IRB Guide for Campus and HRPP

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
Uploading Documents	How and when to upload documents from the HRPP Toolkit

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
Edit Study as an IRB Coordinator	Overview of the role of an IRB Coordinator when it comes to editing a study on behalf of the study team
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.
Study Modifications and CR States and Transitions	Overview of the key transitions in the IRB review process for study modifications and continuing reviews
Submit a Pre-Review	As a reviewer, you may be required to attach and complete any associated checklists for the pre-review
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.
Assign a Coordinator for a Pre-Review	How to assign a specific coordinator to oversee the review process
Perform a Pre-Review	How to perform the pre-review of a submission
Request Clarification on a Submission	Use the request clarification feature when you have questions for the study team or require them to make changes to the study
Compare Versions of a Study	After the study team submits their response to the clarification request you can compare versions to see the changes that were made
Submit a Pre-Review	After you have finished reviewing a submission, move it forward in the review process by submitting a pre-review
Confirm Reliance with an External IRB	For a single-site external IRB 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 and edit the sIRB decision for an externally reviewed study
Update an Approved, Single-Site External Study for Updates that Originate with the Local Study	How to make updates to an approved, single-site study when the update originates with the local study. Both the local PI and local IRB coordinator can make updates to the external study.
Update an Approved, Single-Site External Study for Updates that Originate with the External IRB	How to make updates to an approved, single-site study when the update originates with the external IRB.
Report Continuing Review Data for an External Study	How to report continuing review data for an external study, the local PI, PI proxies, and local IRB coordinator can report continuing review data for a single-site external study

Assign Ancillary Reviewers to a Submission	How to assign ancillary reviewers to a submission. Ancillary reviewers can be assigned to a submission in almost any state, starting with Pre-Submission when they can be assigned by the PI or an IRB director. After Pre-Submission, the assigned coordinator can also assign reviewers.
Override Blocking of Ancillary Reviews	How to override blocking of an ancillary review. If an ancillary reviewer does not accept a study or complete a required ancillary review, the submission can be blocked from moving forward.
Assign a Designated Reviewer	How to assign a study to one committee member to review
Assign to a Committee Meeting	How to assign a study to a committee meeting for review
Assign Committee Reviewers	After assigning a submission to a committee meeting, you can assign specific committee reviewers
Submit a Committee Review	Steps for how to submit a committee review. If the submission went through a committee review, the next step is to record the committee's determination for that submission. You may do this during or after the committee meeting. An IRB staff member, committee admin, or committee chair can submit the committee review.
Post-Review Activities	After the designated member or committee review decision has been submitted for a submission, the next steps are to finalize the documents and prepare and send the determination letter to PI
Manage Editors for RNI	IRB staff and the person who created the RNI can empower additional people to edit and take action on Reportable New Information (RNI) using the Manage Editors activity
Close a Study	The Close Study (Admin) activity allows you to administratively move a submission to the Closed state. You can use this activity to close submissions determined to be Not Human Research or in a Human Research, Not Engaged state, instead of leaving them in their end state.

Reportable New Information

Process	Description
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

Reports

Process	Description
Generate Standard Reports	How to generate a standard report. The IRB system includes many standard reports regarding studies and Reportable New Information (RNI) to help you find relevant submissions and understand the overall operation of the IRB.
Tag a Submission	Add tags, or keywords, to any type of IRB submission so that you can later report on those submissions

Mass Update Administrative Assignments	Mass update activities can update administrative assignments on multiple projects in a single run. This is much more efficient than methods that affect only one project at a time, such as selecting personnel in a SmartForm or running activities from the project workspace. Mass update activities support these assignments: • Replace coordinator • Replace primary contact • Add or remove guests
Run a Mass Update Activity	How to run a mass update

Researcher Tasks

Process	Description
Create a Study	How to create a study
Submit a Study for Review	How to submit the study you have just created for review
Create an External Single-Site Study	How to create an external single-site study. A single-site external study is when an IRB other than UAB oversees the regulatory review of the study.
Submit an External Study for Review	How to submit an external single-site study for review after it has been created
Change Study Documents	How to update your study documents, this can be done any time prior to submitting the study to the IRB for review
Respond to a Clarification Request	How to respond to a clarification request. If a reviewer has questions or requires you to change your submission, you will receive an notification indicating this.
Create and Submit a Continuing Review or Modification	You can submit a Continuing Review (CR), a modification, or both combined: • To close a study or extend your approval period, submit a CR. • To change an approved study or the study team's members, submit a modification.
Common Rule Changes to the Continuing Review Activity	When the IRB Coordinator submits the Pre-Review, after the effective date, they can move studies under the old Pre-2018 Common Rule requirement to the new 2018 requirement
Create, Submit, and Discard Reportable New Information (RNI)	How to create, submit, and discard RNI. You can report any adverse events or new information about a study as soon as you become aware of it.
Checklist of Information to Attach	While editing the study, several forms provide places to attach related files. In some cases, a template file is provided directly on the form for download, such as the protocol. This section provides guidance on information to attach.

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.

Multi-Site Studies

Process	Description
Elements of a Multi-Site Study	Elements and parts of a multi-site study and the multi-site study process and workflow
Site Modification Process	Process of making a modification to a site
Reportable New Information (RNI) for a Multi-Study Process	Overview of the review process for RNI for a multi-site study. 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.
Continuing Review Process	Continuing review process for a multi-site study
External IRB Process for a Multi-Site Study	Workflow for a multi-site study
sIRB System Site States and Transitions	Overview of the possible states for a site submission in the sIRB system
pSite System Sites and Transitions	Overview of the possible states for a site submission in the pSite system
Create a Multi-Site Study	How to create a study as an sIRB Researcher
Manage Participating Sites	How to add or delete participating sites while a study is in the Pre-Submission or Pre-Review Clarification Requested states
Submit a Multi-Site Study	How to submit a multi-site study for review
Create and Submit a Continuing Review for a Multi-Site Study	How to create and submit a continuing review for a multi-site study. A PI at the sIRB institution can create and submit a continuing review (CR) that reports data for the sIRB institution and any pSites involved in the multi-site study.
Create and Submit a New Multi-Site External Study	How to create and submit a new multi-site study for external review
Report CR Data for a Multi-Site External Study	How to report CR data for a multi-site external study. The local PI, PI proxies, and local IRB coordinator can report continuing review data for a multi-site external study.
Create Site Modification for a Multi-Site External Study	How to create a site modification for a multi-site external study. Create Site Modification only updates the site.

Update Study Details for a Multi-Site External Study	How to update study details for a multi-site external study.

pSite Researcher Activities

Process	Description
Manually Create a Site	How to manually create a site
Edit a Site	How to edit site information before submitting the site to the sIRB for review
Submit a Site to the sIRB	Once a multi-site study has been approved, and you have updated the site information, you can submit the site to the sIRB in order to move it to the next stage of review
Report Continuing Review Data for a Site	How a PI submits enrollment data and other data about their local site to the sIRB for continuing review purposes
Create and Submit a Site Modification	How to create and submit the following two types of site modifications: • Study team and research location modifications require local approval • Modifications to other parts of a site (including basic site information, additional local funding sources, and local site documents) require review by the sIRB

Advance 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

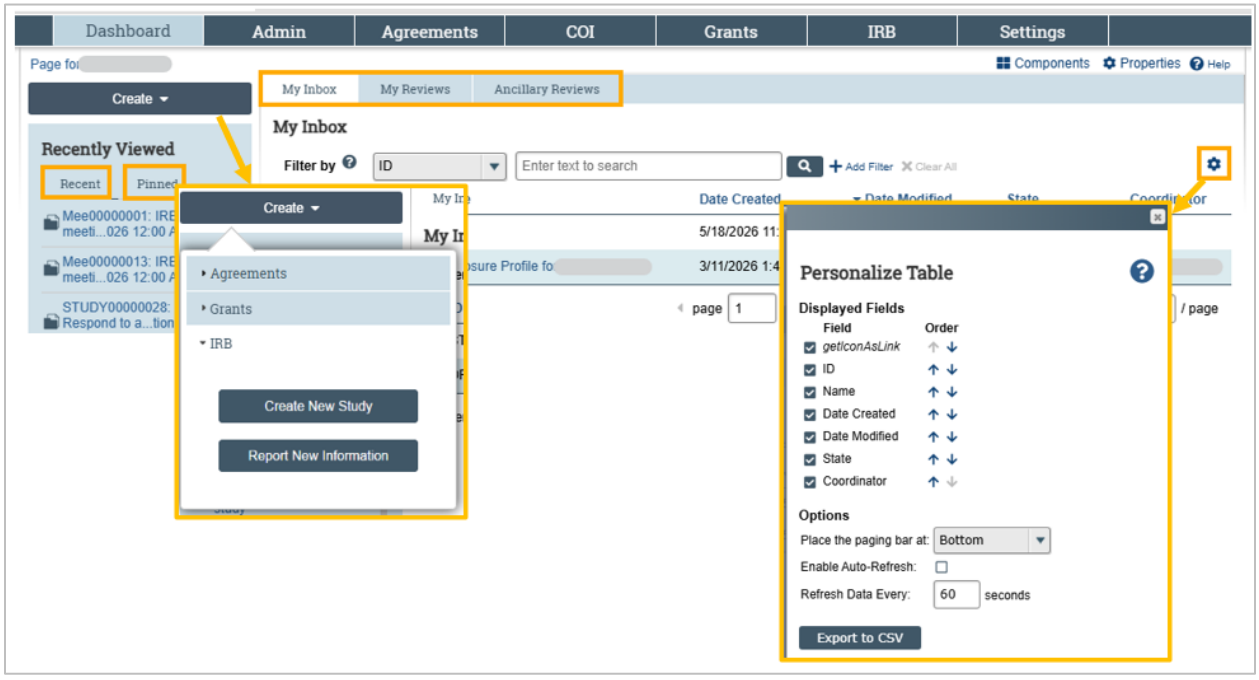
This guide shows Campus Staff and HRPP how to perform tasks and functions in the Institutional Review Board (IRB) module of MyUABResearch.

Important features covered in this guide include:

- Navigation and Basic Tasks
- HRPP Library
- Staff Tasks
- Review Activities
- Reports
- Researcher Tasks

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

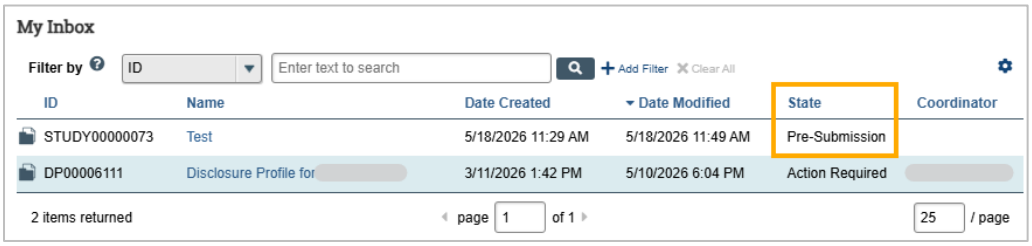
From your Dashboard, you can view:

- **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.
- **Ancillary Reviews:** Items you have been assigned as an ancillary reviewer to will appear here. 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.

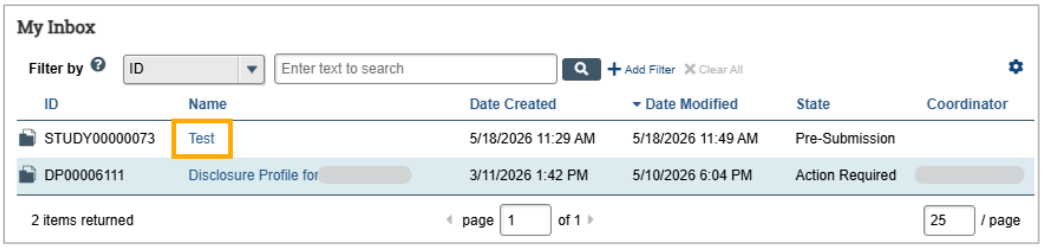
To identify what action is needed

- 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.



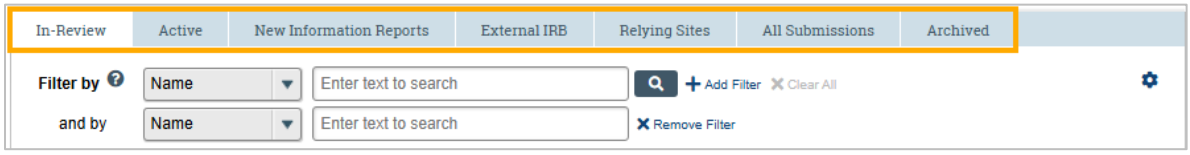
To find previous submissions

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.

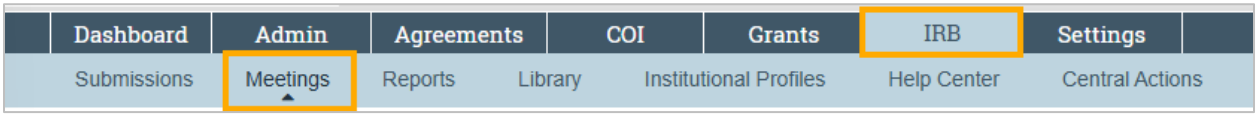
- **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
- **External IRB**: All studies managed by an external IRB.
- **Relying Sites**: All participating sites relying on the local IRB as the single IRB of record.
- **All Submissions**: All submissions, in any state.
- **Archived**: All closed, disapproved, discarded, and terminated submissions.



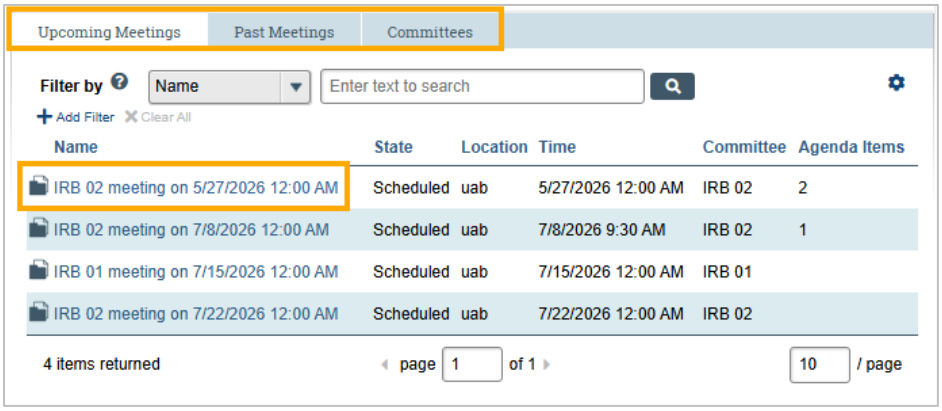
Meetings and Committees

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

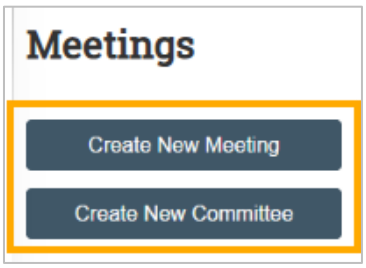
1. In the top navigator, click **IRB** then **Meetings**.



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.



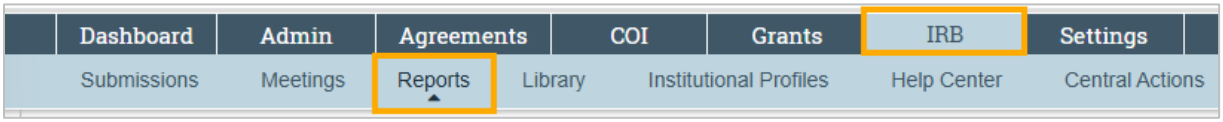
3. To create a new meeting or committee, use the **Create New Meeting** and **Create New Committee** buttons on the left.



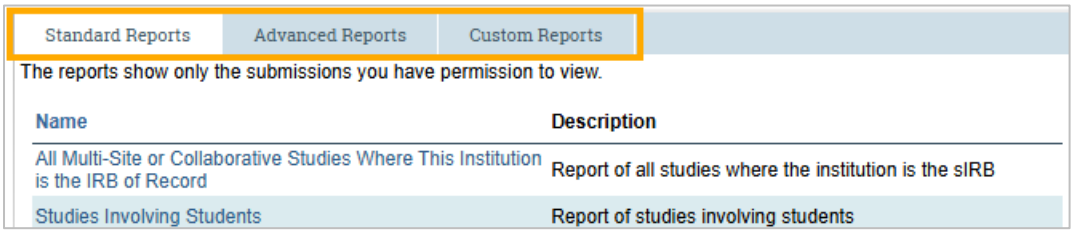
Reports

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

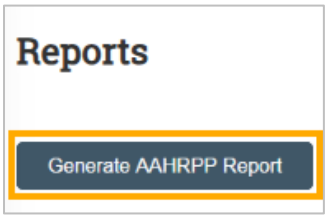
1. In the top navigator click IRB, then Reports.



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.

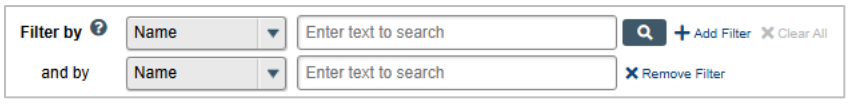


4. For more information on the different types of reports and how to generate them, see the Reports section.

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

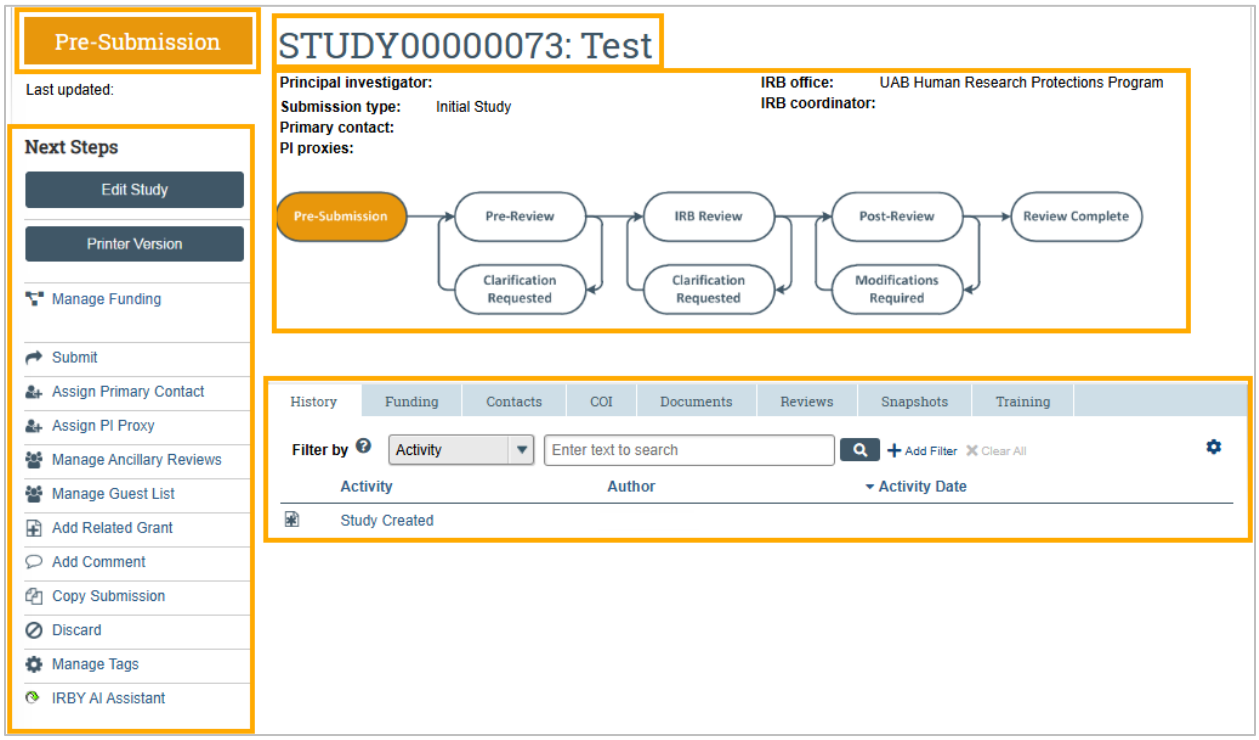
Your Study Workspace allows you to edit your application, submit forms (e.g., modifications, reportable new information), assign ancillary reviewers, and view all information about your submission.

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.

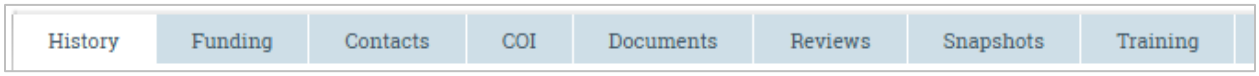
On the left side are all the activities you can take on your study; these will vary depending on your role and what state the study is in.

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.

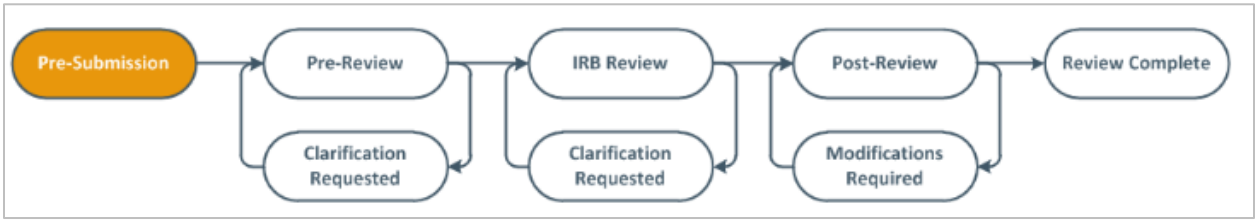
Reviews
The reviews tab is role dependent; researchers will only see ancillary reviews. IRB staff and committee members however will see the full picture, including the most recent Pre-Review, committee reviews, ancillary reviews, and committee member comments.

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.

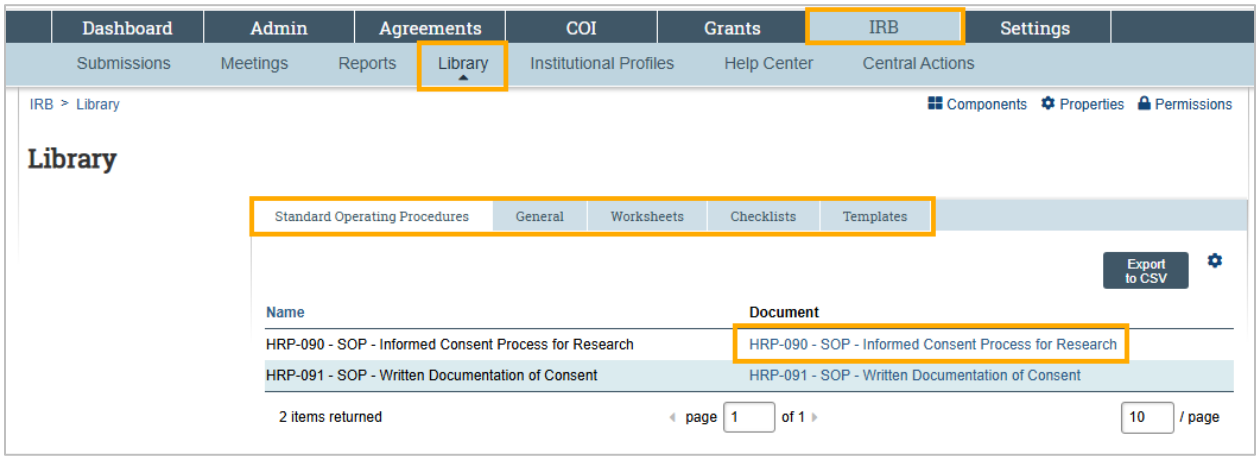
User Role	Typical Activities
Registered User	Users authorized to create submissions.
PI	The Principal Investigator (PI) listed on the submission. While others assist the PI in developing and editing the submission, only the PI (or designated PI proxies) can submit the study or follow-on submissions to 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

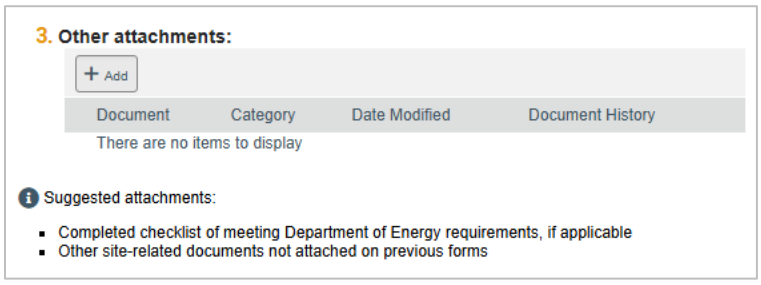
HRP-553 - LETTER - Failure to Submit Emergency Use Protocol	When the emergency use protocol has not been received by the IRB office
HRP-554 - LETTER - Failure to Undergo Training	Your HRPP training has expired and you will not be able to submit new research until your training has been updated
Template 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:





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.

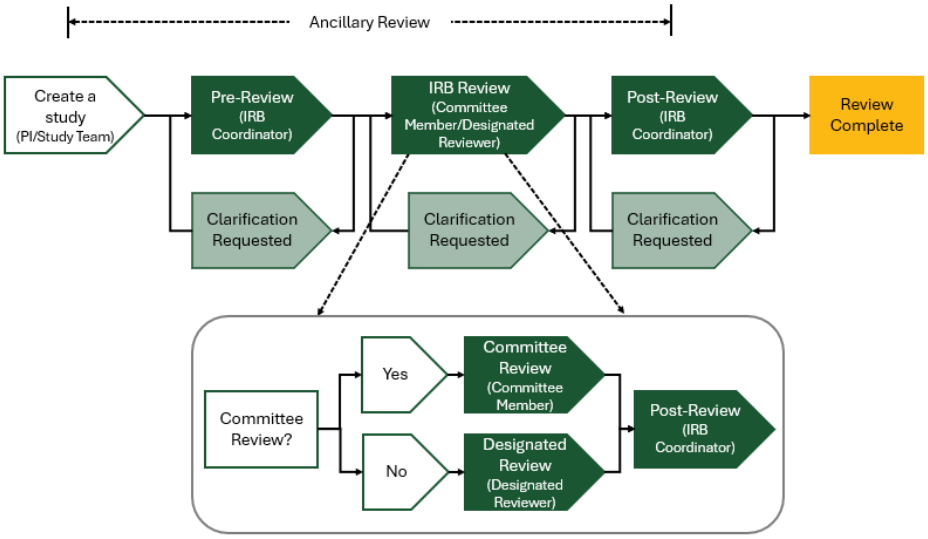
3. During IRB Review, the designated reviewer or the full committee will review the study.

    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.



Edit a Study as an IRB Coordinator

Depending on policy, the assigned IRB coordinator for a study may be allowed to edit the study on behalf of the study team. A system-wide setting must be enabled to allow this.

When editing by the coordinator is enabled, the assigned IRB coordinator for any submission can edit the submission in the same states that the study team can (Pre-Submission, Clarification Requested, and Modifications Required). The PI or PI proxy must then submit the changes to the IRB.

For example, suppose the assigned coordinator is completing the Pre-Review process and notices a small inconsistency in the submission. From talking with the PI, the coordinator knows what needs to be changed, and the PI prefers the coordinator make the change directly. The coordinator requests clarification (which opens the study for editing) and makes the change. The coordinator then uses the Add Comment activity to notify the PI of the change and request the change be submitted to the IRB for review.

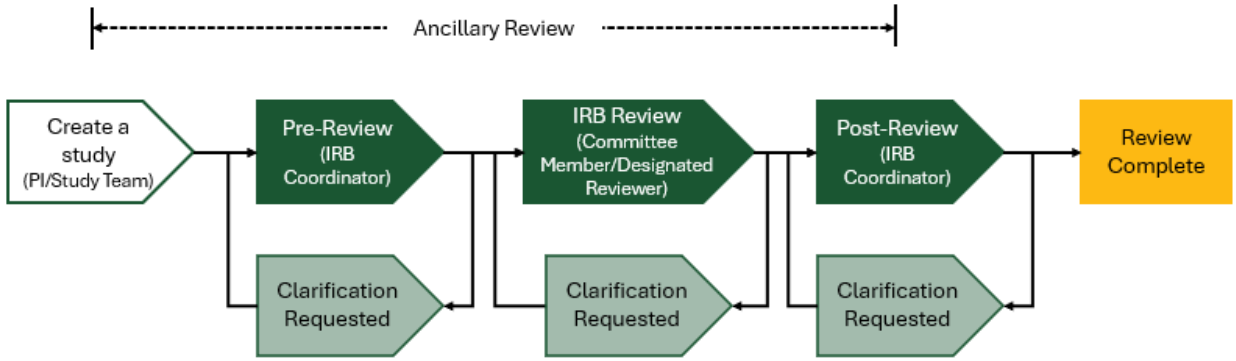
Ancillary Review Process

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 Close, and for

RNI, Complete and Acknowledged. The assigned coordinator is able to add ancillary reviewers in states after Pre-Submission.

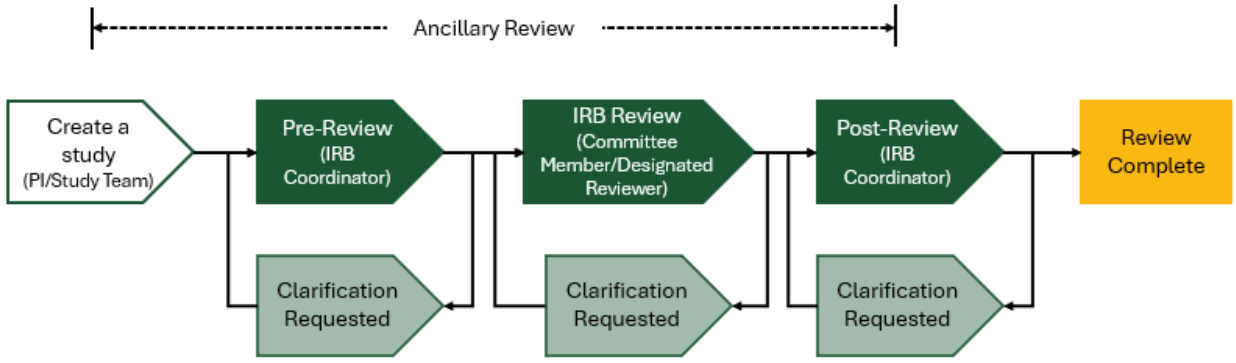


Continuing Review (CR) and Modification Process

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 (completing it through the To send determination letter activity). 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: The local IRB communicates with the external IRB, then records the external IRB's determination using the Record sIRB Decision activity.

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

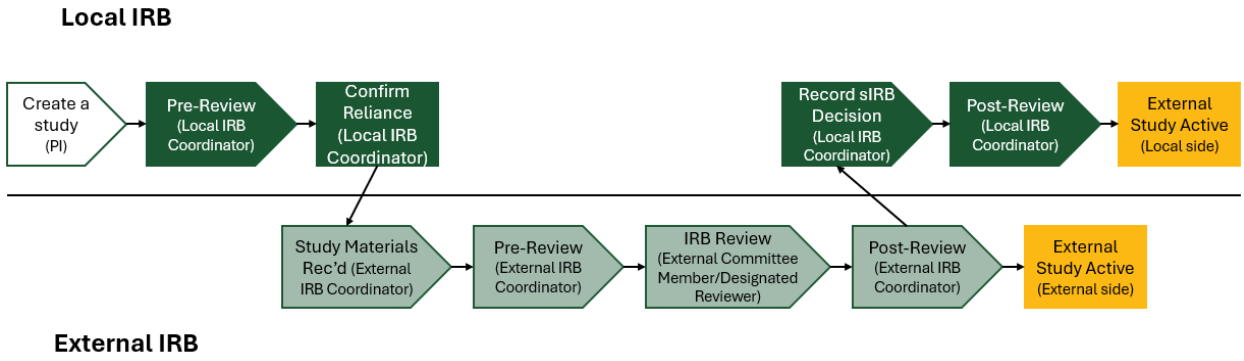
3. The study will move to the Pending sIRB Review state. If the study needs to be revised while in the Pending sIRB state, the assigned IRB coordinator or study staff can directly edit the study.

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. In the Modifications Required state, the coordinator or PI can respond to the external IRB.
    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.



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)
Clarification Requested (Committee Review)	Investigator, PI Proxy	Submit Response	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		Send Letter	Approved

	IRB Coordinator, IRB Director		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 (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**.

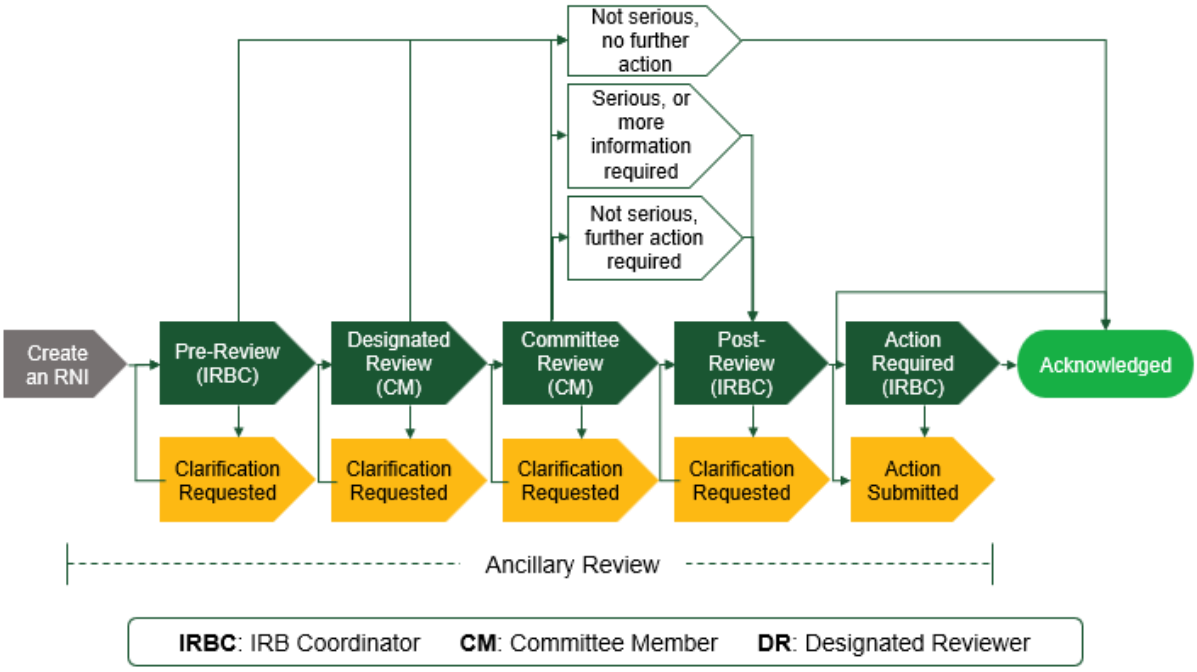
    c. If the RNI submission is considered a serious issue, or if additional information is required before making a determination, the submission transitions to **Post-Review** regardless of whether further action is required.

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.

For information on how to create and submit reportable new information, see the Create and Submit Reportable New Information Section.

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 Coordinator, IRB Director	Review Required Actions	Post-Review
			Action Required
	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			Action Submitted

	Responsible party, IRB Coordinator, reporter, PI and PI proxies of related submissions, RNI editors**	Submit Action Response	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	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Post-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.

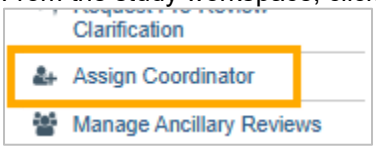
**RNI editors are those assigned to the RNI using the Manage Editors activity. They can edit the RNI, submit it for review, submit a response to a clarification request, and submit an action response.

Complete a Pre-Review

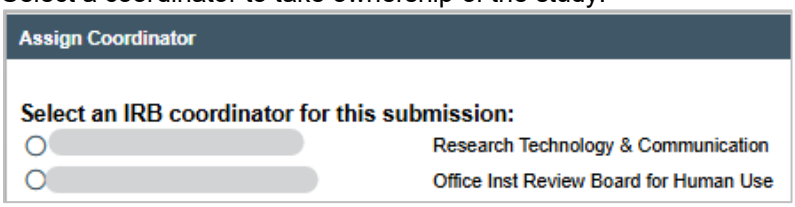
When a study is submitted to the IRB for review, it will appear in all coordinators' inboxes. The first step is to assign it to a specific coordinator to oversee through the review process. Next, the assigned IRB coordinator will check the study for completeness, ensuring all the information is there for the reviewers.

To assign a coordinator

1. From My Inbox or the submissions tab, open the submission that does not have an assigned coordinator.
2. From the study workspace, click **Assign Coordinator**.



3. Select a coordinator to take ownership of the study.



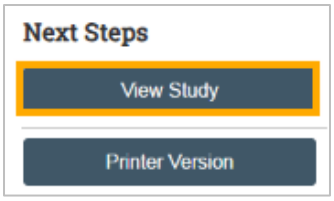
4. Click **OK**. The submission will appear only in the assigned coordinator's inbox.

Note: If you assign a coordinator that is not yourself, the assigned coordinator will receive a notification.

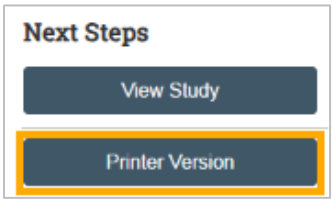
To perform a Pre-Review

Review the submission and its documents. From the workspace, click the following:

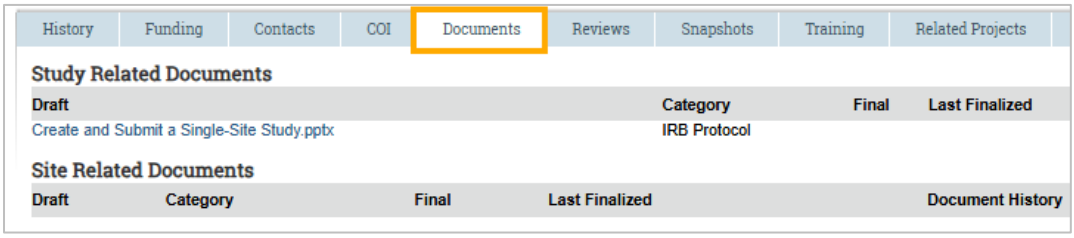
- **View Study**: Opens the study. Click **Continue** to move through the pages.



- **Printer Version**: Shows the study in one scrollable page.



- **Documents tab**: Shows all attached study documents.



Note: You can also access these documents from the study pages and printer version.

Next Steps

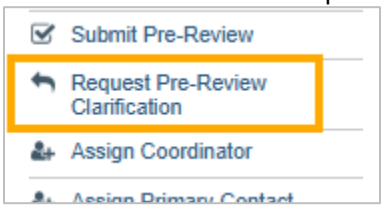
- If you have questions or change requests for the PI, see Request Clarification on a Submission
- If you are finished reviewing the submission, see Submit a Pre-Review

Request Clarification on a Submission

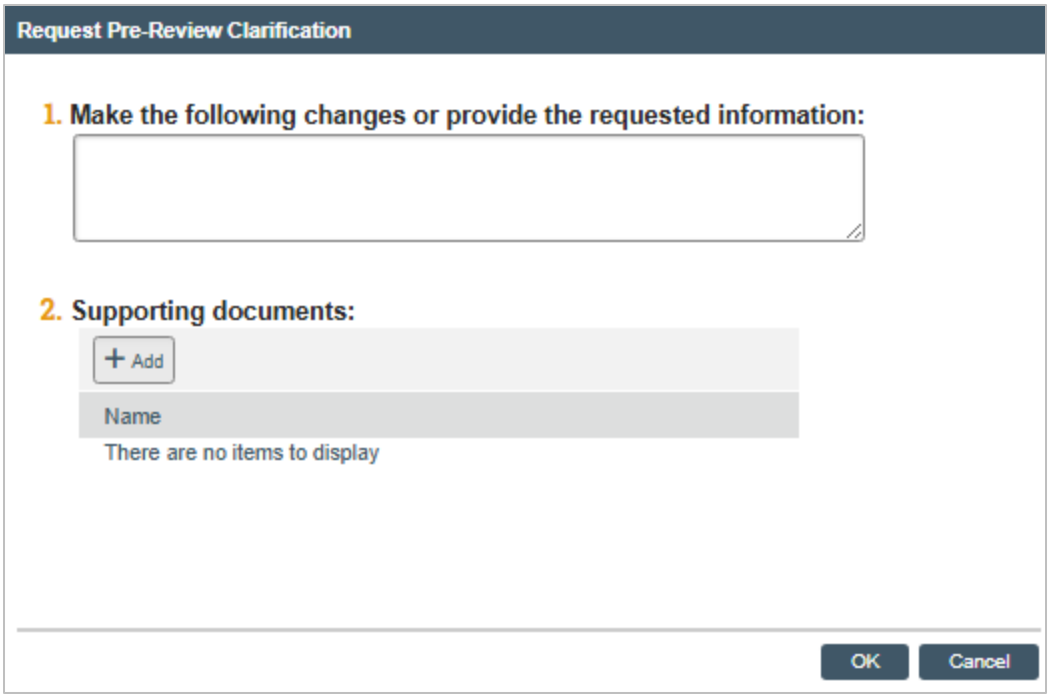
If you have questions for the study team or require them to make changes to the study, use the request clarification feature to communicate back and forth with the team. When all questions have been answered or changes made, submit your pre-review.

To request clarification

1. From the submission workspace, click **Request Pre-Review Clarification**.



2. Type your request.
   Note: If you require more space for your request, add a document with the details in the Supporting documents section. In the text box, instruct the PI to refer to the document.
3. Click **OK**.
   The PI will receive an email about your request. Once the PI responds to your request, you will receive an email and the submission will return to your IRB inbox so you can continue your review.

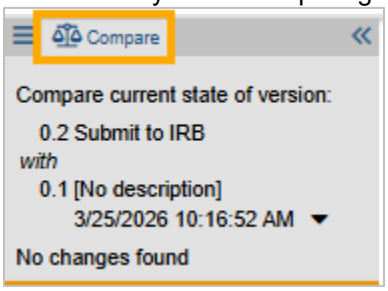


Compare Versions

After the study team submits their response to the clarification request at Pre-Review or Designated Review, you can compare versions to see the changes that were made.

To compare

1. From the study Left Navigator, click **Compare**. The Compare section of the Left Navigator shows the versions you are comparing.



2. Click the down arrow to show the versions that you can compare against.
    a. Select a version to compare against the current version.
3. Click the Pencil icon to view the change made to the Basic Study Information page.
4. The change is shown within the SmartForm. The new information is highlighted in green.

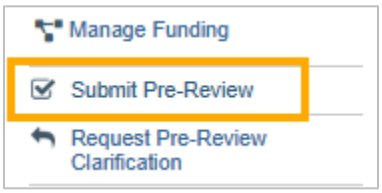
Submit a Pre-Review

After you have finished reviewing a submission for completeness, move it forward in the review process by submitting a pre-review.

Note: The Pre-Review form is editable in all states, including during a follow-on submission. However, if more than one follow-on submission is in progress for the parent study, the Pre-Review form is locked when a change is made to it.

To submit a Pre-Review

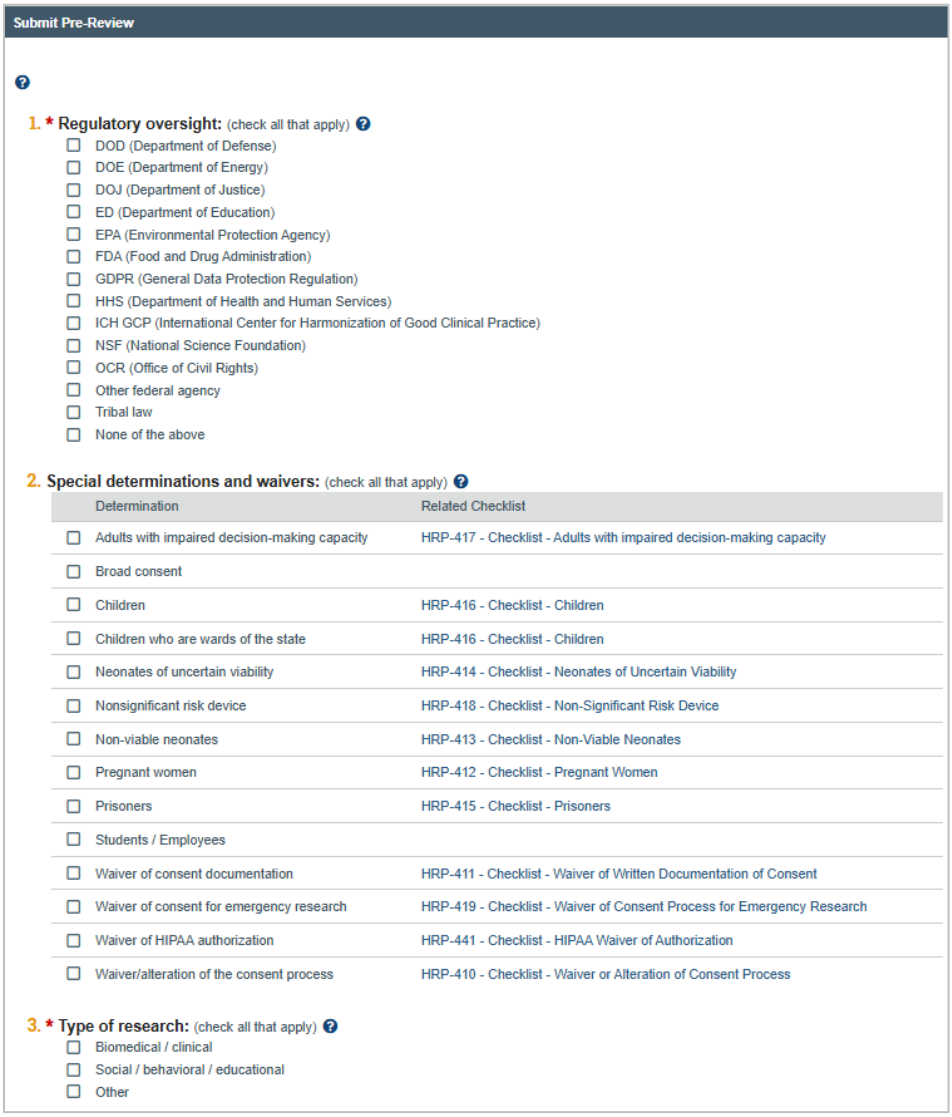
1. From the submission workspace, click **Submit Pre-Review**.



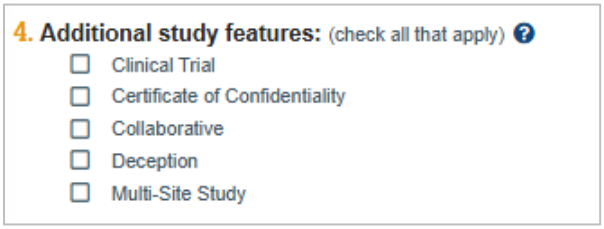
2. Complete the Submit Pre-Review page. Click the links to open and use a checklist.

   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. The Regulatory Authority label on the study workspace will read: 2018 Requirements +FDA +DOJ, depending on your selection.

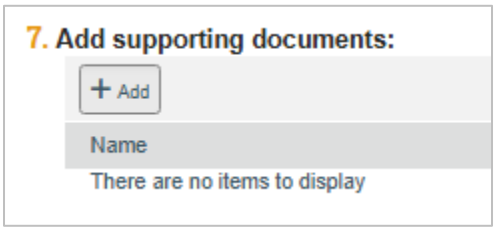
   Note: Broad consent is not a valid selection for studies falling under the Pre-2018 Common Rule requirements.



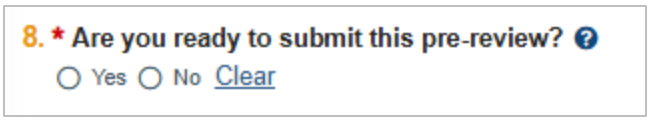
3. Indicate whether the study has any additional features.



4. Under Supporting documents, upload appropriate checklists based on the special determination and waivers selected.



5. Click **Yes** if you are ready to submit your review. If not, click **No** and you can return to this page later to submit.



6. When finished, click **OK**.

   Note: To correct a pre-review after you submit it, you can click **Submit Pre-Review** once more, make corrections, and click **OK** to resubmit.

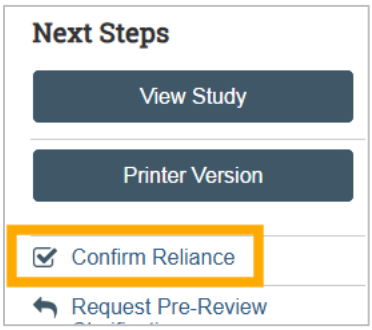
From here, you must decide whether to assign the study to a designated reviewer (non-committee review) or the committee to review.

Confirm Reliance with the External IRB

For a single-site external IRB study, you must confirm reliance on the external IRB before the submission can move forward in the review process. In the Top Navigator, click **IRB** and then **Submissions**. Click the **External IRB** tab, then open the study.

To confirm reliance

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



2. Complete the form.

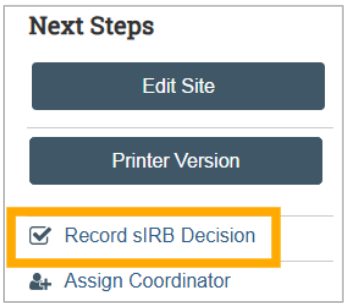
3. Click **OK** to finish. If reliance is confirmed, the site enters a Pending sIRB Review state.

Record the sIRB Decision for an External Study

IRB staff records and edits the sIRB decision for an externally reviewed study.

To record sIRB decision

1. From the study workspace, click **Record sIRB Decision**.

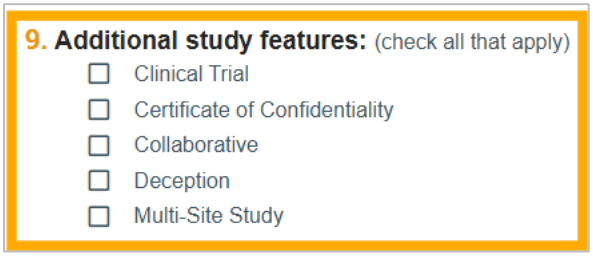


2. Complete the form.

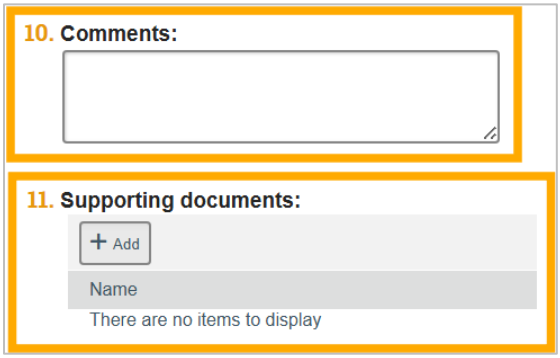
   Note: If you select FDA or DOJ in the Regulatory Oversight section, the study will automatically fall under the Pre-2018 Common Rule requirements, even if it falls after the effective date setting of the 2018 requirements.

   Note: Broad consent is not a valid selection for studies falling under the Pre-2018 Common Rule requirements.

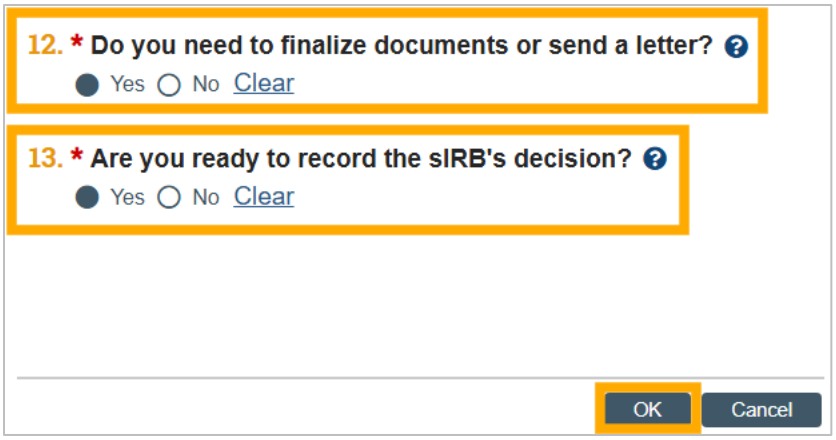
3. Indicate whether the study has any additional features.



4. Under Supporting documents, upload appropriate checklists based on the special determination and waivers selected.



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.



Update an Approved, Single-Site External Study

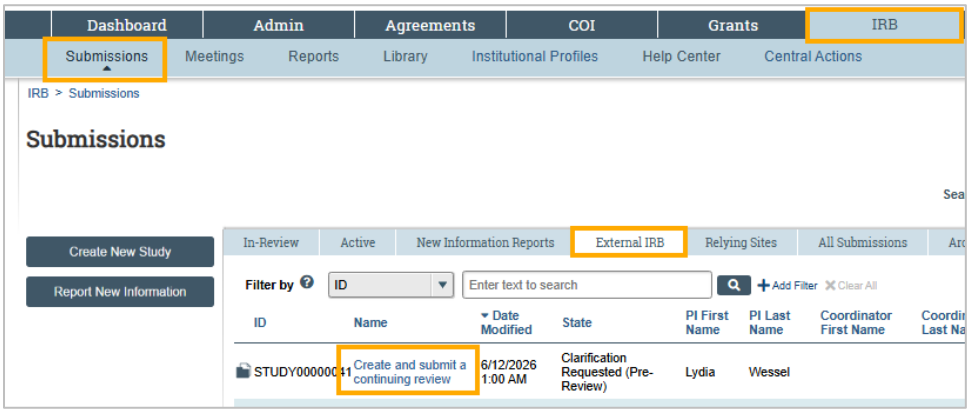
This section covers two scenarios when making an update to an approved, single-site study. Either the update originates with the local study, or the update originates with the external IRB, for example, when approval dates change.

Both the local PI and local IRB coordinator can make updates to the external study. If the local PI cannot finalize updates to the study, the PI can use the **Add Comment** activity to ask the IRB coordinator to finalize the update when the changes are complete.

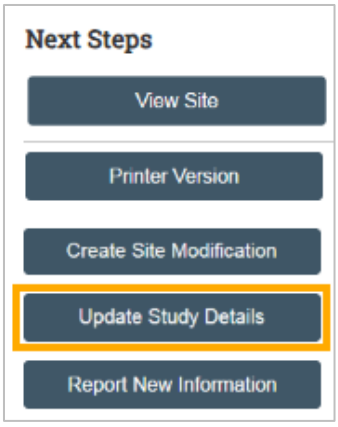
Updates that originate with the local study

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study.

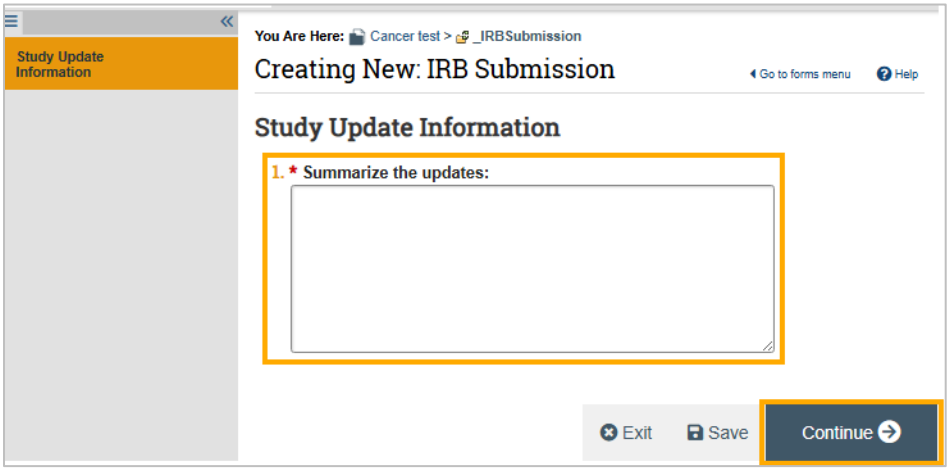
   Note: The active external studies are in the External IRB state.



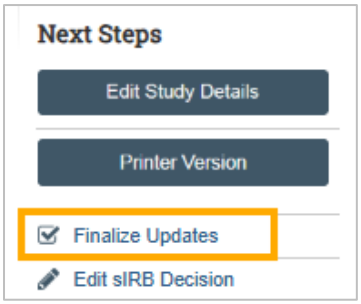
3. Click the **Update Study Details** button.



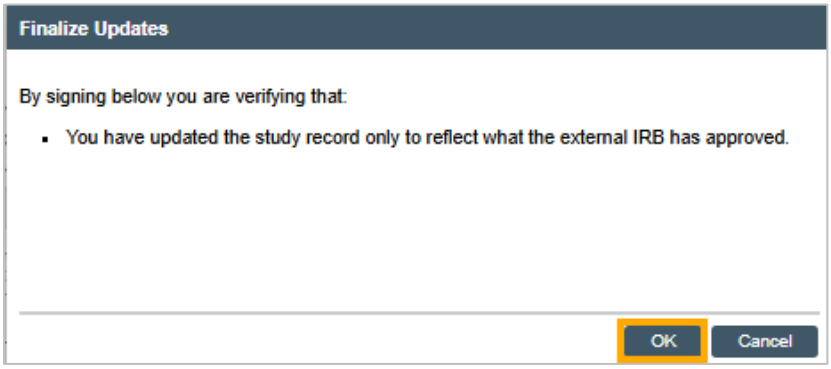
4. Summarize the updates, click **Continue**, then make changes to the study.



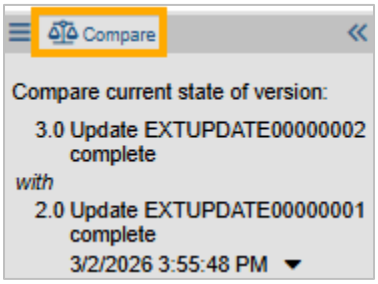
5. From the study workspace, click **Finalize Updates**.



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



7. To review the local PI's updates, from the study workspace, click **View Site** and click **Compare**. If there is an error, the IRB coordinator can send a comment to the PI asking them to submit another update with corrected information.



Note: Alternatively, the IRB coordinator can make another update with the correct information.

Updates that originate with the external IRB

1. After the external IRB notifies the local IRB of a change to the study, the local IRB coordinator runs the **Return to Post-Review** activity from the study workspace.



2. In Post Review, click the **Edit sIRB Decision** activity, then make the necessary changes. The activity presents the option to finalize documents, send a letter, or send the submission directly to Review Complete.



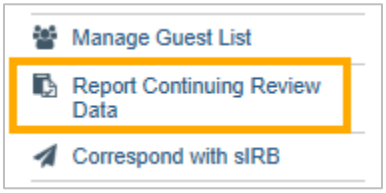
Report Continuing Review Data for an External Study

The local PI, PI proxies, and local IRB coordinator can report continuing review data for a single-site external study.

To report continuing review data for an external study

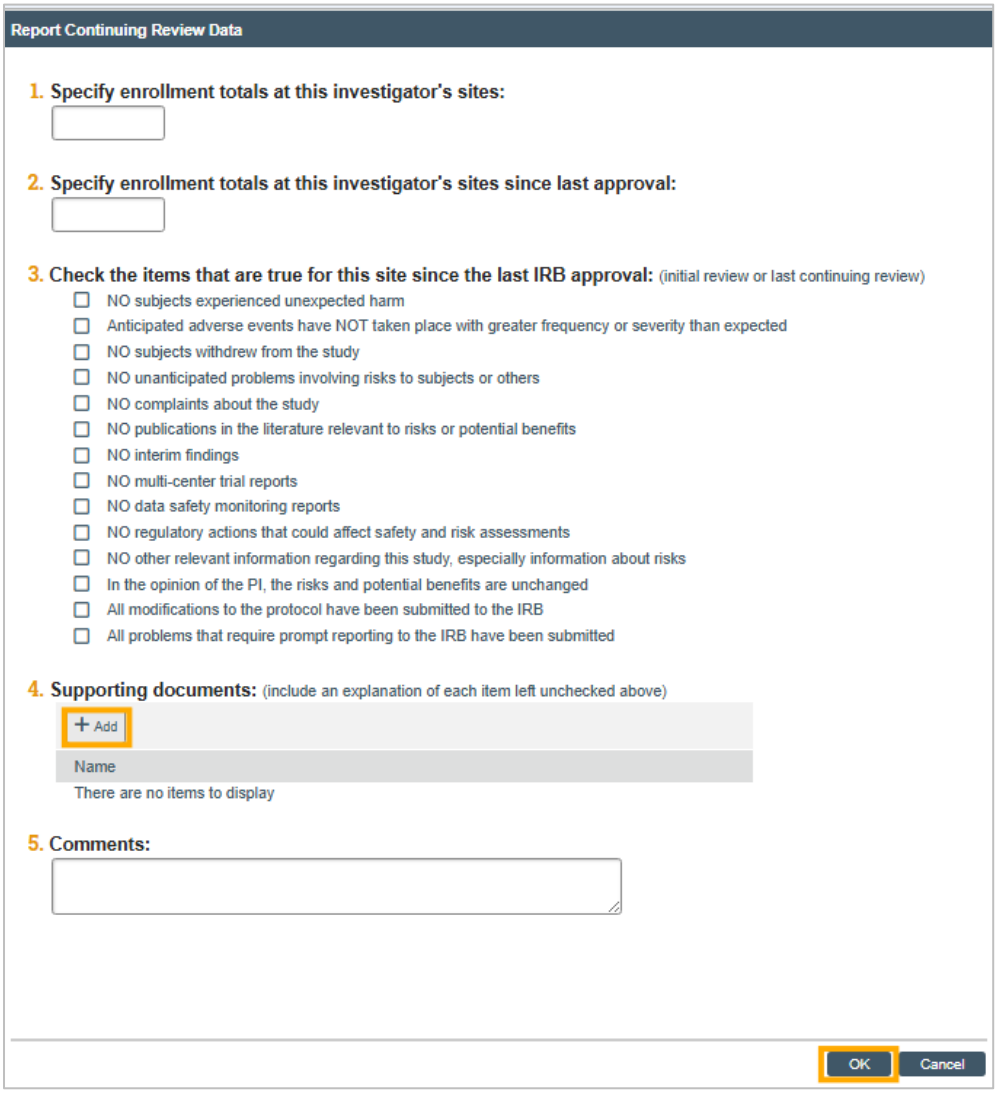
1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study.

   Note: The active external studies are in the External IRB state.
3. Click **Report Continuing Review Data**.



4. Complete the Report Continuing Review Data activity.
5. In **Supporting Documents**, ensure that you include an explanation for each unchecked item in the checklist on the Report Continuing Review Data page.

6. Click **OK**.



Manage Ancillary Reviews

PIs, IRB staff and study team member can invite other people or organizations, beyond IRB committee members, to review the submission. Ancillary reviewers can be assigned to a submission in almost any state, starting with Pre-Submission when they can be assigned by the PI or an IRB director. After Pre-Submission, the assigned coordinator can also assign reviewers.

Usually the reviewers are notified when they are added to the submission, and the submission appears in My Inbox for the reviewer if the ancillary review is required.

To assign ancillary reviewers to a submission

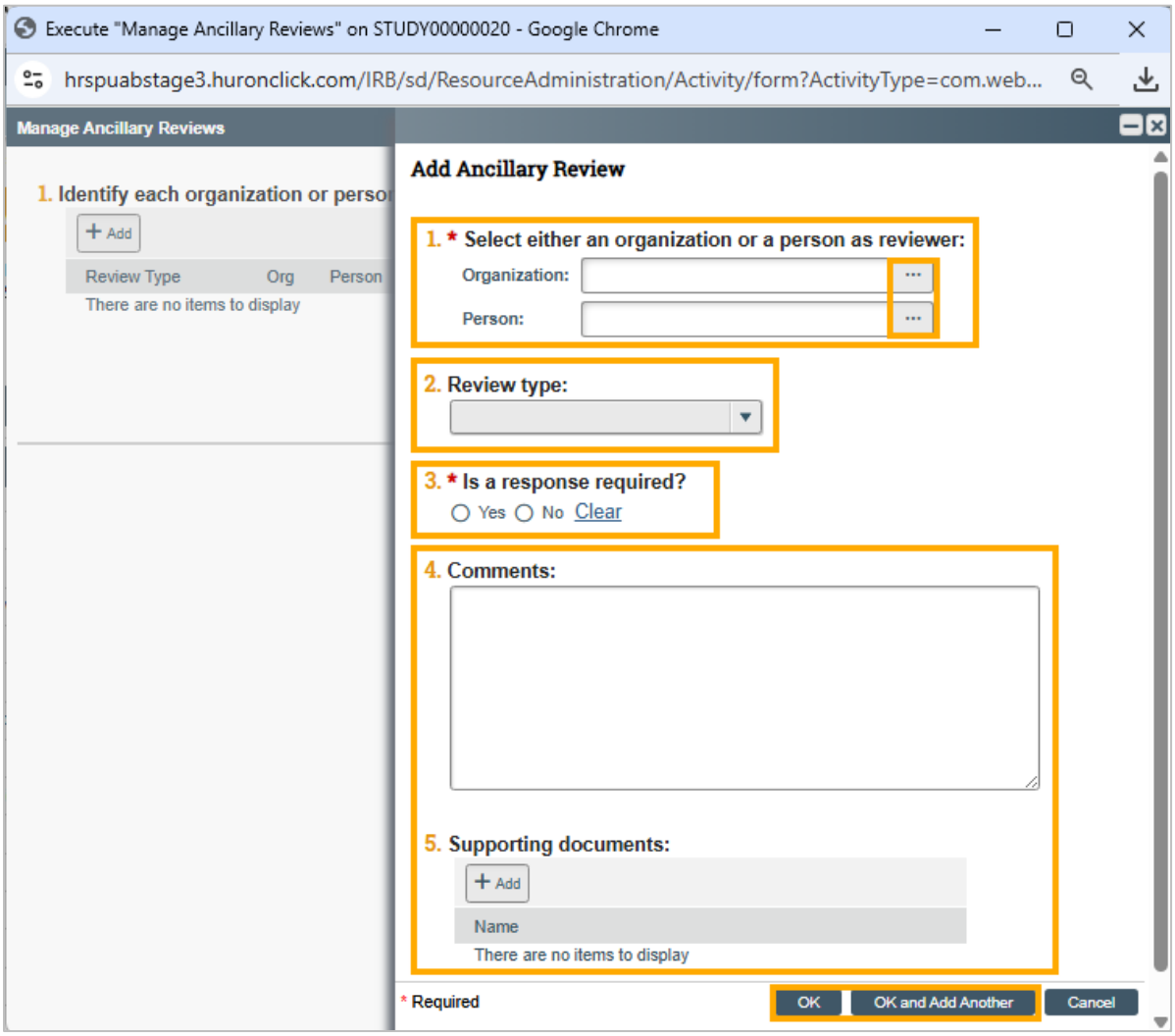
1. From My Inbox or one of the tabs on the appropriate IRB page, click the name of the submission for which you want to assign an ancillary reviewer.
2. In the study workspace, click **Manage Ancillary Reviews**.

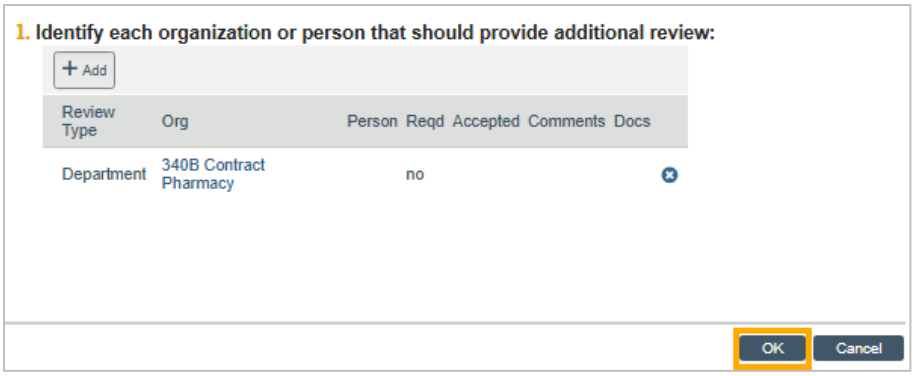


3. In the Manage Ancillary Reviews form, click **Add**.
4. On the Add Ancillary Review form, select an organization or person to do the review.

   Note: Ancillary reviewers must be assigned to an organization for the Organization option to be available.
5. Select the Review type.
6. Select whether a response for this ancillary review is required.

   Note: Site-wide settings can specify states at which outstanding required ancillary reviews block the workflow.
7. If necessary, add the comments and any supporting documents.
8. Click **OK** to add the ancillary review or click **OK and Add Another** to add another ancillary review.





You return to the study workspace. The assigned ancillary reviewers receive email notifications with the relevant details such as review type, comments, and supporting documents.

To override blocking of ancillary reviews

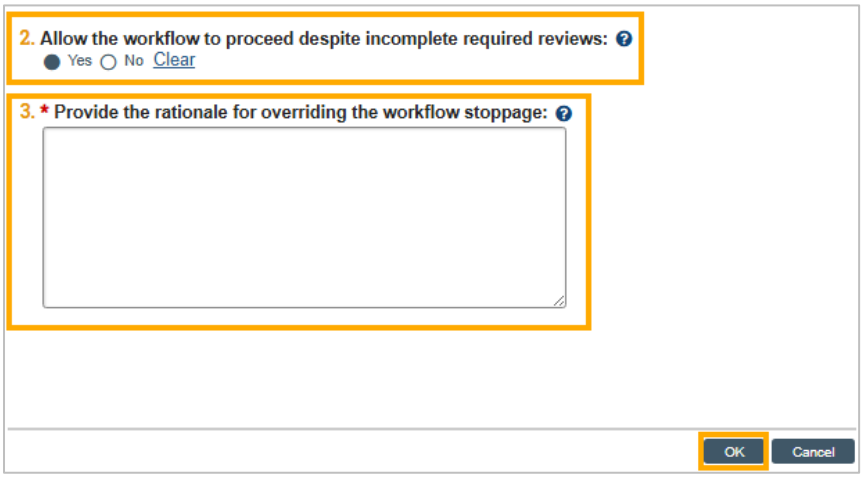
If an ancillary reviewer does not accept a study or complete a required ancillary review, the submission can be blocked from moving forward. If an error message, "All required ancillary reviews must be completed and accepted before executing this activity," displays, the following actions can move the submission past the blockage:

- The reviewer completes the ancillary review.
- The reviewer accepts the submission.
- An IRB staff member overrides the blocking of ancillary review.

1. From My Inbox or one of the tabs on the appropriate IRB page, click the name of the submission for which you want to override the ancillary review.
2. In the study workspace, click **Manage Ancillary Reviews**.



3. Select the **Yes** option for the statement 'Allow the workflow to proceed despite incomplete required reviews.'
4. The next item appears, indicating you must provide a rationale for overriding the workflow stoppage. Provide the rationale for the override, then click **OK**.



You return to the study workspace. The submission moves forward in the workflow.

Assign a Designated Reviewer

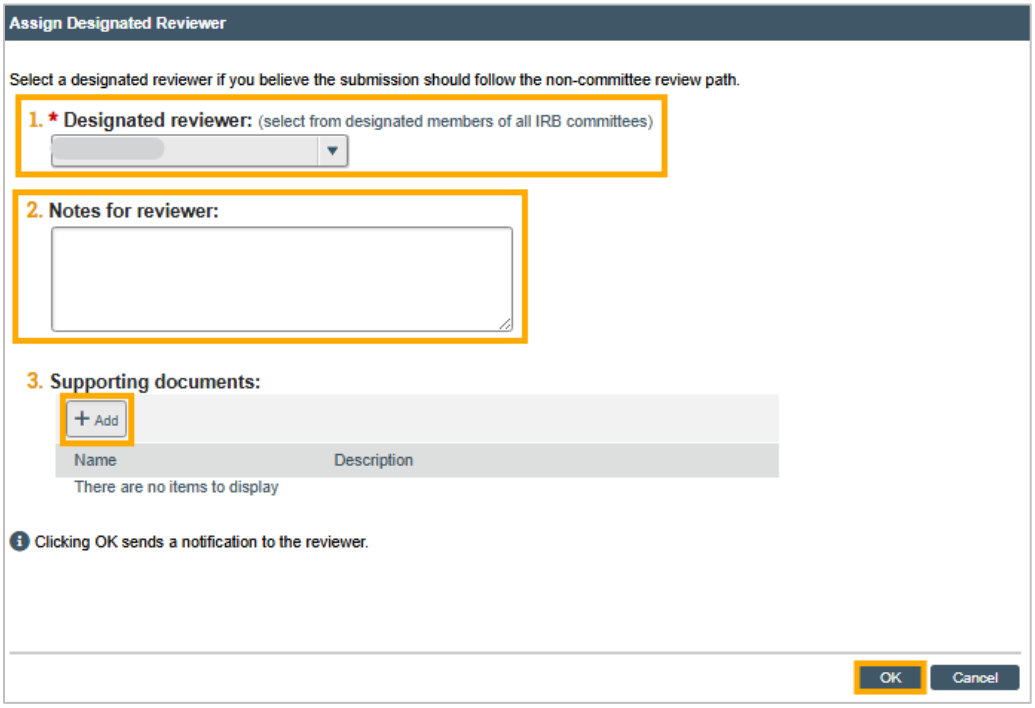
You can assign a study to one committee member to review or to a committee meeting for all committee members to review.

To assign a designated reviewer

1. From the study workspace, click **Assign Designated Reviewer**.



2. Select a committee member from the list.
3. To help the reviewer, you can add checklists or review documentation in the Supporting Documents section along with a note indicating this. This way, the reviewer doesn't have to search for them in the library.
4. Click **OK**.



The reviewer will receive a notification about the review and the study will appear in the reviewer's IRB inbox.

Note: You can correct mistakes in an already-submitted designated review by clicking **Submit Designated Review**, making corrections, and clicking **OK** to resubmit.

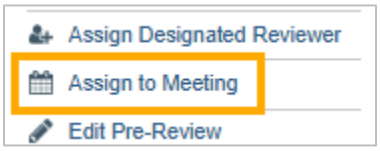


Assign to Committee Review

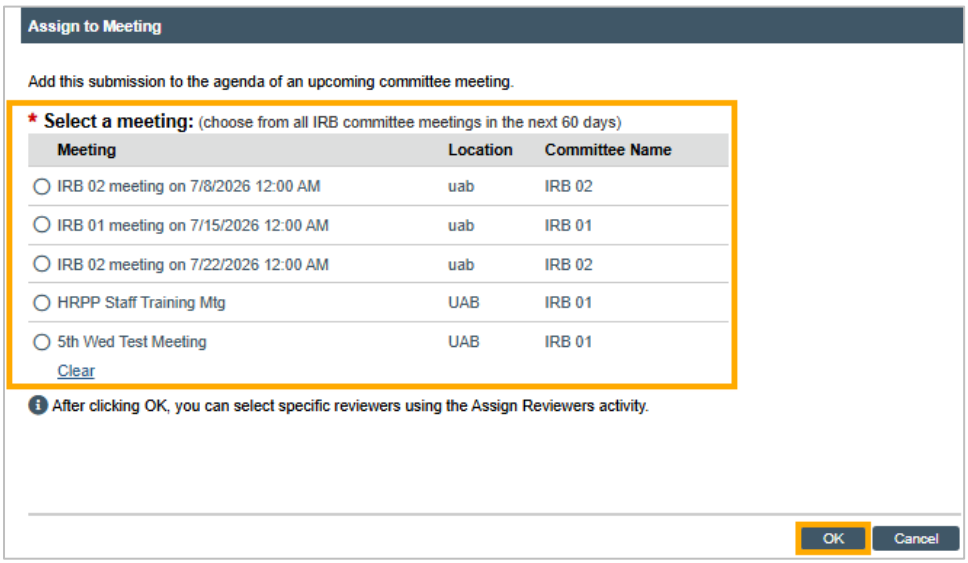
You can assign a study to one committee member to review or to a committee meeting for all committee members to review.

To assign to a committee meeting

1. From the study workspace, click **Assign to Meeting**.



2. Select the upcoming IRB meeting for the office the study belongs to.
3. Click **OK**. The details will appear on the IRB Assignment Details tab.



To assign committee reviewers

After you assign a submission to a committee meeting, you can assign specific committee reviewers.

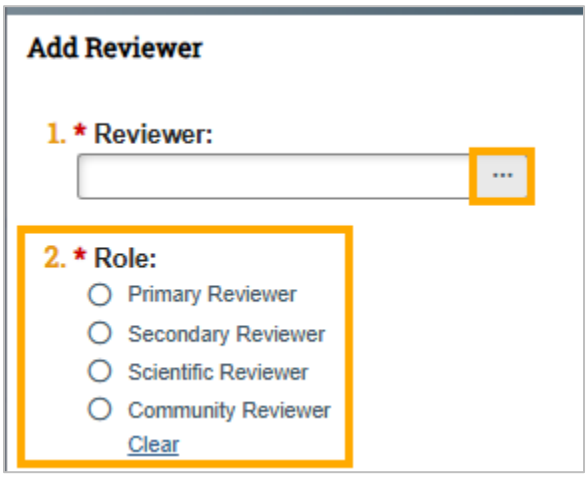
1. From the study workspace, click **Assign Reviewers**.



2. Click **Add**.



3. Click the ellipsis to select a reviewer, then click **OK**.
4. Select the reviewer's role.



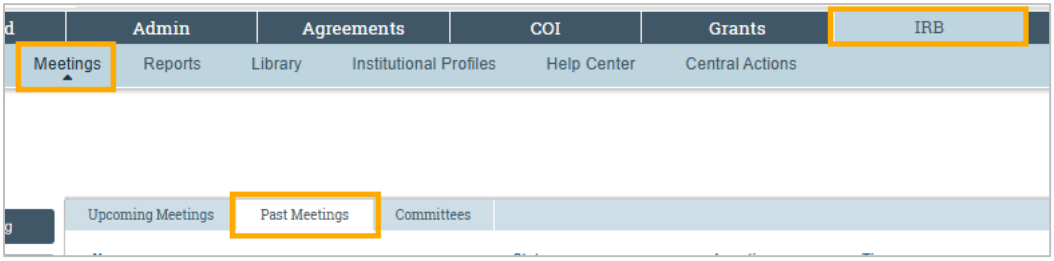
5. Click **OK** to finish, or **OK and Add Another** to select an additional reviewer.

Submit a Committee Review

If the submission went through a committee review, the next step is to record the committee's determination for that submission. You may do this during or after the committee meeting. An IRB staff member, committee admin, or committee chair can submit the committee review.

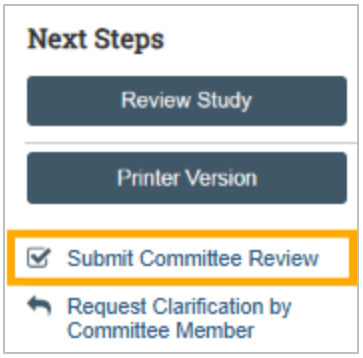
To find the study

1. In the Top Navigator, click **IRB** and then **Meetings**.
2. Click the **Past Meetings** tab and then the meeting name to open it.

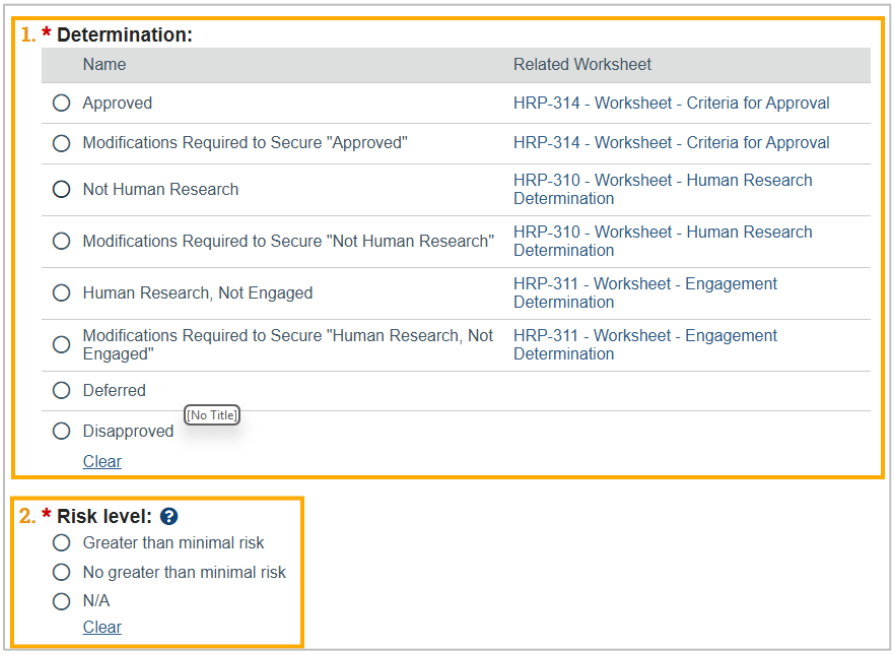


To record decision for a submission

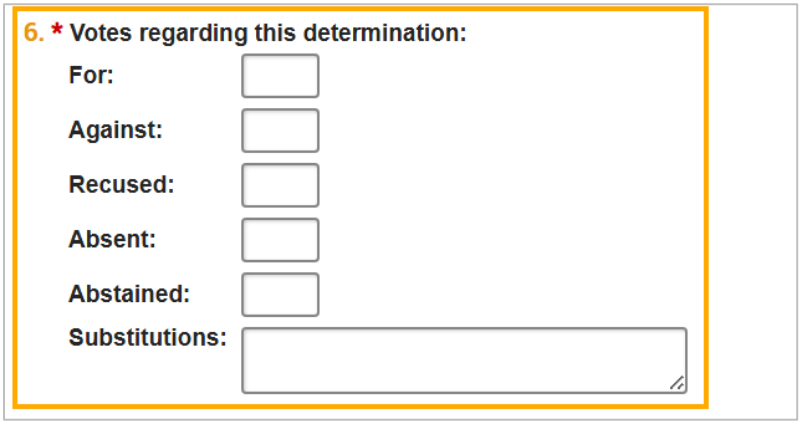
1. From the meeting workspace, in the Record Decision column, click the **Submit Committee Review** link.



2. On the Submit Committee Review page, pay attention to the following sections:
    a. **Determination**: Select the determination
    b. **Risk level**



    c. **Votes**: Fill in all votes regarding the determination.



    d. **Supporting Documents**: Include the final version of any relevant checklists.

e. **Are you ready to submit this review**: Click **Yes** to move the submission to Post-Review, and click **No** to return and finish the review at another time.

3. Click **OK** when done.



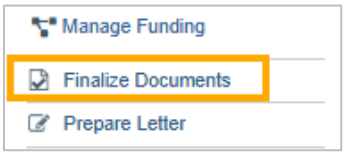
Note: To correct a committee review after you submit it, you can click **Submit Committee Review** once more, make corrections, and click **OK** to resubmit.

Post-Review Activities

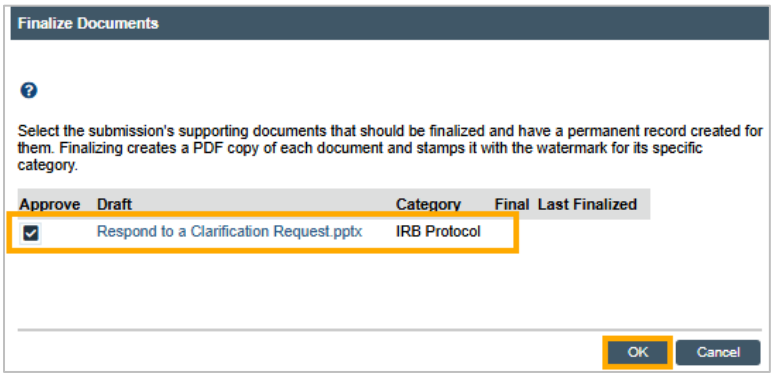
After the designated member or committee review decision has been submitted for a submission, the next steps are to finalize the documents and prepare and send the determination letter to PI.

To finalize documents

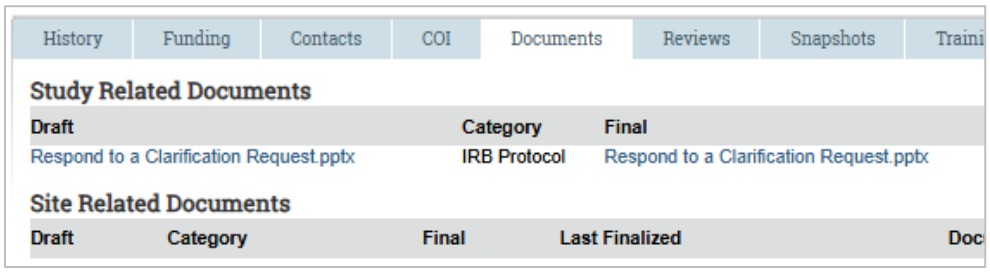
1. From the study workspace, click **Finalize Documents**.



2. Select the documents to change to PDF and watermark.
3. Click **OK**.

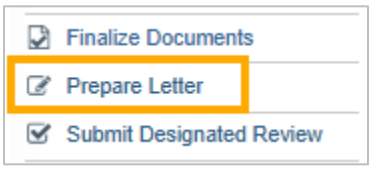


The Documents tab on the study workspace will include links to the final versions of the documents.



To prepare determination letter

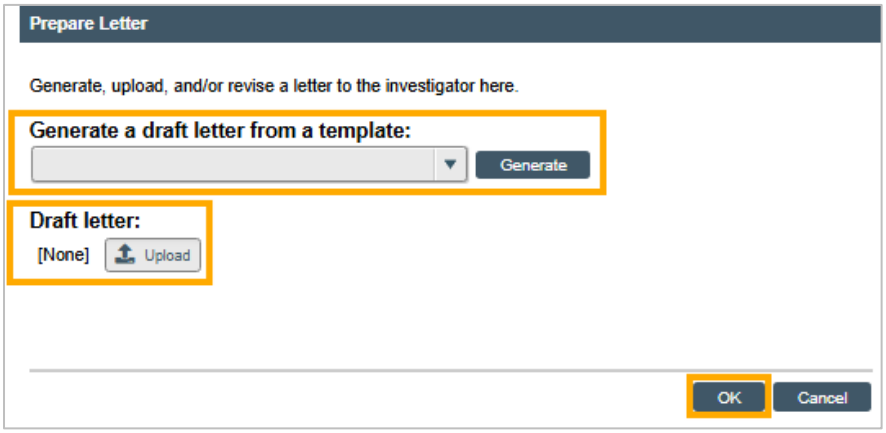
1. From the study workspace, click **Prepare Letter**.



2. You have two options:
   a. To create a letter from a template, select the template from the list and click **Generate**.

      Note: You can open the draft letter, change it as needed, and then add the revised document.

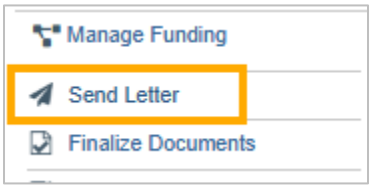
   b. To add a letter, click **Upload** and then browse for the letter.
3. Click **OK** when done.



Until you send the letter, you can use the Prepare Letter activity to regenerate the letter again or upload revisions.

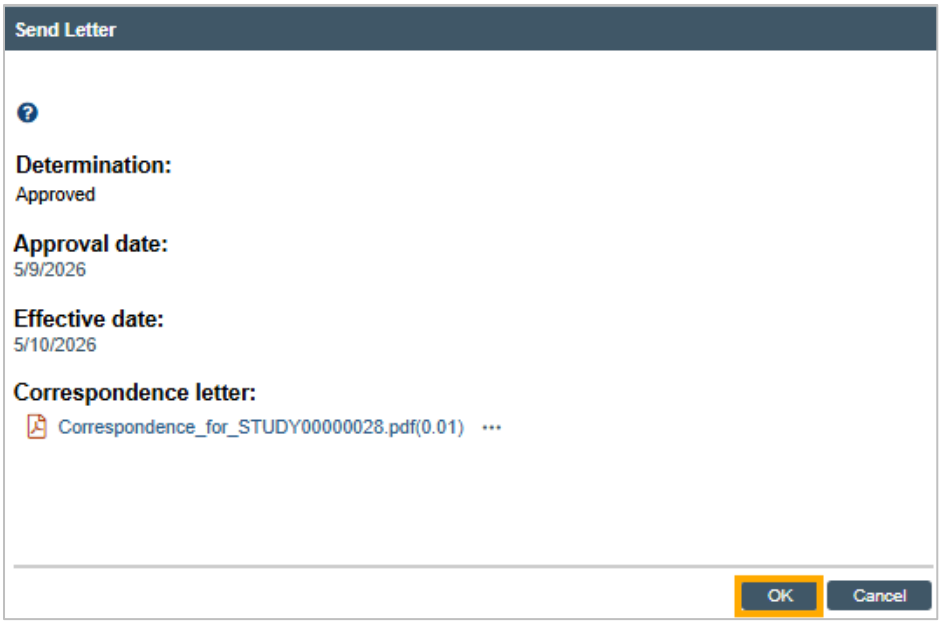
To send determination letter

1. From the study workspace, click **Send Letter**.



2. Review the determination and letter and then click **OK**.

   Note: You may want to verify the accuracy of the dates listed on the Send Letter page before clicking OK.



The letter is sent to the PI, PI proxy, and primary contact.

Manage Editors for RNI

IRB staff and the person who created the RNI can empower additional people to edit and take action on Reportable New Information (RNI) using the Manage Editors activity. The activity is available in any state.

There are two ways to get permissions to edit and perform additional actions on an RNI:

- **Be added as an editor via the Manage Editors activity**, which lets you:
    - Edit the RNI when it is in an editable state, submit it for review, submit a response to a clarification request, and submit an action response.
- **Have a relationship or assignment to the RNI.** The permissions vary based on the relationship, as defined in this table:

Relationship to RNI	Permissions
Reporter/creator of the RNI	Edit the RNI in any state when it is open to editing, submit the RNI for review, and submit a response to a clarification request
Assigned IRB coordinator	Edit the RNI in Pre-Submission, Action Required, or a Clarification Requested state and submit an action response
PIs and PI proxies of all related studies	Edit the RNI in Pre-Submission, Action Required, or a Clarification Requested state, submit the RNI for review, submit an action response, and submit a response to a clarification request
Responsible party for required actions	Edit the RNI in the Action Required state and submit an action response

The top of the Manage Editors activity form identifies the people who already have a relationship to the RNI (because you may not need to explicitly add them as editors). The activity form shows only relationships relevant to the current state of the RNI.

To manage editors

1. From the RNI workspace, click **Manage Editors**.
2. Notice those who already have permissions to edit the RNI and take actions on it in the current state and use the help icons if needed to identify what actions they can take.
3. Under **Additional people who can edit and submit the new information**, type a name or click the ellipsis button, and select one or more people.
4. Click **OK** (and click **OK** again if necessary).

The people you added immediately receive the new permissions. The RNI appears in their inboxes during states when the RNI is editable.

Close a Study (Admin)

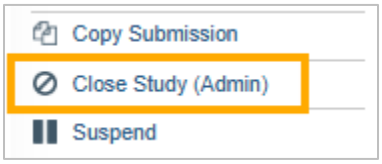
The Close Study (Admin) activity allows you to administratively move a submission to the Closed state. You can use this activity to close submissions determined to be Not Human Research or in a Human Research, Not Engaged state, instead of leaving them in their end state.

The Close Study (Admin) activity is typically used when the PI or study team members are no longer affiliated with the research institution. In such cases, the IRB Coordinator and IRB Director verify that the submission is inactive. If no one is available to close the study, they proceed to close it administratively.

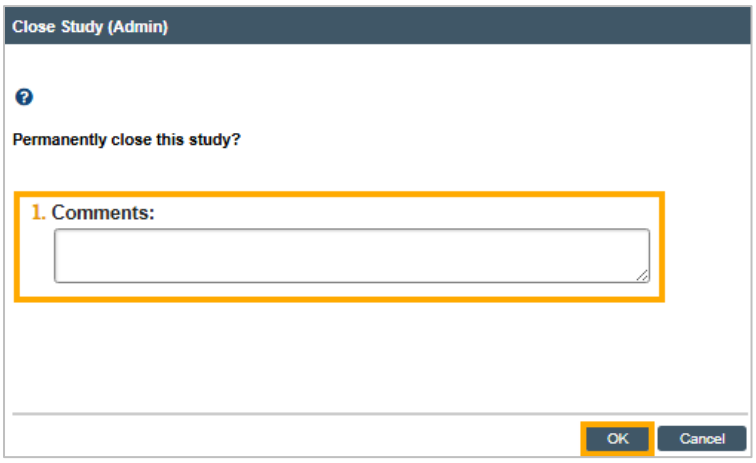
When you use the Close Study (Admin) activity to close a parent study, the system automatically discards any related follow-on submissions.

To close a study administratively

1. Open the study that needs to be closed administratively.
2. From the study workspace, click **Close Study (Admin)**.



3. Add **Comments** if any.
4. Click **OK**.



Reports

Generate Standard Reports

The IRB system includes many standard reports regarding studies and Reportable New Information (RNI) to help you find relevant submissions and understand the overall operation of the IRB. In addition, your institution may create custom reports.

For information about the advanced reports that can help you monitor the performance of your IRB, see the Advanced Reports Section.

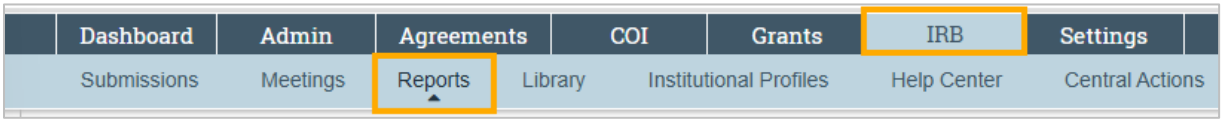
The reports provide links to the individual submissions, as well as sorting and filtering options.

Any user has access to reports, but the data in the reports is limited to the studies visible to the individual. For example, a Studies Involving Children report generated by a PI will include only the studies that person is allowed to see elsewhere in the system.

You can also see the reports on studies for which you are included on the study team or guest list. IRB coordinators, directors, and committee members generally have access to all report data.

To generate a standard report

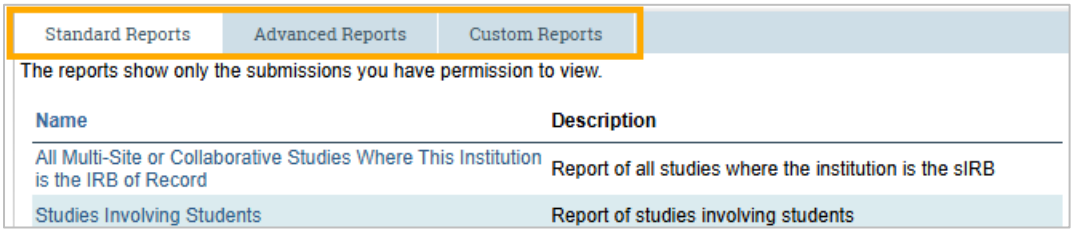
1. In the Top Navigator, click **IRB**.



2. Click **Reports**. The list of standard study and RNI reports appears.

   Tip: To find a custom report, click the **Custom Reports** tab.

3. Identify the report to generate and click the link. The report appears, listing the relevant submissions.



   Tip: Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Approved** for a study report or **Acknowledged** for an RNI report and press **Enter**.

Tag Submissions

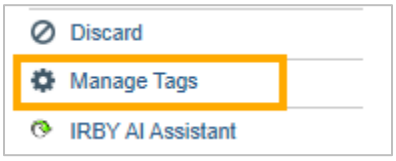
As an IRB staff member, you can add tags, or keywords, to any type of IRB submission so that you can later report on those submissions. For example, you could tag submissions with "Phase III" to identify submissions in that clinical trial phase.

You can associate tags to any type of submission in any state.

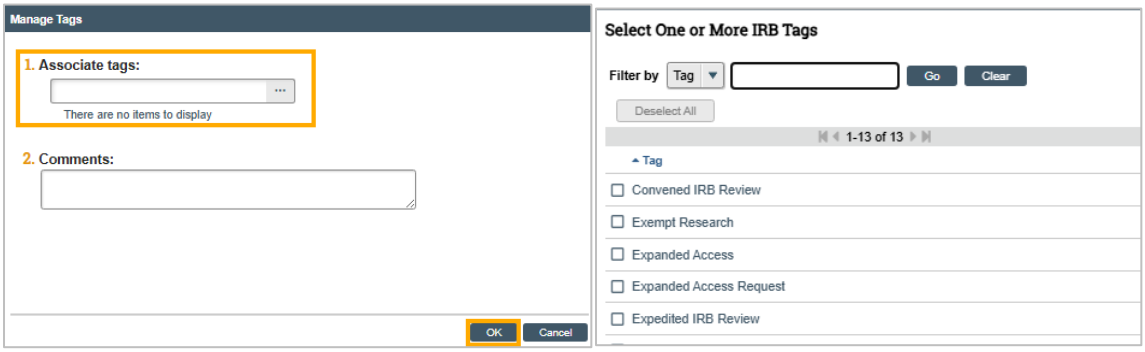
Note: IRB Data Managers can update and add to the list of tags that can be associated with a submission.

To tag a submission

1. From My Inbox, click the name of the submission you want to open.
2. Click **Manage Tags**.



3. Under Associate Tags, start typing the name of the desired tag or click the ellipsis.
4. Select tags from the list and click **OK**. If you want to use a tag that is not in the list, contact your site administrator to add it.
5. Click **OK** again to associate the tags with the submission.



Tip: You can find the tagged submissions by searching for the tag text in the search box on the IRB Submissions page.

Mass Update Administrative Assignments

Mass update activities can update administrative assignments on multiple projects in a single run. This is much more efficient than methods that affect only one project at a time, such as selecting personnel in a SmartForm or running activities from the project workspace.

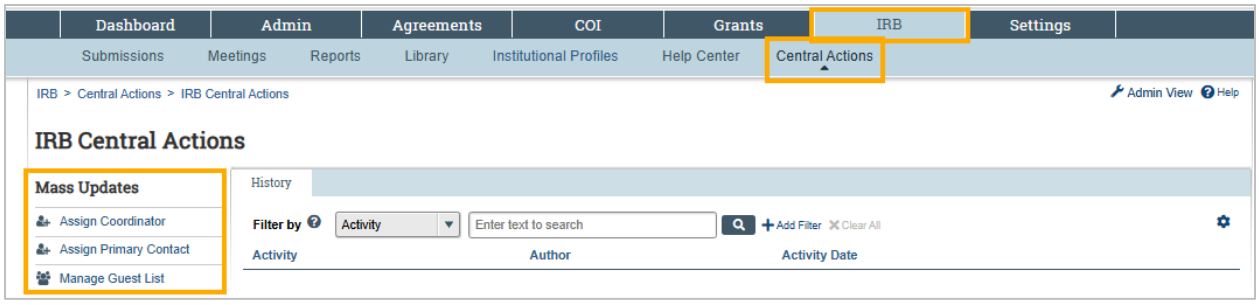
Mass update activities reside on the IRB Central Actions workspace.

When planning a mass update, remember:

- Mass update activities support only administrative assignments that do not require additional reviews and approvals.
- The security and business rules governing mass update activities, such as who can be assigned, and how that will impact a project, are the same as for single-project assignment activities.
- As mass updates can have extensive impacts, only users with the Site Manager or IRB Data Manager role can run them.
- To run a mass update activity, a data manager must also have at least one role with Read rights on the targeted projects, for example, Global IRB Viewer.

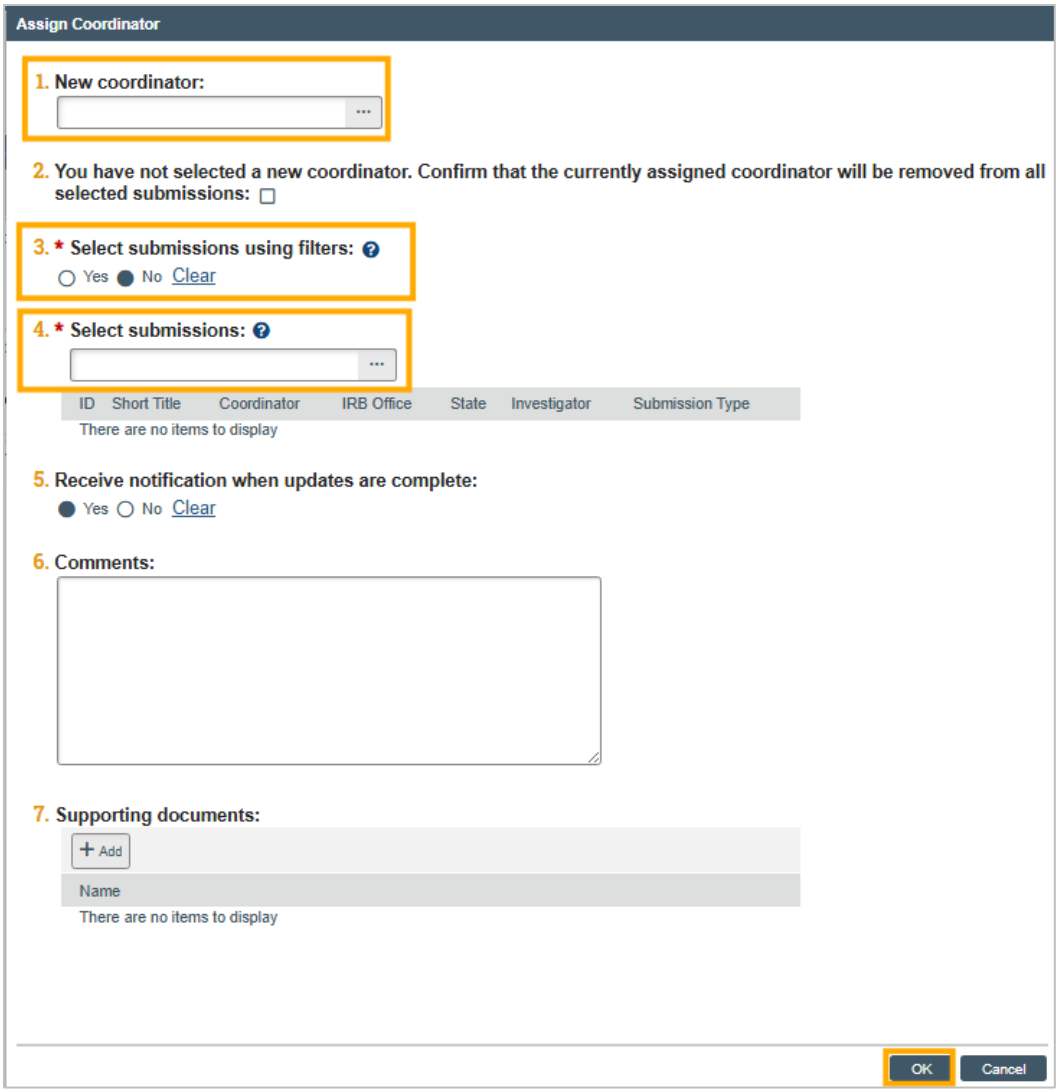
IRB mass update activities support these assignments:

To make this assignment	Run this activity
Replace coordinator	Assign Coordinator
Replace primary contact	Assign Primary Contact
Add or remove guests	Manage Guest List

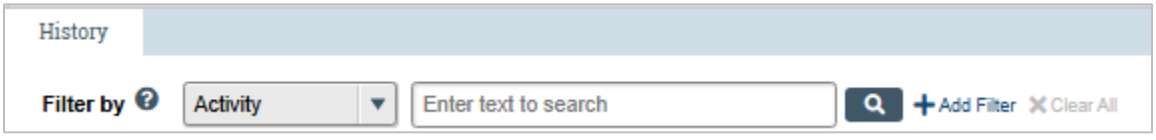


To run a mass update activity

1. Select the appropriate type of activity for the assignment.
2. Select the personnel to perform the activity upon.
3. Select the projects to affect. You can do so in two ways:
   - **Filter projects by specified attributes.** This option lets you define a set of filters to apply. You can select more than one item for each filter. Once you OK a set of filter selections, the activity form reports how many projects satisfy your filter criteria. You can then preview the list of projects to verify they're the ones you intended. If not, you can modify the filters and preview until you are satisfied with the returned list. Executing the activity updates the specified administrative assignments on every project satisfying your filter criteria. Use filtering when you need to update assignments for many projects.
   - **Select projects from a list.** This is the standard selection mechanism used throughout IRB, and offers the standard search features. Selecting projects from a list is a good approach when you need to update assignments for only a few projects.
4. Once you've selected the desired projects, click **OK** on the activity form to run the activity. As the data manager who ran the mass update, you receive a notification when it completes.



5. Review the activity history when the update completes.
   - To examine the filtering criteria that were used, click the activity name on the History tab, and on the resulting summary, click **View More Details**.
   - If the activity history shows skipped or failed updates, click the **Background processing results** link to open a spreadsheet with additional details. This spreadsheet also serves as an audit trail for which projects were affected.



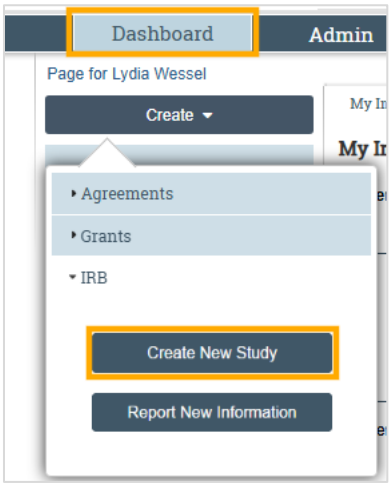
Researcher Tasks

Create and submit a study

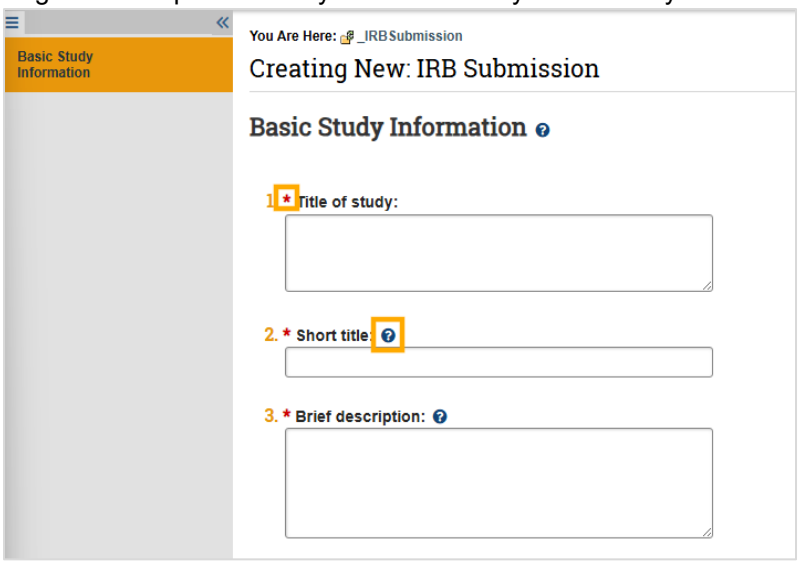
Before you begin, gather files and information about your study. For more details on documents you may want to attach to a study, see the Checklist of Information to Attach.

To create a study

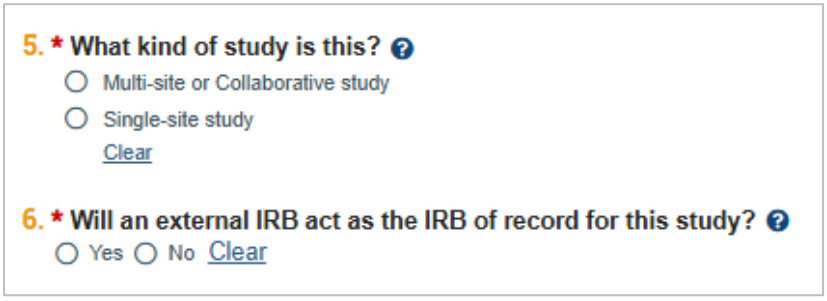
1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



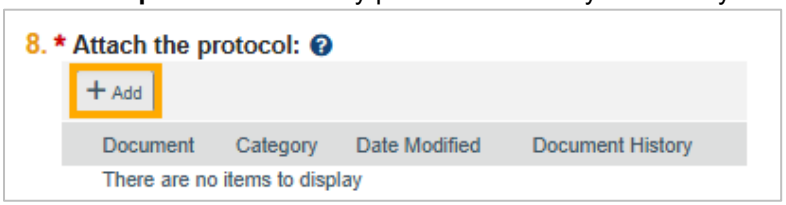
2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following pages:
    a. **Basic Study Information**: use the following questions to indicate whether the study is a single- or multiple-site study or will be locally or externally reviewed.



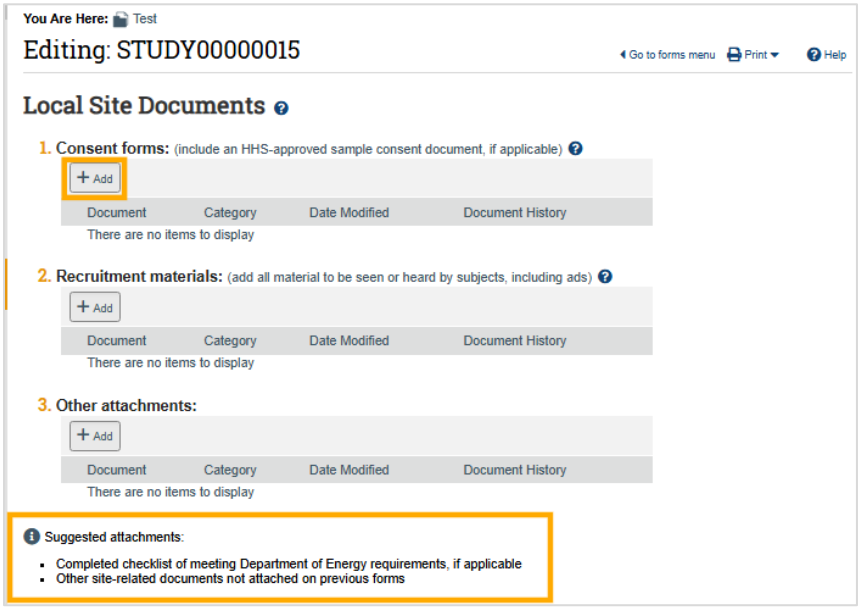
b. **What kind of study is this?**
c. **Will an external IRB act as the IRB of record for this study?**



d. **Attach the protocol**: the study protocol is the only mandatory document to include.



e. **Local Site Documents**: add consent forms, recruitment materials and other documents specific to your study.



f. **Study-Related Documents**: if the study is a multi-site study for which you are serving as the sIRB, use this page to add templates for consent forms, recruitment materials, and other that participating sites will need to access.

4. On the final page, click **Finish**.

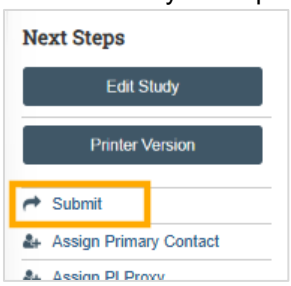
Important! Clicking Finish does not send the study to the IRB office. It remains in the Pre-Submission state. When the study is ready for IRB review, the PI or PI proxy must submit it using the steps that follow.

You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

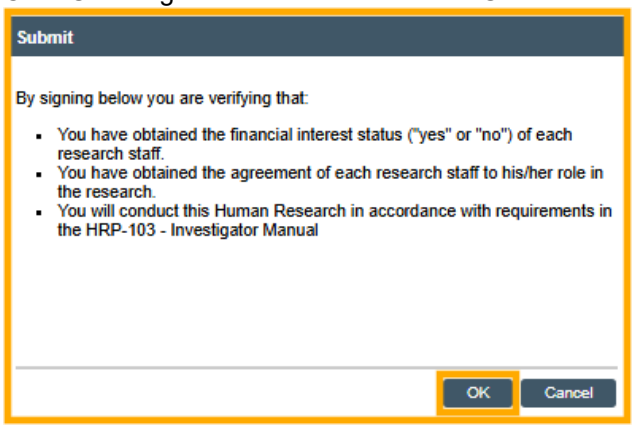
To submit a study for review

Tip: Only the study's PI or an assigned PI proxy can submit it for review.

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



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



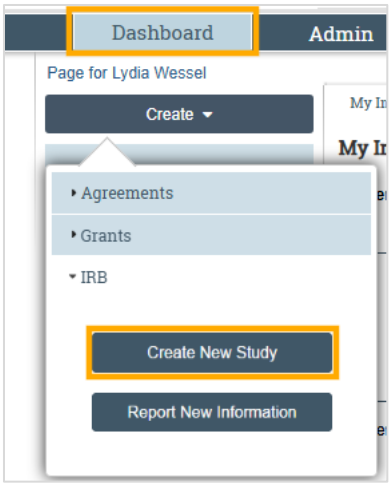
Your study has been submitted and has moved to the Pre-Review state. You can log off the system.

Create and Submit a New Single-Site External Study

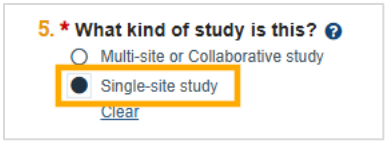
External IRB study forms require less information than normal, but do require information about the external IRB. A single-site external study is when an IRB other than UAB oversees the regulatory review of the study.

To create an external single-site study

1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following pages:
    a. **Basic Study Information**: use the following questions to indicate whether the study is a single-site and that an external IRB will act as the IRB of record (Externally reviewed MSS are covered in the IRB Multi-Site Study Guide.)
        i. **What kind of study is this?**



        ii. **Will an external IRB act as the IRB of record for this study?**

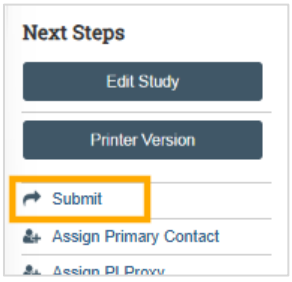


    b. **External IRB**: Specify which institution will serve as the external IRB.
4. On the final page, click **Finish**.

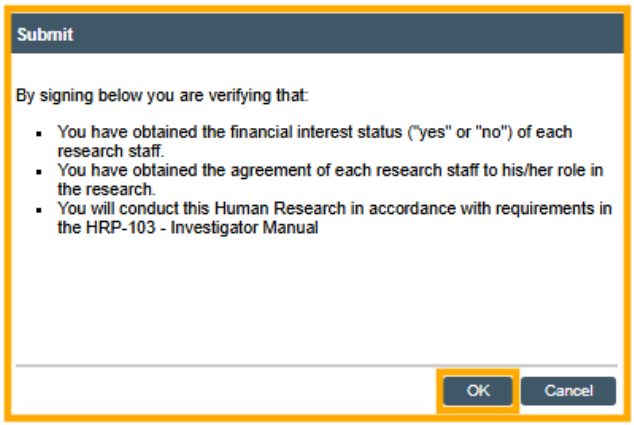
You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

To submit the external study for review

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



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



You can log off the system. Your study has been submitted.

Change Study Documents

You can update your study documents any time prior to submitting the study to the IRB for review. Once it is in the review process, you can only update documents if the IRB coordinator or a committee member requests clarification, or if you are submitting a modification to the study.

To change study documents

1. From My Inbox, open the study you want to edit. If the study is not in your inbox, contact the IRB coordinator assigned to your study.
2. From the submission workspace, click **Edit Study**.
3. Add and update documents on study pages as needed and exit the study when done.
    a. When updating a document previously submitted to the IRB, revise it using Word's Track Changes feature and then replace the original document with the tracked-changes version. When the IRB finalizes documents on approved studies, all tracked changes will be accepted and comments removed.

If responding to a clarification request, see Respond to Clarification Requests to submit the changes back to the IRB.

Respond to a Clarification Request

If a reviewer has questions or requires you to change your submission, you will receive a notification indicating this.

Review the request details and then respond to the request.

To review the request details

1. Click the submission ID link in the email to open it. If you no longer have the email, see Open a Submission and then View History to see reviewer comments.
2. Click the **History** tab and review the Clarification Requested activity.



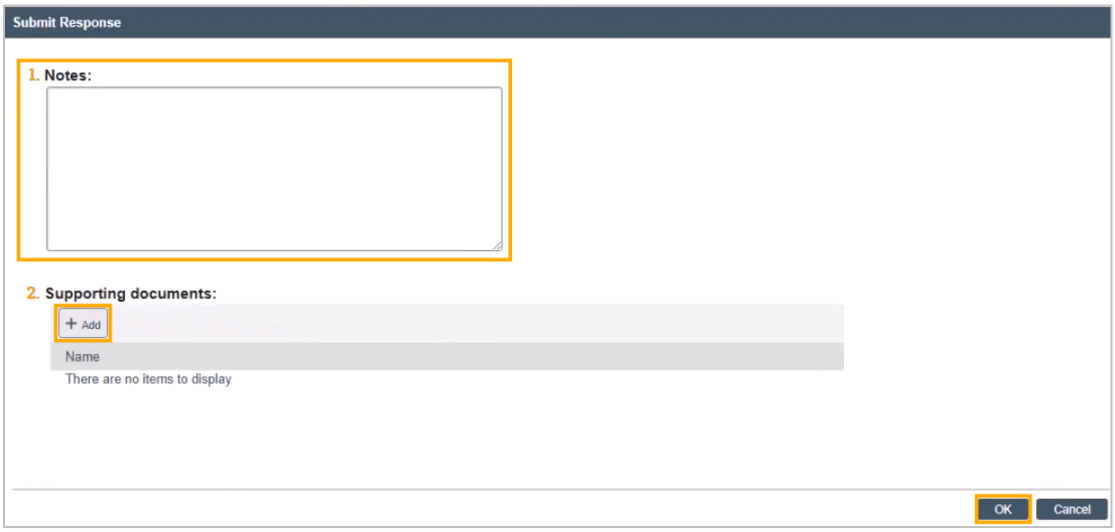
Note: If the reviewer attached a document, a link to open it appears on the History tab.

To submit response

1. On the submission workspace, click **Submit Response**.



2. In the Notes box, explain your response to the reviewer.
   Note: If you responded to the reviewer's request in a document, you can add the document in the Supporting documents area.
3. Click **OK**.



You can log off the system. The study has moved back to the reviewer's inbox to continue the review.

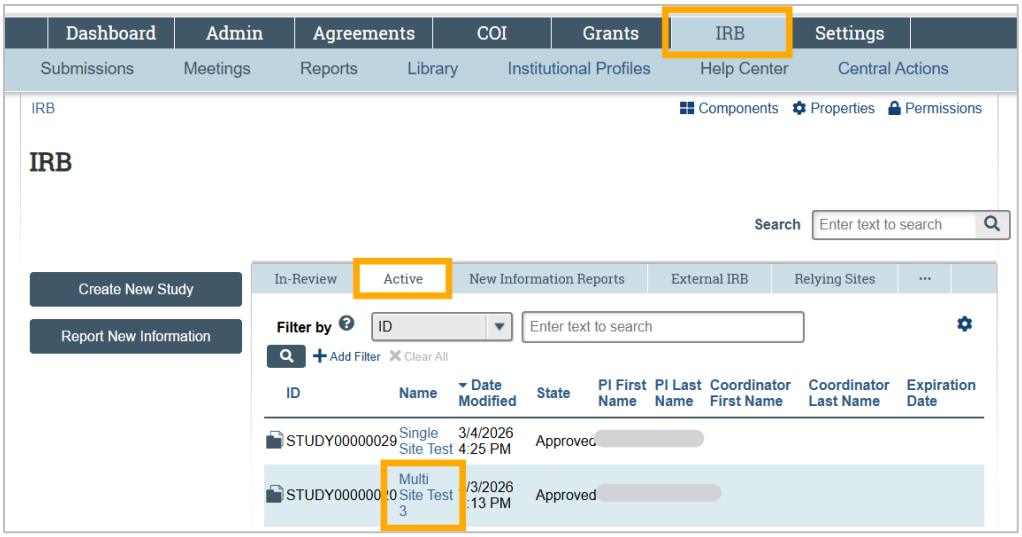
Create and Submit a Continuing Review or Modification

You can submit a Continuing Review (CR), a modification, or both combined:

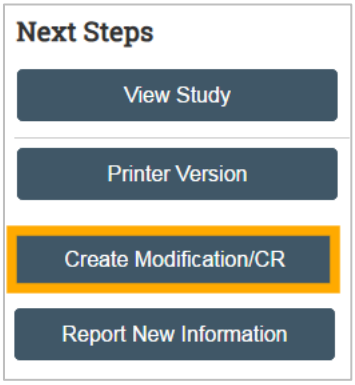
- To close a study or extend your approval period, submit a CR.
- To change an approved study or the study team's members, submit a modification.

To create a CR or modification

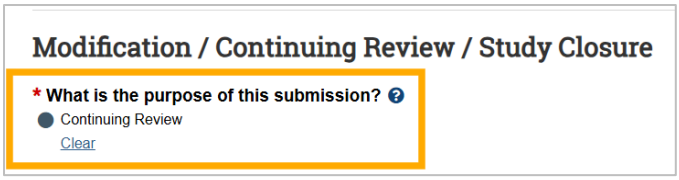
1. In the Top Navigator, click **IRB** and then **Submissions**.
2. On the IRB page, click the **Active** tab and open the approved study.



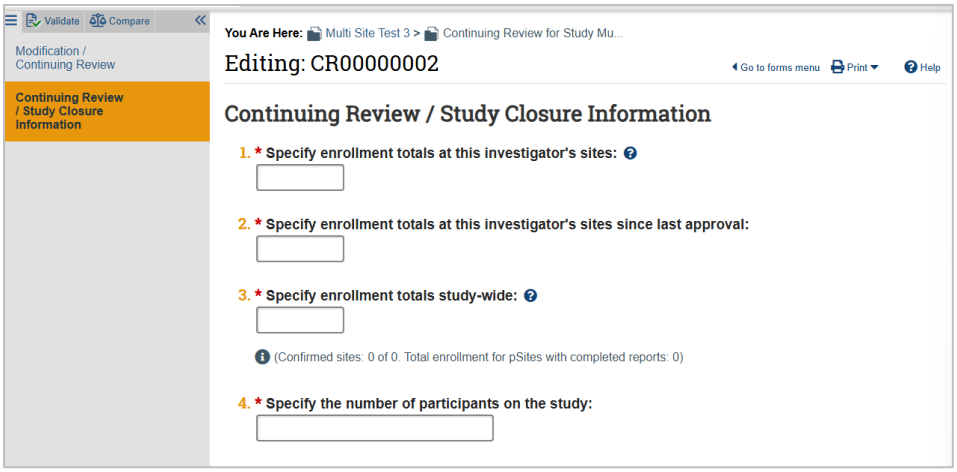
3. Click the **Create Modification/CR** button.



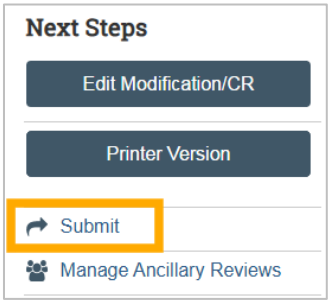
4. Select the purpose of the submission.



5. Complete the pages. Click **Continue** to move through the pages and **Finish** on the last page.



6. From the workspace, click **Submit**.



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

You can log off the system. Your modification or CR has been submitted.

To find your modifications and CRs, go to the Submissions page (In the Top Navigator, click IRB and then Submissions), and then the Follow-On Submissions tab.

Common Rule Changes to the Continuing Review Activity

When the IRB Coordinator submits the Pre-Review, after the effective date, they can move studies under the old Pre-2018 Common Rule requirement to the new 2018 requirement. There are two exceptions though:

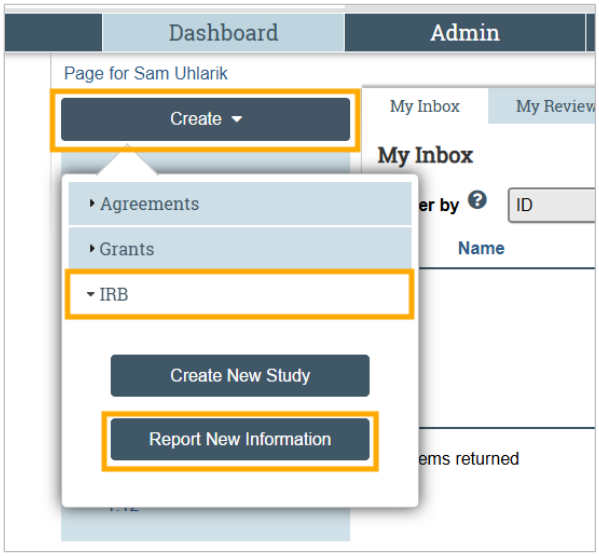
- Studies under FDA and DOJ regulatory oversight remail under the more stringent Pre-2018 requirements.
- When you see FDA or DOJ in the regulatory field, that means the system is functioning under the Pre-2018 requirements.

Create and Submit Reportable New Information

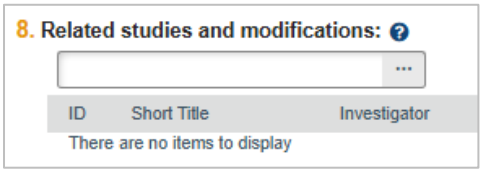
You can report any adverse events or new information about a study as soon as you become aware of it.

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.



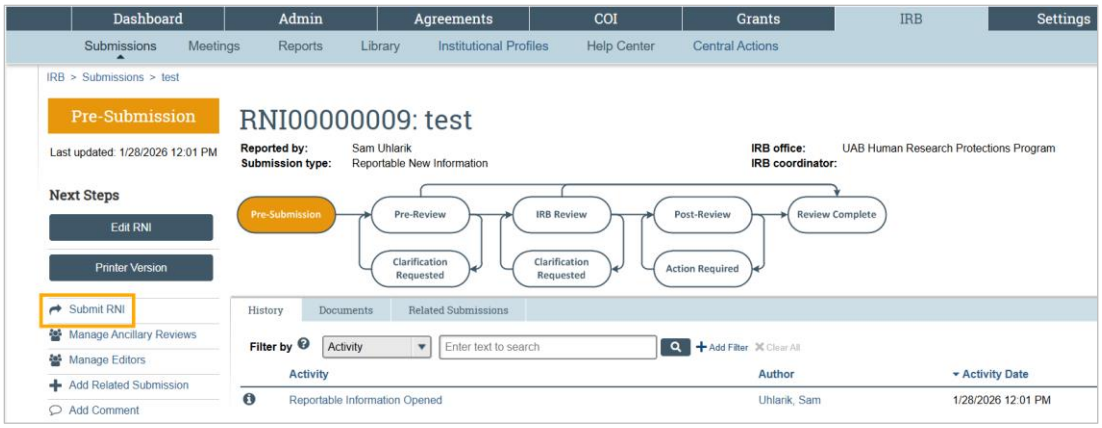
3. Complete the Reportable New Information page. Pay attention to the following question:
   a. **Related studies and modifications**: Select any studies or modifications that the RNI applies to.



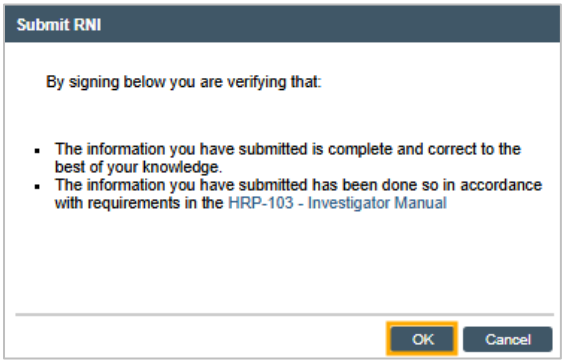
   Notes:
   - To relate a modification to the RNI, first add the parent study. You cannot relate sites, external studies (unless the external study is part of a multi-site study), or other follow-on submissions to an RNI.
   - The PI, PI proxies, and primary contact of each related submission are notified 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.

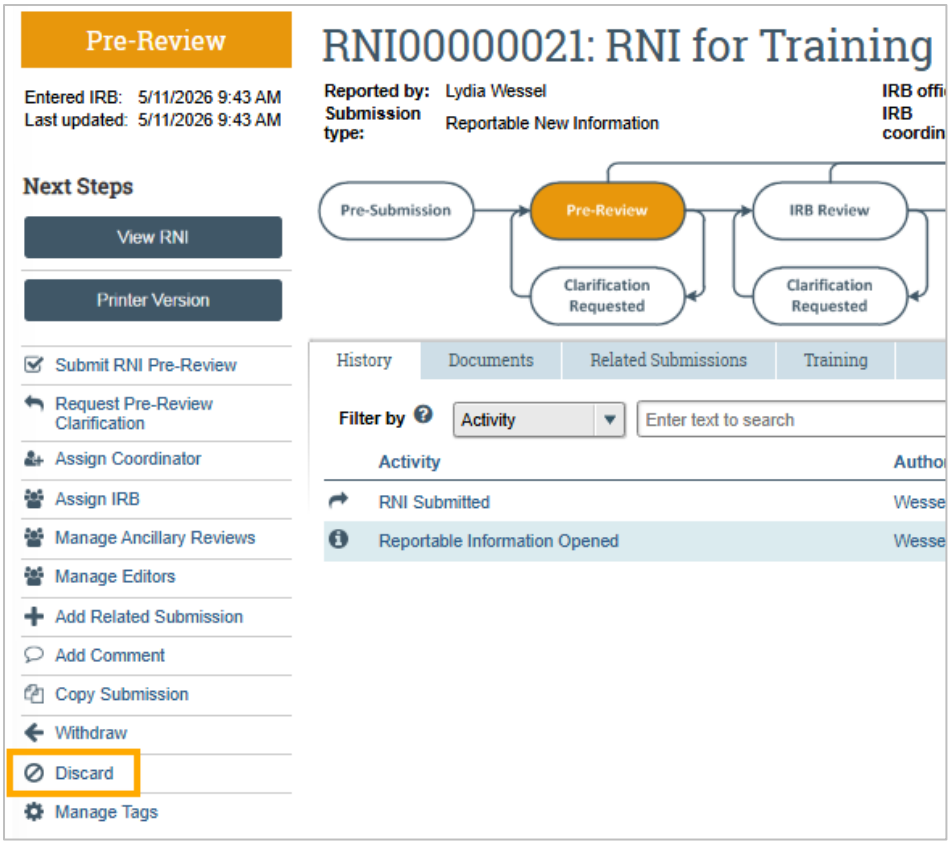


You can log off the system. The RNI has been submitted to the IRB. After reviewing the RNI, the IRB may require specific actions be taken and assign a responsible party to do so.

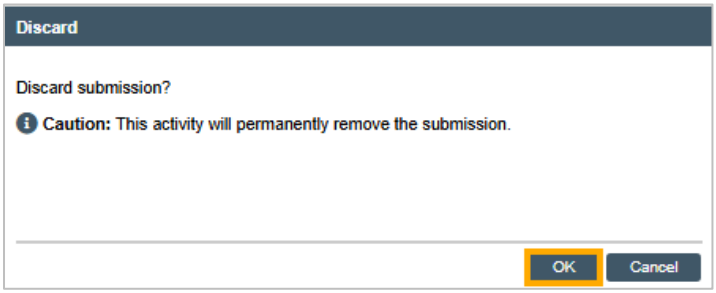
Discard an RNI

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.



Checklist of Information to Attach

While editing the study, several forms provide places to attach related files. In some cases, a template file is provided directly on the form for download, such as the protocol.

When attaching each file, name it as you want it to appear on the IRB approval letter.

Attach the information listed below (if relevant to your study) to the location identified.

Protocol (Basic Information page)

- Investigator protocol
- Complete sponsor protocol

- Site supplement to sponsor protocol
- HHS (Department of Health and Human Services) protocol

Funding information (Funding Sources page, with each source)

- Grant applications

Drug details (Drugs page, with each drug, or on main Drugs page if not specific to one drug)

- Package insert
- Investigator brochure
- Verification of each IND number (one of these):
    - Sponsor protocol with the IND number
    - Communication from the FDA or sponsor with the IND number

Device details (Devices page, with each device, or on main Devices page if not specific to one device)

- Product labeling/device instructions
- Investigator brochure
- Verification of each IDE or HDE number (one of these):
    - Sponsor protocol with the IDE / HDE number
    - Communication from the FDA or sponsor with the IDE / HDE number

Recruitment and consent details (Local Site Documents page)

- Consent documents:
    - Consent forms
    - HHS-approved consent document
    - For non-written consent, a script of the information provided orally to the subjects
- All material to be seen or heard by subjects, such as:
    - Evaluation instruments and surveys
    - Advertisements, including printed, audio, and video
    - Recruitment materials and scripts
- Foreign-language versions of materials for subjects
- Supporting document and other attachments:
    - Conflict of Interest Committee's determination for each financial interest related to the research
    - Completed checklist of meeting Department of Energy requirements

All other relevant documents (Study-Related Documents page)

- Consent document templates for use by participating sites
- Recruitment materials templates for use by participating sites
- Other supporting documents needed by participating sites

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.

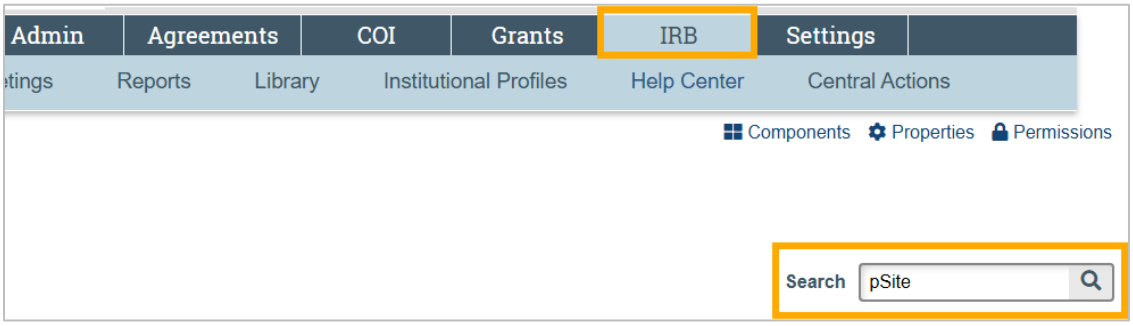
After your initial search, you can further refine results using the following filter options:

- **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.

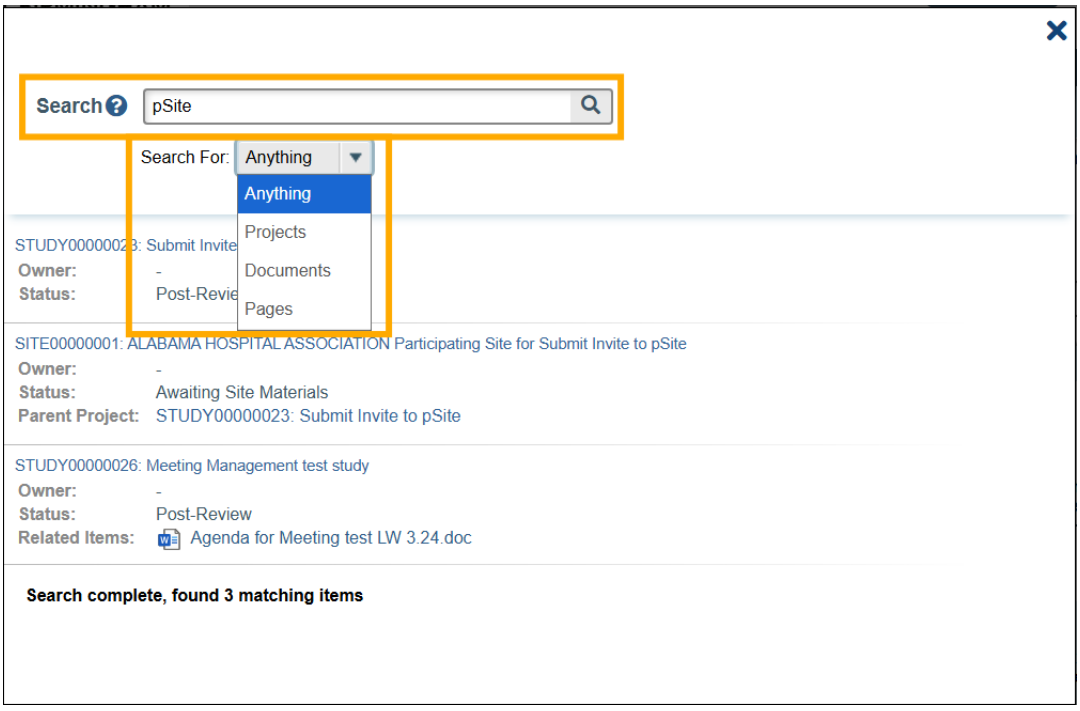
Note: Content on the site is updated periodically. If you are searching for something you just added, results might not be available immediately. Try your search again at another time.

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.



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.

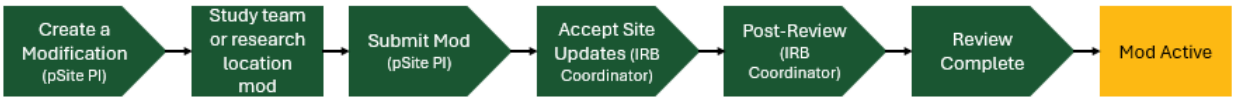
Note: Modifications to a multi-site study submission (as opposed to a site submission) follow the regular study modification process.

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:

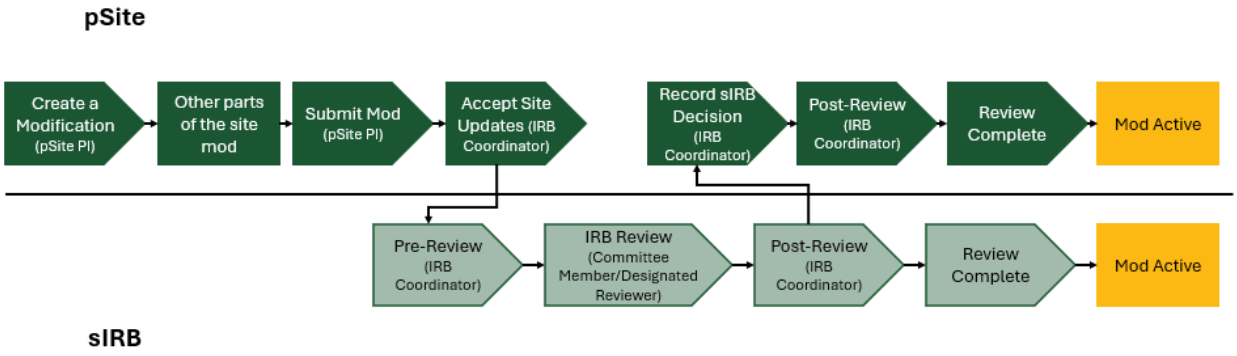
1. After the pSite PI or study team member submits the modification, pSite IRB staff approves the modification on the pSite system using the **Accept Site Updates** activity.

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:

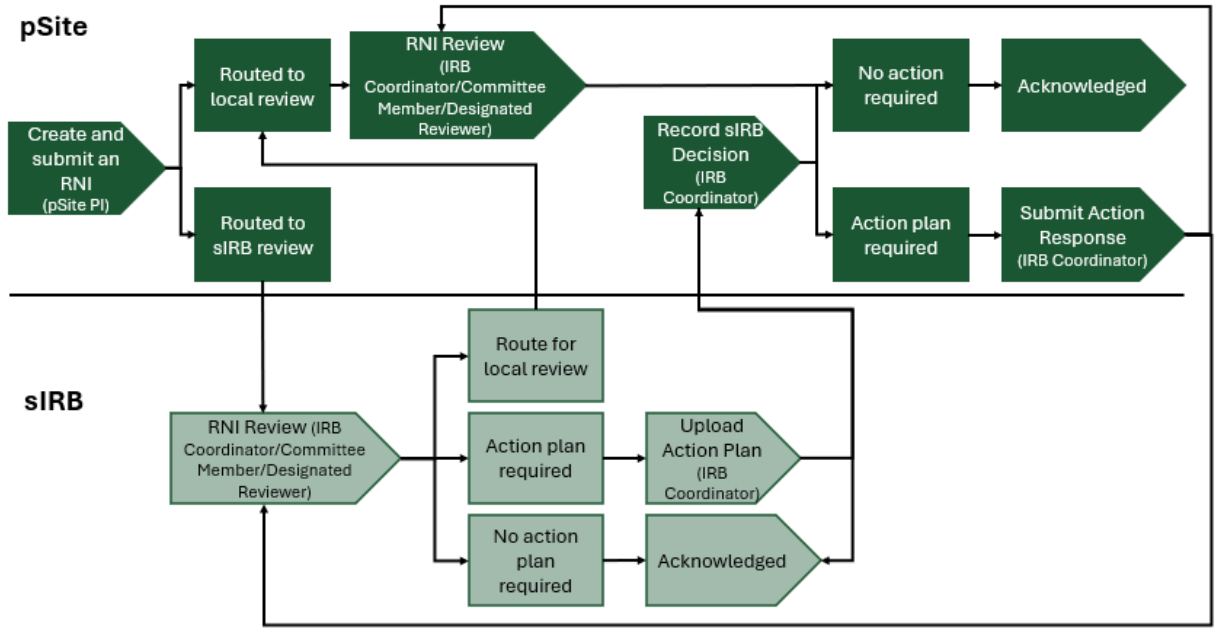
1. The study team on the pSite system creates an RNI submission. When the study team or IRB staff relates a multi-site study to the RNI, the system automatically captures which site is reporting the information.
2. Depending on the institutional profile (IP) settings applied to the sIRB institution, 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 the RNI 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.

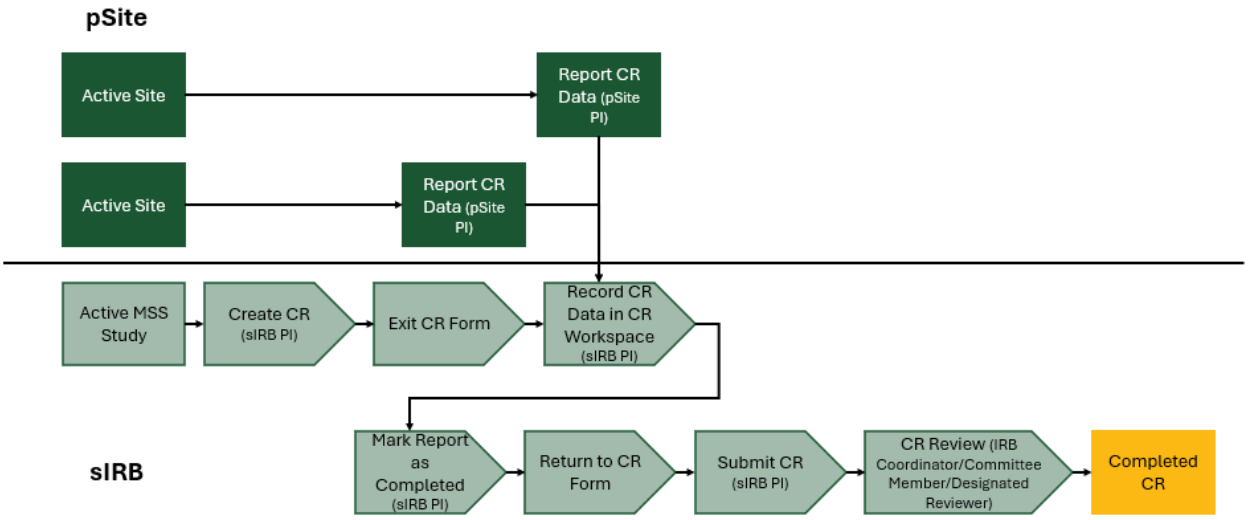
For a pSite, the process is simple:

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).

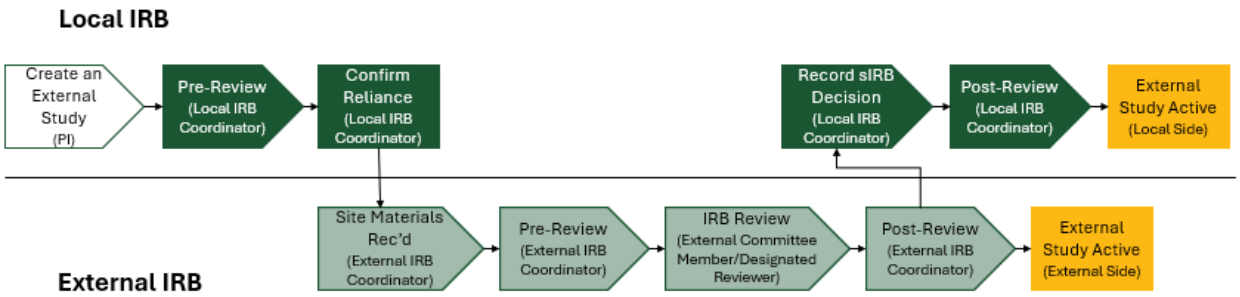
2. During Pre-Review, the assigned coordinator conducts their administrative review of the study, including the external IRB information, and can send the study back to the study team for more information or clarification as needed. When all the information has been supplied, the coordinator uses the **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	IRB Coordinator, IRB Director	Update Site Status	Suspended
			Terminated
		Close Site	Closed
All states prior to Post-Review	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

pSite System Sites 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 Researchers

This section shows how to perform basic actions of a single IRB of record researcher. It provides information on creating a study, managing participating sites, submitting a study, creating and submitting a continuing review for a multi-site study, creating and submitting a new multi-site external study, report continuing review data for a multi-site external study, creating site modification for a multi-site external study and updating study details for a multi-site external study.

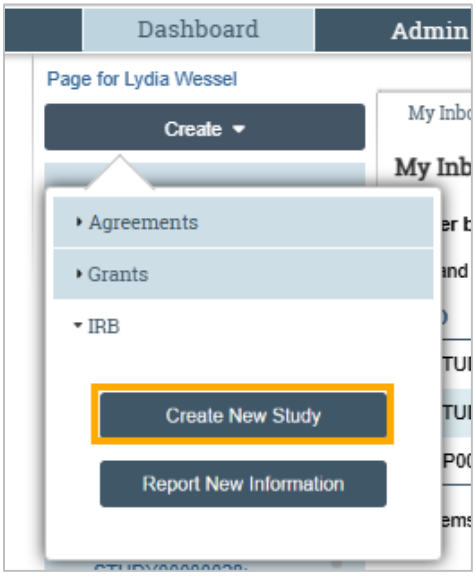
Create a study

Before you begin, gather files and information about your study, such as supporting information (drug and device information, recruitment materials, etc.), financial interest status for each study team member, and consent forms and recruitment materials.

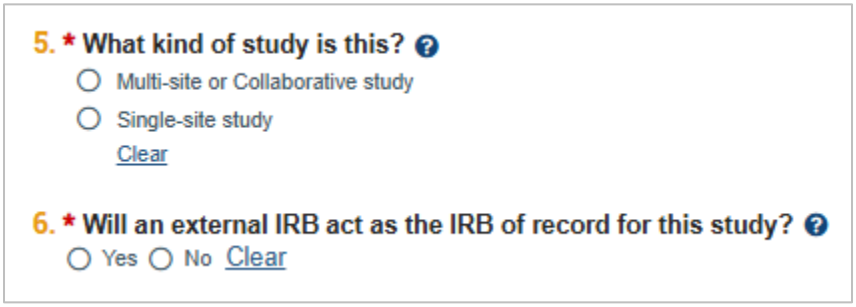
Who performs this activity?	When to perform this activity
sIRB principal investigators	This is the first step in creating a multi-site study.

To create a study

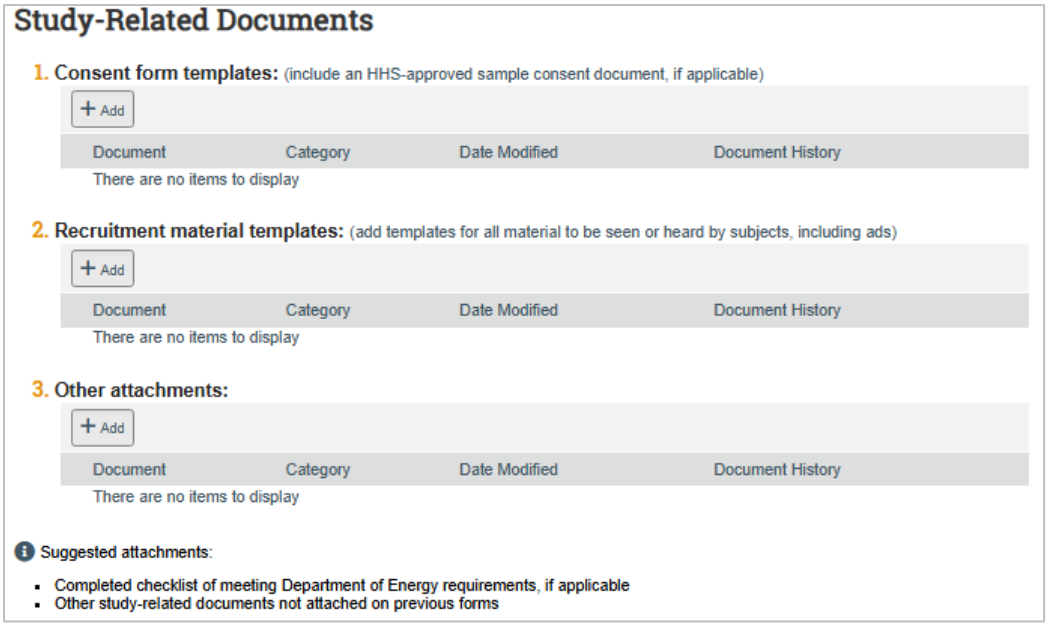
1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



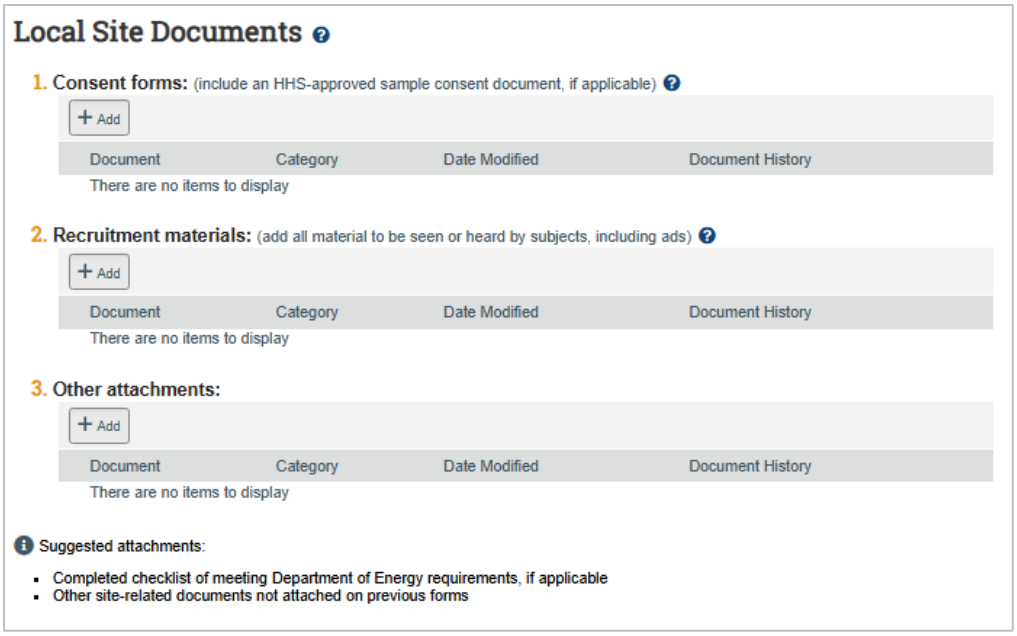
2. Complete the form. Pay attention to the following pages:
    a. **Basic Study Information**: use the following questions to indicate whether the study will be locally or externally reviewed, and whether it is a single- or multiple-site study: What kind of study is this? Will an external IRB act as the IRB of record for this study?



    b. **Study-Related Documents**: add templates for consent forms, recruitment materials, and other documents that are required study-wide and that participating sites will need to access.



    c. **Local Site Documents**: add consent forms, recruitment materials and other documents specific to your site.



3. Click **Continue** to move to the next page. Complete the pages.



4. On the final page, click **Finish**.



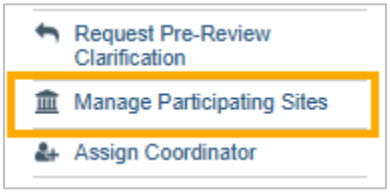
Manage Participating Sites

While a study is in the Pre-Submission or Pre-Review Clarification Requested states, you can add or delete participating sites. While a study is in the Pre-Review Completed state, you can continue to add sites, but you can no longer delete sites. Instead, you can deactivate sites that are no longer associated with the study.

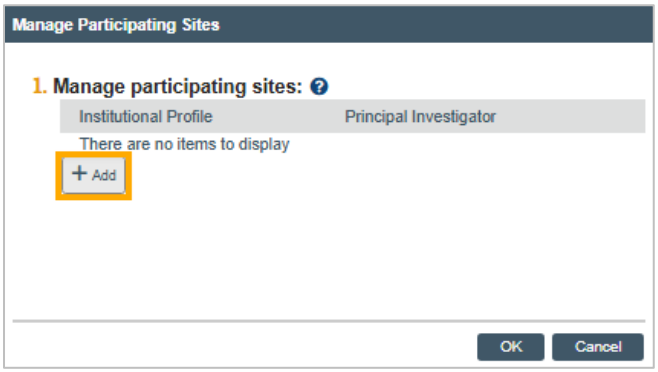
Who performs this activity?	When to perform this activity
• sIRB principal investigators • Study Staff • Reliance coordinators • IRB coordinators and directors	After creating a multi-site study. You can manage sites (add and delete) before the study is in Pre-Review Completed, and add sites after Pre-Review is Completed.

To manage participating sites

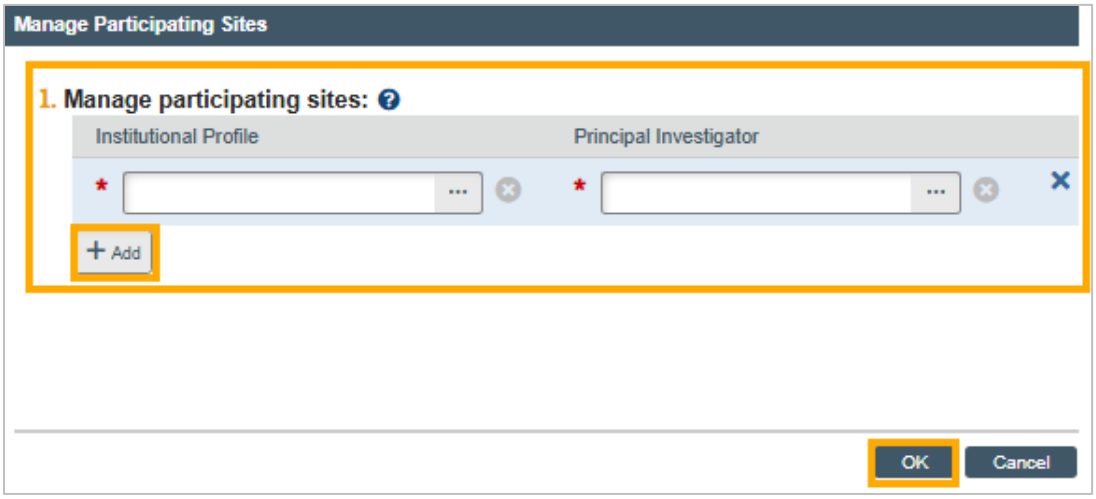
1. From the study workspace, click **Manage Participating Sites**.



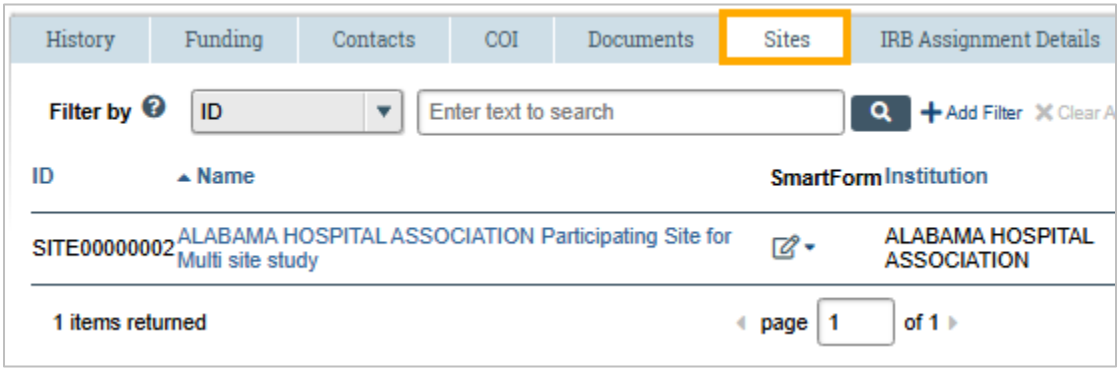
2. Click **Add**. Click the ellipses to add an institutional profile and a principal investigator. Repeat this process to add additional institutions. **Note**: The pSite PI is matched according to email address, so make sure you have the correct PI email



3. Click **OK** when you are finished. Sites are in a "pending creation" state until the study is submitted. Once the study is in Pre-Review Completed, the sites are automatically created.

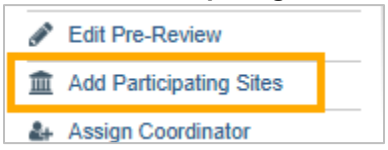


4. Click the **Sites** tab to view participating sites pending creation.

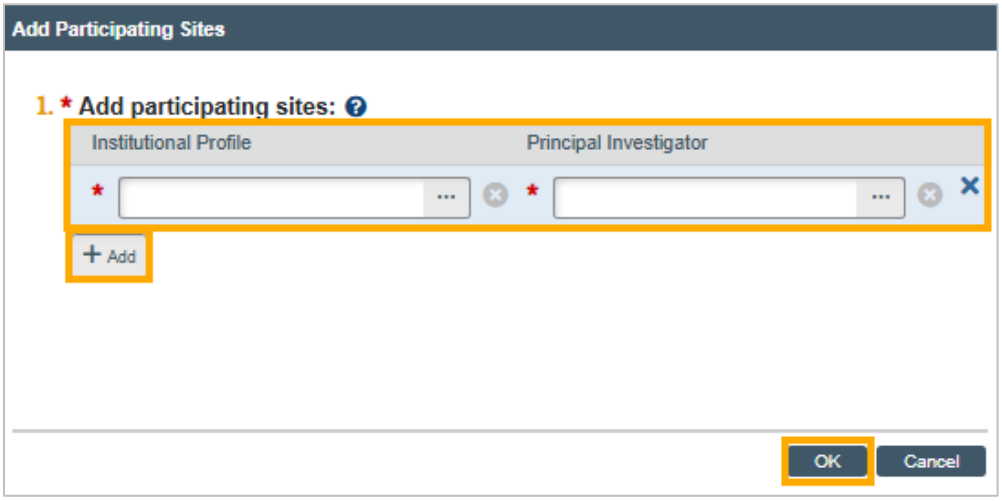


To add participating sites

1. Click **Add Participating Sites**.



2. Follow steps 2-4 in the “To manage participating sites” section above to add sites. A site is automatically created for any institutions you add. In the Sites tab, click the name of a site to go to the site workspace. **Note**: Once participating sites are added to a study, the study cannot be withdrawn until all associated sites are in an Inactive or Discarded state.



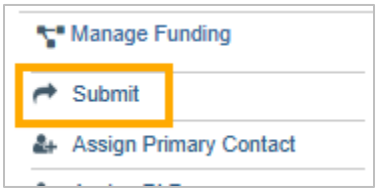
Submit a study

Once you have finished creating an Multi-Site Study (MSS) and managing participating sites, you can submit the study for review.

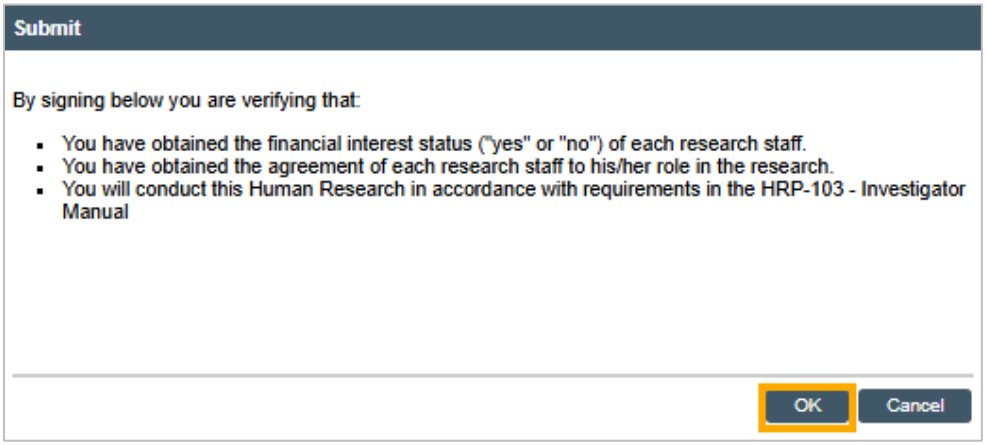
Who performs this activity?	When to perform this activity
sIRB principal investigators	After you have created a study and managed participating sites. Once you submit a study, it moves to the Pre-Review state.

To submit a study

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



2. Click **OK** to agree to the terms.
Note: When you submit an MSS, the PIs and primary contacts of any invited pSites are notified.



You can log off the system. Your study has been submitted to the IRB.

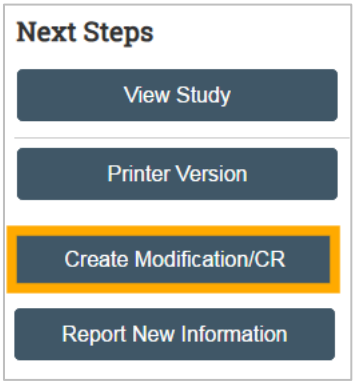
Create and Submit a Continuing Review for a Multi-Site Study

A PI at the sIRB institution can create and submit a continuing review (CR) that reports data for the sIRB institution and any pSites involved in the multi-site study.

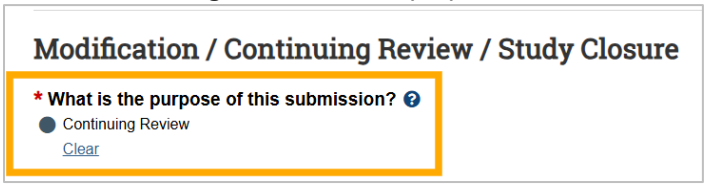
Who performs this activity?	When to perform this activity
sIRB principal investigators or PI proxies	When CR data for the study is required.

To create a continuing review

1. From the study workspace, click **Create Modification/CR**.



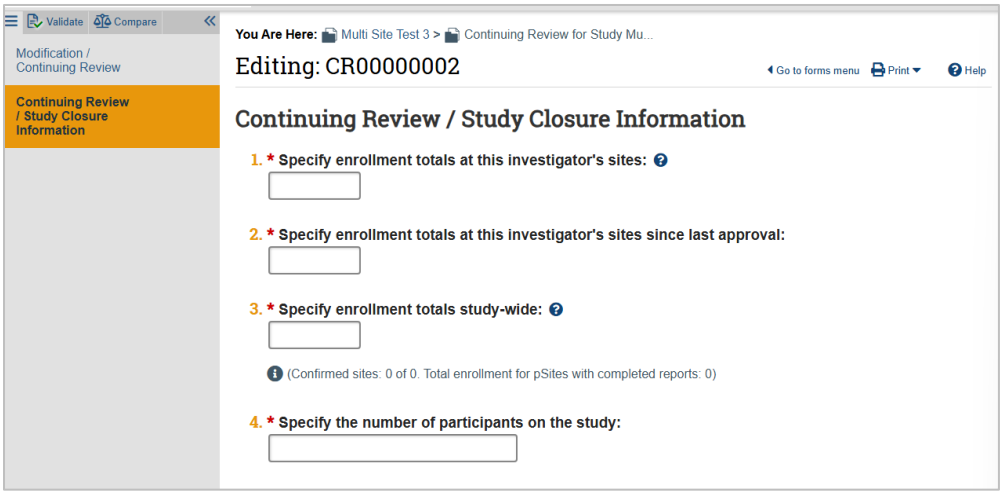
2. Select **Continuing Review** as the purpose of the submission.



3. Click **Continue**.



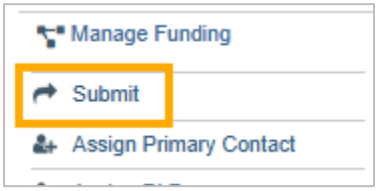
4. On the **Continuing Review / Study Closure** page, pay attention to the Specify enrollment totals question. You must specify the subjects enrolled at your local site as well as the combined enrollment totals for all sites (Study-wide).
    a. If you have received all pSite CR data, you can manually enter the study-wide enrollment count.
    b. If you have not yet received all pSite data, you can exit the Continuing Review form and return to the continuing review workspace. From the workspace, you can complete the steps as site data becomes available.



5. Complete the other questions and click **Continue**. Click **Finish** on the last page. **Note**: If you do not have all the information you need to complete the CR, you can save your information and then click **Exit** to leave the form. To return to the CR, click **Edit Modification/CR** from the CR workspace.

To submit a continuing review

1. If necessary, from the study workspace, click **Edit Modification/CR**, update the CR, and click **Finish**.
2. From the study workspace, click **Submit**.



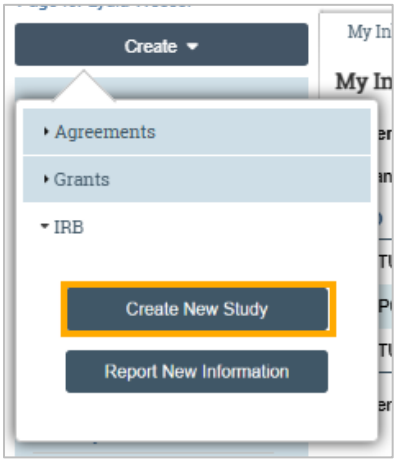
3. Click **OK** to agree to the terms.

Create and submit a new multi-site external study

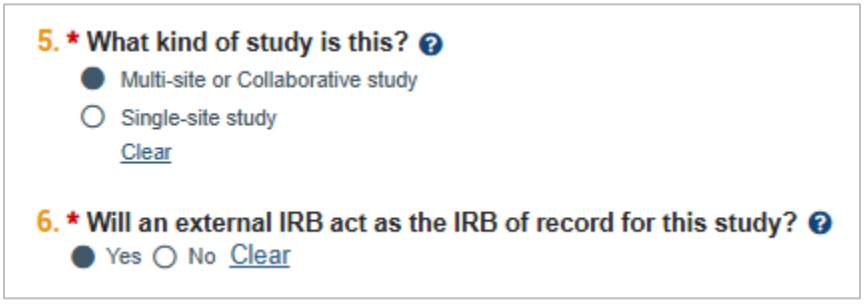
The process of creating and submitting a multi-site study for external review is similar to a single site study, but more information is required.

To create an external multi-site study

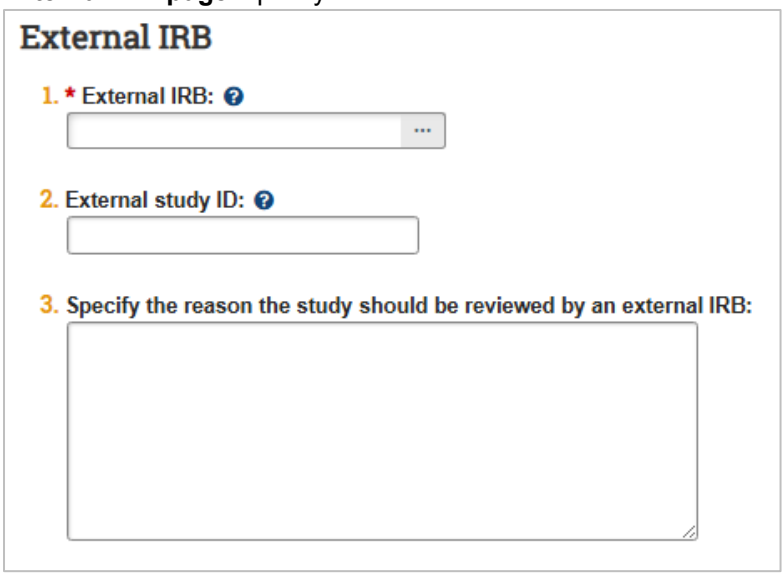
1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following:
    a. **Basic Study Information** page questions: indicate the submission is a multiple-site study (MSS) and that an external IRB will act as the IRB of record.



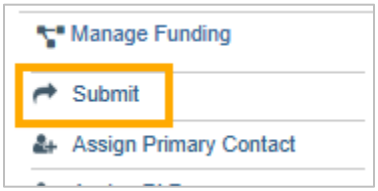
    b. **Basic Site Information page**: describe the activities this site will perform.
    c. **External IRB page**: specify which institution will serve as the external IRB.



4. On the final page, click **Finish**.

To submit the external study for local review

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



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

You can log off the system. Once the IRB confirms reliance, you will receive further information on next steps (for example, submitting to the external IRB).

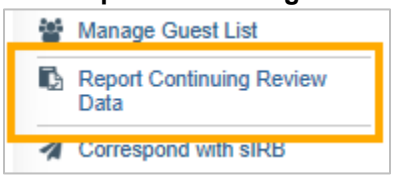
Note: This submission combines both study and site information. After the IRB coordinator confirms reliance, the interface refers to your submission as a site (for example, View Site), but your submission will still have the word Study in the title.

Report CR data for a multi-site external study

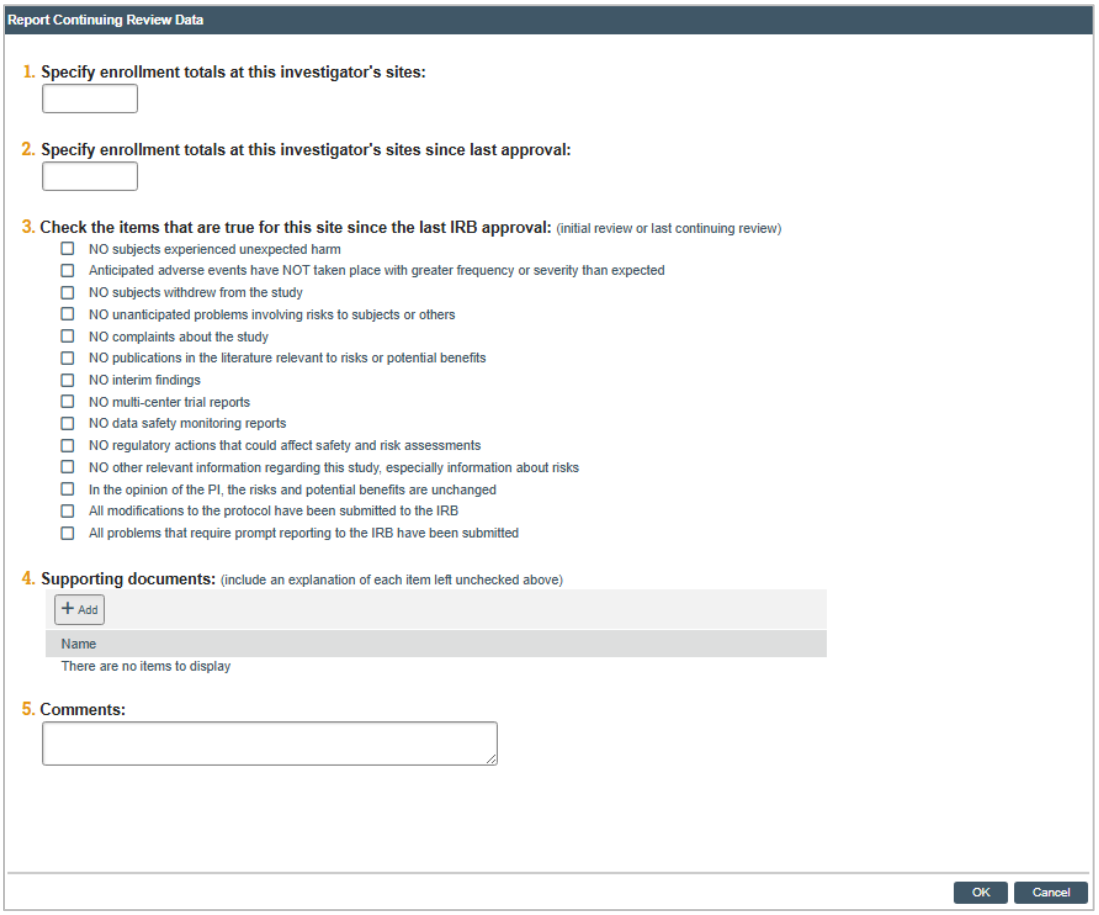
The local PI, PI proxies, and local IRB coordinator can report continuing review data for a multi-site external study.

To report continuing review data for an external study

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study. **Note**: Active multi-site external IRB studies are in the Active state.
3. Click **Report Continuing Review Data**.



4. Complete the **Report Continuing Review Data** activity.
5. In **Supporting Documents**, be sure to include an explanation for each item that is not selected in question 2.
6. Click **OK**.

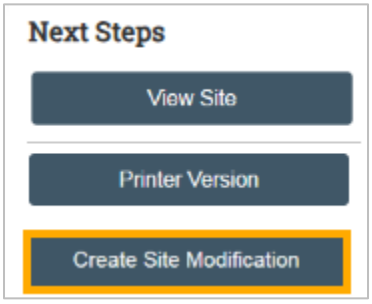


Create site modification for a multi-site external study

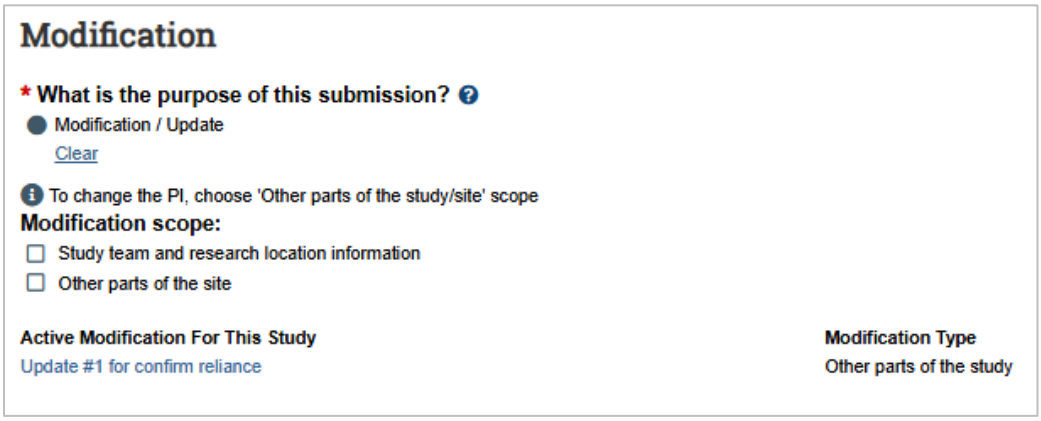
Create Site Modification only updates the site. There is also an option to Update Study Details which is covered in the next section.

To create a site modification for an external study

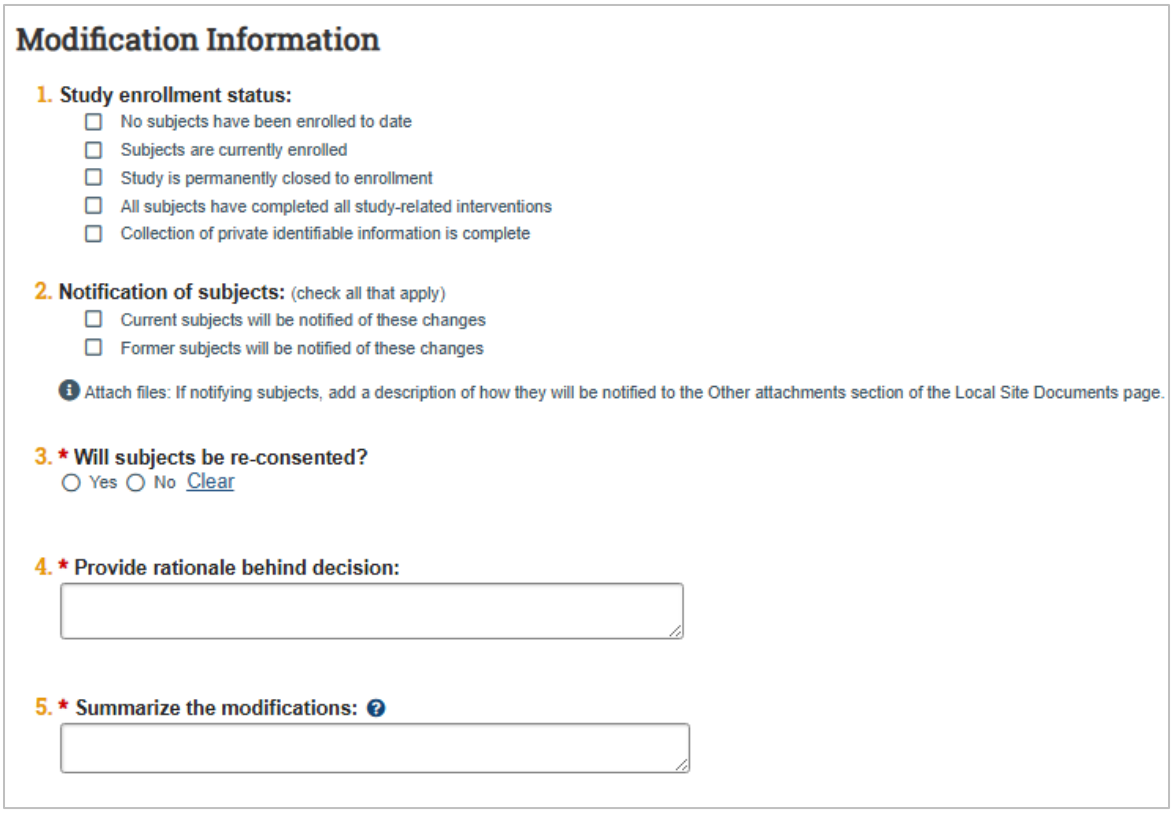
1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the External IRB tab and open the study. **Note**: Active multi-site external IRB studies are in the Active state.
3. Click **Create Site Modification**.



4. After selecting Modification, the **Modification Scope** question appears. Select Study team and research location information to update them, or select Other parts of the study to update Basic Local Information (like the PI), Additional Funding Sources, or Local Site Documents, or you can select both options. Click **Continue**.
   Note: if there is an active modification to a certain scope of the study, you will not be able to make a modification to that section.



5. On the **Modification Information** page, summarize the updates.



6. Complete the rest of the Smartform.
7. From the study workspace, click **Submit**.
8. Click **OK** to agree to the terms.

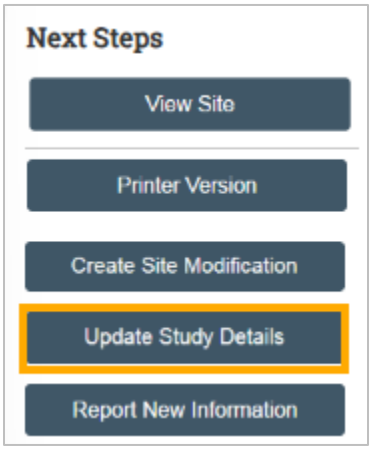
Both selections, whether study team and research location information or other parts of the site, go to your local IRB for review. Other parts of the site will also be reviewed by the external IRB.

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 the study details.

To update study details for an external study

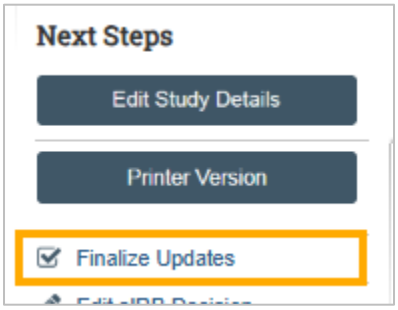
1. From the study workspace, click **Update Study Details**.



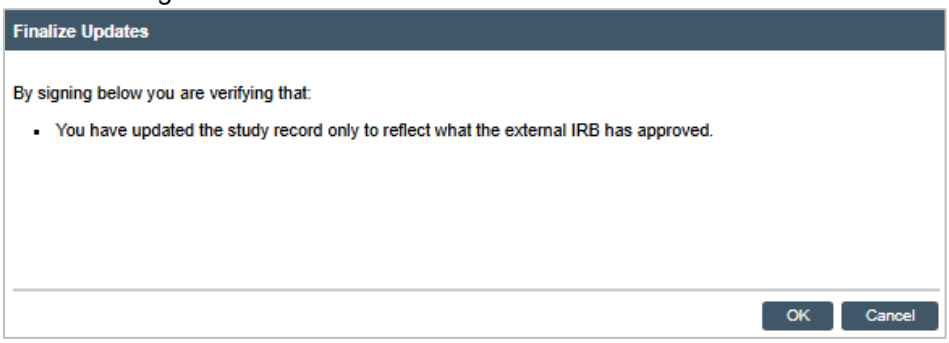
2. On the **Study Update** Information page, summarize the updates.



3. Click **Continue**.
4. Update the required pages and click **Finish** on the last page.
5. From the study workspace, click **Finalize Updates**.



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



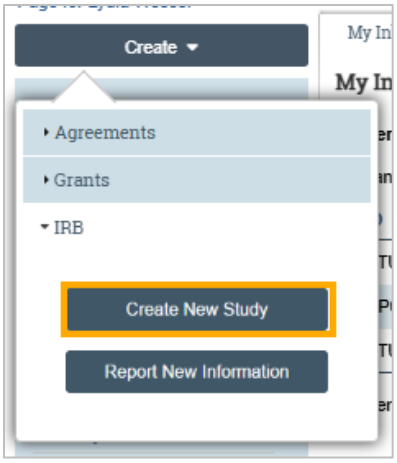
pSite Researchers

This section shows how to perform basic actions of a participating site researcher. It provides information on manually creating a site, editing a site, submitting a site to the sIRB, reporting continuing review data for a site, creating and submitting a site modification and creating and submitting reportable new information.

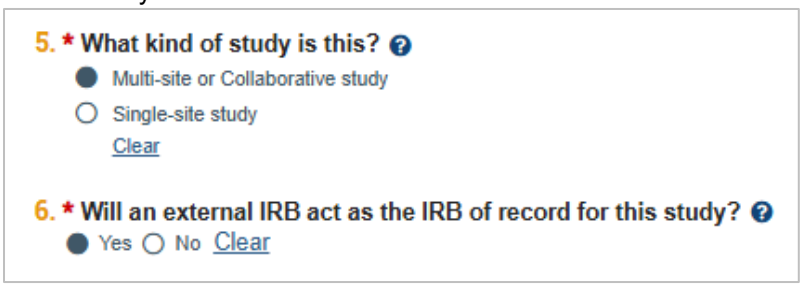
Manually create a site

To create an external multi-site study

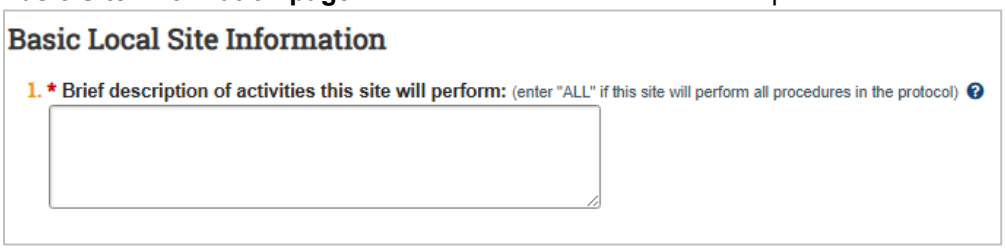
1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



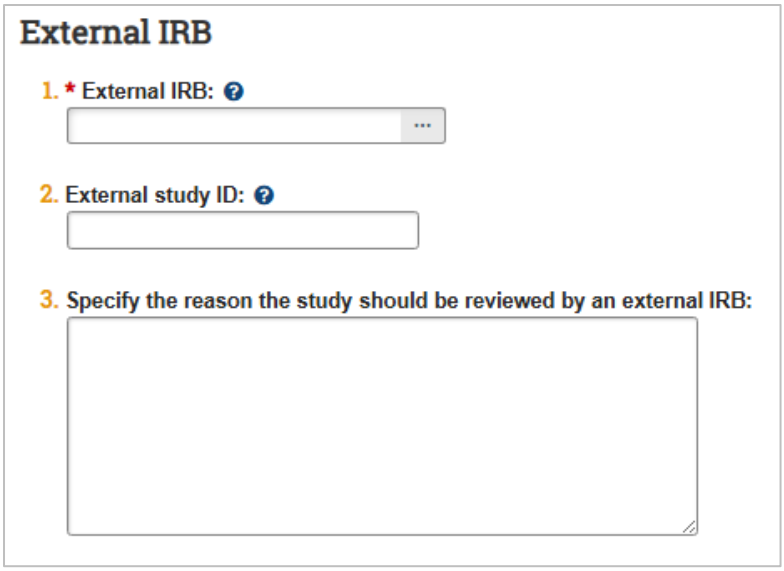
2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following:
    a. **Basic Study Information page questions**: use the following questions to indicate whether the submission is a multiple-site study (MSS) and that an external IRB will act as the IRB of record. What kind of study is this? Will an external IRB act as the IRB of record for this study?



    b. **Basic Site Information page**: describe the activities this site will perform.



    c. **External IRB page**: specify which institution will serve as the external IRB.



4. On the final page, click **Finish**.

You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

To submit the external study for review

1. From the study workspace, click **Submit**. Click **OK** to agree to the terms.

You can log off the system. Once an IRB coordinator confirms reliance on the external IRB, your study will be submitted.

Note: This submission combines both study and site information.

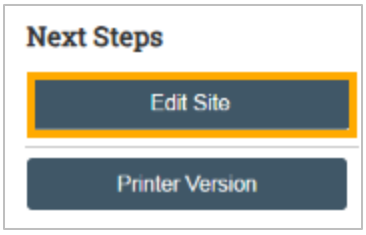
Edit a Site

You can edit site information before submitting the site to the sIRB for review.

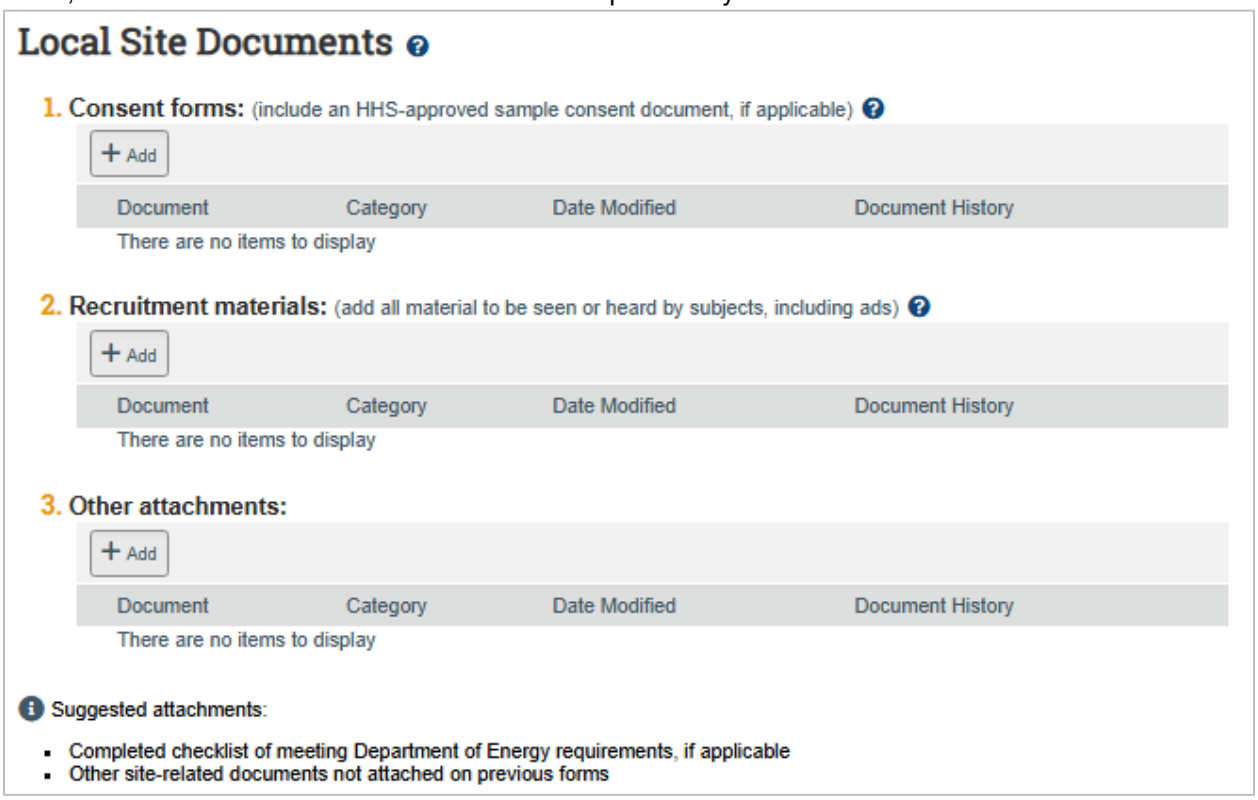
Who performs this activity?	When to perform this activity
pSite principal investigators	You must edit the site before submitting it to the sIRB for review. You can edit the site after you create it, but before you submit it for review. **Note**: The "Edit Study" button becomes "Edit Site" after the submission is in the Pending sIRB Review state. **Note**: In some cases, the pSite Principal Investigator (PI), primary contact, and any PI proxies can also edit a site directly from the sIRB system. This requires prior arrangement with the sIRB institution.

To edit the site

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



2. Complete the form. Pay attention to the following pages: **Local Site Documents**: add consent forms, recruitment materials and other documents specific to your research site.



3. On the final page, click **Finish**.

You can now submit the site to the sIRB for review.

Submit a site to the sIRB

Once a multi-site study has been approved, and you have updated the site information, you can submit the site to the sIRB in order to move it to the next stage of review.

Who performs this activity?	When to perform this activity
pSite principal investigators	After the associated Multi-Site Study (MSS) has been approved, you can submit a site whenever it is ready for review by the sIRB.

To submit the site

1. From the site workspace, click **Submit**. **Note**: The associated MSS must be approved before you can submit the site to the sIRB. **Note**: The Edit Study button becomes Edit Site after the submission is in the Pending sIRB Review state.
2. Click **OK** to agree to the terms.

You can log off the system. Your study has been submitted to the IRB.

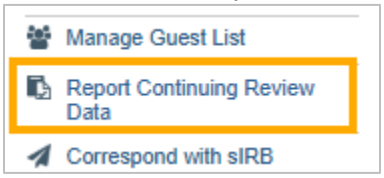
Report continuing review data for a site

A PI can submit enrollment and other data about their local site to the sIRB for continuing review purposes.

Who performs this activity?	When to perform this activity
pSite principal investigators or PI proxies	When you need to report data from your site for continuing review purposes.

To report continuing review data

1. From the site workspace, click **Report Continuing Review Data**.



2. Complete the page. Click **OK** to finish.

The data is reported.

Create and submit a site modification

There are two types of site modifications:

- Study team and research location modifications require local approval
- Modifications to other parts of a site (including basic site information, additional local funding sources, and local site documents) require review by the sIRB.

Who performs this activity?	When to perform this activity
pSite principal investigators and study team members	When you need to make changes to an already approved site.

To create a modification

1. From the site workspace, click **Create Site Modification**.



2. Select the modification scope.
    a. Study team and research location information can be modified without an sIRB review.
    b. Modifications to other parts of the site require sIRB review.
3. Complete the pages. Click **Finish** on the last page.

To submit a modification

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

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

You can log off the system. Your modification or continuing review (CR) has been submitted to the local IRB. To find your modifications, from the site workspace, click the **Follow-On Submissions** tab.

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.

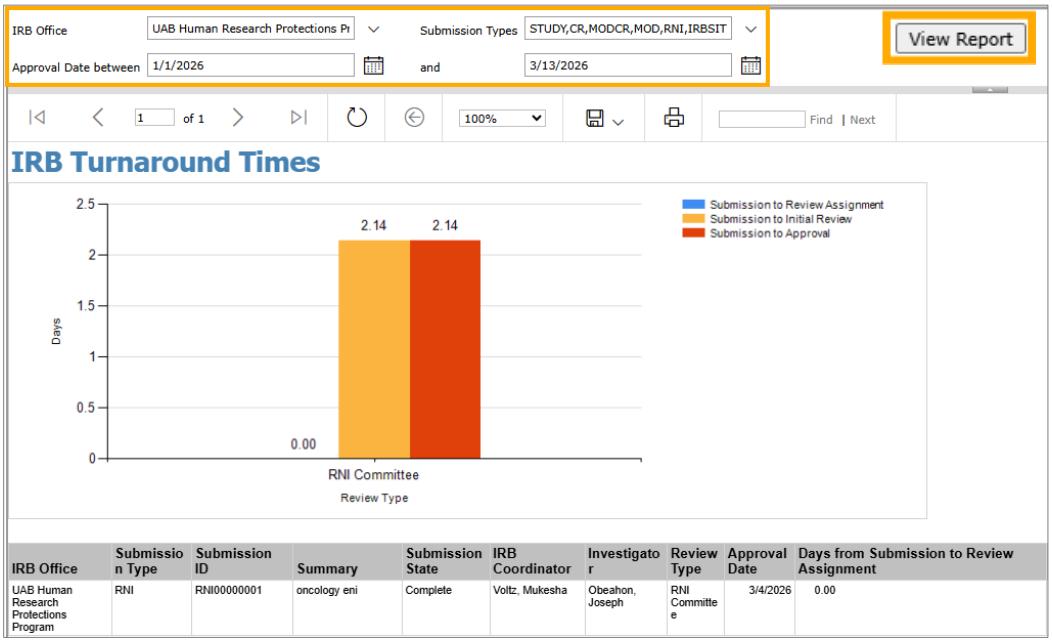
To open an advanced report

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.

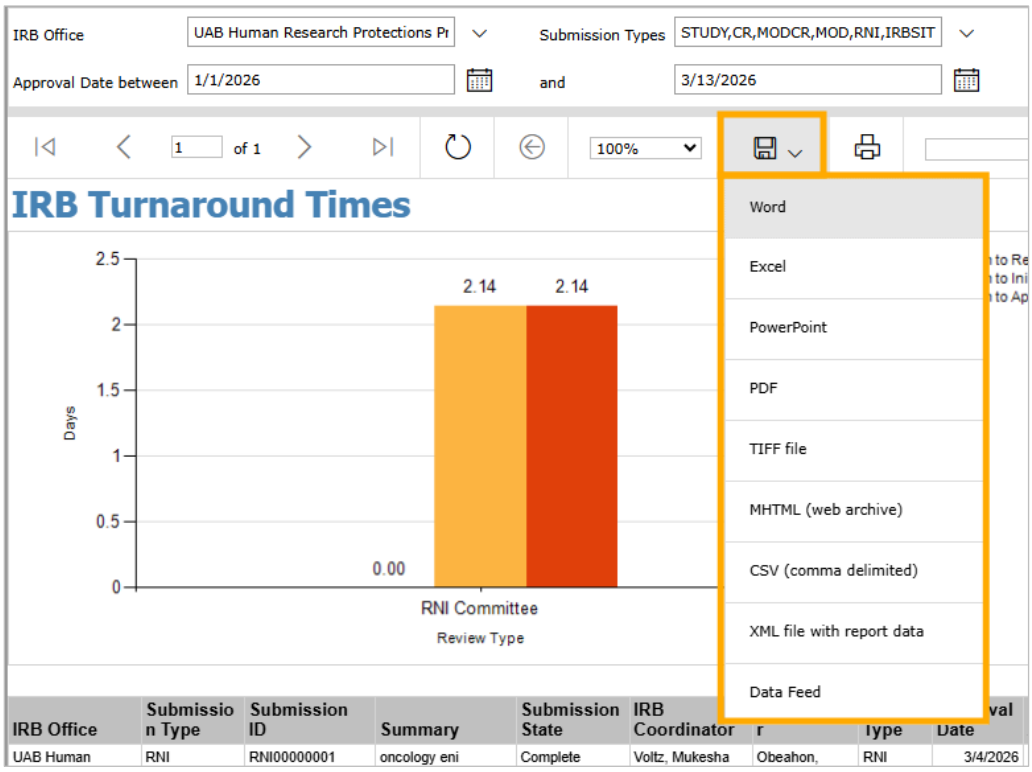


Export and Print Reports

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.

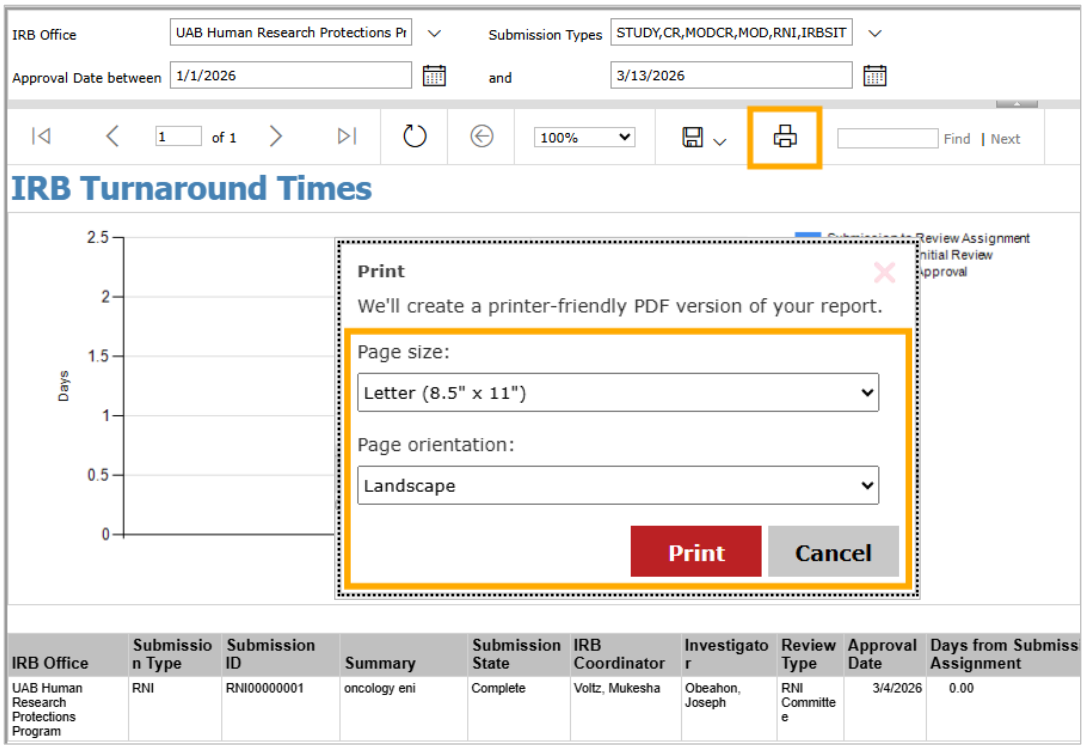
To export a report

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.

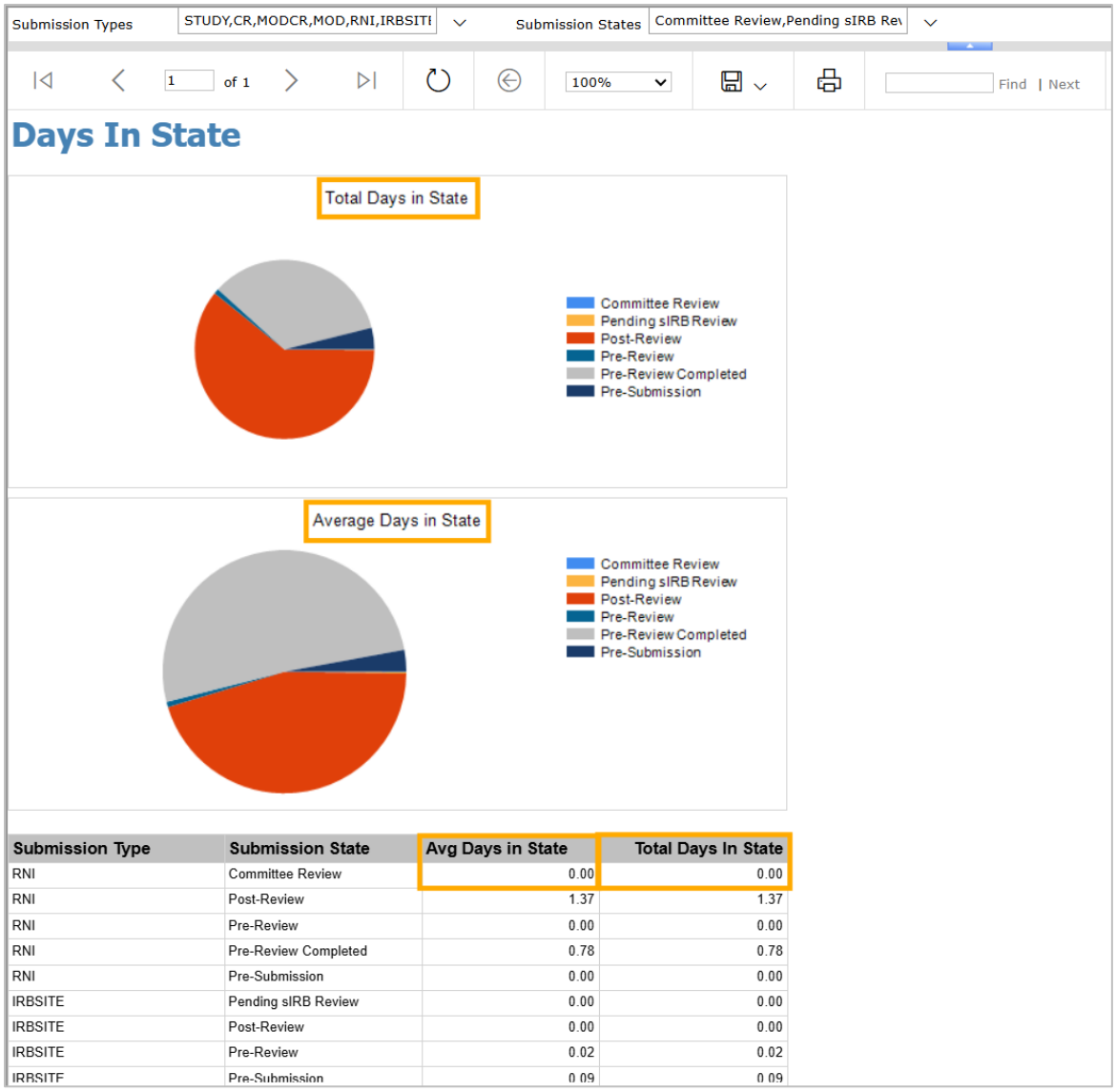
Note: This report shows data for multi-site studies, including site data.

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

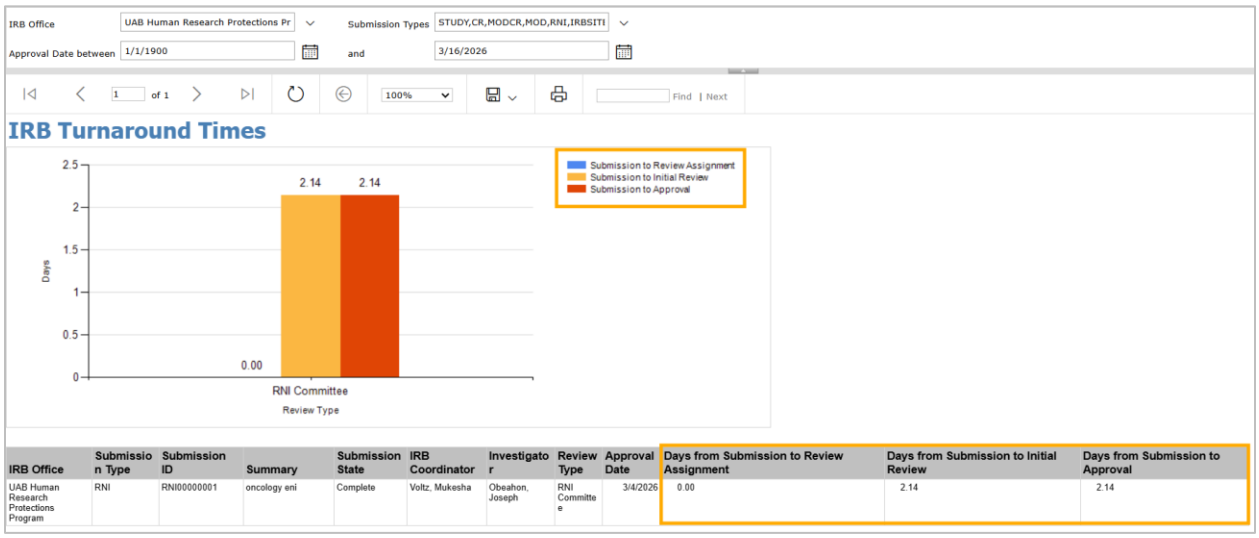


Chart and legend description

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:

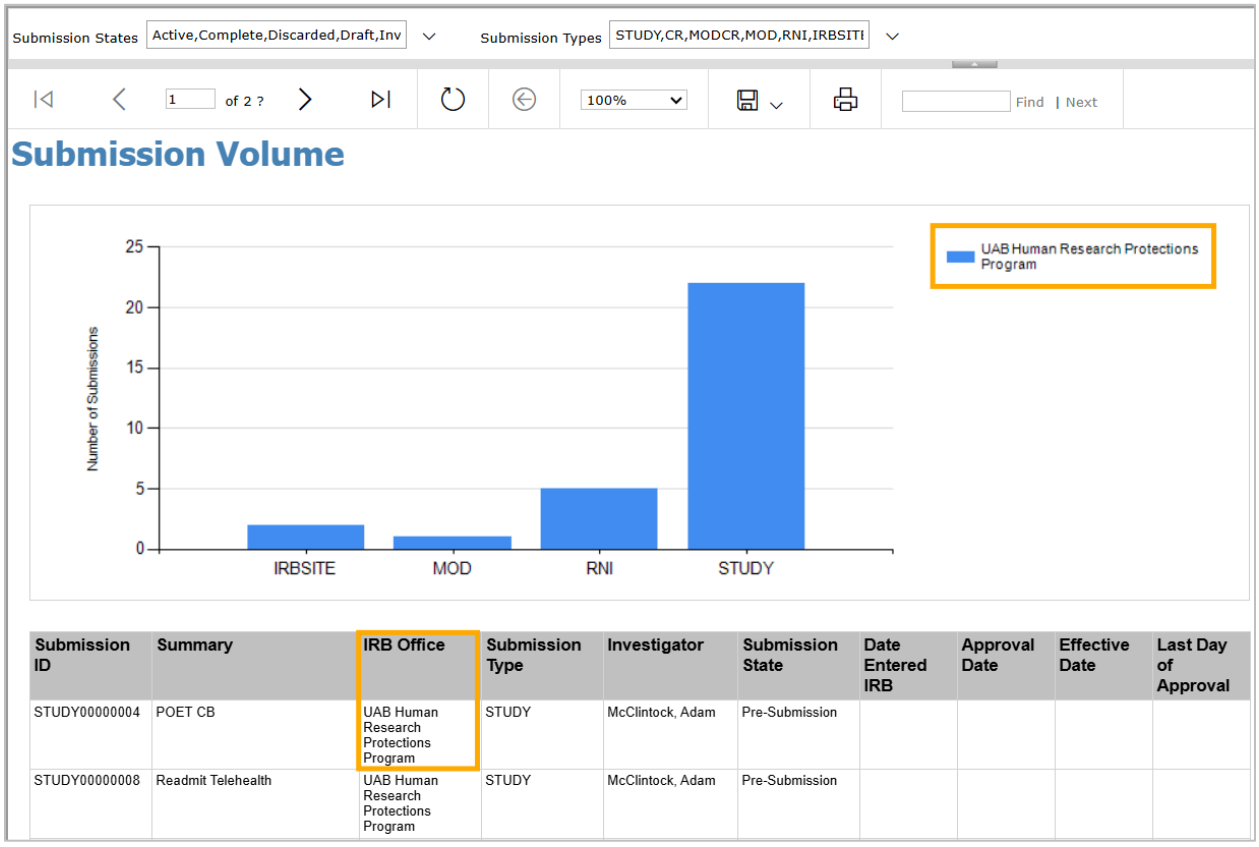
- **Submission States**: The current state of the submission at the time of generating the report. **Note**: If you filter submissions by state, the resulting list shows only those states that have at least one submission.
- **Submission Types**: Such as study, continuing review, modification, and/or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