Click® IRB: IRB Committee Member Manual

Introduction ................................................................................................................. 2
Overview of the Click® IRB System ........................................................................ 2
Overview of the Submission Review Process ......................................................... 3
Overview of Multi-Site Study Review ................................................................. 6
Overview of the Multi-Site sIRB Submission Process ........................................ 6
Navigation and Basic Tasks ...................................................................................... 8
Review Meeting Materials ...................................................................................... 12
Review Requested Changes .................................................................................... 15
Quick Reference Guide: Reviewing Meeting Materials ..................................... 16
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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
</tr>
<tr>
<td>----------------------------</td>
</tr>
<tr>
<td>Initial Submissions</td>
</tr>
<tr>
<td>Study</td>
</tr>
<tr>
<td>Site</td>
</tr>
<tr>
<td>Follow-on Submissions</td>
</tr>
<tr>
<td>Modification (Mod)</td>
</tr>
<tr>
<td>Continuing Review (CR)</td>
</tr>
<tr>
<td>Modification and Continuing Review (Mod/CR)</td>
</tr>
<tr>
<td>Reportable New Information (RNI)</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>Roles</th>
<th>Typical Activities</th>
</tr>
</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>An individual responsible for evaluating study submissions against their department-specific scientific review policy (in accordance with <a href="#">OHSP Policy 505 Scientific Review Standards</a>).</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 <a href="#">OHSP Policy 901 Investigator Responsibilities</a>). Each study and pSite requires a single PI to be identified on the submission. All PIs must meet the <a href="#">University of Rochester (UR) PI Eligibility Policy</a>. 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)</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 <a href="#">OHSP Guideline for Listing Research Personnel</a> 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 Scientific Review Standards. 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: The system does not prevent a submission from being reviewed or approved by the RSRB if an ancillary review is outstanding. 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. The IRBC may also 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. During 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.
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 an 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.
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, 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.

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.

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**.

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.

**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/](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.

## My Inbox

After logging in, you will land on the My Inbox page, where you will find:

3. **Submissions** that require you to take action. For committee members, only items that have been assigned to you as the primary reviewer will appear here.
   - The type of submission can be identified by the ID prefix (e.g., a ‘STUDY’ prefix indicates the submission is a study, a ‘MOD’ prefix indicates the submission is a modification, etc.).
4. **Actions** you can perform, such as create a new study or report new information.
5. **Shortcuts** that provide access to other items, such as all the submissions you can view, meetings and reports.

## Get Help

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

Sort Submissions

To sort data on a page:
7. Prioritize submissions by sorting the headings provided (e.g., ID, date modified, or state).
8. Submissions can also be identified and/or sorted using the filter function (see additional information on filtering data below).

Filter Data

To filter data on a page:
9. Select the column to filter by.
10. 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).
11. Click Go to apply the filter.
12. To combine multiple filter criteria, click Add Filter.
13. To clear a filter, select Remove Filter or Clear All to remove all filters.

Open a Submission

From your inbox (or any other tab):
14. Click the submission name.
15. The submission workspace opens.

Find a Committee Meeting

To open a committee meeting workspace, you may:
16. Click the link in your notification email. You will be directed to log in and then automatically routed to the meeting workspace.
OR
17. From your inbox, click the Meetings shortcut and then [18a] select the meeting you wish to view.
   a. Upcoming and prior meetings appear on separate tabs.
Navigation and Basic Tasks (Continued)

Find Submissions

To find a submission:

18. Click the Submissions shortcut or the IRB tab.

19. 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 submissions.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.
   - **New Information Reports**: All Reportable 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.

20. Click the name of the submission to open the submission workspace. To navigate within a submission, see Study & Follow-On Submission Workspace below.

Find Reviewer Worksheets

21. From your inbox, click on the Library shortcut or, on the horizontal navigation toolbar, select IRB and then Library.

22. From the Library workspace, select the Worksheets tab.
Navigation and Basic Tasks (Continued)

Study & Follow-on Submission Workspace

As applicable to the submission type, you still find the following on study and follow-on submission workspaces:

23. Submission state and details pertaining to the submission (e.g., IRB submission date, initial approval date, approval end date)

24. 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).

25. Submission ID, short title and basic submission information (e.g., PI, submission type, Primary Contact, PI Proxies, IRB Coordinator, approval letter, and legacy link, if applicable).

26. Review workflow, indicating where the submission is in the review process.
   - The workflow will disappear when the submission is in Department Review.

27. 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.
   - **View Differences**: Identifies changes made between 2 versions 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.

28. Submission space navigation toolbar
   - **History**: Lists the activity 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 application as well as individuals with guest access.
   - **Documents**: Identifies all study and site related documents, including final approved and watermarked versions.
   - **Sites**: Identifies all participating sites undergoing single IRB review by the RSRB (for multi-site studies only).
   - **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 ancillary reviews.
   - **Department Reviews**: Identifies all requested and completed department reviews.
   - **Determinations**: Lists the protocol/consent and regulatory determinations made by the IRBC and designated review/committee.
   - **Audits**: Provides historical submission contents.
   - **Funding**: 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).
**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.

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**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 inbox, select the Meetings shortcut.

3. Select the upcoming meeting you wish to review materials for.

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**Confirm / Decline Attendance**

To confirm or decline attendance, from the meeting workspace:

4. Select Confirm Attendance or Decline Attendance, as applicable.

5. Click OK (for confirmations only).

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**Find the Agenda**

6. Click the link in your notification email.

   OR

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

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**Review the Expedited Report**

From the meeting workspace:

8. To review the expedited report, select the link for ‘ Expedited Submissions Approved in the Last 45 Days’ in the workspace heading.

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**Review Previous Minutes**

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

10. To open and review the minutes, select the minutes link in the header of the original meeting’s workspace.
Review Meeting Materials (Continued)

Review an Agenda Item

From the meeting workspace:

11. 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:

12. **View Study/Mod/CR/RNI**: Opens the submission form; click Continue to move through the pages.

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

14. **View Differences**: Displays revisions previously made to the submission.

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

From the submission workspace:

16. Click **Add Review Comments**.

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

18. Click **Add** to attach any supporting documents (e.g., existing literature, tracked consent documents, review checklists, 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 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. If applicable, select the roles that should be notified of the comment (e.g., IRBC and/or IRBD).
27. If applicable, select a specific individuals to be notified of the comment.
28. 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 View Differences activity to review the revisions.

1. From the submission workspace, click View Differences.
2. Select the submission versions to compare (this defaults to the current and most recent, prior version).
3. Use the forward and backward arrows and/or dropdown menu to navigate to smart form components that have been modified.
4. Revisions will be identified by a red ‘Differences’ table that can be expanded/contracted.
5. ‘Changes’ 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; and
   b) Select the Review tab and then All Markup in the Tracking Options pane of the Review tab.
7. Once all changes have been viewed, the forward button will disable.
8. Click Close to exit.
**Quick Reference Guide: Reviewing Meeting Materials**

<table>
<thead>
<tr>
<th>Log into Click® IRB</th>
<th>Review an Agenda Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Go to <a href="http://rochesterirb.huronresearchsuite.com/">http://rochesterirb.huronresearchsuite.com/</a></td>
<td>From the meeting workspace:</td>
</tr>
<tr>
<td>2. Select your UR affiliation.</td>
<td>1. Click on the <strong>Submission ID</strong> or <strong>Name</strong> to open the submission (see below for audits/QI reports).</td>
</tr>
<tr>
<td>• Community Members: Select URMC.</td>
<td>• The submission workspace will open in a new tab in your web browser.</td>
</tr>
<tr>
<td>3. Use your UR active directory credentials to log in (i.e., the credentials used to log into your computer/access your email).</td>
<td>From the submission workspace you may:</td>
</tr>
<tr>
<td>• Community Members: Use the log in information provided by OHSP.</td>
<td>2. <strong>View Study/Mod/CR/RNI</strong>: Opens the submission form; click Continue to move through the pages.</td>
</tr>
<tr>
<td></td>
<td>3. <strong>Printer Version</strong>: Shows the entire submission in one scrollable page.</td>
</tr>
<tr>
<td><strong>Locate the Meeting Workspace</strong></td>
<td>4. <strong>View Differences</strong>: Displays revisions previously made to the submission.</td>
</tr>
<tr>
<td>1. From the meeting notification email, click the meeting link to open the meeting workspace.</td>
<td>• Use the forward and backward arrows and/or dropdown menu to navigate to smart form components that have been modified.</td>
</tr>
<tr>
<td>OR</td>
<td>• Revisions will be identified by a red ‘Differences’ table that can be expanded/contracted. ‘Changes’ (or ‘Added’) can also be expanded/contracted to provide revision details.</td>
</tr>
<tr>
<td>1. Log into Click® IRB and select <strong>Meetings</strong> from the left-hand list of activities in your Inbox workspace.</td>
<td>• If a document was revised, select the <strong>Compare</strong> activity to view tracked changes.</td>
</tr>
<tr>
<td>2. Select the meeting.</td>
<td>5. Additional information is also available in the navigation toolbar (e.g., funding, contacts, documents, reviews, determinations, training details, etc.)</td>
</tr>
<tr>
<td><strong>Confirm or Decline Attendance</strong></td>
<td><strong>Review Quality Improvement Reports</strong></td>
</tr>
<tr>
<td>From the meeting workspace:</td>
<td>1. From the meeting workspace, click on the study ID for the QI report listed under ‘Other Agenda Items’.</td>
</tr>
<tr>
<td>1. Select Confirm Attendance or Decline Attendance on the left-hand activities toolbar, as applicable.</td>
<td>• The submission workspace will open in a new tab in your web browser.</td>
</tr>
<tr>
<td>2. Click <strong>OK</strong> (for confirmations only).</td>
<td>2. From the submission workspace, click on the ellipses on the navigation toolbar and select the <strong>Audits</strong> tab.</td>
</tr>
<tr>
<td></td>
<td>3. Click on the report identified on the agenda to open and review the document.</td>
</tr>
<tr>
<td><strong>Review the Meeting Minutes</strong></td>
<td><strong>Add Review Comments</strong></td>
</tr>
<tr>
<td>From the meeting workspace:</td>
<td>1. From the submission workspace, click <strong>Add Review Comments</strong>.</td>
</tr>
<tr>
<td>1. Select the previous meeting with minutes pending approval.</td>
<td>2. Type your notes in the comments field and/or attach supporting documents (e.g., reviewer checklist, tracked consent forms, etc.). <strong>Click OK</strong>.</td>
</tr>
<tr>
<td>• The <strong>original</strong> meeting’s workspace will open in a new tab of your web browser.</td>
<td><strong>DO NOT SELECT</strong> ‘Request Clarification by Committee Member’. Doing so will send requests directly to the study team.</td>
</tr>
<tr>
<td>2. To open and review the minutes, select the minutes link in the header of the <strong>original</strong> meeting’s workspace.</td>
<td><strong>DO NOT SELECT</strong> ‘Add Comments’. Comments entered here are visible to <em>all</em> users with access to the study, including study team members.</td>
</tr>
<tr>
<td><strong>Review the Expedited Report</strong></td>
<td></td>
</tr>
<tr>
<td>From the meeting workspace:</td>
<td></td>
</tr>
<tr>
<td>1. Click on the link of ‘Expedited Submissions Approved in the Last 45 Days’.</td>
<td></td>
</tr>
<tr>
<td>• 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.</td>
<td></td>
</tr>
</tbody>
</table>