

Integrated Online Research Administration: Click IRB Module

IRB 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 the IRB Reviewer (i.e., Board Chair and Vice Chair) 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:

- 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](#).

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.](#)

Table of Contents

Abbreviations & Acronyms	3
Log In	3
Review a Study or Follow-on Submission	3
Open the Submission	3
Perform a Review	4
Submit Regulatory Determinations	5
Submit Designated Review	7
Committee Reviewer Activities	8
Find Meeting Materials	9
Confirm/Decline Attendance	9
Review the Expedited Report	10
Review Previous Minutes	10
Review Other Agenda Items	10
Find a Quality Improvement Report	10
Find Reviewer Worksheets	11
Add Review Comments	11
Review Requested Changes	11
Review a Report of New Information	12
Perform a RNI Pre-Review	12
Submit RNI Designated Review	13
Additional Activities	14
Assign to Committee Review	14
Add a Comment	14
Add a Private Comment	14

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

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.

Review a Study or Follow-on Submission

You will receive an email notification when:

- A study, site, or follow-on submission has been assigned to you for review. You may be assigned to review a submission as a Designated Reviewer via Non-Committee Review (i.e., expedited review) or as a Committee Reviewer via Committee Review (i.e., full board review). The submission will appear in your inbox on the IORA dashboard.
- A Committee Meeting Agenda is finalized and sent to Committee Members. Submission assigned to the agenda will appear in the meeting workspace.

Open the Submission

To open a submission, you may:

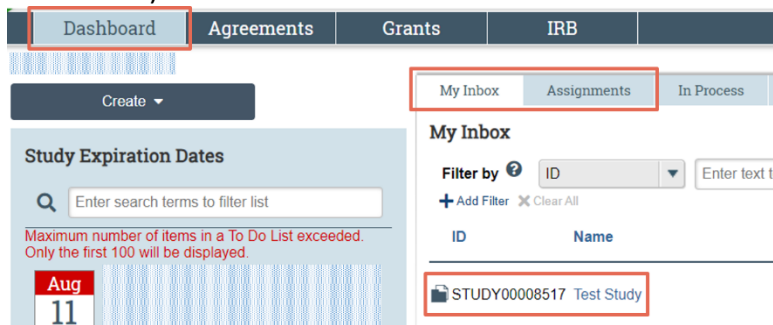
1. Click the link in your notification email. You will be directed to log in and then automatically routed directly to the submission workspace (or meeting workspace, from a Committee Meeting Agenda notice).



OR

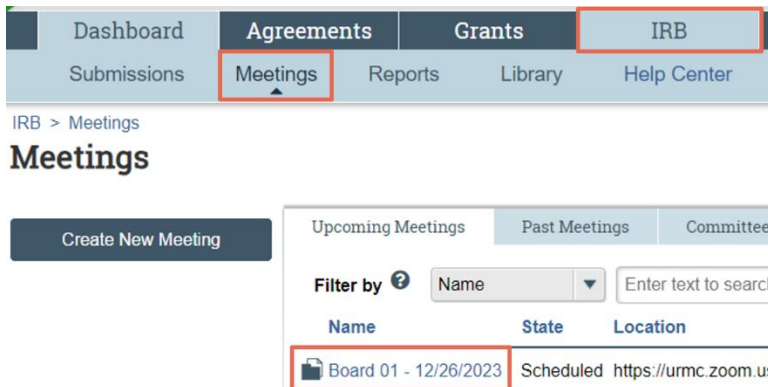
2. From your Inbox or Assignment tabs on the Dashboard, click on the name of the submission. **Note:** Your Inbox identifies submissions assigned to you as an IRB Reviewer for both designated and

committee review; the Assignment tabs only identifies submission assigned to you for designated (non-committee) review.



OR

3. For items assign to a convened meeting:
 - a. Select the **IRB** module.
 - b. Click on **Meetings** and select the meeting the submission has been assigned.
 - c. Click on the submission ID or name.



Perform a Review

1. Click **Review Study (or Review Modification/CR)** 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:
 - a. **Printer Version:** Shows the submission in one scrollable page.
 - b. **Navigation Tabs:** Pulls specific information from the submission form and/or completed activities (e.g., Documents, Funding, etc.).
2. To view revisions to previously submitted materials, use the **Compare** feature.
3. After reviewing each section, select the checkbox at the bottom of the section to confirm your review.
 - a. This is not required but good practice. Sections left unchecked will not prevent submissions from moving forward.
 - b. After confirmation, the section reviewed turns green and a green checkmark appears in the left-hand navigation pane.
 - c. If the submission is later edited, the green check mark is removed and a pencil icon is added, indicating the section should be re-reviewed.

8. * Attach the protocol:

Document	Category	Date Modified	Document History
view Protocol.docx(0.01)	IRB Protocol	8/15/2023	History

Above section has been reviewed:

4. Click **Exit** to return to the submission workspace.

Next Steps

- If the submission has been assigned to you for Designated (Non-Committee) Review and:
 - The submission requires clarification, [Private Comment](#) the IRBC a description of the revisions. The IRBC will then return the submission to the study team for revision. **NOTE: It is generally not recommended for Designated Reviewers to request clarification via the 'Request Clarification by Designated Reviewer' activity as this sends the request DIRECTLY to the study team.**
 - Your review is complete and the submission is eligible for expedited review, complete the [Submit Regulatory Determinations](#) activity.
 - Your review is complete and the submission is qualifies for exemption or is a pSite (for MSS), [Submit Designated Review](#).
 - The submission requires Committee Review, [Assign to Committee Review](#). The submission will be returned to the IRBC and they will assign the submission for review at an upcoming meeting.
 - If the submission is scheduled for Committee Review, see [Committee Reviewer Activities](#).
- If questions were submitted to you from the IRBC via Private Comment, respond via [Private Comment](#).

Submit Regulatory Determinations

Note:

- This activity is **NOT REQUIRED** for:
 - Exemptions;
 - Projects deemed not human research;
 - Projects that are human research but the UR is not engaged;
 - pSites undergoing MSS sIRB review; or
 - Study closures.
- If the submission is a follow-on submission (MOD, CR, or MODCR), the determinations entered via the Submit Regulatory Determinations and Submit Designated Review activities will be pre-populated based on the previous review. Previously documented determinations should be updated/confirmed, as necessary, with the review of each follow-on submission.
- **Once completed, the information entered into this activity is visible to study team members via the History log.**

From the submission workspace, click **Submit Regulatory Determination**. In the corresponding Submit Regulatory Determinations window, respond to all required fields. For the following fields, note:

1. **Type of submission:** This field will pre-populated. If the submission is a follow-on submission, an additional field will be present to indicate whether non-compliance has been identified as part of the review. If yes, an additional follow-up field will appear to indicate whether the non-compliance is serious or continuing.
2. **Is this submission eligible for an expedited review?** Indicate whether the submission is eligible for expedited review.
 - a. Answer yes for:
 - Initial submissions that are minimal risk and fall into one of the expedited categories for review;

- Follow-on submissions that are eligible for expedited review (irrespective of study risk level);
- Concept, Umbrella or Coordinating Center study submissions.
- b. Answer no for:
 - Submissions that require committee review;
 - Projects that qualify for exemption, do not involve human subject research, or is research but the UR is not engaged (if completed).
- 3. Fields 5-10 (consent determinations through vulnerable population determinations) apply to the study as a whole, not the individual follow-on submissions (e.g., modification components). **Determinations documented within these fields should only be updated during the review of a follow-on submission when the components of the follow-on submission change the determinations previously made on the research.**
- 4. **The following consent determinations...** If 'informed consent obtained...', 'parent permission obtained...', or 'waiver of written documentation of consent' is selected, an additional follow-up field concerning general consent regulatory requirements will appear.
- 5. **Confirm HIPAA determinations...** If HIPAA does not apply to the research, select 'No PHI'.
- 6. **Are drugs (and/or devices) included in this study?** Answering yes to either question will provide additional an additional follow-up field to document drug/device determinations, respectively. If multiple drugs/devices are being investigated, it may be necessary to select more than one response.
 - a. **Reminder:** All new submissions involving an IND, IDE, Abbreviated IDE or HDE require committee review.
- 7. **Select risk level of vulnerable populations...** If vulnerable populations are included in the research, select the applicable risk determination for the population included. **Note:**
 - a. **This field only needs to be completed if the submission is undergoing Designated Review** (for research undergoing committee review, these determinations are documented via the meeting minutes).
 - b. Children's determinations appear on the [Submit Designated Review](#) activity.
 - c. If a vulnerable population is missing from this field (pregnant women, prisoners, or adults with decisional impairments), instruct the IRBC to update their Pre-Review via [Private Comment](#).
- 8. **Below are the protocol and consent determinations for additional safeguards...** Additional safeguards for vulnerable populations that are documented via the IRBC's Protocol Determinations activity will automatically populate in this field. If necessary, include any additional comments concerning such safeguards in the text box.
- 9. **The following groups will be notified of changes:** This field will only appear if the submission is a MOD or MODCR. Indicate what groups of subjects, if any, need to be notified of the revisions including in the MOD/MODCR. **Note:** If your determination differs from what the study team has indicated in the MOD/MODCR submission form, the submission form should be updated accordingly prior to approval. Inconsistencies in these field may set the study team up for non-compliance.
- 10. Click **OK**. The information entered here will appear on the Determinations tab and will pull through to future follow-on submissions.

Next Steps

- If the submission has been assigned to you for Designated (Non-Committee) Review and your review is complete, complete the [Submit Designated Review](#).

- If the submission was reviewed at a Convened Meeting, the IRBC will perform the necessary Post-Review activities.

Submit Designated Review

From the submission workspace, click **Submit Designated Review** (or Submit Site Designated Review for pSites). In the corresponding Submit Designated Review window, respond to all required fields. For the following fields, note:

1. **Risk level:** Identify the risk level of the research as a *whole* (not an individual follow-on submission, e.g., modification). The risk level should only be modified when the components of a follow-on submission change the risk level of the research.
 - a. Answer 'N/A' only if the project is 'Not Human Research' or 'Human Research, not Engaged'.
2. **Review level:** This field will only appear if the 'Approved' or 'Modifications Required to Secure Approval' is selected as the approval determination and the risk level is identified as 'No greater than minimal risk'.
 - a. For new studies, select the applicable review level (see [OHSP Policy 501 Levels of RSRB Review](#) and the associated guidelines on [exempt status determinations](#) and [expedited reviews](#)).
 - **Note:** If expedited category 7 applies, select BOTH 7a and 7b (the federal regulations do not split these types of research in the regulations; 7b are methods to achieve 7a).
 - b. For modifications:
 - If the research involves minimal risk and:
 - The modification is minimal risk, leave the review categories as they appear; do not change the review categories (as determined by the previous submission). If the modification is adding additional minimal risk procedures that fall into additional review categories, add the additional categories. **Note:** The research was initially reviewed by the convened board and the board determined future review of the submission could be expedited under Category 9, do not add additional expedited categories when additional minimal risk procedures are added (leave the category as 9 only). Alternately, Category 9 may need to be selected, if this is the first follow-on submission, following the board's Category 9 determination.
 - The modification is adding greater than minimal risk activities, assign the modification for [committee review](#).
 - If the research is greater than minimal risk research and:
 - The modification is minimal risk, select 'mm' (minor modification).
 - The modification is not minor and/or involves the addition of (or modification to existing) greater than minimal risk activities, cancel/exit out of the Submit Designated Review activity and assign the modification for committee review.
 - When the modification involves administrative changes only – e.g., correcting page numbering, fixing approval dates to be consistent with OHSP policy, correcting information in a recruitment flyer to be consistent with the approved protocol, correcting CRFs/data collection forms to be consistent with procedures already identified in the approved protocol (but not adding new fields/procedures), and personnel changes other than the PI – select 'Other' (leave expedited categories as is and add 'Other' as an additional category for the administrative change).
 - **Note:** Review categories pull into the Submit Designated Review activity from the most recent submission. As such, the review categories 'mm' (minor modification) and/or

‘Other’ may need to be removed if they have pre-populated and do not apply to the current submission.

- c. For continuing reviews:
 - If the research is minimal risk and was approved under an exempt or expedited category, leave the review categories as they appear (unless the submission is a MODCR and the modification changes the risk level/review categories of the research).
 - If the research is greater than minimal risk and greater than minimal risk activities have occurred during the review period (i.e., since the last CR), cancel/exit out of the Submit Designated Review activity assign the CR for committee review.
 - If the research is greater than minimal risk and only minimal risk activities have occurred during the review period (i.e., since the last CR), select expedited categories 8a, 8b, and/or 8c, as applicable.
3. **Rationale for continuing review requirement:** This field will only appear if the preceding field, regarding continuing review, is answered ‘Yes’.
4. **Dates:** Minimally, enter the approval date (this should default to the date you are completing the review). The IRBC will complete/verify remaining dates, as necessary. The last day of approval period field will only appear when continuing review is required.
5. **If modifications are required...** Enter the revisions/clarifications required for approval. The information entered here will populate the determination letter sent to the study team by the IRBC in Post-Review and **will be visible to study team members via the History tab.**
6. **Are you ready to submit the review?** Answer yes, if you are ready to submit your review (this will move the submission back into the IRBC’s inbox). If you are not ready to submit your review, answer no, and the information you entered will be saved for submission at a later time.
7. Click **OK**.
 - a. The submission will move back into the IRBC’s inbox for Post-Review activities.
 - b. The information entered here will appear on the Reviews tab and pull through to future follow-on submissions.

Committee Reviewer Activities

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
 - [Review a Report of New Information](#) for RNIs
 - [Review Other Agenda Items](#) for all other agenda items.
 - [Confirming meeting attendance](#).
 - Reviewing the [Expedited Report](#) and previous [Meeting Minutes](#) (if available).

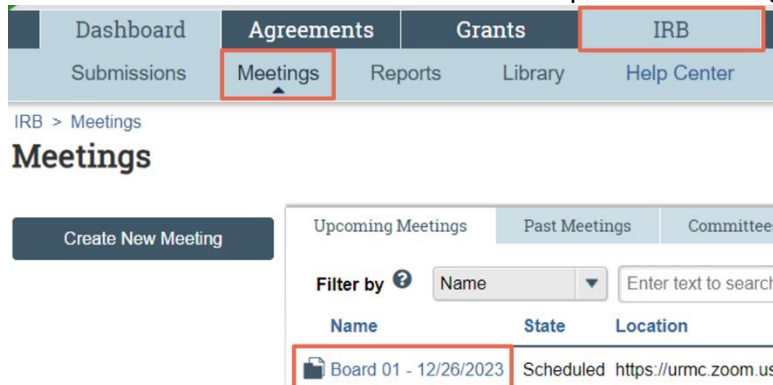
- Committee Reviewers are further responsible for being prepared to present a summary of the submission and provide board determination recommendations at the time of the Convened Meeting. To facilitate this, for each assigned submission, Committee Reviewers should:
 - Complete a [Reviewer Worksheet](#) 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.**

During (or immediately following) the convened meeting, the Board Chair is responsible for completing/updating the [Submit Regulatory Determinations](#) activity for all new studies, MODs and MODCRs.

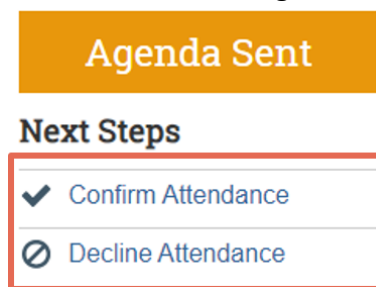
Find Meeting Materials

1. Select the **IRB** module.
2. Click on **Meetings** and select the meeting the submission has been assigned.
3. 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.

Committee: Board 01 – Biomedical

Board 01 - 08/17/2023

Meeting date & time: 8/17/2023 10:00 AM

Agenda:  Agenda for Board 01 - 08_17_2023.doc(0.01) ...

Minutes:  Minutes for Board 01 - 08_17_2023.docx(0.01) ...

Report: Expedited Submissions Approved in the Last 45 Days

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.

Previous meetings with minutes for approval

ID	Name
Mee00000555	Board 01 - 08/17/2023

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





IRB > Meetings

Meetings

[Create New Meeting](#)

Upcoming Meetings | Past Meetings | Committees

Filter by  Name

Name	State	Location
 Board 01 - 12/26/2023	Scheduled	https://urmc.zoom.us

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).

Other Agenda Items

Name	Related Projects
	STUDY00008474

- 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).
- Click on the report identified on the agenda to open and review the report. **Note:**
 - Each instance of an OHSP QI Review and QI-related Consultation is added to this section of the study workspace by the QI Team.

Date of Audit	Audit Type	Audit Rating	Date Audit Reviewed by Board	Supporting Documents
8/16/2023	Routine QI Review	Acceptable		OHSP-QI Final Report(0.01)

Find Reviewer Worksheets

To find protocol/consent checklists and reviewer worksheets:

- Select the **IRB** module (tab).
- Click on **Library**.
- Select the **Worksheets** tab.
- Click on the name of the document to download the worksheet.

Name	Document
IRBC Worksheet New Study	IRBC Worksheet New Study
RSRB Reviewer Worksheet MODCR	RSRB Reviewer Worksheet MODCR
RSRB Reviewer Worksheet New Study	RSRB Reviewer Worksheet New Study

Add Review Comments

- From the submission workspace, click **Add Review Comments**.
- Notes:** Type your notes/comments for other committee members and/or the IRBC/IRBD.
- Checklists:** Click **Add** to attach [Reviewer Worksheets](#).
- Supporting documents:** Click **Add** to attach supporting documents (e.g., existing literature, tracked consent documents, etc.) you want to share.
- 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 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.

- From the submission workspace, click **Review Study (or Review Modification/CR or Review RNI)**.
- 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.

Review a Report of New Information

When an RNI is first submitted to the IRB for review, it will appear in the IRBD inbox. The IRBD will assign the RNI to an IRBC based on the RNI's related submissions. Once a study has been assigned to an IRBC, they will complete an initial review and based, on the information provided, either: a) acknowledge the event (with no further review necessary) or b) move the event forward in the review process by assigning it to either Designated or Committee Review.

You will receive an email notification when a RNI has been assigned to you for review and the submission will appear in your IRB inbox. You may be assigned to review a RNI as a Designated Reviewer via Non-Committee Review (i.e., expedited review) or as a Committee Reviewer via Committee Review (i.e., full board review).

Perform a RNI Pre-Review

From the RNI workspace:

1. Click **Review RNI** to open the submission form and review each section. Alternately, submission components can be reviewed via:
 - a. **Printer Version:** Shows the submission in one scrollable page.
 - b. **Navigation Tabs:** Pulls specific information from the submission form and/or completed activities (e.g., Documents, Funding, etc.).
2. To view revisions to previously submitted materials, use the **Compare** feature.
3. After reviewing each section, select the checkbox at the bottom of the section to confirm your review.
 - a. This is not required but good practice. Sections left unchecked will not prevent submissions from moving forward.
 - b. After confirmation, the section reviewed turns green and a green checkmark appears in the left-hand navigation pane.
 - c. If the submission is later edited, the green check mark is removed and a pencil icon is added, indicating the section should be re-reviewed.

8. * Attach the protocol: 

Document	Category	Date Modified	Document History
 Protocol.docx(0.01)	IRB Protocol	8/15/2023	History

Above section has been reviewed:

- Click **Exit** to return to the submission workspace.

Next Steps

Once you've completed your review:

- If the submission has been assigned to your Designated (Non-Committee) Review and:
 - The submission requires clarification/additional information, notify the IRBC via [Private Comment](#). The IRBC will then return the submission to the study team for revision. **NOTE: It is generally not recommended for Designated Reviewers to request clarification via the 'Request Clarification by Designated Reviewer' activity as this sends the request DIRECTLY to the study team.**
 - Your review is complete, [Submit RNI Designated Review](#).
 - The submission requires Committee Review, [Assign to Committee Review](#). The submission will be returned to the IRBC and they will assign the submission for review at an upcoming meeting.
- If the submission is scheduled for Committee Review, the IRBC will perform the necessary Post-Review activities following the convened meeting.

Submit RNI Designated Review

From the RNI workspace, click **Submit RNI Designated Review**. In the corresponding Submit RNI Designated Review window, respond to all required fields. **Note:** Based on the determination(s) selected, the RNI will move forward in the review process as follows:

- If the event/information is *potentially* serious, the RNI will automatically be assigned to Committee Review and move back into the IRBC's inbox. This applies to any of the following determinations:
 - Unanticipated problem involving risks to subjects or others;
 - Suspension or termination of IRB approval;
 - Serious non-compliance;
 - Continuing non-compliance.
- If the event/information is not serious, the RNI will automatically move to complete and the submission state changes to Acknowledged. The individual who created the RNI, PI/PI Proxies on related submissions, and RNI Editors will receive an email notification to confirm acknowledgement. This applies to any of the following determinations:
 - Non-compliance that is neither serious nor continuing;
 - Allegations of non-compliance with no basis in fact;
 - None of the above.

Next Steps

The information entered will appear on the Reviews tab and the RNI will move forward in the review process, as described above.

Additional Activities

Assign to Committee Review

If a submission in non-committee review requires committee review:

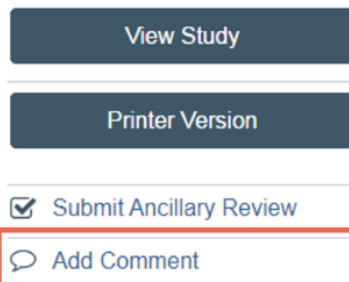
1. Click **Assign to Committee Review**.
2. Indicate the reason the submission requires committee review in the comments field.
3. Click **OK**. The submission will move back into the IRBC's inbox for meeting assignment. If necessary, provide additional comments and/or directions to the IRBC via [Private Comment](#).

Add a 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**.

Next Steps



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.

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, Committee Members, and Global Viewers who are not on the study team.**

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

Next Steps

Review Study

Printer Version

 Request Clarification by
Committee Member

Add Review Comments

 Add Comment

 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.