Introduction

This guide covers information and tasks relevant to committee member and primary reviewer activities for submissions that require full board review.

Note: A 1-page Quick Reference Guide summarizing IRB Committee Member activities is available on the final page of this manual.

Overview of the Click® IRB System

The Click® IRB system provides a mechanism for creating and tracking studies that require Institutional Review Board (IRB) overview. Click® IRB supports the following submission types:

<table>
<thead>
<tr>
<th>IRB Submission Types</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Description</td>
</tr>
<tr>
<td>Initial Submissions</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Documents the details of a study that require oversight by an Institutional Review Board. Studies include single-site studies, multi-site or collaborative studies, and studies reviewed by an External IRB.</td>
</tr>
<tr>
<td>Site</td>
<td>Documents the details specific to a participating site (pSite) engaged in multi-site or collaborative studies, such as local study team members and institution-specific consent forms.</td>
</tr>
<tr>
<td>Follow-on Submissions</td>
<td></td>
</tr>
<tr>
<td>Modification (Mod)</td>
<td>Changes or updates to approved studies. The modification submission consists of a form that lists modification details along with the updated study submission pages and/or study documents.</td>
</tr>
<tr>
<td>Continuing Review (CR)</td>
<td>A review of an approved study. The continuing review submission consists of a form on which the researcher records any changes, incidents, reports, findings or other problems that have occurred since the study was approved, or since the previous continuing review.</td>
</tr>
<tr>
<td>Modification and Continuing Review (Mod/CR)</td>
<td>A combined modification and continuing review submission. This type of submission allows simultaneous review of changes or updates to an approved study with continuing review information.</td>
</tr>
<tr>
<td>Reportable New Information (RNI)</td>
<td>A report of new information about an approved study or active research (e.g., new risk information, breaches in confidentiality, subject complaints or reports of non-compliance).</td>
</tr>
</tbody>
</table>

Access to a study is based on the role a user is assigned in the IRB system and the role a user plays in relation to a particular study. Basic roles include:

<table>
<thead>
<tr>
<th>Position</th>
<th>Typical Activities</th>
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</thead>
<tbody>
<tr>
<td>Ancillary Reviewer</td>
<td>An individual responsible for evaluating study submissions against the requirements set forth for their specific Ancillary Committee (in accordance with Office for Human Subject Protection [OHSP] Policy 503 Ancillary Committee Reviews).</td>
</tr>
<tr>
<td>Committee Administrator</td>
<td>An individual responsible for managing committee meetings.</td>
</tr>
<tr>
<td>Committee Chair (CC)</td>
<td>An IRB committee member assigned to chair the committee.</td>
</tr>
</tbody>
</table>
### Roles (Continued)

<table>
<thead>
<tr>
<th>Position</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee Member (CM)</td>
<td>Individuals on an IRB committee that are responsible for reviewing submissions.</td>
</tr>
<tr>
<td>Committee Reviewer (CR)</td>
<td>The individuals assigned to review and present a submission at a committee meeting (i.e., primary reviewer).</td>
</tr>
<tr>
<td>Department Reviewer</td>
<td>A type of Ancillary Reviewer responsible for evaluating study submissions against their department-specific scientific review policy (in accordance with OHSP Policy 505 Departmental Scientific and Resource Review).</td>
</tr>
<tr>
<td>Designated Reviewer (DR)</td>
<td>An IRB chair or experienced IRB committee member, designated by the chair, to conduct reviews of newly submitted studies and follow-on submissions.</td>
</tr>
<tr>
<td>IRB Coordinator (IRBC)</td>
<td>Individuals who guide submissions through the review process. The coordinator reviews newly submitted studies and follow-on submissions for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner.</td>
</tr>
<tr>
<td>IRB Director (IRBD)</td>
<td>An individual with IRB oversight responsibilities. The director can perform the same actions as coordinators, but is typically less involved with the day-to-day processing of submissions.</td>
</tr>
<tr>
<td>Guest</td>
<td>Study staff may add guests to a study to permit read-only access.</td>
</tr>
<tr>
<td>Primary Contact</td>
<td>A primary contact acts as the study team’s main point of contact for communications with the IRB. The primary contact receives notifications, in addition to the PI (and any designated PI Proxies), when the IRB communicates a decision or requires the study team to take action. Unless modified, the primary contact is defaulted to whomever creates the initial study submission.</td>
</tr>
<tr>
<td>Principal Investigator (PI)</td>
<td>The Principal Investigator has full and final responsibility for the conduct of the research (see OHSP Policy 901 Investigator Responsibilities). Each study and pSite requires a single PI to be identified on the submission. All PIs must meet the University of Rochester [UR] PI Eligibility Policy. While others may assist the PI in developing and editing the initial and follow-on submissions, only the PI (or designated PI proxies) can submit items for IRB review.</td>
</tr>
<tr>
<td>PI Proxy</td>
<td>A PI proxy can perform PI activities in Click® IRB on the PI’s behalf, such as submitting the study to the IRB, modifying the study and submitting continuing review. PI proxies must be listed on the study submission as study team members. Only PIs can assign PI proxies. The PI Proxy designation only applies to activities in Click® IRB.</td>
</tr>
<tr>
<td>Registered User</td>
<td>Users authorized to create submissions.</td>
</tr>
<tr>
<td>Site Manager</td>
<td>An individual who has system-wide access. This includes full access to security and system settings, and all data, workspaces, activities, and actions in the system.</td>
</tr>
<tr>
<td>Study Staff (SS) / Study Team (ST)</td>
<td>Individuals involved in developing the study and listed on the submission as study team members. The study team always includes a PI but can also include co-investigators, sub-investigators statisticians, study coordinators, and other study personnel (see OHSP Guideline for Listing Research Personnel for additional information).</td>
</tr>
</tbody>
</table>

### Overview of the Submission Review Process

**New Studies**: The basic review process for a new study submitted to the Research Subjects Review Board (RSRB), the University of Rochester’s local IRB, is as follows:
1. The PI (and study staff) creates a study, entering study information on a series of user-friendly pages in the Click® IRB system. While the study team is working on the study submission, it is in the **Pre-Submission** state, and once completed, the PI submits the study to the RSRB for review.

2. Upon submission to the RSRB, the IRBD (or designee) will assign and submit the study to Department Review per **OHSP Policy 505 Departmental Scientific and Resource Review**. During this time, Department Reviewers may request clarifications or changes from the PI. If the IRBD notes that considerable components are missing from the submission, the IRBD may choose to request clarifications or changes from the PI prior to submission to Department Review. Further, or additional Department Review may also be requested by the IRBC during Pre-Review.

   Once Department Review approval has been provided, the submission will enter the **Pre-Review** state and the IRBD will:

   - Assign and submit the study to required **Ancillary Committees** per **OHSP Policy 503 Ancillary Committee Review**. **Note:** In accordance with ancillary committee requirements, the IRBD/IRBC may interrupt the RSRB review process to await ancillary approval confirmation. Similar to Department Review, further or additional review by an ancillary committee can be requested any time from Pre-Review to Post-Review, as illustrated below.

   - Assign an IRBC to review the submission. The assigned IRBC will then conduct an initial review for completeness, ensuring the submission includes all the necessary information and documentation for the RSRB designated and/or committee member reviewers. At any point during Pre-Review, the IRBC may request clarification or changes from the PI resulting in a back-and-forth exchange between the PI and IRBC. The IRBC may also communicate questions and/or concerns related to the submission to the designated reviewer (e.g., board chair) via **Private Comment**. Once the IRBC has completed their review, the submission is assigned for review by a designated reviewer or the full committee.

3. During **IRB Review**, the designated reviewer or the full committee will review the study.

   - If the research involves only minimal risk and falls into one of the federally-defined **exempt** or **expedited** review categories, the research can be reviewed by a designated reviewer on behalf of the full committee. During this stage of review, the designated reviewer makes a determination about the study and submits the decision in the Click® IRB system. Submitting a determination in the system moves the submission to Post-Review. Prior to making a determination, however, the reviewer may request clarification or changes from the PI, resulting in a back-and-forth exchange between the PI and designated reviewer. Alternately, the IRBC may communicate requests for clarifications or changes on the designated reviewer’s behalf.

   - If a full committee (i.e., RSRB board) reviews the study, a committee meeting occurs during which the committee makes a determination about the study. The IRBC submits the decision in the Click® IRB system on behalf of the committee. Submitting a determination in the system moves the submission to Post-Review.

4. **Post-Review**, the IRBC prepares and sends the determination letter to the PI. If the study is approved, the IRBC also creates a final version of the study documents and submission moves to **Review Complete (Approved)** state. If the committee/designated reviewer determines modifications are needed for the submission to be approved, the PI can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review (by a designated member or the full committee).

The following diagram illustrates the submission review process, including the roles and states involved in the review. **Note:** Department Review is programmed as a type of Ancillary Review and therefore not depicted separately in the diagram below.
**Modifications & Continuing Reviews**: Reviews of modifications, continuing reviews and mod/CRs follow a process similar to new studies. The only exceptions to the process relate to Department and Ancillary Committee Reviews; these reviews are not required unless warranted by the information set forth in the modification and/or continuing review or ancillary review requirements. **Note**: Revisions identified in a modification are not applied to the parent study and active follow-on submissions until it has been approved.

**Reportable New Information**: The RNI review workflow is similar to the process described above for a new study, but the submission may be routed differently depending on the circumstances of the event being reported. The basic review process of a RNI is as follows:

1. The PI, study staff or IRB staff create and submit the RNI.
2. Upon submission to the RSRB, the IRBD assigns the RNI to an IRBC and the submission enters the Pre-Review state. The IRBC then reviews the report and determines whether further review by a designated reviewer or the full committee is required. The IRBC may also request clarification or changes from the PI resulting in a back-and-forth exchange at this time.
   - Submissions that do not require further review move to an Acknowledged state (no further action is required).
   - Submissions that require further review can be assigned to a designated reviewer or to committee review and the submission will move to the IRB Review state. All submissions that potentially require suspension or termination of IRB approval or potentially meet the definition of an unanticipated problem involving risks to subjects or others (UPIRTSO), serious non-compliance or continuing non-compliance require review by the full committee.
3. During IRB Review, the designated reviewer or full committee reviews the report and makes determinations as follows:
   - If the submission is not considered serious (meaning, it does not require suspension or termination of IRB approval, nor does it meet the definition of a UPIRTSO or serious or continuing non-compliance) and requires no further action on the part of the PI, the submission will move to an Acknowledged state and review of the event is complete.
   - If the submission is not considered serious (as described above) but action is required by the PI, the PI will be notified. Once the requested actions have been completed, the submission moves to an Acknowledged state and review of the event is complete.
   - If a designated reviewer is reviewing a submission and they determine the event to be potentially serious (as described above), the submission must be assigned for committee review.
   - If the submission is reviewed by the full committee and the committee determines that the event is serious (as described above) or that additional information/actions are required, the submission will move to the Post-Review state. Alternately, if the full committee determines that the event is not serious and no further action is required, the submission will move to an Acknowledged state and review of the event is complete.
4. During **Post-Review**, the IRBC will communicate the committee’s determination concerning the report to the PI.

   - If no further action is required, once the letter concerning this determination is sent to the PI, the submission moves to **Review Complete (Complete state)**.

   - If further action or additional information is required by the committee, the committee will assign a responsible party (e.g., PI) for carrying out that plan (or providing additional information). Once the letter concerning this determination is sent, the submission moves to **Action Required** state. In this state, the responsible party can submit their response for continued IRB review. Once all required actions have been completed and a letter is sent to the PI confirming this, the submission moves to **Review Complete (Complete state)**.

The following diagram illustrates the submission review process, including the roles and states involved in the review.

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**Overview of Multi-Site Study Review**

A multi-site study (MSS) involves research from a single protocol carried out at multiple institutions. MSS research is often reviewed by a single IRB of record (sIRB), also referred to as a reviewing IRB, whereby the sIRB assumes the review responsibility for all study sites (as opposed to each study site submitting individually to their own IRB). An institution’s IRB (i.e., the RSRB), a Central IRB or an Independent IRB may act as the sIRB.

When MSS research is conducted locally, the RSRB may:

- Assume responsibility as the sIRB of record for study sites, referred hereinafter as ‘MSS sIRB’ (see **Overview of Multi-Site sIRB Submission Process**);
- Delegate review of the local site to an IRB external to the RSRB, referred hereinafter as ‘External IRB’; or
- Determine that review of the local site should remain in-house, regardless of whether other study sites will utilize a single reviewing IRB, e.g., when the project qualifies for exemption (see the **Overview of the Submission Review Process**).

**Note**: Per [OHSP Policy 504 IRB Reliance and Collaborative Research](https://example.com), all studies that will utilize the RSRB as the sIRB or an External IRB require the execution of a reliance agreement (also referred to as an IRB authorization agreement). **Submissions should not be initiated until a reliance agreement has been executed to accommodate review of the research by the sIRB or External IRB, as appropriate.**

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**Overview of the Multi-Site sIRB Submission Process**

MSS undergoing local sIRB review (i.e., when the RSRB assumes responsibility as the reviewing IRB for study sites) include the following components:

- **A study submission** that describes the research and provides study-related information and documents that apply to the study as a whole (i.e., across all participating sites). If the Lead PI will also enroll subjects and act as the PI for the local participating site, local site-specific details can also be entered as part of this submission.

- **Site submissions** for each participating site (pSite) that describes site-specific study details.

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Each of these submissions have their own workspace and undergo individual review for their respective components. Each site submission is also linked from the main study workspace.

**New Studies:** The basic review process for a new MSS submitted for sIRB review to the RSRB is as follows:

1. The Lead PI (and study staff) creates a study, indicating that the study is multi-site and that the RSRB will serve as the sIRB of record for participating sites (pSites). The Lead PI is the individual with primary responsibility for oversight and management of the conduct of the study at all pSites. While the study team is working on the study application, it is in the Pre-Submission state. Once the submission form is complete, the PI submits the study to the RSRB for review.

2. Upon submission of the study to the RSRB, the study will move through the Department Review, Pre-Review, IRB Review and Post-Review processes, as described above for routine submissions.

3. During Post-Review, the IRBC prepares and sends the determination letter to the PI. If the study is approved, the IRBC creates a final version of the study documents and the submission moves to Review Complete (Approved state). If the committee/designated reviewer determines modifications are needed for the submission to be approved, the PI can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

**New pSites:** Each pSite engaged in the research requires its own submission and therefore will undergo individual IRB review (in addition to review of the study submission). The basic review process for a pSite submitted to the RSRB for sIRB review is as follows:

1. The Lead PI (and study staff) or IRBC adds the pSite from the study workspace, resulting in the creation of a pSite workspace and corresponding submission. Upon creation, the pSite is in the Invitation Pending state. Once the IRBC validates the pSite’s eligibility to participate in the research, the pSite moves to an Awaiting Site Materials site.

2. Following receipt of the pSite’s study-specific documentation, the Lead PI, study staff or IRBC enter the pSite’s site-specific information and documents on their behalf and submit to the RSRB for individual review. **Note:** pSites cannot be submitted for review until the study submission has minimally reached the Pre-Review Complete state.

3. Upon submission of the pSite to the RSRB, the pSite will move through a simplified version of the Pre-Review, IRB Review and Post-Review processes, as described above for routine submissions. **Note:** pSites cannot progress beyond the IRB Review point until the study submission has been approved.

4. As above, during Post-Review, the IRBC prepares and sends the determination letter to the Lead PI. If the study is approved, the IRBC creates a final version of the site documents and the pSite submission moves to Review Complete (Active state). If the committee/designated reviewer determines modifications are needed for the pSite to be approved, the Lead PI, study staff or IRBC can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

The following diagram illustrates the MSS submission review process, including the roles and states involved in the review:

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**Modifications, Continuing Reviews & Reportable New Information:** Follow-on submissions undergo review as described above for routine submissions. **Note:**
• Modifications may be submitted via the study or the pSite. Study modifications apply to the study as a whole, across all pSites. pSite modifications are limited to updating site-specific details only (i.e., site-specific funding and site-specific documents).
• Continuing review, if required, is completed for the study only, not each individual pSite. Rather, individual pSite enrollment and research event data is reported for pSite by the PI (and study staff) or IRBC. Once recorded, the data reported for each pSite is accessible within the study continuing review workspace.
Navigation and Basic Tasks

Log In

To log into the Click® IRB System for the University of Rochester (UR), go to http://rochesterirb.huronresearchsuite.com/ and click on the link for Click® IRB.

1. Select your UR affiliation.
2. Use your UR 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, OHSP recommends enrolling in Duo using a mobile phone.
- Need help logging in? Contact OHSP at 273-4127.

Dashboard

After logging in, you will land on the Dashboard, where you will find:

3. My Inbox: Displays all items that require IRB action (inclusive of all boards). Sort Submissions or Filter Data, as needed.
4. Create Menu: Displays a menu of actions you can perform.
5. Study Expirations: Displays all studies (inclusive of all boards) that are within 60 days of their expiration date. Color coding indicates expiration proximity.
   - Lapsed studies will remain on the list for up to 5 days after expiration.
   - The search box can be used to further narrow results.
6. Recently Viewed: Displays the last 10 projects viewed, with the most recent on top.
7. **Assignments**: Displays workload volume for IRB Staff and Reviewers (determined by number of assigned submissions pending action by IRB staff/reviewers).
   - **Staff Assignments: Pending Staff Action** – Displays workload volume for IRB Staff. Click on the name of an IRB Staff member in the legend to exclude their assigned volume from the chart [7a]. Click on the chart wedge corresponding to an IRB Staff Member to view their assigned submissions and **Sort Submissions**, or **Filter Data**, as needed [7b].
   - **Staff Assignments: Pending Staff Action – Unassigned** – Displays submissions that have not been assigned an IRB Staff member. Assign an IRB directly from the list by selecting **Execute Activities** [7c].
   - **Reviewer Assignments: Pending Reviewer Action** – Displays Non-Committee Review workload volume for IRB Reviewers. Click on the name of an IRB Reviewer or corresponding chart wedge, as above [7a & 7b].
   - **Reviewer Assignments: Pending Reviewer Action – Unassigned** – Displays submissions in Non-Committee Review that have not been assigned an IRB Reviewer.

8. **In Process**: Summarizes volume by stages of review workflow. The number on a tile indicates how many submissions are in that stage. Click on a tile to view underlying submissions. **Sort Submissions**, as needed [8a].

**Get Help**

9. Help text is available anytime you see a ? icon. Click on the icon to review the help text.
Navigation and Basic Tasks (Continued)

10. Select the **IRB** module (tab).

11. Within the IRB module, you can access submissions that are:
   - **In-Review**: Submissions in pre-submission as well as those undergoing IRB review.
   - **Department Review**: Submissions undergoing Department Review.
   - **Active**: All internally approved studies (including exemptions, projects deemed not human research, projects that are human research but the UR is not engaged), as well as lapsed and suspended submissions.
   - **New Information Reports**: All Reports of New Information (RNI) submissions, in any state.
   - **External IRB**: All studies submitted for review by an external IRB, in any state.
   - **Relying Sites**: All pSites engaged in multi-site research, where RSRB is the reviewing IRB, in any state.
   - **All Submissions**: All in-review, active and archived submissions, in any state.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.

12. Click on a column heading to sort submissions by ID, name, PI last name, Coordinator last name, submission type, etc.

13. Select the column to filter by from the dropdown menu.

14. Type the beginning characters for the items you want to filter. You may also type a % symbol as a wildcard before the characters. (e.g., typing 71 shows all items beginning with 71; typing %71 shows all items containing 71).

15. Click **Go** to apply the filter. Submissions can then be further sorted, as described above, if necessary.

16. To combine multiple filter criteria, click **Add Filter**.

17. To clear a filter, select **Remove Filter** or **Clear All** to remove all filters.

Open a Submission

18. From your inbox (or any other tab within the IRB module), click the submission name to open the submission workspace. To navigate within a submission workspace, see the **Study & Follow-On Submission Workspace** below.
Navigation and Basic Tasks (Continued)

Find a Committee Meeting
19. Select the IRB module (tab).
20. Click on Meetings.
21. Select the meeting you wish to view. Note: Upcoming and prior meetings appear on separate tabs.

Find Checklists & Worksheets
To find protocol/consent checklists and reviewer worksheets:
22. Select the IRB module (tab).
23. Click on Library.
24. Select the Worksheets tab.
25. Click on the name of the document to download the worksheet.

Study & Follow-on Submission Workspace
As applicable to the submission type, you will find the following on study and follow-on submission workspaces:
26. Submission type
   - The submission type is identified in the heading of the workspace, as well as in the prefix of the submission ID (e.g., a STUDY prefix indicates the study submission; a MOD prefix indicates a modification submission). All prefixes abbreviations are identified in the IRB Submission Types table above.
27. Webpage breadcrumb
   - When reviewing follow-on submissions, the breadcrumb can be used to navigate to the related study’s workspace (i.e., the study homepage).
28. Submission state and approval details (e.g., IRB submission date, initial approval and effective dates, approval end date, date the submission was last updated).
   - If continuing review is not required, the Approval End data field will not be present.
Navigation and Basic Tasks (Continued)

Study & Follow-on Submission Workspace (Continued)

29. Submission ID, short title and basic submission information (e.g., PI, Primary Contact, PI Proxies, IRBC, approval letter).

30. Review workflow, indicating where the submission is in the review process.

31. Smart forms and activities:
   - **View Study**: Provides a read-only view of the submission form.
   - **Printer Version**: Provides a printer-friendly version of the submission form.
   - **Activities**: Moves submissions through the review workflow. Available activities are dependent on the submission’s state. Hovering your cursor over the activity, provides a description of the activity.

32. Submission space navigation toolbar
   - **History**: Lists the actions taken on a submission including comments, attachments, or correspondence added.
   - **Funding**: Identifies the submission funding source and related grant information.
   - **Contacts**: Identifies study team members listed in the study submission as well as individuals with guest access (including Ancillary and Department Reviewers).
   - **Documents**: Identifies all study and site related documents, including final approved and watermarked versions.
   - **Follow-On Submissions**: Lists all Mods, CRs, Mod/CRs, and RNIs related to the submission.
   - **Reviews**: Identifies determinations made during pre-review, designated/committee review, as well as completed Department and Ancillary Reviews. Review history is maintained for each review type. When a modification is approved, the latest pre-review information from that modification is copied to the parent submission.
   - **Determinations**: Lists the protocol/consent and regulatory determinations made by the IRBC and designated reviewer/committee.
   - **Snapshots**: Provides historical submission contents.
   - **Audits**: Lists internally-conducted audits and quality improvement reviews.
   - **Minutes**: Identifies all previously recorded minutes related to the submission.
   - **Training Details**: Identifies all study team members and the training they have completed through the Collaborative Institutional Training Initiative (e.g., Human Subject Protection, Good Clinical Practice, Animal Care & Use, and Responsible Conduct of Research training).
   - **Sites** (if applicable): Identifies all participating sites undergoing single IRB review by the RSRB (for multi-site studies only).
Review Meeting Materials

You will receive an email notification when: a) you are assigned to act as primary reviewer of a submission or review item; and b) when a committee meeting agenda has been sent.

Find the Meeting Materials

To open the meeting workspace, you may:

1. Click the link in your notification email. You will be directed to log in and then automatically routed to the meeting workspace.

OR

2. From your dashboard, select the IRB module (tab).
3. Click on Meetings.
4. Select the upcoming meeting you wish to review materials for.

Confirm / Decline Attendance

5. From the meeting workspace, select Confirm Attendance or Decline Attendance, as applicable.
6. Click OK (for confirmations only).

Find the Agenda

7. Click on the agenda link in your notification email.

OR

8. From the meeting workspace, select the hyperlink for the agenda in the workspace heading. The agenda will open as a Microsoft Word document.

Review the Expedited Report

9. From the meeting workspace, select the link for ‘Expedited Submissions Approved in the Last 45 Days’ in the workspace heading.

Review Previous Minutes

10. Select the previous meeting with pending minutes. The original meeting’s workspace will open in a new tab of your web browser.
11. From the original meeting’s workspace, select the minutes link in the header.
12. From the meeting workspace, click on the submission ID or name to open the submission (for ‘Other Agenda Items’ see the information provided below). The submission workspace will open in a new tab in your web browser.

From the submission workspace you may:

13. **Review Study/Mod/CR/RNI**: 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. Use the **Compare** feature to review revisions to previously reviewed materials.

14. **Printer Version**: Shows the entire submission in one scrollable page.

15. Additional information is also available in the navigation toolbar (e.g. Documents, Review and Determinations Tabs). See detail described in the **Study & Follow-on Submission Workspace** above.

**Add Review Comments**

16. From the submission space, click **Add Review Comments**.

17. Type your notes for other committee members and/or the IRBC/IRBD.

18. Click **Add** to attach any review checklists and/or supporting documents (e.g., existing literature, tracked consent documents, etc.) you want to share.

- **Primary Reviewer worksheets are available for use in the IRB Library**.

19. Click **OK**.

- The review comments and attachments will then appear on both the History and Reviews navigation 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 your comments.
Review Meeting Materials (Continued)

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 will include audit/quality improvement reports but other materials may also be added via this activity.

To access audit/quality improvement reports:

20. Click on the study ID listed under ‘Other Agenda Items’.

21. From the study workspace, click the ellipses on the navigation toolbar.

22. Select the Audits tab.

23. Click on the report identified on the agenda to open and review the report.

Add Private Comment

Private Comment: If you identify missing information or clarifications that require action prior to committee review, you can communicate such issues to the IRBC via private comment. Private comments are only visible to IRB Staff and Committee Members who are not on the study team.

24. From the submission workspace, click Add Private Comment.

25. Insert your comment.

26. Select the roles and/or specific individuals to be notified of the comment.

27. Click OK. The private comment will appear on the History tab and the individuals selected in Fields 3 and/or 4 will be sent an email notification alerting them to the comment.

Request Clarification by Committee Member: DO NOT select ‘Request Clarification by Committee Member’. Doing so will send requests directly to the study team.
Review Requested Changes

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

Compare

1. From the submission workspace, click **Review Study**.
2. The versions of the submission being compared will appear at the top of the left-hand navigation pane. To change version the current submission is being compared to, click the down arrow to show the submission versions and select the version desired version.
3. Click the pencil icon(s) to view the change(s) made.
4. Revisions are indicated within the SmartForm by a blue ‘Differences’ box that can be expanded/contracted.
5. ‘Changed’ or ‘Added’ can also be expanded/contracted to provide revision details.
6. If a document was revised, select the **Compare** activity to view tracked changes. **Note:** 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 [7a]; and b) Select the **Review** tab and then All Markup in the Tracking Options pane of the Review tab [7b]. Documents can also be compared by viewing the **Document History** [7c].
## Quick Reference Guide: Reviewing Meeting Materials

### Log into Click® IRB

2. Select your UR affiliation.
   - Community Members: Select URMC.
3. Use your UR active directory credentials to log in (i.e., the credentials used to log into your computer/access your email).
   - Community Members: Use the log in information provided by OHSP.

### Locate the Meeting Workspace

1. From the meeting notification email, click the meeting link to open the meeting workspace.
   OR
2. Log into Click® IRB and select the IRB module (tab).
3. Click on Meetings.
4. Select the upcoming meeting you wish to review materials for.

### Confirm or Decline Attendance

From the meeting workspace:

1. From the meeting workspace, select Confirm Attendance or Decline Attendance on the left-hand activities toolbar, as applicable.
2. Click OK (for confirmations only).

### Review the Meeting Minutes

1. From the meeting workspace, select the previous meeting with minutes pending approval.
   - The original meeting’s workspace will open in a new tab of your web browser.
2. From the original meeting’s workspace, select the minutes link in the header.

### Review the Expedited Report

1. From the meeting workspace, click on the link of ‘Expedited Submissions Approved in the Last 45 Days’.
   - Note: The report includes all expedited approvals completed within the past 45 days. It is not limited to approvals completed since the last board meeting, nor is it limited to one particular committee/board.

### Review an Agenda Item

1. From the meeting workspace, click on the Submission ID or Name to open the submission (see below for audits/QI reports).
   - The submission workspace will open in a new tab in your web browser.

From the submission workspace you may:

2. **Review Study/Mod/CR/RNI**: 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.
   - Use the Compare feature to review revisions to previously reviewed materials. The versions of the submission compared will appear at the top of the left-hand navigation pane when Compare is selected (click the down arrow to change the versions being compared). Click on the pencil icon(s) to view the change(s) made. Revisions will be indicated by ‘Differences’ boxes that may be expanded/contracted for additional revision details.

### Printer Version

- Shows the entire submission in one scrollable page.

### Additional Information

- Additional information is also available in the navigation toolbar (e.g., funding, contacts, documents, reviews, determinations, training details, etc.)

### Review Quality Improvement Reports

1. From the meeting workspace, click on the study ID for the QI report listed under ‘Other Agenda Items’.
   - The original meeting’s workspace will open in a new tab of your web browser.
2. From the submission workspace, click on the ellipses on the navigation toolbar and select the Audits tab.
3. Click on the report identified on the agenda to open and review the document.

### Add Review Comments

1. From the submission workspace, click Add Review Comments.
2. Type your notes in the comments field and/or attach supporting documents (e.g., reviewer checklist, tracked consent forms, etc.). Click OK.

**DO NOT SELECT** ‘Request Clarification by Committee Member’. Doing so will send requests directly to the study team.

**DO NOT SELECT** ‘Add Comments’. Comments entered here are visible to all users with access to the study, including study team members.