

# Integrated Online Research Administration: Click IRB Module

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## Department & Ancillary Reviewer Guide

The Integrated Online Research Administration (IORA) system is a suite of research-related software solutions used by the University of Rochester (UR). Within the IORA system, the Institutional Review Board (IRB) module (referred to as Click® IRB) facilitates the review and approval of human subject research.

This guide covers information and activities relevant to Department and Ancillary Committee Reviewer roles in Click IRB. Demo videos of the content provided within this guide are also available for: [Department Review](#) & [Ancillary Review](#).

If you need a Microsoft Word version of this guide (e.g., for accessibility and/or screen reading purposes), please contact the [Office for Human Subject Protection](#).

### Additional Resources:

- Help Text – Within the IORA system, additional help text is available anytime you see a ? icon. Click on the icon to review the help text.
- Click IRB Guides & Demo Videos:
  - [Click IRB Overview & Navigation Basics Guide](#) – Provides an overview of the review process (as performed within Click IRB) and basic information on navigating within the system.
  - [Click IRB Study Staff Guide](#) – Provides instructions related to the submission and management of single-site, multi-site and follow-on submissions by study staff in Click IRB.
  - Additional demo videos related to navigation and study staff activities are available on the Office for Human Subject Protection (OHSP) [website](#).
- [OHSP Explains... The IRB Review Process](#) – Provides a general overview of the IRB review process, as defined by federal regulation, state law and institutional policy, and highlights best practices for facilitating IRB review.

Note: This guide was developed by the University of Rochester based on materials original published by [Huron Consulting Group, Inc.](#)

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## Abbreviations & Acronyms

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IORA: Integration Online Research Administration  
 IRB: Institutional Review Board  
 IRBC: IRB Coordinator  
 IRBD: IRB Director  
 OHSP: Office for Human Subject Protection

PI: Principal Investigator  
 RSRB: Research Subjects Review Board  
 UR: University of Rochester  
 URMC: University of Rochester Medical Center

## Log In

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1. To log into the IORA IRB module, go to <http://rochesterirb.huronresearchsuite.com/>.
2. Select your University of Rochester affiliation (UR vs. URMC).
3. Use your UR/URMC active directory credentials to log in (i.e., the credentials used to log into your computer and/or access your UR email account).

### Note:

- Users will not be able to log in until they receive an email confirming their user account has been created. New user accounts are created automatically, approximately 1-2 business days following completion of the University's required [human subject protection training](#).
- If you are logging in remotely, [two-factor authentication](#) is required. To facilitate this process, the OHSP enrolling in [Duo using a mobile phone](#).
- Need help logging in? Use the contact information on the log in page to contact the Help Desk.

## Department & Ancillary Committee Reviewer Role Designation

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- **Department Reviewers:** Department (aka Scientific) Reviewers are designated by Department/Center/School leadership. Changes in Departments Reviewer (adding/removing reviewers) should be communicated in writing, via email, by the Department Chair or other appropriate Department/Center/School leadership to the [RSRB](#) (i.e., RSRB Director or IRB Coordinator with the RSRB Director cc'd).
- **Ancillary Committee Reviewers:** Ancillary Committee Reviewers are designated by the Ancillary Committee. Changes in Ancillary Committee Reviewers (adding/removing reviewers) should be communicated in writing, via email, by an existing committee reviewer to the [RSRB](#) (i.e., RSRB Director or IRB Coordinator with the RSRB Director cc'd).

## Perform a Department or Ancillary Committee Review

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Department and Ancillary Committee Reviews are facilitated by the RSRB in accordance with [OHSP Policy 505 Departmental Scientific and Resource Review](#) and [OHSP Policy 503 Ancillary Committee Review](#), respectively.

- Department Review is required at the time of initial submission for all new studies.
- The nature and time of Ancillary Committee Review is set forth by each respective Ancillary Committee (additional information is available in [OHSP Explains... Ancillary Committee Review](#)).

The IRBD (the RSRB Director or their designee) will assign submissions for Department and/or Ancillary Committee Review, as applicable, within the Click IRB system. Each reviewer for the assigned Department/Ancillary Committee(s) will receive an email notification alerting them to the submission. In some cases, in lieu of selecting a department or committee, the IRBD can select one specific Department/Ancillary Committee Reviewer to conduct the review (in which case, only the selected reviewer will receive the email notification).

Additional or further Department/Ancillary Committee Review may also be requested by the IRBD or IRBC at any point during the IRB review process, as well as at any point during the review of a follow-on submissions.

**Note: Generally, individuals should not perform Department/Ancillary reviews on studies where they are also identified as study staff as this may constitute a conflict of interest.**

## Find the Submission

To open a submission that requires Department/Ancillary Committee Review, you may:

1. Click the link in your notification email. You will be directed to log in and then automatically routed to the study workspace for the submission that requires review.

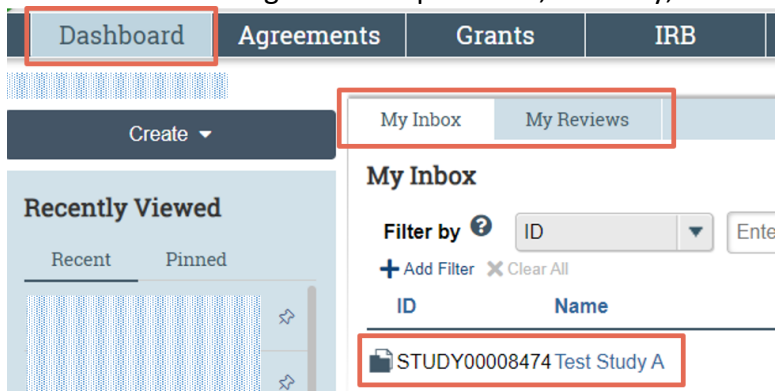
### Notification of Ancillary or Department Review

To:  
 Link: [STUDY00008474](#)  
 P.I.:  
 Title: Test Study A  
 Review Summary: Organization Review Type

An IRB submission has been assigned for ancillary or department review. Click the link above to access the study. Click the Reviews tab for information related to your review.

## OR

2. From your Dashboard, click the submission name from the My Inbox or My Reviews tab and the study workspace will open.
  - The My Inbox tab displays submissions across the entire IORA suite that require action, including submissions you may be listed on as study staff, as well as submissions you are assigned to review.
  - **To find Department/Ancillary Committee Review assignments more readily, use the My Reviews tab.** The My Reviews tab displays the *subset* of the submissions listed in My Inbox that are assigned to you for review. Within the Click IRB module, depending on your role, this may include reviews assigned for Department, Ancillary, and Designated/Committee review.



- **EXCEPTION:** For Ancillary Committees that require notification only (i.e., Ancillary Committee approval is not required prior to IRB review or approval, such as the Clinical Research Center, Investigational Drug Service, and affiliated hospitals), the submission will not appear in your inbox. To access the submission:
  - Select the **IRB** module.
  - Find the submission under the **In-Review** (i.e., undergoing IRB review), **Active** (i.e., approved) or the **All Submissions** tab. The location of the submission will depend on its current state, though, the All Submissions tab will display all submissions in-review, active and archived submission, in any state. Data in each tab can be filtered by ID, Study Name, and PI Name.



## Perform a Review

From the study workspace, you can view the submission and its attached documents by selecting:

1. **View Study:** Opens the submission form. You can scroll through the submission or use the left-hand navigation pane to jump to specific sections of the form.
2. **Printer Version:** Shows the submission in one scrollable page.
3. **Navigation Tabs:** Pulls specific information from the submission form and/or completed activities (e.g., Documents, Funding, Training Details, etc.).

**Pre-Review**

Entered IRB: 8/3/2023 12:31 PM  
Last updated: 8/3/2023 2:33 PM

**Department Review In Process**

**Next Steps**

[View Study](#)

[Printer Version](#)

[Request Department Review Clarification](#)

[Submit Ancillary Review](#)

[Add Comment](#)

## STUDY00008474: Test Study A

**Principal investigator:** [REDACTED]

**Submission type:** Initial Study

**Primary contact:** [REDACTED]

**PI proxies:** [REDACTED]

**IRB office:** Office for Human Subject Protection

**IRB coordinator:** [REDACTED]

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graph LR
    A([Pre-Submission]) --> B([Pre-Review])
    B --> C([IRB Review])
    C --> D([Post-Review])
    D --> E([Review Complete])
    C --> B
    D --> B
    
```

**Navigation Tabs:** History | Funding | Contacts | Documents | **Reviews** | Snapshots | Training Details

**Filter by:** Activity | [Dropdown] | [Search] | + Add Filter | X Clear All

Activity | Author | Activity Date

**Note:** The [Click IRB Study Staff Guide](#) provides detailed information on how each page of the submission form should be completed.

### Next Steps:

- **FOR DEPARTMENT REVIEWERS ONLY:** If you have questions or changes for the PI, see [Request Department Reviewer Clarification](#).
- If you are finished reviewing the submission, see [Submit Department and/or Ancillary Review](#).

## Request Department Reviewer Clarification

**Note:** This activity is only available for reviewers conducting Department Reviews.

1. From the study workspace, click **Request Department Reviewer Clarification**.

Pre-Review

Entered IRB: 8/3/2023 12:31 PM  
Last updated: 8/3/2023 2:33 PM

Department Review In Process

**Next Steps**

View Study

Printer Version

↩ Request Department Review Clarification

Submit Ancillary Review

2. In the corresponding Request Department Review Clarification window:
  - a. **Make the following changes...:** Enter your requested revisions/clarifications in the text box.
  - b. **Supporting documents:** If you require more space for your request, add a memo identifying your requests as a supporting document. Instruct the PI to refer to the memo in the textbox in the preceding field. Additional supporting documentation may also be uploaded here.
  - c. Click **OK**. The PI, PI Proxy and Primary Contact will then receive an email notification about your request and the submission state will change to 'Clarifications Requested by Department'.

**Next Steps:** When the study team submits their revisions, applicable Department Reviewers will receive an e-mail notification. See [Review Requested Changes](#) below.

## Submit Department and/or Ancillary Committee Review

After you have finished reviewing the submission, submit the Department/Ancillary Review. Completing this form documents your review and approval of the research, commensurate with [OHSP Policy 505 Departmental Scientific and Resource Review](#) and/or [OHSP Policy 503 Ancillary Committee Reviews](#), as applicable.

1. From the study workspace, click **Submit Ancillary Review**.

Pre-Review

Entered IRB: 8/3/2023 12:31 PM  
Last updated: 8/3/2023 4:20 PM

**Next Steps**

View Study

Printer Version

Submit Ancillary Review

Add Comment

2. In the Submit Ancillary Review window:
  - a. **Select the review...:** Select the Department/Committee for which you are completing the reviewing.

- b. **Do you accept...?** Indicate whether you accept the proposed study.
  - DEPARTMENT REVIEWERS: If you answer no, following the submission of this activity, complete [the Request Department Reviewer Clarification](#) activity to return the submission to the study team with rationale for your determination. **If this additional step is not taken, the submission will remain in your inbox (with no notification to the PI, nor the IRB).**
  - ANCILLARY COMMITTEE REVIEWERS: If you answer no, comments should be provided in the following Comments field.
- c. **Comments:** Insert any comments concerning the proposed study, as applicable.
- d. **Supporting documents:** Upload any supporting documentation.
  - **DEPARTMENT REVIEWERS: Upload your completed scientific review checklist.** In accordance with [OHSP Policy 505 Departmental Scientific and Resource Review](#), each Department/Center/School is responsible for developing a department-specific policy for conducting and documenting department review. **Submissions that are approved without documentation of scientific review (i.e., the scientific review checklist) will be returned to the reviewer. If the submission is returned, the reviewer will need to upload the scientific review checklist in both assigned reviewed within the Manage Ancillary Reviews activity (the checklist will need to be uploaded in both the Department and Individual Reviewer record).**
- e. Click **OK**. The review will then be marked as completed on the Reviews navigation tab in the study workspace.

## Review Requested Changes

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Once the study team has responded to changes and/or clarifications that have been requested. Use the compare feature review the revisions made to the submission.

1. From the submission workspace, click **View Study**.
2. Click **Compare** on the left-hand navigation pane.
  - The top portion of the navigation pane identifies the versions of the submission form being compared (defaulting to the most recent versions). To change versions, select the down arrow.
3. Pencil icons identified within the navigation pane indicate where revisions have been made within the submission form; click on the pencil icon to review the revisions.
  - Revisions made within the form are identified in a gray box. Depending on the revision made, additional details may be available by clicking the down arrow adjacent to the Difference, Changed or Added fields.
4. If a document was revised, select the Compare activity to view tracked changes. **Note:**
  - This feature is only available for documents uploaded as MS Word files. In order to view the tracked changes in the Word document, you may need to: a) Select Enable Editing (in the yellow toolbar) when the document is first opened; and b) Select the Review tab and then All Markup in the Tracking Options pane of the Review tab.
  - Documents can also be compared by viewing the Document History.
5. Click **Exit** to close out of the submission form.

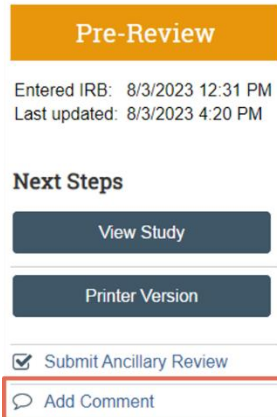
### Next Steps:

- **FOR DEPARTMENT REVIEWERS ONLY:** If additional revisions are required, see [Request Department Reviewer Clarification](#).
- If you are finished reviewing the submission, see [Submit Department and/or Ancillary Committee Review](#).

## Add Comment

Comments may be added at any time, to any type of submission and **are visible to ALL individuals with read access to the submission**. To add a comment to a submission:

1. From the submission workspace, click **Add Comment**.



The screenshot shows a submission workspace with the following elements:

- Pre-Review** (orange header)
- Entered IRB: 8/3/2023 12:31 PM
- Last updated: 8/3/2023 4:20 PM
- Next Steps** (header)
- View Study** (button)
- Printer Version** (button)
- Submit Ancillary Review
- Add Comment** (button, highlighted with a red box)

2. In the corresponding Add Comment window:
  - a. **Comment & Supporting documents:** Insert your comment in the textbox provided and attach supporting documentation, when applicable.
  - b. **Who should receive an e-mail notification?** Select all the roles that you want notified of the comment. Once the comment is submitted, those selected will receive an email notification regarding the comment.
  - c. Click **OK**. The comment will appear on the History tab and the individuals selected in the preceding field will be sent an email notification alerting them to the comment.

**Note:** Adding a comment does not move a submission into a specific individual's inbox.

## Department & Ancillary Review Reports

For your reference, Click IRB can facilitate reporting on Department and Ancillary Committee Review activities. Note, however, that based on Click IRB programming **reporting results are not inclusive of all submissions assigned to a given Department/Ancillary Committee for review. Rather, reporting results are based on the timing of a user's reviewer role designation, a user's reviewer assignments, and their ability to access other (potentially unrelated) submissions.**

For example, if Dr. Smith is assigned as a Department Reviewer for the Biology Department on 1/1/2023, when Dr. Smith runs a report, the report will only reflect: a) submissions that have been assigned to the Biology Department (or Dr. Smith specifically) for Department Review *as of* 1/1/2023; and b) any other submissions Dr. Smith has access to (e.g., studies Dr. Smith is listed as personnel and/or studies Dr. Smith has been given guest access to). The report would not reflect submissions assigned to the Biology Department for



review *prior to* 1/1/2023, nor would it reflect submissions assigned specifically to *other* Biology Department reviewers (e.g., a submission that is assigned specifically to Dr. Jones for Department Review based on Dr. Smith's conflict with the submission).

**Therefore, reports accessed by an individual reviewer may not be entirely accurate.**

### Ancillary Committee Report

The '**UR Protocols Reviewed by Ancillary Committee**' report identifies submissions assigned to an Ancillary Committee for review (with the caveat regarding role designation described above).

To access this report:

1. From the IRB workspace, select **Reports** from the horizontal navigation menu.
2. Click on the **Custom Reports** tab.



3. Select the **UR Protocols Reviewed by Ancillary Committee**.
  - Report results can be filtered by selecting the report column you wish to filter in the dropdown menu and entering the text you want to filter for.
 
    - Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., filtering the name column by 'exercise' will identify all submissions that *start* with the word 'exercise'; filtering name by '%exercise' will identify all submissions that include the word exercise *within* the name).
    - As a reminder, the report identifies all submissions the user has access to. So, for example, if a Radiation Safety Ancillary Reviewer is identified as personnel on a submission that did *not* require Radiation Safety Review, they should filter by the Ancillary Name 'Radiation Safety' to identify submissions that have been reviewed by Radiation Safety (thereby filtering out other submissions that did not undergo this type of review).
  - Report results can also be sorted by clicking on the column heading you wish to sort by.

### Department Report

The '**Studies by Department**' report identifies submissions by department, per Principal Investigator primary appointment (with the caveat regarding role designation described above).

To access this report:

1. From the IRB workspace, select **Reports** from the horizontal navigation menu.
2. From the **Standard Reports** tab, select **Studies by Department**.



- Report results can be filtered by selecting the report column you wish to filter in the dropdown menu and entering the text you want to filter for.

Filter by ? ID

- Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., filtering the name column by 'exercise' will identify all submissions that start with the word 'exercise'; filtering name by '%exercise' will identify all submissions that include the word exercise *within* the name).
- As a reminder, the report identifies all submissions the user has access to. So, for example, if a Biology Department Reviewer is identified as personnel on a submission that when through Pediatric Department Review (based on the Principal Investigator's appointment), they should filter by the Department 'Biology' to identify submissions that have been reviewed by the Biology Department (thereby filtering out submissions that underwent review by other departments).
- Report results can also be sorted by clicking on the column heading you wish to sort by.