Integrated Online Research Administration: Click IRB Module

IRB Committee Member 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 the IRB Committee Member (i.e., Board Member) role in Click IRB. 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 Click IRB Resources:

- 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.
    - Demo Videos – A Click IRB: IRB Committee Member Demo Video is available via OHSP Board Member Resources in Box.com. Additional demo videos related to navigation and study staff activities are available via Click IRB Resources.

Additional RSRB Member Resources (available via the shared Board Member Box Folder):

- Preparing for Your Next Board Meeting
- The Primary Reviewer Role
- Utilizing 'The Tabs' to Assist Review
- Review of Board Meeting Minutes
- Tips for Reviewing: New Studies; Modifications; Continuing Reviews; Deferred Submissions; and Research Events.
- Quality Improvement Guidance:
    - Tips for Reviewing Quality Improvement Reports
    - OHSP-QI Final Report Overview
    - Guidance for RSRB Review of OHSP Quality Improvement Reports

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

CR: Continuing Review
IORA: Integration Online Research Administration
IRB: Institutional Review Board
IRBC: IRB Coordinator
IRBD: IRB Director
MOD: Modification
MODCR: Modification and Continuing Review
MSS: Multi-Site Study
OHSP: Office for Human Subject Protection
PI: Principal Investigator
RNI: Report of New Information
RSRB: Research Subjects Review Board
sIRB: Single Institutional Review Board
UR: University of Rochester
URMC: University of Rochester Medical Center

Committee Member Responsibilities

The IRBC is responsible for assigning submissions that require Committee Review to a scheduled Committee Meeting. When a submission is added to an agenda, the IRBC will also assign the submission to a Committee Reviewer (i.e., primary or secondary reviewer). You will receive an email notification when:

- You have been assigned as a Committee Reviewer to a submission.
- A Committee Meeting Agenda is finalized and sent to Committee Members.

Prior to the committee meeting:

- All Committee Members are responsible for:
  - Conducting a comprehensive review of *each* agenda item. To perform this review see:
    - Review a Study or Follow-On Submission for all new studies, MODs, CRs, MODCRs & RNIs
    - Review Other Agenda Items for all other agenda items.
  - Confirming meeting attendance.
  - Reviewing the Expedited Report and previous Meeting Minutes (if available).
- Committee Members assigned as Reviewers are further responsible for being prepared to present a summary of the submission and provide board determination recommendations at the time of the Convened Meeting. To facilitate this, for each assigned submission, Committee Reviewers should:
  - Complete a Reviewer Worksheet to document their review of the submission; and
  - Upload completed worksheets and any revised study documents (e.g., tracked consent forms or recruitment materials) via Review Comments.

Note: If a Committee Reviewer or Committee Member identifies missing information or clarifications that require action *prior* to committee review, the Reviewer/Member should communicate such issues to the IRBC via Private Comment. **Committee Reviewers/Members should not select 'Request Clarification by Committee Member'. Doing so will send requests DIRECTLY to the study team. Furthermore, this activity only allow study team members to provide a written response; it does not allow them to edit the submission form or study documents.**

Log In

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:

- 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.

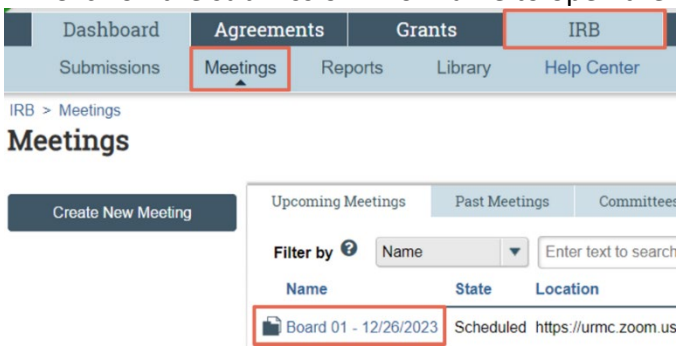
Pre-Meeting Activities

Find Meeting Materials

1. Click the link in your meeting agenda notification email. You will be directed to log in and then automatically routed directly to the meeting workspace.
    - For Committee Members assigned as Reviewers, an additional notification email will be sent once a submission is assigned to you for review. Clicking the link in the reviewer notification email will route you directly to the agenda item assigned for review.

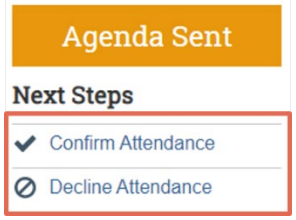
OR

2. Select the **IRB** module.
3. Click on **Meetings** and select the meeting the submission has been assigned.
4. Click on the submission ID or name to open the meeting workspace.



Confirm/Decline Attendance

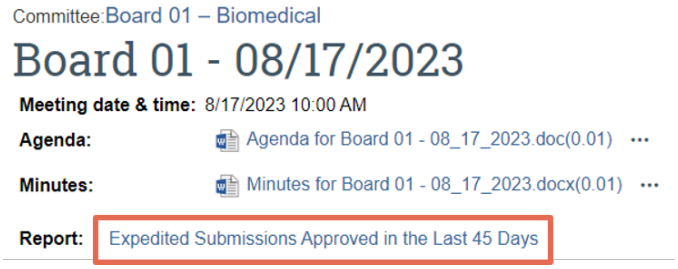
1. From the meeting workspace: select **Confirm Attendance** or **Decline Attendance**, as applicable.



2. Click **OK** to confirm/decline attendance.

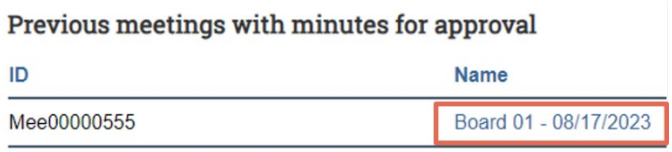
Review the Expedited Report

From the meeting workspace, select the link for 'Expedited Submission Approved in the Last 45 Days' in the workspace heading.

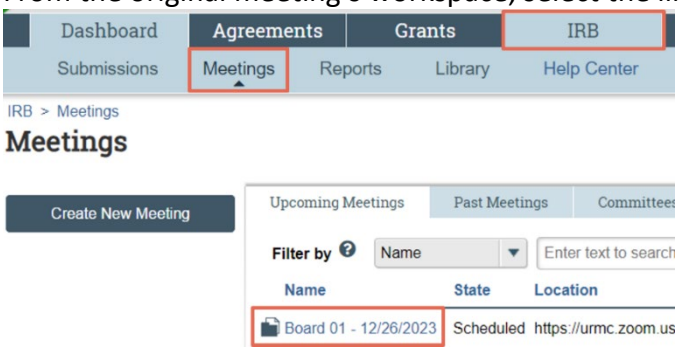


Review Previous Minutes

1. Select the previous meeting with pending minutes. The original meeting's workspace will open in a new tab of your web browser.



2. From the original meeting's workspace, select the link to the minute's document in the header.

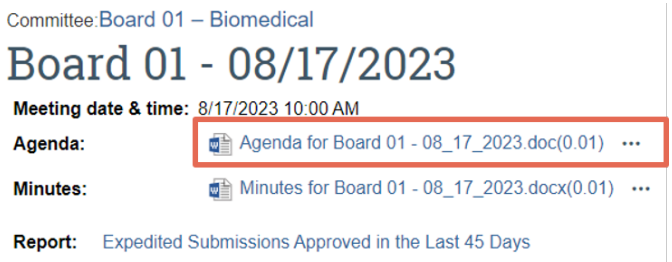


Review a Study or Follow-on Submission

Open a Submission

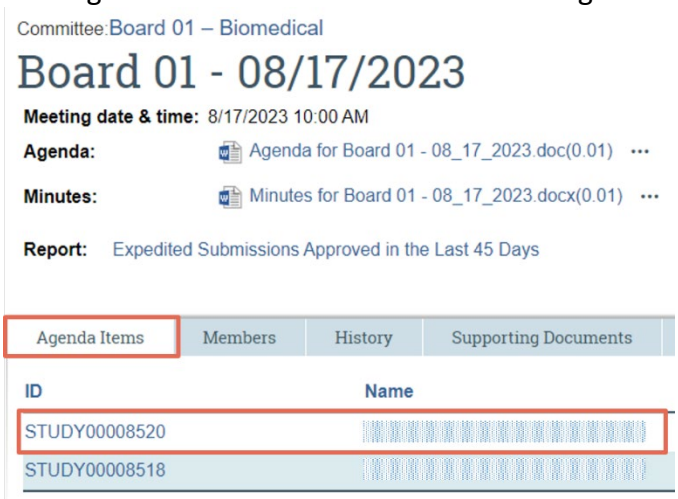
From the meeting workspace, agenda items can be accessed by doing the following:

1. Open the meeting agenda (in the workspace heading) and clicking on the hyperlink to each agenda item.



OR

2. Clicking on Submission ID or Name on the 'Agenda Items' tab.



Perform a Review

1. Click **Review Study (or Review Modification/CR or Review RNI)** to open the submission form and review each section. You can scroll through the submission or use the left-hand navigation pane to jump to specific sections of the form. Alternately, submission components can be reviewed via:
    - **Printer Version**: Shows the submission in one scrollable page.
    - **Navigation Tabs**: Pulls specific information from the submission form and/or completed activities (e.g., Documents, Funding, etc.).
    - Additional information is also available in the navigation tools (e.g., Documents, Reviews and Determinations Tabs). See Utilizing 'The Tabs' to Assist Review for additional information.
2. To view revisions to previously submitted materials, see Review Requested Changes.

Add Review Comments

1. From the submission workspace, click **Add Review Comments**.
2. **Notes**: Type your notes/comments for other committee members and/or the IRBC/IRBD.
3. **Checklists**: Click **Add** to attach Reviewer Worksheets.
4. **Supporting documents**: Click **Add** to attach supporting documents (e.g., existing literature, tracked consent documents, etc.) you want to share.
5. Click **OK**.
    - The review comments and attachments will then appear on both the History and Reviews tabs of the submission workspace. Once the review of the submission is complete, comments will be removed from the Reviews tab but will remain accessible via the History log.
    - **All committee members and IRB staff will be able to view these comments**.

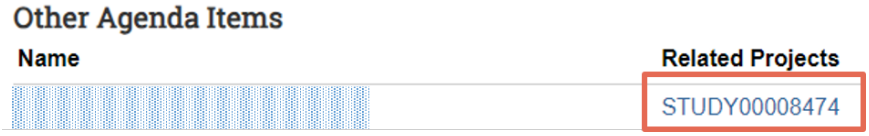
Review Other Agenda Items

'Other Agenda Items' allow for materials external to a study or follow-on submission to be reviewed by the board. A description of the materials and how to locate applicable documents should be included in the agenda. Routinely, this functionality is used for reviewing OHSP Quality Improvement Reports but other materials may also be added via this activity.

Find a Quality Improvement Report

To access an OHSP Quality Improvement (QI) Report, from the meeting workspace:

1. Click on the study ID listed under 'Other Agenda Items' (e.g., STUDY00001234).



2. From the study workspace, select the **Audits** tab from the navigation toolbar (if the Audits tab is not visible, click on the ellipses […] at the end of the toolbar).
3. Click on the report identified on the agenda to open and review the report. **Note**:
    a. Each instance of an OHSP QI Review and QI-related Consultation is added to this section of the study workspace by the QI Team.

Review Requested Changes

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 **Review Study (or Review Modification/CR or Review RNI)**.
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.

Additional Activities

Find Reviewer Worksheets

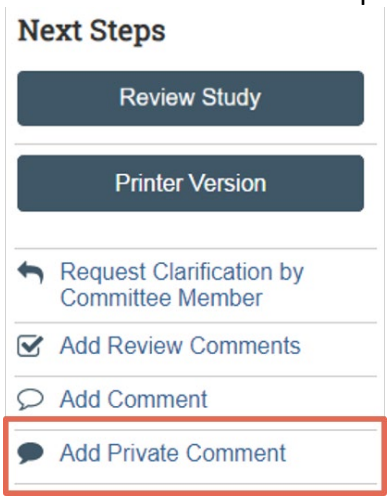
To find protocol/consent checklists and reviewer worksheets:

1. Select the **IRB** module (tab).
2. Click on **Library**.
3. Select the **Worksheets** tab.
4. Click on the name of the document to download the worksheet.

Add a Private Comment

Private comments may be added at any time by IRB Staff, Reviewers and Committee Members to any type of submission. **Private comments are only visible to IRB Staff, Reviewers, and Committee Members who are not on the study team**.

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



2. Insert your comment.
3. Select the roles and/or specific individuals to be notified of the comment.
    a. **Note**: If Assigned Reviewers, Committee Chair, and IRB Director is select in Field 3 ('Who should receive an e-mail notification?') in lieu of identifying specific individuals in Field 4, ***all*** Assigned Reviewers, Committee Chairs and IRB Directors will receive the notification. See the help text for additional information.
4. Click **OK**. The private comment will appear on the History tab and the individuals selected in the preceding fields will be sent an email notification alerting them to the comment.