tr>
<td></td>
<td>• Cognitively Impaired Adults (HRP-417)</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Drugs (HRP-306)</td>
<td>• Devices (HRP-307)</td>
</tr>
<tr>
<td></td>
<td>• Emergency Use (HRP-322)</td>
<td>• Criteria for HUD Approval and Additional Considerations (HRP-323)</td>
</tr>
<tr>
<td>Devices</td>
<td>• Non-Significant Risk Device (FDA) (HRP-418)</td>
<td></td>
</tr>
<tr>
<td>Federal agencies/laws</td>
<td>• HIPAA Waiver of Authorization (HRP-441)</td>
<td>• Additional Federal Criteria (HRP-318)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• HIPAA Authorization (HRP-330)</td>
</tr>
</tbody>
</table>
Review a Submission

You will receive an email when a study, site, or follow-on submission has been assigned to you to review and the submission will appear in your IRB inbox. As part of your review, you will want to access the necessary review checklists and worksheets, and the submission pages. Review comments and related files are not visible to study team members.

Open the Submission (Committee Reviewer)

1. Click the meeting link in your email to open it.
   You can also log into the site and click the Meetings link from your Inbox to see a list of upcoming meetings.
2. In the meeting workspace, you will see a list of all the protocols that are on the meeting agenda.
3. Click the name of the submission you want to open.

Open the Submission (Designated Reviewer)

4. Click the submission ID link in your email to open it.
   If you no longer have the email, see Open a Submission and then View History.
5. On the History tab, read any “Assigned to Designated Reviewer” comments.

Review the Submission Pages

Review the submission and attached documents using the following tools:

6. View Study: Opens the submission pages. Click Continue to move through the pages.
7. Printer Version: Shows the entire submission in one scrollable page.
8. View Differences: Shows changes made between two submission versions.
9. Documents tab: Shows all documents attached to the submission. Note: You can access these documents from the printer version and submission pages as well.
10. Click the Reviews tab to access reviews completed by other committee members or reviewers.
Request Clarification on a Submission

If you have questions for the study team or require they make a change to the submission, use the request clarification feature to communicate back and forth with the team. When all questions have been answered or changes made, you can submit your review.

1. From the submission workspace, click Request Clarification by…
2. Type your clarification request.
3. Click OK.

The PI will receive an email about your 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 Clarifications 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 Clarifications Requested state to the Committee Review state so their reviews can be recorded.
Prepare Review Comments for a Committee Meeting

If the committee plans to review a study, site, or follow-on submission, then you may want to record your review comments in the IRB system for other committee members to view before and during the meeting. Review comments and related files are not visible to study team members and are purged from the system when the approval letter is sent.

Add Review Comments

1. From the submission workspace, click **Add Review Comments**.
2. Type your notes for other committee members.
3. Add any checklists or documents you want to share with other committee members. **Note:** You can access the appropriate checklist to upload by clicking the Library link and downloading the document from the Checklists tab.
4. Click **OK**.

The review comments and attachments will appear on the Reviews tab of the submission workspace.

**Note:** There are three activities that will allow you to add a comment to a study. IRB members must ensure they select the appropriate activity based on the intended audience. In addition to **Add Review Comments**, you will also have the following activities available:

- **Add Comments:** Anyone who has “read” access to a study may add comments to the study and read comments posted by others. These comments will be visible only in the History Log of the study/submission. The system will NOT send an email notification to notify others that you have posted a comment unless you select them as recipients.
- **Add Private Comments:** IRB staff and committee members may also post private comments that are not visible to anyone outside of the HSRO/IRB. These comments will be visible only in the History Log of the study/submission. Unlike review comments, private comments are always accessible in the submission history.
Submit a Designated Review

You may be assigned to perform a designated review, a process which doesn’t involve other committee members. After reviewing the assigned submission, you must record your decision in the IRB system. Recording your decision completes the designated review and moves the submission forward in the review process. (For committee meeting decisions, an IRB staff member will record the decision on behalf of the committee.)

Submit Designated Review

1. From the submission workspace, click **Submit Designated Review**.

2. Complete the Submit Designated Review page. Use the worksheets to support your determination and selections.

   **Note:** Different determinations and exempt categories are available based on whether the study falls under the Pre-2018 or 2018 Common Rule requirements.

3. For a study that falls under the 2018 Common Rule requirements, indicate whether continuing review is required.

4. Under Supporting documents, add any documents related to your review such as a completed checklist.

5. Click **Yes** if you are ready to submit your review. If not, click **No**, and the information you entered will be saved. You can submit your review later.

6. When finished, click **OK**.

   If you said Yes, the submission moves to the IRB coordinator’s inbox so the coordinator can send a determination letter to the PI.
Submit an Ancillary Review

You may be assigned to review a submission as an ancillary reviewer. After reviewing the submission, you must record your decision in the IRB system. This step completes the ancillary review but does not change the state of a submission.

Submit Ancillary Review

1. From the submission workspace, click Submit Ancillary Review.
2. Complete the Submit Ancillary Review page.
3. Indicate whether you accept or do not accept the proposed study.
4. Under Supporting documents, add any documents related to your review.
5. When finished, click OK.

Your ancillary review responsibilities are complete.