Huron IRB
Reviewer's Guide

with edits for UT IRB Committee Members and Designated Reviewers

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Find Important Documents

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

To locate meeting agendas

As a committee member, you can access a meeting agenda 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. Click the agenda link for a printable agenda document.

To locate reviewer checklists and worksheets

Several worksheets and checklists are provided in the system.

Note: Worksheets are for the reviewer's benefit only, but checklists must be completed and attached when submitting review comments. Note For Designated Reviewers: Checklists completed by the analyst can be found in the "Assigned to Designated Reviewer" event in the History tab.

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

1. In the study workspace, click the Reviews tab.
2. Under Latest Pre-Review, click the link to download checklists relevant to your review.
3. Click to see previous reviews.

You can also find a list of all worksheets and checklists in the IRB Library (see below).
1. In the top navigator, click **IRB** and then **Library**.

![Library](image1)

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.

## Open the 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.

### To open the submission (committee reviewer)

As a committee member, you can access a meeting agenda from the agenda notification email or by navigating to it in the IRB system.

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.

   ![Notification of Reviewer Assignment](image2)

2. In the meeting workspace, you will see a list of all the protocols that are on the meeting agenda.
3. Click the agenda link if you'd like to print the agenda document.

### To open the submission (designated reviewer)

1. 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**.
2. On the History tab, read any Assigned to Designated Reviewer comments. Download any checklists completed by the analyst.

**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.

- **To review the submission pages**

  Review the submission and attached documents using the following tools:

  1. Click **Review Study** and review each section. You can scroll through the submission or use the Left Navigator to jump to specific sections of the form.

  2. To see what changed between this and a previous version, look in the Compare section of the Left Navigator.

  3. After reviewing each section, select the check-box at the bottom to indicate you have reviewed it.

  4. The section turns green, and a green check mark appears in the Left Navigator.

  5. If the submission is edited later, the green check mark is removed and a pencil icon is added, indicating to review that section again.

   **Note:** This Review Tracker feature does not stop a submission from moving forward in the review process, it’s simply a tool for the reviewer’s personal use.

  6. Click the **Reviews** tab to access reviews completed by other committee members or reviewers. The completed pre-review with the necessary checklists for committee reviewers attached is found in the Reviews tab.
Request Clarification on a Submission

If you have questions for the study team or require that they make a change to the submission, the assigned IRB coordinator (analyst) will use the request clarification feature to route your questions and communicate back and forth with the study team. Any questions for the study team should be sent to the analyst via a private comment. Private comments are only viewable by IRB staff and committee members.

On the left side menu, click Add Private Comment. There is a text box to enter your feedback and upload any documents necessary. For Question 3, select IRB Coordinator. The IRB Coordinator (analyst) will receive an email notifying them that they need to take action.

Once the analyst receives a response from the study team, they will notify the reviewer via a private comment and corresponding email notification. The reviewer should click the link in the email notification to go to the study record and review the notes from the analyst and/or the response from the study team. Any responses or feedback from the reviewer to the analyst can be made using subsequent private comments. When you are ready to complete the necessary checklists and submit your review, click Add Review Comments (see below).

Prepare Your Review for a Committee Meeting

Primary and secondary reviewers should use this function to confirm that they have reviewed the submission and to attach any necessary completed checklists. If you would like to get feedback from the study team, add a private comment (see above) and the analyst will follow up with the study team.

Review comments and related files are not visible to study team members and are purged from the system when the approval letter is sent.

To add review comments

1. From the submission workspace, click Add Review Comments.

2. Type your notes for other committee members or the analyst.

3. Add any checklists or documents as necessary.

   Note: Checklists will be linked in the pre-review. You can also 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.
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.)

To 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. Select the check-box in question 7 affirming that you do not have a conflict of interest.
6. 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.
7. When finished, click **OK**.

If you said Yes, the submission moves to the IRB coordinator’s (analyst’s) inbox so that they 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.

To 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.

**Navigation and Basic Tasks**

When you first log in, you will be on your Dashboard, which is the starting point for finding items and performing many basic tasks.

**To find key items**

From your Dashboard, you will see:
- **My Inbox**: Items that require you to take action.
- **My Reviews**: Items assigned to you to review. These are a subset of the items in My Inbox.
- **Create menu and buttons**: Actions you can perform. The menu will not show if you do not have access to any buttons.
- **Recently Viewed**: The last several items you viewed. Look here for an item you worked on recently.
To identify what action is needed
1. Review the state of submissions in My 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.

To open a submission
1. From My Inbox, or from the Submissions page, click the submission name.
2. The submission workspace opens.

To view history
1. From the submission workspace, click the History tab.
2. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.

To find previous submissions
1. In the Top Navigator, click IRB and then Submissions.
2. Click the tab to see submissions you can access:
   - **In-Review**: Submissions undergoing IRB review.
   - **Active**: All approved submissions as well external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
   - **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
   - **External IRB**: All studies managed by an external IRB.
   - **Relying Sites**: All participating sites relying on the local IRB as the single IRB of record.
   Click the ellipsis to see:
   - **All Submissions**: All submissions, in any state.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.

To filter data

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

1. Select the column to filter by.

2. 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

3. Click Help for operators you can type in the text box.
4. Click Go to apply the filter.
5. To combine multiple filter criteria, click Add Filter.