

Integrated Online Research Administration: Click IRB Module

Study Staff Guide

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

This guide covers information and activities relevant to the submission of the following in Click IRB:

- Single-site studies;
- Multi-site studies undergoing single Institutional Review Board (sIRB) review by the Research Subjects Review Board (RSRB), including participating sites;
- Follow-on submissions (modifications, continuing reviews, and reportable new information) to single and multi-site research; and
- Local administrative review of External IRB study submissions, including updates to External IRB submissions.

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

Additional Resources:

- Help Text – Within the IORA system, additional help text is available anytime you see a ? icon. Click on the icon to review the help text.
- Click IRB Guides & Demo Videos:
 - [Click IRB Overview & Navigation Basics Guide](#) – Provides an overview of the review process (as performed within Click IRB) and basic information on navigating within the system.
 - [Click IRB Department & Ancillary Reviewer Guide](#) – Provides instructions for performing Department and Ancillary Committee Review within Click IRB.
 - Additional demo videos related to navigation and study staff activities available (and linked below, as applicable) on the Office for Human Subject Protection (OHSP) [website](#).
- [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

COI: Conflict of Interest

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

Log In

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

Note:

- 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.

Create & Submit a Single-Site Study

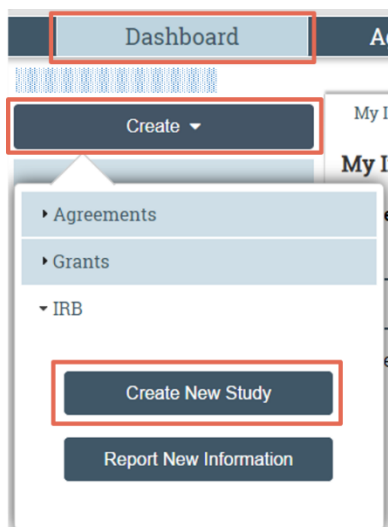
The instructions below are for submitting a new, **single-site study for review by the Research Subject Review Board (RSRB)**. The submission form is a smart form; specific fields will appear/disappear based on preceding responses. A demo video of this information is also available here: [Click IRB Demo Video – Create & Submit a Study](#).

Tips:

- It is best practice to wait to initiate an application until you have determined what IRB will review and approve the research (i.e., the RSRB or an external IRB).
- Before you begin, gather all necessary files and information about your study. For a complete list of submission components, see [OHSP's IRB Submission Checklist](#).

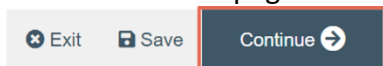
Create a Study

1. From the Dashboard page, click the **Create** menu, expand the IRB section (if applicable), and select **Create New Study** under the IRB heading.

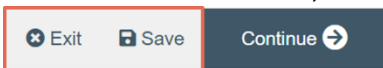


2. Within the submission form:

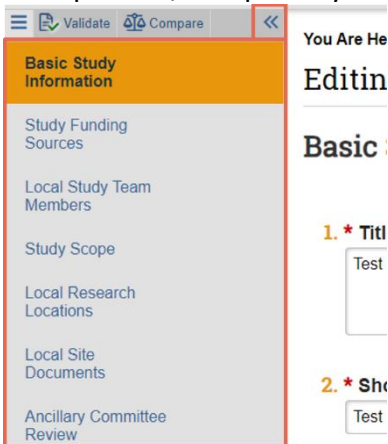
- Navigate through the form using the 'Continue' button, in the lower right corner of the page, to move to the next page.



- All fields marked with an asterisk (*) are required.
- To save or exit the form, click on 'Save' and 'Exit' in the lower right corner of the page.



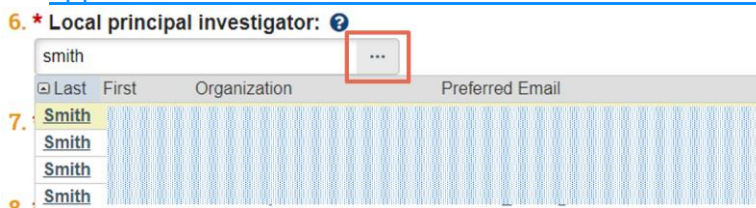
- Use the left-hand navigation pane to jump from page to page within the form. This pane may be expanded/collapsed by selecting the << icon.



Basic Study Information

1. **Title of study:** Enter the complete study title.
2. **Short title:** The short title will be used to identify the study throughout the system, such as in the dashboard, study workspace and search fields. The short title should allow users to easily identify the study and be less than 50 characters.
3. **Brief description:** Enter a short, 2-3 sentence summary of the primary objectives and design/methods.
4. **What kind of study is this?** Select single-site if research activities will only occur at the UR (including UR/URMC Affiliates). Select multi-site or collaborate study if the research will be conducted at two or more institutions.

5. **Will an external IRB act as the IRB of record for this study?** Answer yes if an IRB external to the RSRB will be responsible for the review and approval of the research. Answer no if the RSRB will be responsible for the review and approval of the research.
- If yes, see instructions for [creating and submitting to an External IRB](#) below.
 - If no and 'multi-site or collaborative study' is identified in the preceding field, see the instructions for [creating and submitting multi-site research for local, single IRB review](#) below.
6. **Local principal investigator:** This field defaults to whomever creates the submission. The Principal Investigator has full and final responsibility for the conduct of the research and must meet the [UR PI Eligibility Policy](#). To edit the field, clear the field by clicking the 'X' adjacent to the name and type the PI's name (full name or last name) in the search space provided; select the PI from the list of search results. Alternately, click on the ellipses to search the full database of study staff. Within the search results, note that you may need to page forward to view additional results.
- If you are unable to locate the PI, see [OHSP FAQ: I need to add a study team member to an application but can't find them in Click IRB. What should I do?](#)



7. **Does the local principal investigator have a financial interest related to the research?** Indicate whether the PI has a financial interest. For additional information, see the [UR Policy on Faculty Conflict of Commitment and Interest](#).
- If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.
8. **Attach the protocol:** Click **Add** to attach the study protocol and any applicable protocol addendums (**DO NOT** upload study measures, consent forms, recruitment materials, etc. in this field; they are uploaded elsewhere within the submission). In the corresponding 'Add Attachment' window:
- Click **Choose File** to attach the study protocol and click OK. Alternately, drag and drop the file into this field.
 - **Tip:** It is best practice to manually enter a protocol name in Field 2 and version number in Field 3. The information entered here will appear on the approval letter and should be consistent with the document's contents and the version identified in the document. If these fields are left blank, the protocol name will default to the file name and Click IRB program will assign a version number. For additional information, see [OHSP Explains... Document Management in Click IRB](#).
 - For instructions on uploading *revised* documents, see [Update Study Documents](#).
9. Click **Continue** to proceed to the next page of the application.

Study Funding Sources

Note: If there is no funding for the research, click 'Continue' to skip this section. For internal funding (e.g., by department), add the department/center as a funding source.

1. **Identify each organization...:** Identify each funding sources by clicking **Add** (multiple funding sources may be identified). In the corresponding 'Add Funding Source' window:

- **Funding organization:** Type the organization’s name in the search space provided and select the funding source from the list of search results. Alternately, click on the ellipses to search the full database of organizations. When searching:
 - Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., searching ‘pediatric’ will identify all organizations that *begin* with the word pediatric; searching ‘%pediatric’ will identify all organizations that include the word pediatric *within* their name).
 - Use the full name of the organization; acronyms will not produce a complete list of results.
 - If the funding source does not appear in the database contact your [IRB Coordinator](#), providing the organization’s name, address and type (e.g., foundation, government agency, industry).
 - **Sponsor funding ID:** If available/applicable, enter the Award ID/Sponsor Award ID.
 - **Grants office ID:** If available/applicable, enter the IORA Awards Number (e.g., AWD00000XXXX). If the proposal has not yet been funded, add the IORA Funding Proposal Number.
 - Click **OK**.
2. Click **Continue** to proceed to the next page of the application.

[Local Study Team Members](#)

Note: All local study team members engaged in the conduct of the research must be added to the study (including the individual creating the submission, if they are not identified as the PI). This includes individuals who: interact with human subjects; are involved with collecting, reporting, or analyzing identifiable subject data; and faculty advisors providing direct oversight of the research. Individuals do not need to be added as study team members when they are:

- Identified as the PI on the [Basic Study Information](#) page; or
- Functioning within their regular work practice (e.g., phlebotomist) and their involvement in the research is limited to their regular work responsibilities only (without further contribution to the research).

External study team members should generally only be added to as *local* study team members when:

- The research is exempt (irrespective of funding) and the individuals engaged at the non-UR site are not tied to an institution with an IRB and the RSRB agrees to review the research on their behalf;
- The research has no funding or funding other than federal funding and the individuals engaged at the non-UR site are not tied to an institution with an IRB and the RSRB agrees to review the research on their behalf; or
- The individual is not paid UR faculty, staff & student but is engaged in the research on behalf of the UR (e.g., summer student).

In accordance with [OHSP Policy 201 Education Program](#), **all study team members must have current Human Subject Protection (HSP) training** (i.e., Biomedical or Social-Behavioral-Educational Research training). Submissions will not be approved when any one member of the study team does not have *current* training (i.e., the training not expired). Once a submission has been created, local (UR) study staff training can be verified on the ‘Training’ tab in the study workspace. For additional information on training options for external team members, see [OHSP’s Guideline on Human Subject Protection Training for External Research Personnel](#).

To add/remove **University of Rochester** faculty, staff & students:

1. **Identify each additional person involved...:**

- To add: Click **Add** to add an internal (UR) study team member (including the individual creating the submission, if they are not identified as the PI). In the corresponding 'Add Study Team Member' window:
 - **Study Team Member:** Type the individual's name (full name or last name) in the search space provided and select the individual from the list of search results. Alternately, click on the ellipses to search the full database of study staff. If you are unable to locate an individual, see [OHSP FAQ: I need to add a study team member to an application but can't find them in Click IRB. What should I do?](#)
 - **Role in research:** Identify the individual's role.
 - **Does the team member have a financial interest...:** Identify whether the individual has a conflict of interest. If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.
 - Click **OK**.
 - Repeat this process to add all internal (UR) study team members to the submission.
- To remove: Click the 'x' to the right of the individual's name/information.

To add/remove study team members **external** to the University of Rochester:

1. **External team member information:**

- To add: Click **Add** to add an external study team member. **Note:** Adding external study team members here will **not** create a Click IRB user account for them (external study team members are not generally permitted access to IORA/Click IRB). Rather, this field provides a mechanism for uploading documentation of an external study team member's human subject protection training. To add the document, in the corresponding 'Submit a Document' window:
 - **Title:** Enter the individual's name.
 - **File:** Click **Choose File** to upload documentation of the individual's current human subject protection training (e.g., CITI Course Completion Report).
 - Select Show Advanced Options.
 - Enter the external study team member's role in the 'Description' field (e.g., recruiter).
 - Click **OK**.
 - Repeat this process to add all external study team members to the submission.
- To remove: Click the ellipses [...] to the right of the individual's training documentation and select **Delete**.

2. Click **Continue** to proceed to the next page of the application.

Study Scope

1. **Does the study evaluate the safety or effectiveness of a drug, biologic, or food/dietary supplement...?**

- Answer yes if a drug/biologic/supplement is 'under study' (i.e., is being investigated) or if data is being collected about a drug/biologic/supplement that is not used according to an approved indication. Answering yes will add a 'Drugs' page to the submission form, to collect additional information about the drug/biologic/supplement.

- Answer no if a drug/biologic/supplement is involved in the research but is being used as part of a study procedure (i.e., is not being investigated) and is being used in an approved/routine manner (e.g., sedation drugs or dilation drops).
2. **Does the study evaluate the safety or effectiveness of a device...?**
 - Answer yes if a device is being investigated or is ‘under study’ or if data is being collected on a device that is not being used according to an approved indication. Answering yes will add a ‘Devices’ page to the submission form, to collect additional information about the device.
 - Answer no if a device is being used as part of the research but it is not ‘under study’ (i.e., it’s being used in an approved/routine manner or is being used to collect data, such as a motion sensor or imaging modalities).
 3. **Are there any potential institutional conflicts...?** Answer yes if the *institution* may own stock, stock options, has licensed intellectual property (e.g., patents or copyrights), or has other financial interests in the research/sponsor. If yes, attach a copy of the management plan on the [Local Site Documents](#) page.
 4. **Is this study a clinical trial that requires registration on ClinicalTrials.gov?** To determine if registration is required (i.e., is an ‘Applicable Clinical Trial’), see the [Office of Regulatory Support’s Support for ClinicalTrials.gov Study Registration](#) website.
 - Answering yes will provide an additional field to enter the ClinicalTrials.gov Identifier. Enter the NCT prefix (in capital letters) followed by the 8 digit NCT number (e.g., NCT123456789).
 5. Click **Continue** to proceed to the next page of the application.

Local Research Locations

Note: Add all non-UR locations where research activities will be conducted *by UR faculty/staff* in collaboration with non-UR staff (e.g., Rochester City School District, Advent House). Also add all UR-affiliated sites where research activities will be conducted (e.g., Highland Hospital, FF Thompson). **If there are no additional research locations, click ‘Continue’ to skip this section.**

1. **Identify research locations...:** Click **Add** to add a research location. In the corresponding ‘Add Research Location’ window:
 - **Select the research location:** Type the location’s name in the search space provided and select the location from the list of search results. Alternately, click on the ellipses to search the full database of locations. When searching:
 - Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., searching ‘school’ will identify all locations that *begin* with the word school; searching ‘%school’ will identify all locations that include the word school *within* their name).
 - **Location name, address, etc. (Fields A-E):** Enter the location’s information manually into these fields **ONLY** if the location does **not** appear in the database search in the preceding field.
 - Click **OK**.
 - Repeat this process to add all locations to the submission.

Drugs

Note: You will only be directed to complete this page, if you answered yes to Field 1 (drugs, biologics & supplements) on the [Study Scope](#) page.

1. **List all drugs, biologics...:** Click **Add** to add the drug/biologic/supplement that is being investigated (is 'under study'). In the corresponding 'Add Drug' window:
 - **Select the drug:** Type the *generic* name of the drug/biologic/supplement in the search space provided and select the product from the list of search results. Alternately, click on the ellipses to search the full database of drug/biologics/supplements.
 - **Generic/Brand name:** Enter the generic and/or brand name of the product into these fields **ONLY** if the drug/biologic/supplement does **not** appear in the database search in the preceding field.
 - **Specify the type:** Identify the type of product. If 'Other' is select, an additional field will appear to provide a description of the drug type.
 - **Attach files...:** Click **Add** to attach the product's package insert or investigator brochure.
 - Click **OK**.
 - Repeat this process to add any additional drugs/biologics/supplements that are being investigated.
2. **Will the study be conducted under any IND number?** Answer yes, if an Investigational New Drug (IND) has been filed with the Food & Drug Administration for the conduct of the research. Refer to [OHSP Policy 605 Research Involving FDA Regulated Drugs, Biologics and Supplements](#) for additional information.
3. **Identify each IND:** This field will only appear if the preceding question is answered yes. For each IND, click **Add** to add IND number and identify who holds the IND. Click **OK**.
4. **Attach files:** Click **Add** to attach additional files related to the use of the drug/biologic/supplement, including but not limited to (as applicable): IND 'no hold' documentation from the FDA and PI IND training documentation (this training is required by the [Office of Regulatory Support](#) when a UR PI holds the IND).
5. Click **Continue** to proceed to the next page of the application.

Devices

Note: You will only be directed to complete this page, if you answered yes Field 2 (devices) on the [Study Scope](#) page.

1. **Select each device...:** Click **Add** to add the device that is being investigated (is 'under study'). In the corresponding 'Add Device' window:
 - **Select the device:** Type the name of the device that in the search space provided and select the product from the list of search results. Alternately, click on the ellipses to search the full database of devices.
 - Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., searching 'cardiac' will identify all devices that *begin* with the word cardiac; searching '%cardiac' will identify all devices that include the word cardiac *within* their name).
 - **Device name:** Enter the name of the device into this field **ONLY** if the device does **not** appear in the database search in the preceding field.
 - **Is this a humanitarian use device?** Complete this field **ONLY** if you are identified the device name manually in the preceding field.
 - **Attach files...:** Click **Add** to attach the package insert and/or manufacturer brochure.
 - Click **OK**.
 - Repeat this process to add any additional devices that are being investigated.

2. **Device exemptions...**: Indicate what device exemption(s) apply. Refer to [OHSP Policy 606 Research Involving FDA Regulated Devices](#) for additional information.
3. **Identify each IDE or HDE number**: This field will only appear if IDE or HDE is selected in the preceding question. For each IDE/HDE, click **Add** to add the IDE/HDE number and identify who holds the IDE/HDE. Click **OK**.
6. **Attach files**: Click **ADD** to attach additional files related to the use of the device, including but not limited to (as applicable): IDE documentation from the FDA and PI IDE training documentation (this training is required by the [Office of Regulatory Support](#) when a UR PI holds the IDE).
4. Click **Continue** to proceed to the next page of the application.

Local Site Documents

Attach all consent forms, recruitment materials and other study-specific documents to their respective sections. **All consent forms and recruitment materials should be uploaded as Microsoft Word documents.** To facilitate watermarking upon approval, maintain a margin of at least 1 inch in the bottom margin/footer of the document and do not include text in the lower right hand corner of the margin/footer.

To add documents:

- Click **Add** in the section that corresponds to the type of document being attached.
 - Click **Choose File** to attach the document the document and click **OK**. Alternately, drag and drop the file into this field.
 - **Tip**: It is best practice to manually enter the document name in Field 2 and version number in Field 4. The information entered here will appear on the approval letter and should be consistent with the document's contents and the version identified in the document. If these fields are left blank, the protocol name will default to the file name and Click IRB program will assign a version number. For additional information, see [OHSP Explains... Document Management in Click IRB](#).
 - For instructions on uploading *revised* documents, see [Update Study Documents](#).
 - **Category**: Select the category (type) of document uploaded.
5. Click **OK**.
 6. Once all documents have been added, click **Continue** to proceed to the next page of the application.

Ancillary Committee Review

1. **Does this research involve any of the following...?** Indicate whether the research requires review by **any** of the UR Ancillary Committees listed (see [OHSP Policy 503 Ancillary Committee Review](#) and [OHSP Explains... Ancillary Committee Review](#) for additional information).
 - **Note**: Minimally, *most* types of research will collect, transmit or store electronic data and therefore **the answer should be 'Yes' for most submissions**.
2. **Fields 2-13**: These fields will only appear if the preceding question is answered yes. Each field corresponds to a specific type of Ancillary Committee. Review all questions and respond accordingly.
 - If yes to Field 6, concerning Surgical Pathology, attach the [Request for Human Tissue Form](#) in Field 14.
 - If yes to Field 7, concerning University Pharmacy and Investigational Drug Service (IDS), indicate whether IDS will be used to manage the drug/biologic/supplement in the corresponding follow-up question.

- If yes to Field 9, concerning the Human Use of Radiation Committee (HURC), attach the [HURC Research Form](#) in Field 14.
 - If yes to Field 13, concerning the collecting, transmission or storage of electronic data, attach the [Data Security Assessment Form](#) in Field 14. **As stated above, this form is required for most types of research.**
3. Click **Continue** to proceed to the next page of the form.

Finish & Submit the Study

1. Click **Finish** to save and exit the form. **This does not submit the application.**

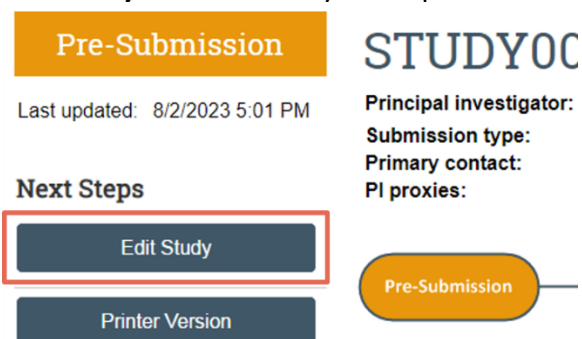
Final Page

You have reached the end of the IRB submission form. Read the next steps carefully.

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.



2. Once an application has been completed, you may edit the application prior to submission by clicking **Edit Study** from the study workspace.



3. Prior to study submission, it is recommended to consider the following additional activities:
- [Assign a Primary Contact](#)
 - [Assign a PI Proxy](#)
 - When a student assumes the role of PI, including research conducted by residents and fellows, their faculty mentor should be assigned the PI Proxy role.
 - [Manage Guest List](#)
 - Department Research Administrators should be added as guests to all sponsored research.
 - [Add Related Grant](#)
 - **Note: DO NOT** select the Manage Ancillary Review activity and attempt to assign Ancillary Committee Reviews; review will be facilitated by the RSRB following submission.
4. To submit the study, click **Submit** from the study workspace. **Note:**
- **Only the PI and study team members designated the PI Proxy role will have the 'Submit' activity.**
 - At the time of initial submission, the PI should submit the study (**not** a PI Proxy). Initial submissions submitted by the PI Proxy will be sent back to the PI to confirm their certification of their responsibilities as PI, as well as the PI Proxy designations.

Pre-Submission

Last updated: 8/2/2023 5:01 PM

STUDYOC

Principal investigator:
Submission type:
Primary contact:
PI proxies:

Next Steps

Edit Study

Printer Version

Submit

Pre-Submission

5. Read the terms provided and click **OK** to agree. The study has now been submitted.

Next Steps

Once submitted, the study will undergo review as described in the [Click IRB Overview & Navigation Basics Guide](#), as well as [OHSP Explains... The IRB Review Process](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations concerning the research (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Note: Research cannot be initiated until the study submission is approved (submitted ≠ approved).

Create & Submit a Modification or Continuing Review

A modification ('MOD') is required any time previously approved materials requires updating. This may include updating the study protocol, study submission form, local study team members, consent forms, recruitment methods or materials, or other approved study documents. **Review and approval of the modification is required prior to implementation of the changes included.**

Some types of research require the submission of a Continuing Review ('CR'), or progress report, to re-approve the research and/or to close the research:

- Studies that require CR for re-approval are assigned an expiration date (this date cannot exceed 1 year from approval). For these studies, **the CR must be submitted and approved in order for the research to continue beyond the date of expiration; if the approval period lapses, all study activities must cease.** Studies that do not require re-approval via the CR process are not assigned an expiration date. Expiration dates (or lack thereof) are identified on the study's approval letter, as well as in the study workspace (below the orange 'state' box).
- All studies must also be formally closed once the research is complete EXCEPT for: studies deemed exempt; proposals that do not involve human subject research; and proposals that involve human subjects but where the University of Rochester is not engaged in the research.

If a MOD and a CR are required at the same time, they can be combined into one submission (referred to as a 'MODCR'). **Note: It is best practice to limit the submission of MODCRs to those that involve modification to study personnel and/or editorial revisions to study documents only.** MODCRs that include more extensive revisions can delay the re-approval of the CR component of the submission, thereby putting the study team at risk for a lapse in approval (i.e., non-compliance).

Additional information on types of submissions can be found in [OHSP Policy 502 Types of RSRB Submissions](#). Demo videos are also available for:

- [Click IRB Demo Video – Create & Submit a Modification](#)
- [Click IRB Demo Video – Create & Submit a Continuing Review](#)

Create a MOD, CR or MODCR

1. Find and open the applicable study by opening the **IRB** module, clicking on the **Active** tab and then the name of the study.

The screenshot shows the IRB system interface. At the top, there is a navigation menu with tabs: Dashboard, Agreements, Grants, IRB (highlighted with a red box), and Help Center. Below this, there are sub-tabs: Submissions, Meetings, Reports, Library, and Help Center. The main content area shows the IRB > Submissions page. On the left, there are buttons for 'Create New Study' and 'Report New Information'. On the right, there are tabs for 'In-Review', 'Department Review', 'Active' (highlighted with a red box), and 'New In'. Below the tabs, there is a filter section with 'Filter by' and a dropdown menu set to 'Coordinator Last' with the value 'bhear'. Below the filter, there is a table with columns 'ID', 'Name', and 'Date Modified'. The table contains one row: 'STUDY0000847' with 'Test Study A' in the Name column and '8/14/2023 5:53 PM' in the Date Modified column. The 'Test Study A' cell is highlighted with a red box.

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

Next Steps

The screenshot shows the 'Next Steps' section with four buttons: 'View Study', 'Printer Version', 'Create Modification/CR' (highlighted with a red box), and 'Report New Information'.

3. Complete the Modification/CR form as follow:
 - **What is the purpose of this submission?** Identify whether the submission is a continuing review (CR), a modification (MOD), or combined modification and continuing review (MODCR).
 - **Modification scope:** This field will only appear if modification or combined modification and continuing review is selected in the preceding question. Select the checkboxes that apply as follows:
 - **Study team member information:** Select if the modification involves adding/removing study team members (other than the Principal Investigator).
 - **Other parts of the study:** Select for all other types of modifications, including revisions to:
 - a. Components of the submission form (e.g., basic study information, funding sources, research locations, study scope, drugs/devices, and/or ancillary review);
 - b. Study documents (protocol, consent form, recruitment materials, data security assessment form, etc.); and/or
 - c. Principal Investigator (updating the Principal Investigator requires revision to both the submission form [basic study information] and applicable study documents).

- Click **Continue** to proceed.
 - **Note:** Once the submission has been created, you will not be able to edit the first page of the form. If revisions are required and the form has not yet been submitted to the IRB, you may [discard](#) the submission from the submission workspace and start over.
- See [Complete a CR Form](#) and/or [Complete a MOD Form](#) below for instructions on completing the remaining components of the form.

Complete a CR Form

1. **Specify enrollment totals at this investigator's site:** Enter the *total* number of subjects enrolled for which the PI is responsible for (including withdrawals, screen failures, and subjects lost to follow-up).
 - For multi-site research undergoing sIRB review, enter the total number of subjects enrolled study-wide (i.e., across all participating sites).
 - For research involving data/specimen collection only, enter the number of records/specimens accessed or used.
 - For additional guidance on who is considered 'enrolled', see [OHSP Explains... Defining & Reporting Subject Enrollment](#).
2. **Specify enrollment totals at this investigator's site since last approval:** Enter the number of subjects enrolled *since the last CR submission*.
 - If this is the first CR submitted since the study's initial approval, enter the same number as the total enrolled in Field 1.
 - If this is *not* the first CR submitted, enter the number of subjects enrolled since the submission of the previous CR. Refer to the previous CR to verify enrollment numbers; enrollment reports that do not agree with the previous CR will be returned for clarification.
 - For multi-site research undergoing single IRB review, enter the total number of subjects enrolled study-wide (across all sites) since the last CR submission.
3. **Specify enrollment totals study-wide:** Enter the *total* number of subjects enrolled for which the PI is responsible for (including withdrawals, screen failures, and subjects lost to follow-up).
 - For single-site studies, enter the same number as the total enrolled in Field 1 ('enrollment totals at this investigator's site').
 - For multi-site research undergoing sIRB review, enter the same number as the total enrolled in Field 1 ('enrollment totals at this investigator's site'). **Note:** pSite enrollment information will appear in parentheses once [pSite CR data is reported](#).
4. **Research milestones:** Select **ALL** milestones that apply to the research (select the checkbox if the corresponding statement is **TRUE**). **Note:**
 - Do not respond based on individual subjects or cohorts of subjects; responses should be based on the study as whole.
 - If none of the milestones have been met (e.g., the study continues to enroll subjects), all checkboxes should be left blank.
 - To close a study, the 1st four milestones must be met.
 - Additional guidance on identifying milestones is available in [OHSP Explains... Reporting Research Milestones in Click IRB](#).
5. **I acknowledge that this study will be closed:** This field will only appear when the 1st four 'Research milestones' checkboxes are selected. Select the checkbox to confirm acknowledgement. If are not ready to close the study:

- Re-assess whether all selected research milestones have been met. If you wish to keep a study open because the analysis described in the study protocol is not yet complete or there is a possibility that you may need to go back and collect additional, or edit existing, data, uncheck the ‘analysis of private identifiable information is complete...’
 - If you determine that all milestones have been reached, assess whether the study needs to remain with the IRB in order to accomplish remaining tasks. **Note:** Data analysis is still permitted following study closure provided all identifiers have been removed from the analysis dataset. Identifiers that have been removed from the dataset do not need to be destroyed, just removed from the dataset and maintained in a separate dataset.
6. **Do any investigators or research staff have a financial interest...?** Answer yes if additional conflicts of interest, *that have not previously been reported*, have been identified. If yes, a modification will need to be submitted to add a copy of the management plan and transparency checklist to the submission (attaching the documentation within the CR form, will not encapsulate COI documentation into the study submission).
7. **Check the items that are true since the last IRB approval...:** Select **ALL** events that have occurred since the previous CR (select the checkbox if the corresponding statement is **TRUE**; leave the checkbox unchecked if the statement is **FALSE**). For example, if no subjects have withdrawn from the research since the previous CR, select the checkbox ‘No subjects withdrew from the study’ (because the statement is true). Alternately, if one or more subjects *have* withdrawn since the previous CR, leave the checkbox for ‘No subjects withdrew from the study’ *unchecked* (because the statement is false).
- For multi-site research undergoing sIRB review, responses should reflect events that have occurred study-wide (across all sites).
8. **Attach supporting documents:** As applicable, attach:
- Documentation related to and/or clarifying **EACH** research event left unchecked in the preceding field (e.g., related publications, data and safety monitoring reports, interim findings);
 - Ancillary Committee re-approval documentation; and/or
 - Other research events, including non-compliance, that have occurred since the previous CR but did not require prompt IRB reporting (in accordance with [OHSP Policy 801 Reporting Research Events](#) and the corresponding [OHSP Guideline for Reporting Research Events](#)).
 - For multi-site research undergoing sIRB review, attach documentation identifying the total number of subjects enrolled at each pSite. Alternately, this can be identified in the comments field below.
9. **Comments:** As applicable, provide an explanation of the research events/circumstances described above that are not addressed in attached supporting documentation.
10. **Have any NEW subjects enrolled...?** Answer yes, if new subjects have enrolled since the previous CR that required a signed consent (in accordance with the approved study protocol).
- For multi-site research undergoing sIRB review, upload the last signed consent from each pSite.
11. **Attach files:** This field will only appear when the preceding field is answered yes. Click **Add** to attach a copy of the last signed document for **EACH** type of consent obtained since the previous CR. E.g., if the research is approved with a Parent Permission and a Written Assent Form and both documents have been used to enroll since the previous CR, attach a copy of the last signed permission form and the last signed written assent form. Prior to attaching a document:
- To protect subject confidentiality, conceal the subject’s name and signature but *not* the date the subject signed the form. Note:
 - Ensure the name and signature of the person who obtained consent remains visible.

12. Click **Continue** to proceed.

- If the submission is for a CR only, jump to [Finish & Submit a MOD, CR or MODCR](#).

Complete a MOD Form

1. **Subject enrollment status:** Select **ALL** applicable checkboxes.
 - For research involving data/specimen collection only, consider the number of records/specimens accessed or used as ‘subjects’.
 - For multi-site research undergoing single IRB review, respond based on the study as a whole (i.e., across all participating sites).
 - For additional guidance on who is considered ‘enrolled’, see [OHSP Explains... Defining & Reporting Subject Enrollment](#).
2. **Notification of subject:** Indicate whether current and/or former subjects will be notified of the revisions including in the modification. Generally, notification is required when a modification *may* impact a subject’s willingness to continue participation and/or their health, safety or welfare (e.g., changes in study procedures, payment, risks, etc.). Leave this field blank if notification is not applicable.
3. **Describe the subjects to be notified and how they will be notified:** This field will only appear when the preceding field indicates that either (or both) current or former subjects will be notified. Describe:
 - What specific groups of subjects will be notified (this may be a subset of those indicated the preceding field, e.g., subjects currently undergoing interventional procedures or subjects enrolled into a specific cohort); and
 - How subjects will be notified of the information (e.g., via re-consent with a full consent form, re-consent via consent addendum, information sheet).
4. **Summarize the modification & Attach files:** Insert a summary of the modifications included in the submission, ***including the rationale/justification for the revisions***. Alternately, a document/memo summarizing the revisions and rationale may be uploaded via the ‘Attach files’ field.
 - a. **Note: DO NOT** attach additional or revised study documents in the ‘Attach files’ field; these are added/updated later in the submission form.
5. Click **Continue** to proceed.
6. The remaining pages of the modification form are comprised of the current study submission. Click **Continue** through the pages to edit applicable sections. **Note:** The pages you are provided access to to edit are dependent on the modification scope field (described above) and the study type (single-site vs. multi-site). For additional information on:
 - Completing/Updating pages in a single-site submission, see [Create & Submit a Single-Site Study](#) or jump to: [Basic Study Information](#); [Study Funding Sources](#); [Local Study Team Members](#); [Study Scope](#); [Local Research Locations](#); [Drugs](#); [Devices](#); [Local Site Documents](#); and [Ancillary Committee Review](#).
 - Completing/Updating pages within a MSS undergoing sIRB review, see [Create & Submit a Multi-Site Study for Single IRB Review](#) or jump to: [MSS Basic Study Information](#); [Study Funding Sources](#); [MSS Local Study Team Members](#); [Study Scope](#); [Local Research Locations](#); [Drugs](#); [Devices](#); [MSS Study-Related Documents](#); [MSS Local Site Documents](#); and [MSS Ancillary Committee Review](#).
 - Revising study documents, see [Update Study Documents](#). **Note:** Revisions to existing documents should be attached via the **Update** button (adjacent to the current document).

Only new documents (that have not yet been reviewed by the IRB) should be attached via the **Add** button.

Finish & Submit the MOD, CR or MODCR

1. On the final page of the submission form, click **Finish** to exit the form. **This does not submit the form.**
2. Once the form has been completed, you may edit it prior to submission by clicking **Edit Modification/CR**.
3. When you're ready to submit the form, click **Submit** from the submission workspace.
 - **Note: Only PIs and PI Proxies can submit MODs, CRs, and MODCRs.**

Pre-Submission

Last updated: 8/15/2023 1:59 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

4. READ the terms provided and click **OK** to agree. The MOD, CR or MODCR has now been submitted.

Next Steps

The submission will undergo review as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the submission, and/or makes determinations concerning the submission (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Note:

- **Revisions included in a modification cannot be implemented until the submission is approved (submitted ≠ approved).**
- Following MSS MODs, CRs, and MODCRs, it is the responsibility of the study team to ensure all approved documents are forwarded to the pSite (as applicable).
- If a modification is disapproved, no new modifications of the same type can be created until the disapproved submission is either re-submitted and approved or discarded.

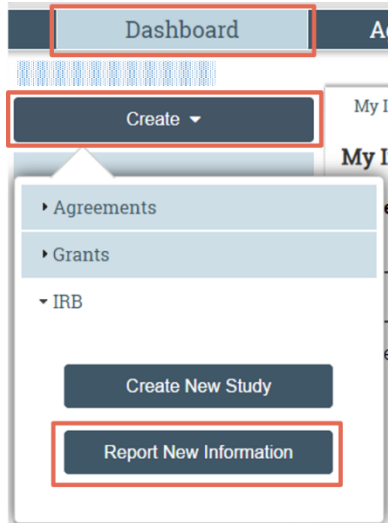
Create & Submit Reportable New Information

Report events or new information, per the requirements set forth in [OHSP Policy 801 Reporting Research Events](#) and the associated [Guideline for Reporting Research Events](#), via the Report New Information' (RNI) process. **Note: Events that do not require *prompt* reporting as defined in the [Guideline for Reporting Research Events](#) can be reported at the time of Continuing Review.**

A demo video of this information is also available here: [Click IRB Demo Video – Create & Submit a Report of New Information](#).

Create an RNI

- From the Dashboard page, click the **Create** menu, expand the IRB section (if applicable), and select **Report New Information** under the IRB heading. Alternately, select **Report New Information** from the study workspace.



- Complete the Report New Information form as follow:
 - **RNI short title:** Enter a RNI short title. The short title will be used to identify the RNI throughout the system, such as in the dashboard, study workspace and search fields.
 - **Date you became aware of the information:** Enter the date you became aware of the event/new information.
 - **Identify the categories...:** Select the type(s) of event/new information (select all that apply). **Note:** Events that do not fit into one of the categories described, do not require prompt IRB reporting and should be reported at the time of Continuing Review (see [OHSP Policy 801 Reporting Research Events](#) and the associated [Guideline for Reporting Research Events](#) for additional information).
 - **Briefly describe the new information:** Provide a description of the event/new information, include (as applicable): the nature of the incident/information; whether the event was internal or external; an assessment of the relatedness to the research; the outcome/impact on subjects and/or others; and applicable corrective and preventative action plan. Additional memos and/or supporting documentation can be added in the 'Attach files...' field below.
 - **Does this information indicate a new or increased risk, or safety issue?** Answer yes if the event/information indicates an increase in the frequency or magnitude of a previously known risk **OR** if previously unknown risk or safety issue has been identified.
 - **Does the study need revision?** Answer yes if any component of the current study submission requires revision, including contents of the submission form and any documents uploaded within the submission (other than consent forms). This includes but is not limited to the study protocol, study personnel, Investigator's Brochure, package inserts and assessments. All revisions will need to be submitted via [modification](#) (the RNI form does not facilitate revision to the submission form or submission documents).

- **Does the consent need revision?** Answer yes if *any* consent form requires revision. All revisions will need to be submitted via [modification](#) (the RNI form does not facilitate revision to the submission documents).
 - **Related studies and modifications:** Click on the ellipses to identify all related studies, sites and/or follow-on submissions the RNI applies to.
 - If the RNI was created from within a study workspace, the applicable study will automatically appear; additional sites and/or follow-on submissions may need to be added.
 - If the RNI was created from the Dashboard, add applicable studies first. You will not be able to add sites or follow-on submissions until the parent study has been added first.
 - If the RNI is created from within a multi-site study or participating site, additional fields to identify the reporting site and affected sites are provided.
 - Only submissions that the individual creating the RNI is listed on or has access to will appear in the search box. If additional submissions should be identified, use the [Add Comments](#) activity in the RNI workspace to notify the IRB Coordinator of the additional submissions.
 - **Attach files...:** Click **Add** to attach any supporting documentation.
3. Click **Continue** to proceed to the next page for the form.

Finish & Submit a RNI

4. On the final page of the form, click **Finish** to exit. **This does not submit the RNI.**
5. Once the form has been completed, you may edit it prior to IRB submission by clicking **Edit RNI** from the RNI workspace.
6. **Prior to study submission, consider who may need access to edit and/or respond to clarification requests related to the RNI submission.** The PI and PI Proxy of each related submission will automatically be provided access to do so. To review these individuals and/or provide additional study personnel access to edit/respond to the RNI, use [Manage Editors](#) activity on the RNI workspace.
7. When you're ready to submit the form, click **Submit RNI** from the submission workspace.

Next Steps

Edit RNI

Printer Version

➔ Submit RNI

8. READ the terms provided and click **OK** to agree to the terms. The RNI has now been submitted.

Next Steps

The submission will undergo review as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#) and/or makes determinations concerning the submission, an email notification will be provided to the individual who submitted the RNI and PI/PI Proxies on submissions related to the RNI.

Create & Submit a Multi-Site Study for Single IRB Review

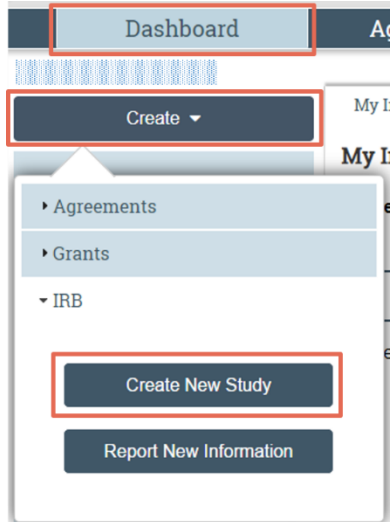
The instructions below are for submitting a new multi-site study (MSS) for single IRB (sIRB) review by the RSRB. Per [OHSP Policy 504 IRB Reliance and Collaborative Research](#), all studies that utilize the RSRB as the sIRB of record require the execution of a reliance agreement (or IRB authorization agreement). To initiate this process, **prior to IRB submission**, follow the flow chart provided in the [OHSP Guideline for When the University of Rochester is the Reviewing IRB](#). Once OHSP has confirmed that the RSRB will serve as the Reviewing IRB, the Click IRB study submission can be developed.

Note:

- MSS submissions include multiple components:
 - a) A study submission that describes the research and provides study-related information/documents that apply to the study as a whole; and
 - b) Individual site submissions for each participating site (pSite) that provides site-specific details.
- If the PI will also act as the PI for the UR pSite, the UR pSite details can be entered on the study submission; a separate pSite submission is not required. If two separate PIs will act as the lead PI and the local pSite PI, the local pSite details should be entered on a separate pSite submission (additional details are provided below).
- Study and pSite application forms are smart forms; specific fields will appear/disappear based on preceding responses.

Create a Multi-Site Study

1. From the Dashboard page, click the **Create** menu, expand the IRB section (if applicable), and select **Create New Study** under the IRB heading.



MSS: Basic Study Information

1. Complete Fields 1-3, entering the title of the study, short title and a brief description that summarizes the primary objectives and design of the research.
 - **Note:** The short title will be used to identify the study throughout the system, such as in the dashboard, study workspace and search fields.
2. **What kind of study is this?** Select 'Multi-site or Collaborative study'.
3. **Will an external IRB act as the IRB of record for this study?** Answer no.

4. **Will your IRB act as the single IRB of record for other participating sites?** Answer yes.
5. **Local principal investigator:** This field defaults to whomever creates the submission. The Principal Investigator has full and final responsibility for the conduct of the research, oversees conduct of the research across all participating sites, and must meet the [UR PI Eligibility Policy](#). To edit the field, clear the field by clicking the 'X' adjacent to the name and type the PI's name (full name or last name) in the search space provided; select the PI from the list of search results. Alternately, click on the ellipses to search the full database of study staff. Within the search results, note that you may need to page forward to view additional results.
 - If you are unable to locate the PI, see [OHSP FAQ: I need to add a study team member to an application but can't find them in Click IRB. What should I do?](#)
6. **Does the local principal investigator have a financial interest related to this research?** Indicate whether the PI has a financial interest. For additional information, see the [UR Policy on Faculty Conflict of Commitment and Interest](#).
 - If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.
7. **Attach the protocol:** Click **Add** to attach the study protocol. If applicable (and maintained separately from the study protocol), attach as protocol addendums:
 - PI oversight plan (PI oversight plans are required for all MSS research undergoing sIRB review; for additional information see [OHSP's Guideline for PI Oversight for Multi-Site Research](#)).
 - If the PI will also act at the PI for the local UR pSite, additional details specifying research conduct at the UR pSite (e.g., local recruitment methods) can also be attached here (if necessary). If a separate PI will act as the pSite PI, this information will be attached via the pSite submission.In the corresponding 'Add Attachment' window:
 - Click **Choose File** to attach the study protocol and click OK. Alternately, drag and drop the file into this field.
 - **Tip:** It is best practice to manually enter a protocol name in Field 2 and version number in Field 3. The information entered here will appear on the approval letter and should be consistent with the document's contents and the version identified in the document. If these fields are left blank, the protocol name will default to the file name and Click IRB program will assign a version number. For additional information, see [OHSP Explains... Document Management in Click IRB](#).
 - For instructions on uploading *revised* documents, see [Update Study Documents](#).
8. Click **Continue** to proceed to the next page of the application.

MSS: Study Funding Sources

Identify all funding sources, including any internal funding (e.g., by department) as described above for single-site studies. See: [Study Funding Sources](#).

MSS: Local Study Team Members

1. **Identify each additional person involved...** Click **Add** to add all internal (UR) study team members, including: the individual creating the submission, if they are not identified as the PI; all UR study team member engaged in site oversight, and all UR pSite personnel (the UR pSite submission does not provide the opportunity to add pSite personnel separately). In the corresponding 'Add Study Team Member' window:

- **Study Team Member:** Type the individual's name (full name or last name) in the search space provided and select the individual from the list of search results. Alternately, click on the ellipses to search the full database of study staff. If you are unable to locate an individual, see [OHSP FAQ: I need to add a study team member to an application but can't find them in Click IRB. What should I do?](#)
 - **Role in research:** Identify the individual's role.
 - **Does the team member have a financial interest...:** Identify whether the individual has a conflict of interest. If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.
 - Click **OK**.
 - Repeat this process to add all internal (UR) study team members to the submission.
 - To remove: Click the 'x' to the right of the individual's name/information.
2. **External team member information:** **SKIP THIS FIELD**; pSite PIs will be identified via the pSite submission and all other pSite staff should be managed per pSite policy/requirements.
 3. Click **Continue** to proceed to the next page of the application.

MSS: Study Scope

Complete the Study Scope section as described above for single-site studies. See: [Study Scope](#).

MSS: Local Research Locations

Add all local (UR) research locations where research activities will be conducted by UR faculty/staff (regardless of who the UR pSite PI is); complete the Local Research Locations page as described above for single-site studies. See: [Local Research Locations](#). **DO NOT** add participating sites (pSites) as research locations.

MSS: Drugs & Devices

You will only be directed to complete the Drugs and Devices pages if you answered yes to Fields 1 and 2, respectively on the [MSS Study Scope](#) page. To complete these pages, see the instructions provided above for single-site studies. See: [Drugs](#) &/or [Devices](#).

MSS: Study-Related Documents

Attach all study-related documents (meaning, documents that apply to the study as a *whole*; **NOT** documents that are specific to an individual pSite). This includes all applicable model consent for templates, model recruitment materials, and any other study-related template/form that will be distributed for use at each pSite.

To add documents:

- Click **Add** in the section that corresponds to the type of document being attached.
- Click **Choose File** to attach the document the document and click OK. Alternately, drag and drop the file into this field.
 - **Tip:** It is best practice to manually enter the document name in Field 2 and version number in Field 4. The information entered here will appear on the approval letter and should be consistent with the document's contents and the version identified in the document. If these fields are left blank, the protocol name will default to the file name and Click IRB program will assign a version number. For additional information, see [OHSP Explains... Document Management in Click IRB](#).

- For instructions on uploading *revised* documents, see [Update Study Documents](#).
- **Category:** Select the category (type) of document uploaded.

MSS: Local Site Documents

Complete this section if the PI will also act as the PI for the local UR pSite. Add all consent forms, recruitment materials and other *site*-specific documents to their respective sections (e.g., template consent/recruitment forms that have been customized to include UR site-specific information). **All consent forms and recruitment materials should be uploaded as Microsoft Word documents.** To facilitate watermarking upon approval, maintain a margin of at least 1 inch in the bottom margin/footer of the document and do not include text in the lower right hand corner of the margin/footer. To add documents, follow the instructions provided in the section above.

DO NOT add:

- UR site-specific documents if a separate PI will act as the local pSite PI (these documents will be added via the pSite submission);
- Site-specific documents for other pSites.

MSS: Ancillary Committee Review

1. **Does this research involve any of the following...** Answer yes. Given the nature of MSS research, all research will *minimally* involve the collection, transmission or storage of electronic data.
 - **Note:** For additional information on Ancillary Committee Review, see [OHSP policy 503 Ancillary Review](#) and [OHSP Explains... Ancillary Committee Review](#).
2. **Fields 2-13:** These fields will after the preceding question is answered yes.
 - Fields 2-12: Answer yes, if applicable and the PI is also acting as the PI for the local UR pSite.
Note:
 - If yes to Field 6, concerning Surgical Pathology, attach the [Request for Human Tissue Form](#) in Field 14.
 - If yes to Field 7, concerning University Pharmacy and Investigational Drug Service (IDS), indicate whether IDS will be used to manage the drug/biologic/supplement in the corresponding follow-up question.
 - If yes to Field 9, concerning the Human Use of Radiation Committee (HURC), attach the [HURC Research Form](#) in Field 14.
 - Field 13: Answer yes to Field 13, concerning the collecting, transmission or storage of electronic data, attach the [Data Security Assessment Form](#) in Field 14.
3. Click **Continue** to proceed to the next page of the form.

Finish & Submit the MSS

Complete the final page of the submission and submit the study as described above for single-site studies. See: [Finish & Submit the Study](#).

Next Steps

Once submitted, the study will undergo review as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations concerning the research (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Note: Submissions for each Participating Site (pSite) should not be initiated until the study has been approved. For each pSite: [Add the pSite](#); [Edit the pSite](#); and [Submit pSite Materials](#). **Research cannot be initiating at a pSite until the pSite submission is approved (study approval ≠ pSite approval).**

Add a Participating Site

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

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

 Add Participating Sites

2. In the corresponding 'Add Participating Sites' activity, click '**Add**'.
3. Type the site's name in the 'Institutional Profile' field and select the pSite from the list of search results. Alternately, click on the ellipses to search the full database of pSites. When searching:
 - Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., searching 'Arizona' will identify all sites that *begin* with the word Arizona; searching '%Arizona' will identify all sites that include the word Arizona *within* their name).
 - If the Institutional Profile does not appear in the database, contact the IRB Coordinator.
4. Type the name of the pSite PI in the 'Principal Investigator' field and select the PI from the list of search results. Alternately, click on the ellipses to search the full database.
 - If the PI's name does not appear in the database, contact the IRB Coordinator.
5. Click **OK** or **Add** to add additional pSites.
 - A submission form for each added pSite has been created. The pSite state is Invitation Pending and the IRB Coordinator is notified of the pSite. The pSite must be edited (see below), prior to submission.

Edit a Participating Site

1. To open the pSite submission, select the **Sites** tab from the study workspace and:
 - Click on the name of the pSite. The pSite workspace will then open; click **Edit Site**. **OR**
 - Click on the edit (pencil) icon, under the 'SmartForm' heading, adjacent to the pSite name and select **Basic Site Information** to jump into the site submission form.

Approved

STUDY00008522: MSS Test Study A

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

Entered IRB: 8/22/2023 9:46 AM
 Initial approval: 8/22/2023
 Initial effective: 8/22/2023
 Effective: 8/22/2023
 Approval end: 8/21/2024
 Last updated: 8/22/2023 11:44 AM

IRB Letter
 Reg

Next Steps

View Study
 Printer Version
 Create Modification/CR
 Report New Information

Add Participating Sites
 Assign Primary Contact

Pre-Submission → Pre-Review → IRB Review → Post-Review
 Clarification Requested → Clarification Requested → Clarification Requested

History Funding Contacts Documents **Sites** Follow-on Submis

Filter by ID Enter text to search

ID	Name	SmartForm
SITE00000371	Johns Hopkins University Participating Site for MSS Test Study A	[SmartForm Icon]

2. Complete all pages of the pSite submission form:

- **Basic Site Information:**
 - Update the short title and local PI, as necessary. The short title will be used to identify the pSite throughout the system, such as in the dashboard, study workspace and search fields.
 - **Does the local investigator have a financial interest...?** If yes, attach a copy of the management plan and/or transparency checklist on the Local Site Documents page (documentation will depend on COI reporting requirements at the PI's local institution).
 - **Brief description...:** Summarize the activities that will take place at the pSite (e.g., all research activities as described in the study protocol vs. portions of the research, such as performing only specific activities or enrolling a specific cohort).
- **Additional Local Funding Sources:** Only add funding that is specific to the pSite (**not** funding that applies to the research as a whole; this type of funding should be identified in the STUDY submission). **If there is no additional funding, click 'Continue' to skip this section.**
- **Local Site Documents:** Add all pSite consent forms, recruitment materials and other documents specific to the pSite to their respective sections (e.g., template consent/recruitment forms that have been customized to include pSite site-specific information). **All consent forms and recruitment materials should be uploaded as Microsoft Word documents.** To facilitate watermarking upon approval, maintain a margin of at least 1 inch in the bottom margin/footer of the document and do not include text in the lower right hand corner of the margin/footer.
- **Ancillary Committee Review:** Answer yes, only if applicable and the pSite submission is for a UR pSite. In the follow-up fields:
 - If yes to Field 6, concerning Surgical Pathology, attach the [Request for Human Tissue Form](#) in Field 14.
 - If yes to Field 7, concerning University Pharmacy and Investigational Drug Service (IDS), indicate whether IDS will be used to manage the drug/biologic/supplement in the corresponding follow-up question.
 - If yes to Field 9, concerning the Human Use of Radiation Committee (HURC), attach the [HURC Research Form](#) in Field 14.
 - Field 13: If the [Data Security Assessment Form](#) was uploaded as part of the STUDY submission, this does not need to be uploaded again.

3. On the final page of the submission form, click **Finish** to exit the form. **This does not submit the pSite.**

Submit Participating Site Materials

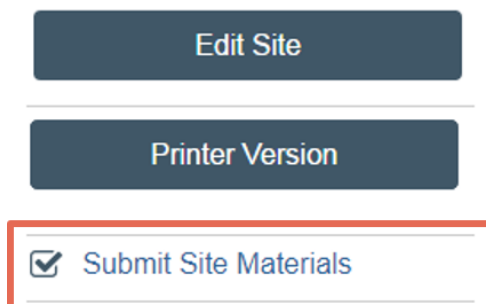
Note:

- pSites should not be submitted until all site-specific materials have been received from the pSite. This includes all site-specific protocol addendums, consent forms, recruitment materials, and any materials that require IRB review.
- pSites cannot be submitted until the IRB Coordinator has confirmed that the pSite meets the criteria to participate in the research.
- **Only the PI and study team members designated the PI Proxy role will have the 'Submit Site Materials' activity.**

To submit site materials:

1. From the site workspace, select **Submit Site Materials**.

Next Steps



2. In the 'Submit Site Materials' activity, select the checkbox to confirm that all site-specific materials have been received and provide additional comments, as necessary.
3. Click **OK**. The pSite has now been submitted.

Next Steps

Once submitted, the pSite will undergo review as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations concerning the research (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Note:

- **Research cannot be initiated at the pSite until the pSite submission is approved (pSite submission ≠ pSite approval).**
- Following pSite approval, it is the responsibility of the study team to ensure all approved documents are forwarded to the pSite.

Update a Multi-Site Study with Single IRB Review

Once a MSS study has been approved, the following types of follow-on submission can be submitted:

- **Study Modification (MOD):** Study modifications provide a mechanism to submit revisions that *apply to the study as a whole, across all pSites* (e.g., protocol revisions that all pSites will implement), for review and approval. To submit a study MOD, see: [Create & Submit a Modification or Continuing Review](#) above.

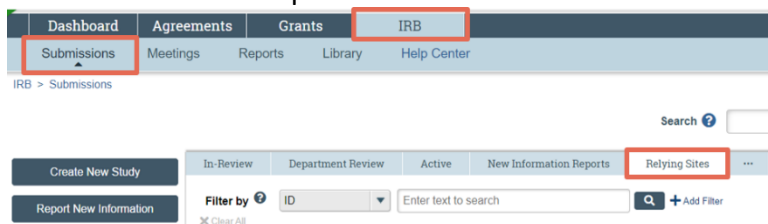
- **pSite Modification:** pSite modifications provide a mechanism for submitting revisions that *apply to the pSite only* (e.g., submission of revised or additional consent documents or recruitment materials for a specific pSite), for review and approval. To submit a pSite modification, see: [Create a Participating Site Modification](#) below.
 - **EXCEPTION:** When the PI is also acting as the local, UR pSite PI, all modifications specific to the UR pSite should be submitted via a study modification (as described above), as opposed to a pSite modification.
- **Study Continuing Review (CR):** Study CRs provide a mechanism to report study enrollment and research events (across all pSites) and are routinely required at least annually. Submitting CR information for MSS undergoing sIRB review is a multi-step process:
 - pSite CR data (i.e., subject enrollment and research events) is reported for each *active* pSite. To submit pSite CR data, see [Record Participating Site CR Data](#) below.
 - A study CR is submitted. Within the study CR, enrollment data is pulled in from all pSites CR reports once the data within the report is confirmed by the IRB. To create a study CR, see: [Create & Submit a Modification or Continuing Review](#) above.

Study closures are also completed via the CR process. To close a pSite, submit a [pSite Modification](#) that includes documentation confirming site closure. To close an entire study, submit a final CR (see [Create & Submit a Modification or Continuing Review](#)). **Note:** In order to close a study, all of the pSites must be closed.
- **Report of New Information (RNI):** Research events can be submitted for a study (events affecting the study as a whole) or a specific pSite per the requirements set forth in [OHSP Policy 801 Reporting Research Events](#) and the associated [Guideline for Reporting Research Events](#). To submit an RNI, see [Create and Submit Reportable New Information](#).

[Create & Submit a Participating Site Modification](#)

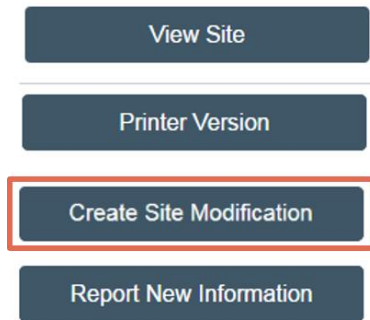
Note: As described [above](#), a pSite modification provides a mechanism to submit revisions that apply to a *specific pSite only*. Modifications that apply to the *whole study (all pSites)* should be submitted via [Study Modification](#).

1. Find and open the applicable pSite by opening the **IRB** module, clicking on the **Relying Site** tab and then the name of the pSite.



2. From the pSite workspace, click the **Create Site Modification** button.

Next Steps



3. **Subject enrollment status:** Indicate the status of subject enrollment *at the pSite*.
 - For additional guidance on who is considered ‘enrolled’, see [OHSP Explains... Defining & Reporting Subject Enrollment](#).
4. **Notification of subject:** Indicate whether current and/or former subjects will be notified of the revisions including in the modification. Generally, notification is required when a modification *may* impact a subject’s willingness to continue participation and/or their health, safety or welfare (e.g., changes in study procedures, payment, risks, etc.). Leave this field blank if notification is not applicable.
5. **Describe the subjects to be notified and how they will be notified:** This field will only appear when the preceding field indicates that either (or both) current or former subjects will be notified. Describe:
 - What specific groups of subjects will be notified (this may be a subset of those indicated the preceding field, e.g., subjects currently undergoing interventional procedures or subjects enrolled into a specific cohort); and
 - How subjects will be notified of the information (e.g., via re-consent with a full consent form, re-consent via consent addendum, information sheet).
6. **Summarize the modification & Attach files:** Insert a summary of the pSite modifications included in the submission, *including the rationale/justification for the revisions*. Alternately, a document/memo summarizing the revisions and rationale may be uploaded via the ‘Attach files’ field.
 - **Note: DO NOT** attach additional or revised study documents in the ‘Attach files’ field; these are added/updated later in the submission form.
7. Click **Continue** to proceed to the next page of the form.
8. The remaining pages of the pSite modification form are comprised of the current pSite submission. Click **Continue** through the pages to edit applicable sections. For additional information on completing/updating these pages, jump to: [Edit a Participating Site](#).
 - Revising study documents, see [Update Study Documents](#). **Note:** Revisions to existing documents should be attached via the **Update** button (adjacent to the current document). Only new documents (that have not yet been reviewed by the IRB) should be attached via the **Add** button.
9. On the final page of the submission form, click **Finish** to exit the form. **This does not submit the form.**
10. Once the form has been completed you may edit it prior to IRB submission by clicking **Edit Modification**.
11. When you’re ready to submit the form, click **Submit** from the submission workspace. **Note:** Only PIs and PI Proxies can submit pSite modifications.
12. READ the terms provided and click **OK** to agree. The modification has now been submitted.

Next Steps

Once submitted, the pSite modification will undergo review as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations concerning the research (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Note:

- **Revisions included in a modification cannot be implemented until the submission is approved (submitted ≠ approved).**
- Following pSite approval, it is the responsibility of the study team to ensure all approved documents are forwarded to the pSite.

Report Participating Site CR Data

Note:

- As described [above](#), a pSite CR Data Report provides a mechanism to submit information regarding enrollment and research events at a specific pSite. Once submitted and confirmed by the IRB, this information is pulled into the study CR.
- It is best practice to wait to initiate the report until all necessary data/information has been collected from the pSite. **Once submitted, the report cannot be modified.**
- **Only PIs and PI Proxies can report pSite CR data.**

To report pSite CR Data:

1. Find and open the applicable pSite by opening the **IRB** module, clicking on the **Relying Site** tab and then the name of the pSite.

The screenshot shows the IRB system interface. The 'IRB' tab is selected in the top navigation bar. Below it, the 'Submissions' menu item is highlighted. The main content area shows a table of 'Relying Sites'. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. One row is highlighted: SITE00000378, Emory University Participating Site for MSS Test Study A, 8/22/2023 3:33 PM, Active.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name
SITE00000378	Emory University Participating Site for MSS Test Study A	8/22/2023 3:33 PM	Active			

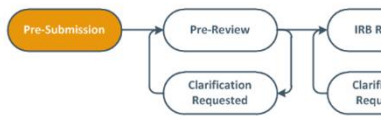
2. From the pSite workspace, click **Report Continuing Review Data**.

The screenshot shows the 'Next Steps' sidebar in the pSite workspace. The options are: View Site, Printer Version, Create Site Modification, Report New Information, Assign Primary Contact, Manage Guest List, and Report Continuing Review Data. The 'Report Continuing Review Data' option is highlighted with a red box.

- **Note:** If the study CR has been created, the Report Continuing Review Data activity can also be accessed via study CR workspace, by clicking the **Execute Activity** option, adjacent to the pSite listing, on the Sites tab.

CR00006414: Continuing

Principal investigator:
Submission type:
Primary contact:



3. Within the Report Continuing Review Data activity:

- **Specify enrollment totals at this investigator's site:** Enter the total number of subjects enrolled at the pSite, including withdrawals, screen failures and subjects lost to follow-up.
 - For additional guidance on who is considered 'enrolled', see [OHSP Explains... Defining & Reporting Subject Enrollment](#).
- **Specify enrollment totals at this investigator's site since last approval:** Enter the number of subjects enrolled *since the last pSite CR report*.
 - If this is the first CR submitted since the pSite's initial approval, enter the same number as the total enrolled in Field 1.
 - If this is not the first pSite CR, enter the number of subjects enrolled since the previous CR report (refer to the previous CR report to verify enrollment numbers, if necessary).
- **Check the items that are true for this site the last IRB approval:** Select **ALL** events that have occurred since the previous CR report (select the checkbox if the corresponding statement is **TRUE**; leave the checkbox unchecked if the statement is **FALSE**). For example, if no subjects have withdrawn from the pSite since the previous CR, select the checkbox 'No subjects withdrew from the study' (because the statement is true). Alternately, if one or more subjects *have* withdrawn since the previous CR report, leave the checkbox for 'No subjects withdrew from the study' *unchecked* (because the statement is false). **For each item left unchecked, provide an explanation of the event in the Comments field and/or attach documentation in the 'Supporting documents' field.**
- Click **OK**. The continuing review data has now been reported, with notification to the study PI/PI Proxy and pSite PI. **Note:**
 - **The report cannot be updated once submitted.**
 - pSite enrollment data will not pull into the study CR until the pSite CR data is *recorded* by the IRBC.

Create & Submit an External IRB Study

The instructions below are for submitting a new study for external IRB review (i.e., an IRB other than the Research Subjects Review Board). A demo video of this information is also available here: [Click IRB Demo Video – Create & Submit a Study for External IRB Review](#).

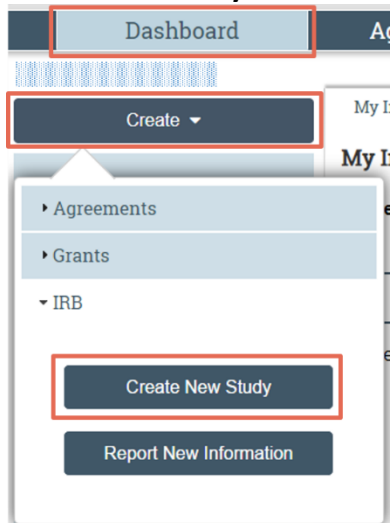
Per [OHSP Policy 504 IRB Reliance and Collaborative Research](#), all studies that utilize an External IRB as the IRB of record require the execution of a reliance agreement (or IRB authorization agreement). Agreements with the following IRBs are already in place: Advarra, National Cancer Institute, and WCG (WIRB). For all submissions wishing to utilize an alternate External IRB, see the [OHSP Guideline for When the University of Rochester Relies on a Non-UR IRB](#).

Note:

- Creating and submitting the study in Click IRB facilitates local administrative review of the study only; it does **not** submit the study for review to the External IRB. The purpose of administrative review process is to ensure compliance with institutional policies.
- Submissions can be submitted to the External IRB, per their policies and procedures, once the administrative review is complete.
- The submission form is a smart form; specific fields will appear/disappear based on preceding responses.

Create an External IRB Study

1. From the Dashboard page, click the **Create** menu, expand the IRB section (if applicable), and select **Create New Study** under the IRB heading.



External IRB: Basic Study Information

1. Complete Fields 1-3, entering the title of the study, short title and a brief description that summarizes the primary objectives and design of the research.
 - **Note:** The short title will be used to identify the study throughout the system, such as in the dashboard, study workspace and search fields.
2. **What kind of study is this?** Select 'Multi-site or Collaborative study'.
3. **Will an external IRB act as the IRB of record for this study?** Answer yes.

4. **Lead principal investigator:** The lead PI is the individual responsible for the conduct of the research across all participating sites. Provided the UR PI is not acting as the Lead PI (overseeing all sites), this field can be skipped.
5. **Local principal investigator:** This field defaults to whomever creates the submission. The Principal Investigator has full and final responsibility for the conduct of the research at the UR site and must meet the [UR PI Eligibility Policy](#). To edit the field, clear the field by clicking the 'X' adjacent to the name and type the PI's name (full name or last name) in the search space provided; select the PI from the list of search results. Alternately, click on the ellipses to search the full database of study staff. Within the search results, note that you may need to page forward to view additional results.
 - If you are unable to locate the PI, see [OHSP FAQ: I need to add a study team member to an application but can't find them in Click IRB. What should I do?](#)
6. **Does the local principal investigator have a financial interest related to this research?** Indicate whether the PI has a financial interest. For additional information, see the [UR Policy on Faculty Conflict of Commitment and Interest](#).
 - If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.
7. **Attach the protocol:** Click **Add** to attach the study protocol. If additional details specifying research conduct at the UR site are detailed in a document separate from the study protocol (e.g., a protocol addendum describing local recruitment methods), add the document here as an additional attachment. In the corresponding 'Add Attachment' window:
 - Click **Choose File** to attach the study protocol and click OK. Alternately, drag and drop the file into this field.
 - **Tip:** It is best practice to manually enter a protocol name in Field 2 and version number in Field 3. The information entered here will appear on the approval letter and should be consistent with the document's contents and the version identified in the document. If these fields are left blank, the protocol name will default to the file name and Click IRB program will assign a version number. For additional information, see [OHSP Explains... Document Management in Click IRB](#).
 - For instructions on uploading *revised* documents, see [Update Study Documents](#).
8. Click **Continue** to proceed to the next page of the application.

External IRB: Basic Site Information

1. **Brief description...:** Summarize the activities that will take place at the UR site (e.g., all research activities as described in the study protocol vs. portions of the research, such as performing only specific activities or enrolling a specific cohort).
2. Click **Continue** to proceed to the next page of the application

External IRB: External IRB

1. **External IRB:** Type the IRB's name (or Institution's name) in the search field and select the IRB/Institution from the list of search results. Alternately, click on the ellipses to search the full database. When searching:
 - a. Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., searching 'Arizona' will identify all sites that *begin* with the word Arizona; searching '%Arizona' will identify all sites that include the word Arizona *within* their name).
 - b. If the IRB/Institutional does not appear in the database, contact the IRB Coordinator.

2. **External study ID:** If known, enter the study ID assigned by the External IRB.
3. Click **Continue** to proceed to the next page of the application

[External IRB: Study Funding Sources](#)

Identify all funding sources that will support the conduct of the study, across all participating sites. To add a funding source:

1. **Identify each organization...:** Identify each funding sources by clicking **Add** (multiple funding sources may be identified). In the corresponding 'Add Funding Source' window:
 - **Funding organization:** Type the organization's name in the search space provided and select the funding source from the list of search results. Alternately, click on the ellipses to search the full database of organizations. When searching:
 - Use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., searching 'pediatric' will identify all organizations that *begin* with the word pediatric; searching '%pediatric' will identify all organizations that include the word pediatric *within* their name).
 - Use the full name of the organization; acronyms will not produce a complete list of results.
 - If the funding source does not appear in the database contact your [IRB Coordinator](#), providing the organization's name, address and type (e.g., foundation, government agency, industry).
 - **Sponsor funding ID:** If available/applicable, enter the Award ID/Sponsor Award ID.
 - **Grants office ID:** If available/applicable, enter the IORA Awards Number (e.g., AWD00000XXXX). If the proposal has not yet been funded, add the IORA Funding Proposal Number.
 - Click **OK**.
2. Click **Continue** to proceed to the next page of the application.

[External IRB: Additional Local Funding Sources](#)

Follow the instructions above to add additional funding that is specific to the UR site (e.g., department funding), **not** funding that applies to the research as a whole that is already identified on the previous page. **If there is no additional local funding, click 'Continue' to skip this section.**

[External IRB: Local Study Team Members](#)

Complete the Local Study Team Members section as described above for single-site studies. See: [Local Study Team Members](#).

[External IRB: Study Scope](#)

Complete the Study Scope section as described above for single-site studies. See: [Study Scope](#).

[External IRB: Local Research Locations](#)

Complete the Local Research Locations section as described above for single-site studies. See: [Local Research Locations](#).

DO NOT add other lead or participating sites that the UR PI is not responsible for.

External IRB: Drugs & Devices

You will only be directed to complete the Drugs and Devices pages if you answered yes to Fields 1 and 2, respectively on the [External IRB: Study Scope](#) page. To complete these pages, see the instructions provided above for single-site studies. See: [Drugs](#) &/or [Devices](#).

External IRB: Study-Related Documents

Attach all model consent template documents provided by the sponsor/lead site. To add documents:

- Click **Add** in the section that corresponds to the type of document being attached.
- Click **Choose File** to attach the document the document and click OK. Alternately, drag and drop the file into this field.
 - **Tip:** It is best practice to manually enter the document name in Field 2 and version number in Field 4. The information entered here will appear on the approval letter and should be consistent with the document's contents and the version identified in the document. If these fields are left blank, the protocol name will default to the file name and Click IRB program will assign a version number. For additional information, see [OHSP Explains... Document Management in Click IRB](#).
 - For instructions on uploading *revised* documents, see [Update Study Documents](#).
- **Category:** Select the category (type) of document uploaded.

External IRB: Local Site Documents

Add all UR-specific consent forms, recruitment materials and other UR-specific documents to their respective sections (e.g., template consent/recruitment forms that have been customized to include UR site-specific information). **All consent forms and recruitment materials should be uploaded as Microsoft Word documents.** To add documents, follow the instructions provided in the section above.

DO NOT submit UR-specific consent forms that have not yet been updated to include [UR template language](#). For additional information on how to update UR consent forms, see: [OHSP Preparing Local Site Consent Documents for External IRB Submission](#).

External IRB: Ancillary Committee Review

1. **Does this research involve any of the following...** Answer yes. Given the nature of MSS research, all research will *minimally* involve the collection, transmission or storage of electronic data.
 - **Note:** For additional information on Ancillary Committee Review, see [OHSP policy 503 Ancillary Review](#) and [OHSP Explains... Ancillary Committee Review](#).
2. **Fields 2-13:** These fields will after the preceding question is answered yes.
 - Fields 2-12: Answer yes, if applicable and the PI is also acting as the PI for the local UR pSite.

Note:

 - If yes to Field 6, concerning Surgical Pathology, attach the [Request for Human Tissue Form](#) in Field 14.
 - If yes to Field 7, concerning University Pharmacy and Investigational Drug Service (IDS), indicate whether IDS will be used to manage the drug/biologic/supplement in the corresponding follow-up question.
 - If yes to Field 9, concerning the Human Use of Radiation Committee (HURC), attach the [HURC Research Form](#) in Field 14.

- Field 13: Answer yes to Field 13, concerning the collecting, transmission or storage of electronic data, attach the [Data Security Assessment Form](#) in Field 14.
3. Click **Continue** to proceed to the next page of the form.

Finish & Submit the External IRB Study

Complete the final page of the submission and submit the study as described above for single-site studies. See: [Finish & Submit the Study](#).

Next Steps

Once submitted, the study will undergo administrative review by an IRB Coordinator, as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations concerning the research (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Once administrative review is complete, the IRB Coordinator will confirm reliance on the External IRB; an email notification will be provided to the PI, PI Proxy and Primary Contact. The study can then be submitted to the External IRB for review.

Note:

- **Research cannot be initiated until the study (and UR site) has been approved by the External IRB (administrative approval ≠ IRB approval, nor does IRB submission ≠ IRB approval).**
- **Following approval by the External IRB, the study team is responsible for notifying the IRB Coordinator of approval.** To do so, upload a copy of the IRB approval letter and all watermarked documents via the [Add Comment](#) activity (with notification to the IRB Coordinator selected within the Add Comment activity).

Update an External IRB Study

Following approval by the External IRB, the External IRB is responsible for reviewing and approving all follow-on submissions. In accordance with [OHSP Policy 504 IRB Reliance and Collaborative Research](#), RSRB review and/or reporting is generally only required when:

- Modifications that impact the original institutional administrative review are required. E.g., changes to the study team, financial interests, compensation for injury, and/or the addition of study procedures that require [Ancillary Committee Review](#). To submit a modification, see additional information [below](#).
- The External IRB has re-approved the research (via continuing review). Re-approvals should be reported to the RSRB via [External IRB Site Modification](#).
- The External IRB determines that a research event is serious non-compliance, continuing non-compliance or is a UPIRTSO (an unanticipated problem involving risks to subjects or others), or when the External IRB suspends or terminates the research. To report one of these research events, see [Create and Submit Reportable New Information](#).
- The External IRB closes the research because the research is complete. To report closure, use the [Add Comment](#) activity to notify the IRB Coordinator of the closure and attach documentation of IRB closure.

If you are unsure whether an event requires reporting to the RSRB, contact your IRB Coordinator.

Type of External IRB Modifications

If the modification involves any of the following, [Create & Submit a Participating Site Modification](#), for institutional administrative review ***prior to submission to the External IRB*** (if applicable).

- Local PI (and/or PI financial interests);
- Additional local funding sources (i.e., ***additional*** funding that is specific to the UR site only);
- Local research locations (i.e., non-UR locations where research activities will be conducted ***by UR faculty/staff*** in collaboration with non-UR staff and/or UR-affiliated sites where research activities will be conducted);
- Local study team members (and/or local study team member financial interests);
- Local site documents (i.e., all UR-specific consent forms, recruitment materials and other ***UR***-specific documents); and/or
- Ancillary Committee review.

If the modification involves any of the following, use the [Update Study Details](#) activity to submit the revisions ***after External IRB approval***. As a reminder, only the modifications described in [OHSP Policy 504 IRB Reliance and Collaborative Research](#) are required to be submitted to the RSRB (see additional information above).

- Basic study information, including the title and study protocol;
- Study funding sources; and
- Study scope, including institutional financial interests, ClinicalTrials.gov registration, and updates to any investigational products under study (drugs, biologics, supplements and/or devices); and
- Study-related documents.

Create & Submit an External IRB Site Modification

1. Find and open the applicable pSite by opening the **IRB** module, clicking on the **External IRB** tab and then the name of the study.

The screenshot shows the IRB system interface. At the top, there are tabs for Dashboard, Agreements, Grants, and IRB. The IRB tab is selected. Below the IRB tab, there are sub-tabs for Submissions, Meetings, Reports, Library, and Help Center. The Submissions tab is selected. Below the Submissions tab, there are buttons for Create New Study and Report New Information. The main content area shows a table of study submissions. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, and Coordinator Last Name. The first row in the table is for a study with ID STUDY0000857, Name External IRB Study Test, Date Modified 8/24/2023 4:55 PM, and State Active. The External IRB Study Test name is highlighted with a red box.

2. From the study workspace, click the **Create Site Modification** button.

Next Steps

The screenshot shows the Next Steps section with four buttons: View Site, Printer Version, Create Site Modification, and Report New Information. The Create Site Modification button is highlighted with a red box.

4. **What is the purpose of this submission?** Select 'Modification/Update'.

5. **Modification scope:** Select the checkboxes that apply as follows:
 - **Study team member and research location information:** Select if the modification involves adding/removing study team members (other than the Principal Investigator), local research locations and/or Ancillary Committee Review.
 - **Other parts of the study:** Select for all other types of modifications, including revisions to: local funding sources and/or local site documents.
6. Click **Continue** to proceed to the next page of the form.
7. **Subject enrollment status:** Indicate the status of subject enrollment *at the UR Site*.
 - For additional guidance on who is considered ‘enrolled’, see [OHSP Explains... Defining & Reporting Subject Enrollment](#).
3. **Notification of subject:** Indicate whether current and/or former subjects will be notified of the revisions including in the modification. Generally, notification is required when a modification *may* impact a subject’s willingness to continue participation and/or their health, safety or welfare (e.g., changes in study procedures, payment, risks, etc.). Leave this field blank if notification is not applicable.
4. **Describe the subjects to be notified and how they will be notified:** This field will only appear when the preceding field indicates that either (or both) current or former subjects will be notified. State: Re-consent will be obtained in accordance with the Reviewing IRB’s determination.
5. **Summarize the modification & Attach files:** Insert a summary of the pSite modifications included in the submission, including the rationale/justification for the revisions. Alternately, a document/memo summarizing the revisions and rationale may be uploaded via the ‘Attach files’ field.
 - **Note: DO NOT** attach additional or revised study documents in the ‘Attach files’ field; these are added/updated later in the submission form.
6. Click **Continue** to proceed to the next page of the form.
7. The remaining pages of the site modification form are comprised of components of the current submission. Click **Continue** through the pages to edit applicable sections. For additional information on completing/updating these pages, jump to: [Additional Local Funding Sources](#); [Local Study Team Members](#); [Local Research Locations](#); [Local Site Documents](#); and [Ancillary Committee Review](#).
 - Revising study documents, see [Update Study Documents](#). **Note:** Revisions to existing documents should be attached via the **Update** button (adjacent to the current document). Only new documents (that have not yet been reviewed by the IRB) should be attached via the **Add** button.
8. On the final page of the submission form, click **Finish** to exit the form. **This does not submit the form.**
9. Once the form has been completed you may edit it prior to IRB submission by clicking **Edit Modification**.
10. When you’re ready to submit the form, click **Submit** from the submission workspace. **Note:** Only PIs and PI Proxies can submit pSite modifications.
11. READ the terms provided and click **OK** to agree. The modification has now been submitted.

Next Steps

Once submitted, the modification will undergo administrative review by an IRB Coordinator, as described in the [Click IRB Overview & Navigation Basics Guide](#). When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations concerning the research (e.g., approval), an email notification will be provided to the PI, PI Proxy and Primary Contact.

Once administrative review is complete, the IRB Coordinator will confirm reliance on the External IRB; an email notification will be provided to the PI, PI Proxy and Primary Contact. The study can then be submitted to the External IRB for review. **Following approval by the External IRB, the study team is responsible for notifying the IRB Coordinator of approval.**

Update Study Details

1. Find and open the applicable pSite by opening the **IRB** module, clicking on the **External IRB** tab and then the name of the study.

IRB > Submissions

Create New Study
Report New Information

In-Review Department Review Active New Information Reports **External IRB**

Filter by ID Enter text to search + Add Filter

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name
STUDY0000857	External IRB Study Test	8/24/2023 4:55 PM	Active				

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

Next Steps

View Site

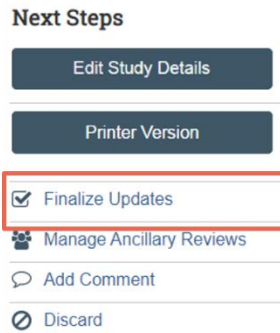
Printer Version

Create Site Modification

Update Study Details

Report New Information

3. **Summarize the updates:** Insert a summary of the modifications included in the submission, including the rationale/justification for the revisions.
4. Click **Continue** to proceed to the next page of the form.
5. The remaining pages of the site modification form are comprised of components of the current submission. Click **Continue** through the pages to edit applicable sections. For additional information on completing/updating these pages, jump to: [Basic Study Information](#); [External IRB](#); [Study Funding Sources](#); [Study Scope](#); and [Study-Related Documents](#).
 - Revising study documents, see [Update Study Documents](#). **Note:** Revisions to existing documents should be attached via the **Update** button (adjacent to the current document). Only new documents (that have not yet been reviewed by the IRB) should be attached via the **Add** button.
6. On the final page of the submission form, click **Finish** to exit the form. **This does not submit the form.**
7. Once the form has been completed you may edit it by clicking **Edit Modification**.
8. To finalize study updates, select **Finalize Updates** from the update workspace. **Note: Only the PI and study team members designated the PI Proxy role will have the 'Finalize Updates' activity.**



9. Read the acknowledgement and click **OK** to agree.
 - The IRB Coordinator is notified of the update and the update moves to complete.

Respond to Clarification Requests

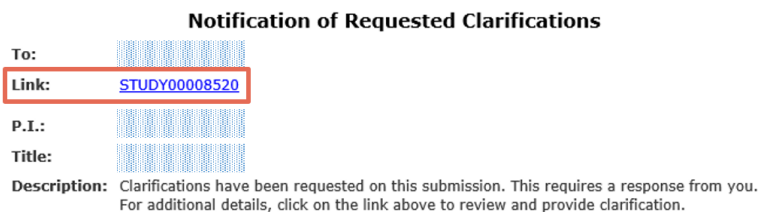
If an IRB Coordinator or IRB Reviewer has questions or requires changes to a submission, email notifications will be sent to the following:

- For new studies and follow-on submissions (MODs, CRs, MODCRs), the PI, PI Proxy and Primary Contact.
- For RNIs, the individual who submitted the RNI and PI/PI Proxies on submissions related to the RNI.

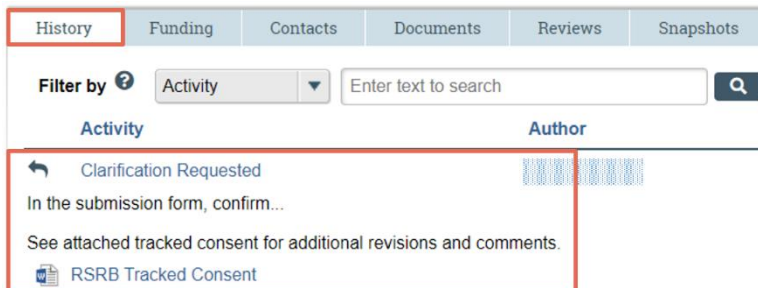
Once a notification is received, review the request and respond accordingly, as described below. A demo video of this information is also available here: [Click IRB Demo Video – Respond to Clarification Requests](#).

Review the Requested Details

1. Click the submission ID link provided in the email to open the submission. Alternately, you may open the submission from your Inbox on the Dashboard.



2. From the submission workspace, review the 'Clarification Requested' activity in the History tab. If the reviewer attached a document, a link to open it will also appear on the History tab.



Edit the Submission

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

Next Steps

[Edit Study](#)

[Printer Version](#)

[→ Submit Response](#)

- Make the changes *in the submission* form as requested.
- **DO NOT** upload revised/additional study documents (e.g., protocol or consent form) via the Add Comment activity.
- When uploading revised documents, **click Update adjacent to the existing document. DO NOT add the updated file as an additional document and delete the outdated document as this eliminates the document's history.** For additional instructions on adding/editing documents, see [Update Study Documents](#) and/or [OHSP Explains... Document Management in Click IRB](#).

Submit Response

Once all requested clarifications have been made:

1. From the submission workspace, click **Submit Response** (or Submit Action Response for RNIs in an 'Action Required' state).

Next Steps

[Edit Study](#)

[Printer Version](#)

[→ Submit Response](#)

- Only PIs and PI Proxies can submit clarification requests.
2. In the corresponding 'Submit Response's window, provide your response to the IRB in the '**Notes**' field. Indicate what changes have been made and provide additional clarifications as necessary.
 - If you wish to provide a response via memo, it can be uploaded in the 'Supporting Documents' field.
 - **DO NOT** upload revised/additional study documents (e.g., protocol or consent form) as 'Supporting Documents'. All study documents that require IRB approval must be uploaded within the submission form.
 - If you have not addressed any clarifications or do not agree with the IRB's requests, provide your rationale in the 'Notes' field and upload supporting documentation, if applicable.
3. Click **OK**. The submission has now been re-submitted to the IRB for continued review.

Update Study Documents

Once a study has been created, you can update the study documents included in a submission any time prior to submitting for IRB review. Once the study has been submitted for review, you will only be able to update

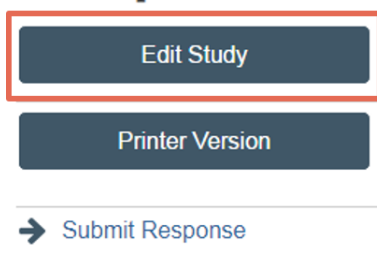
documents if changes or clarifications have been requested by IRB Reviewers (i.e., the submission is in your inbox).

Once a study has been approved, study documents can only be updated via the [modification](#) process. As above, once a modification has been created, you can update the study documents included in the modification any time prior to submission.

Note: Limit document uploads to Microsoft Word and PDF files, when feasible. **DO NOT upload Rich Text Files.** If you have questions about how to upload documents or what types of files can be uploaded, contact your [IRB Coordinator](#).

- From your inbox, open the submission you wish to edit.
 - If the submission is not in your inbox (i.e., the submission is in Pre-Review, IRB-Review, or Post-Review), use the [Add Comment](#) activity to request that the IRB Coordinator return the submission to the study team for revision (ensure the IRB Coordinator is selected for notification within the Add Comment activity). **Note:** Depending on the submission's state, it may not be feasible to return the submission straightaway (e.g., if the submission has been assigned for convened board review).
- From the submission workspace, click **Edit** (Edit Study, Edit Modification/CR, or Edit RNI).

Next Steps



- To add an additional document (i.e., a new document that has not yet been reviewed by the IRB), find the appropriate location within the submission form and click **Add**.
- To update an existing document (i.e., upload a revised version of a document), find the appropriate location within the submission and click **Update** adjacent to the current version of the form. **DO NOT add the updated file as an additional document and delete the outdated document as this eliminates the document's history.**

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable) [?](#)

Document	Category	Date Modified	Document History
 Update	 Consent form.docx(0.01)	Consent Form	8/15/2023 History 

- Save** your changes and **Exit** the submission form.
 - If responding to a clarification request, see [Respond to Clarification Requests](#) for additional instructions.

Find Approved Study Documents

From the study workspace, select the **Documents** tab. Final, approved and watermarked (as applicable) versions of study documents are listed under the 'Final' heading.

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			

Additional Activities

The additional activities described below appear on the left-side of a submission workspace. As noted below, access to some types of activities are dependent on role assignment and submission type.

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

Assign Primary Contact

Assign PI Proxy

Manage Guest List

Add Related Grant

Add Comment

Copy Submission

Assign Primary Contact

A Primary Contact can be assigned to a study, as well as a pSite, and acts as the study's main point of contact for communications. The Primary Contact will receive notification when the IRB communicates a determination or requires the study staff to take action (in addition to the PI/PI Proxy). Only one Primary Contact can be selected for each study/pSite.

1. From the study (or pSite) workspace, click **Assign Primary Contact**.
2. Type the individual's name (full name or last name) in the search space provided and select the individual from the list of search results. Alternately, click on the ellipses to search the full database of study staff.
3. Click **OK**.

Note: The individual identified as Primary Contact is not automatically identified as engaged in the research (i.e., a study team member). All individuals engaged in the research must be identified as such in the study submission.

Assign PI Proxy

A PI Proxy can perform PI responsibilities on their behalf. Multiple PI proxies may be assigned to each study.

Only the PI can assign PI proxies. For additional information on the PI Proxy designation, see [OHSP Explains... PI Proxy Designation in Click IRB](#).

1. From the study workspace, click **Assign PI Proxy**.
2. Type the individual's name (full name or last name) in the search space provided and select the individual from the list of search results. Alternately, click on the ellipses to search the full database of study staff.
 - **Only individuals identified in the submission as study team members can be assigned the PI Proxy role.**
3. Click **OK**.

Manage Guest List

The guest list, available in study and pSite workspaces, allows you to provide read-only access to additional individuals (in addition to study team members).

1. From the study (or pSite) workspace, click **Manage Guest List**.
2. Type the individual's name (full name or last name) in the search space provided and select the individual from the list of search results. Alternately, click on the ellipses to search the full database of study staff.
3. Click **OK**.

Add Related Grant

Grants may be added or removed from study submissions.

1. From the submission workspace, click **Add Related Grant**.
2. Click the ellipses [...] to view a listing of awards.
3. Select the checkbox for applicable awards.
4. Click **OK**.
5. To remove associated grants, click the **X** to the right of the grant.

Add Comment

Comments may be added at any time, to any type of submission. **Comments are visible to ALL individuals with read access to the submission.**

1. From the submission workspace, click **Add Comment**.
2. Insert your comment.
3. If applicable, add supporting documentation.
4. Select the roles related to the submission that you want notified of the comment.
5. Click **OK**. The comment will appear on the History tab and the individuals selected in the 'Who should receive an e-mail notification' field will be sent an email notification alerting them to the comment.

Note:

- **Adding a comment does not move a submission into a specific individual's inbox.**
- **Uploading documents via Add Comment does not replace prior versions of the document that are included within a submission form.**

Manage Editors

RNI programming provides the following users access to edit an RNI and/or respond to IRB requests: 1) the individual who creates the RNI; and 2) PIs and PI Proxies submissions created to the RNI. The Managed Editors activity, available in RNI workspaces, allows IRB Staff and the creators of an RNI to provide additional individuals access to edit and/or respond to IRB requests/clarifications related to the RNI.

1. From the RNI workspace, click **Manage Editors**.
2. In the Manage Editors activity, the heading identifies individuals who already have permission to edit/take action on the RNI. If additional individuals need access to edit/submit the RNI, type the individual's name (full name or last name) in the search space provided and select the individual from the list of search results. Alternately, click on the ellipses to search the full database of study staff.
3. Click **OK**.

Add Related Submission

Based on the nature of an RNI, more than one type of submission may be related to the event being reported via the RNI. The Add Related Submissions activity links a RNI to a submission (including a study, pSite, and/or follow-on submission). Submissions can be related to an RNI by IRB staff, the creators of an RNI submission, and the PI/PI Proxy on submissions already related to the RNI.

1. From the RNI workspace, click **Add Related Submission**.
2. In the Add Related Submission activity, the heading identifies submissions that have already been related to the RNI. If additional submissions need to be added, click on the ellipses to select the submission.
 - a. Note: Only submissions that you have access to will appear in the search box. If additional submissions should be identified, use the [Add Comments](#) activity in the RNI workspace to notify the IRB Coordinator.
3. Click **OK**.

Copy a Submission

The PI and PI Proxy can copy a current study into a new study submission for IRB submission.

1. From the study submission workspace, click **Copy Submission**.
2. Enter the name of the new submission.
3. Click **OK**.
4. Once the copying process is complete, you can open the submission from history log of the original submission or from your inbox (on the Dashboard). **The copied submission must then be edited accordingly (i.e., with updated study-specific documents) and submitted for IRB review and approval.**

Withdraw

Submissions that have not yet reached Post-Review may be withdrawn from the IRB review process any time the submission resides with the study team (i.e., the submission has not yet been submitted by the study team for review or revisions/clarifications have been requested by the study team).

1. From the submission workspace, click **Withdraw**.
2. Enter a comment, providing the reason for withdrawal and attach any applicable supporting documents.
3. Click **OK**. The submission will move to a Pre-Submission state where it can be revised and re-submitted or discarded.

Discard

Discarding a submission permanently removes the submission from the review process.

1. From the submission workspace, click **Discard**.
2. Click **OK**.
3. Once discarded, the submission will appear under the Archived tab.