

Integrated Online Research Administration: Click IRB Module

Overview & Basic Navigation

The Integrated Online Research Administration (IORA) system is a suite of research-related software solutions used by the University of Rochester (UR). Within the IORA system, the Institutional Review Board (IRB) module (referred to as Click IRB) facilitates the review and approval of human subject research.

This guide provides an overview of the Click IRB module, including a description of the submission and review process (as performed within Click IRB), as well as basic information on navigating within the system. A demo video of the basic navigation activities described within this guide is available here: [Click IRB Demo Video – Log In & Basic Navigation](#).

If you need a Microsoft Word version of this guide (e.g., for accessibility and/or screen reading purposes), please contact the [Office for Human Subject Protection](#).

For detailed instructions related to activities/roles see:

- [Click IRB Study Staff Guide](#) – Provides specific instructions related to the submission and management of single-site, multi-site and follow-on submissions by study staff in Click IRB.
- [Click IRB Department & Ancillary Reviewer Guide](#) – Provides instructions for performing Department and Ancillary Committee Review within Click IRB.
- [Click IRB Committee Member Guide](#) – Provides instructions related to performing board-related reviews by Research Subject Review Board (RSRB) Committee Members.
- [Click IRB Reviewer Guide](#) - Provides instructions for performing designated and committee reviews by Research Subject Review Board (RSRB) Chairs within Click IRB.

Additional Resources:

- Help Text – Within the IORA system, additional help text is available anytime you see a ? icon. Click on the icon to review the help text.
- [OHSP Explains... The IRB Review Process](#) – Provides a general overview of the IRB review process, as defined by federal regulation, state law and institutional policy, and highlights best practices for facilitating IRB review.

Note: This guide was developed by the University of Rochester based on materials original published by [Huron Consulting Group, Inc.](#)

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Abbreviations & Acronyms

CR: Continuing Review
 IORA: Integration Online Research Administration
 IRB: Institutional Review Board
 IRBC: IRB Coordinator
 IRBD: IRB Director
 MOD: Modification
 MODCR: Modification and Continuing Review
 MSS: Multi-Site Study

OHSP: Office for Human Subject Protection
 PI: Principal Investigator
 pSite: Participating Site
 RNI: Report of New Information
 RSRB: Research Subjects Review Board
 sIRB: Single Institutional Review Board
 UR: University of Rochester
 URMC: University of Rochester Medical Center

Overview of the Click IRB System

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

- **Study** – Documents the details of a study that require oversight by an IRB. Studies include single-site studies, multi-site or collaborative studies, and studies reviewed by an External IRB.
- **Site** – Documents details specific to a participating site (pSite) engaged in multi-site or collaborative studies, such as local study team members and institution-specific consent forms.

Once an initial submission have been approved, Click IRB supports the following types of follow-on submissions for approved studies/sites:

- **Modification (MOD)** - Changes or updates to approved studies. The modification submission consists of a form that lists modification details along with the updated study submission pages and/or study documents.
- **Continuing Review (CR)** – A review of an approved study. The continuing review submission consists of a form on which the researcher records any changes, incidents, reports, findings or other problems that have occurred since the study was approved, or since the previous continuing review.
- **Modification and Continuing Review (MODCR)** – A combined modification and continuing review submission. This type of submission allows simultaneous review of changes or updates to an approved study with continuing review information.
- **Reportable New Information (RNI)** – A report of new information about an approved study or active research (e.g., new risk information, breaches in confidentiality, subject complaints or reports of non-compliance).

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

Role	Typical Activities
Ancillary Reviewer	An individual responsible for evaluating study submissions against the requirements set forth for their specific Ancillary Committee (in accordance with Office for Human Subject Protection [OHSP] Policy 503 Ancillary Committee Reviews).
Committee Administrator	An individual responsible for managing committee meetings.
Committee Chair (CC)	An IRB committee member assigned to chair the committee.
Committee Member (CM)	Individuals on an IRB committee that are responsible for reviewing submissions.
Committee Reviewer (CR)	The individuals assigned to review and present a submission at a committee meeting (i.e., primary reviewer).

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

Overview of the Submission Review Process

New Studies

The basic review process for a new study submitted to the Research Subjects Review Board (RSRB), the University of Rochester's local IRB, is as follows:

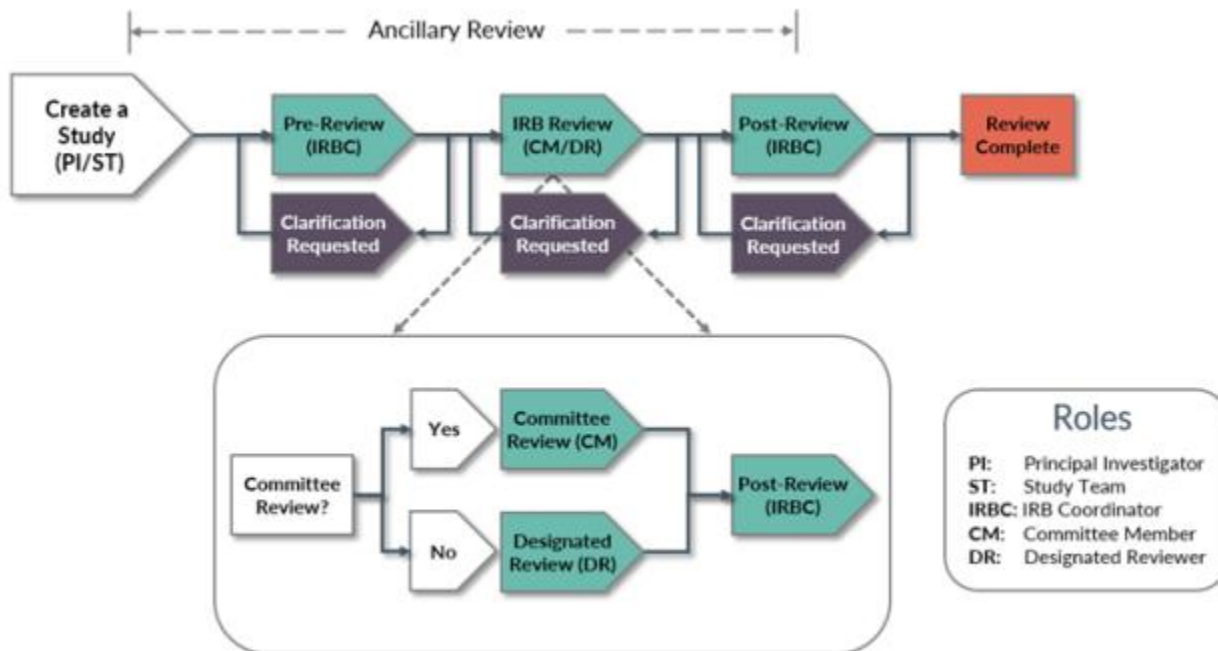
1. The PI (and study staff) creates a study, entering study information on a series of user-friendly pages in the Click IRB system. While the study team is working on the study submission, it is in the **Pre-Submission** state, and once completed, the PI submits the study to the RSRB for review.
2. Upon submission to the RSRB, the IRBD (or designee) will assign and submit the study to **Department Review** per [OHSP Policy 505 Departmental Scientific and Resource Review](#). During this time, Department Reviewers may request clarifications or changes from the PI. If the IRBD notes that considerable components are missing from the submission, the IRBD may choose to request clarifications or changes from the PI *prior* to submission to Department Review. Further, or additional Department Review may also be requested by the IRBC during Pre-Review.

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

- Assign and submit the study to required **Ancillary Committees** per [OHSP Policy 503 Ancillary Committee Review](#). Note: In accordance with Ancillary Committee requirements, the IRBD/IRBC may interrupt the RSRB review process to await ancillary approval confirmation. Similar to Department Review, further or additional review by an Ancillary Committee can be requested any time from Pre-Review to Post-Review, as illustrated below.
 - Assign an IRBC to review the submission. The assigned IRBC will then conduct an initial review for completeness, ensuring the submission includes all the necessary information and documentation for the RSRB designated and/or committee member reviewers. At any point during Pre-Review, the IRBC may request clarification or changes from the PI resulting in a back-and-forth exchange between the PI and IRBC. Once the IRBC has completed their review, the submission is assigned for review by a designated reviewer or the full committee.
3. During **IRB Review**, the designated reviewer or the full committee will review the study.
 - If the research involves only minimal risk and falls into one of the federally-defined [exempt](#) or [expedited](#) review categories, the research can be reviewed by a designated reviewer on behalf of the full committee. During this stage of review, the designated reviewer makes a determination about the study and submits the decision in the Click IRB system. Submitting a determination in the system moves the submission to Post-Review. Prior to making a determination, however, the reviewer may request clarification or changes from the PI, resulting in a back-and-forth exchange between the PI and designated reviewer. Alternately, the IRBC may communicate requests for clarifications or changes on the designated reviewer's behalf.
 - If a full committee (i.e., RSRB board) reviews the study, a committee meeting occurs during which the committee makes a determination about the study. The IRBC submits the decision in the Click IRB system on behalf of the committee. Submitting a determination in the system moves the submission to Post-Review.

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

The following diagram illustrates the submission review process, including the roles and states involved in the review. (Note: Department Review is programmed as a type of Ancillary Review and therefore not depicted separately in the diagram below.)



Modification (MOD) & Continuing Review (CR):

Modifications are required anytime previously approved submission materials require updating (e.g., the study submission form [including study team members], study protocol, consent forms, recruitment materials, study measurements, etc.). Modifications can be submitted once a study has been approved (or determined to be exempt) and **approval is required prior to implementation of the changes**. Upon approval, all changes identified in the modification form are applied to the parent study and any other active follow-on submissions.

Continuing review (i.e., a progress report) is required at least annually for all research deemed greater than minimal risk and *may* be required for minimal risk research. Study closure is required once the research is complete for all research other those deemed exempt. Study renewals and closures are completed via the continuing review function.

Modifications and continuing reviews (MODCRs) can also be submitted as one, if both activities need to take place.

Reviews of modifications, continuing reviews and mod/CRs follow a process similar to new studies. The only exceptions relate to Department and Ancillary Committee Reviews; these reviews are not required unless warranted by the information set forth in the modification and/or continuing review or [ancillary review requirements](#).

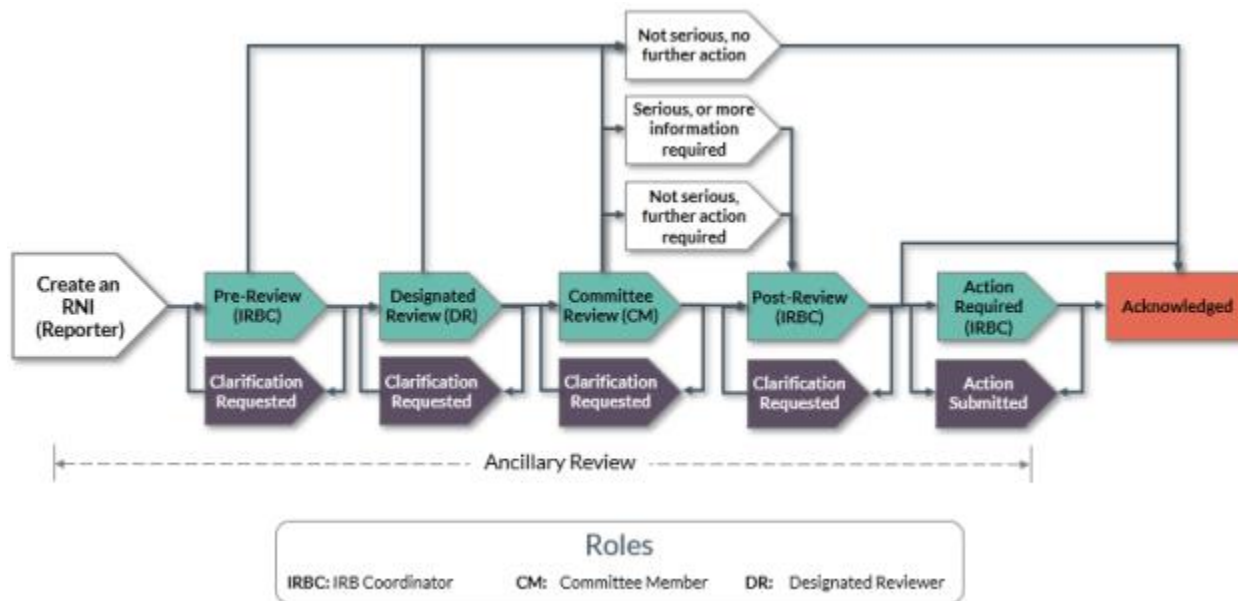
Reportable New Information (RNI)

Reports of new information are required as described in [OHSP Policy 801 Reporting Research Events](#) and its associated [Guideline for Reporting Research Events](#). The RNI review workflow is similar to the process described above for a new study, but the submission may be routed differently depending on the circumstances of the event being reported. The basic review process of a RNI is as follows:

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

information). Once the letter concerning this determination is sent, the submission moves to an **Action Required** state. In this, state the responsible party can submit their response for continued IRB review. Once all required actions have been completed and a letter is sent to the PI confirming this, the submission moves to **Review Complete** (Complete state).

The following diagram illustrates the review process for an RNI, including the roles and states involved in the review:



Overview of Multi-Site Review Processes

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

When MSS research is conducted locally, the RSRB may:

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

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

Overview of the Multi-Site sIRB Submission Process

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

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

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

New Studies

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

1. The Lead PI (and study staff) creates a study, indicating that the study is multi-site and that the RSRB will serve as the sIRB of record for participating sites (pSites). The Lead PI is the individual with primary responsibility for oversight and management of the conduct of the study at all pSites. While the study team is working on the study application, it is in the **Pre-Submission** state. Once the submission form is complete, the PI submits the study to the RSRB for review.
2. Upon submission of the study to the RSRB, the study will move through the **Department Review, Pre-Review, IRB Review** and **Post-Review** processes, as described [above](#) for routine submissions.
3. During **Post-Review**, the IRBC prepares and sends the determination letter to the PI. If the study is approved, the IRBC creates a final version of the study documents and the submission moves to **Review Complete (Approved)** state. If the committee/designated reviewer determines modifications are needed for the submission to be approved, the PI can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

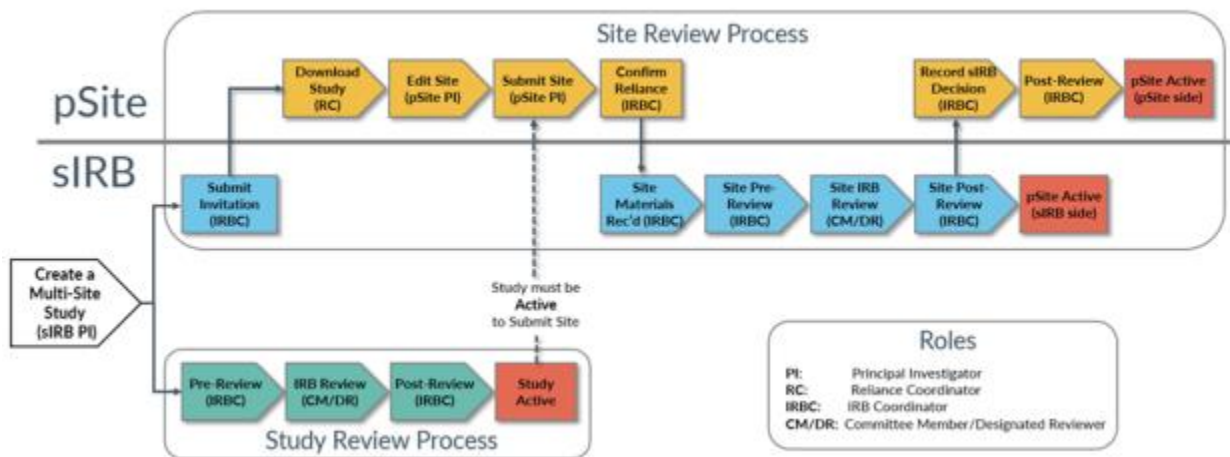
New pSites

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

1. The Lead PI (and study staff) or IRBC adds the pSite from the study workspace, resulting in the creation of a pSite workspace and corresponding submission. Upon creation, the pSite is in the **Invitation Pending** state. Once the IRBC validates the pSite's eligibility to participate in the research, the pSite moves to an **Awaiting Site Materials** state.
2. Following receipt of the pSite's study-specific documentation, the Lead PI, study staff or IRBC enter the pSite's site-specific information and documents on the behalf of the pSite and submit to the RSRB for individual review. **Note:** pSites cannot be submitted for review until the study submission has minimally reached the Pre-Review Complete.

- Upon submission of the pSite to the RSRB, the pSite will move through a simplified version of the Pre-Review, IRB Review and Post-Review processes, as described [above](#) for routine submissions. **Note:** pSites cannot progress beyond the IRB Review point until the study submission has been approved.
- As above, during **Post-Review**, the IRBC prepares and sends the determination letter to the Lead PI. If the study is approved, the IRBC creates a final version of the site documents and the pSite submission moves to **Review Complete (Active state)**. If the committee/designated reviewer determines modifications are needed for the pSite to be approved, the Lead PI, study staff or IRBC can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

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



Modifications, Continuing Reviews & Reportable New Information

Follow-on submissions undergo review as described above for routine submissions. **Note:**

- Modifications may be submitted via the study or the pSite. Study modifications apply to the study as a whole, across all pSites. pSite modifications are limited to updating site-specific details only (i.e., site-specific funding and site-specific documents).
- Continuing review, if required, is completed for the study only, not each individual pSite. Rather, individual pSite enrollment and research event data is reported for pSite by the PI (and study staff) or IRBC. Once recorded, the data reported for each pSite is accessible within the study continuing review workspace.

Overview of the External IRB Submission Process

New Studies

Per [OHSP Policy 504 IRB Reliance and Collaborative Research](#), all studies reviewed and approved by an External IRB require the execution of a reliance agreement (in respect to Policy 504, the External IRB is the reviewing IRB and the Research Subjects Review Board [RSRB] is the relying IRB). When the RSRB cedes authority to an External IRB, an institutional administrative review of the research is still required via Click IRB. As such, submitting to an External IRB is a two-step process:

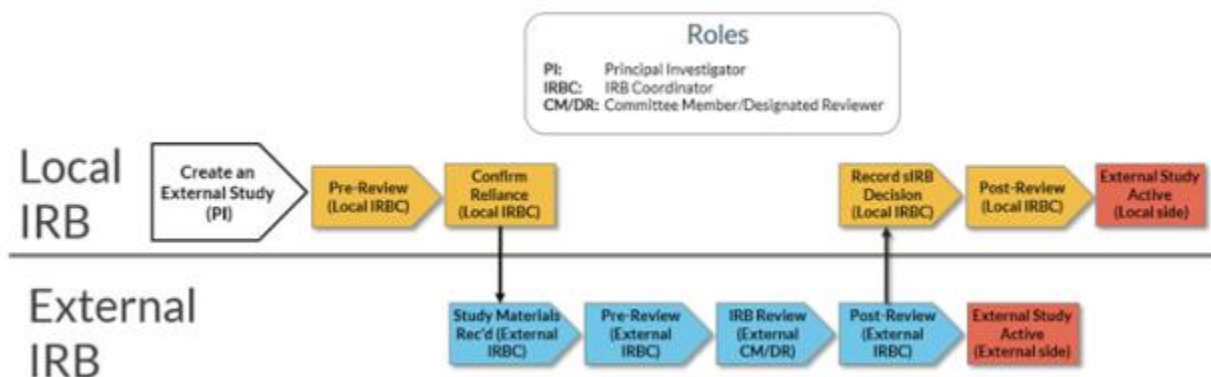
1. The study is submitted to Click IRB for institutional review (as described below). This process ensures compliances with institutional policies and allows the institution to track research that isn't reviewed locally.
2. Once the RSRB's institutional review is complete, the study is submitted to the External IRB for review and approval per their standard operating procedures. Upon approval of the research, all further review of the research (modifications and continuing review) is deferred to the External IRB.

Note: It is best practice to wait to initiate a submission in Click IRB until you: a) determine what IRB will review and approve the research; and b) ensure a reliance agreement exists to accommodate review of the research by the external IRB.

In Click IRB, the institutional review process is as follows:

1. The PI (and study staff) creates a study, indicating that the study will be reviewed by an External IRB. Study and local site-specific information are entered on a series of user-friendly pages. While the study team is working on the study application, it is in the **Pre-Submission** state. Once the submission form is complete, the PI submits the study to the RSRB for institutional review.
2. Upon submission of the study to the RSRB, similar to the process described [above](#) for routine submissions, the IRBD (or designee) will assign the study to **Department Review**. Once Department Review approval has been provided, the IRBD will assign the submission to required Ancillary Committees, as required per [OHSP Policy 503 Ancillary Committee Review](#), and an IRBC for administrative review. As noted above, in accordance with Ancillary Committee requirements, the IRBD/IRBC may interrupt the RSRB review process to await ancillary approval confirmation.
3. During **Pre-Review**, the IRBC will review the study to ensure all institutional requirements for externally reviewed research are met. Once these requirements have been met, the IRBC will confirm reliance activities have been met and that the External IRB is the sIRB of record. At this point, the institutional administrative review is complete, the submission enters into the **Pending sIRB Review** state and the study may be submitted to the External IRB for review.
4. Following External IRB review, the IRBC will record the External IRB's determinations in the Click IRB study workspace. If the determination requires the RSRB to finalize documents and/or send a determination or acknowledgement letter, the study moves to **Post-Review**. If no further documentation/acknowledgement is required by the RSRB, the study moves to **Review Complete (Active or External IRB state)**.

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



Follow-On Submissions

Following approval by the External IRB, the External IRB is responsible for reviewing and approving all follow-on submissions. Further review by the institutional administrative review by the RSRB is only required in certain circumstance, as defined by [OHSP Policy 504 IRB Reliance and Collaborative Research](#). The process for reviewing these submissions is also dependent on the circumstance. For additional details see the [Click IRB Study Staff Guide](#).

Navigation and Basic Tasks

Log In

1. To log into the IORA IRB module, go to <http://rochesterirb.huronresearchsuite.com/>.
2. Select your University of Rochester affiliation (UR vs. URM).C).
3. Use your UR/URMC active directory credentials to log in (i.e., the credentials used to log into your computer and/or access your UR email account).

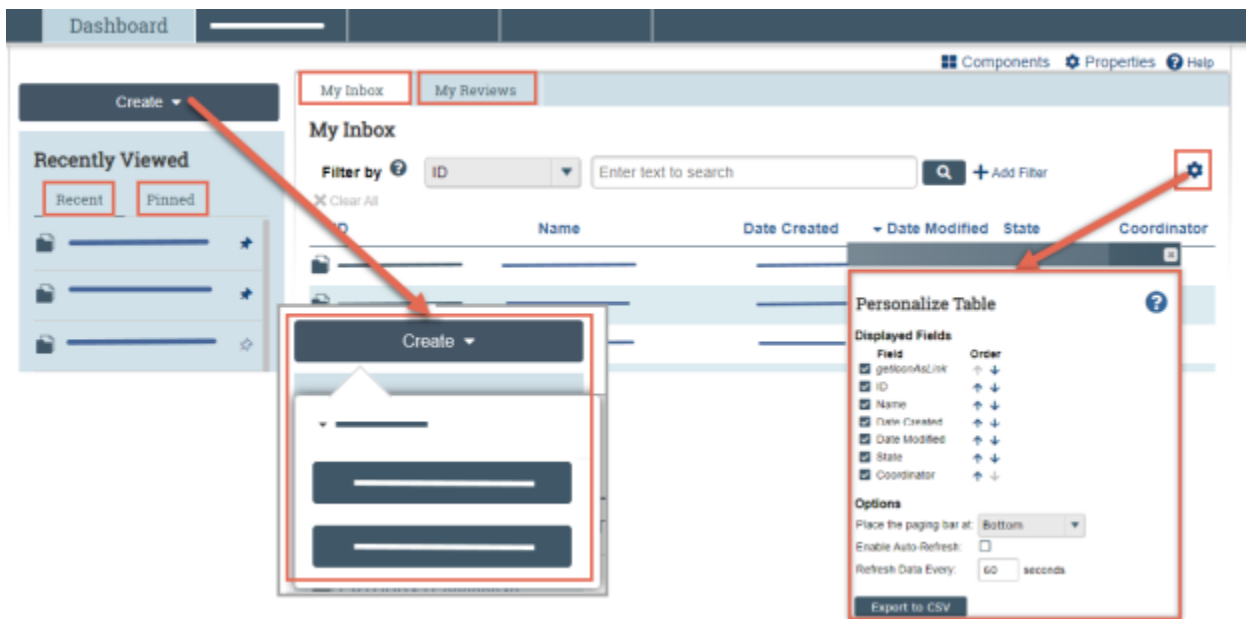
Note:

- Users will not be able to log in until they receive an email confirming their user account has been created. New user accounts are created automatically, approximately 1-2 business days following completion of the University's required [human subject protection training](#).
- If you are logging in remotely, [two-factor authentication](#) is required. To facilitate this process, the OHSP enrolling in [Duo using a mobile phone](#).
- Need help logging in? Use the contact information on the log in page to contact the Help Desk.

Dashboard

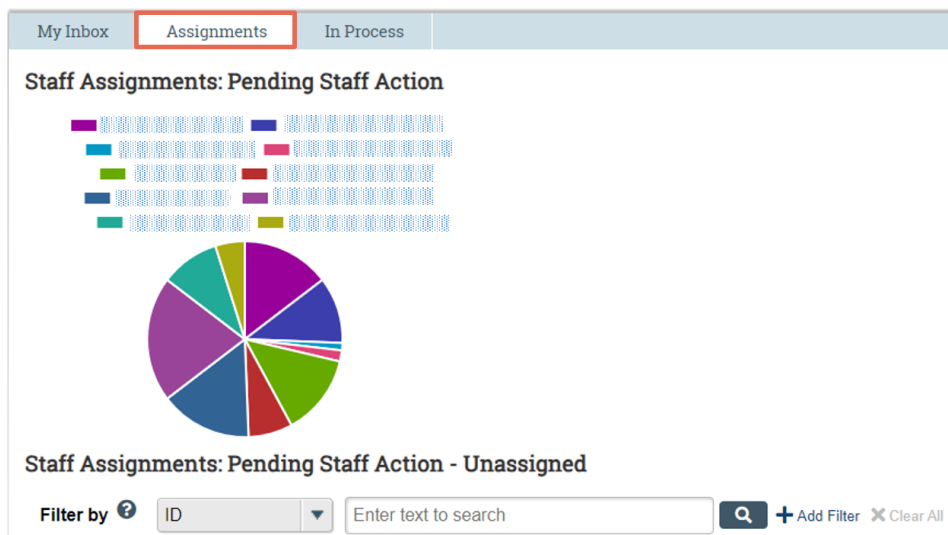
After logging in you will land on the Central Dashboard page, where you will find (as applicable to your role):

- **My Inbox:** Displays submissions across the entire research suite that require action (inclusive of all IORA modules – e.g., IRB, Grants, Agreements, etc.). The type of submission can be identified by the ID prefix:
- **My Reviews:** Displays a subset of the submissions listed in My Inbox that are assigned to you for review. For the IRB module, this includes reviews assigned to Department & Ancillary Reviewers for review.
- **Create Menu:** Displays a menu of actions you can perform. The actions available to a user are dependent on assigned roles.
- **Recently Viewed:** Displays the last 10 items viewed, with the most recent at the top.
 - Selecting **'Pinned'** displays recently viewed items that have been pinned for quick and easy access. To pin an item, click the thumbtack icon adjacent to the submission listing.
- **Personalize Table:** You can alter the information displayed on the Dashboard by using the Personalize Table gear icon (see additional information [below](#)).



Dashboard features applicable to IRB Staff, IRB Reviewers (Chairs), and IRB Committee Member only:

- **Assignments:** Displays workload volume and assignments (determined by the number of assigned submissions pending action by IRB Staff/Reviewers)
 - **Staff Assignments: Pending Staff Action** – Displays workload volume for IRB Staff. Click on the name of an IRB Staff member in the legend to exclude their assigned volume from the chart. Click on the chart wedge corresponding to an IRB Staff member to view their assigned submissions.
 - **Staff Assignments: Pending Staff Action – Unassigned** – Displays submissions that have not been assigned an IRBC. Assign an IRBC directly from the list by selecting **Execute Activities**.
 - **Reviewer Assignments: Pending Reviewer Action** – Displays Non-Committee Review workload volume for IRB Reviewers. Click on the name of an IRB Reviewer in the legend to exclude their assigned volume from the chart. Click on the chart wedge corresponding to an IRB Reviewer to view their assigned submissions.
 - **Reviewer Assignments: Pending Reviewer Action – Unassigned** – Displays submissions in Non-Committee Review that have not been assigned an IRB Reviewer.



- In Process:** Summarizes your assigned volume by state (My Submissions) and all volume by state (All Submissions). The number on a tile indicates how many submissions are in that stage. Click on a tile to view underlying submissions.



- Study Expiration Dates:** Displays all studies (inclusive of all boards) that are within 60 days of their expiration date. Color coding indicates expiration proximity (Blue = 15-60 days; Orange = ≤ 15 days; Red = expiration date or expired)
 - Lapsed studies will remain on the list for up to 5 days after expiration.
 - The search box can be used to further narrow results.

Create

Study Expiration Dates

Enter search terms to filter list

Maximum number of items in a To Do List exceeded. Only the first 100 will be displayed.

Aug 3 2023

STUDY0000
CR: none
Coordinator: .

My Inbox

My Inbox

Filter by ID

STUDY0000

STUDY0000

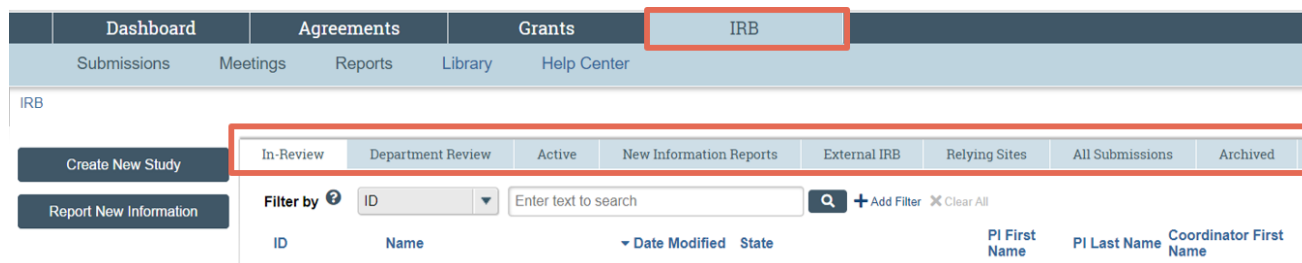
Find Submissions

To find submissions:

1. Select the **IRB** module.

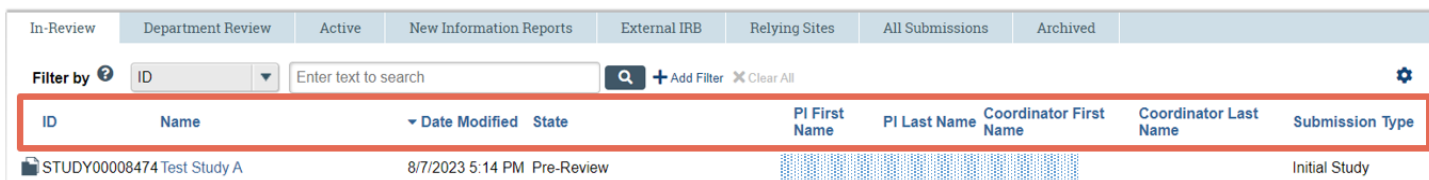
2. Within the IRB module, you can access submissions via the tabs as follows:

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



Sort Submissions

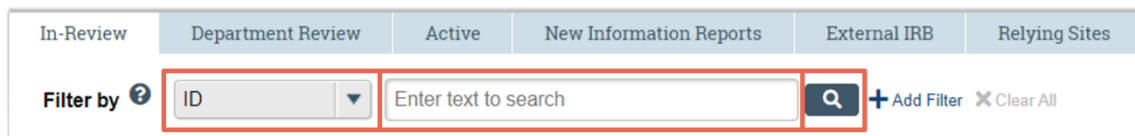
To sort submissions within a list, click on the column heading to sort by ID, Name, PI Last Name, Submission Type, etc. **Note:** ‘Coordinator’ headings refer to the IRB Coordinator assigned to the submission, not the Study Coordinator.



Filter Submissions

To filter submissions within a list:

1. Select the column to filter by from the dropdown menu.
2. Type the text you want to filter by in the text box.
 - Use the % symbol as a wildcard before the text entered to search for all entries containing the text entered (e.g., searching ‘exercise’ will identify fields that *begin* with the word exercise; searching ‘%exercise’ will identify all entries that include the word exercise *within* the field).
3. Click search icon to apply the filter. Submission can then be further sorted, as described [above](#).



4. To combine multiple filter criteria, click Add Filter.
5. To clear a filter, select **Remove Filter** or **Clear All** to remove all filters.

Personalize the Data Display

To personalize data in a list/table:

1. Click on the gear icon in the upper right corner.
2. Within the Personalize Table window, under the **Displayed Fields** heading, you can:
 - a. Check or uncheck the box adjacent to the field name to show or hide the field, respectively.
 - b. Change the order fields appear in by clicking the up or down arrow adjacent to the field name.
3. Within the Personalize Table window, under the **Options** heading, you can:
 - a. Change the position of the paging bar, by selecting where you want to the page bar to display from the dropdown menu.
 - b. Enable Auto Refresh by selecting the Auto Refresh checkbox and entering the interval at which you want the data to refresh. Doing so, will refresh data displayed within the list/table automatically. Alternately, if this field is not checked, data will only be refreshed after an interaction with the page.
4. Click Export to CSV to export the data in the list/table to a CSV file.
5. Click Reset to Default to restore all list/table display settings to the default.
6. Click **OK** to view the updated list/table.



Study & Follow-On Submission Workspace

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

1. Basic submission information including submission type, ID number, short title, Principal Investigator (PI), Primary Contact, PI Proxies, IRB Coordinator, approval letter, and legacy study link (if applicable).
 - The submission type is identified in the heading of the workspace as well as in the prefix of the submission (STUDY = study submission; MOD = modification; CR = continuing review; MODCR = combined modification and continuing review; RNI = Report of New Information).

STUDY00008474: Test Study A

Principal investigator: [Redacted]
 Submission type: Initial Study
 Primary contact: [Redacted]
 PI proxies: [Redacted]

IRB office: Office for Human Subject Protection
 IRB coordinator: [Redacted]

2. Navigation breadcrumbs that aids users in identifying their current location within the IORA platform.
 - When reviewing follow-on submissions, the breadcrumb can be used to navigate to the related study’s workspace (i.e., study homepage).

Dashboard	Agreements	Grants	IRB
Submissions	Meetings	Reports	Library
Institutional Profiles		Help Center	

IRB > Test Study A > Modification and Continuing Review #1 for Study Test Study A

Pre-Review MODCR00002246: Modification and

3. Submission state and approval details (e.g., IRB submission state, initial approval date, approval end date).
 - If a continuing review is not required, the Approval End date field will not be present

Approved

Entered IRB: 4/7/2023 1:35 PM
 Initial approval: 8/8/2023
 Initial effective: 8/8/2023
 Effective: 8/8/2023
 Approval end: 8/7/2024
 Last updated: 8/8/2023 12:55 AM

4. Review workflow, indicating where the submission in in the review process. When submissions appear on the bottom row of the workflow (e.g., clarification requested), action is required by the study team.



5. Smart forms and activities:

- **View Study:** Provides a read-only view of the submission form.
- **Printer Version:** Provides a printer-friendly version of the submission form.
- **Report New Information:** Allows users to create and submit a report of new information.
- **Activities:** Moves submissions through the review workflow. Available activities are dependent on the submission’s state. Hovering your cursor over the activity, provides a description of the activity.

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

[Assign Primary Contact](#)

6. Submission space navigation toolbar:

- **History:** Lists the actions taken on a submission including comments, attachments or correspondence added.
- **Funding:** Identifies the submission funding sources and related grant information.
- **Contacts:** Identifies study team members listed in the study submission as well as individuals with guest access (including Department and Ancillary Reviewers).
- **Documents:** Identifies all study and site related documents, including final approved and watermarked versions.

➤ **Note: Watermarked versions are listed under the ‘FINAL’ heading within this tab.**

History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	...
Study Related Documents							
Draft	Category	Final	Last Finalized	Document History			
Protocol	IRB Protocol	Protocol	8/14/2023 5:46 PM	History			
Site Related Documents							
Draft	Category	Final	Last Finalized	Document History			
Parental Permission.docx	Consent Form	Parental Permission.pdf	8/14/2023 5:46 PM	History			

- **Sites:** Identifies all participating sites undergoing single IRB review by the RSRB (applies to multi-site studies only).
- **Follow-on Submissions:** Lists all MODs, CRs, MODCRs, and RNIs related to the submission.
- **Reviews:** Identifies the status of Department and Ancillary Reviews.
 - For IRB Staff, IRB Reviewers (Chairs) and Committee Members, this tab will also identify determinations made during Pre-Review and Designated/Committee Review. The review history is maintained for each review type. When a modification is approved,

the latest Pre-Review information from the modification is copied into the parent (study) submission.

- **Snapshots:** Provides historical submission contents.
- **Training Details:** Identifies all study team members and the training they have completed through the Collaborative Institutional Training Initiative (e.g., Human Subject Protection, Good Clinical Practice, Animal Care & Use, and Responsible Conduct of Research training).
- Additional tabs for IRB Staff, IRB Reviewers (Chairs) and Committee Members only:
 - **Determinations:** Lists the protocol/consent and regulatory determinations made by the IRBC and Designated Reviewer/Committee.
 - **Minutes:** Identifies all previously recorded minutes related to the submission.
 - **Audits:** Identifies all internally-conducted audits and quality improvement reviews.
 - **IRB Assignment Details:** Provides details related to IRB Coordinator, Reviewer and Convened Meeting (if applicable) assignment while a submission is in review.

STUDY00008474: Test Study A

Principal investigator: [Redacted]
Submission type: [Redacted]
Primary contact: [Redacted]
PI proxies: [Redacted]

IRB office: Office for Human Subject Protection
IRB coordinator: [Redacted]
Letter: [Correspondence_for_STUDY00008474.pdf\(0.02\) ...](#)
Regulatory authority: 2018 Requirements



History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	Determinations	Audits	Minutes	...
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