IRB Guide for Reviewers

UAB

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Quick Links

Navigation and Basic Tasks

Process	Description
Find Key Items	Find key items on your dashboard
Identify Action Needed	Identify the action needed to be performed on a submission
Open a Submission	How to open a submission
Find Previous Submissions	How to locate previously submitted submissions
Meetings and Committees	How to locate upcoming, past, and committee meetings
Reports	Where to locate standard, advanced, and custom reports and where to generate the AAHRPP report
Filter Data	How to use filters to show specific data
Study Workspace	Overview of the submission workspace
Resource Tabs	Overview of the resource tabs on the submission workspace
Submission States	Overview of the different states that a submission may go through
IRB Overview	Overview of the different submission types and user roles

HRPP Toolkit

Process	Description
Navigating the HRPP Toolkit	Instructions on how to access documents in the HRPP Toolkit
Choosing the Correct Document	Lists all the available types of documents in the HRPP Toolkit with a short description to help you decide which document you should select

Reviewer Tasks

Process	Description
Locate Meeting Agendas	How to locate an agenda for a meeting
Locate Reviewer Checklists and Worksheets	How to locate the worksheets and checklists uploaded by an IRB Coordinator for a study. Checklists must be completed and attached when submitting review documents
Open the Submission (Committee Reviewer)	How to open and view a submission that you have been assigned as a committee reviewer for

Open the Submission (Designated Reviewer)	How to open and view a submission that you have been assigned as a designated reviewer for
Review a Submission	How to review a submission and the attached documents
Request Clarification	How to request clarification if you have questions for the study team or require they make a change to the submission
Prepare Review Comments for a Committee Meeting	If a committee is planning to review a study, site, or follow-on submission you can record your review comments for committee members to view before and during the meeting
Submit a Designated Review	How to submit a designated review
Submit an Ancillary Review	How to submit an ancillary review
Search Your Solution	You can use the search tool to locate a wide range of information such as: project data, documents, or content from specific pages on your site

Staff Tasks

Process	Description
Common Rule Requirements	Overview of Pre-2018 and 2018 Common Rule requirements and when a study would fall under each category
Submission Review Process Overview	Overview of the basic process for an initial submission
Submit a Pre-Review	As a reviewer, you may be required to attach and complete any associated checklists for the pre-review
Assign a Pre-Review for Further Review	After the study has been submitted for pre-review, it can be assigned for further review, either to a designated reviewer or a meeting of the full IRB Committee
Assign the Study to a Committee Meeting	How to assign a study to a committee meeting
Review Modifications Required	How to review the required modifications made by the PI
Ancillary Review Process	Overview of the ancillary review process. Ancillary reviews allow individuals, departments, and other organization to give feedback on the submission in parallel with the IRB review.
Continuing Review (CR) and Modification Process	Overview of the continuing review and modification process. Continuing reviews are submitted to close a study or extend the approval period.

External IRB Process for a Single-Site Study	Overview of the external IRB process for a single-site study.
Confirm Reliance with an External IRB	How the IRB Coordinator will confirm reliance with the External IRB
Record the sIRB Decision	How to IRB Coordinator will record the determination from the external IRB
Post Review of a Single-Site External Study	Details how the IRB Coordinator will finalize documents and prepare and send the determination letter
Study Modifications and CR States and Transitions	Overview of the key transitions in the IRB review process for study modifications and continuing reviews

Reportable New Information

Process	Description
Reportable New Information Process	Overview of the reportable new information (RNI) process. The RNI workflow uses similar states to a study, but the IRB review process routes the submission differently depending on the significance of the determinations selected.
Reportable New Information States and Transitions	Table containing information on key transitions in the RNI Review process that cause an RNI to move from one state to another.
Create Reportable New Information (RNI)	How to report any adverse events or new information about a study
Submit an RNI	How to submit an RNI after it has been created
Discard an RNI	How to delete an RNI you created
RNI Pre-Review	How to conduct a pre-review of an RNI, typically this is done by the IRB Coordinator
RNI Designated Review	How to perform a designated review of an RNI, this will occur after the pre-review
Submit RNI Committee Review	How to submit the committee review after the committee has met and made a determination, this is typically done by the IRB Coordinator
RNI Post Review	How to complete post review activities for RNI
Review RNI Action Required	How to review action required, this is done by the responsible party

Meeting Management

Process	Description
Create a Meeting	How to create a new meeting

Find/Open a Meeting	How to locate and open up a meeting
Assign Submission to a Meeting	How to assign a submission to a meeting
Assign Reviewers to a Meeting	How to assign reviewers to a meeting
Add Documents to a Meeting	How to add any supporting documents to a meeting
Add Other Items to the Meeting Agenda	How to add items such as text-based items, and links to related projects to the agenda
Prepare and Send the Agenda	How to prepare and send the meeting agenda
Remove an Agenda Item	How to remove a submission or other item from the agenda
Prepare Meeting Minutes	How to prepare the meeting minutes, this is typically done by the committee administrator
Start the Meeting	How to convene the meeting, this is typically done by the committee administrator
Approve the Previous Meeting Minutes	How to approve previous meetings with minutes for approval, this is typically done by the committee administrator
Display Submission Details	How to display submission information and reviewer comments during the meeting, this is typically done by the committee administrator
Submit a Committee Review	How to record the committee decision and submit it
Update Other Agenda Items from a Committee Meeting	How to record decisions about non-submission agenda items, which will appear in the generated meeting minutes
Prepare Meeting Minutes to Wrap Up the Meeting	How to prepare the meeting minutes at the end of the committee meeting, this is typically done by committee administrators
Close a Meeting	How to complete the meeting
Approve Meeting Minutes	How to approve the meeting minutes after all approvals for meeting minutes have been collected
Meeting Management Checklists	Checklists of tasks to complete in advance of the meeting, just before the meeting, when conducting committee meetings, and wrapping up committee meetings

Multi-Site Studies

Process	Description
Multi-Site Study Process Overview	Overview of information on multi-site study, site modification, reportable new information, continuing review and multi-site external studies
Site Modification Process	Overview of the process of making a modification to a site
Reportable New Information for a Multi-Site Study Process	Overview of the RNI process associated with a multi-site study. This differs depending on whether the RNI originates from the sIRB or the pSite system, and on where the RNI is routed for review. An RNI originating from the sIRB system follows a review process like that of single-site study RNIs.
Continuing Review Process	Overview of the Continuing Review (CR) for a multi-site study. A continuing review (CR) for a multi-site study requires data from the sIRB institution and from all pSites associated with the study.
External IRB Process for a Multi-Site Study	Overview of the workflow for a multi-site study and a single-site study where the local IRB cedes authority to an external IRB
sIRB System Site States and Transitions	Explanation of the possible states for a site submission in the sIRB system
pSite System Sites States and Transitions	Explanation of the possible states for a site submission in the pSite system
Create an Institutional Profile	How to create an institutional profile as a single IRB of record coordinator. Institutional profiles contain a record of information about institutions with whom your institution collaborates on multi-site research.
Correspond with a Site	How to correspond with researchers at a site
Submit an Invitation Decision to a pSite	How to submit an invitation decision to a pSite
Mark Site Materials as Received	Once you receive site materials from a pSite, you can mark them as received
Confirm Reliance on the External IRB	How to confirm reliance on the external IRB, for a multi-site external study, you must confirm reliance on the external IRB before the submission can move forward in the review process
Record the sIRB Decision for an External Study	How to record the sIRB decision for an external study, this is done by the IRB Staff
Accept Site Updates for a Multi-Site External Study	How to accept site updates; for a multi-site study you must accept the site updates before the submission will move forward in the review process

Update Study Details for a Multi-Site External Study	How to update study details for a multi-site external study. For a multi-site external IRB study, the local IRB is notified when the PI updates study details.
Confirm Reliance with the sIRB	How to confirm reliance with the sIRB, if an sIRB determines that you meet the criteria to participate in a multi-site study, they will invite you to join the study
Correspond with the sIRB	How to correspond with sIRB researchers and coordinators
Record the sIRB Decision	How to record the sIRB decision, edit the decision, and submit a response to the sIRB
Approve a Site Modification	How to approve site modifications submitted by investigators, modifications that concern other parts of the site require sIRB review in addition to local approval
Close a Site	How to close a site, if the site is in the Review Complete state, IRB coordinators and directors can close the site at any time

Advanced Reports

Process	Description
About Advanced Reports	Overview of the three different advanced reports: IRB Turnaround Times, Submission Volume, and Days in State
Open an Advanced Report	How to open an advanced report
Generate an Advanced Report	How to generate an advanced report
Filter Data on a Report	How to filter data on a report, at the top of the report are filtering options so you can view a subset of data on the report
Export a Report	How to export a report and save to your computer
Print a Report	How to print a report
Days in State Report	In-depth overview of the Days in State Report
IRB Turnaround Times Report	In-depth overview of the IRB Turnaround Times Report
Submission Volume Report	In-depth overview of the Submission Volume Report

Introduction

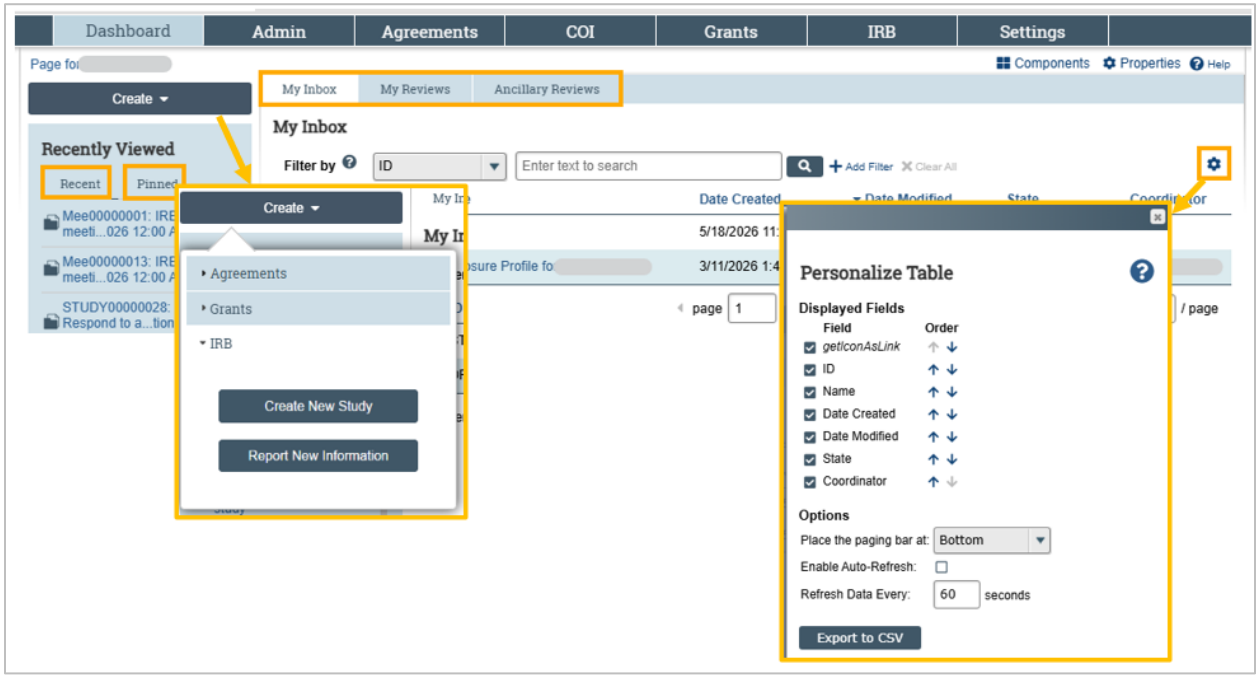
This guide shows Campus Staff and HRPP how to perform tasks and functions in the Institutional Review Board (IRB) module of MyUABResearch.

Important features covered in this guide include:

- Navigation and Basic Tasks
- HRPP Library
- Review Activities
- Reportable New Information
- Meeting Management
- Multi-Site Studies
- Reports

Navigation and Basic Tasks

When you first log in, you will be on your Dashboard, which is the starting point for finding items and performing many basic tasks.



To find key items

From your Dashboard, you can view:

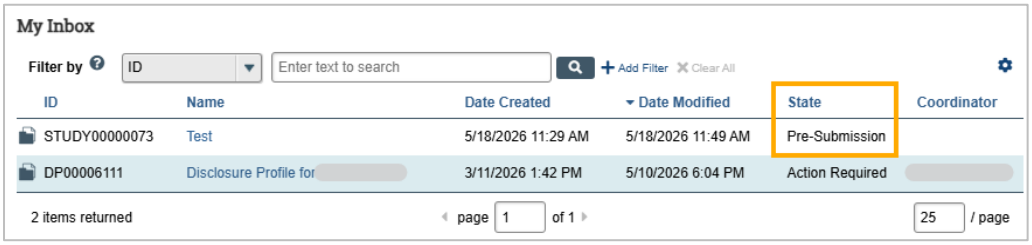
- **My Inbox:** Items that require you to take action.
- **My Reviews:** Items assigned to you to review if you are a reviewer. These are a subset of the items in My Inbox.
- **Recently Viewed:**
    - **Recent**: The last several items you viewed. Scroll through this list to find an item you worked on recently.

- **Pinned:** You can pin the items in the Recently Viewed section for quick and easy access. This is where those pinned items are listed.

- **Personalize Table:** You can alter the tables displayed on the dashboard by using the Personalize Table gear icon.

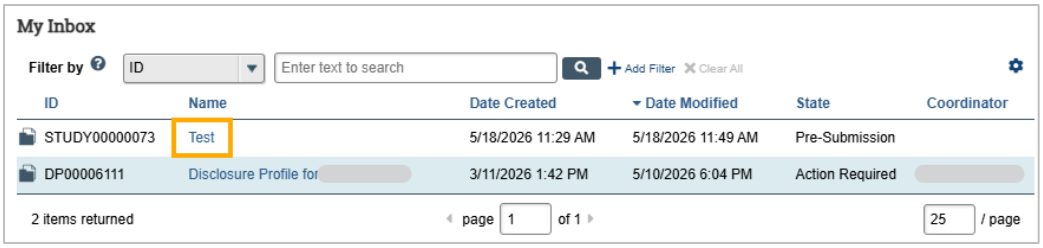
To identify what action is needed

- Review the state of the project in My Inbox. The state gives a clue as to what to do next. For example, Committee Review means a study is scheduled or in-review by an IRB committee.



To open a submission

1. From My Inbox, or from the Submissions page, click the submission name.
2. The submission workspace opens.

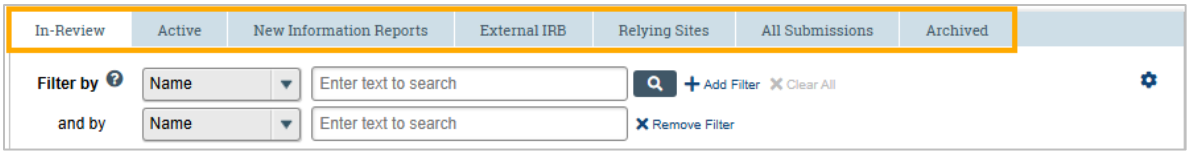


To find previous submissions

1. In the Top Navigator, click **IRB** and then **Submissions.**



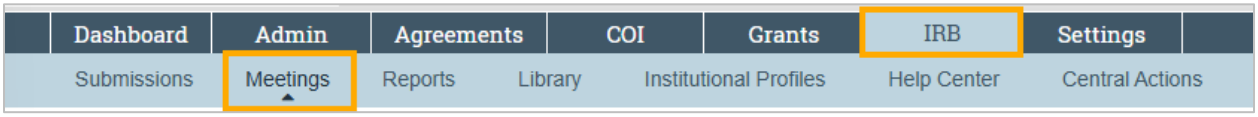
2. Click the tab to see submissions you can access:
   - **In-Review**: Submissions undergoing IRB review.
   - **Active**: All approved submissions as well external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
   - **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
   - **External IRB**: All studies managed by an external IRB.
   - **Relying Sites**: All participating sites relying on the local IRB as the single IRB of record.
   - **All Submissions**: All submissions, in any state.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.



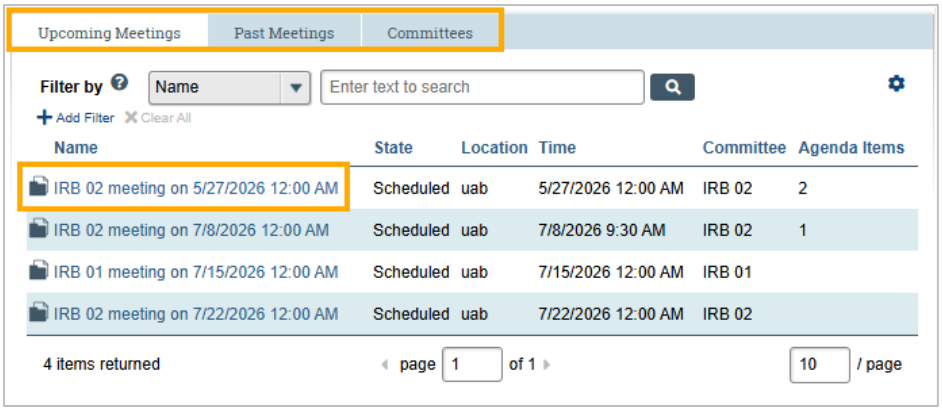
Meetings and Committees

You can use the meetings tab to find upcoming or past meetings, view committees, create new meetings, and create new committees.

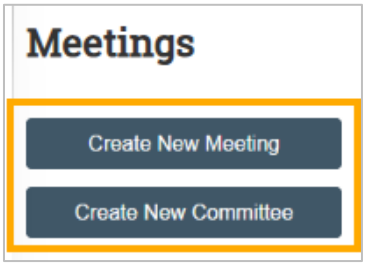
1. In the top navigator, click **IRB** then **Meetings**.



2. Click on the tabs to view upcoming meetings, past meetings, and committees. Click on the name of a meeting or committee to open the workspace.



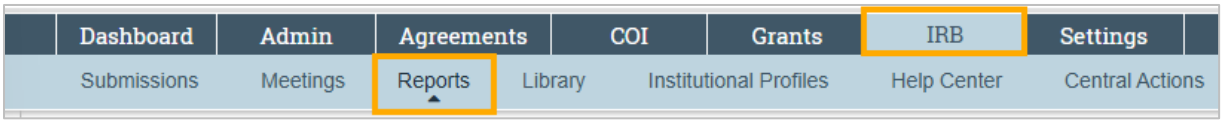
3. To create a new meeting or committee, use the **Create New Meeting** and **Create New Committee** buttons on the left.



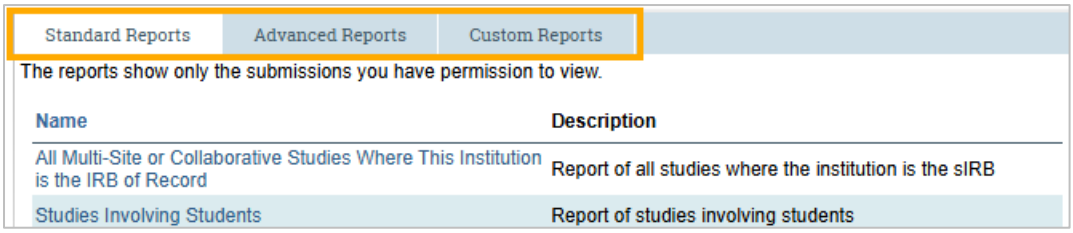
Reports

Use the reports tab to run reports and generate the AAHRPP Report.

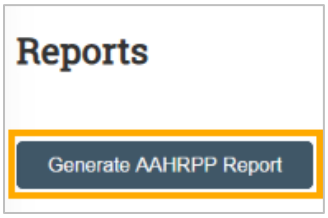
1. In the top navigator click IRB, then Reports.



2. Use the tabs to view the available Standard, Advanced, and Custom reports.



3. Click on the Generate AAHRPP Report button on the left side to generate the AAHRPP Report.

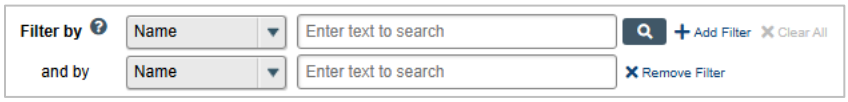


4. For more information on the different types of reports and how to generate them, see the Reports section.

To filter data

Many pages contain tables that you can filter to show specific data.

1. Select the column to filter by.
2. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71
3. Click **Help** for operators you can type in the text box.
4. Click **Go** to apply the filter
5. To combine multiple filter criteria, click **Add Filter**.



Study Workspace

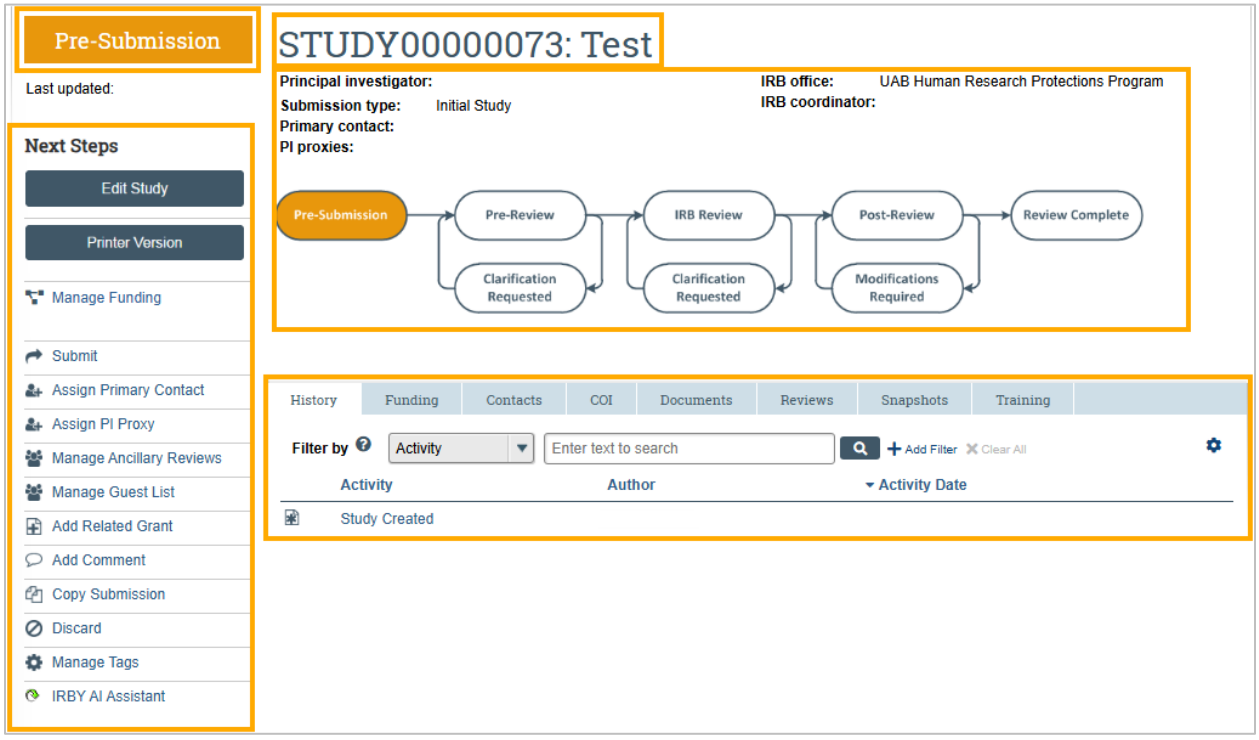
Your Study Workspace allows you to edit your application, submit forms (e.g., modifications, reportable new information), assign ancillary reviewers, and view the history of your submission.

At the top you can see the study name and ID and the current state the submission is in.

The middle section shows all the information about the study including the PI, IRB Coordinator, and where the study is at in the study workflow.

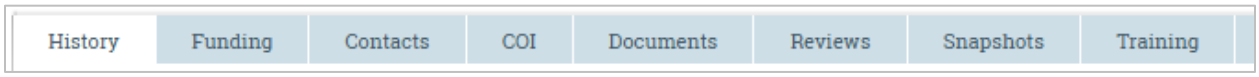
On the left side are all the activities you can take on your study; these will vary depending on your role and what state the study is in.

At the bottom are all the resource tabs for your study, these allow you to view different information about the study. These may vary slightly depending on the state the study is in.



Resource tabs

The resource tabs allow you to view information about the study from the study workspace.



History

The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.

Funding

The funding tab reports on funding sources and related grant information.

Contacts

The contacts tab displays the Principal Investigator, the Study Team, and any Guest Reviewers.

COI

The COI tab shows any conflicts of interest.

Documents

The documents tab gives you access to all submission documents including version history where applicable.

Follow-On Submissions
The follow-on submissions tab only appears on active studies and shows all associated modification, continuing reviews, and reportable new information.

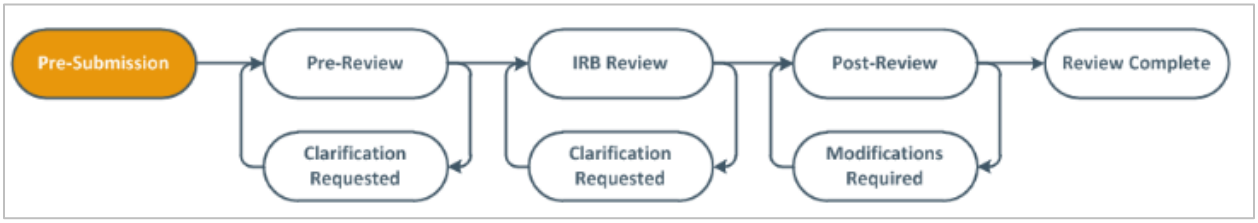
Reviews
The reviews tab is role dependent; researchers will only see ancillary reviews. IRB staff and committee members however will see the full picture, including the most recent Pre-Review, committee reviews, ancillary reviews, and committee member comments.

Snapshots
The snapshots tab contains HTML documents that capture the review process at a single point in time. Snapshots are generated automatically, typically when the PI submits a study, a clarification, or a response to required modifications, or when the IRB sends a determination letter.

Training
The training tab contains any necessary training courses the PI needs to take.

Submission States

The following explains the different states that a study may go through throughout the study lifecycle.



Pre-Submission	The study has not been submitted to HRPP/IRB for review. The study still sits with the PI /research team.
Pre-Review	The submission is with the HRPP/IRB office for review.
Clarification Requested	Clarification is requested, and the submission is open to the study team for response.
IRB Review	The study has been assigned for review by the IRB.
Modifications Required	Modifications are requested by the reviewer(s) prior to final determination.
Post-Review	The study has been reviewed and the determination letter will be generated shortly.
Review Complete	The review of the submission is complete and the study is now active / approved.

Overview of IRB

The IRB system provides a mechanism for creating and tracking studies that require IRB overview. IRB supports the following submission types:

Submission Type	Description
Initial Submissions	
Study	Documents the details of a study that require oversight by an Institutional Review Board. Studies include external studies, single-site studies, and multi-site or collaborative studies.
Site	Documents the study details specific to a particular institution, such as local team members and institution-specific consent forms.
Follow-on Submissions	
Modification	Changes or updates to approved studies. The modification submission consists of a form that lists modification details along with the updated study pages.
Continuing Review (CR)	A review of an approved study. The continuing review submission consists of a form on which the researcher records any changes, accidents or other problems that have occurred since the study was approved, or since the previous continuing review.
Reportable New Information (RNI)	A report of new information about an approved study or active research.

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. For example, Study Staff is a system-wide role, whereas PI is a role in relation to a study; a user with the Study Staff role must be explicitly assigned the role of PI.

User Role	Typical Activities
Registered User	Users authorized to create submissions.
PI	The Principal Investigator (PI) listed on the submission. While others assist the PI in developing and editing the submission, only the PI (or designated PI proxies) can submit the study or follow-on submissions to start the review process.
Study Staff	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 a PI proxy, other coinvestigators, science contributors, and administrative staff.

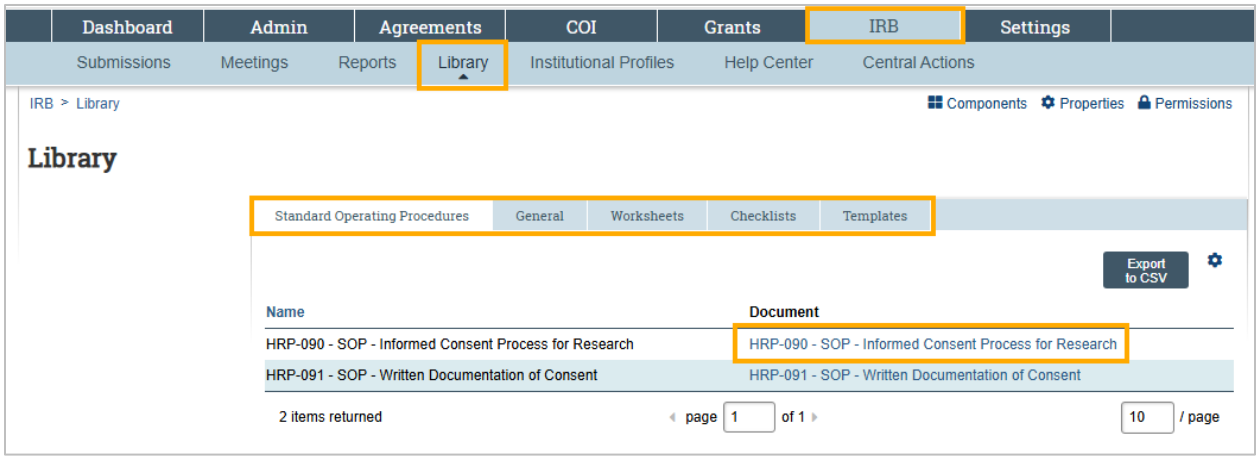
IRB Coordinator	Individuals who guide submissions through the review process. The coordinator reviews a newly submitted study for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner.
IRB Director	An individual with IRB oversight responsibilities. Can perform the same actions as coordinators, but is typically less involved with the day-to-day processing of submissions.
Committee Member	Individuals on an IRB committee who are responsible for reviewing submissions.
Committee Chair	An IRB committee member assigned to chair the committee.
Committee Administrator	An individual responsible for managing committee meetings. See the Meeting Management Guide for tasks this person performs.
Site Manager	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.

HRPP Toolkit

The HRPP Toolkit is a centralized library of documents and resources to help ensure that research is conducted ethically and in compliance with regulations.

Navigating the HRPP Toolkit

1. In the top navigator, click **IRB**, then **Library**.
2. Navigate to the document you wish to open and click on the name to download the document to your computer. You will see the following tabs:
    a. **Standard Operating Procedures**: Step by step rules for IRB processes
    b. **General**: General documents to guide you through IRB processes
    c. **Worksheets**: Used by IRB reviewers to evaluate regulatory criteria
    d. **Checklists**: Used to ensure required regulatory determinations are made and documented
    e. **Templates**: Use these templates when creating protocol and consent documents.



Choosing the correct document

Use the guide below as a reference when deciding which document to select from the Library:

Document Name	Description
Standard Operating Procedures	
HRP-001 – SOP – Definitions	This policy establishes the definitions followed by the human research protection program. This is a non-exhaustive list and regulatory agencies should be referenced for complete definitions where applicable.
HRP-012 – SOP – Observation of Consent Process	This procedure establishes the process to observe the consent process.
HRP-013 – SOP – LARs, Children, and Guardians	This policy establishes how to determine which individuals meet the following DHHS and FDA definitions: Legally Authorized Representative (LAR), Children, Guardian
HRP-020 – SOP – Incoming Items	This procedure establishes the process to triage information submitted to the IRB.
HRP-021 – SOP – Pre-Review	This procedure establishes the process to pre-review a request for approval (approval of new research, approval to rely on an external IRB, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research
HRP-023 - SOP - Emerg and Device Comp Use Review	This procedure establishes the process to review notifications of emergency use of a drug, biologic, or device in a life-threatening situation, non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use), non-emergency individual patient expanded

	access use of an investigational drug for which an IRB waiver is requested.
HRP-024 - SOP - New Information	This procedure establishes the process to manage information reported to the IRB.
HRP-025 - SOP - Investigations	This procedure establishes the process to conduct investigations.
HRP-026 - SOP- Susp or Term Issued Outside of Conv IRB	This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.
HRP-027 - SOP - Emerg Use Comp Use Indiv Pt Access Post Rev	This procedure establishes the process to communicate the review of: emergency use of a drug, biologic, or device in a life-threatening situation, non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use), non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.
HRP-030 - SOP - Designated Reviewers	This procedure establishes the process for an IRB chair to designate IRB members who can conduct Non-Committee Reviews.
HRP-031 - SOP - Non-Committee Review Preparation	This procedure establishes the process to prepare for a Non-Committee Review.
HRP-032 - SOP - Non-Committee Review Conduct	This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review or a Limited IRB Review.
HRP-040 - SOP - IRB Meeting Preparation	This procedure establishes the process to prepare for a convened IRB meeting.
HRP-041 - SOP - IRB Meeting Conduct	This procedure establishes the process to conduct convened meetings.
HRP-042 - SOP - IRB Meeting Attendance Monitoring	This procedure establishes the process to monitor quorum at convened IRB meetings.
HRP-043 - SOP - IRB Meeting Minutes	This procedure establishes the process to record minutes for convened meetings.
HRP-044 - SOP - Not Otherwise Approvable Research	This procedure establishes the process for the organization to review research that is not otherwise approvable.
HRP-050 - SOP - Conflicting Interests of IRB Members	This procedure establishes the process to identify and manage Conflicting Interest of IRB members.
HRP-051 - SOP - Consultation	This procedure establishes the process for the IRB to obtain consultants.
HRP-052 - SOP - Post-Review	This procedure establishes the process for communications after a protocol is reviewed.
HRP-054 - SOP - Institutional Conflicts of Interests	This procedure establishes the process to identify institutional financial interests that may cause an institutional conflict of interests.

HRP-055 - SOP - Financial Conflicts of Interests	This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research.
HRP-060 - SOP - Annual Evaluations of the HRPP	This procedure establishes the process to conduct annual evaluations of the human research protection program.
HRP-061 - SOP - Quarterly Evaluations of the HRPP	This procedure establishes the process to conduct quality improvement of the human research protection program.
HRP-062 - SOP - Daily Tasks	This procedure establishes the process to complete daily tasks required to monitor the research review process.
HRP-063 - SOP - Expiration of IRB Approval	This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in expired research.
HRP-064 - SOP - NIH GDS Institutional Certification	This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository.
HRP-065 - SOP - Response Plan for Emergencies-Disasters Impacting the HRPP	This SOP establishes the process for initiating a response to an emergency/disaster situation impacting the HRPP or HRPP operations.
HRP-070 - SOP - IRB Records	This procedure establishes the process to maintain IRB records.
HRP-071 - SOP - Toolkit Management	This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.
HRP-072 - SOP - IRB Records Retention	This procedure establishes the process to retain IRB records.
HRP-080 - SOP - IRB Formation and Registration	This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.
HRP-081 - SOP - IRB Removal	This procedure establishes the process to remove an IRB.
HRP-082 - SOP - IRB Membership Addition	This procedure establishes the process to appoint and re-appoint an IRB member.
HRP-083 - SOP - IRB Membership Removal	This procedure establishes the process to remove an IRB member.
HRP-084 - SOP - IRB Meeting Scheduling and Notification	This procedure establishes the process to schedule and notify individuals of convened meetings.
HRP-090 - SOP - Informed Consent Process for Research	This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable

	to consent, or the parents or guardians of children.
HRP-091 - SOP - Written Documentation of Consent	This procedure establishes the process to document the informed consent process in writing.
Forms	
HRP-202 - FORM - IRB Member Information	The purpose of this checklist is to have IRB members provide information to the IRB staff to ensure the IRB is appropriately composed.
HRP-211 - FORM - Basic Study Information	Use for new proposals.
HRP-212 - FORM - Continuing Review	Use for both continuing review and as a final report to close a protocol. If modifications are being requested, submit a separate request for a modification.
HRP-213 - FORM - Modification	Use to request a modification to previously approved activity.
HRP-214 - FORM – Reportable New Information	Use to report information items.
Worksheets	
HRP-301 - WORKSHEET - Review Materials	The purpose of this worksheet is to provide support for IRB staff who prepare review materials for convened IRB meetings or prepare materials for Non-Committee Review.
HRP-302 - WORKSHEET - Approval Intervals	The purpose of this worksheet is to provide support for IRB staff who prepare review materials for convened IRB meetings or prepare materials for Non-Committee Review.
HRP-303 - WORKSHEET - Communication of Review Results	The purpose of this worksheet is to provide support for staff who send communications after an IRB review.
HRP-304 - WORKSHEET - IRB Composition	The purpose of this worksheet is to provide support for IRB staff reviewing whether the IRB is appropriately composed.
HRP-305 - WORKSHEET - Quorum and Expertise	The purpose of this worksheet is to provide support for staff who monitor attendance at convened IRB meetings.
HRP-306 - WORKSHEET - Drugs and Biologics	The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving drugs or biologics.
HRP-307 - WORKSHEET - Devices	The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving devices.
HRP-308 - WORKSHEET - Pre-Review	The purpose of this worksheet is to provide support for IRB staff conducing screening submission materials.
HRP-309 - WORKSHEET - Ancillary Review Matrix	Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB's review

	of a new study or a modification to an existing study.
HRP-310 - WORKSHEET - Human Research Determination	The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated.
HRP-311 - WORKSHEET - Engagement Determination	The purpose of this worksheet is to provide support for Designated Reviewers making engagement determinations when there is uncertainty regarding whether the organization is engaged in Human Research.
HRP-312 - WORKSHEET - Exemption Determination	The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations.
HRP-313 - WORKSHEET - Expedited Review	The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure.
HRP-314 - WORKSHEET - Criteria for Approval	The purpose of this worksheet is to provide support for IRB members reviewing research.
HRP-314a - WORKSHEET - Criteria for Consent	The purpose of this worksheet is to provide support for IRB members reviewing research consent process(es) and documentation.
HRP-315 - WORKSHEET - Advertisements	The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating advertisement meant to be seen or heard by subjects.
HRP-316 - WORKSHEET - Payments	The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating payments to subjects or their Legally Authorized Representatives.
HRP-317 - WORKSHEET - Short Form of Consent Documentation	The purpose of this worksheet is to provide support for IRB members or Designated Reviewers using HRP-314 - WORKSHEET - Criteria for Approval when reviewing research involving the short form of consent documentation.
HRP-318 - WORKSHEET - Additional Federal Agency Criteria	The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies.
HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent	The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews and/or reviewing broad consent.
HRP-320 - WORKSHEET - Scientific or Scholarly Review	The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research. Use this worksheet to determine whether the research has scientific or scholarly validity.
HRP-321 - WORKSHEET - Review of Information Items	The purpose of this worksheet is to provide support for the convened IRB reviewing Serious

	Non-Compliance, Continuing Non-Compliance, Unanticipated Problem Involving Risks to Subjects or Others, Suspension of IRB Approval, and Termination of IRB Approval.
HRP-322 - WORKSHEET - Emergency Use	The purpose of this worksheet is to provide support for investigators conducting an emergency use of unapproved drug, biologic, or device in a life-threatening situation, and to provide support Designated Reviewers reviewing such uses.
HRP-323 - WORKSHEET - Criteria for Approval HUD	The purpose of this worksheet is to provide support for the convened IRB when evaluating an initial application to use a Humanitarian Use Device (HUD), and for Designated Reviewers when evaluating a continuing review submission.
HRP-324 - WORKSHEET - Contracts	The purpose of this worksheet is to provide support for individuals reviewing contracts and other funding agreements and the budgets associated with those contracts.
HRP-325 - WORKSHEET - Device Compassionate Use	The purpose of this worksheet is to provide support for investigators conducting non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) and to provide support Designated Reviewers reviewing such uses.
HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs	The purpose of this worksheet is to provide support for the Institutional Official/ Organizational Official (IO/OO) or designee when evaluating the performance of the IRB Chair(s) as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP.
HRP-327 - WORKSHEET - Performance Evaluation for IRB Members	The purpose of this worksheet is to provide support for the IRB Chair or IRB Manager when evaluating the performance of the IRB Members and Alternates as part of the annual HRPP evaluation conducted in HRP- 060 - SOP - Annual Evaluations of the HRPP.
HRP-328 - WORKSHEET - Performance Evaluation for IRB Staff	The purpose of this worksheet is to provide support for the IRB Chair or IRB Manager when evaluating the annual performance of the IRB staff as part of the annual HRPP evaluation conducted in HRP-060 – SOP – Annual Evaluations of the HRPP.
HRP-330 - WORKSHEET - HIPAA Authorization	The purpose of this checklist is to provide support for IRB staff when evaluating whether a HIPAA authorization is valid.
HRP-331 - WORKSHEET - FERPA Compliance	The purpose of this worksheet is to provide support for the FERPA officer determining whether personally identifiable information can be released from student education records or

	personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education).
HRP-332 - WORKSHEET - NIH GDS Institutional Certification	The purpose of this worksheet is to allow the IRB Director or designee to evaluate whether an investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository.
HRP-333 - WORKSHEET - Certificate of Confidentiality	The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating whether a Certificate of Confidentiality is required or appropriate for a study.
HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning	The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to modify research during an emergency/disaster situation impacting the investigator's ability ensure the ongoing safety of research subjects.
HRP-352 - WORKSHEET - Additional Emergency-Disaster Review Considerations	The purpose of this worksheet is to provide IRB members with additional considerations that may become relevant when reviewing Human Research during an emergency/disaster situation.
Checklists	
HRP-401 - CHECKLIST - Pre-Review	The purpose of this checklist is to provide support for IRB Staff conducting Pre-review.
HRP-402 - CHECKLIST - Non-Committee Review	The purpose of this checklist is to provide support for Designated Reviewers conducting Non-Committee Review.
HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 – WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process.
HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves the waiver of written documentation of consent.
HRP-412 - CHECKLIST - Pregnant Women	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves pregnant women as subjects.

HRP-413 - CHECKLIST - Non-Viable Neonates	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves non-viable neonates as subjects.
HRP-414 - CHECKLIST - Neonates of Uncertain Viability	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves neonates of uncertain viability as subjects.
HRP-415 - CHECKLIST - Prisoners	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves Prisoners as subjects.
HRP-416 - CHECKLIST - Children	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves children as subjects.
HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when both of the following are true: 1. The research involves adults with impaired decision-making capacity as subjects, AND 2. The research involves a consent process or other intervention or interaction with the impaired decision making capacity subject(s).
HRP-418 - CHECKLIST - Non-Significant Risk Device	The purpose of this checklist is to provide support for IRB members following HRP-314 - WORKSHEET - Criteria for Approval when research involves an abbreviated IDE.
HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research	The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver of consent for planned emergency research.
HRP-430 - CHECKLIST - Investigator Quality Improvement	The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment and for IRB staff to conduct a quality improvement assessment of investigators.
HRP-431 - CHECKLIST - Minutes Quality Improvement	The purpose of this checklist is to allow individuals to conduct a quality improvement self-assessment of IRB minutes.
HRP-441 - CHECKLIST - HIPAA Waiver of Authorization	The purpose of this checklist is to provide support for the Privacy Board Member designated to conduct

	Privacy Board Reviews to document a waiver or alteration of HIPAA authorization using the expedited procedure or at committee review.
Templates	
HRP-500 - TEMPLATE BROAD CONSENT DOCUMENT	Template for broad consent.
HRP-501 - TEMPLATE MINUTES	Template for IRB meeting minutes.
HRP-502 - TEMPLATE CONSENT DOCUMENT	Standard consent template.
HRP-503 - TEMPLATE PROTOCOL	Study protocol template.
HRP-503a - TEMPLATE SBS PROTOCOL	Alternative protocol formats.
HRP-503b - TEMPLATE NHSR PROTOCOL	Alternative protocol formats.
HRP-504 - TEMPLATE LETTER - School Permission to Conduct Research	Form to obtain permission from schools at which your research is conducted
HRP-505 - TEMPLATE SOP	Blank protocol template
HRP-506 - TEMPLATE CONSENT DOCUMENT – Expanded Access	Templates for consent documents
HRP-507 - TEMPLATE CONSENT DOCUMENT - Short Form	Templates for consent documents
HRP-508 - TEMPLATE - SITE SUPPLEMENT	Study protocol template for a site supplement
Template Letter – Post Review	
HRP-510 - LETTER - Approval	Approval template letter
HRP-510a - LETTER - Approval - CR NOT Req	Approval template letter if no continuing review is required
HRP-511 - LETTER - Closure	Letter template for if the IRB acknowledges your request for closure of the protocol effective
HRP-512 - LETTER - Modifications Required to Secure Approval	Letter template informing that the IRB determined that modifications are required to approve the protocol
HRP-513 - LETTER - Not Human Research Determination	Letter template informing that the IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations
HRP-514 - LETTER - Exemption	Letter template informing that the IRB determined that this protocol meets the criteria for exemption from IRB review
HRP-515 - LETTER - Suspension or Termination	Letter template informing that the IRB determined that modifications are required to approve the protocol
HRP-515a - LETTER - Lifting of Suspension	Letter template informing that the convened IRB lifted the suspension
HRP-516 - LETTER - Deferral	Letter template informing that the IRB deferred the protocol

HRP-517 - LETTER - Disapproval	Letter template informing that the IRB disapproved the protocol
HRP-518 - LETTER - Tabled	Letter template informing that the IRB tabled the protocol because it was unable to review the protocol due to reasons unrelated to your application
HRP-519 - LETTER - Information Item	Letter template informing that the IRB determined that this information <is/is not any of the following>: • An unanticipated problem involving risks to subjects or others • Serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB • A suspension or termination of IRB approval
HRP-520 - LETTER - External Report NOT Including OHRP	Letter template to send when certain federal agencies listed in the template require reporting
HRP-520a - LETTER - External Report OHRP and Other Agencies	Letter template to send when certain federal agencies listed in the template require reporting
HRP-521 - LETTER - Significant Risk Device	Letter template informing that the following protocol is a <*significant/non-significant*> risk device study
HRP-522 - LETTER - Certification of Prisoner Research	Letter template to send if the organization is requesting certification research involving prisoners as subjects
HRP-523 - LETTER - Not Otherwise Approvable Research	Letter template to send if the organization s requesting DHHS review of research that has been determined by our IRB to not meet the requirements of 45 CFR §46.404, §46.405, or §46.406, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
HRP-525 - LETTER - OHRP Notification of Emergency Waiver	Letter template to Send when the research is subject to OHRP oversight
HRP-527 - LETTER - Not Engaged	Letter template informing that the IRB determined that the proposed activity is research involving human subjects as defined by <DHHS/FDA/both DHHS and FDA> regulations but that this organization is not engaged in the research.
HRP-529 - LETTER - AAHRPP Notice of Information Item	Letter template informing the AAHRPP that the IRB was notified of certain information
Template Letters - Reminders	
HRP-530 - LETTER - Continuing Review Reminder	Continuing review reminder letter template
HRP-531 - LETTER - Training Reminder	Letter template reminding that your required HRPP training will expire on a certain date

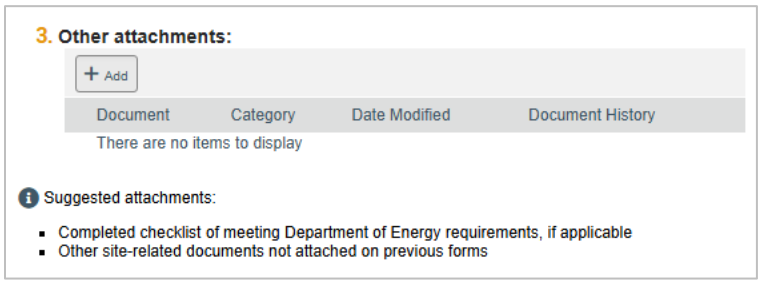
HRP-532 - LETTER - Continuation of Subjects in Expired Research	When the protocol has expired but certain subjects or class of subjects may continue
HRP-533 - LETTER - Expiration of IRB Approval	IRB approval of the following protocol has expired and all research activities must stop
HRP-534 - LETTER - Investigator Quality Improvement Assessment	Quality improvement assessment letter
HRP-535 - LETTER - Annual Reminder	Annual reminder that you are required to continue to meet all institutional requirements for conducting research with human subjects as outlined in the HRP-103 - INVESTIGATOR MANUAL
Template Letter – IRB Review	
HRP-540 - LETTER - Designated Reviewer Materials	Materials needed for designated review
HRP-541 - LETTER - IRB Member Review Materials	Materials needed for IRB review meeting
HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan	Use this template to inform the human research community of the need to consider protocol-specific risk mitigation plans in response to an emergency/disaster impacting HRPP operations or the ability of investigators to conduct human research
Template Letters – Failure Notifications	
HRP-550 - LETTER - Failure to Submit Continuing Review	When the continuing review form has not been received by the IRB office
HRP-551 - LETTER - Failure to Submit Emergency Use Report	When the emergency use of a test article in a life-threatening situation report has not been received by the IRB office
HRP-553 - LETTER - Failure to Submit Emergency Use Protocol	When the emergency use protocol has not been received by the IRB office
HRP-554 - LETTER - Failure to Undergo Training	Your HRPP training has expired and you will not be able to submit new research until your training has been updated
Template Letter – Committee Management	
HRP-560 - LETTER - IRB Member Appointment	You have been appointed to be a member of the IRB
HRP-561 - LETTER - IRB Member Thank You	Letter expressing thanks for being an IRB member
HRP-562 - LETTER - IRB Member Appreciation	Letter expressing appreciation of contributions of IRB member
Template Letter – Emergency Use	
HRP-570 - LETTER - Pre-Review of Emergency Use - Criteria Met	IRB determined that as proposed the use complies with regulatory requirements
HRP-571 - LETTER - Pre-Review of Emergency Use - Criteria Not Met	The IRB reviewed your proposed use of an unapproved [drug/biologic/device]. If you proceed

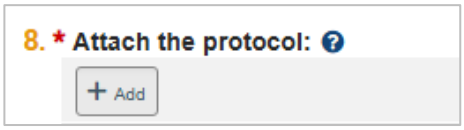
	with this use, you will be non-compliant with federal regulations for the following reasons (list reasons)
HRP-572 - LETTER - Review of Emergency Use - Criteria Met– Emergency Use	The IRB determined that your use of an unapproved [drug/biologic/device] complied with regulatory requirements
HRP-573 - LETTER - Review of Emergency Use - Criteria Not Met	The IRB determined that your proposed use of an unapproved [drug/biologic/device] was non-compliant with federal regulations
HRP-574 - LETTER - Device Compassionate Use	The IRB reviewed your proposed non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) and determined that as proposed the use <does/does not> comply with regulatory requirements and concurrence of the IRB Chair <has been/has not been> obtained.
HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access	The IRB reviewed your request for IRB waiver for non-emergency individual patient expanded access use of an investigational drug and concurs with the proposed treatment use
sIRB Documents	
HRP-801 - SOP - Establishing Authorization Agreements	The purpose of this process is to execute Authorization Agreements with other institutions and agreements with individuals for reliance for non-exempt human research
HRP-802 - SOP - Institutional Profile Management	The purpose of this process is to manage Institutional Profiles.
HRP-804 - SOP - External IRB Post-Review	The purpose of this process is to conduct post-review for submissions where this institution is being asked to rely on an external IRB.
HRP-805 - SOP - External IRB Updates	The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB or when the local investigator makes changes at the site level.
HRP-806 - SOP - Review Request to Cede Review	This procedure establishes the process to ensure the criteria for this Institution to rely on an external IRB for review and oversight of non-exempt human research have been met.
HRP-811 - FORM - Basic Site Information	Use for new participating site proposals
HRP-812 - FORM - Site Continuing Review	Use for both continuing review and as a final report to close a protocol
HRP-813 - FORM - Site Modification	Use to request a modification to previously approved site activities
HRP-814 - FORM - Site Reportable New Information	Use to report information items listed at the end of this form

HRP-815 - FORM - Institutional Profile	The purpose of this form is to record information about the Authorization Agreement established with another institution/organization
HRP-816 - FORM - External IRB Study Update	Use to notify local IRB of study changes approved by the external IRB of record
HRP-830 - WORKSHEET - Communication and Responsibilities	The purpose of this worksheet is to provide support for the Reliance Coordinator or IRB staff to identify roles and responsibilities of the IRB of Record and Participating Sites as a supplement to an Authorization Agreement that does not specify this information
HRP-832 - WORKSHEET - Considerations for Relying on an External IRB	The purpose of this worksheet is to provide considerations that the institution may evaluate when considering requests to outsource review to a commercial IRB or to require a pSite's IRB to serve as sIRB
HRP-833 - WORKSHEET - Considerations for Serving as the sIRB	The purpose of this worksheet is to provide information on considerations that the institution will evaluate when considering requests for the institution's IRB to serve as single IRB of record for multi-site or collaborative research
HRP-850- LETTER - Decline to Serve	This notification serves to inform you that this institution has declined to serve as the IRB of record for <participating site> for the study above
HRP-851 - LETTER - Invitation Decision	This notification serves to inform you that this institution has agreed to serve as the IRB of record for your site for the study above
HRP-856 - LETTER - Decline Reliance on an External IRB	This notification serves to inform you that this institution has **declined** the request to rely on <Name of External IRB> as the IRB of record for the above listed study
HRP-857 - LETTER - Acknowledge External IRB	This notification serves to acknowledge your request to rely on <Name of External IRB> as the IRB of record for the above listed study and does not constitute an approval to conduct the research
HRP-859 - LETTER - Acknowledge External IRB Update	This notification serves to acknowledge the updates you provided for the above listed study
HRP-870 - LETTER - Site Approval	The IRB approved the protocol
HRP-872 - LETTER - Site Modifications to Secure Approval	The IRB determined that modifications are required to approve the site submission
HRP-876 - LETTER - Site Deferral	The IRB deferred the site submission
HRP-877 - LETTER - Site Disapproval	The IRB disapproved the site submission
HRP-879 - LETTER - Review of Site Information Item	States the items reviewed by the IRB and any additional information needed

Uploading Documents

When creating submissions in the IRB workspace, you will be required to upload a checklist, study protocol, or other document. These documents will be found in the Library and will be uploaded using the Add button. Often, there will be text in the submission form recommending you attach a certain type of document, as seen below:





Reviewer Tasks

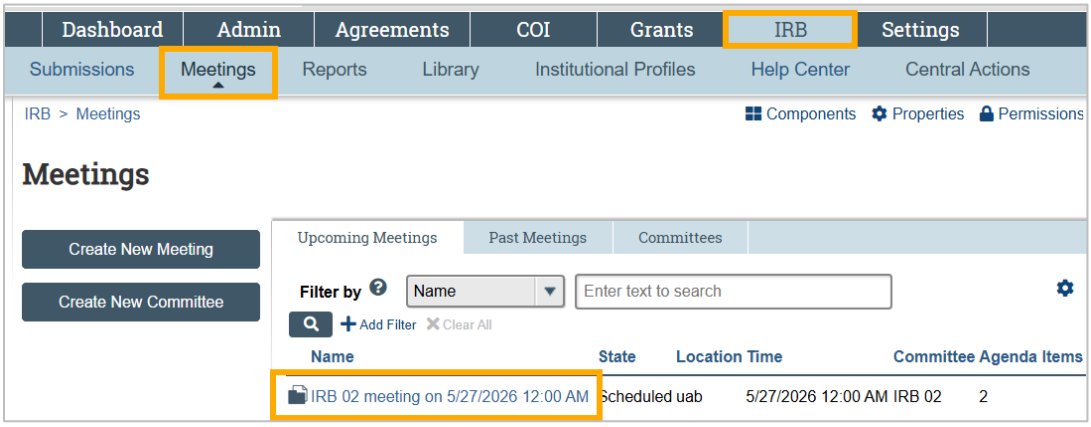
Find Important Documents for Meetings

If you are an IRB committee member or reviewer, you may want to access meeting agendas, worksheets, or checklists

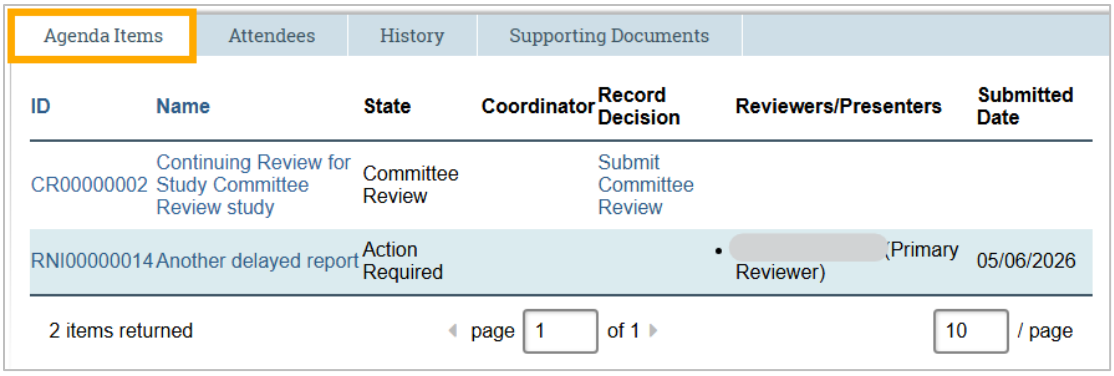
To locate meeting agendas

As a committee member, you can access a meeting agenda from the agenda notification email or by navigating to it in the IRB system.

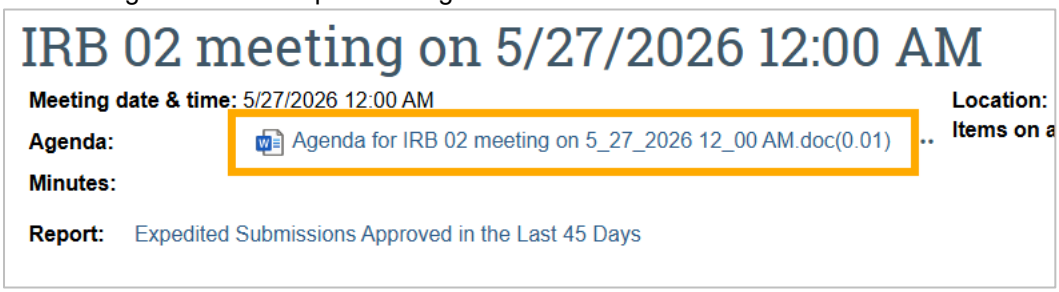
1. In the Top Navigator, click **IRB** and then **Meetings**.



2. From the list of meetings, click the name of the meeting. The meeting workspace displays the list of agenda items.



3. Click the agenda link for a printable agenda document.



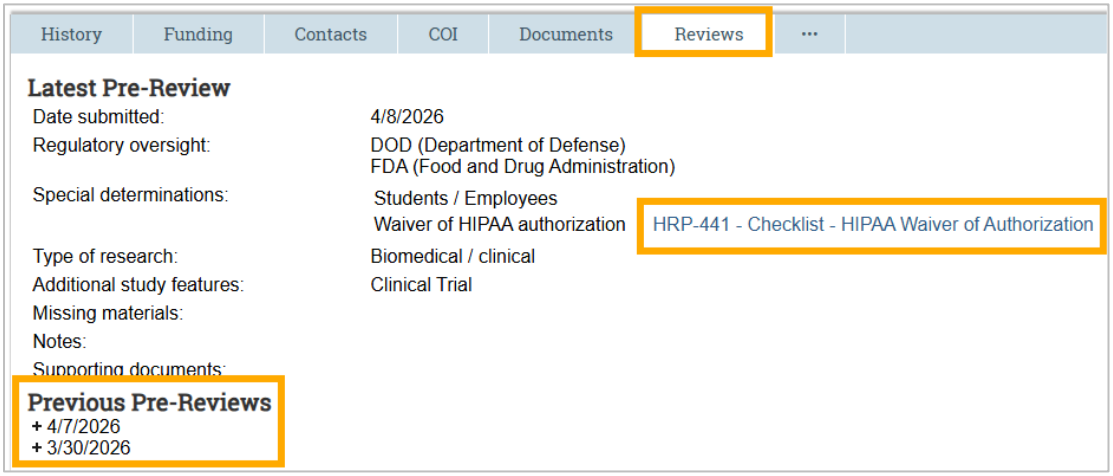
To locate reviewer checklists and worksheets

Several worksheets and checklists are provided in the system.

Note: Worksheets are for the reviewer's benefit only, but checklists must be completed and attached when submitting review comments.

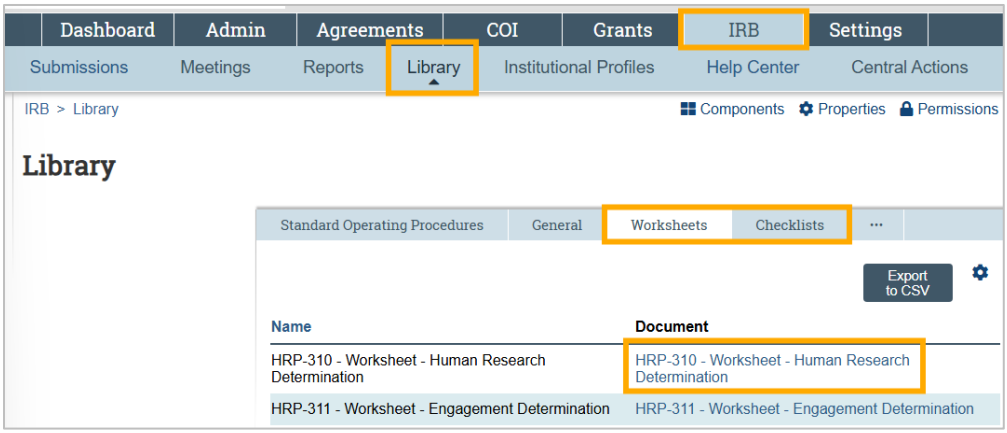
Checklists uploaded by an IRB coordinator will be most relevant to your review. To find them:

1. In the study workspace, click the **Reviews** tab.
2. Under Latest Pre-Review, click the link to download checklists relevant to your review.
3. Click to see previous reviews.



You can also find a list of all worksheets and checklists in the IRB Library. For more information on this, see the HRPP Toolkit section.

1. In the top navigator, click **IRB** and then **Library**.
2. Click the **Worksheets** or **Checklists** tab, depending on the document you want to view.
3. Click a link to open or save the applicable document, which is in Microsoft Word format.



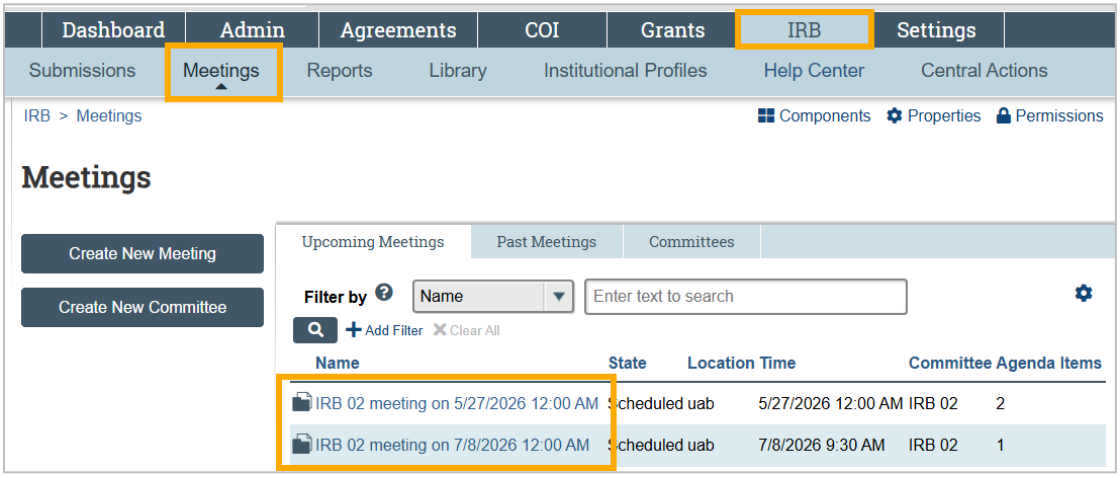
Open the Submission

You will receive an email when a study, site, or follow-on submission has been assigned to you to review and the submission will appear in your IRB inbox. As part of your review, you will want to access the necessary review checklists and worksheets, and the submission pages. Review comments and related files are not visible to study team members.

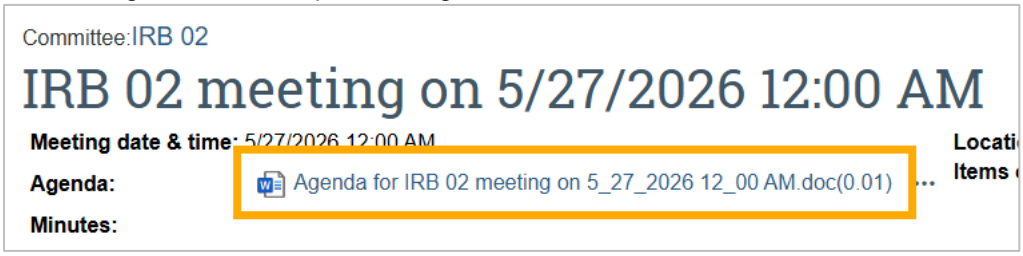
To open the submission (as a committee reviewer)

As a committee member, you can access a meeting agenda from the agenda notification email or by navigating to it in the IRB system.

1. Click the meeting link in your email to open it. Alternatively, in the Top Navigator, click **IRB** and then **Meetings** to see a list of upcoming meetings.



2. In the meeting workspace, you will see a list of all the protocols that are on the meeting agenda.
3. Click the agenda link for a printable agenda document.



To open the submission (as a designated reviewer)

1. Click the submission ID link in your email to open it. If you no longer have the email, see Open a Submission and then View History.
2. On the **History** tab, read any Assigned to Designated Reviewer comments.

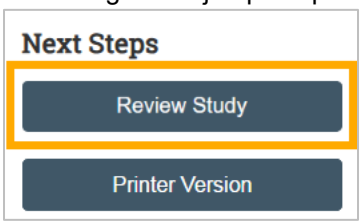
Review a Submission

You will receive an email when a study, site, or follow-on submission has been assigned to you to review and the submission will appear in your IRB inbox. As part of your review, you will want to access the necessary review checklists and worksheets, and the submission pages. Review comments and related files are not visible to study team members.

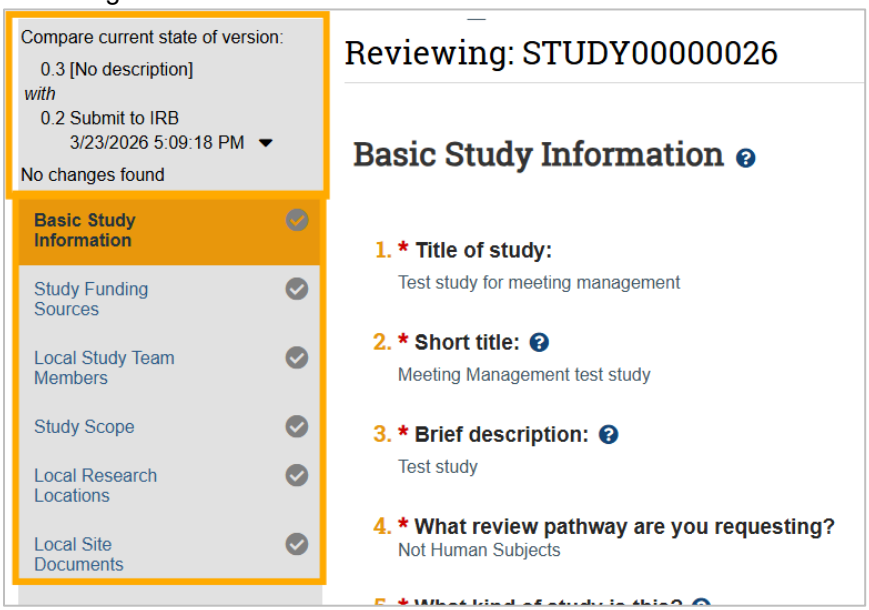
To review the submission pages

Review the submission and attached documents using the following tools:

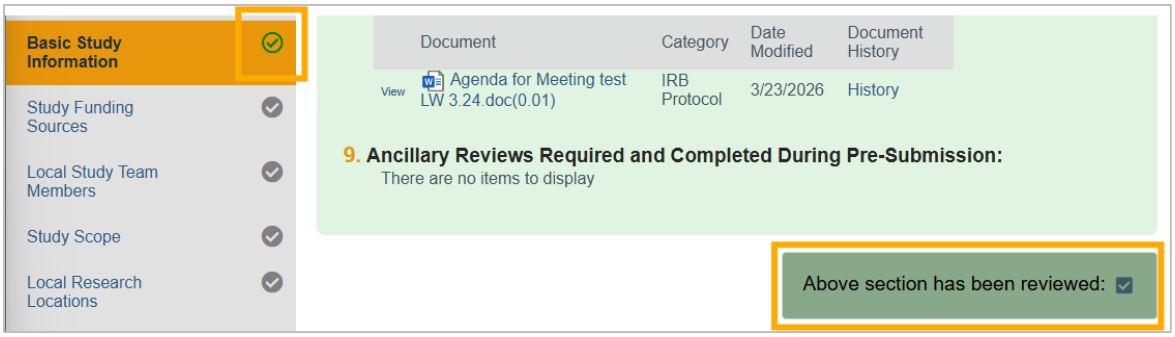
1. Click **Review Study** and review each section. You can scroll through the submission or use the Left Navigator to jump to specific sections of the form.



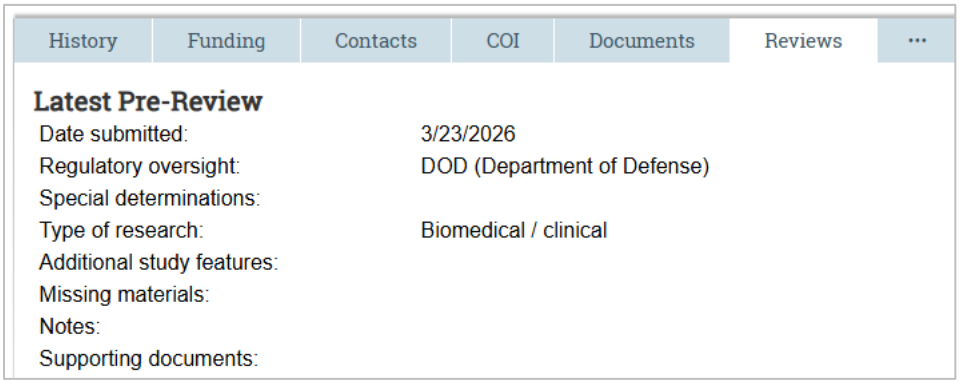
2. To see what changed between this and a previous version, look in the Compare section of the Left Navigator.



3. After reviewing each section, select the check-box at the bottom to indicate you have reviewed it.
4. The section turns green, and a green check mark appears in the Left Navigator.



5. If the submission is edited later, the green check mark is removed and a pencil icon is added, indicating to review that section again.
    a. **Note**: This Review Tracker feature does not stop a submission from moving forward in the review process.
6. Click the Reviews tab to access reviews completed by other committee members or reviewers.



Request Clarification

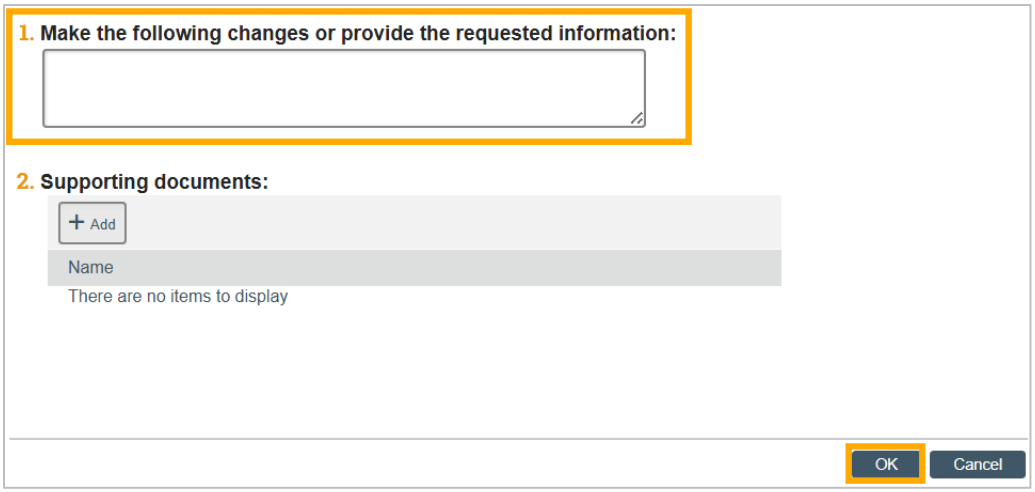
If you have questions for the study team or require they make a change to the submission, use the request clarification feature to communicate back and forth with the team. When all questions have been answered or changes made, you can submit your review.

To request clarification

1. From the submission workspace, click **Request Clarification by…**



2. Type your clarification request.
3. Click **OK**. The PI will receive an email about your request.

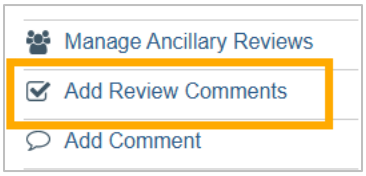


Prepare Review Comments for a Committee Meeting

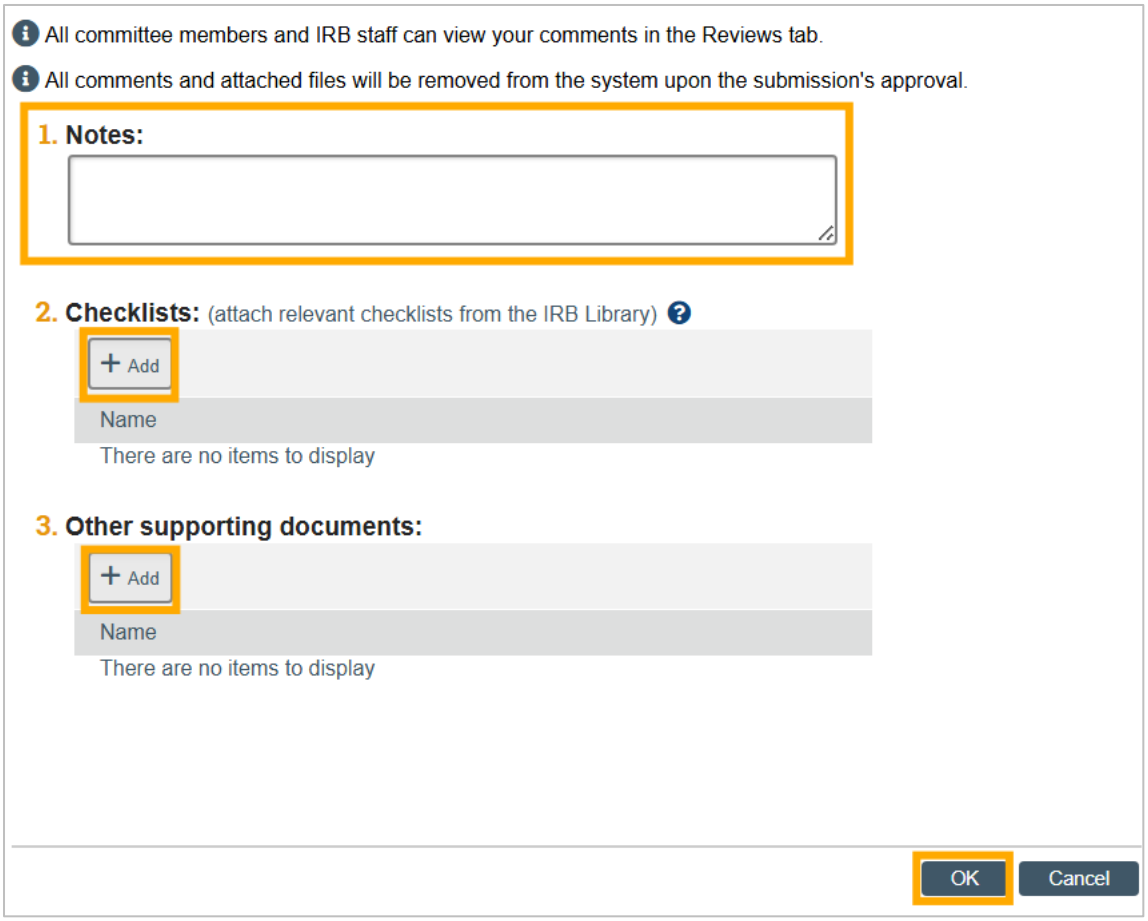
If the committee plans to review a study, site, or follow-on submission, then you may want to record your review comments in the IRB system for other committee members to view before and during the meeting. Review comments and related files are not visible to study team members and are purged from the system when the approval letter is sent.

To add review comments

1. From the submission workspace, click **Add Review Comments**.



2. Type your notes for other committee members.
3. Add any checklists or documents you want to share with other committee members. **Note**: You can access the appropriate checklist to upload by clicking the **Library** link and downloading the document from the **Checklists** tab. For more information on finding checklists, see the HRPP Toolkit tab.
4. Click **OK**. The review comments and attachments will appear on the Reviews tab of the submission workspace.



Submit a Designated Review

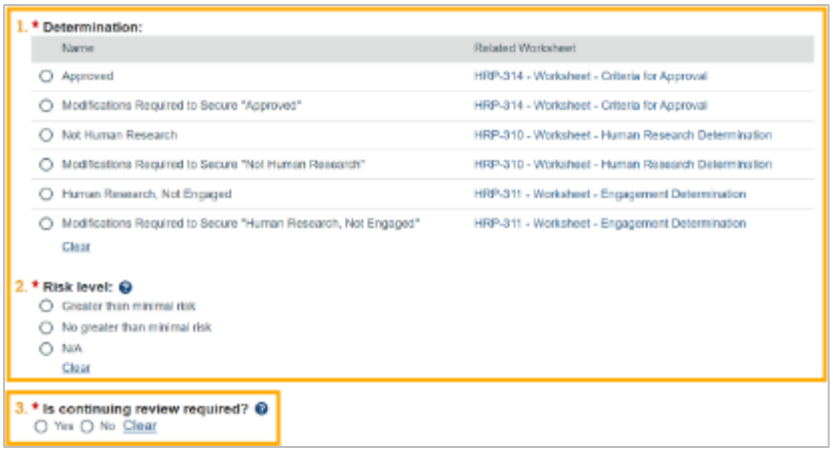
You may be assigned to perform a designated review, a process which doesn't involve other committee members. After reviewing the assigned submission, you must record your decision in the IRB system. Recording your decision completes the designated review and moves the submission forward in the review process. (For committee meeting decisions, an IRB staff member will record the decision on behalf of the committee.)

To submit a designated review

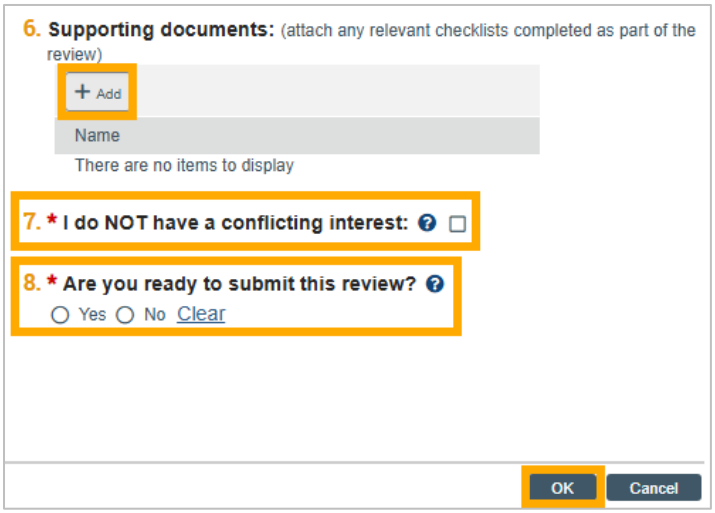
1. From the submission workspace, click **Submit Designated Review**.



2. Complete the Submit Designated Review page. Use the worksheets to support your determination and selections. **Note**: Different determinations and exempt categories are available based on whether the study falls under the Pre-2018 or 2018 Common Rule requirements.
3. For a study that falls under the 2018 Common Rule requirements, indicate whether continuing review is required.



4. Under Supporting documents, add any documents related to your review such as a completed checklist.
5. Select the check-box in question 7 affirming that you do not have a conflict of interest.
6. Click **Yes** if you are ready to submit your review. If not, click **No**, and the information you entered will be saved. You can submit your review later.
7. When finished, click **OK**.



If you said Yes, the submission moves to the IRB coordinator's inbox so the coordinator can send a determination letter to the PI.

Submit an Ancillary Review

You may be assigned to review a submission as an ancillary reviewer. You will receive a notification. The submission will also appear in your inbox if it is a required ancillary review. After reviewing the submission, you must record your decision in the IRB system. This step completes the ancillary review but does not change the state of a submission.

To submit an ancillary review

1. From the submission workspace, click **Submit Ancillary Review**.
2. Complete the Submit Ancillary Review page.
3. Indicate whether you accept or do not accept the proposed submission.

4. Under Supporting documents, add any documents related to your review.
5. When finished, click **OK**.

Your ancillary review responsibilities are complete.

Search Your Solution

To help you work more efficiently, you can use search to locate a wide range of information in your solution. You can search for project data, documents, or content from specific pages on your site. The search results appear in a secondary window and display only those items you have permission to view. Results are ranked to show items where the search term is most prevalent at the top.

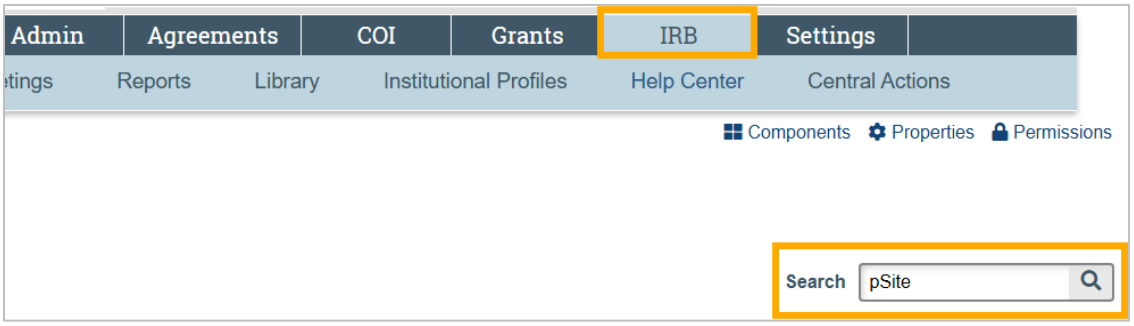
After your initial search, you can further refine results using the following filter options:

- **Projects**— Projects are the day-to-day items you use to manage your research in a Huron solution. They include items such as funding proposals, studies, protocols, agreements, and disclosures. You can search for any project in your solution using properties on the project, including its name, ID, and description. Depending on the solution, other properties are also available to search. When you select the Projects filter, the system will only display results that match search criteria in your project data.
- **Documents**— Documents are third-party files uploaded to your solution outside the context of a project. When you select the Documents filter, the system will only display results that match search criteria from documents. The search includes metadata on a document, such as its name and description. It also includes the contents of a document. From the results, you can click directly on the provided link to open a document.
- **Pages**— Pages organize information on your site into a hierarchy that you can use to view and manage your work. The Pages filter provides a way for you to search one type of page within your solution - content pages. Content pages are presented outside the context of a project. They supply supporting information for your solution, such as the Help Center, Reports, and Meetings. Dashboards and project workspaces are not included with this filter.

Note: Content on the site is updated periodically. If you are searching for something you just added, results might not be available immediately. Try your search again at another time.

To search your solution

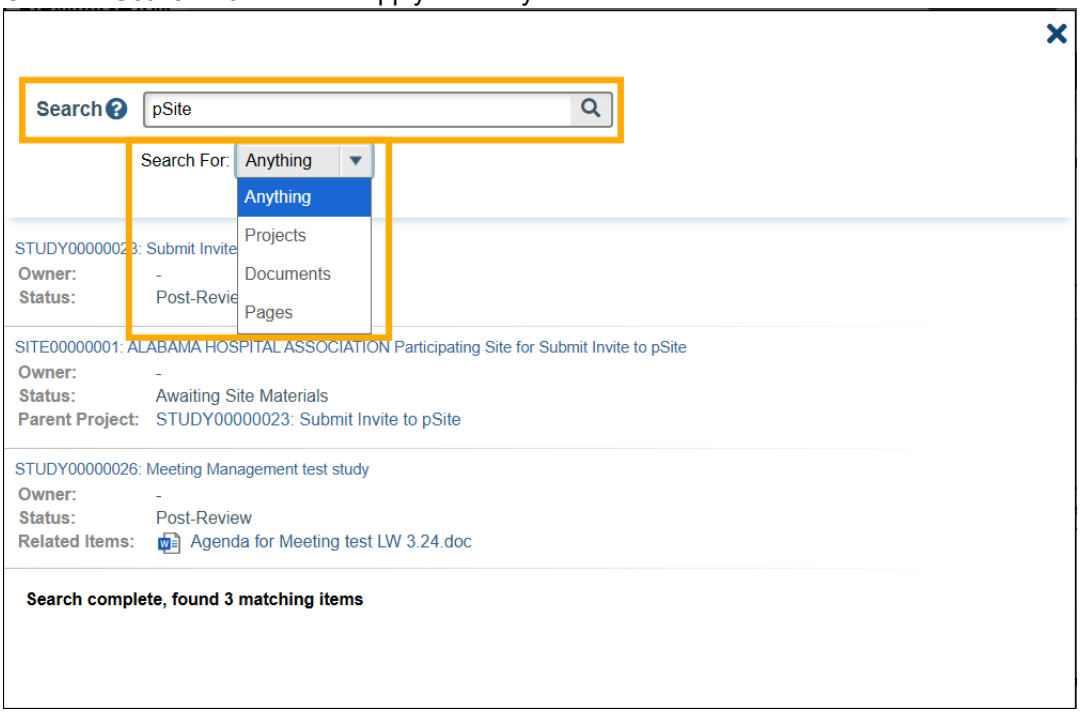
1. In the Top Navigator, click **IRB**.



2. In the Search box, type your search criteria. You can use the following operators:
    a. **And**: Finds all the specified words.
    b. **Or**: Finds at least one of the specified words.
    c. **Not**: Excludes the specified word. You cannot start a search with the Not operator.

d. **Quotation marks**: Finds the exact phrase.

3. Press **Enter** or click the search icon to perform the search. The search results appear.
4. Click the **Search For** arrow to apply filter of your choice.



Staff Tasks

Common Rule Requirements

Studies in the IRB system may fall under the Pre-2018 or 2018 Common Rule requirements, based on the dates they were created and reviewed, the agencies providing regulatory oversight, and other factors. Institutions can evaluate which Common Rule requirements are applied to a study. There are several ways to do this:

- For new studies, the Common Rule effective date listed in the IRB settings page determines which rule is applied to the study, based on the study's Pre-Review submission date. For example, if the effective date in the settings is January 19, 2018, studies with a Pre-Review submission date before that date will fall under the Pre-2018 requirements, and studies with a Pre-Review submission date on or after the effective date will fall under the 2018 requirements.

- For new external studies, the study team can record which Common Rule requirements are applied during creation of the study. **Note**: The decision of which Common Rule requirements the study falls under is made by the external IRB and the local study team should record the requirements communicated to them by the external IRB.

- For existing studies created before the effective date of the 2018 Common Rule requirements, all studies in a draft state or a state past Pre-Review will automatically have the Pre-2018 requirements applied. IRB coordinators and directors can move the study from the Pre-2018 rule to the 2018 rule as part of the continuing review process. When a Pre-Review for a CR is submitted, the IRB coordinator can specify whether the study should remain under the Pre-2018 requirements or be moved under the 2018 requirements.

- In the case of an error or discrepancy, the IRB Director or the Site Administrator can revert a study in a post-approval state from under the 2018 rule to under the Pre-2018 rule. If the study has any active follow-on submissions, they must be completed or discarded before the study can be reverted.

Note: The Common Rule requirements (Pre-2018 or 2018) applied to a study are also applied to any sites related to the study (in the case of external or multi-site studies) and to any follow-on submissions for which it is the parent study.

The Common Rule requirements applied to a study are displayed on the study workspace:

Agency Oversight

If the FDA or DOJ is selected in the Pre-Review form as an oversight agency for a study, the study will automatically fall under the Pre-2018 Common Rule requirements, even if the date of the study falls after the effective date setting of the 2018 requirements. This remains true even if other oversight agencies are selected in addition to the FDA or DOJ.

If, during a continuing review, you edit the Pre-Review form and change the study to fall under the 2018 requirements, the system will not allow the change if the FDA or DOJ remains selected. You must deselect these options in order to move the study under the 2018 requirements.

Exempt Categories

Some exempt categories are only available for studies under the Pre-2018 requirements, and some exempt categories are only available for studies under the 2018 requirements.

When you change a study under the Pre-2018 requirements to fall under the 2018 requirements, a Pre-2018 exempt category may still be displayed, but you will not be able to proceed with the change until it is deselected.

Overview of the Submission Review Process

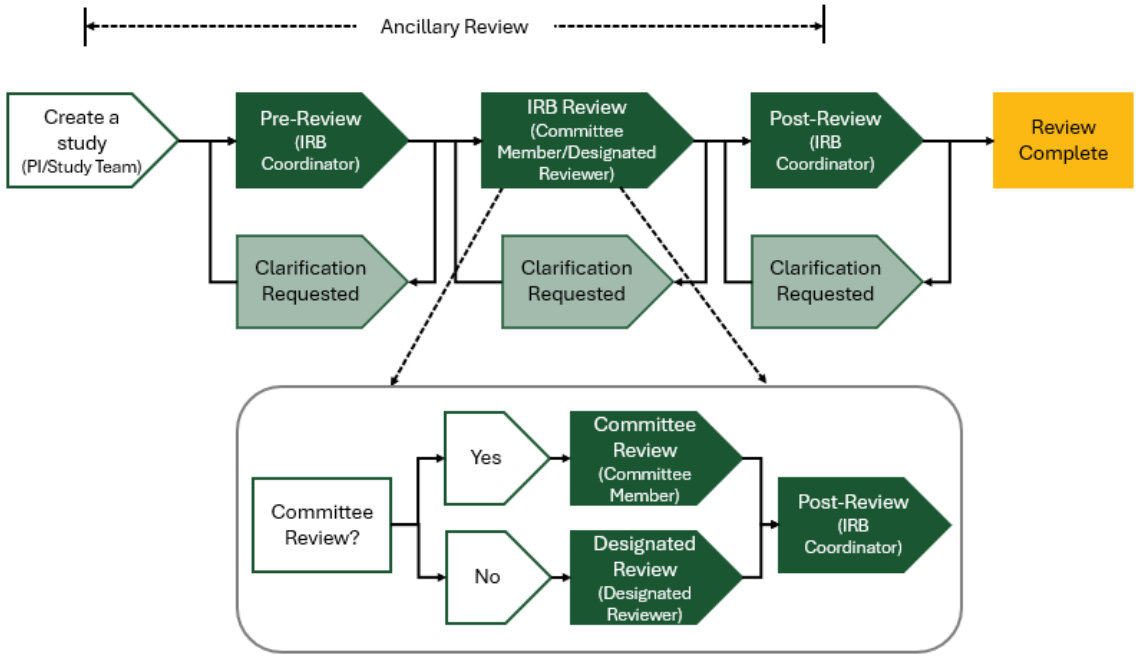
The basic process for a study, or initial submission, is as follows:

1. The PI (and study team) creates a study, entering study information on a series of user-friendly pages in the IRB system. While the team is working on the study, it is in the Pre-Submission state, and when they finish working on it, the PI submits the study to the IRB for review.
2. The study first goes through Pre-Review, in which an assigned IRB coordinator reviews the study for completeness, ensuring it includes all the necessary information and documentation for the IRB committee member reviewers. At any point during Pre-Review, the IRB coordinator may request clarification or changes from the PI resulting in a back-and-forth exchange between the PI and IRB coordinator. The IRB coordinator also determines if the study should be reviewed by a designated reviewer or the full committee.
3. During IRB Review, the designated reviewer or the full committee will review the study.
    a. If it is being reviewed by a designated reviewer, that reviewer makes a determination about the study and submits the decision in the IRB system. Before making a decision, however, the reviewer may request clarification or changes from the PI, resulting in a back-and-forth exchange between the PI and designated reviewer.
    b. If a full committee reviews the study, a committee meeting occurs in which the committee makes a determination about the study. The committee may also request clarification before making a decision, but they can choose to make a determination without receiving

a response. The IRB coordinator submits the decision in the IRB system on behalf of the committee. Submitting a determination in the system moves the study to Post-Review.

4. During Post-Review, the IRB coordinator prepares and sends the determination letter to the PI. If the study was approved, the IRB coordinator also creates a final, PDF version of the study documents and the review process is complete (Review Complete). If the committee determines modifications are needed for the study to be approved, the PI can make changes to the study. The IRB coordinator reviews the changes and decides if the study 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, as well as the decision points that govern whether a submission undergoes committee or designated review.



Pre-Review

Submit a Pre-Review

When the study has been created and is ready to proceed to the next level of review, the researcher will submit the Pre-Review. For information on how the researcher submits a pre-review, see the *Researchers Reference Guide*.

As the reviewer, you will be required to attach and complete any associated checklists. For information on where to find those checklists, see the *HRPP Toolkit* section of this document.

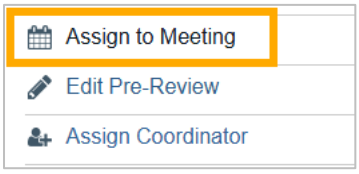
Assign for Further Review

After submitting the study for Pre-Review, the final step is to assign the study for further review, either to a designated reviewer, or a meeting of the full IRB Committee.

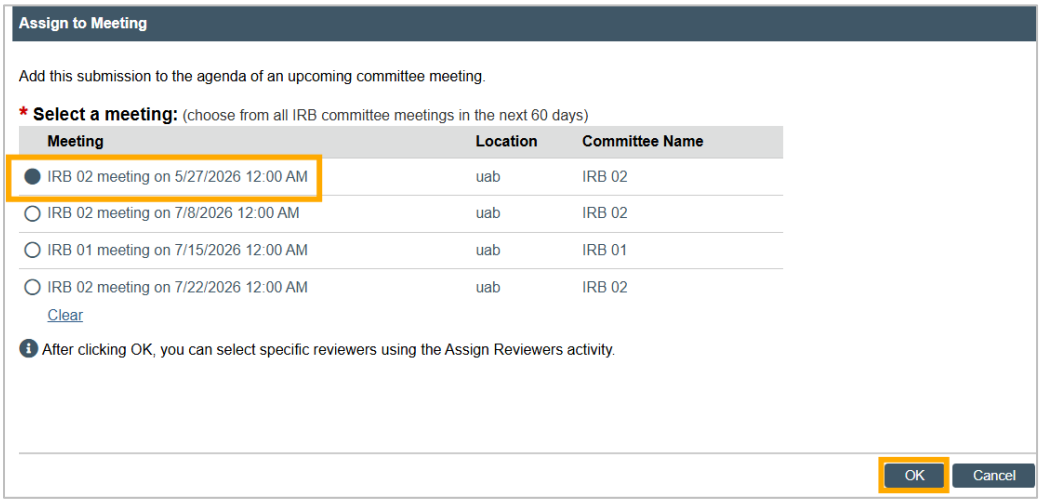
You can assign the study to a designated reviewer if the study is either exempt from review or can go through expedited review. All other studies require full committee review.

Assign the Study to a Committee Meeting

1. Click **Assign to Meeting**.



2. Select an upcoming meeting and click **OK**.



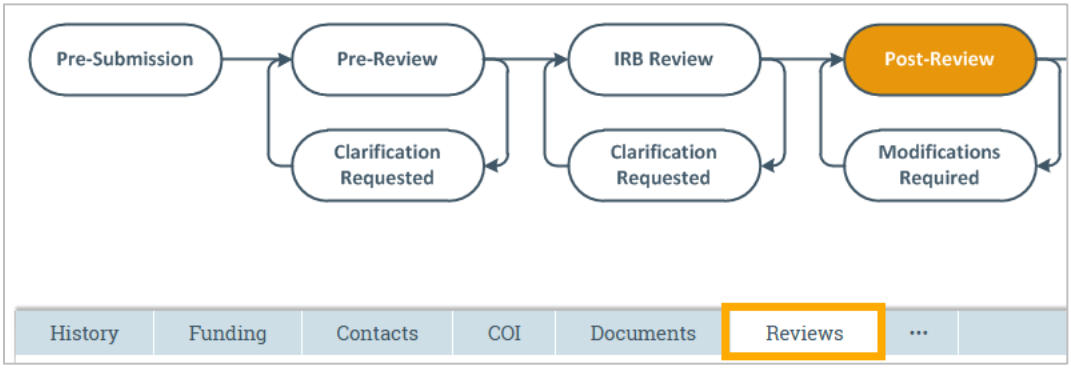
Post Review

Post Review steps are the responsibility of the IRB Staff, for more information about staff tasks, see the *Researchers Reference Guide*.

Review Modifications Required

After the PI has made the required modifications, the IRB Coordinator or Committee Chair can review the required modifications.

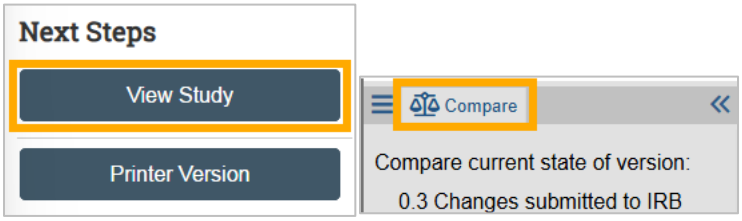
1. Review the required modifications in the **Reviews** tab.



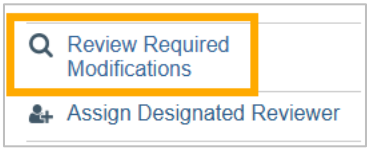
2. Check the approval and effective dates.
3. Check the **History** tab to see what the PI had to say about the modification.



4. Check to see that the required modification is complete by clicking **View Study**, then **Compare**. The pencil icon indicates a change was made on the page.



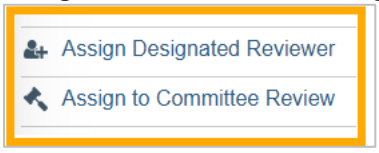
5. Click on the page to view the modification made.
6. Click **Review Required Modifications**. Fill out the form, adding in any notes or supporting documents.



7. Click **Yes** or **No** to indicate if the modifications were completed or not.
    a. If you select **Yes**: Click **OK** and the submission will go back to Post Review.
    b. If you select **No**: the submission would stay in the modifications required state and the PI would need to go back and make the changes required.



8. If after reviewing, you decide the submission needs to go back to either a designated reviewer or the full committee, instead of selecting **Review Required Modification**, select either **Assign Designated Reviewer,** or **Assign to Committee Review**.

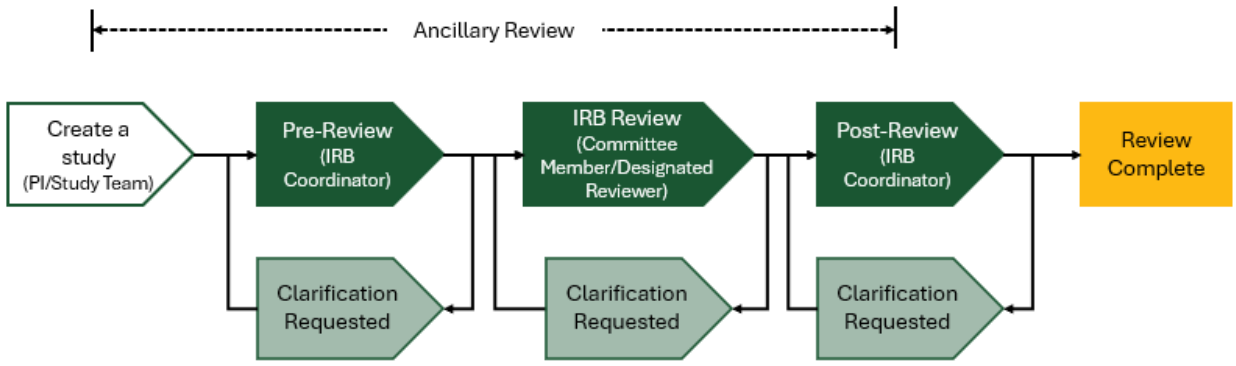


Ancillary Review Process

Ancillary reviews allow individuals, departments, and other organizations to give feedback on the submission in parallel with the IRB review. Both PIs and the IRB staff can add optional or required ancillary reviewers, however, the system does not prevent a submission from being reviewed or approved by the IRB if an ancillary review is outstanding.

Ancillary reviews can be configured to block the workflow if the review is not completed or if the reviewer does not accept the submission when completing a required ancillary review. If necessary, the IRBC can bypass any workflow stoppage for this submission, effectively ignoring any outstanding required reviews for this submission. Refer to your IRB policies about how, when, and whether to interrupt the IRB review process to wait for ancillary reviews.

Ancillary reviews can occur in almost all states, starting from Pre-Submission when they can be initiated by the PI or an IRB director. A few end states are excluded, specifically Discarded and Closed—and for RNI, Complete and Acknowledged. The assigned coordinator is able to add ancillary reviewers in states after Pre-Submission.

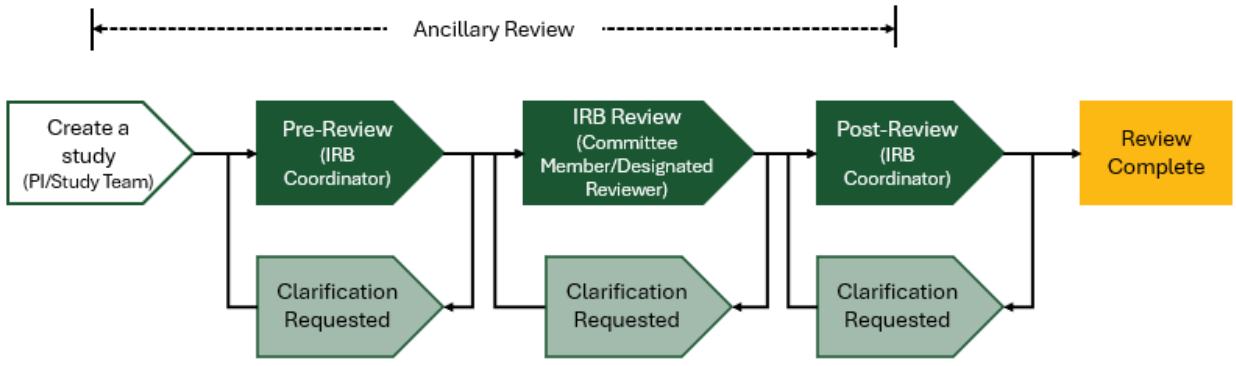


Continuing Review (CR) and Modification Process

Continuing reviews are submitted to close a study or extend the approval period. The IRB periodically reviews all approved studies involving human research. To start the review process, the study team submits a CR for the approved study in the IRB system. After that, the CR follows a similar review process to an IRB study and can also include ancillary reviews that are conducted concurrently with IRB reviews.

Note: Before closing a study via a CR, make sure to discard or approve any active modifications related to the study.

Modifications fall into the following categories: those that affect the study team membership, those that affect other parts of the study, or both. The study team submits a modification for any changes to the approved study; for example, to change the study team membership or update a consent form. Then, the modification follows a similar review process to an IRB study and can also include ancillary reviews that are conducted concurrently with IRB reviews.



When a modification is approved, the changes made in the modification are applied to the approved study. If an approved modification changes the determination of the parent study, the parent study's state will be updated according to the new determination.

A modification that is disapproved remains active until the modification is either approved (which applies the modifications to the study) or discarded (in which case, no modifications are applied to the study). No new modifications of the same type can be created until the disapproved modification is approved or discarded.

Modifications and continuing reviews can be created either separately or combined into a single submission. Combining them often makes sense. For example, suppose the study team wants to submit a consent form change about the same time that a continuing review is due. Both can be submitted and reviewed together, reducing the overhead for the study team, IRB staff, and reviewers.

Note: Only one CR can be open for a study at a time. Similarly, only one modification affecting a certain part of the study (study team membership or other parts of the study) can be open at once. A modification/CR submission counts as a CR and affecting one or more parts of the study, depending on what portions the modification includes. After an open follow-on submission has been closed (through approval, discarding, etc.), another submission covering that same scope can be opened.

Important!

There can be a situation where separate modification and CR submissions that are open concurrently can both affect the study's attached documents. This creates potential contention over the finalization and stamping of documents. Contention can occur when a CR (or a combined modification / CR submission) is open concurrently with a separate modification that includes other parts of the study (not limited to study team membership).

To handle potential conflicts in these situations, we recommend this approach:

- Approve the modification first before approving the CR. This prevents contention.
- If you must approve the CR first, be aware that the modification will later overwrite the stamping of documents done by the CR. To correct this, make sure you finalize again in the modification all documents you finalized in the CR.

External IRB Process for a Single-Site Study

For a single-site study, when the local IRB cedes authority to an external IRB (or single IRB of record), the local IRB system tracks less information about the study throughout its life cycle. The basic process for reviewing and tracking a single-site external IRB study locally is shown below.

Note: For information on multi-site studies reviewed by an external IRB, see the IRB Multi-Site Study Section.

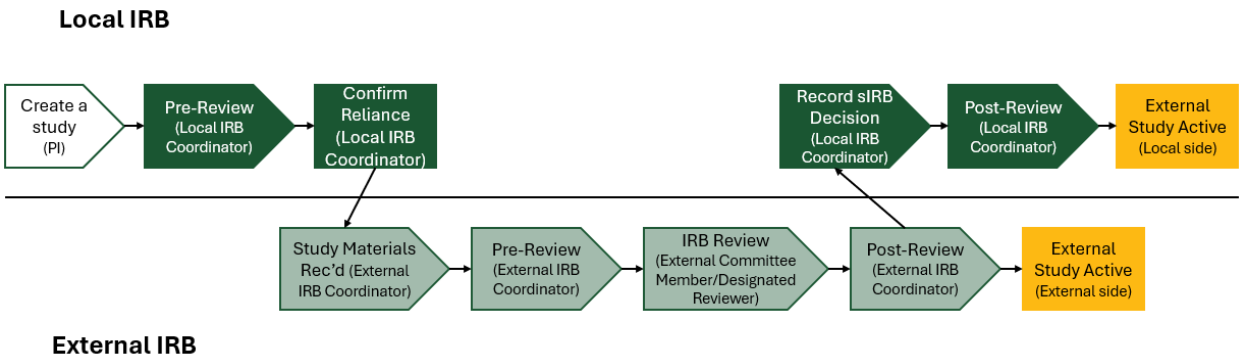
1. During Pre-Submission when the study team is creating the study, they will indicate that they are using an external IRB. This causes subsequent pages to require less information for the local IRB to review and require information about the external IRB.
2. During Pre-Review, the assigned coordinator reviews the study, including the external IRB information, and can send the study back to the study team for more information or clarification as

needed. When all the information has been supplied, the coordinator uses the **Confirm Reliance** activity to confirm that the external IRB is indeed overseeing the review process.

3. The study will move to the Pending sIRB Review state. If the study needs to be revised while in the Pending sIRB state, the assigned IRB coordinator or study staff can directly edit the study.
4. Once the external IRB communicates their decision, the local IRB coordinator records the decision using the Record sIRB Decision activity. The Record sIRB Decision activity is where you will record which Common Rule regulatory requirements apply to the study – Pre-2018 or 2018. Depending on the decision, and whether the coordinator needs to finalize documents and send an acknowledgement letter, the study moves to the Post-Review, Modifications Required, or Review Complete state:
    a. In the Modifications Required state, the coordinator or PI can respond to the external IRB.
    b. During Post-Review, the IRB coordinator can prepare and send the acknowledgement letter.
    c. Once the study is in the Review Complete state, the local IRB process is complete.

Note: All submissions reviewed by an external IRB are found on the External IRB tab.

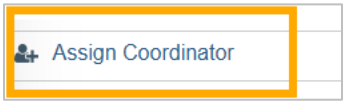
The following diagram illustrates the review process for a single-site external submission.



Confirm Reliance with an External IRB

The IRB Coordinator will confirm reliance with the External IRB.

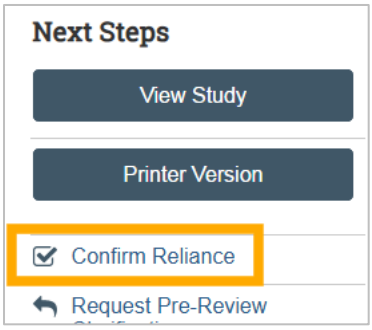
1. Click **Assign Coordinator.**



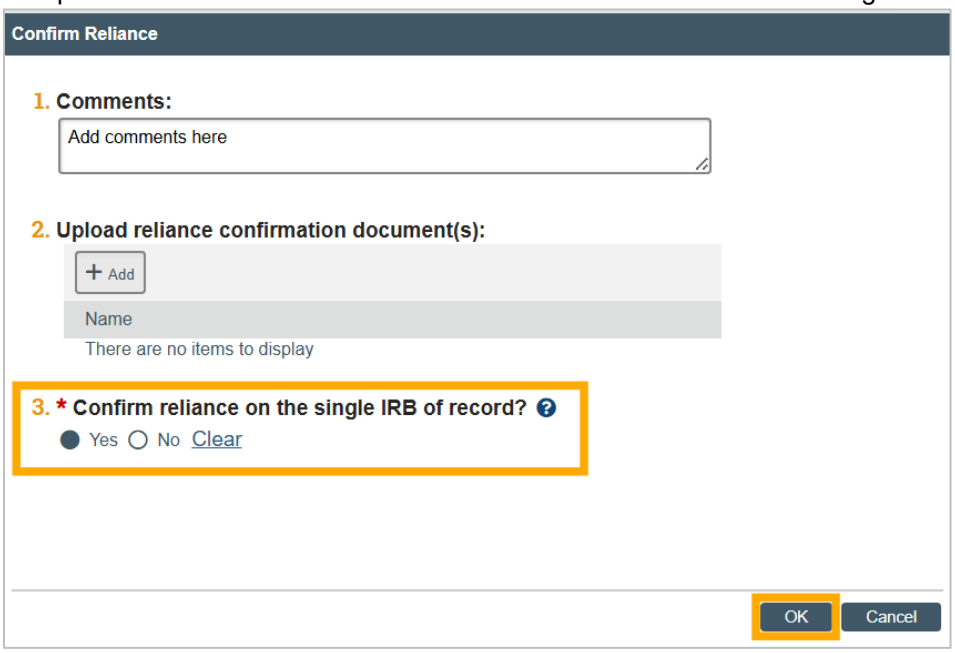
2. Assign the IRB coordinator and click **OK**.



3. Review the submission, and when complete, click **Confirm Reliance**.



4. Complete the form and click **OK**. The submission will move to the Pending sIRB Review state.

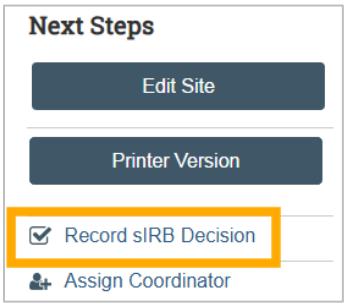


Next the IRB Coordinator will notify the external IRB acting as the IRB of record that their institution has confirmed reliance.

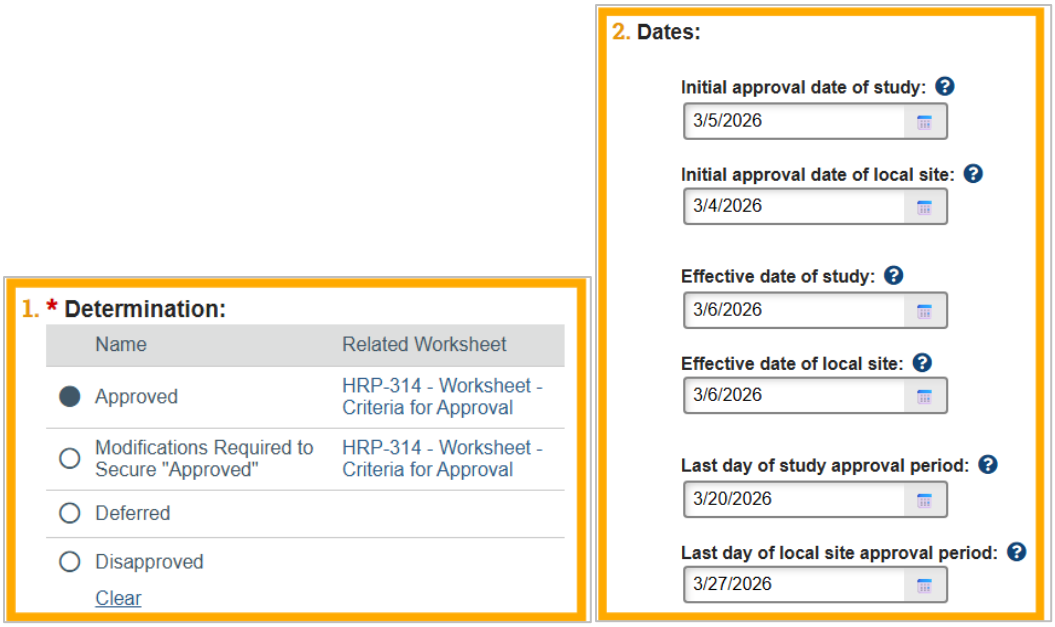
Record the sIRB Decision

After receiving the determination from the external IRB, the IRB Coordinator will record their decision.

1. Click **Record sIRB Decision**.

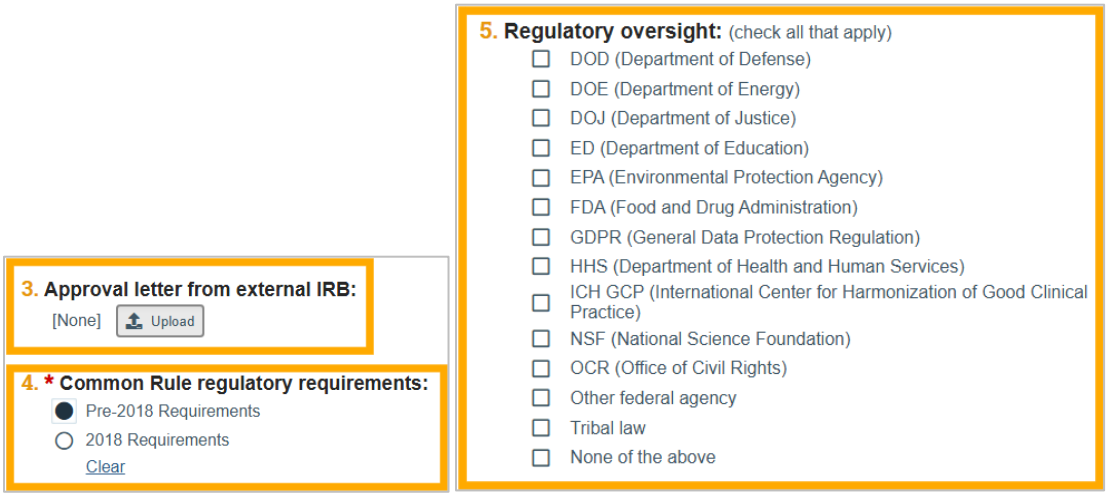


2. Record the determination. Record the initial approval date, initial effective date, and the last day of the study approval period.

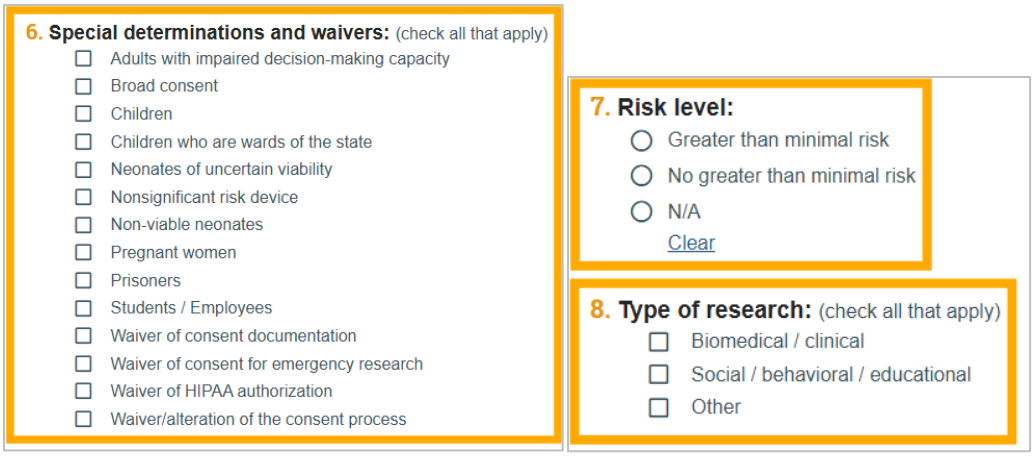


Note: the last day of the study approval period is what triggers the continuing review notification.

3. Upload the approval letter from the external IRB, if you have it. Select the Common Rule regulatory requirements and the regulatory oversight.



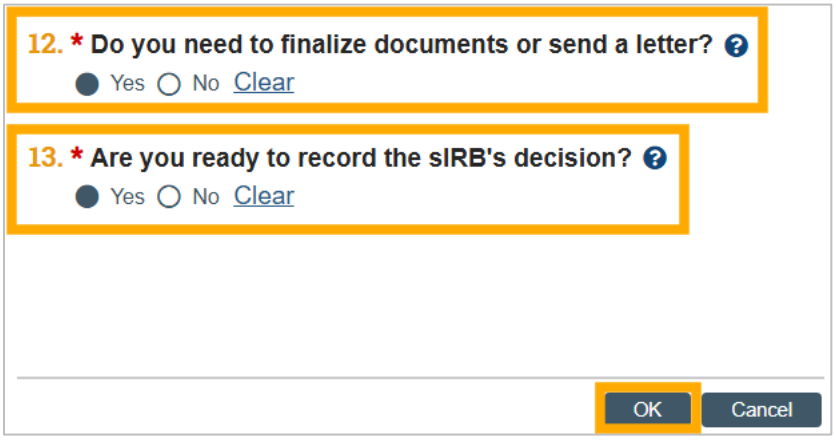
4. Select all the special determinations and waivers that apply. Risk level and Type of Research are unchanged from earlier versions.



5. Additional study features gives you the option of selecting from the following study features for reporting purposes. You have the option to finalize documents or send a letter.



6. If you select **No**, the submission moves directly to the Review Complete state. Once in the Review Complete state, you still have the option to send the submission back to Post Review.
7. Select, **Yes** for the **Are you ready to record the sIRB's decision?** question.
8. If you select **No**, your responses are saved and you can complete this later.
9. Click **OK**. After recording the external IRB's decision, the submission moves to either Post Review or Review Complete.



Post Review of a Single-Site External Study

The IRB Coordinator can finalize documents, then prepare and send the determination letter. The submission is in the Review Complete stage, at this point you have the option to return the submission to Post-Review.

At Post-Review, you can send the determination letter, and you have the option to edit the sIRB decision. The **Update Study Details** button will appear.

Both the PI and the IRB Coordinator can Update Study Details, but typically the role falls to the PI. Update Study Details sends a notification to the IRB that a change was made, and it creates a snapshot of the submission so the IRB Coordinator can see the change. You can learn more about Update Study Details in the *Researchers Reference Guide*.

Study Modifications and CR States and Transitions

This table contains information on key transitions in the IRB review process that cause a submission to move from one state to another. The table lists the original state, the action required to change the state, the users that can perform this action, and the resulting state of the submission.

Note: To view the states and transitions available for a site connected to an externally-reviewed study, refer to the "pSite System Site States and Transitions" section.

In this state…	These roles…	Can perform these actions…	Changing the state to…
Pre-Submission	Investigator, PI Proxy	Submit	Pre-Review
Pre-Review	IRB Coordinator, IRB Director	Submit Pre-Review	Pre-Review Completed
		Request Pre-Review Clarification	Clarification Requested (Pre-Review)
Pre-Review Completed	IRB Coordinator, IRB Director	Assigned Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
Clarification Requested (Pre-Review)	Investigator, PI Proxy	Submit Response	Pre-Review
Committee Review	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
	Committee Member, IRB Coordinator, IRB Director	Request Clarification by Committee Member	Clarification Requested (Committee Review)
	Investigator, PI Proxy	Submit Response	Committee Review

Clarification Requested (Committee Review)	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review
Non-Committee Review	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
		Submit Designated Review	Post-Review
	Designated Reviewer	Request Clarification by Designated Reviewer	Clarification Requested (Designated Review)
Clarification Requested (Designated Review)	Investigator, PI Proxy	Submit Response	Non-Committee Review
Post-Review	IRB Coordinator, IRB Director	Send Letter	Approved
			Modifications Required
			Deferred
			Human Research, Not Engaged
			Not Human Research
			Disapproved
Approved	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
		Submit Committee Review	Post-Review
		Submit Designated Review	
	IRB Director	Terminate	Terminated
		Suspend	Suspended
Suspended	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
	IRB Director	Terminate	Terminated
	Registered User	Continuing Review Closed	Approved
Deferred	Investigator, PI Proxy	Submit Response	Pre-Review

	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
Disapproved	Investigator, PI Proxy	Submit Response	Pre-Review
	IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
		Submit Designated Review	
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded
Modifications Required	Investigator, PI Proxy	Submit Response	Modifications Submitted
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded
Modifications Submitted	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
	Committee Chair, Coordinator, IRB Director	Review Required Modifications	Post-Review
			Modifications Required
Lapsed	IRB Director	Suspend	Suspended
		Terminate	Terminated
	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
	Registered User	Continuing Review Closed	Approved
Terminated	IRB Coordinator, IRB Director	Submit Committee Review	Post-Review

		Submit Designated Review	
External IRB	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
All states prior to Post-Review	Study Staff	Withdraw	Pre-Submission
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

Reportable New Information

This section contains information about the Reportable New Information (RNI) process, RNI states and transitions, how to submit RNI, and the RNI review process.

Reportable New Information (RNI) Process

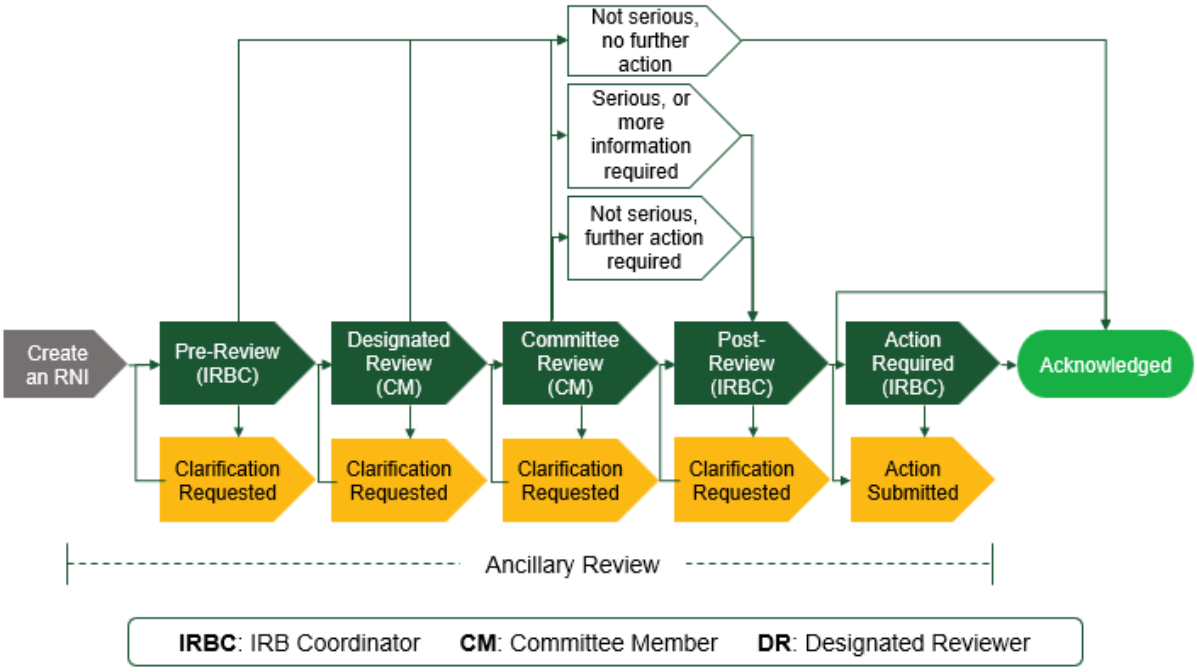
The RNI workflow uses similar states to a study, but the IRB review process routes the submission differently depending on the significance of the determinations selected. For an RNI submission to be considered a serious issue, the determinations selected must include an unanticipated problem involving risks, serious or continuing non-compliance, or suspension or termination of IRB approval. This reduces the IRB's time spent handling insignificant issues.

1. The review process starts with a pre-review that enables the coordinator to make the final determinations regarding any RNI submission that is not considered serious.
    a. If the RNI submission is not considered a serious issue and is not marked as Additional review required, the submission transitions directly to **Acknowledged**.
    b. Otherwise, the coordinator can assign the submission to a designated reviewer or to committee review.
2. The RNI designated reviewer starts from the determinations selected in pre-review and can modify them as needed.
    a. If the RNI submission is not considered a serious issue, the submission transitions directly to **Acknowledged**.
    b. Otherwise, the submission transitions to **Committee Review** so it can be assigned to a meeting.
3. The committee review starts from the determinations selected in the previous review and can be modified as needed.
    a. If the RNI submission is not considered a serious issue, and no further action is required, the submission transitions directly to **Acknowledged**.
    b. If the RNI submission is not considered a serious issue, but further action is required, the submission transitions to **Post-Review**.
    c. If the RNI submission is considered a serious issue, or if additional information is required before making a determination, the submission transitions to **Post-Review** regardless of whether further action is required.
4. If further action is required to resolve the reported issue, the committee can specify an action plan and assign a responsible party for carrying out the plan. If action is required, the submission transitions from **Post-Review** to **Action Required** when the letter is sent. The responsible party

(and others) can respond using the **Submit Action Response** activity when the action has been completed. Then the completed action can be reviewed and verified in the **Action Submitted** state. Alternatively, the submission can be assigned to a designated reviewer or to committee review to verify the completed action.

5. When there is no further action required, and a letter is sent, the submission transitions to **Complete**.
6. Depending on how your IRB solution is configured, an RNI for a single-site external study may follow the workflow described above, or it may be routed directly to **Pending sIRB Review**. Once the external IRB communicates their decision, the local IRB coordinator uses the **Record sIRB RNI Decision** activity to record the decision.

   Note: If the external IRB decision is to recommend local review, select the **sIRB recommends local IRB Review** determination in the **Record sIRB RNI Decision** activity.



Reportable New Information States and Transitions

This table contains information on key transitions in the RNI Review process that cause an RNI to move from one state to another. The table lists the original state, the action required to change the state, the users that can perform this action, and the resulting state of the RNI.

In this state…	These roles..	Can perform these actions…	Changing the state to…
Pre-submission	Reporter, PI and PI proxies of related submissions, RNI editors	Submit RNI	Pending sIRB Review*
			Pre-Review

Pre-Review	IRB Coordinator, IRB Director	Submit RNI Pre-Review	Acknowledged
			pSite Review*
			Pre-Review Completed
		Route for sIRB Review*	Pending sIRB Review*
		Request Pre-Review Clarification	Clarification Requested (Pre-Review)
Clarification Requested (Pre-Review)	Reported, PI and PO proxies of related submissions, RNI editors**	Submit Responses	Pre-Review
Pre-Review Completed	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
Committee Review	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Post Review
			Acknowledged
		Review Required Actions	Post-Review
			Action Required
	Committee Member, IRB Coordinator, IRB Director	Request Clarification by Committee Member	Clarification Requested (Committee Review)
Clarification Requested (Committee Review)	Reporter, PI and PI proxies of related submissions, RNI editors	Submit Response	Committee Review
Non-Committee Review	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
	Designated Reviewer, Committee Chair, Committee Administrator, IRB	Review Required Actions	Post-Review
			Action Required

	Coordinator, IRB Director		
	Designated Reviewer	Submit RNI Designated Review	Acknowledged
			Committee Review
		Request Clarification by Designated Reviewer	Clarification Requested (Designated Review)
Clarification Requested (Designated Review)	Reporter, PI and PI proxies of related submissions, RNI editors***	Submit Response	Non-Committee Review
Pending sIRB Review*	IRB Coordinator, IRB Director	Record sIRB Decision*	Pre-Review
			Action Required
			Complete
Action Required	Responsible party, IRB Coordinator, reporter, PI and PI proxies of related submissions, RNI editors**	Submit Action Response	Action Submitted
			Action Submitted (sIRB Review)*
Action Submitted	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Review Required Actions	Post-Review
			Action Required
	IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
		Assign Designated Reviewer	Non-Committee Review
Action Submitted (sIRB Review)*	IRB Coordinator, IRB Director	Record sIRB Decision*	Complete
			Action Required
Post-Review	IRB Coordinator, IRB Director	Send Letter	Action Required
			Complete
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Acknowledged
Complete			Post-Review

	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Acknowledged
Acknowledged	IRB Coordinator, IRB Director	Submit RNI Pre-Review	Pre-Review Completed
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Post-Review
	Designated Reviewer, IRB Coordinator, IRB Director	Submit RNI Designated Review	Committee Review
All states prior to Post-Review	Study Staff	Withdraw	Pre-Submission
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

*This action or state applies to RNI's related to externally-reviewed studies only.

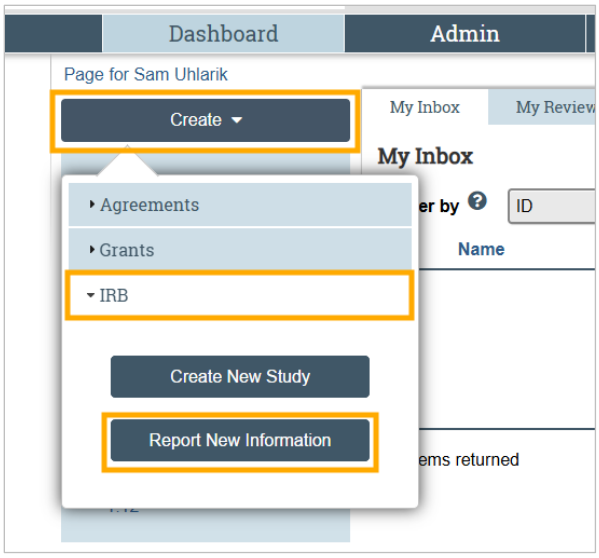
**RNI editors are those assigned to the RNI using the Manage Editors activity. They can edit the RNI, submit it for review, submit a response to a clarification request, and submit an action response.

Create and Submit Reportable New Information (RNI)

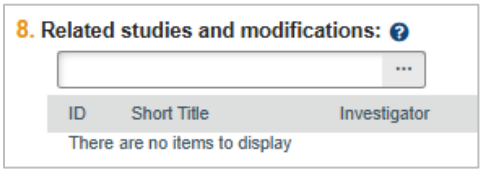
You can report any adverse events or new information about a study as soon as you become aware of it.

To create reportable new information (RNI)

1. In the Top Navigator, click IRB and then Submissions.
2. Click the Report New Information button.
   Note: You can also open an active study and report new information from the study workspace.



3. Complete the Reportable New Information page. Pay attention to the following question:
    a. **Related studies and modifications:** Select any studies or modifications that the RNI applies to.



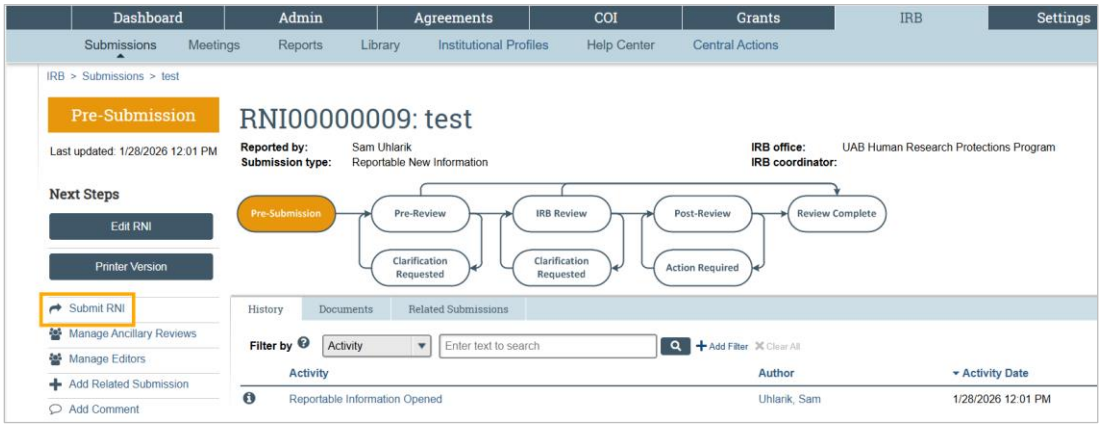
Notes:

- To relate a modification to the RNI, first add the parent study. You cannot relate sites, external studies (unless the external study is part of a multi-site study), or other follow-on submissions to an RNI.
- The PI, PI proxies, and primary contact of each related submission are notified at several points in the RNI workflow. In addition, the PI and PI proxies of each related submission can edit the new information, submit it for review, and submit a response to a clarification request.

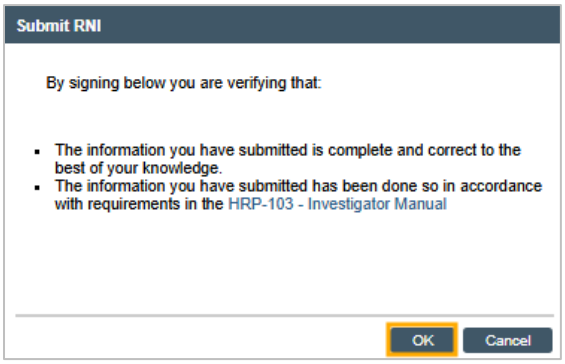
4. Click **Continue**.
5. If applicable, select the IRB office and then click **Finish**.

To submit an RNI

1. From the RNI workspace, click **Submit RNI**.



2. Click **OK** to agree to the terms.



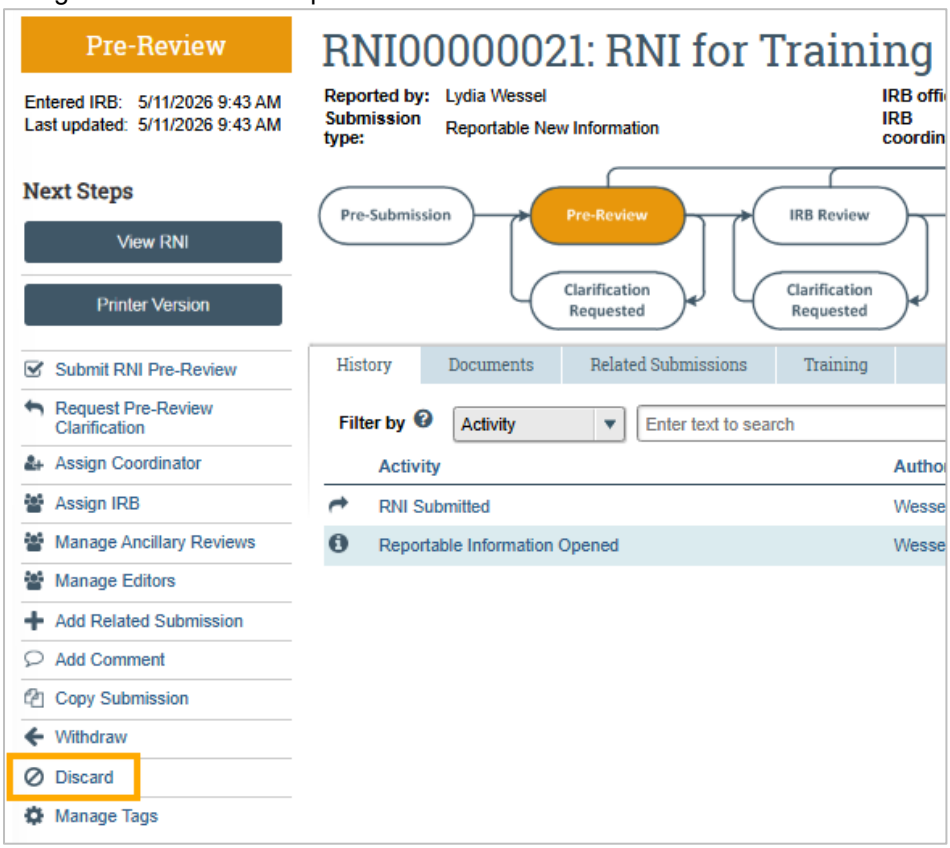
3. Click **OK** to submit.

You can log off the system. The RNI has been submitted to the IRB. After reviewing the external RNI, the IRB system generates and displays the correspondence letter.

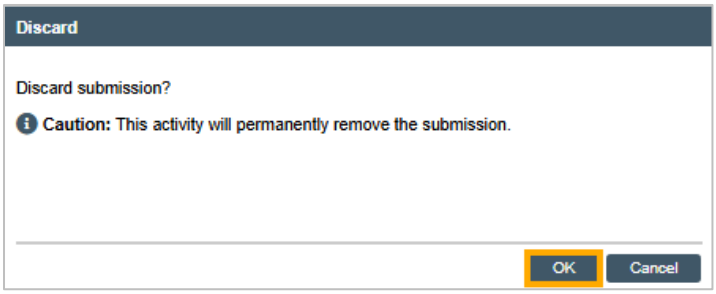
Discard an RNI

If you need to delete the RNI you created:

1. Navigate to the RNI workspace and click on the Discard button on the left side.



2. Click OK to agree to discard the submission. This will permanently remove the submission.



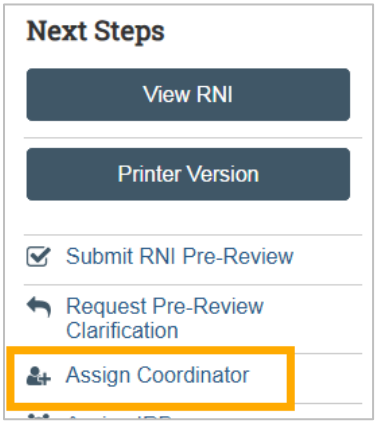
RNI Review Activities

This section covers different review activities for Reportable New Information (RNI), including pre-review, designated review, committee review, and post review.

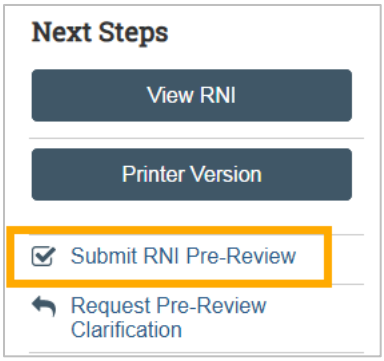
RNI Pre-Review

The RNI Pre-Review process is very similar to the study pre-review. For more information on that, see the Submit a Pre-Review section. Typically, the IRB Coordinator will conduct the Pre-Preview.

1. Open the RNI and assign the Coordinator.



2. After reviewing the RNI, click **Submit RNI Pre-Review**.



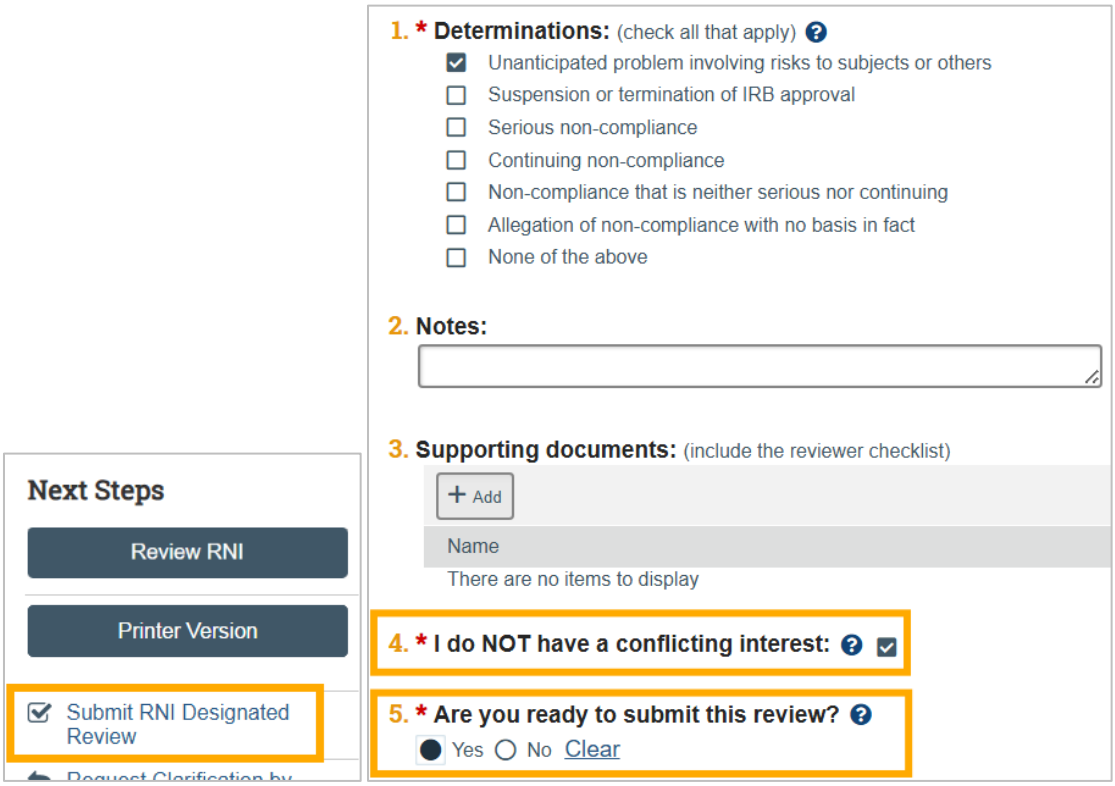
   a. The following determinations are deemed NOT serious:
      i. Non-compliance that is neither serious nor continuing
      ii. Allegation of non-compliance with no basis in face
      iii. None of the above.

b. The following determinations are deemed serious:
    i. Unanticipated problem involving risks to subjects or others
    ii. Suspension or termination of IRB approval
    iii. Serious non-compliance
    iv. Continuing non-compliance
3. An RNI submission that is not serious transitions to the Acknowledged state and an email is sent to the study team indicating that the review is complete.
   Note: an RNI submission can be determined to be not serious at Pre-Review, Designated Review, and Committee Review.
4. If a serious determination is selected, or "Additional Review Required" is selected, then the submission requires review.

RNI Designated Review

Following the pre-review, the designated reviewer will perform a designated review.

1. Review the RNI, then select **Submit RNI Designated Review**.
   Note: the selections will be carried over from the Submit RNI Pre-Review activity, you can modify this as needed.



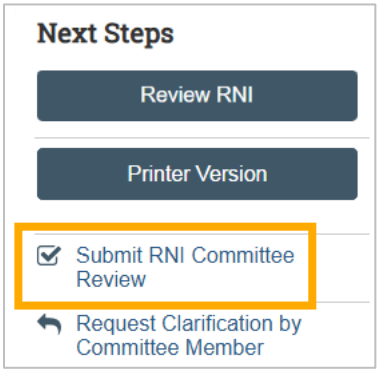
If the designated review determination is serious, the RNI will undergo committee review.

RNI Committee Review

Since the RNI determination was serious, it now must go through committee review.

After the committee has met and made a determination, the next step is for the IRB Coordinator to submit the Committee Review.

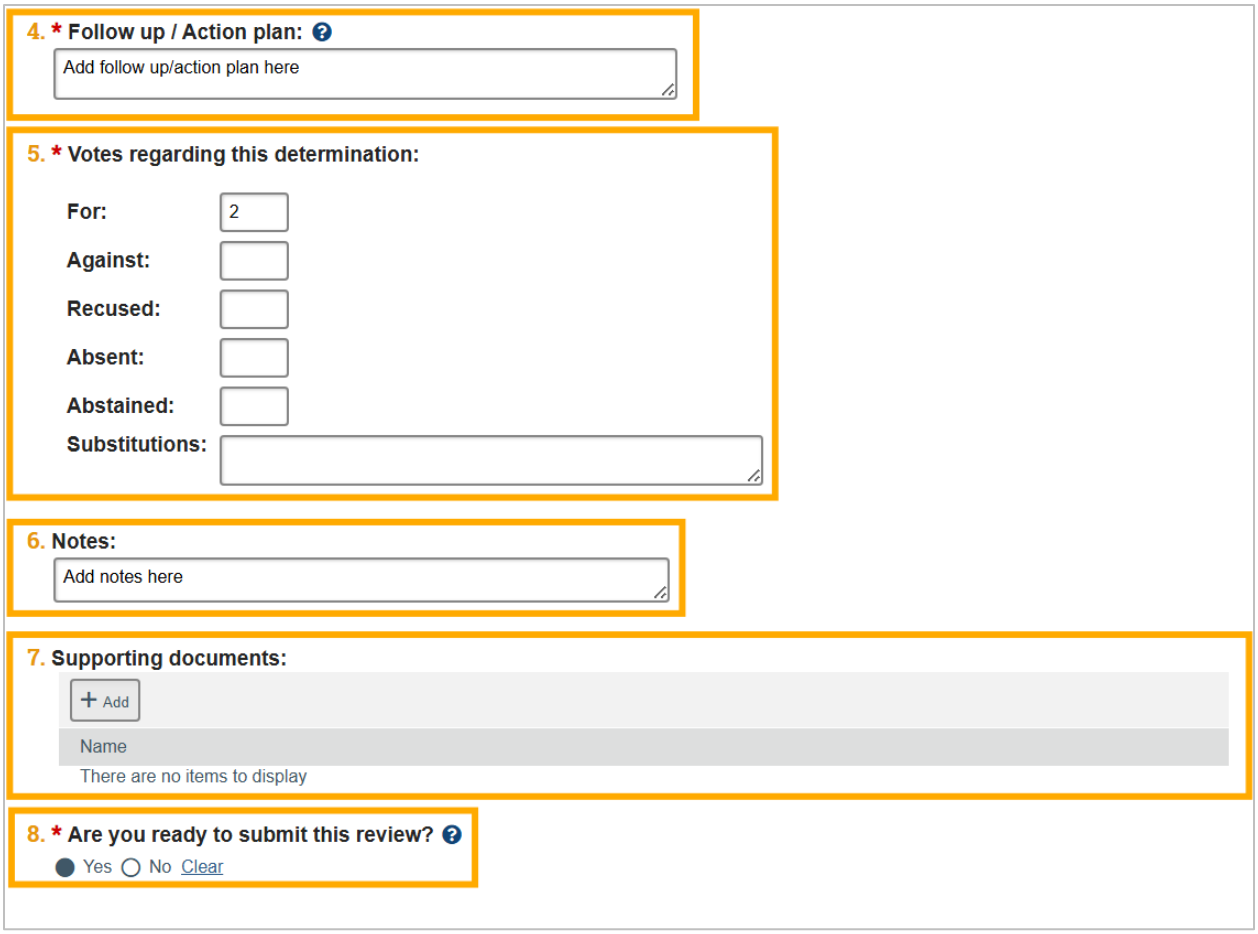
1. Select **Submit RNI Committee Review**.
   Note: the determination selection has carried over from the designated review. The committee can modify this as necessary.



2. If the committee determines that the RNI is not serious, it will transition to Acknowledged and an email will be sent to the study team.
3. Answer **Yes** or **No** to the question, **Is further action required?.**
   a. If you select **Yes**, you must select the responsible party.
      i. Note: the responsible party is the person who will complete the required action.
   b. If you select **No**, move on to the next question.



4. If further action is required, include an action plan.
5. Record the votes and attach any supporting documents.

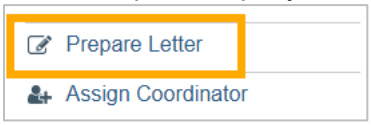


After submitting, the RNI transitions to Post-Review.

RNI Post Review

The post review tasks for RNI and a study are essentially the same. See the *post review for a study* section for more details.

1. The IRB Coordinator will prepare the letter.
   Note: a responsible party and action plan are included in the determination letter.



2. Make the necessary changes to the letter and send it. The letter will go to the responsible party, the PI, PI Proxy, and Primary Contact of any associated study.
3. The letter will be automatically converted from an editable, Microsoft Word document to a read only PDF.

RNI Action Required

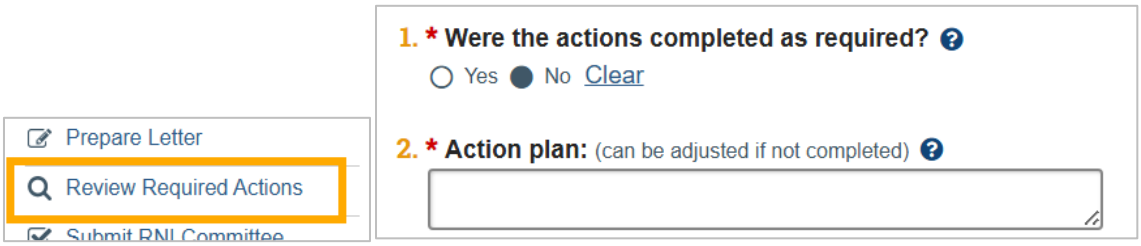
As the responsible party you will review action required.

1. After completing the required action, select **Submit Action Response**.
   Note: the RNI will start in the Action Required state, then will change to the Action Submitted state.

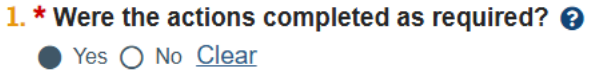


2. The IRB Coordinator will review the action response to see that it was completed.
3. After reviewing, the coordinator has four options:
   a. Send the RNI submission back to the Designated Reviewer
   b. Send the RNI submission back to the full committee review
   c. Send the RNI submission to the responsible party for further action
   d. Determine that the required action is complete.

   Note: Sending the RNI back to the designated reviewer or full committee review, will repeat the designated review and committee review processes.
4. To send the RNI submission to the responsible party, select **Review Required Actions**, then select **No**. Write a description of what needs to be completed and click **OK**.
   Note: After clicking **OK**, the RNI transitions to Post Review and you may now prepare and send another letter.



5. If you determine that the required action is complete, select **Yes**.
   Note: the action plan is now read only.



Meeting Management

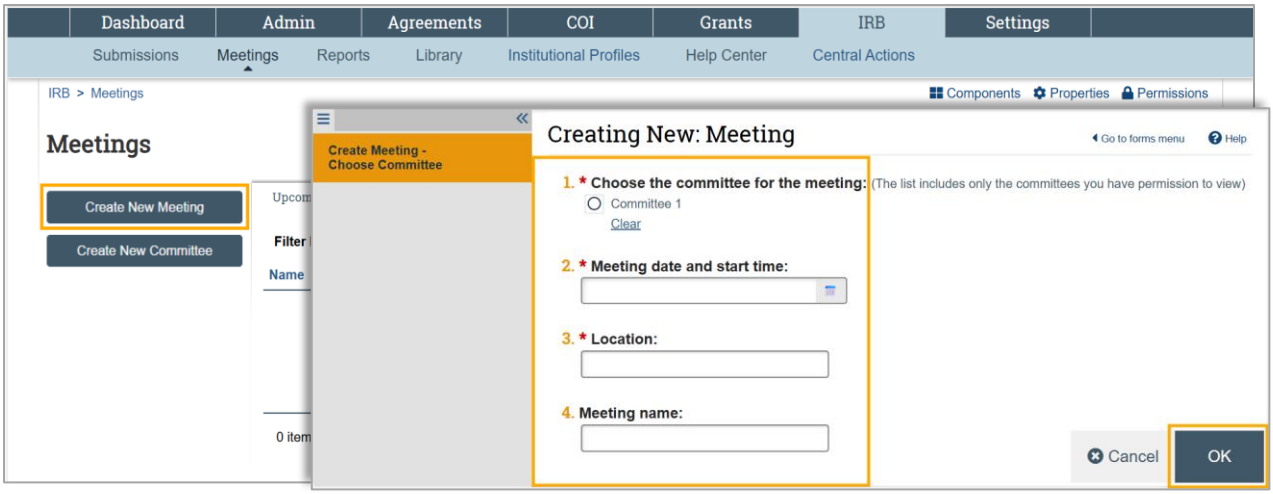
Create a Meeting

Typically, the committee's administrators or chairs create the meetings.

Tip: For best results in handling meetings, make sure the committee administrator also has one of these user roles, as appropriate: COI Administrator, IACUC Coordinator, IRB Coordinator, or Safety Specialist.

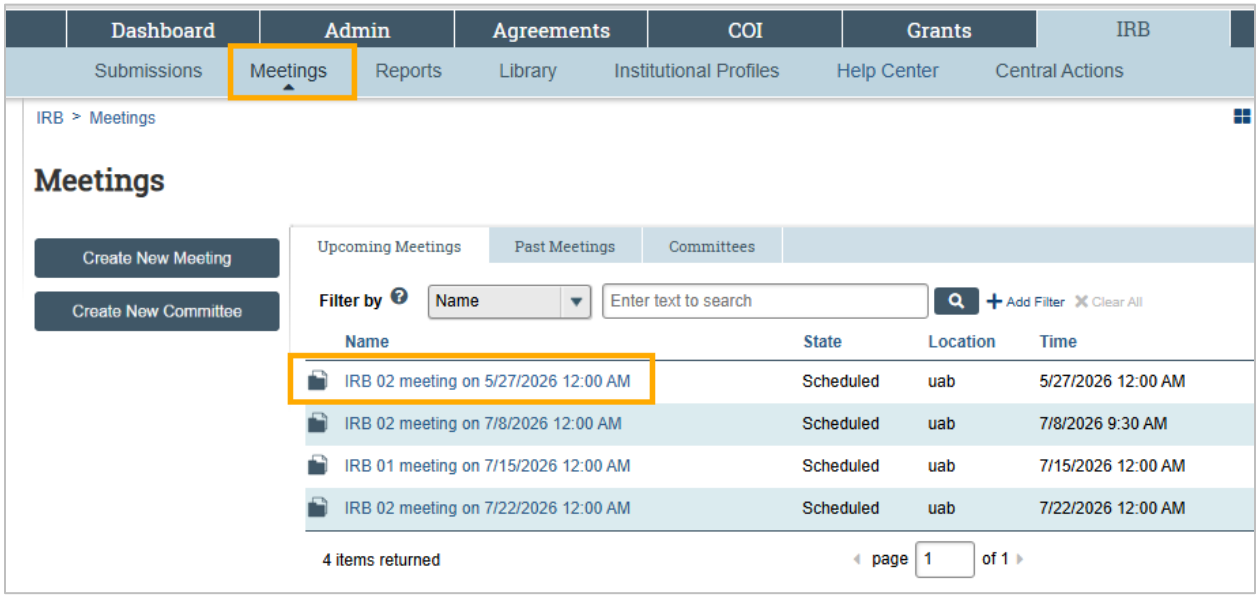
To create a meeting

1. From the Sub-Navigator, or from My Inbox, click **Meetings**.
2. From the meetings page, click **Create New Meeting.**
3. Complete the SmartForm.
4. When you're done, click **OK**. The meeting workspace appears.



To find/open a meeting

From the Meetings page, under the Upcoming Meetings tab, click the name of the meeting to open it.



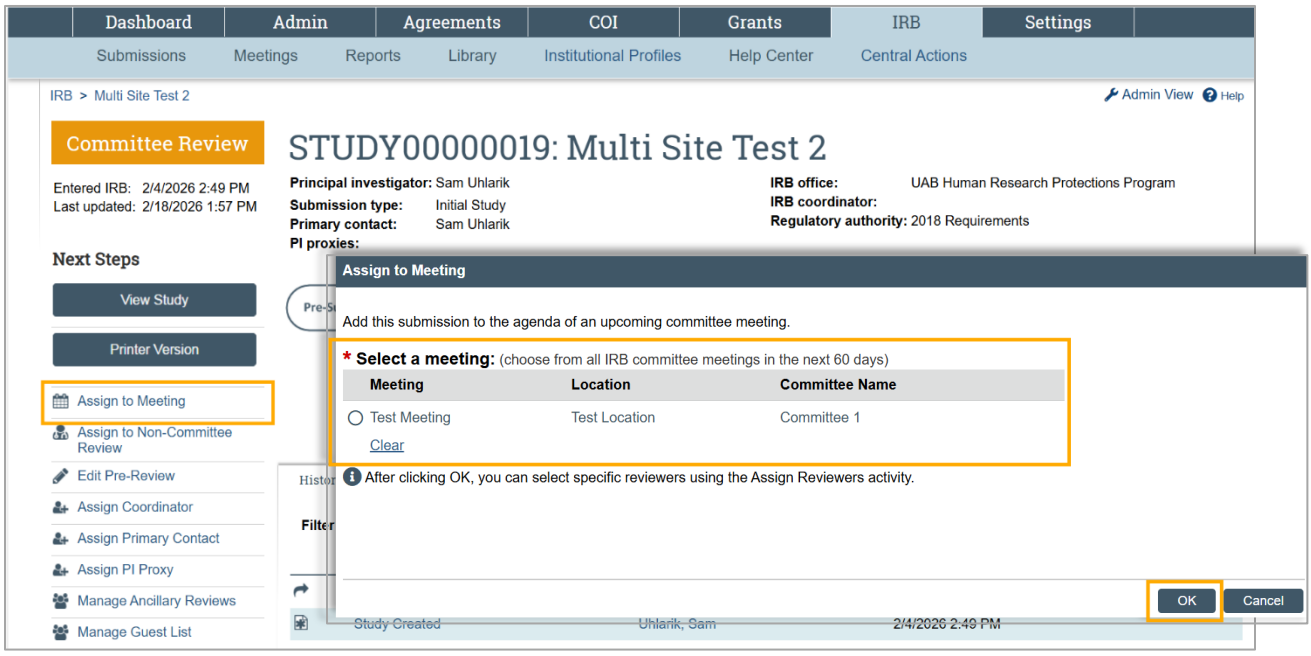
Prepare for Committee Meetings

From the committee meeting page, users designated as committee administrators can manage meetings, agendas, and minutes for that committee's meetings.

Note: Multiple users can be simultaneously designated as committee administrators.

To assign submissions to meeting

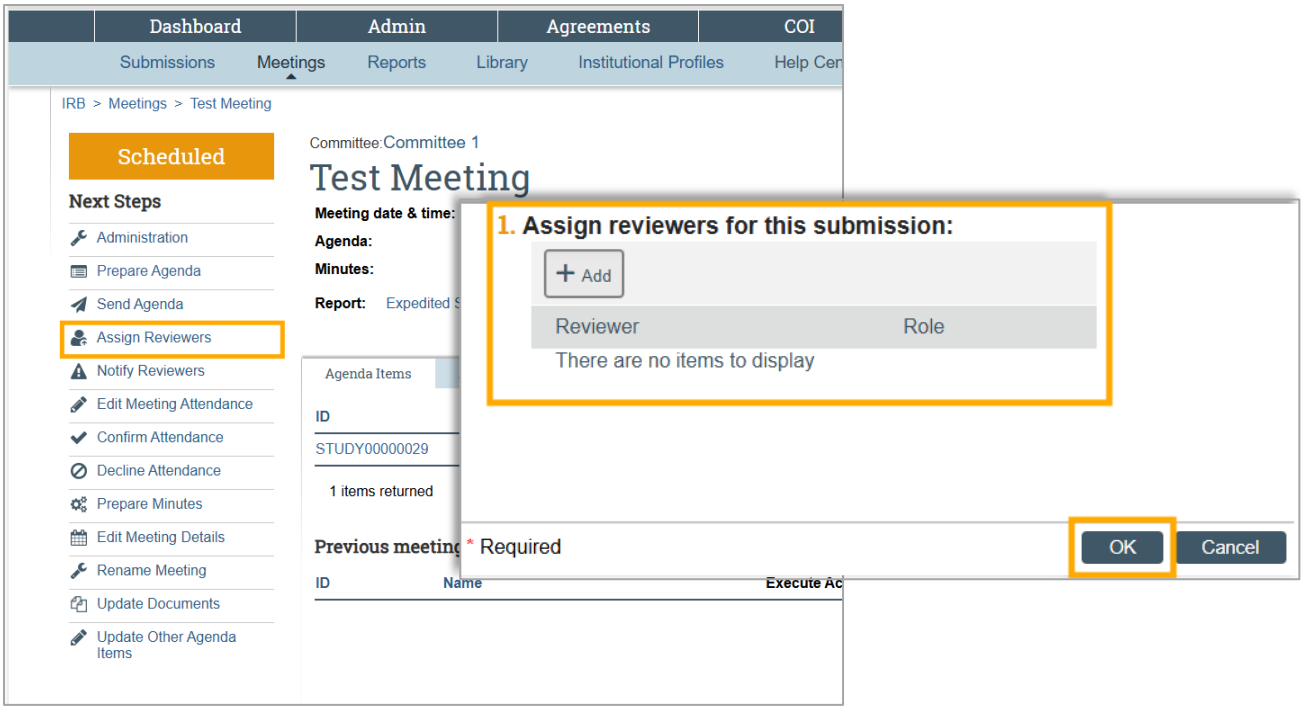
1. From the submission workspace, click **Assign to Meeting**.
2. Complete the form and click **OK**.



To assign reviewers

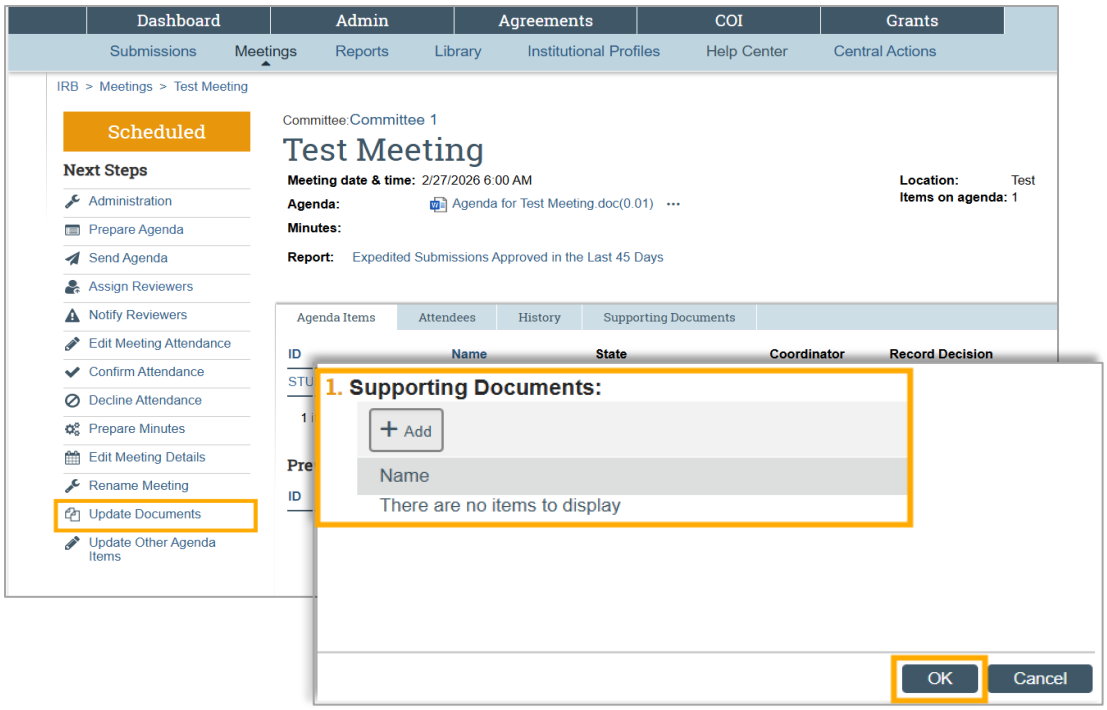
Once you assign an agenda item to a meeting, the **Assign Reviewers** activity is available.

1. From the submission or meeting workspace, click **Assign Reviewers**.
    a. **Note**: for COI and non-submission agenda items: Click Assign Reviewers from the meeting workspace.
2. Complete the forms and click **OK**.



To add documents

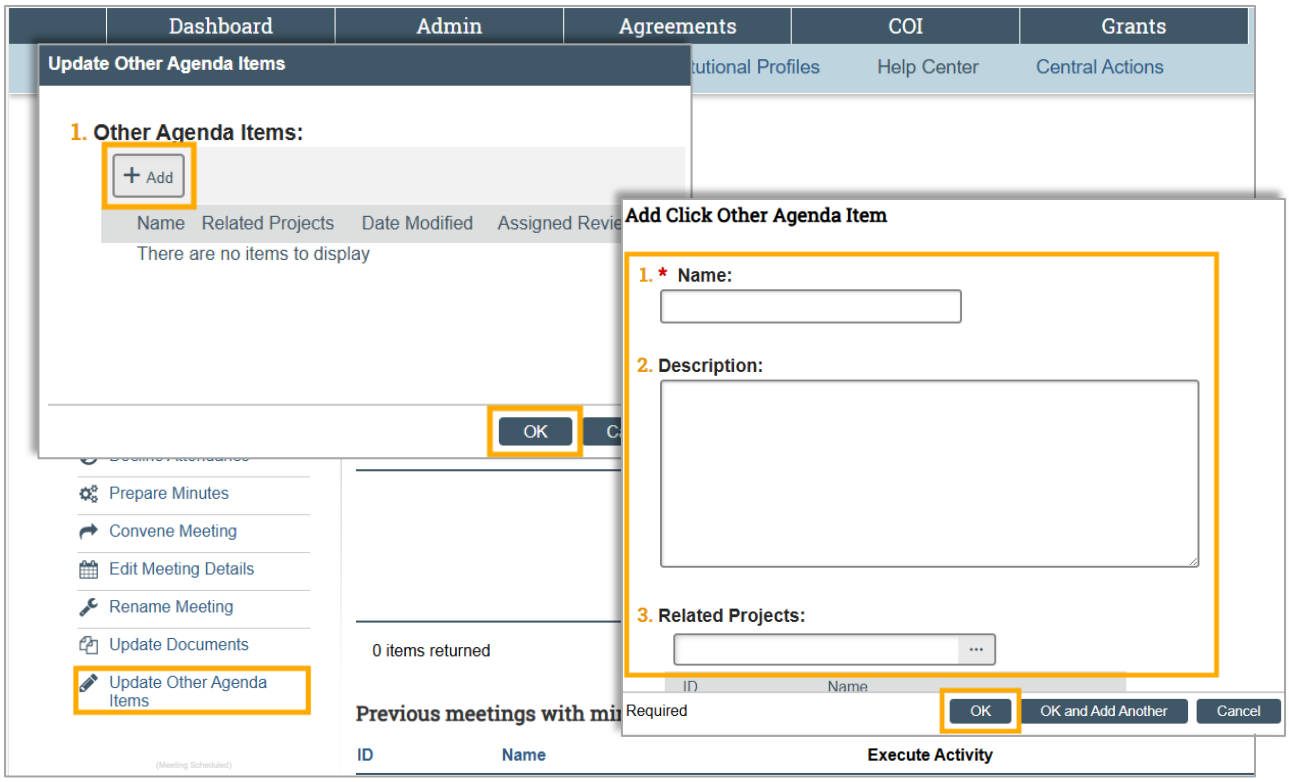
1. From the meeting workspace, click **Update Documents** to add any supporting documents to the meeting.
2. Complete the forms and click **OK**. The documents are displayed in the Supporting Documents tab.



To add other items to the agenda

You can add text-based items, and links to related projects to the agenda.

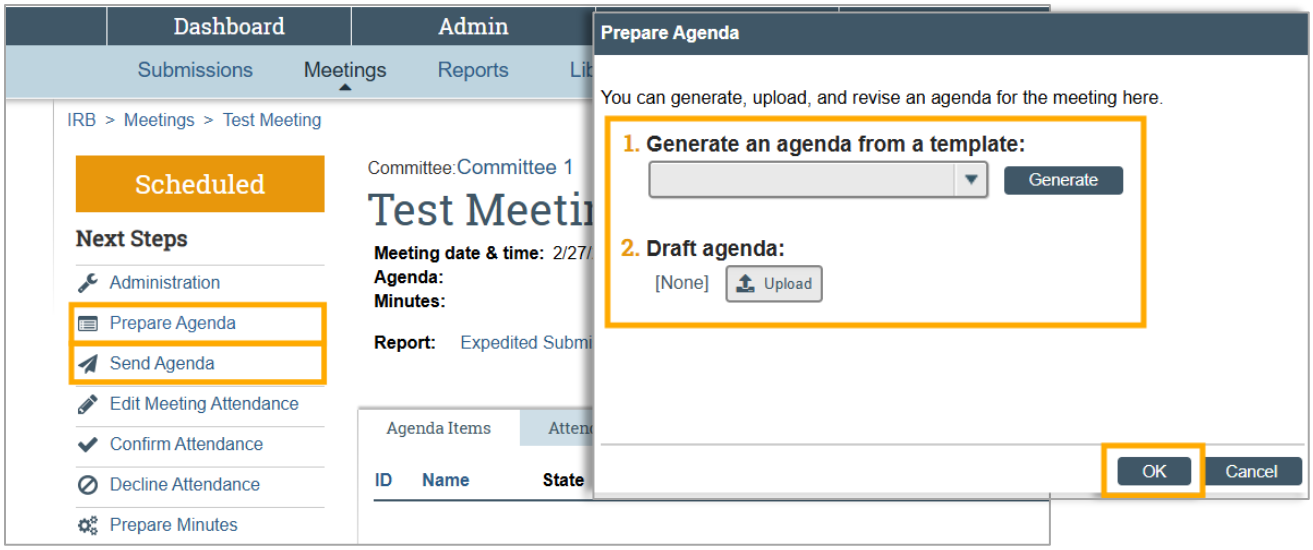
1. From the meeting workspace, click **Update Other Agenda Items**.
2. Click **Add**.
3. Complete the forms, add a related project if desired, and click **OK**.
4. When done adding items, click **OK**. The items you added are displayed in the Other Agenda Items section below the list of submissions
5. (Optional) Assign Reviewers to the new items from the meeting workspace. (See To assign reviewers).



To prepare and send the agenda

You can prepare the agenda from the meeting workspace.

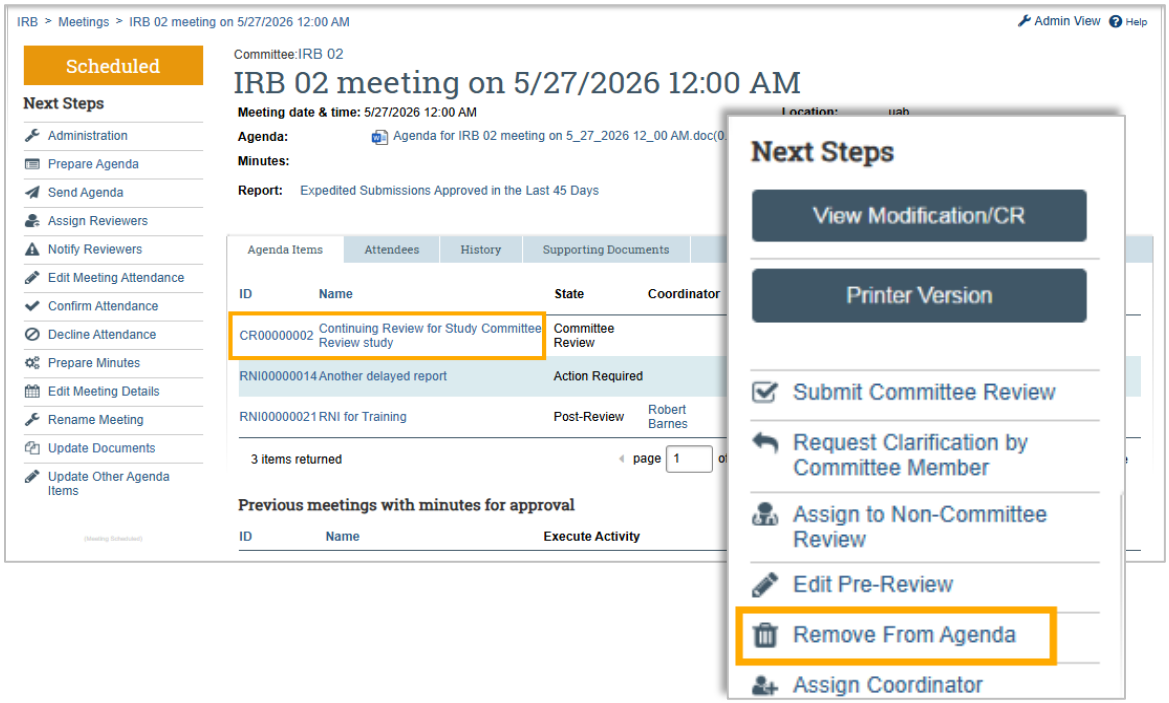
1. Click **Prepare Agenda** and generate an agenda or upload your own agenda document.
2. Click **Send Agenda** to e-mail the agenda to committee members.



To remove an agenda item

You can remove a submission or other item from the agenda.

1. To remove a submission, click the submission name and then click **Remove from Agenda** in the submission workspace.
2. To remove a non-submission (other) agenda item:
    a. Click **Update Other Agenda Items**.
    b. Click **X** (delete button) on the right of the item.

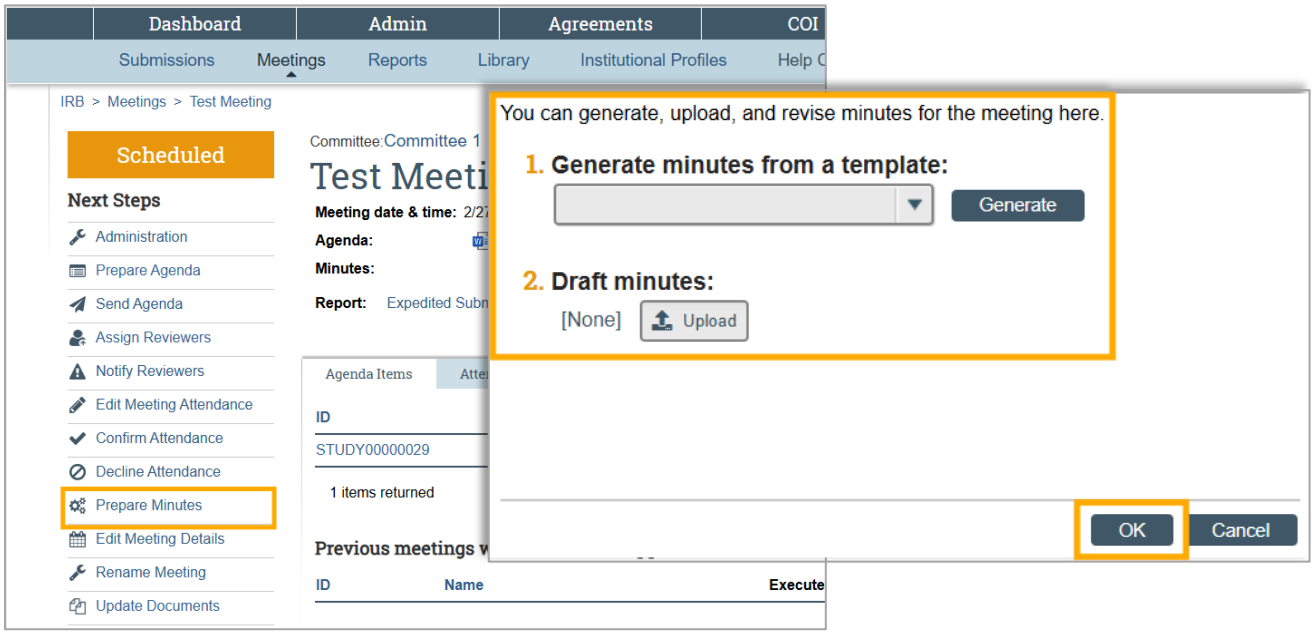


Conduct Committee Meetings

During committee meetings, the committee administrator typically prepares minutes, records submission and non-submission information, and displays submissions to aid the committee's discussion.

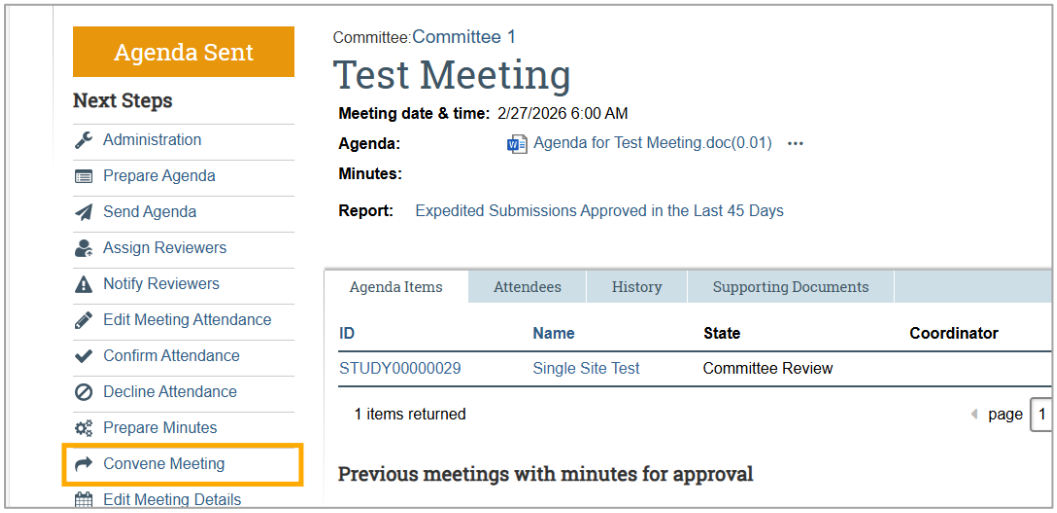
To prepare minutes

1. (Optional) To create a meeting minutes document to update during the meeting, from the meeting workspace click **Prepare Minutes** and generate the minutes from a template. Save the document to your local system and update it during the meeting.
    a. **Tip**: Use Track Changes in Word so later you can copy your notes into the final minutes document.



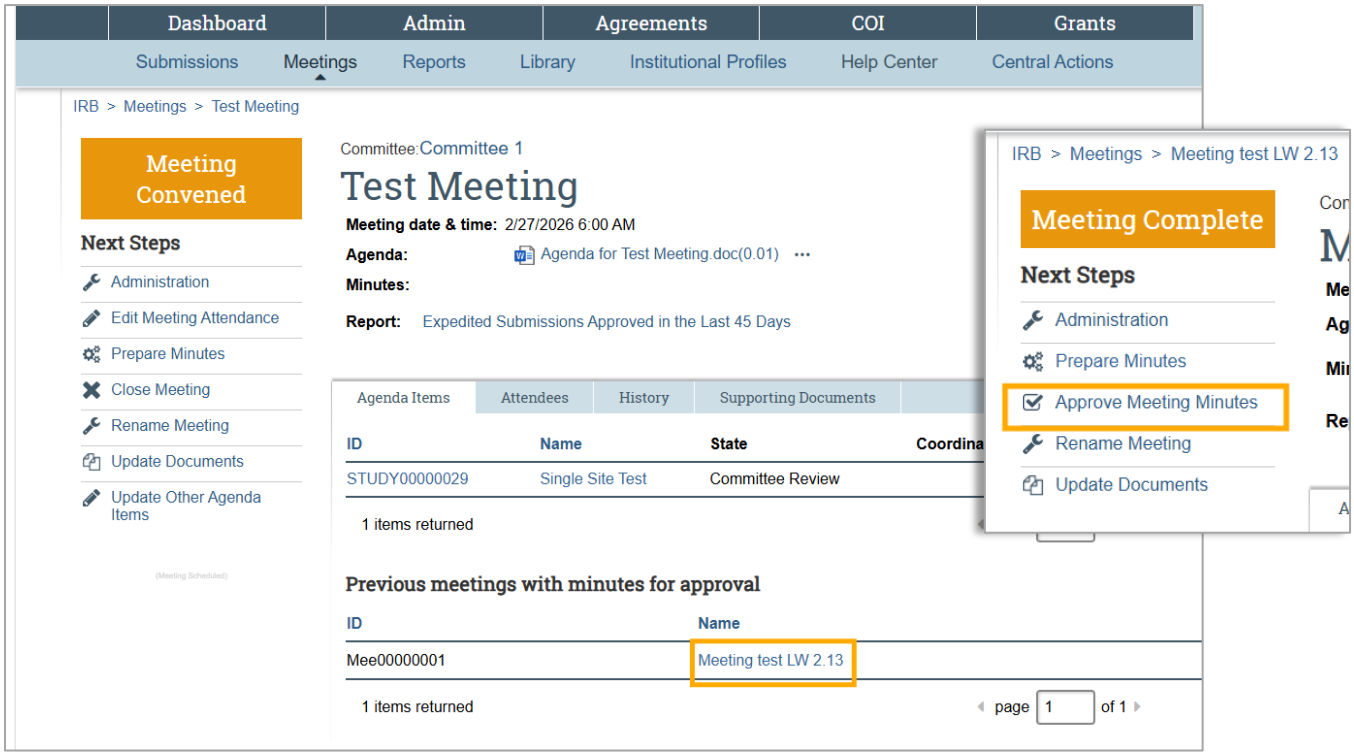
To start the meeting

To start the meeting, click Convene Meeting.



To approve previous meeting minutes

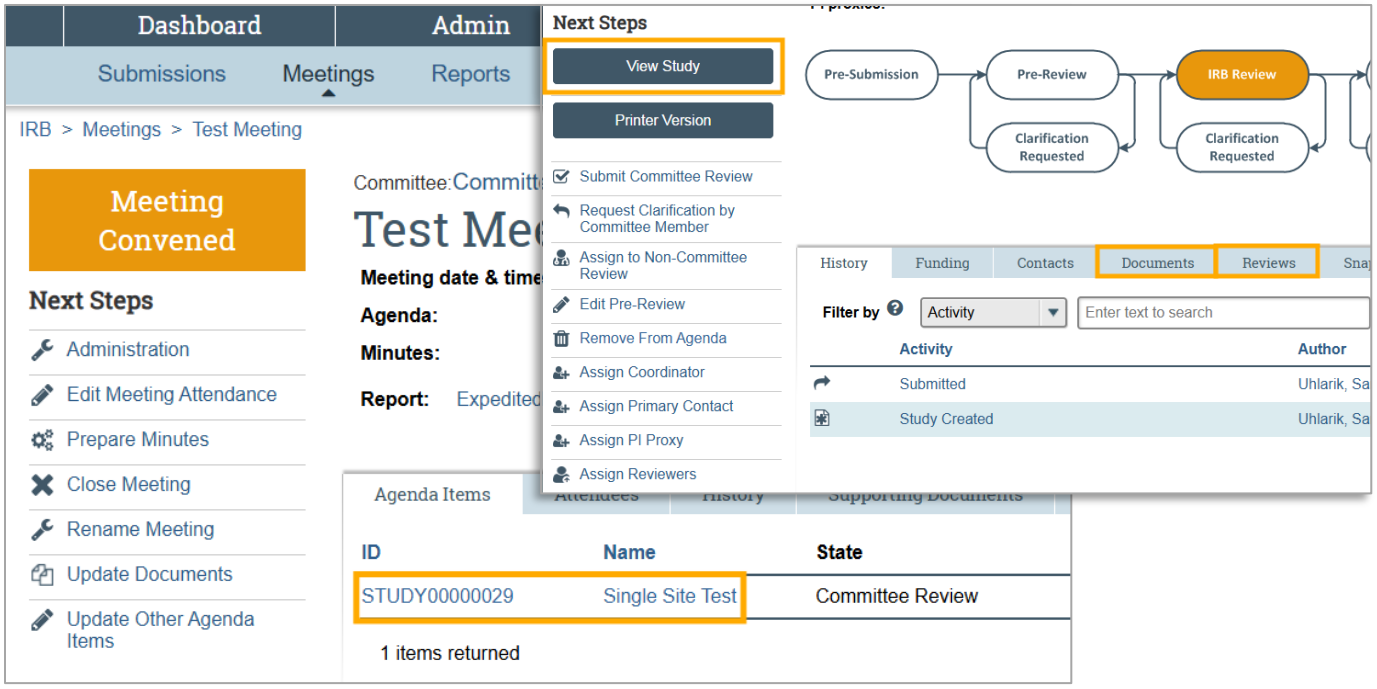
(Optional) From the meeting workspace on the Agenda Items tab, under Previous meetings with minutes for approval, click a previous meeting to go to its workspace. Then you can display its minutes, approve them, and return to the current meeting.



To display submission details

It may be helpful to display submission information and reviewer comments during the meeting.

1. From the meeting workspace:
    a. To view submission information, click the submission ID or name on the **Agenda Items** tab.
2. From the submission workspace:
    a. To show detailed contents of the forms, use the **View Study** button.
    b. To show attached documents, use the **Documents** tab.
    c. To show information recorded during previous reviews, as well as committee, meeting, and reviewer assignments, use the **Reviews** tab.



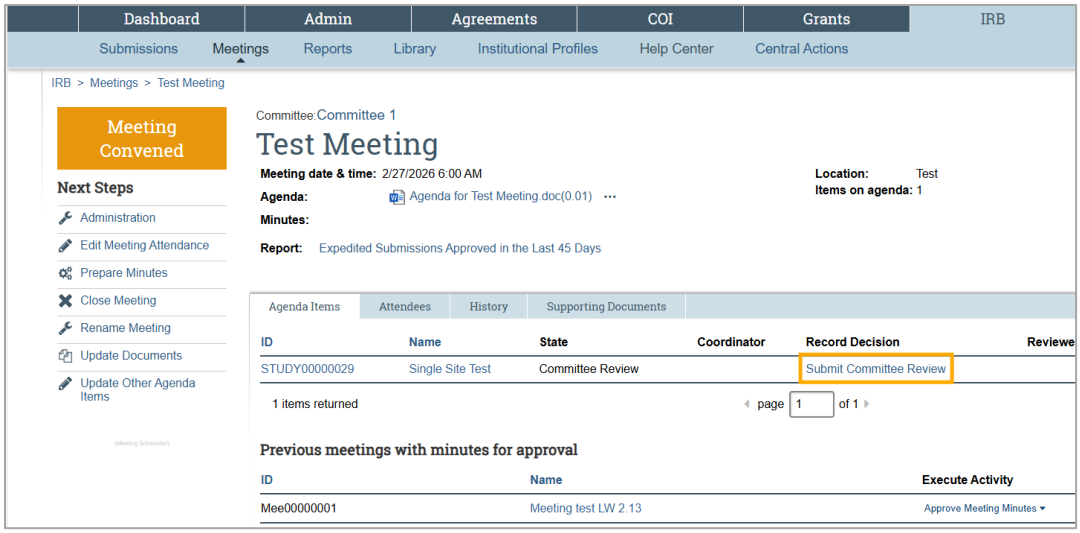
Submit Committee Reviews

Once the committee has reviewed a submission or other agenda item and determined how to handle it, a coordinator, committee admin, or committee chair typically records the committee's decisions.

To submit a review

For each submission, you must record the committee decision, which will appear in the generated letter and meeting minutes.

1. From the meeting workspace, on the Agenda Items tab under Record Decision, click **Submit Committee Review**.
    a. **Tips**: You can also click the name of the submission and submit the review from the submission workspace. From the meeting workspace, check the Record Decision column next to the submissions. The column will show a link to an activity for any submission that has not yet had a decision recorded.

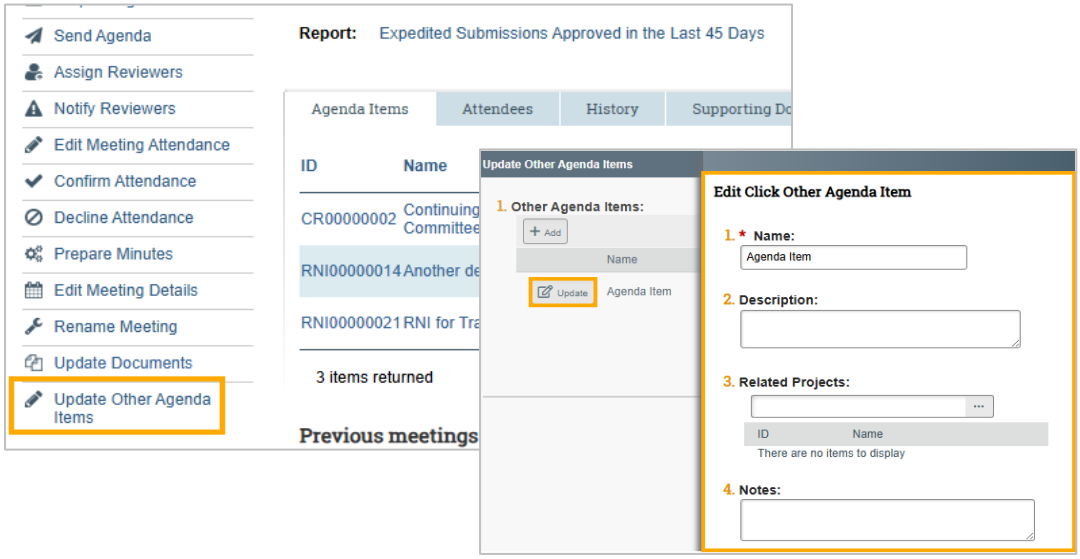


2. Complete the resulting form.
3. Click **OK** to submit the committee review. The submission enters the Post-Review state, which enables you to notify the researcher of the review decision.
    a. **Important!** Do not miss the Submit Committee Review step. Letters cannot be prepared and sent to researchers until this step has been completed.

To update other agenda items

You can record decisions about non-submission agenda items, which will appear in the generated meeting minutes.

1. From the meeting workspace, click **Update Other Agenda Items**.
2. Click **Update** next to the item.
3. Add notes reflecting the decision and click **OK**. Both the description and notes will appear in the meeting minutes.

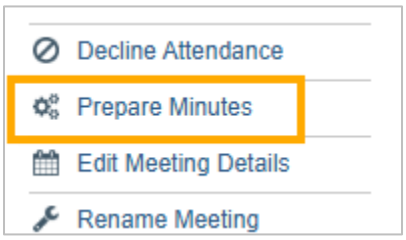


Wrap Up Committee Meetings

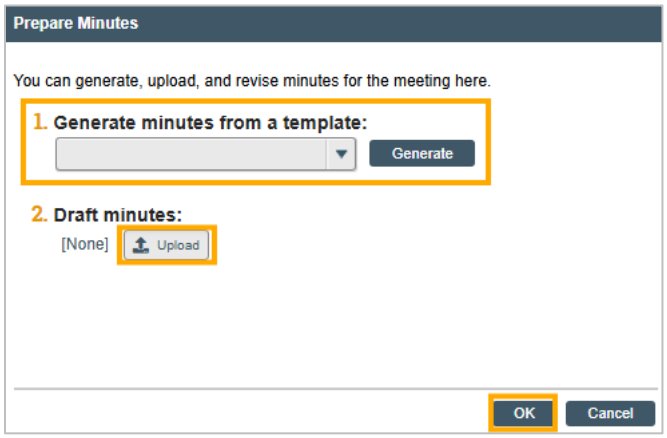
At the end of a committee meeting, committee administrators can prepare the final minutes, close the meeting, and prepare and send correspondence.

To prepare minutes

1. From the meeting workspace, click **Prepare Minutes** to generate new minutes containing committee decisions.

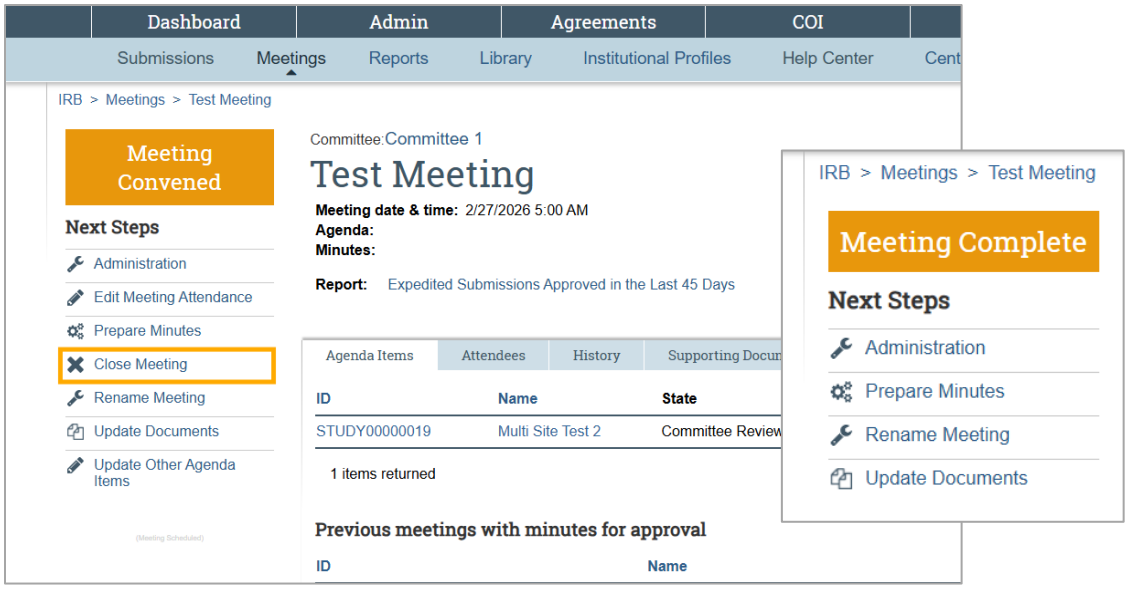


2. Save the meeting minutes document on your local system and revise the document.
    a. Add meeting times and other non-submission information.
    b. Cut and paste your notes from the document used during the meeting to this new document and save it.
3. Click **Prepare Minutes** again to upload the final meeting minutes.
4. Follow your internal processes for obtaining approvals of meeting minutes and sending them to committee members.



To close a meeting

1. From the meeting workspace, click **Close Meeting** to complete the meeting.
2. Inform coordinators and specialists that they can prepare and send letters to researchers notifying them of the committee's decisions.



To approve minutes

Once approvals for meeting minutes have been collected, you can approve minutes in the meeting workspace.

1. From the meeting workspace, click **Approve Meeting Minutes**.
2. In the resulting dialog, select the checkbox to confirm approval.
3. Click **OK**.

Meeting Management Checklists

Well in advance of the meeting:

- ✓ Assign submissions to the meeting agenda (from the submission workspace).
- ✓ If needed, assign reviewers to the agenda items (from the meeting or submission workspace). Reviewers must be committee members.
- ✓ (Optional) Add any relevant documents to the agenda.
- ✓ (Optional) Add any other agenda items, such as text-based items or links to other projects in the system.
- ✓ Prepare the agenda.
- ✓ Send the agenda to committee members and any additional recipients.

Tip: If you assign new items to the meeting or remove items after you have sent the agenda, make sure to prepare and send out the updated agenda.

Just before the meeting:

- ✓ Edit the meeting attendance if you know who is planning to attend.

- ✓ Remove any submissions in the Clarification Requested (Committee Review) state from the agenda, especially if the missing clarification requires delaying the committee decision. Reassign them to a later meeting.

Conducting Committee Meetings

- ✓ (Optional) Prepare the minutes.

Tip: You may wish to record non-submission information such as meeting start and end times using the generated meeting minutes document during the meeting. To do so, prepare the meeting minutes, save the generated document to your local system, and then use it to record the information. After the meeting, copy and paste the items recorded during the meeting into the final version of the minutes. You can then upload the revised final version of the minutes.

- ✓ Convene the meeting in the system.
- ✓ Record meeting times, attendance, and other non-submission items (in the generated minutes document or elsewhere). We recommend dedicating one person to submit the committee reviews and record the non-submission information.
- ✓ (Optional) Approve the minutes from previous meetings.
- ✓ Click the **Expedited Submissions Approved** link to display a report of recently approved submissions.
- ✓ Record decisions, events, and notes.

Tip: If there is not enough time to completely fill out the committee review form during the meeting, finish it as soon as possible after the meeting.

- ✓ From the individual reviewer checklists, reviewer comments, and committee discussion, fill out all relevant checklists to reflect the final committee opinion and reasoning. Then attach these final checklists in the Submit Committee Review activity.

Tip: You have the option to save your incomplete information in the Submit Committee Review form by saying no to Are you ready to submit this review? and then clicking **OK**.

Wrapping up Committee Meetings

- ✓ Make sure the final committee review has been recorded for each submission on the agenda. This is critical before you prepare the minutes and notify the researchers.
- ✓ Update the non-submission (other) agenda items to record the committee decision in the notes field.
- ✓ Prepare the minutes. The generated minutes document will contain the committee decisions for each agenda item, including the description and notes for the non-submission (other) agenda items.
    - Open and save the minutes on your local system.
    - Add the meeting times, attendance, and any other non-submission items to the minutes. **Note**: If you used the minutes template to record information during the meeting, simply cut and paste the information from that document into this version of the minutes.
    - Perform Prepare Minutes again to upload the revised minutes.
    - Send the minutes to the committee members.
    - Follow your internal processes to obtain the appropriate approvals of the meeting minutes.
- ✓ Close the meeting.
- ✓ Inform the coordinator(s) that they can send letters to the researchers.

Tip: Minutes show the most recent determination for an item, not the one at the time of the meeting. If this is a concern, make sure to generate meeting minutes before sending letters, particularly for Modifications Required to Secure Approval items.

- ✓ After the period for receiving comments from committee members has passed, perform Approve Meeting Minutes activity.
  Note: Until you perform this activity, the minutes are listed in the next meeting's workspace with the approve activity available there as well.

Multi-Site Studies

Multi-Site Study Process Overview

This section provides information on multi-site study, site modification, reportable new information, continuing review and multi-site external studies.

Elements of a multi-site study

A multi-site study (MSS) involves research from a single protocol carried out at multiple institutions. For a multi-site study, one institution serves as the single IRB of record (sIRB), and the other institutions serve as participating sites. The sIRB assumes review responsibility for the study at all sites, including the institution where the sIRB is located and any other participating institutions.

Note: The institution's role depends on the particular multi-site study. For example, an institution that serves as the single IRB of record for one MSS can act as a participating site for another MSS.

A multi-site study includes several parts:

- A **study submission** that describes the research and the study-related details of the institution serving as the single IRB of record (sIRB).
- **Site submissions** that represent the study-related details of each participating site (pSite).

The multi-site study will appear differently based on whether you are in the IRB system of the sIRB institution or the IRB system of a pSite institution.

- The sIRB system is where the main multi-site study submission is housed. This includes a study submission, and all the site submissions for every pSite participating in the study. For example, if a multisite study involves 3 pSites, the sIRB system will have 4 separate submissions: 1 study submission, and 3 site submissions (1 for each pSite). Each of these submissions has its own workspace and their own review process. Each site submission is also linked from the study workspace.
- The pSite system only includes an abbreviated version of the multi-site study, including 1 study submission and 1 site submission, which is the pSite's own site submission. The site submission is editable in the pSite system, but the study submission is read-only. A multi-site study may have more than one pSite associated with the study, but an institution that is serving as a pSite will only see the site submission for their institution.

Study review process

The Principal Investigator (PI) at the sIRB institution initiates the study, specifying that the study is multi-site and that their local institution will serve as the single IRB of record for participating institutions. This is when the study submission is created.

Once the study submission is created, the PI, study team, and IRB staff can add participating sites to the study. Site submissions are created after the study reaches the Pre-Review Complete state; each newly created site corresponds to each participating site added to the study submission. The PI and study staff can continue to add participating sites after the study is in the Pre-Review Complete state. New site submissions are created immediately in the sIRB's system when participating sites are added in Pre-Review Complete and later states.

The study submission moves through the standard review process in the same manner as a single-site study.

Site review process

The site submissions require review from both the sIRB institution and the participating site institution.

Users on both the sIRB and pSite systems will manually enter and update site data on their respective systems. In this scenario, the submission in the pSite system resembles an externally-reviewed study with an associated site submission. In some cases, with prior agreement, the pSite PI, primary contact, and PI proxies may be granted account access to the sIRB system so that they can edit the site submission directly in the sIRB system.

For a more detailed explanation of the site review workflow for institutions, see the following table.

Site review workflow

#	Action	Description
Creation of Site Submissions		
1.	Create a Multi-Site Study	After a PI and study team create a multi-site study submission, the study team and IRB staff add participating institutions to the study using the **Manage Participating Sites** activity. This activity relies upon Institutional Profiles (IPs) already created in the system to represent the pSite institutions. IPs include authorization agreements and pSite contact information.
2.	Submit Study	The PI submits the study to the IRB for review, thus starting the Study Review Process. Upon reaching the Pre-Review Complete state, site submissions are created in the sIRB system for all pSites associated with the study. **Note**: After Pre-Review Complete, the study team and IRB staff can add additional pSites.

Site Submission Workflow		
3.	Submit Invitation	A site submission in the sIRB system begins in the Invitation Pending state. For each site, the assigned coordinator uses the Submit Invitation Decision activity to invite a pSite to join the study (or to disapprove the pSite's participation, thereby deactivating that site). When a site is invited, the pSite PI and institutional contacts are notified. The site submission moves to the Awaiting Site Materials state and remains in that state until the site submission information is completed by the pSite.
4.	Download Study	When the pSite receives an invitation to participate, the reliance coordinator downloads a read-only copy of the onto their own system. A site submission will need to be created in their system.
5.	Edit and Submit Site	The study team enters their local site information on a series of pages, including information about the local study team, research locations and local consent forms. They send their completed site submission back to the pSite's IRB for Pre-Review. **Important!** The pSite PI cannot submit the site submission until the study has been approved.
6.	Confirm Reliance	When the assigned coordinator is satisfied that the site submission is complete and the necessary agreements and communication plans with the sIRB are in place, they use the **Confirm Reliance** activity to confirm that they accept review by a sIRB of record. Now, the site submission is in a Pending sIRB Review state on the pSite system. It will remain in this state until the sIRB completes their review of the site submission.

7.	sIRB Reviews the Site Submission	In the sIRB system, the assigned coordinator updates the site information and then uses the **Site Materials Received** activity to confirm receipt. The site is now in the Pre-Review state in the sIRB system. The site first undergoes Pre-Review, in which an assigned IRB coordinator reviews the site submission, ensures it includes all the necessary information, and assigns it to a committee meeting or a designated reviewer. During IRB Review, a designated committee member or the full committee reviews the site. Once a determination is submitted, the system moves the site to PostReview. **Important!** If the associated study is not yet approved, IRB staff cannot submit designated or committee reviews. Once the study is approved, the site workflow can resume. During Post-Review, the IRB coordinator sends the determination letter. If the site is approved, it moves to the Active state in the sIRB system. If the site submission requires changes, it moves to Modifications Required.
8.	Record sIRB Decision	The assigned coordinator in the pSite updates the site information and uses the **Record sIRB Decision** activity. The coordinator can choose to proceed to Post-Review to send a letter or to skip to the next appropriate state. **Important!** If the associated study is not yet approved, the pSite will not be able to record the sIRB decision for the site. If the site is approved, it moves to the Active state in the pSite system. If it requires changes, it moves to the Modifications Required state. From Modifications Required, the pSite PI can modify the site submission.

Site modification process

Modifications to active sites require additional review. Modifications fall into the following categories:

- Changes that affect the study team membership and research locations. These modifications only require local review by IRB staff.
- Changes that affect other parts of the site submission. These modifications require review by the sIRB of record.

- Changes that affect both categories. These modifications also require review by the sIRB of record.

Note: Modifications to a multi-site study submission (as opposed to a site submission) follow the regular study modification process.

Site modifications to the study team membership or to research locations follow an abbreviated local review process:

1. The pSite PI creates and submits the site modification, moving it into the Pre-Review state.
2. A pSite IRB staff member reviews the modification and either requests clarifications or approves the modification using the **Accept Site Updates** activity.
3. If the pSite staff decides that finalized documents or a letter are required, the modification is sent to PostReview, then to Review Complete.
   Note: If no documents or letters are required, the modification is directly sent to Review Complete.

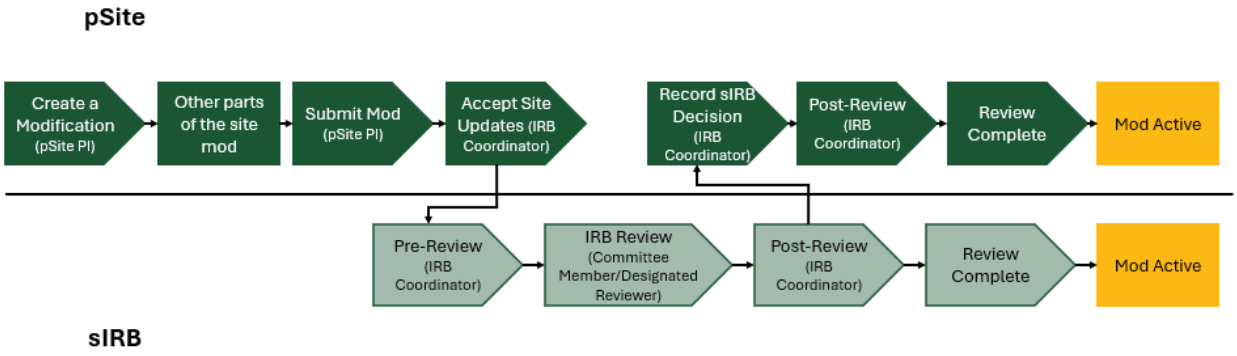
The following diagram illustrates the tasks, roles, and states involved in the creation and review of a site modification that only requires local review:



Site modifications to other parts of the site require sIRB review:

1. After the pSite PI or study team member submits the modification, pSite IRB staff approves the modification on the pSite system using the **Accept Site Updates** activity.
2. On the sIRB side, sIRB staff take the modification through the review process. While this happens, the modification remains in the Pending sIRB Review state on the pSite system.
3. Once the sIRB review is completed, pSite IRB staff record the sIRB decision, moving the modification to either Post Review (if a letter is required) or Review Complete on the pSite system.
   Note: If modifications are required for approval, the modification submission moves to Modifications Required. The pSite PI can then submit a response to the sIRB, which moves the modification submission back to Pending sIRB Review until a new determination is received by the pSite and recorded in the pSite system.

The following diagram illustrates the tasks, roles, and states involved in the creation and review of a modification that requires sIRB review.



Note: A modification (of any category) that is disapproved remains active until the modification is either approved (which applies the modifications to the study) or discarded (in which case, no modifications are applied to the study).

Reportable New Information for a Multi-Site Study Process

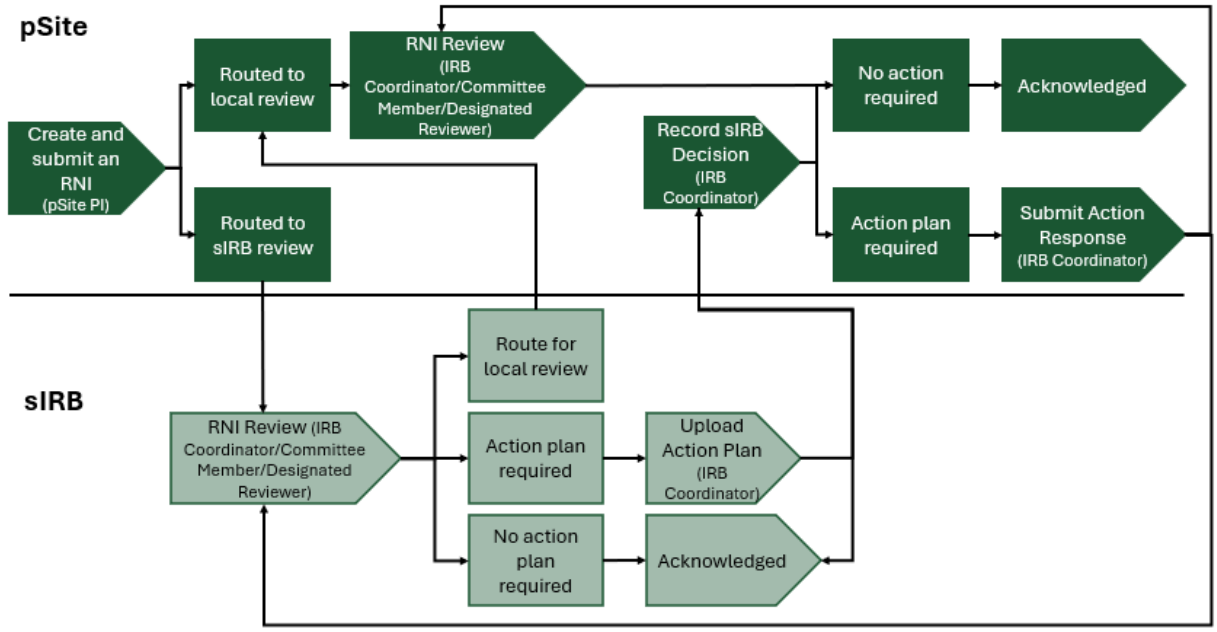
The review process for reportable new information (RNI) associated with a multi-site study differs depending on whether the RNI originates from the sIRB or the pSite system, and on where the RNI is routed for review. An RNI originating from the sIRB system follows a review process like that of single-site study RNIs.

For an RNI originating from the pSite system:

1. The study team on the pSite system creates an RNI submission. When the study team or IRB staff relates a multi-site study to the RNI, the system automatically captures which site is reporting the information.
2. Depending on the institutional profile (IP) settings applied to the sIRB institution, the RNI may be routed to either local or sIRB review on submission:
    a. If the IP for the sIRB institution specifies that all RNIs should be routed to the sIRB for review, then a notification is sent to the sIRB.
    b. If not, the RNI is routed for local review.
    Note: After submission, an IRB coordinator in the system the RNI has been routed to can change this selection and route the RNI to the other system (for example, the sIRB coordinator can choose to route the RNI for local review) by using the **Route for**… activities in the RNI workspace. A notification is sent when the RNI is re-routed.
3. If the RNI is sent for sIRB review:
    a. The RNI begins in the Pre-Review state. **Note**: The sIRB cannot request clarification on RNI's created by a pSite.
    b. The RNI moves through the IRB Review process (which may include local review by a designated reviewer, full committee review, or both) and is sent to Post-Review, where further actions may be required, and eventually to Review Complete.
    c. On the pSite system, a staff member can record the sIRB decision and move the RNI to the Post-Review or Review Complete states.
4. If the RNI is sent to local review:
    a. A pSite IRB staff member reviews the RNI and either requests clarifications or submits a pre-review.

b. Depending on the staff member's pre-review determination, the RNI remains in Pre-Review pending assignment for further review, or goes straight to Review Complete if the reported issue is neither serious nor continuing.
c. RNI's that require further review are sent through the local IRB review process, which may include local review by a designated reviewer, full committee review, or both.
d. Next, the RNI is sent to Post-Review, where further actions may be required, and eventually to Review Complete.

The following diagram illustrates the tasks, roles, and states involved in the creation and review of an RNI.



Continuing Review Process

A continuing review (CR) for a multi-site study requires data from the sIRB institution and from all pSites associated with the study. While the pSite is responsible for reporting CR data from their site, the sIRB PI is responsible for creating and submitting a CR that encompasses the entire multi-site study.

For a pSite, the process is simple:

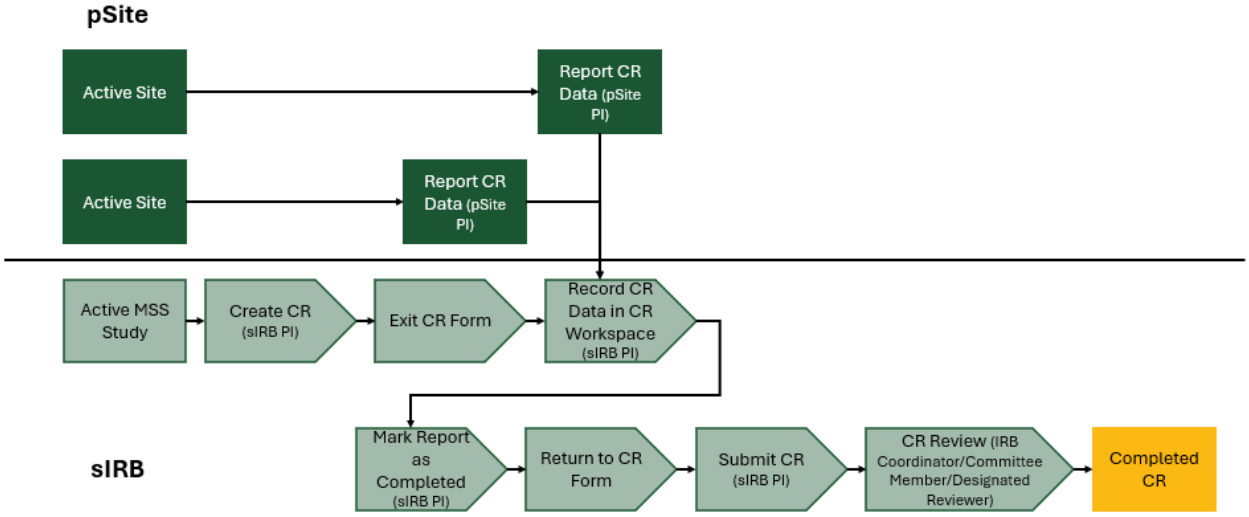
1. The PI on the pSite system receives reminders beginning 90 days before a continuing review is due and reports CR data from the site workspace using **the Report Continuing Review Data** activity.
    a. The pSite PI must manually send their CR data to the sIRB so the sIRB PI can manually enter the data into a continuing review submission.
2. After the pSite PI reports the data, the CR is in the hands of the sIRB PI.

The sIRB system is where the bulk of the CR process takes place. When the sIRB PI is ready to complete a continuing review, they have a few options:

1. The sIRB PI can complete steps 4-5 above in the CR workspace, except that they must manually enter the CR data from a site into the **Report Continuing Review Data** activity.

2. The sIRB PI can manually enter data into the CR form as they receive it from pSites.

The following diagram illustrates the tasks, roles, and states involved in the creation and review of a continuing review.



External IRB Process for a Multi-Site Study

The workflow for a multi-site study and a single-site study where the local IRB cedes authority to an external IRB are similar. The difference is in the amount of information collected: A multi-site study collects both study and site information, so the SmartForm is considerably longer.

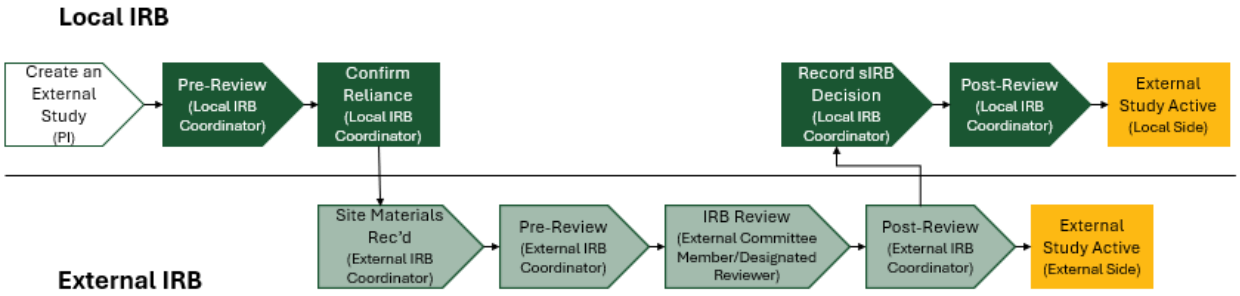
Note: The local IRB communicates with the external IRB, then records the external IRB's determination using the Record sIRB Decision activity.

1. During Pre-Submission when the study team is creating the study, they will indicate that they are using an external IRB. For a multi-site study, the study team records both study information (Study SmartForm pages include: Basic Study Information, External IRB, Study Funding Sources, Study Scope, and Study Related Documents) and site information (Site SmartForm pages include: Basic Site Information, Additional Local Funding Sources, Local Study Team Members, Research Locations, and Local Site Documents).
2. During Pre-Review, the assigned coordinator conducts their administrative review of the study, including the external IRB information, and can send the study back to the study team for more information or clarification as needed. When all the information has been supplied, the coordinator uses the **Confirm Reliance** activity to confirm that an external IRB is able to oversee the review process.
3. The study will move to the Pending sIRB Review state. If the study needs to be revised while in the Pending sIRB state, the assigned IRB coordinator or study staff can directly edit the study.
4. Once the external IRB communicates their decision, the local IRB coordinator records the decision using the Record sIRB Decision activity. The Record sIRB Decision activity is where you will record which Common Rule regulatory requirements apply to the study – Pre-2018 or 2018. Depending on the decision, and whether the coordinator needs to finalize documents and send an acknowledgement letter, the study moves to the Post-Review, Modifications Required, or Review Complete state:

a. In the Modifications Required state, the coordinator or PI can respond to the external IRB.
b. During Post-Review, the IRB coordinator can prepare and send the acknowledgement letter and finalize documents.
c. Once the study is in the Review Complete state, the local IRB process is complete.

Note: All submissions reviewed by an external IRB are always found on the External IRB tab.

The following diagram illustrates the review process for a multi-site study external submission.



sIRB System Site States and Transitions

The table below outlines the possible states for a site submission in the sIRB system.

In this state…	These roles…	Can perform these actions…	Changing the state to…
Invitation Pending	IRB Coordinator, IRB Director	Submit Invitation Decision	Inactive
			Awaiting Site Materials
Awaiting Site Materials	IRB Coordinator, IRB Director	Site Materials Received	Pre-Review
Pre-Review	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
Non-Committee Review	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
		Submit Site Designated Review	Post-Review
Committee Review	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review

	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit Site Committee Review	Post-Review
Post-Review	IRB Coordinator, IRB Director	Send Letter	Deferred
			Modifications Required
			Active
			Inactive
Deferred	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
Active	IRB Coordinator, IRB Director	Update Site Status	Inactive
			Suspended
			Terminated
		Return to Post-Review	Post-Review
		Close Site (Admin)	Closed
Modifications Required	IRB Coordinator, IRB Director	Site Materials Received	Modifications Submitted
Modifications Submitted	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
	IRB Committee Chair, IRB Coordinator, IRB Director	Review Required Modifications	Post-Review
			Modifications Required
Inactive	IRB Coordinator, IRB Director	Record Response	Pre-Review
			Invitation Pending
		Update Site Status	Suspended
			Terminated
		Close Site (Admin)	Closed
Suspended		Update Site Status	Suspended

	IRB Coordinator, IRB Director		Terminated
		Close Site	Closed
All states prior to Post-Review	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

pSite System Sites States and Transitions

The table below outlines the possible states for a site submission in the pSite system.

In this state…	**These roles…**	**Can perform these actions…**	**Changing the state to…**
Pre-Submission	Investigator	Submit	Pre-Review
Pre-Review	IRB Coordinator, IRB Director	Confirm Reliance	Pending sIRB Review
			Inactive
		Request Clarification	Clarification Requested (Pre-Review)
	IRB Coordinator, Reliance Coordinator, IRB Director	Accept Site Updates	Post-Review
			Approved
			Pending sIRB Review
Clarification Requested (Pre-Review)	Investigator	Submit Response	Pre-Review
Pending sIRB Review	IRB Coordinator, IRB Director	Record IRB Decision	Approved
			Post-Review
			Deferred
			Modifications Required
			Active
			Inactive
Modifications Required	IRB Coordinator, IRB Director	Submit Response	Pending sIRB Review

	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded
Deferred	IRB Coordinator, IRB Director	Submit Response	Pending sIRB Review
Disapproved*	IRB Coordinator, IRB Director	Submit Response	Pending sIRB Review
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded
Post-Review	IRB Coordinator, IRB Director	Send Letter	Approved
			Disapproved*
			Deferred
			Modifications Required
			Active
			Inactive
		Edit sIRB Decision	Approved
			Disapproved*
			Deferred
			Modifications Required
			Active
			Inactive
Active	IRB Coordinator, IRB Director	Deactivate Site	Inactive
		Return to Post-Review	Post-Review
		Close Site	Closed
Inactive	IRB Coordinator, IRB Director	Record Response	Pre-Review
		Close Site	Closed
		Activate Site	Active
All states prior to Post-Review	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

* Only site modifications use the Disapproved state. Initial site submissions move to the Inactive state after receiving a Disapproved determination.

sIRB Coordinators

This section shows how to perform basic actions of a single IRB of record coordinator. It provides information on creating an institutional profile, corresponding with a site, submitting an invitation decision to a pSite, recording the sIRB decision for an external study, accepting site updates for a multi-site external study and updating study details for a multi-site external study.

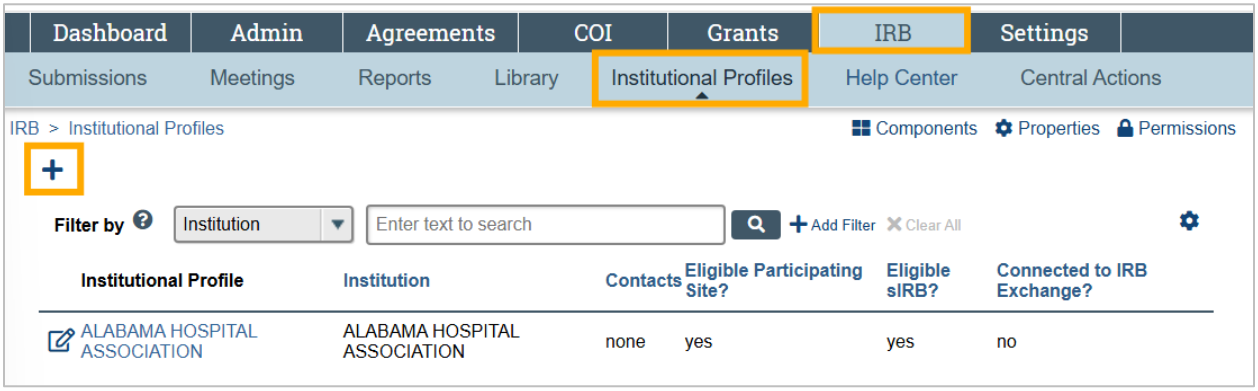
Create an Institutional Profile

Institutional profiles contain a record of information about institutions with whom your institution collaborates on multi-site research. Researchers use institutional profiles to add participating sites to studies, but before they do so, you must create them in your system.

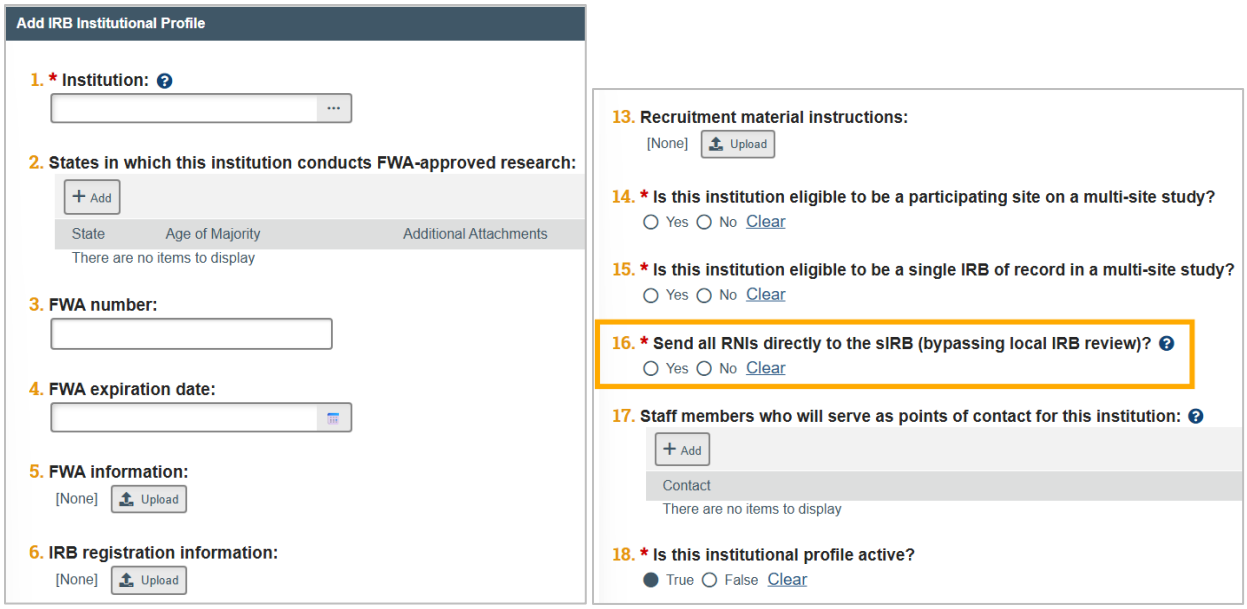
Who performs this activity?	When to perform this activity
Reliance Coordinator on the sIRB side	The Reliance Coordinator must create Institutional Profiles before investigators can add participating sites to their multi-site studies.

To add an institutional profile

1. In the Top Navigator, click **IRB**.
2. In the Sub-Navigator, click **Institutional Profiles**.
3. On the left side, click the plus sign to add.



4. Complete the form. Pay attention to the following question:
    a. **Send RNIs directly to the sIRB (bypassing local IRB review)**: This determines whether Reportable New Informations (RNIs) originating from a pSite are sent to local IRB review or if they are automatically sent to the sIRB institution for review.



5. Click **OK**.

The institutional profile is created.

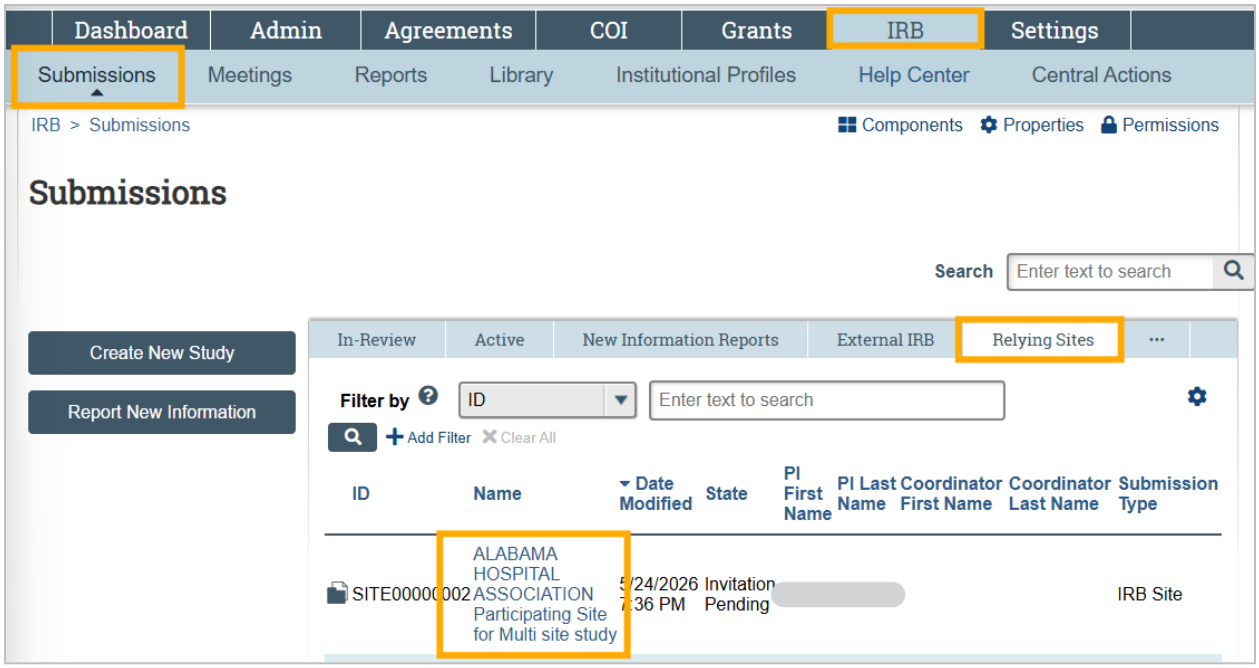
Correspond with a Site

At any point during the review process, you can correspond with the researchers and coordinators at a Site.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	This activity is available before a site is submitted for review and while it is going through the review process.

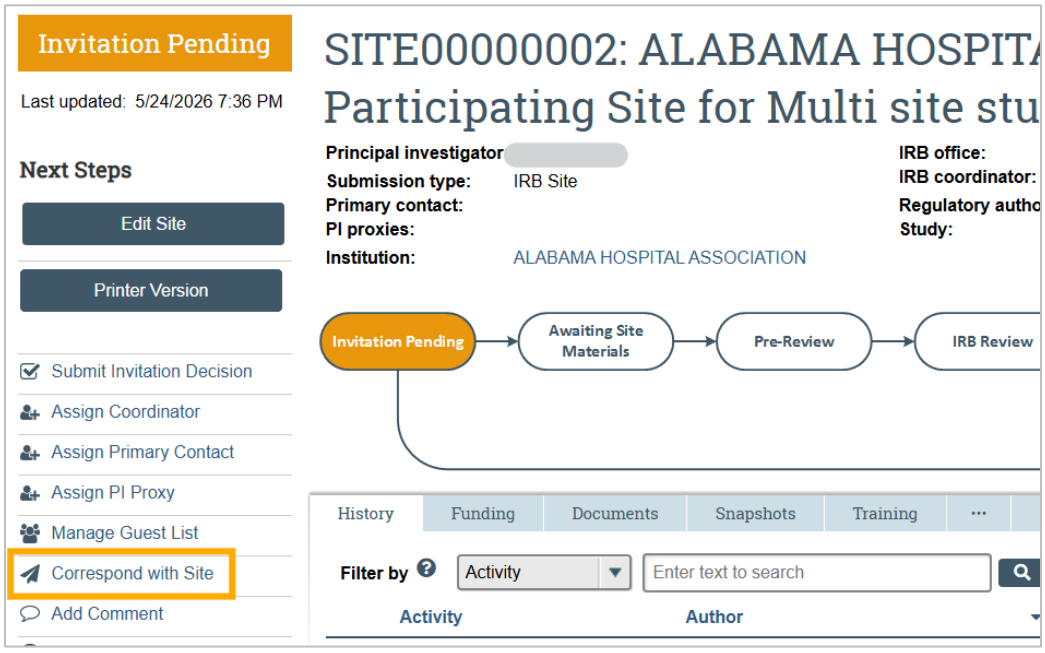
To navigate to the site workspace

1. In the Top Navigator, click **IRB**.
2. In the Sub-Navigator, click **Submissions**.
3. Click the **Relying Sites** tab.
4. Click the name of the site you want to open.
   Note: To find sites related to a specific Multi-Site Study (MSS), navigate to the MSS workspace and click the **Sites** tab.

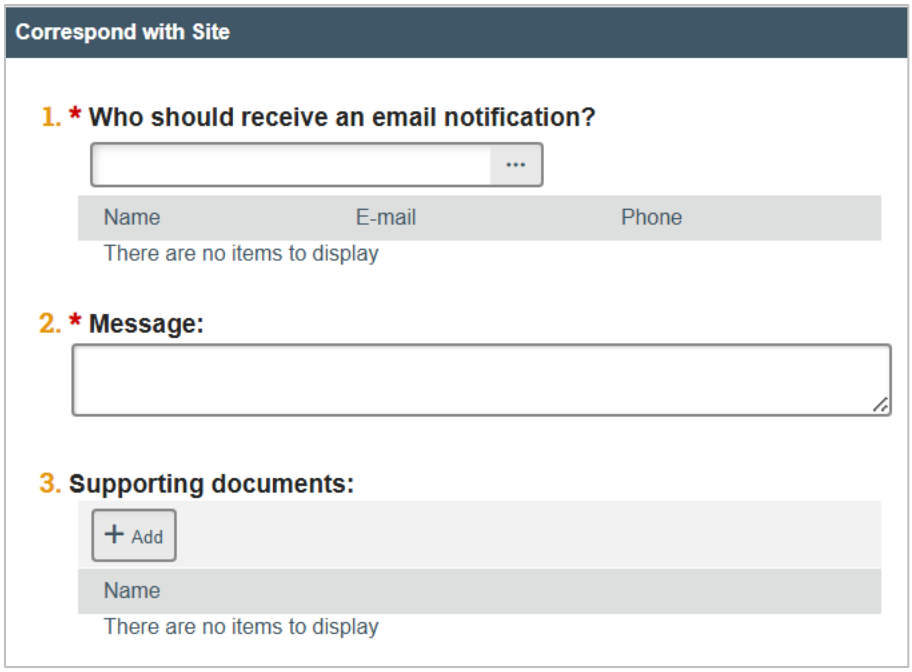


To correspond with a pSite

1. From the site workspace, click **Correspond with Site**.



2. Complete the form and click **OK**.



Your correspondence is sent to the designated receiver.

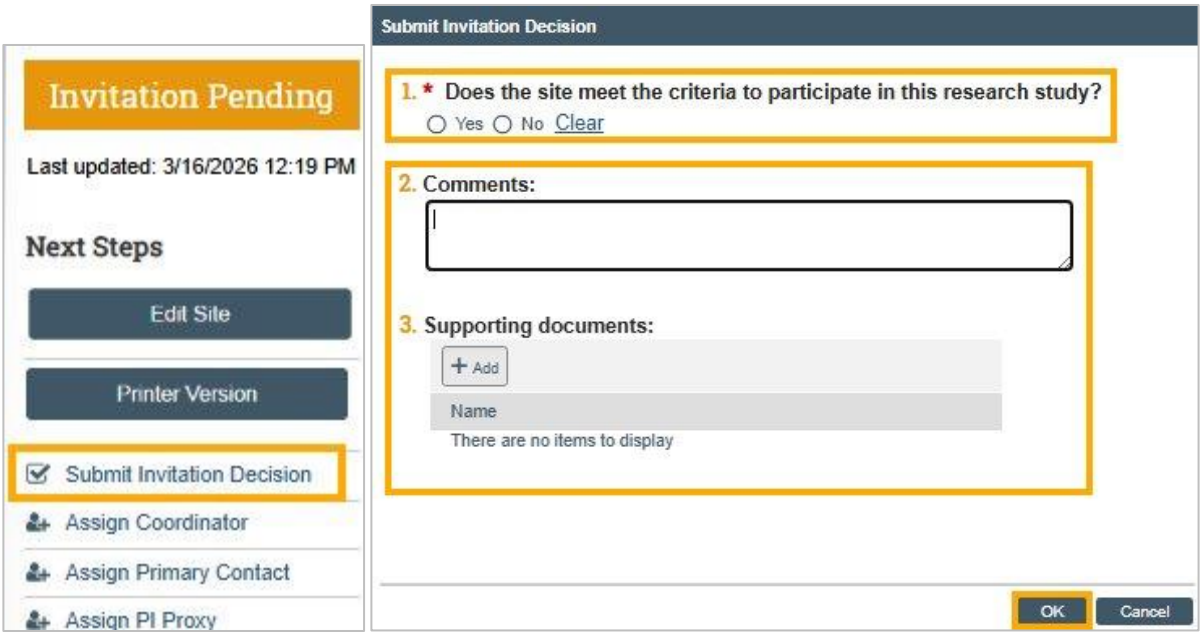
Submit an Invitation Decision to a pSite

Once a study has been submitted to the sIRB for review, you can submit an invitation decision to a pSite.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	After adding a participating site to a multi-site study, and after submitting the study, you can submit invitation decisions to participating sites.

To submit an invitation decision

1. From the site workspace, click **Submit Invitation Decision**.
2. Complete the form and click **OK**.



The pSite PI and institutional contacts are notified.

Mark Site Materials as Received

Once you receive site materials from a pSite, you can mark them as received in order to move to the next state of review.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	After you have received completed materials from a pSite.

To mark site materials received

1. From the site workspace, click **Site Materials Received**.
2. Complete the form and click **OK**.

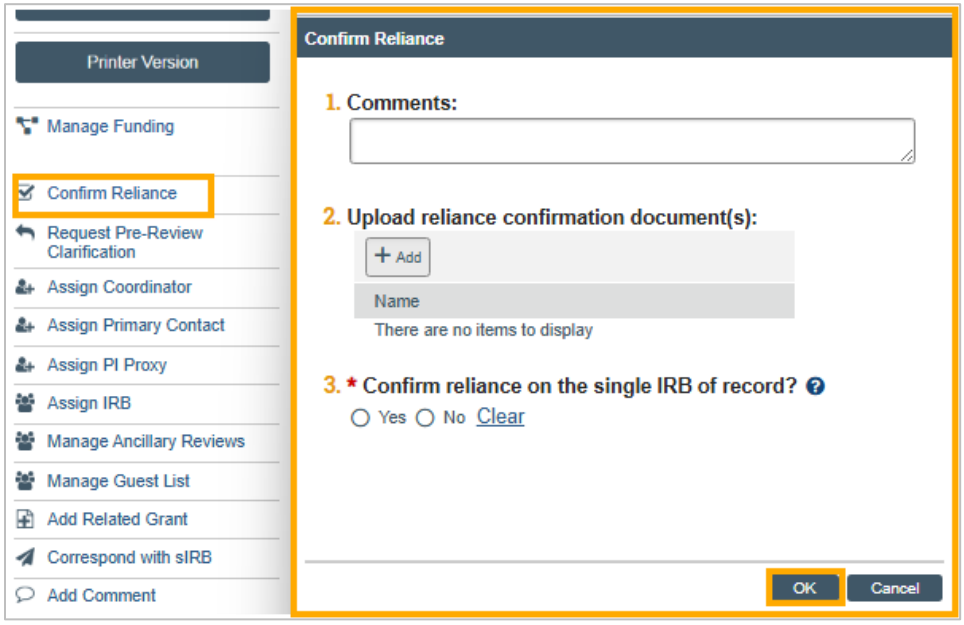
Confirm Reliance on the External IRB

For a multi-site external IRB study, you must confirm reliance on the external IRB before the submission can move forward in the review process. From the Submissions link, click the **External IRB** tab, then open the study.

To confirm reliance

1. From the site workspace, click **Confirm Reliance**.

2. Complete the form.
3. Click **OK** to finish.



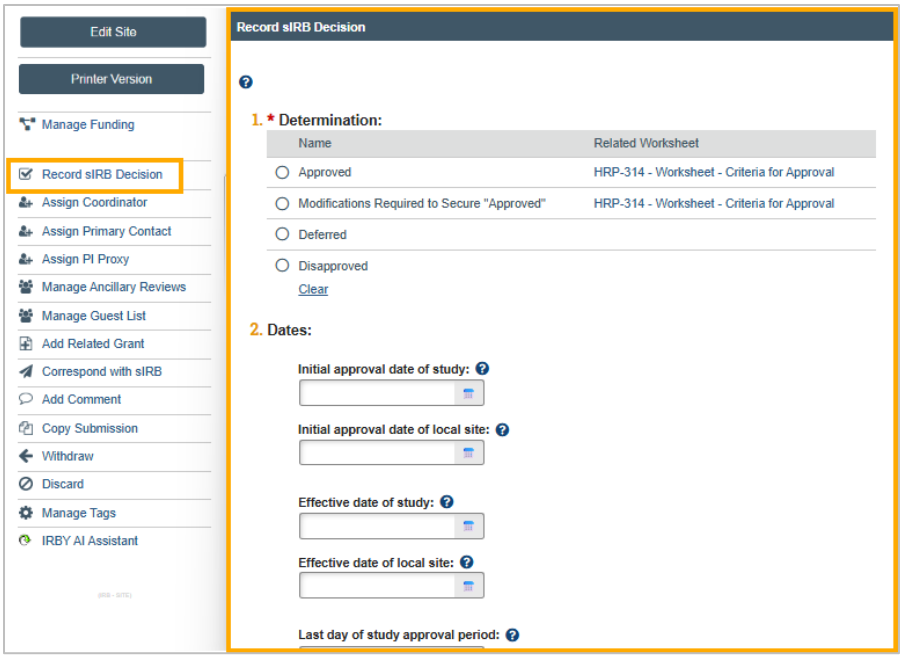
If reliance is confirmed, the site enters a Pending sIRB Review state.

Record the sIRB Decision for an External Study

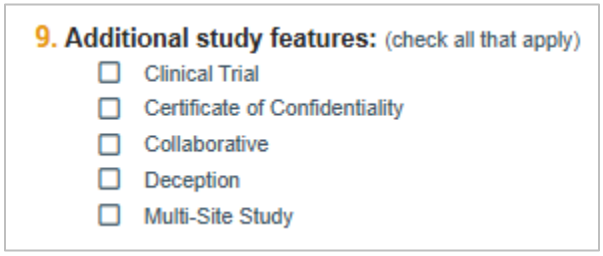
IRB staff record and edit the sIRB decision for an external IRB study.

To record the sIRB decision

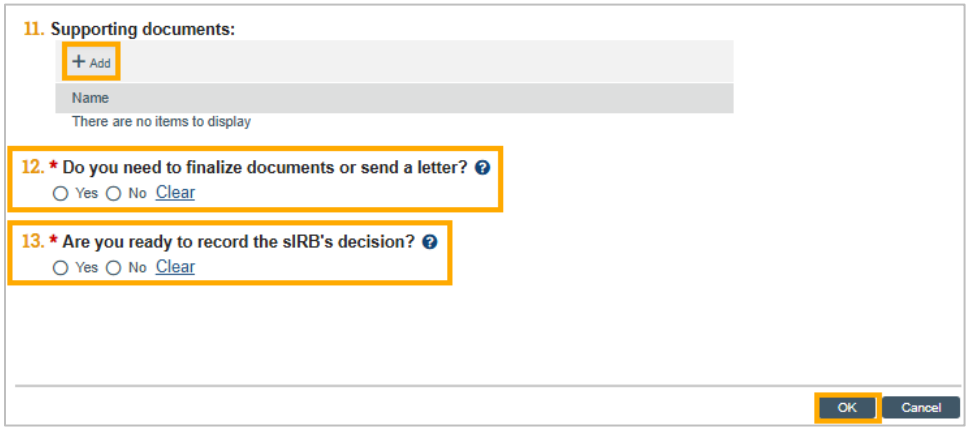
1. From the site workspace, click **Record sIRB Decision**.
2. Complete the form.
   Note: If you select FDA or DOJ in the Regulatory Oversight section, the study will automatically fall under the Pre-2018 Common Rule requirements, even if it falls after the effective date setting of the 2018 requirements.
   Note: Broad consent is not a valid selection for studies falling under the Pre-2018 Common Rule requirements.



3. Indicate whether the study has any additional features.



4. Under Supporting documents, upload appropriate checklists based on the special determination and waivers.
5. For **Do you need to finalize documents or send a letter?**, select **Yes** to send the item to Post-Review, and select **No** to send the item to Review Complete.
6. For **Are you ready to record the sIRB's decision?,** select **No** to note the sIRB determination without recording it and your selections will be saved.
7. Click **OK** to finish.

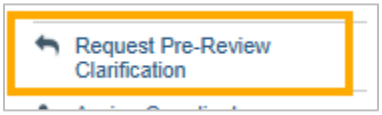


Accept Site Updates for a Multi-Site External Study

For a multi-site external IRB study, you must accept the site updates before the submission will move forward in the review process. If the modification scope is “Study team and research location information”, you will have the option to finalize documents or send a letter. If you pass on these options, the submission moves to Review Complete. If the modification scope is “Other parts of the site”, once you accept the updates, the submission moves to Pending sIRB Review (you do not have the option to finalize documents or send a letter at this point.)

To accept site updates

1. From the site workspace, click **Accept Site Updates**.
2. Notice that you also have the option to Request a Pre-Review Clarification.



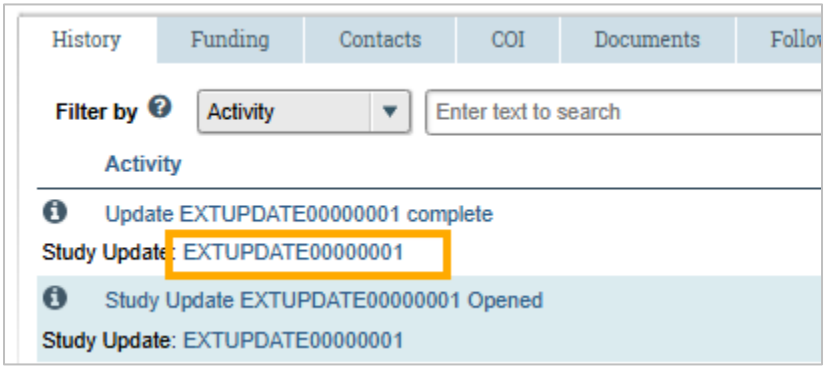
3. Complete the form.
4. Click **OK** to finish.

Update Study Details for a Multi-Site External Study

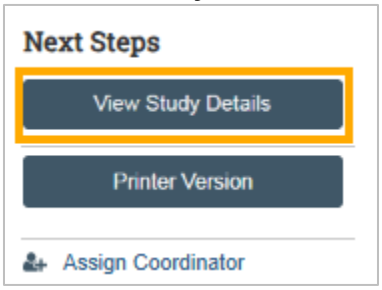
For a multi-site external IRB study, the local IRB is notified when the PI updates study details. Note that the IRB receives the update in the Updates Complete state, so the workflow is complete. But you can still review the update using the procedure described below.

To update study details

1. From the site workspace, open the update.



2. Click **View Study Details** so see the updates.



3. Add a comment if there is an error that needs to be addressed asking the Principal Investigator (PI) to make the change with another update.



pSite Coordinators

This section shows how to perform basic actions of a participating site coordinator. It provides information on confirming reliance with the sIRB, corresponding with the sIRB, recording the sIRB decision, approving a site modification and closing a site.

Confirm Reliance with the sIRB

If an sIRB determines that you meet the criteria to participate in a multi-site study, they will invite you to join the study.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	After downloading a local copy of a multi-site study to your system. You must confirm reliance on the sIRB before the PI can submit the site for sIRB review.

To confirm reliance

1. From the site workspace, click **Confirm Reliance**.
2. Complete the form and click **OK** to finish.
3. If reliance is confirmed, the site enters a Pending sIRB Review state.

Note: the process is the same as the process of confirming reliance with an external IRB.

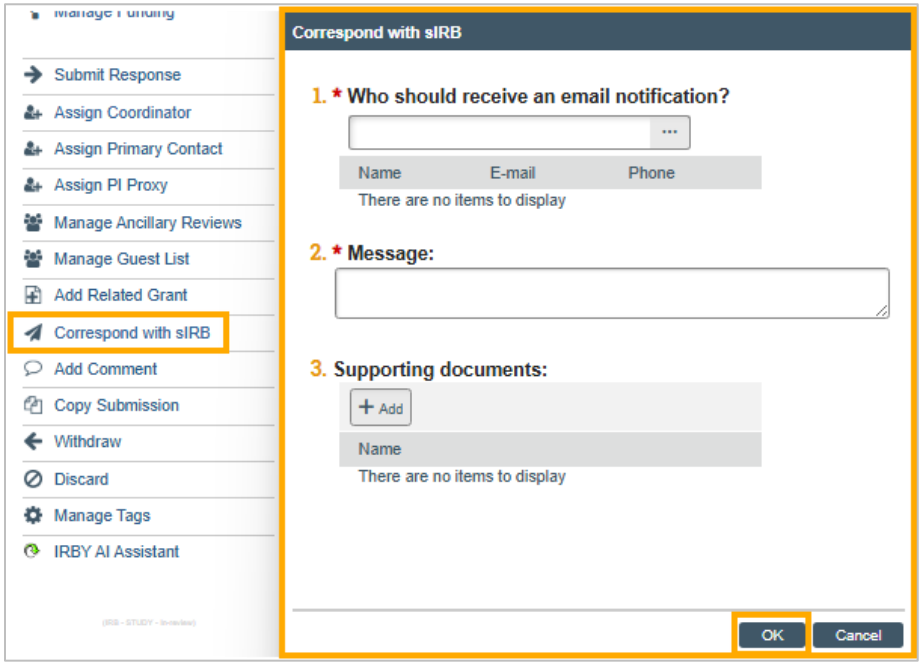
Correspond with the sIRB

At any point during the review process, you can correspond with sIRB researchers and coordinators.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	At any point during the review process.

To correspond with a pSite

1. From the site workspace, click **Correspond with sIRB**.
2. Complete the form and click **OK** to finish.



Your correspondence is sent.

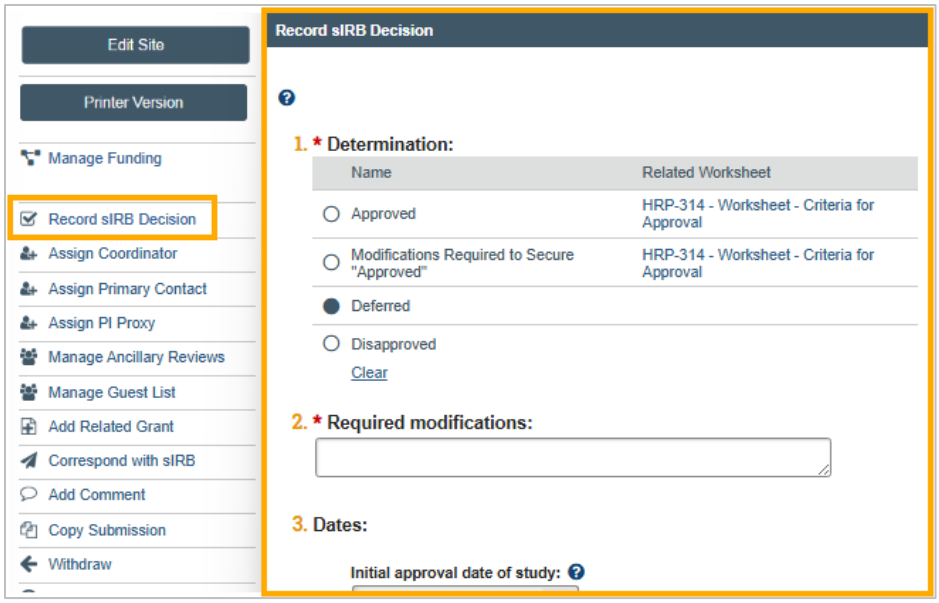
Record the sIRB Decision

pSite IRB staff can record and edit sIRB determinations for a site, site modification, or reportable new information.

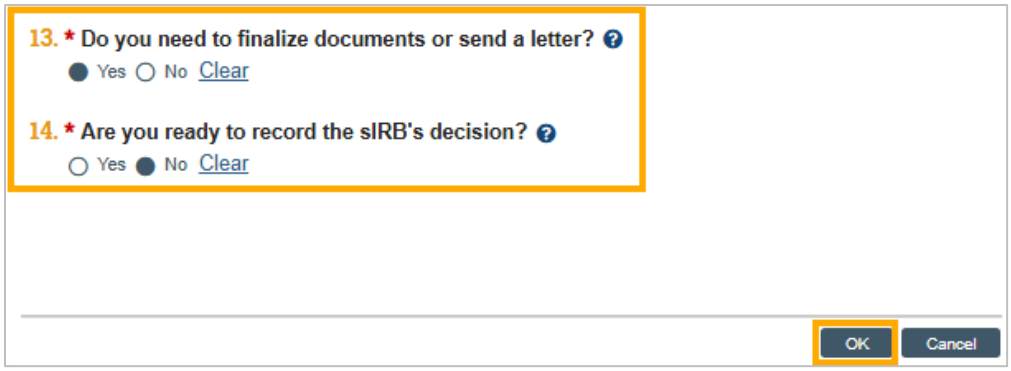
Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	After you have been notified of the sIRB's review decision.

To record sIRB decision

1. From the site workspace, click **Record sIRB Decision**.
2. Complete the form.



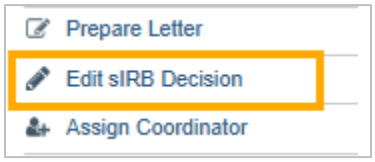
3. For sites and site modifications, pay attention to the following questions:
    a. **Do you need to finalize documents or send a letter?**, select **Yes** to send the item to Post-Review, and select **No** to send the item to Review Complete.
    b. **Are you ready to record the sIRB's decision?**, select **No** to note the sIRB determination without recording it, and your selections will be saved.
4. Click **OK** to finish.



To edit sIRB decision

Note: You can only edit the sIRB decision for Approved sites in the Post-Review state.

1. From the site workspace, click **Edit sIRB Decision**.



2. Edit the form and click **OK**.

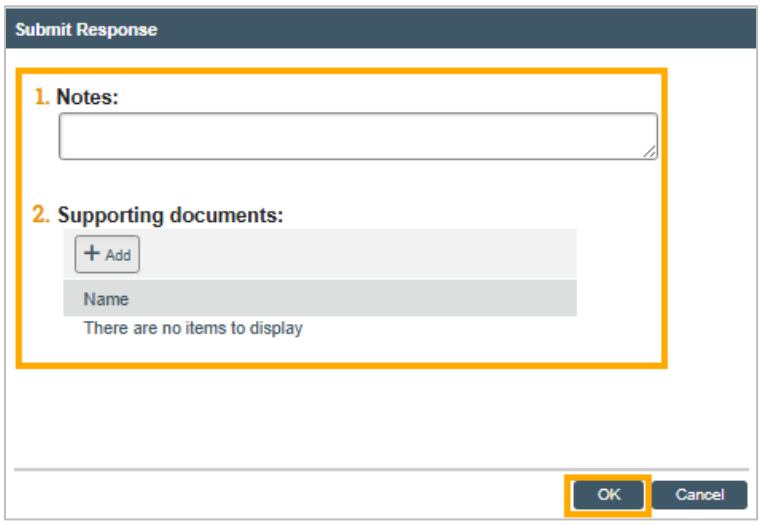
To submit a response to the sIRB

For sites that are deferred, disapproved, or require modifications, you can submit a response to the sIRB.

1. From the site workspace, click **Submit Response**.



2. Complete the form and click **OK**.



Approve a Site Modification

IRB staff can approve site modifications submitted by investigators. Modifications that concern other parts of the site (including basic information, funding, and local site-specific documents) require sIRB review in addition to local approval.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	After a site modification has been submitted by a PI.

To approve a site modification

1. From My Inbox, click the link to open the modification.
   Note: You can also find the modification by clicking **IRB** and then **Submissions** in the Top Navigator and search for the modification in the **In-Review** tab.

2. From the modification workspace, click **Accept Site Updates**.
3. Complete the form. Depending on the type of modification, the submission enters different states:
    a. For a modification to the study team or research locations, pay attention to the following question:
    Do you need to finalize documents or send a letter? Selecting **Yes** will send the modification to Post-Review, where you will have a chance to complete these activities. Selecting **No** will send the modification to Review Complete.
    b. **For a modification to other parts of the study** (including basic information, funding, or local site-specific documents), the modification will be available for the sIRB to review. While in review, the modification will remain in the Pending sIRB Review state.
4. Click **OK** to finish.

Close a Site

If a site is in the Review Complete state, IRB coordinators and directors can close the site at any time.

Who performs this activity?	When to perform this activity
• sIRB Coordinators assigned to a submission • IRB Reliance Coordinators • IRB Directors	You can close Active or Inactive sites in the Review Complete state. **Note**: If you close a site, the associated external study will also be closed.

To close the site

1. From the site workspace, click **Close Site**.

The site is closed.

Advanced Reports

About Advanced Reports

IRB includes several ready-to-use advanced reports to help you monitor the performance and effectiveness of your operations.

IRB staff (IRB coordinators and directors) and committee members can generate the following advanced reports:

Report	Description
IRB Turnaround Times	The average number of days it took for approved submissions (studies, continuing reviews, modifications, and/or Reportable New Information (RNI)) to go through an IRB review.
Submission Volume	The total number of all submissions in the IRB system, per IRB office (as applicable).
Days in State	The total and average number of days that approved submissions were in a particular state for a specified date range.

Open and Generate Advanced Reports

IRB staff (coordinators and directors) and committee members can access IRB advanced reports.

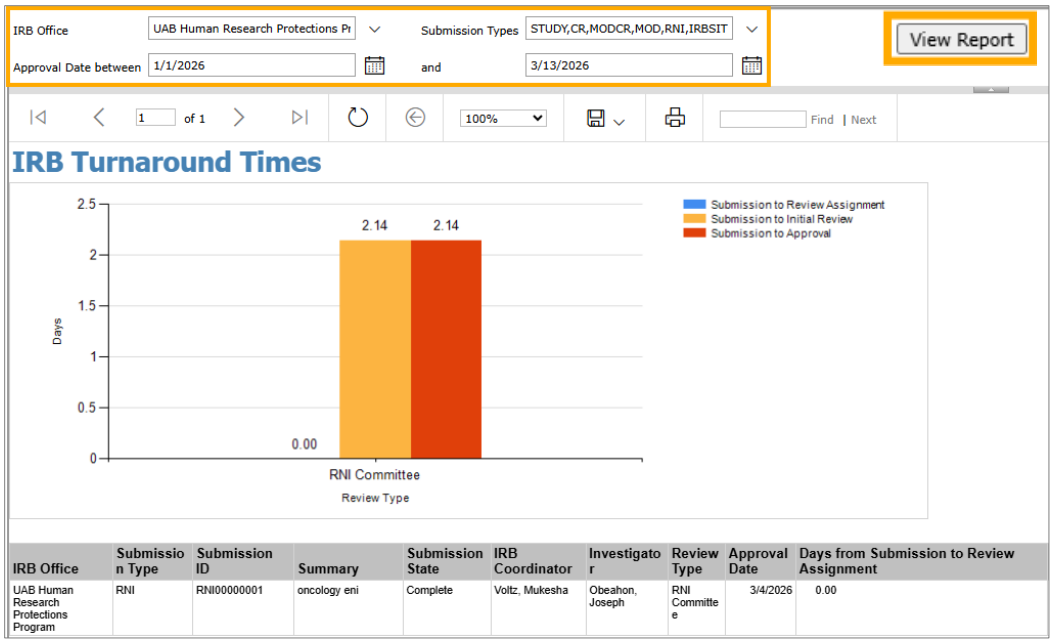
To open an advanced report

1. In the top navigator, click **IRB**.
2. Click **Reports**.
3. Click the **Advanced Reports** tab. The list of advanced reports appear.
4. Click the report name link to open it.



To generate an advanced report

1. Open the applicable advanced report.
2. Filter the data as required.
3. On the right, click **View Report**.



Filter Data on Reports

At the top of the report are filtering options so you can view a subset of data on the report.

To filter data on a report

1. Specify criteria for data you want to see on the report:
    a. From a drop-down list, click the down arrow and select from the available options.
    b. For a date field, type the date in MM/DD/YYYY format or click the calendar icon and select the date.
2. Click the **View Report** button.

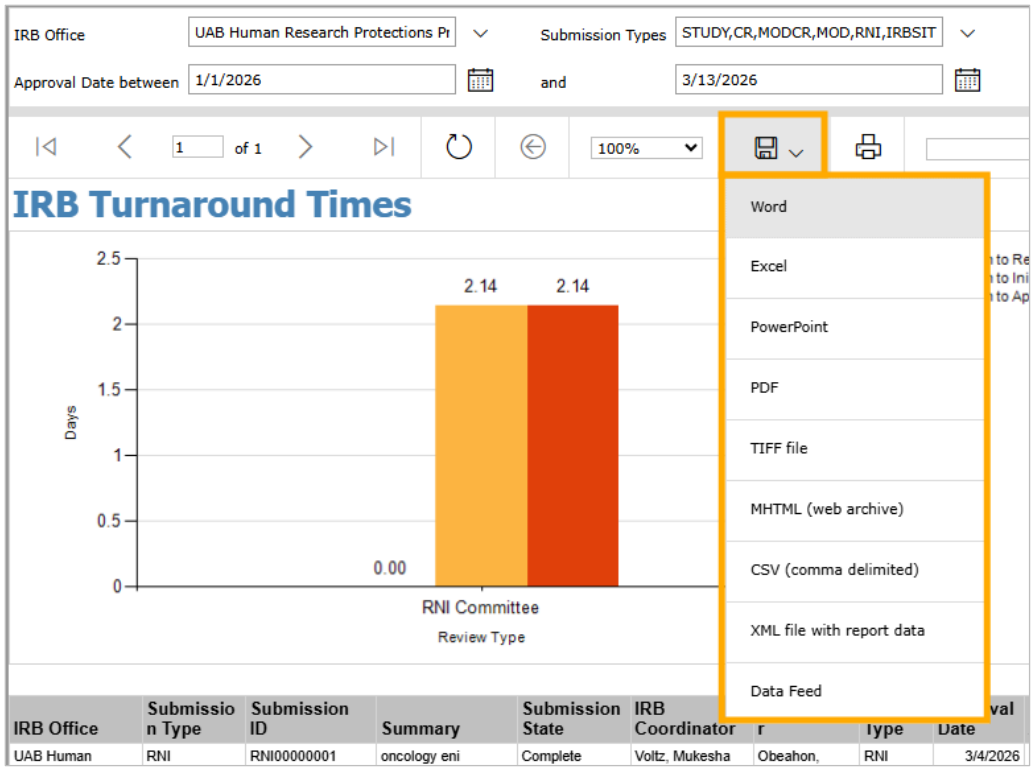


Export and Print Reports

From the report toolbar, you can export an advanced report to a variety of file formats, such as PDF or Excel, and print the report.

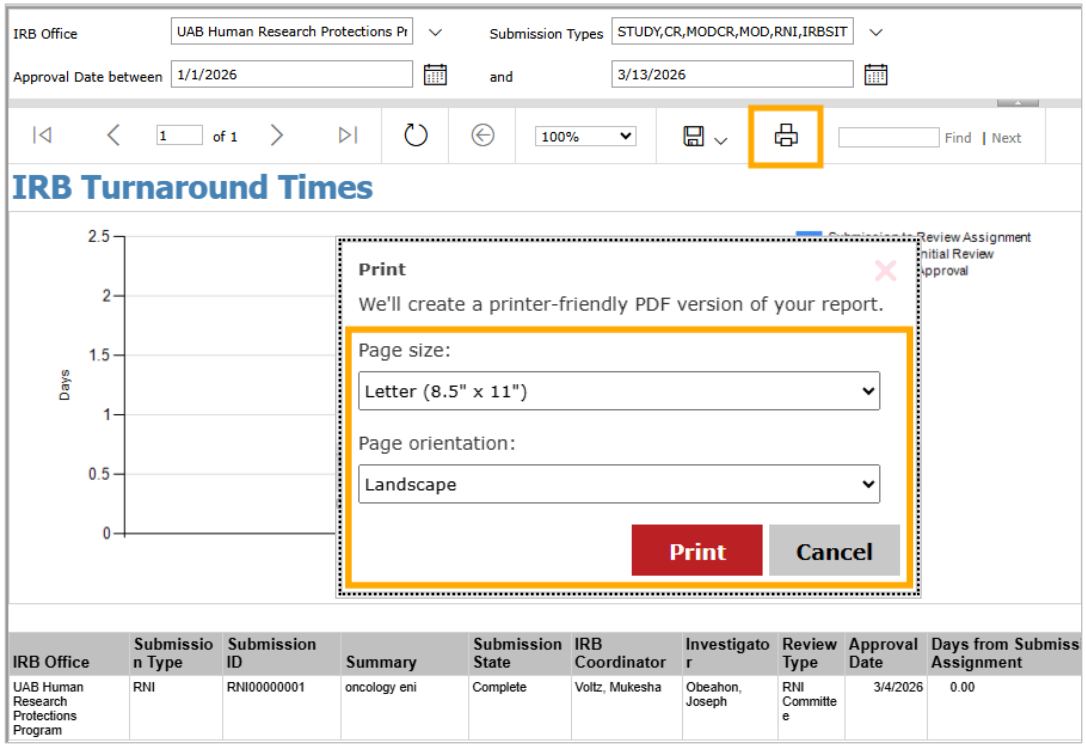
To export a report

1. In the report toolbar, click the export icon down arrow.
2. Select a file format from the list.
3. Click **Open** to open the file or click **Save** to save the file to a location on your computer or network.



To print a report

1. In the report toolbar, click the print icon.
2. In the print window, select the appropriate print options and click **Print**.



Report Details

This section covers the days in state report, the IRB turnaround times report, and the submission volume report.

Days in state report

This report shows the total and average number of days that approved submissions were in a particular state for a specified date range. Use this report to assess workflow efficiency and identify bottlenecks in the review process.

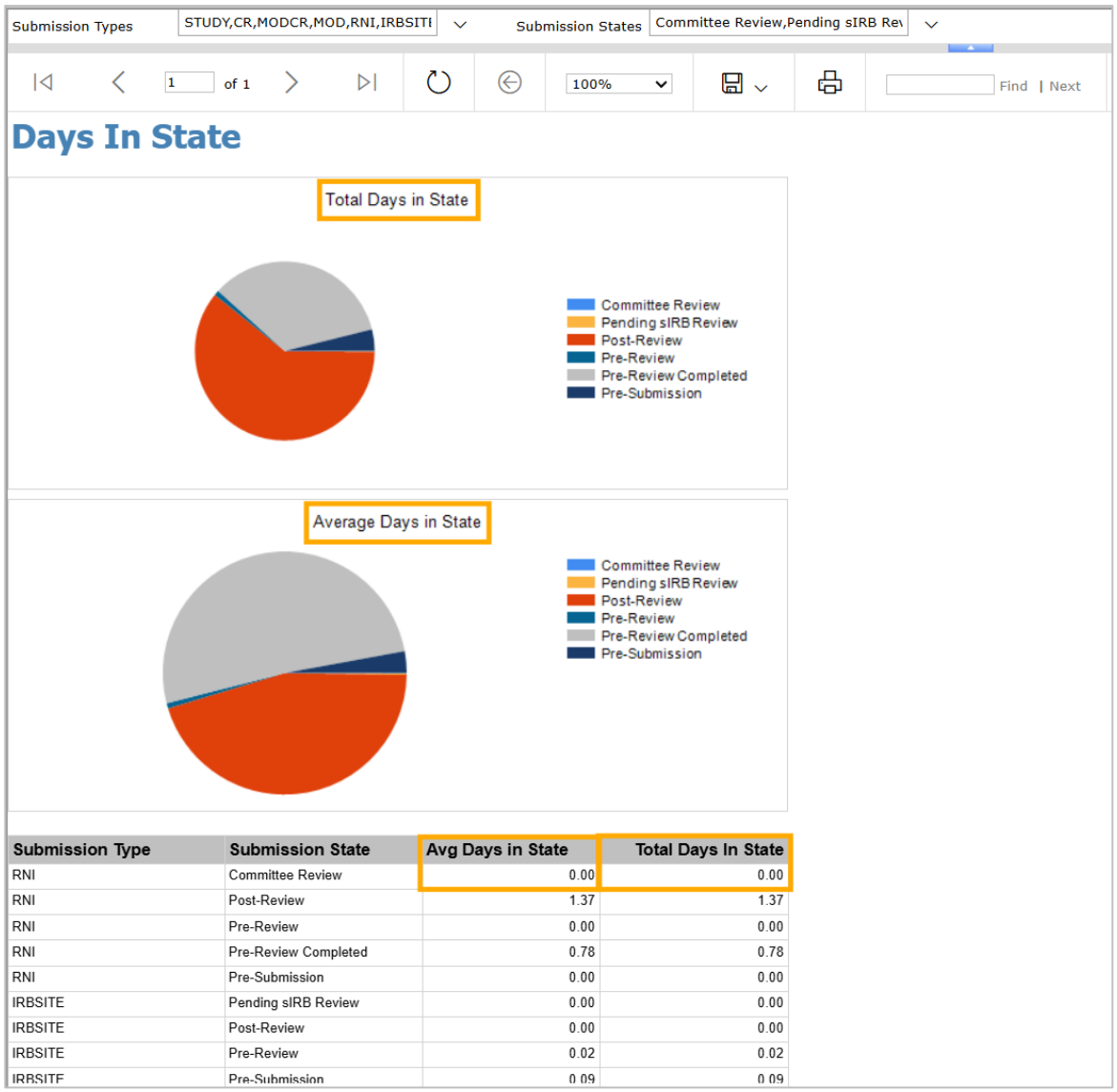
Note: This report shows data for multi-site studies, including site data.

Report filters

You can filter approved submissions by specifying:

- **Approval Date**: The approval date is the date selected on the Approval Date field when a committee or designated review is submitted for a submission.
- **Submission Types**: Includes study, modification/continuing review, and/or RNI.
- **Submission States**: The current state of the submission at the time of generating the report.
  Note: If you filter submissions by state, the resulting list shows only those states in which there is at least one submission.

Sample Report



Submission Type	Submission State	Avg Days in State	Total Days In State
RNI	Committee Review	0.00	0.00
RNI	Post-Review	1.37	1.37
RNI	Pre-Review	0.00	0.00
RNI	Pre-Review Completed	0.78	0.78
RNI	Pre-Submission	0.00	0.00
IRBSITE	Pending sIRB Review	0.00	0.00
IRBSITE	Post-Review	0.00	0.00
IRBSITE	Pre-Review	0.02	0.02
IRBSITE	Pre-Submission	0.09	0.09

Chart Description

Two pie charts show the filtered data:

- **Total Days in State**: The total number of days submissions were in each state
- **Average Days in State**: The average number of days submissions were in each state

Table Description

Several table rows showing total and average days may appear for each selected state. State data is first separated into rows by IRB office, then by submission type, and then by state.

IRB Turnaround Times Report

This report shows the average number of days it took for approved submissions (studies, continuing reviews, modifications, and/or Reportable New Information (RNI)) to go through an IRB review.

Note: This report shows data for multi-site studies, including site data. However, data for externally-reviewed studies is not included.

Report filters

You can filter approved submissions by specifying:

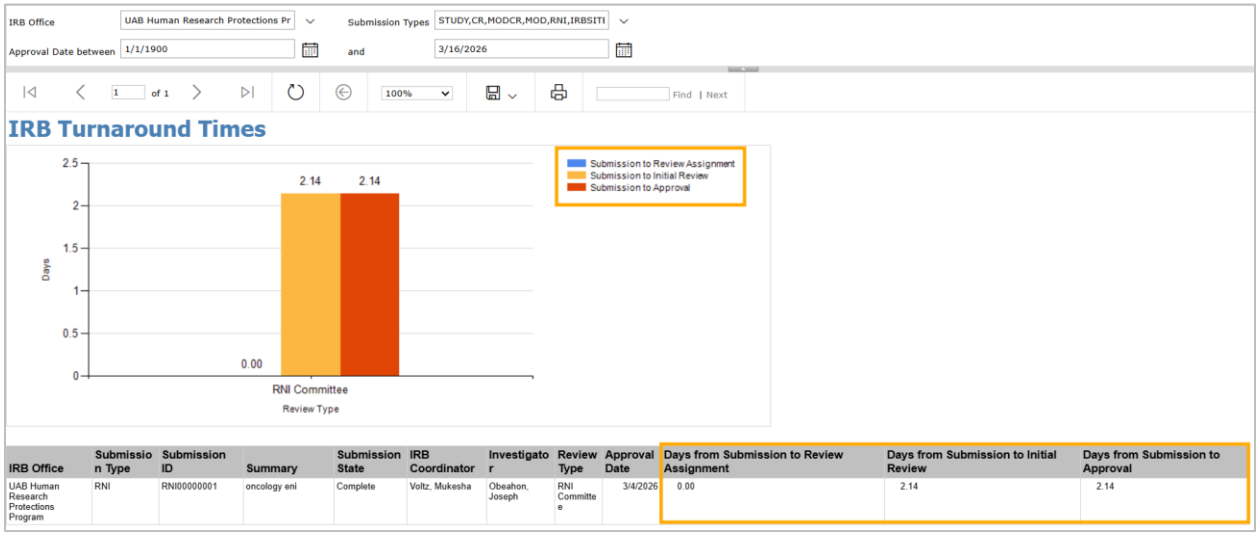
- **IRB Office**: The administrative office assigned to the submission.
- **Submission Types**: The type of submission such as study or modification.
- **Approval Date Range**: The approval date is the date selected on the Approval Date field when a committee or designated review is submitted for a submission.

Report definitions

Data	Description
Chart Legend	
Submission to Review Assignment	From: The date the PI first sent (submitted) the submission to the IRB office. To: The date the IRB coordinator assigned the submission to a designated reviewer or a meeting for full committee review.
Submission to Initial Review	From: The date the PI first sent (submitted) the submission to the IRB office. To: The date the first IRB determination letter was sent to the PI, regardless of the determination.
Submission to Approval	From: The date the PI first sent (submitted) the submission to the IRB office. To: The date the final determination letter was sent to the PI. Final determinations include (not a complete list): • Approved • Not Human Research • Human Research, Not Engaged • Disapproved • Deferred **Note**: The approval date may be the same as the initial review date if the first and only review resulted in a final IRB determination.
Review Type	
Committee	Full committee review of a non-RNI submission.
Exempt	Non-committee review of an exempt submission.
Expedited	Non-committee review of an expedited submission.

RNI Committee	Full committee review of an RNI submission.
RNI Non-Committee	Non-committee review as the final review of an RNI submission.
RNI Pre-Review	Pre-review as the final review of an RNI submission.

Sample report



IRB Office	Submission Type	Submission ID	Summary	Submission State	IRB Coordinator	Investigator	Review Type	Approval Date	Days from Submission to Review Assignment	Days from Submission to Initial Review	Days from Submission to Approval
UAB Human Research Protections Program	RNI	RNI00000001	oncology eni	Complete	Voltz, Mukesha	Obeahon, Joseph	RNI Committee	3/4/2026	0.00	2.14	2.14

Chart and legend description

For each review type (determined by the last review performed), the chart shows the average number of days for a submission to move between milestones.

The height of the bar shows the total days from submission to approval. The numbers on each bar indicate the days to complete these milestone intervals.

Submission Volume Report

This report shows the total number of all submissions in the IRB system, per IRB office (as applicable).
Note: This report shows data for multi-site studies, including site data.

Report filters

You can filter submissions by specifying:

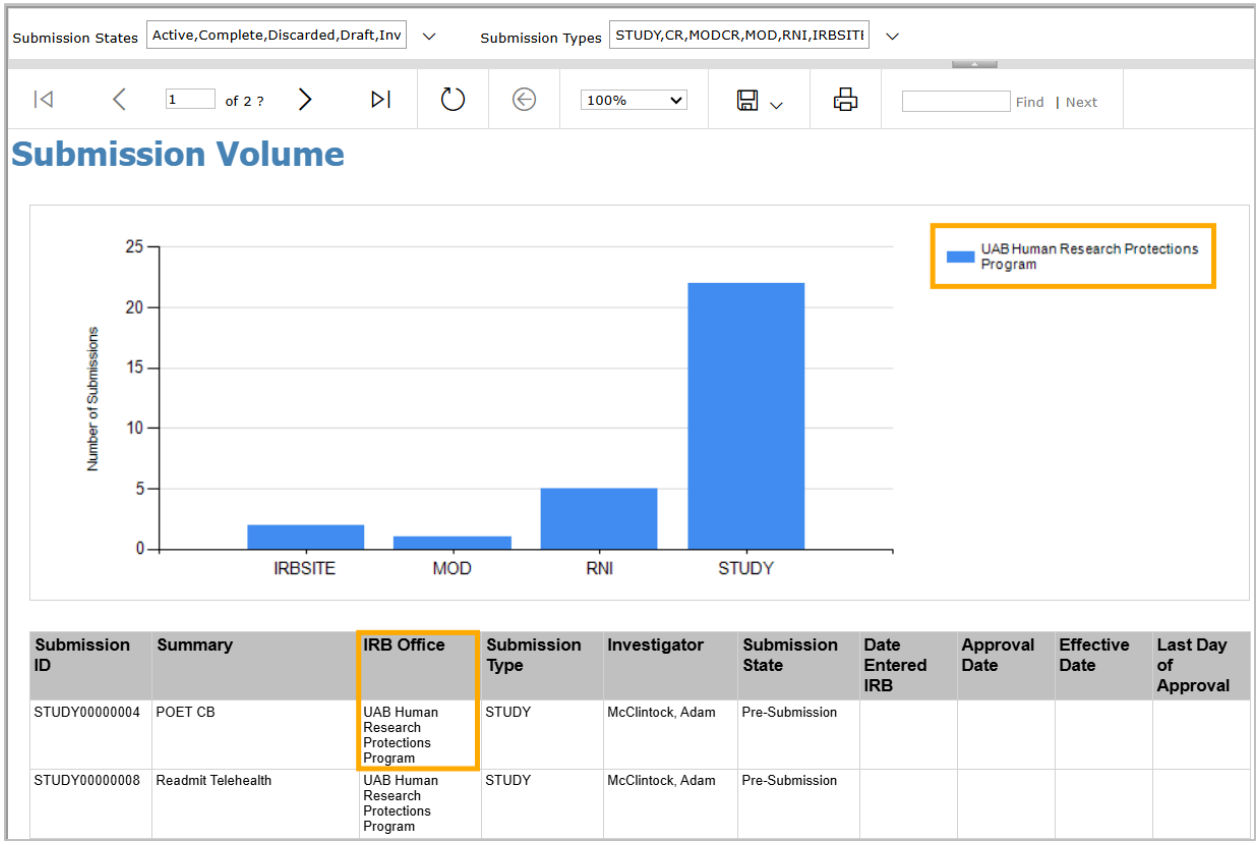
- **Submission States**: The current state of the submission at the time of generating the report.
  Note: If you filter submissions by state, the resulting list shows only those states that have at least one submission.
- **Submission Types**: Such as study, continuing review, modification, and/or RNI.

Report definitions

The data table includes several dates related to the submission:

Column	Description
Date Entered IRB	The date the PI first sent (submitted) the submission to the IRB office.
Approval Date	The date the IRB decision was made.
Effective Date	The date the IRB decision takes effect.
Last Day of Approval	The last day of the approval period as recorded on the submission.

Sample report



Submission ID	Summary	IRB Office	Submission Type	Investigator	Submission State	Date Entered IRB	Approval Date	Effective Date	Last Day of Approval
STUDY00000004	POET CB	UAB Human Research Protections Program	STUDY	McClintock, Adam	Pre-Submission				
STUDY00000008	Readmit Telehealth	UAB Human Research Protections Program	STUDY	McClintock, Adam	Pre-Submission				

Chart and legend description

The chart shows the number of submissions for each submission type, and includes a bar for each IRB office. The legend shows the IRB office responsible for the submissions.