

Click® IRB: Study Staff Manual

Introduction.....	2
Overview of the Click® IRB System.....	2
Overview of the Submission Review Process.....	4
Overview of Multi-Site Study Review.....	6
Overview of the Multi-Site sIRB Submission Process.....	7
Overview of the External IRB Submission Process.....	8
Navigation and Basic Tasks.....	10
Create and Submit a Study.....	13
Create and Submit a Modification or Continuing Review.....	21
Create and Submit Reportable New Information.....	25
Create and Submit a Multi-Site Study for Single IRB Review.....	26
Update a Multi-Site Study with Single IRB Review.....	30
Create and Submit an External IRB Study.....	33
Update an External IRB Study.....	35
Respond to Clarification Requests.....	37
Update Study Documents.....	38
Find Approved Study Documents.....	38
Additional Activities.....	39
Quick Reference Guide: Study Submission Checklist.....	42
Quick Reference Guide: Ancillary Committee Review.....	43
Quick Reference Guide: Watermarked Documents.....	44
Quick Reference Guide: Submitting to the RSRB.....	45

Introduction

This guide covers information and tasks relevant to:

- Single-site studies, including initial single-site study submissions and follow-on submissions (modifications, continuing reviews, and reportable new information);
- Multi-site studies undergoing local single Institutional Review Board (sIRB) review, including initial sIRB study and site submissions and follow-on submissions; and
- External IRB study submissions, including local administrative review of initial External IRB submissions and updates to External IRB submissions.

Note: A 1-page [Quick Reference Guide](#) summarizing the review activities described in this manual, as they relate to the Study Staff role, is available in the appendix.

Overview of the Click® IRB System

The Click® IRB system provides a mechanism for creating and tracking studies that require Institutional Review Board (IRB) overview. Click® IRB supports the following submission types:

IRB Submission Types	
Type	Description
Initial Submissions	
Study	Documents the details of a study that require oversight by an Institutional Review Board. Studies include single-site studies, multi-site or collaborative studies, and studies reviewed by an External IRB.
Site	Documents the details specific to a participating site (pSite) engaged in multi-site or collaborative studies, such as local study team members and institution-specific consent forms.
Follow-on Submissions	
Modification (Mod)	Changes or updates to approved studies. The modification submission consists of a form that lists modification details along with the updated study submission pages and/or study documents.
Continuing Review (CR)	A review of an approved study. The continuing review submission consists of a form on which the researcher records any changes, incidents, reports, findings or other problems that have occurred since the study was approved, or since the previous continuing review.
Modification and Continuing Review (Mod/CR)	A combined modification and continuing review submission. This type of submission allows simultaneous review of changes or updates to an approved study with continuing review information.
Reportable New Information (RNI)	A report of new information about an approved study or active research (e.g., new risk information, breaches in confidentiality, subject complaints or reports of non-compliance).

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

Roles	
Position	Typical Activities
Ancillary Reviewer	An individual responsible for evaluating study submissions against the requirements set forth for their specific Ancillary Committee (in accordance with Office for Human Subject Protection [OHSP] Policy 503 Ancillary Committee Reviews).
Committee Administrator	An individual responsible for managing committee meetings.
Committee Chair (CC)	An IRB committee member assigned to chair the committee.
Committee Member (CM)	Individuals on an IRB committee that are responsible for reviewing submissions.
Committee Reviewer (CR)	The individuals assigned to review and present a submission at a committee meeting (i.e., primary reviewer).
Department Reviewer	A type of Ancillary Reviewer responsible for evaluating study submissions against their department-specific scientific review policy (in accordance with OHSP Policy 505 Departmental Scientific and Resource Review).
Designated Reviewer (DR)	An IRB chair or experienced IRB committee member, designated by the chair, to conduct reviews of newly submitted studies and follow-on submissions.
IRB Coordinator (IRBC)	Individuals who guide submissions through the review process. The coordinator reviews newly submitted studies and follow-on submissions for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner.
IRB Director (IRBD)	An individual with IRB oversight responsibilities. The director can perform the same actions as coordinators, but is typically less involved with the day-to-day processing of submissions.
Guest	Study staff may add guests to a study to permit read-only access.
Primary Contact	A primary contact acts as the study team's main point of contact for communications with the IRB. The primary contact receives notifications, in addition to the PI (and any designated PI Proxies), when the IRB communicates a decision or requires the study team to take action. Unless modified, the primary contact is defaulted to whomever creates the initial study submission.
Principal Investigator (PI)	The Principal Investigator has full and final responsibility for the conduct of the research (see OHSP Policy 901 Investigator Responsibilities). Each study and pSite requires a single PI to be identified on the submission. All PIs must meet the University of Rochester [UR] PI Eligibility Policy . While others may assist the PI in developing and editing the initial and follow-on submissions, only the PI (or designated PI proxies) can submit items for IRB review.
PI Proxy	A PI proxy can perform PI activities in Click® IRB on the PI's behalf, such as submitting the study to the IRB, modifying the study and submitting continuing review. PI proxies must be listed on the study submission as study team members. Only PIs can assign PI proxies. The PI Proxy designation only applies to activities in Click® IRB.
Registered User	Users authorized to create submissions.
Study Staff (SS) / Study Team (ST)	Individuals involved in developing the study and listed on the submission as study team members. The study team always includes a PI but can also include co-investigators, sub-investigators, statisticians, study coordinators, and other study personnel (see OHSP Guideline for Listing Research Personnel for additional information).

Overview of the Submission Review Process

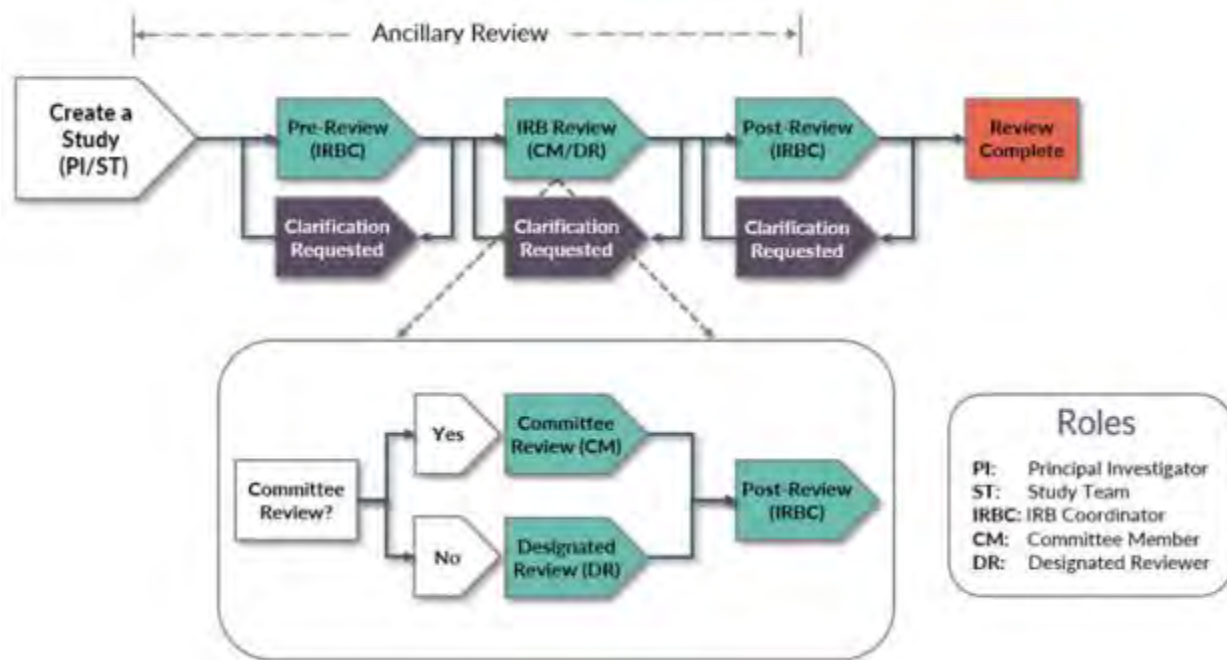
New Studies: The basic review process for a new study submitted to the Research Subjects Review Board (RSRB), the University of Rochester's local IRB, is as follows:

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

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

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

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



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

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

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

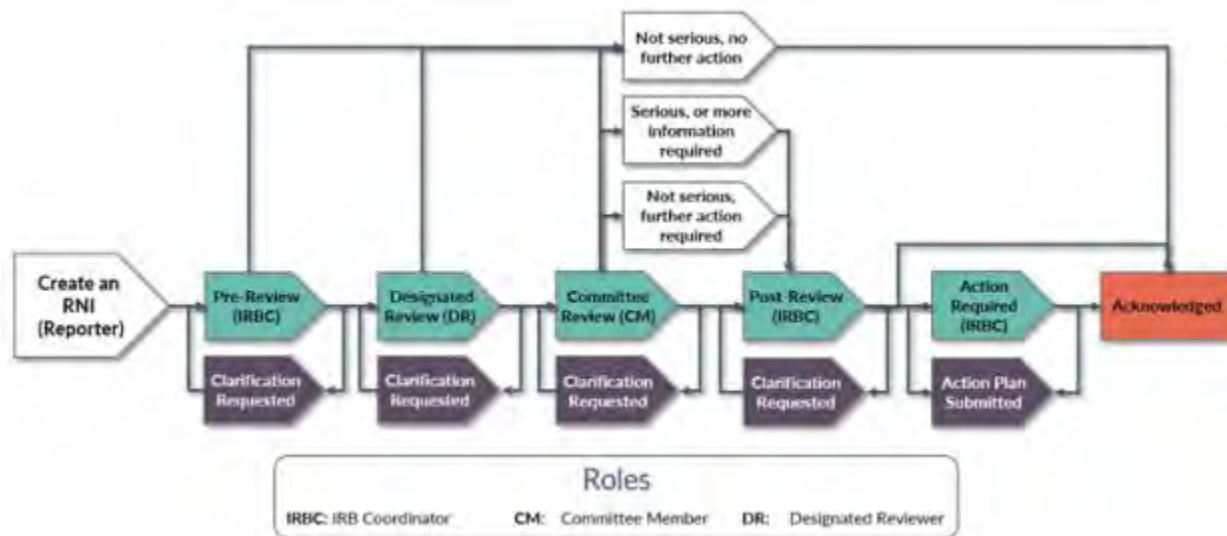
Reviews of modifications, continuing reviews and mod/CRs follow a process similar to new studies. The only exceptions to the process relate to Department and Ancillary Committee Reviews; these reviews are not required unless warranted by the information set forth in the modification and/or continuing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

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

1. The PI, study staff or IRB staff create and submit the RNI.
2. Upon submission to the RSRB, the IRBD assigns the RNI to an IRBC and the submission enters the **Pre-Review** state. The IRBC then reviews the report and determines whether further review by a designated reviewer or the full committee is required. The IRBC may also request clarification or changes from the PI resulting in a back-and-forth exchange at this time.
 - Submissions that do not require further review move to an **Acknowledged** state (no further action is required).
 - Submissions that require further review can be assigned to a designated reviewer or to committee review and the submission will move to the **IRB Review** state. All submissions that potentially require suspension or termination of IRB approval or potentially meet the definition of an unanticipated problem involving risks to subjects or others (UPIRTSO), serious non-compliance or continuing non-compliance require review by the full committee.
3. During **IRB Review**, the designated reviewer or full committee reviews the report and makes determinations as follows:
 - If the submission is not considered serious (meaning, it does not require suspension or termination of IRB approval, nor does it meet the definition of a UPIRTSO or serious or continuing non-compliance) and requires no further action on the part of the PI, the submission will move to an **Acknowledged** state and review of the event is complete.

- If the submission is not considered serious (as described above) but action is required by the PI, the PI will be notified. Once the requested actions have been completed, the submission moves to an **Acknowledged** state and review of the event is complete.
 - If a designated reviewer is reviewing a submission and they determine the event to be potentially serious (as described above), the submission must be assigned for committee review.
 - If the submission is reviewed by the full committee and the committee determines that the event is serious (as described above) or that additional information/actions are required, the submission will move to the **Post-Review** state. Alternately, if the full committee determines that the event is not serious and no further action is required, the submission will move to an **Acknowledged** state and review of the event is complete.
4. During **Post-Review**, the IRBC will communicate the committee's determination concerning the report to the PI.
- If no further action is required, once the letter concerning this determination is sent to the PI, the submission moves to **Review Complete (Complete state)**.
 - If further action or additional information is required by the committee, the committee will assign a responsible party (e.g., PI) for carrying out that plan (or providing additional information). Once the letter concerning this determination is sent, the submission moves to an **Action Required** state. In this, state the responsible party can submit their response for continued IRB review. Once all required actions have been completed and a letter is sent to the PI confirming this, the submission moves to **Review Complete (Complete state)**.

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



Overview of Multi-Site Study Review

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

When MSS research is conducted locally, the RSRB may:

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

Note: Per [OHSP Policy 504 IRB Reliance and Collaborative Research](#), all studies that will utilize the RSRB as the sIRB or an External IRB require the execution of a reliance agreement (also referred to as an IRB authorization agreement). **Submissions**

should not be initiated until a reliance agreement has been executed to accommodate review of the research by the sIRB or External IRB, as appropriate.

Overview of the Multi-Site sIRB Submission Process

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

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

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

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

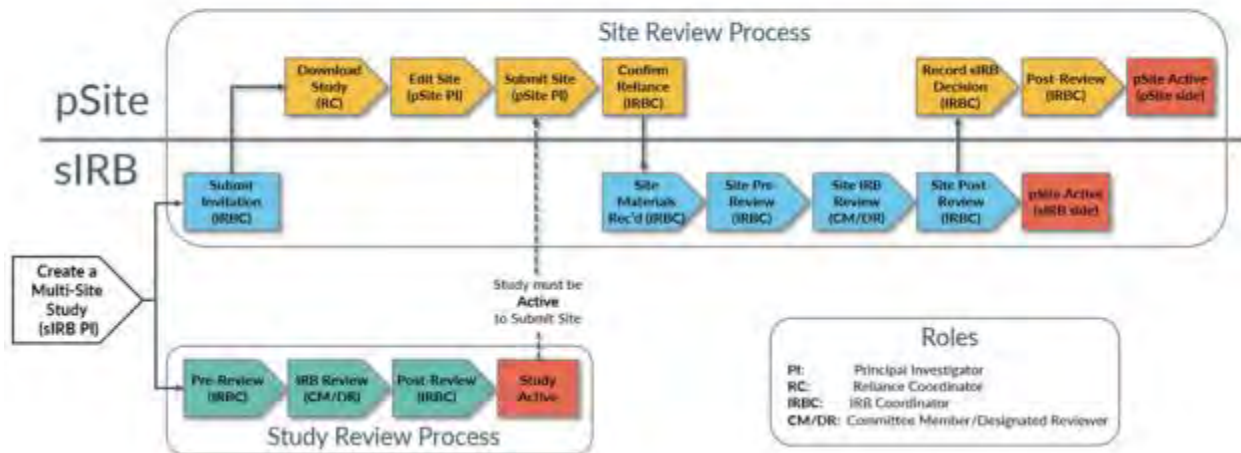
1. The Lead PI (and study staff) creates a study, indicating that the study is multi-site and that the RSRB will serve as the sIRB of record for participating sites (pSites). The Lead PI is the individual with primary responsibility for oversight and management of the conduct of the study at all pSites.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

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

1. The Lead PI (and study staff) or IRBC adds the pSite from the *study* workspace, resulting in the creation of a pSite workspace and corresponding submission. Upon creation, the pSite is in the **Invitation Pending** state. Once the IRBC validates the pSite's eligibility to participate in the research, the pSite moves to an **Awaiting Site Materials** site.
2. Following receipt of the pSite's study-specific documentation, the Lead PI, study staff or IRBC enter the pSite's site-specific information and documents on their behalf and submit to the RSRB for individual review. **Note:** pSites cannot be submitted for review until the *study* submission has minimally reached the **Pre-Review Complete**.
3. Upon submission of the pSite to the RSRB, the pSite will move through a simplified version of the **Pre-Review, IRB Review** and **Post-Review** processes, as described [above](#) for routine submissions. **Note:** pSites cannot progress beyond the IRB Review point until the *study* submission has been approved.
4. As above, during **Post-Review**, the IRBC prepares and sends the determination letter to the Lead PI. If the study is approved, the IRBC creates a final version of the site documents and the pSite submission moves to **Review Complete (Active state)**. If the committee/designated reviewer determines modifications are needed for the pSite to be approved, the Lead PI, study staff or IRBC can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

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

Multi-Site Study Workflow



Modifications, Continuing Reviews & Reportable New Information: Follow-on submissions undergo review as described [above](#) for routine submissions. **Note:**

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

Overview of the External IRB Submission Process

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

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

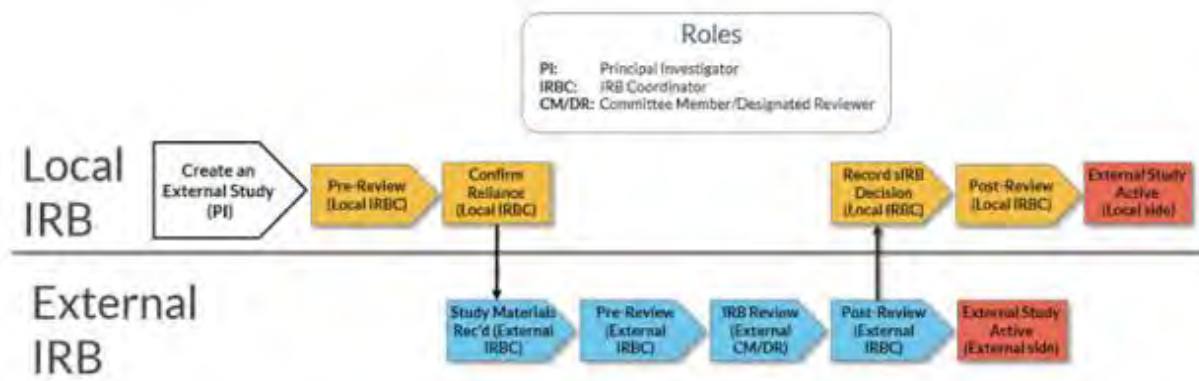
Note: It is best practice to wait to initiate an application until you: a) determine what IRB will review and approve the research; and b) ensure a reliance agreement exists to accommodate review of the research by the external IRB.

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

1. The PI (and study staff) creates a study, indicating that the study will be reviewed by an External IRB. Study and local site-specific information are entered on a series of user-friendly pages. While the study team is working on the study application, it is in the **Pre-Submission** state. Once the submission form is complete, the PI submits the study to the RSRB for institutional review.
2. Upon submission of the study to the RSRB, similar to the process described [above](#) for routine submissions, the IRBD (or designee) will assign the study to **Department Review**. Once Department Review approval has been provided, the IRBD will assign the submission to required Ancillary Committees, as required per [OHSP Policy 503 Ancillary Committee Review](#), and an IRBC for administrative review. As noted above, in accordance with [Ancillary Committee requirements](#), the IRBD/IRBC may interrupt the RSRB review process to await ancillary approval confirmation.

3. During **Pre-Review**, the IRBC will review the study to ensure all institutional requirements for externally reviewed research are met. Once these requirements have been met, the IRBC will confirm reliance activities have been met and that the External IRB is the sIRB of record. At this point, the institutional administrative review is complete, the submission enters into the **Pending sIRB Review** state and the study may be submitted to the External IRB for review.
4. Following External IRB review, the IRBC will record the External IRB's determinations in the Click@ IRB study workspace. If the determination requires the RSRB to finalize documents and/or send a determination or acknowledgement letter, the study moves to **Post-Review**. If no further documentation/acknowledgement is required by the RSRB, the study moves to **Review Complete (Active or External IRB state)**.

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



Modifications, Continuing Reviews & Reportable New Information: Following initial approval by an External IRB, all follow-on submissions should be reported directly to the External IRB per their standard operating procedures (administrative review by the RSRB is not generally required). Nevertheless, updates including modifications and continuing reviews, as well as Reportable New Information reports may be reported to the RSRB via Click@ IRB.

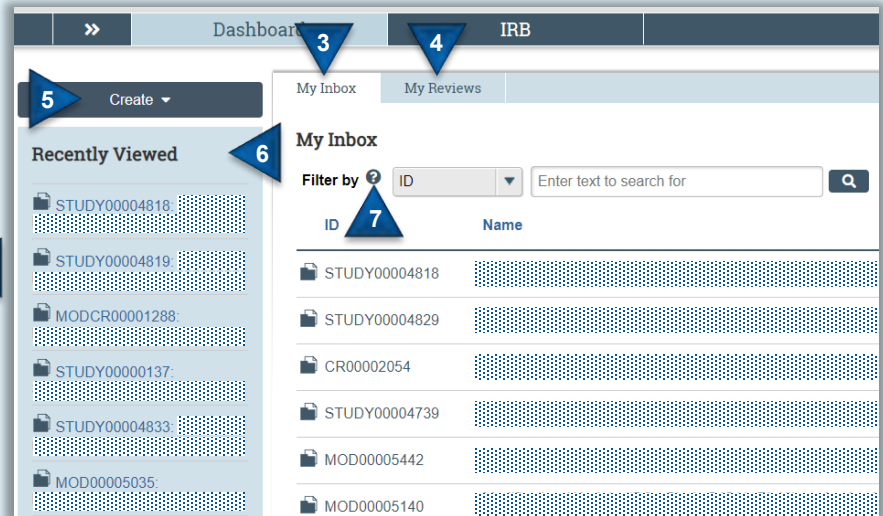
The review process of these submissions in Click@ IRB is altered compared to routine submissions based on the RSRB's relying IRB role:

- **Modifications** – Based on the nature of the research and the intended revision, the PI (and study staff) create and submit either a study update or site modification. Upon submission, study updates are reported to the RSRB for notification purposes only (no formal RSRB review is completed) and site modifications undergo administrative RSRB review and acceptance by the IRBC.
- **Continuing Reviews** – The PI (and study staff) create and submit a report of continuing review data. Upon submission, the report is provided to the RSRB for notification purposes only (no formal RSRB review is completed).
- **Reportable New Information** – The PI (and study staff) create and submit the RNI. Upon submission, the IRBC will review the event and determine whether formal review by the RSRB is required. If RSRB review is required, the RNI will undergo review as described above for routine submission. Alternately, if RSRB review is not required, the IRBC can record the External IRB's determinations concerning the event in the Click@ IRB RNI workspace.

Navigation and Basic Tasks



The image shows a login form with two input fields: 'Username' and 'Password'. Below the fields is a yellow 'Sign in' button. A blue arrow labeled '2' points to the 'Sign in' button.



Log In

To log into the Click® IRB System for the University of Rochester (UR), go to <http://rochesterirb.huronresearchsuite.com/> and click on the link for Click® IRB.

1. Select your UR affiliation.
2. Use your UR 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 to Click® IRB until they receive a user account confirmation email (approximately 1-2 business days following completion of the UR's required [human subjects training](#)).
- If you are logging in remotely, [two-factor authentication](#) is required. To facilitate this process, OHSP recommends 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.

Get Help

7. Help text is available anytime you see a ? icon. Click on the icon to review the help text.

Dashboard

After logging in, you will land on the Dashboard page, where you will find:

3. **My Inbox:** Displays submissions across the entire research suite that require action (inclusive of all research suite modules – e.g., IRB, Grants, etc.).
 - The type of submission can be identified by the ID prefix (see [IRB Submission Types](#) for additional information).
4. **My Reviews:** Displays a *subset* of the submissions listed in My Inbox of items assigned to you for *review*. For the IRB module, this includes reviews assigned for Department, Ancillary, Designated & Committee Reviewers.
5. **Create Menu:** Displays a menu of actions you can perform.
6. **Recently Viewed:** Displays the last 10 projects viewed, with the most recent on top.

Navigation and Basic Tasks (Continued)

The screenshot displays the IRB system interface. At the top, the 'Dashboard' tab is selected, and the 'IRB' module is active. Below the navigation bar, the 'IRB' section contains several tabs: 'In-Review', 'Department Review', 'Active', 'New Information Reports', 'External IRB', 'Relying Sites', 'All Submissions', and 'Archived'. A search bar is present with a 'Filter by' dropdown set to 'ID' and a search input field. Below the search bar is a table of submissions with columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, and Coordinator Last Name. A callout '16' points to the 'Name' column header. At the bottom, a filter bar includes a 'Filter' dropdown (callout '11'), a search input field (callout '12'), a 'Go' button (callout '13'), an '+ Add Filter' button (callout '14'), and an 'x Clear All' button (callout '15').

Find Submissions

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

Sort Submissions

10. Click on a column heading to sort submissions by ID, name, PI last name, Coordinator last name, submission type, etc. **Note:** The 'Coordinator' headings refers to the IRB Coordinator assigned to the submission, not the Study Coordinator.

Filter Data

11. Select the column to filter by from the dropdown menu.
12. Type the beginning characters for the items you want to filter. You may also type a % symbol as a wildcard before the characters. (e.g., typing 71 shows all items beginning with 71; typing %71 shows all items containing 71).
13. Click **Go** to apply the filter. Submissions can then be further sorted, as described above, if necessary.
14. To combine multiple filter criteria, click **Add Filter**.
15. To clear a filter, select **Remove Filter** or **Clear All** to remove all filters.

Open a Submission

16. From your inbox (or any other tab within the IRB module), click the submission name to open the submission workspace. To navigate within a submission workspace, see the [Study & Follow-On Submission Workspace](#) below.

Navigation and Basic Tasks (Continued)

Study & Follow-on Submission Workspace

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

19. Submission ID, short title and basic submission information (e.g., PI, submission type, Primary Contact, PI Proxies, IRB Coordinator, approval letter, and legacy study link, if applicable).
 - The submission type is identified in the heading of the workspace, as well as in the prefix of the submission ID (e.g., a STUDY prefix indicates the study submission). See [IRB Submission Types](#) for prefix abbreviations.
20. Submission state and approval details (e.g., IRB submission date, initial approval date, approval end date)
 - If continuing review is not required, the Approval End data field will not be present.
21. Webpage breadcrumb
 - When reviewing follow-on submissions, the breadcrumb can be used to navigate to the related study's workspace (i.e., the study homepage)

22. Review workflow, indicating where the submission is in the review process.
 - When submissions appear on the bottom row of the workflow (e.g., clarifications requested), action is required by the study team.
23. Smart forms and activities:
 - **View Study:** Provides a read-only view of the submission form.
 - **Printer Version:** Provides a printer-friendly version of the submission form.
 - **Report New Information:** Allows users to create and submit a report of new information.
 - **Activities:** Moves submissions through the review workflow. Available activities are dependent on the submission's state. Hovering your cursor over the activity, provides a description of the activity.

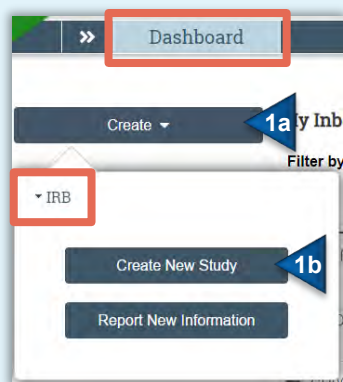
24. Submission space navigation toolbar:

- **History:** Lists the actions taken on a submission including comments, attachments, or correspondence added.
- **Funding:** Identifies the submission funding source and related grant information.
- **Contacts:** Identifies study team members listed in the study submission as well as individuals with guest access (including Ancillary and Department Reviewers).
- **Documents:** Identifies all study and site related documents, including final approved and watermarked versions. **WATERMARKED VERSIONS ARE LISTED UNDER THE 'FINAL' HEADING WITHIN THIS TAB.**
- **Sites** (if applicable): Identifies all participating sites undergoing single IRB review by the RSRB (for multi-site studies only).
- **Follow-On Submissions:** Lists all Mods, CRs, Mod/CRs, and RNIs related to the submission.
- **Reviews:** Identifies the status of Department, Ancillary and IRB Reviews.
- **Snapshots:** Provides historical submission contents.
- **Training Details:** Identifies all study team members and the training they have completed through the Collaborative Institutional Training Initiative (e.g., Human Subject Protection, Good Clinical Practice, Animal Care & Use, and Responsible Conduct of Research training).

Create and Submit a Study

The instructions below are for submitting a new, **single-site study for local IRB review**. The application form is a smart form; specific fields will appear/disappear based on preceding responses. Instructions for submitting research to an external IRB are provided [here](#). Instructions for submitting multi-site research for local, single IRB review are available in the [here](#). **Note: It is best practice to wait to initiate an application until you have determined what IRB will review and approve the research.**

Before you begin, gather the necessary files and information about your study. For more details on documents you may be required to submit for review, see the [Study Submission Checklist](#).



- 4** **4. * What kind of study is this?** ?
- Multi-site or Collaborative study
- Single-site study
- [Clear](#)
- 5** **5. * Will an external IRB act as the IRB of record for this study?** ?
- Yes No [Clear](#)

Create a Study

- From the Dashboard page, click the **Create [1a]** menu, expand the IRB section (if applicable), and select **Create New Study [1b]** under the IRB heading.
- Within the submission form:
 - Navigate through the form using the 'Continue' button on the floating navigation bar.
 - Use the left-hand navigation pane to jump from page to page within the submission (additional pages become available once the first page is completed). This pane may be opened/closed by selecting the << icon.
 - All * fields are required.
 - Help text is available anytime you see a ? icon. Click on the icon to review the help text

Basic Study Information

- Enter a title, short title and brief description of the study. The short title will appear as the study name in the study workspace and in the search fields within Click® IRB.
- Indicate the study type.
- Indicate whether an IRB external to the University of Rochester will review the research.
 - If yes, see [External IRB](#) instructions below.
 - Selecting no, with 'multi-site or collaborative study' identified in Field 4 will provide a follow-up field concerning the single IRB of record. For further instruction on submitting [multi-site research for local, single IRB review](#), see the instructions below.

Create and Submit a Study (Continued)

6. * Local principal investigator: ?

7. * Does the local principal investigator have a financial interest related to this research? ?
 Yes No

8. * Attach the protocol: ?

+ Add

Document	Category	Date Modified	Document History
Protocol(0 01)	IRB Protocol	5/4/2020	History

10

Exit Save Continue →

Add Attachment

1. * File to attach:

Choose File

2. Name: (if not supplied, the file name will be shown) ?

3. Version number:

* Required OK OK and Add Another Cancel

Study Funding Sources ?

1. Identify each organization supplying funding for the study: ?

11 + Add

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

15

Exit Save Continue →

Add Funding Source

1. * Funding organization: ?

12

2. Sponsor's funding ID: (assigned by external sponsor)

13

3. Grants office ID: (assigned internally)

4. Attach files: (include any grant applications)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

14

* Required OK OK and Add Another Cancel

- Click on the ellipses to enter a Principal Investigator. **Note:** This field defaults to whomever creates the submission.
- Indicate whether the PI has a financial conflict of interest. If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.
- Click **Add** to attach the study protocol.
- In the Add Attachment pop-up box, click **Choose File** to attach the study protocol and click **OK**. For instructions on uploading revised documents, see [Update Study Documents](#).
 - While not required, it is best practice to enter a protocol name in Fields 2; **do not rely on the file name to adequately identify protocol documents**. The name entered into Field 2 will appear on the approval letter and should be consistent with document contents.
 - If the version number field is left blank, a default version number will be assigned.
- Click **Continue** to proceed to the next page of the application.

Study Funding Source

- Identify funding sources by clicking **Add**. **If there is no funding for the research, SKIP this section.**
 - Funding by an internal department should be identified as such.
 - Multiple funding sources may be identified.
- Click on the ellipses to find and add a funding source. Reminder: When searching, use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., %pediatric). If the funding source does not appear in the database contact your [IRB Coordinator](#).
- Enter sponsor funding ID, grants office ID and attach grant applications, as applicable.
- Click **OK**.
- Click **Continue** to proceed to the next page of the application.

Create and Submit a Study (Continued)

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

16 + Add

Name	Roles	Financial Interest	E-mail	Phone
There are no items to display				

2. External team member information: ?

21 + Add

Name	Description
There are no items to display	

25

Exit Save Continue →

Add Study Team Member

1. * Study team member: ?

17

2. * Role in research: (check all that apply) ?

18

Co-Principal Investigator

Sub-Investigator

Study Coordinator

Statistician

Other Study Personnel

3. * Does the team member have a financial interest related to this research? ?

19 Yes No [Clear](#)

* Required

20 OK OK and Add Another Cancel

Submit a Document [? Help](#)

Title: 22
If not provided, the name of the file will be used

* File: Choose File 23

Show Advanced Options

* Required 23a

24 OK OK and Add Another Cancel

Description: 23b

Local Study Team Members

All local study team members involved in the design, conduct and reporting of the research must be added to the study. For additional information see the [OHSP Guideline for Listing Research Personnel](#).

Note: The PI does not need to be re-entered as they are already included on the Basic Information page.

Add **Internal** Study Team Members:

16. Click **Add** in Field 1 to add all *internal* (UR) study team members. **Note:** The individual completing the application must be added (if not already listed as the PI); this does occur automatically.

17. Click on the ellipses to find and add internal study personnel. **Note:** Individuals will not appear in the search box (and therefore you will not be able to add them) until their user account has been created (see [Log In](#) information).

18. Identify the study team member's role.

19. Identify whether the study member has a conflict of interest. If yes, attach a copy of the management plan and transparency checklist on the [Local Site Documents](#) page.

20. Click **OK**.

Add **External** Study Team Members:

Note: External study team members do not have access to Click® IRB; adding an external study team member here will not create a user account for them.

21. Click **Add** in Field 2 to add all *external* study team members.

22. Enter the external study member's name as the 'Title'.

23. Click **Choose File** to upload documentation of the external study team member's *current* human subject protection training (e.g., CITI Course Completion Report).

a. Select **Show Advanced Options**.

b. Enter the external study team member's role in the 'Description' field.

24. Click **OK**.

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

Create and Submit a Study (Continued)

The image shows two screenshots from a web application. The first screenshot, titled 'Study Scope', contains four numbered questions (26-29) with radio button options and 'Clear' links. Question 26 asks about evaluating drug safety, 27 about device safety, 28 about institutional conflicts, and 29 about ClinicalTrials.gov registration. A 'Continue' button is at the bottom right, with a callout 30 pointing to it. A separate callout 29a points to a text input field for the 'ClinicalTrials.gov Identifier'. The second screenshot, titled 'Local Research Locations', shows a search interface with an 'Add' button (callout 31), a table with columns for Location, Contact, Phone, and Email, and a 'Continue' button (callout 34). Below it, the 'Add Research Location Information' pop-up is shown, with callout 32 pointing to a search ellipsis and callout 33 pointing to the 'OK' button. The pop-up contains fields for 'Location name', 'Address line 1', and 'Address line 2'.

Study Scope

26. Indicate whether the research involves *evaluating* the safety or effectiveness of a drug, biologic or supplement (see [RSRB Policy 605 Research Involving FDA Regulated Drugs, Biologics, and Supplements](#) for additional information).
 - Answering yes will add a 'Drugs' page to the application, where additional information will be collected.
27. Indicate whether the research involves *evaluating* the safety or effectiveness of a device or humanitarian use device (see [RSRB Policy 606 Research Involving FDA Regulated Devices](#) for additional information).
 - Answering yes will add a 'Devices' page to the application, where additional information will be collected.
28. Indicate whether there are any potential *institutional* conflicts of interest related to the research. If yes, attach a copy of the management plan on the [Local Site Documents](#) page.
29. Indicate whether the study requires registration on ClinicalTrials.gov (see [NIH flowchart for additional guidance](#)).
 - Answering yes will provide an additional field to enter the ClinicalTrials.gov Identifier.
30. Click **Continue** to proceed to the next page of the application.

Research Locations

31. Click **Add** to add research locations. Research locations are non-UR locations (e.g., Rochester City School District) or UR-affiliated sites (e.g., Highland Hospital, FF Thompson) where research activities are conducted by UR faculty/staff or UR faculty/staff in collaboration with non-UR staff.
 - See the Help Text (? icon) for additional information on what constitutes a research location.
 - **If there are no additional research locations, SKIP this section.**
32. In the corresponding pop-up box, click on the ellipses to add a research location. Reminder: When searching, use the % symbol as a wildcard before the text entered to search for all entries containing the text (e.g., %school).
 - Enter the location information manually in the additional name/address fields **ONLY** if a research location does not appear in the database.
33. Click **OK**.
34. Click **Continue** to proceed to the next page of the application.

Create and Submit a Study (Continued)

Drugs ?

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

35

Generic Name	Brand Name	Attachment Name
There are no items to display		

2. * Will the study be conducted under any IND numbers? ?

39 Yes No [Clear](#)

3. * Identify each IND:

39a

IND Number	IND Holder	Other Holder
There are no items to display		

4. Attach files: (such as IND or other information that was not attached for a specific drug) ?

40

Document	Category	Date Modified	Document History
There are no items to display			

41

Add Drug Information

1. Select the drug: ?

36

36a If you cannot find the drug in the list above, enter its information here:

Generic name:

Brand name:

2. Attach files related to this drug: ?

37

Document	Category	Date Modified	Document History
There are no items to display			

* Required

38

Add IND Information

1. * IND number:

39b

2. * Who holds the IND?

39c Sponsor
 Investigator
 Other
[Clear](#)

3. If 'Other,' identify the IND holder:

* Required

39d

Drugs

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

35. Click **Add** to add the drugs/biologics/supplements used as part of the research.
36. In the corresponding pop-up box, click the ellipses to find and add the drug/biologic/supplement.
 - a. If the drug/biologic/supplement does not appear in the database, enter the name of the drug in the textboxes provided. **Note:** This information should **only** be entered manually if you are unable to find the drug/biologic/supplement in the database.
37. Click **Add** to attach drug-specific files (e.g., package insert, investigator brochure).
38. Click **OK**.
39. Indicate whether an Investigational New Drug (IND) has been filed with the Food & Drug Administration for the conduct of the research. Answering yes will provide a follow-up field to identify each IND used in the research. For each IND:
 - a. Click **Add** to insert IND information.
 - b. Insert the IND number.
 - c. Identify who holds the IND.
 - d. Click **OK**.
40. **Attach** additional files related to use of the drug/biologic/supplement, as necessary (e.g., IND exemption documentation, PI IND training documentation).
41. Click **Continue** to proceed to the next page of the application.

Create and Submit a Study (Continued)

Devices

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness: ?

42 + Add

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. * Device exemptions applicable to this study: ?

46

IDE number
 HDE number
 Claim of abbreviated IDE (nonsignificant risk device)
 Exempt from IDE requirements
[Clear](#)

3. * Identify each IDE or HDE number:

46a + Add

IDE / HDE Number	IDE / HDE Holder	Other Holder
There are no items to display		

4. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device) ?

47 + Add

Document	Category	Date Modified	Document History
There are no items to display			

48

Exit Save Continue

Add Device Information

1. Select the device: ?

43

43a If you cannot find the device in the list above, enter its information here.

Device name:

Is this a humanitarian use device (HUD)?
 Yes No [Clear](#)

2. Attach files related to this device: ?

44 + Add

Document	Category	Date Modified	Document History
There are no items to display			

Attachments may include a copy of investigator brochure and the product labeling/device instructions.

* Required

45 OK OK and Add Another Cancel

Add IDE and HDE Information

1. * IDE or HDE number:

46b

2. * Who holds the IDE or HDE?

46c

Sponsor
 Investigator
 Other
[Clear](#)

3. If 'Other,' identify the IDE / HDE holder:

46d

* Required

OK OK and Add Another Cancel

Devices

Note: You will only be directed to complete this page, if you answered 'yes' to Field 3 (devices) on the [Study Scope](#) page.

42. Click **Add** to list devices used as part of the research.
43. In the corresponding pop-up box, click the ellipses to find and add the device.
 - a. If the device does not appear in the database, enter the name of the device in the textbox provided and indicate whether it is a Humanitarian Use Device (HUD). **Note:** The device should **only** be entered manually if you are unable to find it in the database. Furthermore, the question referencing whether the device is a HUD should only be entered if device is entered manually.
44. Click **Add** to attach device-specific files (e.g., manufacturer brochure).
45. Click **OK**.
46. Indicate what device exemption(s) apply. Selecting IDE or HDE will provide a follow-up field to identify each IDE or HDE used in the research.
 - a. Click **Add** to insert the IDE/HDE information.
 - b. Insert the IDE/HDE number.
 - c. Identify the IDE/HDE holder.
 - d. Click **OK**.
47. **Attach** additional files related to use of the drug/biologic/supplement, as necessary.
48. Click **Continue** to proceed to the next page of the application.

Create and Submit a Study (Continued)

Local Site Documents

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

49 + Add

Document	Category	Date Modified	Document History
There are no items to display			

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Add Attachment

1. * **File to attach:**

Choose File 50

2. **Name:** (if not supplied, the file name will be shown)

3. * **Category:**

51

4. **Version number:**

53

52 OK OK and Add Another Cancel

* Required

Ancillary Committee Review

1. * **Does this research involve any of the following which may require additional institutional ancillary reviews?** ?

- Patients with cancer
- Resources within the Clinical Research Center
- Pregnant to post-partum women
- Hospitalized newborns
- Surgical Pathology tissue samples
- University Pharmacy / Investigational Drug Services
- Recruitment in the Emergency Department
- Oversight by the Human Use of Radiation Committee (HURC)/Radioactive Drug Research Committee (RDRC)
- Oversight by Institutional Biosafety Committee (IBC)
- University of Rochester Center for Advanced Brain Imaging & Neurophysiology (UR CABIN)
- Patients receiving radiation therapy

54 Yes No [Clear](#)

55 Exit Save Continue

2. * **Does this research plan to enroll individuals with cancer or review Cancer Center patient health information, which requires review by the Cancer Center Peer Review Committee?** ?

54a Yes No [Clear](#)

3. * **Does this research involve pregnant to post-partum women, who require review by the Obstetrical Research Committee?** ?

54b Yes No [Clear](#)

13. **Upload relevant documents:** ?

+ Add

Document	Category
There are no items to display	

Final Page

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

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

56 Exit Save Finish

Local Site Documents

On the Local Site Documents page, attach all consent forms, recruitment materials and other study-specific documents in their respective sections. To do so:

- Click **Add** in the section that corresponds to the type of document being attached.
- Click **Choose File** to attach the document.
 - While not required, it is best practice to enter a document name into Field 2; **do not rely on the file name to adequately identify the document.**
- Select the category (type) of document uploaded.
- Click **OK**.
- Once all documents have been added, click **Continue** to proceed to the next page of the application.

Ancillary Committee Review

- Indicate whether the research requires review by any of the UR Ancillary Committees listed (see [quick reference guide](#) for additional information).
 - Answering yes, will provide several follow-up questions that correspond to each type of Ancillary Committee. *All* questions require a response.
 - Answering yes to Fields 6 & 9 (Surgical Pathology and Radiation Safety, respectively), will provide an additional upload field to provide their respective review forms (see help text).
- Click **Continue** to proceed to the next page of the application.

Final Page

- Click **Finish** to exit the form.
 - This does not submit the application.**

Create and Submit a Study (Continued)

Pre-Submission STUDY00004818: Training Manual Demo A

Last updated: 5/5/2020 10:53 AM

Principal investigator: [Redacted] IRB office: Office for Human Subject Protection
 Submission type: Initial Study IRB coordinator: [Redacted]
 Primary contact: [Redacted]
 PI proxies: [Redacted]

Next Steps

- Edit Study (57)
- Pre-Submission (58)
- Submit (59)
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Copy Submission

History Funding Contacts Documents Reviews Determinations Snapshots ...

Filter by Activity [Dropdown] Enter text to search for [Input] + Add Filter [Dropdown]

Activity	Author	Activity Date
Study Created	[Redacted]	5/4/2020 12:48 PM

Submit

By submitting this application, I certify that I will comply with all of the responsibilities and requirements of a Principal Investigator (PI) to ensure the research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable; consistent with OHSP Policy 901 Investigator Responsibilities and OHSP Policy 902 Investigator Financial Conflict of Interest.

In addition, I am aware of and will comply with the following requirements:

- To conduct the study in accordance with the approved protocol and only implement changes after receiving IRB approval, except when necessary to protect the safety, rights or welfare of subjects.
- To follow University and Hospital standards of care, policies, procedures and guidelines for research conducted in a clinical/treatment setting.
- To ensure all study team members are adequately informed about their obligations in meeting the above commitments.

60 OK Cancel

Submit a Study Submission

- Once an application has been completed, you may edit the application prior to submission by clicking **Edit Study**.
- Prior to study submission, you may also wish to:
 - [Assign a Primary Contact](#)
 - [Assign a PI Proxy](#)
 - All student research, including research conducted by residents and fellows, should assign the PI Proxy role to their faculty mentor.**
 - [Manage Guest List](#)
 - Department Research Administrators should be added as guests to all sponsored research.**
 - [Add Related Grant](#)
 - [Add Comment](#)
- When you're ready to submit the study, click **Submit** from the study workspace.
 - Only PIs and PI Proxies can submit new study applications.**
- 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 introductory [overview](#) pages. 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 \neq approved). All revisions to approved materials, including the protocol, consent form, recruitment materials, study measures, and content identified in the submission form, must be submitted for re-review via [modification](#). The modification must be approved prior to implementing the changes.**
- If a study is disapproved, the submission moves to Archived once the determination letter is sent. From there, the submission may be edited and re-submitted.

Create and 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 application, 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.**

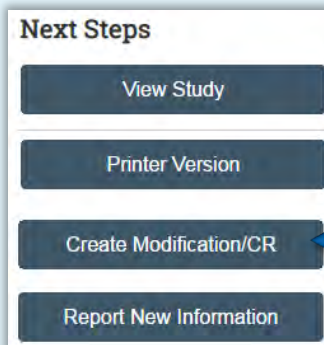
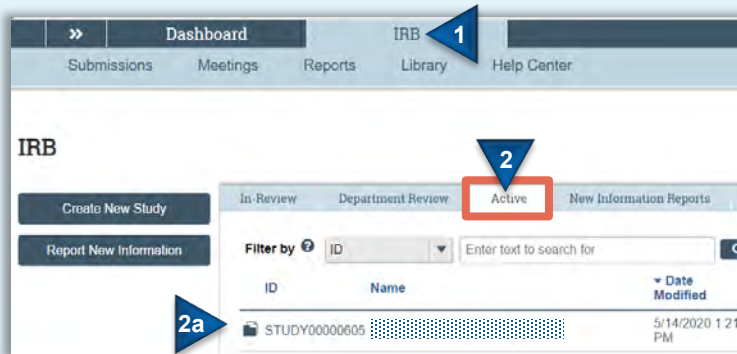
Some types of research require the submission of a Continuing Review ('CR'), or progress report, at least annually for re-approval of the research. Studies that do not require re-approval via the CR process are not assigned an expiration date, as indicated in your approval letter and the on the study workspace. All studies other than those deemed exempt, must also be formally closed once the study is complete. Study closures are also completed via the CR process.

If a Mod and a CR are required at the same time, they can be combined into one submission (referred to as a 'Mod/CR').

Additional information on types of submissions can be found in [OHSP Policy 502 Types of RSRB Submissions](#).

Create a Mod or CR

1. Select the **IRB** module (tab).
2. Find and open the applicable study by clicking on the **Active** tab and then the name of the study [2a]. See instructions on how to [Sort Submissions](#) and [Filter Data](#) for additional help.
3. From the study workspace, click the **Create Modification/CR** button.
4. In the submission form, identify whether the submission is a CR, a modification, or combined Mod/CR submission.
 - If the Mod only involves adding/removing study team members BUT, consequently, requires revision to the protocol/consent/recruitment documents, select both checkboxes. To change the PI, select both scope options.
6. Click **Continue** to proceed to the next page of the submission form.
 - **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 additional instructions.



Modification / Continuing Review / Study Closure

4 * What is the purpose of this submission? ?

- Continuing Review
 Modification / Update
 Modification and Continuing Review

[Clear](#)

5 To change the PI, choose 'Other parts of the study/site' scope

5 Modification scope:

- Study team member information
 Other parts of the study

✖ Exit

Save

Continue →

Create and Submit a Modification or Continuing Review (Continued)

Continuing Review / Study Closure Information

1. * Specify enrollment totals at this investigator's sites: 7

2. * Specify enrollment totals at this investigator's sites since last approval: 7

3. * Specify enrollment totals study-wide: 7

(Confirmed sites: 1 of 1. Total enrollment for pSites with completed reports: 10)

4. Research milestones: (select all that apply) 8

Study is permanently closed to enrollment OR was never open for enrollment

All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)

Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)

Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)

Remaining study activities are limited to data analysis

Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

5. * Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? 9

Yes No [Clear](#)

6. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review) 10

NO subjects experienced unexpected harm

Anticipated adverse events have NOT taken place with greater frequency or severity than expected

NO subjects withdrew from the study

NO unanticipated problems involving risks to subjects or others

NO complaints about the study

NO publications in the literature relevant to risks or potential benefits

NO interim findings

NO multi-center trial reports

NO data safety monitoring reports

NO regulatory actions that could affect safety and risk assessments

NO other relevant information regarding this study, especially information about risks

In the opinion of the PI, the risks and potential benefits are unchanged

All modifications to the protocol have been submitted to the IRB

All problems that require prompt reporting to the IRB have been submitted

7. Attach supporting documents: (include an explanation of each item left unchecked above) 9

[+ Add](#)

Name

There are no items to display

8. Comments: 8

9. * Have any NEW subjects enrolled since the last review requiring a signed consent document? 11

Yes No [Clear](#)

10. * Attach files: 12

[+ Add](#)

Name

There are no items to display

[Exit](#) [Save](#) [Continue](#)

Complete a CR Form

Note: Additional guidance on completing the enrollment [Fields 1-3] and research milestone [Field 4] questions is available [here](#).

7. Enter the number of subjects enrolled in total and since the last approval for the local site and study wide. For single-site research, enter the same number for the total enrolled locally and study wide. For multi-site research undergoing single IRB review, pSite enrollment will pull into the CR form once the [pSite CR data is recorded](#).
8. Select **ALL** milestones that apply to the research (select the checkbox if the corresponding statement is **TRUE**).
 - If none of the milestones have been met, all checkboxes should be left blank.
 - To close a study, the 1st four milestones must be met. When the 1st four checkboxes are selected, a follow-up closure acknowledgment statement will appear and the study will be closed following IRB review.
9. Identify whether any additional conflicts of interest, that have not previously been reported, have been identified. If yes, attach supporting documentation (e.g., COI Management Plan in Field 6).
10. Select **ALL** events that apply to the research (select the checkbox if the corresponding statement is true). **For each item left unchecked, provide an explanation of the event in the comments section in Field 8 and/or attach further supporting documentation in Field 7.**
11. Identify whether any new subjects have enrolled since the previous review that required a signed consent. If yes, attach a copy of the last signed document for each type of consent obtained in the past year. For each signed document attached:
 - **Conceal the subject's name and signature but not the date the subject signed the form.**
 - **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](#)

Create and Submit a Modification or Continuing Review (Continued)

Modification Information

- 13** **1. Study enrollment status:**
- No subjects have been enrolled to date
 - Subjects are currently enrolled
 - Study is permanently closed to enrollment
 - All subjects have completed all study-related interventions
 - Collection of private identifiable information is complete

- 14** **2. Notification of subjects:** (check all that apply)
- Current subjects will be notified of these changes
 - Former subjects will be notified of these changes

14a **a. * Describe the subjects to be notified and how they will be notified:**

15 **3. * Summarize the modifications:**

4. Attach Files

+ Add

Name	Description
There are no items to display	

16 Exit Save Continue

17

Complete a Mod Form

13. Indicate the status of local subject enrollment (see help text for additional instructions).
14. Indicate whether subjects will be notified of the modifications (leave blank if notification is not applicable).
 - a. If subjects will be notified, a follow-up field to identify what subset of subjects will be notified and how will appear.
15. Insert a summary, including rationale, of the modifications included in the submission. Alternately, a document/memo summarizing the revisions may be attached in Field 4.

Note: Additional or revised study documents should not be attached in Field 4; these are added/updated later in the submission form.
16. Click **Continue** to proceed.
17. The remaining pages of the modification form is comprised of the original study submission. Click **Continue** through the submission pages to edit applicable sections. **The pages you are provided access to for editing are dependent on the modification scope selected in Step 5 above and the study type (e.g. single-site vs. multi-site).** Alternately, use the left-hand navigation pane to **Jump To** a specific section of the submission form.

- For additional information on completing these pages, see the instructions provided above on submitting a new study: [Basic Study Information; Funding Sources; Local Study Team Members; Study Scope; Local Research Locations; Drugs; Local Site Documents; Ancillary Committees.](#)
- To add/edit study documents, see [Update Study Documents.](#)

Create and Submit a Modification or Continuing Review (Continued)

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.

✕ Exit 📁 Save **18** Finish

Next Steps

Edit Modification/CR **19**

Printer Version

 Submit **20**

Submit

By submitting this application, I certify that I will comply with all of the responsibilities and requirements of a Principal Investigator (PI) to ensure the research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable; consistent with OHSP Policy 901 Investigator Responsibilities and OHSP Policy 902 Investigator Financial Conflict of Interest.

In addition, I am aware of and will comply with the following requirements:

1. To conduct the study in accordance with the approved protocol and only implement changes after receiving IRB approval, except when necessary to protect the safety, rights or welfare of subjects.
2. To follow University and Hospital standards of care, policies, procedures and guidelines for research conducted in a clinical/treatment setting.
3. To ensure all study team members are adequately informed about their obligations in meeting the above commitments.

21 OK Cancel

Finish & Submit a Mod or CR

18. On the final page of the submission form, click **Finish** to exit the form.
 - **This does not submit the application.**
19. Once the form has been completed, you may edit it prior to IRB submission by clicking **Edit Modification/CR**.
20. When you're ready to submit the form, click **Submit** from the submission workspace.
 - **Only PIs and PI Proxies can submit Mods, CRs, and Mod/CRs.**
21. READ the terms provided and click **OK** to agree.
 - The Modification and/or Continuing Review has now been submitted.

Next Steps

The submission will undergo review as described in the introductory [overview](#) pages. When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the submission, and/or makes determinations (e.g., approval) concerning the submission, 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).**
- If you wish to [withdraw](#) a submission, see the instructions provided below.
- 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 and 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.

The screenshot displays the 'Reportable New Information' form with the following numbered callouts:

- 1**: Dashboard
- 1a**: Create menu
- 1b**: Report New Information button
- 2**: RNI short title field
- 3**: Date you became aware of the information field
- 4**: Identify the categories that represent the new information (checkboxes for Risk, Harm, Non-compliance, Audit, Report, Researcher error, Confidentiality, Unreviewed change, Incarceration, Complaint, Suspension)
- 5**: Briefly describe the new information field
- 6**: In the submitter's opinion section (a, b, c questions)
- 7**: Related studies and modifications table
- 8**: Attach files containing supporting information section
- 9**: Edit RNI button
- 10**: Submit RNI button
- 11**: OK/Cancel buttons at the bottom of the form

Create an RNI

- From the Dashboard page, click the **Create** [1a] menu, expand the IRB section (if applicable), and select **Report New Information** [1b] under the IRB heading. Alternately, select **Report New Information** from the study workspace.
- Enter a RNI short title.
- Enter the date you became aware of the event/new information.
- Select the type(s) of event/new information.
- Provide a description of the event/new information. **Note:** A memo and/or other supporting documentation may also be uploaded into Field 7.
- Complete Field 5, indicating if there is new or increased risk and whether study and/or consent documents require revision as a result of the event/new information.
- Click on the ellipses and select all studies 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.
 - Only submissions that the individual creating the RNI is listed on or has access to will appear in the search box.
 - 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.
- Click **Continue** when done.
 - This does not submit the RNI.**
- Once the form has been completed, you may edit it prior to IRB submission by clicking **Edit RNI**.
- When you're ready to submit the form, click **Submit RNI** from the submission workspace.
- 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 introductory overview pages. When and if the IRB [requests clarifications](#) and/or makes determinations (e.g., approval) concerning the submission, an email notification will be provided to the individual who submitted the RNI and, if applicable, the individual the IRB identifies as being responsible for following up on board-requested actions.

Create and 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. Per [OHSP Policy 504 IRB Reliance and Collaborative Research](#), all studies that utilize the local IRB as the sIRB of record require the execution of a reliance agreement (or IRB authorization agreement). **Submissions should not be initiated until a reliance agreement has been executed. Note:**

- MSS submissions include multiple components: 1) a study submission that describes the research and provides study-related information/documents that apply to the study as a whole; and 2) individual site submissions for each participating site (pSite) that provide site-specific details.
- If the lead PI will also act as the PI for the local (UR) pSite, the local pSite details can be entered on the study submission; a separate pSite application 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 (see exception in Step 5 below).**
- Study and pSite application forms are smart forms; specific fields will appear/disappear based on preceding responses.

Basic Study Information

1. * Title of study:
Training Manual Demo MSS sIRB

2. * Short title:
Training Manual Demo MSS sIRB

3. * Brief description:
This is a multi-site <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...

4. * What kind of study is this?
 Multi-site or Collaborative study
 Single-site study
[Clear](#)

5. * Will an external IRB act as the IRB of record for this study?
 Yes No [Clear](#)

6. * Will your IRB act as the single IRB of record for other participating sites?
 Yes No [Clear](#)

7. * Local principal investigator:

8. * Does the local principal investigator have a financial interest related to this research?
 Yes No [Clear](#)

9. * Attach the protocol:
[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

Study Funding Sources

1. Identify each organization supplying funding for the study:
[+ Add](#)

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:
[+ Add](#)

Name	Roles	Financial Interest	E-mail	Phone
There are no items to display				

2. External team member information:
[+ Add](#)

Name	Description
There are no items to display	

Create a Multi-Site Study

- From the Dashboard page, click the **Create** [1a] menu, expand the IRB section (if applicable), and select **Create New Study** [1b] under the IRB heading.
- Complete the form, providing [basic information](#) about the study in Fields 1-9.
 - Select 'Multi-site or Collaborative study' in Field 4.
 - Answer no to Field 5.
 - Answer yes to Field 6.
 - Click on the ellipses to enter the Principal Investigator who will act as the 'lead PI', overseeing the conduct of the research across all participating sites. **Note:** This field defaults to whomever creates the submission.
- Click **Continue** to proceed to the next page of the application.
- Identify [funding sources](#) by click **Add** and click **Continue** to proceed to the next page of the application.
- Identify all local [study team members](#) involved in the study by clicking **Add** in Fields 1 or 2, as appropriate. **Both study and UR pSite personnel should be entered. Separate UR pSite submissions (when the pSite PI is different than the study PI), will not have the opportunity to add local study personnel separately and therefore should be listed here.** Click **Continue** to proceed to the next page of the application.

Create and Submit a Multi-Site Study for Single IRB Review (Continued)

Study Scope

6. 1. * Does the study evaluate the safety or effectiveness of a drug, biologic, or food/dietary supplement to diagnose, cure, treat or mitigate a disease? Yes No [Clear](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)? Yes No [Clear](#)

3. * Are there any potential institutional conflicts of interest related to this study? Yes No [Clear](#)

4. * Is this study a clinical trial that requires... Yes No [Clear](#)

Local Research Locations

7. 1. Identify research locations where research activities will be conducted or overseen by the local investigator:

+ Add

Location	Contact	Phone	Email
There are no items to display			

Drugs

8. 1. * List all

+ Add

Devices

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

+ Add

Device	Humanitarian Use Device Attachment Name
There are no items to display	

Study-Related Documents

9. 1. Consent form templates: (include an HHS-approved sample consent document, if applicable)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. Recruitment material templates: (add templates for all material to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Local Site Documents

10. 1. Consent forms: (include an HHS-approved sample consent document, if applicable)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

4. Study Measurement Documents:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Ancillary Committee Review

11. 1. * Does this research involve any of the following which may require additional institutional ancillary reviews? Yes No [Clear](#)

- Patients with cancer
- Resources within the Clinical Research Center
- Pregnant to post-partum women
- Hospitalized newborns
- Surgical Pathology tissue samples
- University Pharmacy / Investigational Drug Services
- Recruitment in the Emergency Department
- Oversight by the Human Use of Radiation Committee (HURC)/Radioactive Drug Research Committee (RDRC)
- Oversight by Institutional Biosafety Committee (IBC)
- Rochester Center for Brain Imaging (RCBI)
- Patients receiving radiation therapy

Final Page

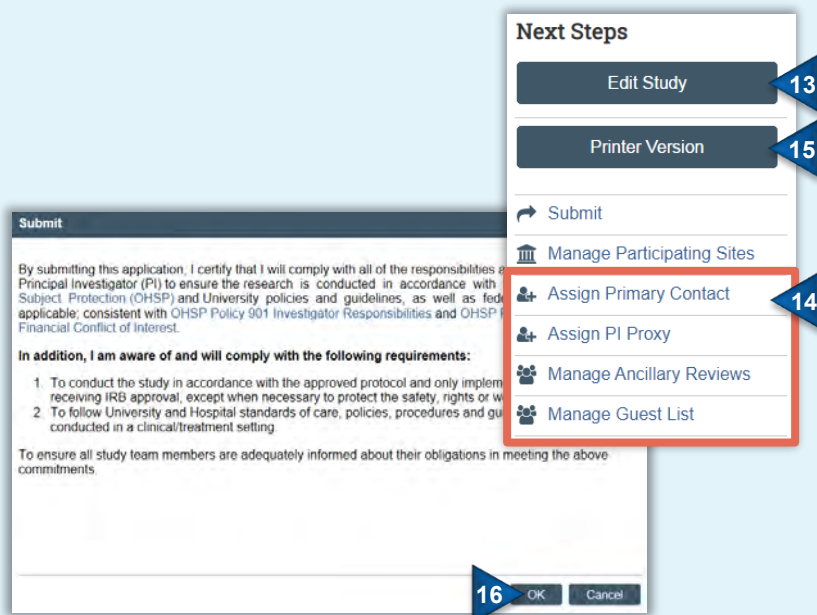
12. You have reached the end of the IRB submission form. Read the next steps carefully.

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

Exit Save **Finish**

- Complete the [Study Scope](#) page and click **Continue** to proceed to the next page of the application.
- If the lead PI is acting as the local psite PI, click **Add** to add research locations. **If a separate PI will act as the local pSite PI, this page can be skipped.** Click **Continue** to proceed to the next page of the application.
- Click **Add** to add all [drugs/biologics/supplements](#) and/or [devices](#) under study. Click **Continue** to proceed to the next page of the application.
 - You will only be directed to these pages, if you answered 'yes' to Fields 1 and 2, respectively, on the Study Scope page.
- On the [Study-Related Documents](#) page, click **Add** in the corresponding sections, to upload all **model** consent forms, **model** recruitment materials, and any other **study-specific** templates or attachments that will be distributed for use at each pSite. Site-specific documentation should not be uploaded here. Click **Continue** to proceed to the next page of the application.
 - While not required, it is best practice to enter a document name when uploading materials; **do not rely on the file name to adequately identify the document.**
- If the lead PI is acting as the local psite PI, click **Add** in the corresponding sections of the [Local Site Documents](#) page, to upload local, **site-specific** consent forms, recruitment materials and any other site-specific documentation. **If a separate PI will act as the local pSite PI, this page can be skipped.** Click **Continue** to proceed to the next page of the application.
- Indicate whether the research requires review by any of the UR [Ancillary Committees](#). Click **Continue** to proceed to the next page of the application.
- On the final page of the submission form, click **Finish** to exit the form.
 - This does not submit the application.**

Create and Submit a Multi-Site Study for Single IRB Review (Continued)



13. Once an application has been completed, you may edit the application prior to submission by clicking **Edit Study**.
14. Prior to submission, you may also wish to:
 - [Assign a Primary Contact](#)
 - [Assign a PI Proxy](#)
 - [Manage Guest List](#)
15. When you're ready to submit the form, click **Submit** from the submission workspace.
 - **Only PIs and PI Proxies can submit new study applications.**
 - 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 introductory [overview](#) pages. When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or makes determinations (e.g., approval) concerning the research, an email notification will be provided to the PI, PI Proxy and Primary Contact.

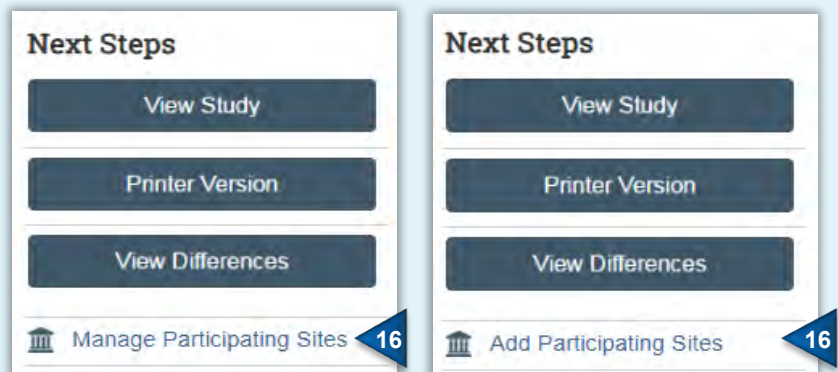
Submissions for each pSite should not be initiated until the study has been approved. For each pSite: a) [add the pSite](#); b) [edit the pSite](#) submission form to include details specific to the individual pSite once the IRB has confirmed their eligibility to participate; and c) [submit the pSite's materials](#).

Note:

- **Research cannot be initiated at participating sites until the pSite submission is approved (study submitted ≠ pSite approval).**
- The IRB Coordinator may add, edit and submit the pSite submission on behalf of the PI.
- If you wish to [withdraw](#) a submission, see the instructions provided below.
- If a study is disapproved, the submission moves to Archived once the determination letter is sent. From there, the submission may be edited and re-submitted.

Add a Participating Site

16. From the *study* workspace, click **Manage Participating Sites**.
 - **Note:** If the study has been submitted and review has progressed past the Pre-Review phase, select **Add Participating Sites**.



Create and Submit a Multi-Site Study for Single IRB Review (Continued)

17. Click on the ellipses to add: a) the pSite's Institutional Profile and; b) the corresponding PI.

- Click **Add** and repeat these steps to add additional pSites [17c].
- If the Institutional Profile and/or PI do not appear in the database contact the IRBC.

18. Click **OK**.

- A submission form for each added pSite has been created. The pSite state is **Invitation Pending** and the IRBC is notified of the pSite.

Edit a Participating Site

19. From the study workspace, select the 'Sites' tab.

20. To open the pSite submission form:

- Click on the name of the pSite submission. The pSite workspace will open. Click **Edit Site**. OR
- To jump to the pSite submission, click on the icon under the 'SmartForm' heading and select the Basic Site Information page.

21. Complete all pages of the pSite submission form, as appropriate. **Note:**

- Only additional funding, specific to the pSite, should be added on the Additional Local Funding Sources.
- All documents uploaded in the Local Site Documents should be specific to pSite.
- Provided the pSite is not a UR site, answer 'no' to the institutional ancillary review question.

22. On the final page of the submission form, click **Finish** to exit the form.

- **This does not submit the pSite application.**
- Prior to pSite submission, the IRBC must confirm the pSite meets the criteria to participate in the research. Once confirmed, [Submit Site Materials](#).

Create and Submit a Multi-Site Study for Single IRB Review (Continued)

Next Steps

Edit Site

Printer Version

View Differences

Submit Site Materials **23**

Submit Site Materials

1. Comments:

24

2. * Confirm that all site-specific materials have been received:

25

OK Cancel

Submit Site Materials

23. From the *site* workspace, select **Submit Site Materials**.
24. Confirm that all site-specific materials have been received by selecting the checkbox in Field 2.
25. Click **OK**.
 - The pSite has now been submitted.

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:** 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. See the instructions provided above for [creating and submitting a modification](#).
- **pSite Modification:** pSite modifications provide a mechanism for submitting revisions that apply to the pSite only (e.g., submission of an additional recruitment material specific to the pSite), for review and approval. See the instructions below for [creating and submitting a site modification](#).
- **Study Continuing Review ('CR'):** Study CRs provide a mechanism to report study enrollment and research events (across all pSites) and may be required, at least annually, based on the nature of the research. Study closures are also completed via the CR process. See the instructions provided above for [creating and submitting a continuing review](#).
- **pSite Continuing Review ('CR') Data Report:** Subject enrollment and research events specific to a pSite can be submitted as a report of continuing review data. These reports are provided to the RSRB as notification only; formal approval by the RSRB for individual pSite continuing review is not provided. Once reported, study staff and the IRBC can confirm the report as complete and the enrollment data provided in the report will be added to the pSite enrollment total in the continuing review for the *study*. See the instructions below for [submitting a continuing review data report](#) and [recording site continuing review data](#). To close a site prior to study closure, contact the IRBC.
- **Report of New Information:** 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](#). See the instructions provided above for [creating and submitting reportable new information](#).

Dashboard IRB **1**

Submissions Meetings Reports Library Help Center

Create New Study

Report New Information

In-Review Department Review Active **Relying Sites 2**

Filter by ID Enter text to search for

ID	Name	Date Modified	State	PI First Name	PI Last Name
SITE00000237		5/20/2020 11:26 AM	Active		

2a

Create a Site Modification

1. Select the **IRB** module (tab).
2. Find and open the applicable study by clicking on the **Relying Sites** tab and then the name of the study [2a] (use the **External IRB** tab if creating a site modification for an External IRB study). See instructions on how to [Sort Submissions](#) and [Filter Data](#) for additional help.

Update a Multi-Site Study with Single IRB Review (Continued)

Next Steps

- View Site
- Printer Version
- Create Site Modification
- Report New Information

Modification

* What is the purpose of this submission? ?

Modification / Update

[Clear](#)

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team and research location information

Other parts of the site

- From the site workspace, click **Create Site Modification**.
 - Note:** Site Modifications for External IRB studies will be directed to an initial page regarding the purpose of the modification. Select 'Modification/Update' as the purpose and the applicable scope in the corresponding follow-up question. Click **Continue** to proceed to the next page.

- Indicate the status of local subject enrollment.
- Indicate whether subjects will be notified of the modifications (leave blank if notification is not applicable).

- If subjects will be notified, a follow-up field to identify what subset of subjects will be notified and how will appear.

- Insert a summary of the modifications included in the submission. Alternately, a document/memo summarizing the revisions may be attached in the Attach Files field.

- Click **Continue** to proceed.

- The remainder of the update form is comprised of [original site submission](#). **Note:** The submission pages available for updating are specific to the site only; updates that apply to the entire study (across all sites) must be submitted via a separate [study modification/update](#).

- To add/edit study documents, see [Update Study Documents](#).

- On the final page of the submission form, click **Finish** to exit the form.
- Once the form has been completed you may edit it prior to IRB submission by clicking **Edit Modification**.

- When you're ready to submit the form, click **Submit** from the submission workspace.

- Only PIs and PI Proxies can submit Site Modifications.**

- READ the terms provided and click **OK** to agree.

- The modification has now been submitted.

Modification Information

- Study enrollment status:** ?
 - No subjects have been enrolled to date
 - Subjects are currently enrolled
 - Study is permanently closed to enrollment
 - All subjects have completed all study-related interventions
 - Collection of private identifiable information is complete
- Notification of subjects:** (check all that apply)
 - Current subjects will be notified of these changes
 - Former subjects will be notified of these changes

3. * Summarize the modifications: ?

4. Attach Files ?

Name	Description
There are no items to display	

[+ Add](#)

[Exit](#) [Save](#) [Continue](#)

Basic Site Information

- * Short title:**
- * Local:**
- Additional Local Funding Sources**
 - Identify each organization supplying funding for the local site:
- Local Site Documents**
 - Consent forms: (include an HHS-approved sample consent document, if applicable) ?
- Ancillary Committee Review**
 - Does this research involve any of the following which may require additional institutional ancillary reviews? ?

Final Page ?

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

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

[Exit](#) [Save](#) [Finish](#)

Next Steps

- Edit Modification
- Printer Version
- Submit

Submit

By submitting this application, I certify that I will comply with all of the responsibilities and requirements of a Principal Investigator (PI) to ensure the research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable, consistent with OHSP Policy 901 Investigator Responsibilities and OHSP Policy 902 Investigator Financial Conflict of Interest.

In addition, I am aware of and will comply with the following requirements:

- To conduct the study in accordance with the approved protocol and only implement changes after receiving IRB approval, except when necessary to protect the safety, rights or welfare of subjects
- To follow University and Hospital standards of care, policies, procedures and guidelines for research conducted in a clinical/treatment setting.

To ensure all study team members are adequately informed about their obligations in meeting the above commitments.

[OK](#) [Cancel](#)

Update a Multi-Site Study with Single IRB Review (Continued)

Dashboard IRB 13

Submissions Meetings Reports Library Help Center

Create New Study Report New Information

In-Review Department Review Active **Relying Sites** 14

Filter by ID Enter text to search for

ID	Name	Date Modified	State	PI First Name	PI Last Name
SITE00000237		5/20/2020 11:26 AM	Active		

14a

Next Steps

- View Site
- Printer Version
- Create Site Modification
- Report New Information
- Assign Primary Contact
- Manage Guest List
- Report Continuing Review Data 15

Report Continuing Review Data

16

1. Specify enrollment totals at this investigator's sites:

2. Specify enrollment totals at this investigator's sites since last approval:

17

3. Check the items that are true for this site since the last IRB approval: (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect the study
- NO other relevant information
- In the opinion of the PI, the risks are minimized
- All modifications to the protocol are approved
- All problems that require prompt attention are resolved

4. Supporting documents: (include an explanation of each item left unchecked above)

5. Comments:

18 OK Cancel

CR00000018: Continuing Review

Principal investigator: Juan Pablo (pi3)
Submission type: Continuing Review
Primary contact: Juan Pablo (pi3)

Pre-Submission → Pre-Review → Clarification Requested → Review

History Contacts Documents **Sites** 19

Active Participating Sites

Filter Institution Enter text to search for

Execute Activity	Institution	Report Date	Total Enrollment
			5

History Contacts Documents Sites Related 990s Department Reviews Snapshots Training Details

Active Participating Sites

Filter by Institution Enter text to search for

Execute Activity	Institution	Report Date	Total Enrollment	Enrollment Since Last Approval	Potential Concerns	Documents	Report Completed?
					None	None	<input type="checkbox"/> no
		5/30/2019	10	10	Subjects experienced unexpected harm. SAE P...		<input checked="" type="checkbox"/> yes
					None	None	<input type="checkbox"/> no
		5/30/2019	5	5	None	None	<input checked="" type="checkbox"/> yes

20

Report CR Data

13. Select the **IRB** module (tab).
14. Find and open the applicable study by clicking on the **Relying Sites** tab and then the name of the study [14a]. See instructions on how to [Sort Submissions](#) and [Filter Data](#) for additional help.
15. From the site workspace, click **Report Continuing Review Data**.
 - For MSS undergoing sIRB review, this activity can also be accessed via the **Execute Activity** option on the **Sites** tab in the *study's* CR workspace [see images 19].
16. Enter the number of subjects enrolled at the site in total and since the last approval.
17. Select all events that apply to the site (select the checkbox if the corresponding statement is true). For each item left unchecked, provide an explanation of the event in the Comments field and/or attach documentation in the Supporting Documents field.
18. Click **OK**.
 - The continuing review data has now been reported and the submission moves to **Review Complete**; sIRB review and approval of individual pSite CR data is not required. Rather, the reported CR enrollment data should be included in the *study* CR. In order for the enrollment data to appear in the *study* CR, the site CR data needs to be recorded (see below).

Record Site CR Data

19. From the *study* CR workspace, click the **Sites** tab.
20. Under **Report Completed**, click the checkbox for the applicable pSite.
 - The pSite enrollment data will be added to the *study's* CR form.

Create and 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). 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). **Submissions should not be initiated until a reliance agreement has been executed. Note:**

- Creating and submitting this form provides for local administrative review of the study (to ensure compliance with institutional policies) only; it does not submit the study for review to the external IRB. Applications, per the external IRB's policies and procedures, can be submitted once the RSRB has completed their administrative review.
- The application form is a smart form; specific fields will appear/disappear based on preceding responses.
- The submission form collects information pertaining to the study as a whole (i.e., all participating sites, if multi-site), as well as local site-specific information. When a field references 'local' information, respond accordingly for the local, University of Rochester (UR) site.

Create an External IRB Study

1. From the Dashboard page, click the **Create** [1a] menu, expand the IRB section (if applicable), and select **Create New Study** [1b] under the IRB heading.
2. Complete the form, providing [basic information](#) about the study in Fields 1-9.
 - a. Answer yes to Field 5.
 - b. Identifying that the study is multi-site or collaborative in Field 4 provides an additional 'Lead principal investigator'. The lead PI is the individual responsible for the conduct of the research across all participating sites. **Provided the Local PI is not acting as the Lead PI (overseeing all sites), this field can be skipped.**
 - c. Click on the ellipses to enter the local, UR Principal Investigator. **Note:** This field defaults to whomever creates the submission.
3. Click **Continue** to proceed to the next page of the application.
4. Enter a description of the study activities that the local, UR site will perform.
5. Click **Continue** to proceed to the next page of the application.
6. Click on the ellipses to identify the external IRB that will review and approve the research. If the external IRB does not appear in the search box, contact the IRBC.
7. Click **Continue** to proceed to the next page of the application.

Basic Study Information

1. * Title of study: Training Manual Demo External IRB
2. * Short title: Training Manual Demo External IRB
3. * Brief description: This is a multi-site <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...
4. * What kind of study is this?
 - Multi-site or Collaborative study
 - Single-site study
5. * Will an external IRB act as the IRB of record for this study?
 - Yes
 - No
6. Lead principal investigator: [Ellipsis]
7. * Local principal investigator: [Ellipsis]
8. * Does the local principal Investigator have a financial interest related to this research?
 - Yes
 - No
9. Attach the protocol:

Document	Category	Date Modified	Document History
There are no items to display			

Basic Local Site Information

4. * Brief description of activities this site will perform: (enter 'ALL' if this site will perform all procedures in the protocol)
5. [Continue]

External IRB

6. * External IRB: [Ellipsis]
2. External study ID: [Ellipsis]
3. Specify the reason the study should be reviewed by an external IRB: [Text Area]
7. [Continue]

Dashboard

- Create [1a]
- IRB [1b]
- Create New Study
- Report New Information

Create and Submit an External IRB Study (Continued)

8

Study Funding Sources

1. Identify each organization supplying funding for the study:

Additional Local Funding Sources

1. Identify each organization supplying funding for the local site:

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

Study Scope

1. **Local Research Locations**

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

Drugs

1. List all drugs, biologics, foods, and dietary supplements to be used in the study:

Devices

1. List all devices that the study will use on the study site:

Study-Related Documents

1. **Consent form templates:** include an IRB-approved consent form template, if applicable:

Local Site Documents

1. **Consent forms:** include an IRB-approved sample consent document, if applicable:

Ancillary Committee Review

1. **Does this research involve any of the following which may require additional institutional ancillary reviews?**

- Patients with cancer
- Resources within the Clinical Research Center

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.

9

Next Steps

Edit Study **10**

Printer Version

Submit **12**

Manage Participating Sites

Assign Primary Contact **11**

Assign PI Proxy **11**

Submit

By submitting this application, I certify that I will comply with all of the responsibilities and requirements of a Principal Investigator (PI) to ensure the research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable; consistent with OHSP Policy 901 Investigator Responsibilities and OHSP Policy 902 Investigator Financial Conflict of Interest.

In addition, I am aware of and will comply with the following requirements:

1. To conduct the study in accordance with the approved protocol and only implement changes after receiving IRB approval, except when necessary to protect the safety, rights or welfare of subjects.
2. To follow University and hospital standards of care, policies, procedures and guidelines for research conducted in a clinical/treatment setting.

To ensure all study team members are adequately informed about their obligations in meeting the above commitments.

13 OK Cancel

Next Steps

Once submitted, the application will undergo administrative review as described in the introductory [overview](#) pages. When and if the IRB [requests clarifications](#), provides [comments](#) to study staff regarding the research, and/or confirms reliance with External IRB, an email notification will be provided to the PI, PI Proxy and Primary Contact.

8. Complete the remaining pages of the submission, as applicable. See [Funding Sources](#), [Local Study Team Members](#), [Study Scope](#), [Local Research Locations](#), [Drugs](#), [Devices](#), [Local Site Documents](#), and [Ancillary Committee Review](#) for additional guidance. **Note:**
 - a. The **Study Funding Sources** page should identify funding sources that apply to the *study* as a whole (i.e., across all sites, if multi-site). The **Additional Local Funding Sources** page should only identify *additional* funding for the local UR *site*.
 - b. Only documents utilized study-wide (i.e., across all sites, if multi-site) should be uploaded in the **Study-Related Documents** page. **Provided the Local PI is not acting as the Lead PI (overseeing all sites), the Study-Related Documents page can be skipped.** Documents that have been customized to include site-specific information or that apply only to the local *site* (e.g., UR-specific consent forms or recruitment material) **must** be uploaded on the **Local-Site Documents** page.
9. On the final page of the submission form, click **Finish** to exit the form.
 - **This does not submit the application.**
10. Once an application has been completed, you may edit the application prior to submission by clicking **Edit Study**.
11. Prior to submission, you may also wish to:
 - [Assign a Primary Contact](#)
 - [Assign a PI Proxy](#)
12. Once you're ready to submit the form, click **Submit** from the submission workspace.
 - **Only PIs and PI Proxies can submit new study applications.**
13. READ the terms provided and click **OK** to agree.
 - The study has now been submitted.

Update an External IRB Study

Once an External IRB study has been approved, the External IRB is responsible for reviewing and approving all follow-on submissions. RSRB administrative review of follow-on submissions prior to External IRB submission is generally *not* required. Nevertheless, follow-on submissions *may* still be submitted to the RSRB as doing so helps maintain accurate, current information for local reporting purposes.

- **Exception:** Modifications that involve revisions to the compensation for injury language must be submitted to the RSRB for review and approval prior to submission to the External IRB.

The following types of follow-on submissions can be submitted for External IRB studies:

- **Update of Study Details:** Study detail updates provide a mechanism for reporting modifications that apply to the study as a whole, across all participating sites (if multi-site). Updates should only be submitted in Click@ IRB following approval by the External IRB. Updates are provided to the RSRB as notification only; formal approval by the RSRB is not provided. See the instructions below for [Update Study Details](#).
- **Site Modifications:** Site modifications provide a mechanism for submitting and reporting modifications that apply to the local, UR pSite only. See the instructions above for [Creating a Site Modification](#). This activity *only* applies to multi-site studies; all modifications to single-site, External IRB studies are submitted via the **Update Study Details** activity.
- **Report of New Information:** 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](#). See the instructions provided above for [creating and submitting reportable new information](#).
- External IRB closures and/or deactivations can only be complete by the IRBC. Utilize the [Add Comment](#) activity to notify the IRBC.

Update Study Details

Note: Study detail updates should only be submitted following review and approval by the External IRB.

1. Select the **IRB** module (tab).
2. Find and open the applicable study by clicking on the **External IRB** tab and then the name of the study [2a]. See instructions on how to [Sort Submissions](#) and [Filter Data](#) for additional help.
3. From the study workspace, click **Update Study Details**.

Update an External IRB Study (Continued)

Study Update Information

1. * Summarize the updates: ?

4

5 Continue →

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.

9

Exit Save Finish

Next Steps

Edit Study Details 7

Printer Version

Finalize Updates 8

Finalize Updates

By signing below you are verifying that:

- You have updated the study record only to reflect what the external IRB has approved.

9 OK Cancel

4. Insert a summary of the modifications included in the update.
5. Click **Continue** to proceed to the next page of the submission form. The remainder of the update form is comprised of applicable components of the [original study submission](#). **Note:** For multi-site research, the only pages of the submission that are applicable to study as a whole will be accessible in this activity (Basic Study Information, External IRB, Funding Sources, Study Scope, Drugs, Devices, and Study-Related Documents). Submission pages that capture information specific to the local participating site are only accessible via the [Site Modification](#) activity. Click **Continue** to navigate through the form and update, as appropriate.
 - To add/edit study documents, see [Update Study Documents](#).
6. On the final page of the submission form, click **Finish** to exit the form.
 - **This does not submit the update.**
7. Once the update has been completed, you may edit it prior to finalization by clicking **Edit Study Details**.
8. When you're ready to finalize (submit) the update, click **Finalize Updates** from the study workspace.
 - **Only PIs and PI Proxies can finalize Updates.**
9. Click **OK** to affirm that you have only updated the study record to reflect what the External IRB has already approved.
 - The submission moves to **Updates Complete** and the RSRB is notified of the update.

Respond to Clarification Requests

If an IRB Reviewer has questions or requires you to change your submission, the PI, PI Proxy and Primary Contact will receive an email notification. Review the request details and then respond to the request.

The image illustrates the process of responding to clarification requests through several screenshots:

- Notification of Requested Clarifications:** An email from Jack Fletcher with a link to the submission (STUDY0000071).
- My Inbox:** A view of the submission workspace showing a list of items. The submission ID 'STUDY00004818' for 'Training Manual Demo A' is highlighted.
- Next Steps:** A menu with options: 'Edit Study', 'Printer Version', and 'Submit Response'.
- History Tab:** A view of the submission workspace with the 'History' tab selected. A 'Clarification Requested' activity is highlighted, with the message: 'Please upload revised consent documents in the study.'
- Submit Response:** A dialog box with two sections: '1. Notes:' (containing the text 'I attached the updated consent forms as requested') and '2. Supporting documents:' (with an 'Add' button and a list of documents).

Review the Requested Details

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

6. Click **Edit** (Edit Study, Edit Modification/CR, or Edit RNI).
 - Make the changes in the submission form as requested.
 - **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](#).

Submit Response

Once all requested clarifications have been made:

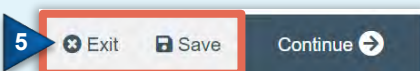
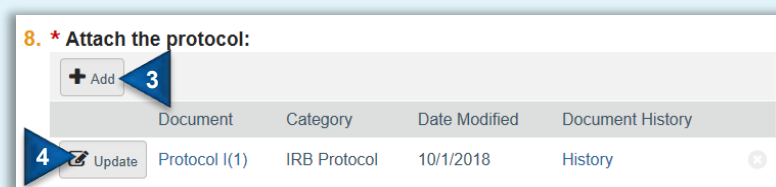
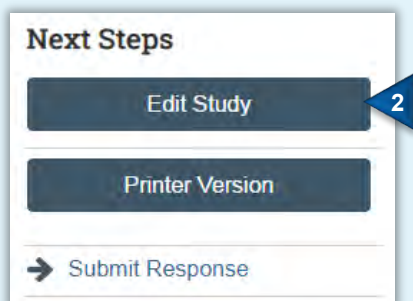
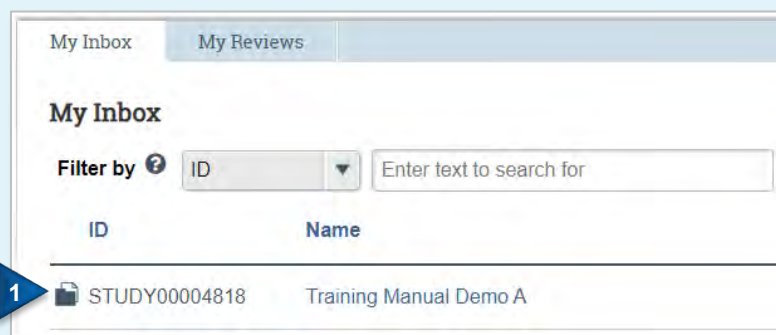
3. From the submission workspace, click **Submit Response**.
 - **Only PIs and PI Proxies can submit clarification requests.**
4. In the Notes box, provide your response to the IRB Reviewer. Indicate what changes have been made and provide additional clarifications as necessary.
 - If you have not addressed any clarifications or do not agree with request changes, provide your rationale here.
 - If you wish to provide a response via memo or wish to upload, it can be uploaded in Field 2.
 - **DO NOT upload revised/additional study documents in Field 2. All study documents that require IRB approval must be uploaded within the submission form.**
5. 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 submission any time prior to submission. Once the modification has been submitted for review, you will only be able to update documents if changes or clarifications have been requested.

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.

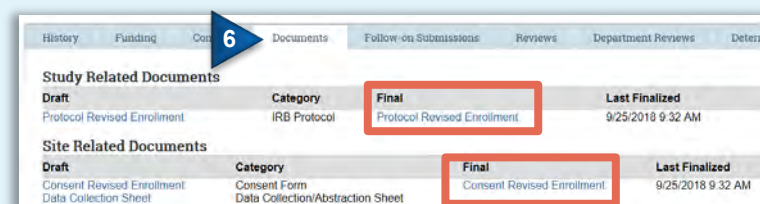


Update Study Documents

- From your inbox, open the submission you wish to edit.
 - If the submission is not in your inbox, contact the IRB Coordinator to notify them additional changes are necessary.
- From the submission workspace, click **Edit Study**.
- To add an *additional* document (i.e., a *new* document), 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**. **Do not add the updated file as an additional document and delete the outdated document** as this eliminates the document's 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.

Additional Activities

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

Assign Primary Contact **1**

Assign PI Proxy **4**

Manage Ancillary Reviews

Manage Guest List **7**

Assign Primary Contact

The Primary Contact will act as the study's main point of contact for communications. The Primary Contact will receive notifications, in addition to the PI (and PI Proxies), when the IRB communicates a determination or requires the study staff to take action. Only one primary contact can be selected for each study.

1. From the study workspace, click **Assign Primary Contact**.
2. Click on the ellipses to select the primary contact.
 - **The individual selected 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.**
3. Click **OK**.

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.**

4. From the study workspace, click **Assign PI Proxy**.
5. Click on the ellipses to select the PI Proxy.
 - **Only study team members identified in the submission can be assigned the PI Proxy role.**
6. Click **OK**.

Manage Guest List

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

7. From the study workspace, click **Manage Guest List**.
8. Click on the ellipses to select applicable individuals.
9. Click **OK**.

Additional Activities (Continued)

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.**

- From the submission workspace, click **Add Comment**.
- Insert your comment.
- If applicable, add supporting documentation.
- Select the roles related to the submission that you want notified of the comment.
- Click **OK**. The comment will appear on the History tab and the individuals selected in Field 3 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.

Copy a Submission

Existing study submissions may be copied into a new study submission for IRB review and approval.

- From the study submission workspace, click **Copy Submission**.
- Enter the name of the new submission.
- Click **OK**.
- 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.**

Next Steps

- View Study
- Printer Version
- Create Modification/CR
- Report New Information
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Copy Submission

Add Comment

Your comment is visible to anyone who has access to this submission.

- 1. Comment:** [Text area]
- 2. Supporting documents:**
 - + Add

Name	Description
There are no items to display	
- 3. Who should receive an e-mail notification?**
 - PI/PI Proxy/Primary Contact
 - Study Team
 - IRB Coordinator

14 OK Cancel

Copy Submission

This activity copies your submission. You remain the principal investigator for the new submission, and it appears in your inbox.

*** New submission name:** [Text input]

16

17 OK Cancel

History | Funding | Contacts | Documents

Filter by [Activity] [Enter]

Activity

- Copied Submission
- New Copy: STUDY00003086 Co... 18 New

My Inbox

Filter by [ID] [Enter]

ID	Name
STUDY00003086	Copied New Study 18

Additional Activities (Continued)

Next Steps

Edit Study

Printer Version

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant 19

Add Comment

Copy Submission

Withdraw 25

Discard 28

Add Related Grant

1. Related grants

20

Grant ID	Grant Title	
GrantID123456	Demo Grant	24 <input type="button" value="X"/>

23

Add IRB Grant Info

Grant Information

21 1. Grant ID:

2. Grant title:

* Required

Withdraw

Discontinue the IRB's review of this submission?

The submission will be returned to the Pre-Submission state where you can choose to change and resubmit it.

1. Comments:

2. Supporting documents:

Name

There are no items to display

27

Discard

Discard submission?

Caution: This activity will permanently remove the submission.

29

Add Related Grant

Grants may be added or removed from study submissions.

- From the submission workspace, click **Add Related Grant**.
- Click **Add**.
- Enter the grant ID and title and click **OK**.
- Click **OK**.
- To updated associated grants, click **Update**.
- To remove associated grants, click the **X** to the right of the grant title.

Withdraw

Submissions 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).

- From the submission workspace, click **Withdraw**.
- Enter a comment, providing the reason for withdrawal and attach any applicable supporting documents.
- Click **OK**.
 - Once withdrawn, the submission will move to a Pre-Submission state where it can be revised and re-submitted or discarded (it will appear in your inbox and under the In-Review tab).

Discard

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

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

Quick Reference Guide: Study Submission Checklist

In preparing to submit a new study, gather the following information/documents to include in your IRB 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, contacted your IRB Coordinator.:

Basic Information:

- [Study protocol](#) and any applicable site-specific supplements and/or addendums
- Study team members (for guidance on who should be added as research personnel see [OHSP's Guideline for Listing Research Personnel on the RSRB Application](#)):
 - ✓ For each study team member, verify whether they have a financial interest related to the research. If yes, obtain a copy of their Conflict of Interest Management Plan.
 - ✓ For external study team members, obtain documentation of their [current human subject protection training](#).
- Funding sources
- Research locations (i.e., non-UR locations where research activities will be conducted by UR faculty/staff)
- ClinicalTrials.gov registration number, if applicable

Drug Details (if applicable):

- Drug name
- Package insert or investigators brochure
- If the study is being conducted under an IND:
 - ✓ IND number, IND holder
 - ✓ Drug management and accountability plan, if not included in the study protocol
 - ✓ Verification from the FDA (or sponsor) of the IND
 - ✓ If PI is IND holder: documentation of required IND training via the [CTSI Office of Regulatory Support](#)

Device Details (if applicable):

- Device name
- Manufacturers brochure/device instructions
- If the study is being conducted under an IDE/HDE:
 - ✓ IDE/HDE number, IDE/HDE holder
 - ✓ Device management and accountability plan, if not included in the study protocol
 - ✓ Verification from the FDA (or sponsor) of the IDE/HDE
 - ✓ If PI is IDE holder: documentation of required IDE training via the [CTSI Office of Regulatory Support](#)

Study & Local Site Documents:

- All [consent, permission and assent forms](#), as applicable
 - ✓ All consent, permission and assent forms should be submitted on UR letterhead.
 - ✓ For studies undergoing review by an External IRB, ensure all consent and permission forms have been edited to include local, site-specific information (minimally this includes local site contact information and [template, UR language](#) for the HIPAA authorization and compensation for injury).
 - All recruitment materials (i.e., all direct advertising materials that may be seen/heard by potential subjects), as applicable
 - All study measures (e.g., surveys/questionnaires, interview/focus group scripts, behavioral assessments, diaries)
 - ✓ If the research involves a secondary analysis, include a data collection sheet that identifies all data points that will be collected
 - All supplemental subject educational materials, including any instructions/information sheets (e.g., concerning drug administration)
 - Completed [Data Security Assessment Form](#), if data will be collected, transmitted or stored electronically
 - Certificate of confidentiality, if applicable
 - *For multi-site research undergoing local, single IRB review by the RSRB*, gather all *model* consent forms, recruitment materials and any other study-specific templates that will be distributed for use at each participating site.
- ### Ancillary Review Documents (if applicable):
- [Surgical Pathology Request for Human Tissues Form](#)
 - [Human Use of Radiation Committee Research Form](#)

Quick Reference Guide: Ancillary Committee Review

As defined by [OHSP Policy 503 Ancillary Committee Reviews](#), the table below summarizes what Ancillary Committee reviews are required and when. The table also identifies when Ancillary Committee approval is required in relation to IRB review.

Ancillary Committees requiring approval prior to IRB *review* should not progress beyond Pre-Review without Ancillary Committee approval. Ancillary Committees requiring approval prior to IRB *approval* should not progress beyond Post-Review without Ancillary Committee approval.

The following Ancillary Committees require notification only (meaning the Ancillary Committee must be notified of the research but a **response is not required** prior to IRB review or approval): Clinical Research Center; Investigational Drug Service (IDS); Highland Hospital*; FF Thompson*.

If the study involves...	Approval is required by...	When...	Additional review(s)...
Enrolling individuals with cancer or reviewing patient health information generated by the Cancer Center [^]	Cancer Center Peer Review Committee (PRC)	Prior to IRB Review	Modifications, as appropriate
Pregnant to post-partum women	Obstetrical Research Committee (ORC)	Prior to IRB Review	N/A
Study procedures on hospitalized newborns in the Birth Center, Newborn Nursery, or Neonatal Intensive Care Unit	Neonatal Clinical Trials Group (NCTG)	Prior to IRB Review	N/A
Administration of radiation therapy at UMRC & Affiliates [^]	Department of Radiation Oncology Review Committee (DROIPR)	Prior to IRB Review	Modifications, as appropriate
Enrolling patients in the Emergency Department [^]	Emergency Medicine Research Committee (EMRC)	Prior to IRB Approval	Modifications Annual re-approval
<ul style="list-style-type: none"> • Introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.) into human subjects • Cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects • Introduction of genetically engineered micro-organisms into human subjects • Biohazardous organisms or materials handled at Biosafety Level 2 or higher 	Institutional Biosafety Committee	Prior to IRB Approval	N/A
Obtaining fresh, banked or archived human tissue	Surgical Pathology	Prior to IRB Approval	N/A
Radioisotopes or radiation-generating devices used for research purposes	Human Use of Radiation Committee (HURC) / Radiation Safety	Prior to IRB Approval	Annual re-approval
Access to the Center for Advanced Brain Imaging & Neurophysiology (CABIN)	Center for Advanced Brain Imaging & Neurophysiology (CABIN)	Prior to IRB Approval	N/A

[^]When a study requires review by the PRC, DROIPR or EMRC and the PI's primary appointment is the Cancer Center, Radiation Oncology, or Emergency Medicine, respectively, further review by the Ancillary Committee is not required; Department Review and approval is sufficient.

Quick Reference Guide: Watermarked Documents

During the approval process (Post-Review), the IRBC prepares a final version of the documents supporting a submission. Finalizing a document: a) creates a PDF version of the document; b) identifies the document on the approval letter; and c) watermarks documents, as applicable.

Watermarks are applied per Click® IRB programming, based upon the field in which a document is uploaded and the category applied to the document as identified below (e.g., a document uploaded in the Consent Forms field and identified as an Assent Form).

All watermarks appear in the lower right-hand corner of a document; the location of the watermark cannot be manually adjusted. To ensure the watermark is not obstructed, **study teams to use a 1-inch footer (minimally) on all consent and recruitment documents and to leave the right-hand space of a document footer blank.** In the event a consent/recruitment document watermark is missing or does not appear to be accurate, contact the IRB Coordinator.

Note: Watermarks for studies that do not require continuing review will not include an expiration date (the expiration date field will appear blank).

Documents Watermarked with Approval & Expiration Dates

- Consent Form
- Parental Permission Form
- Consent to Procedures; Consent to Data Use (Deception Studies)
- Short Form

Documents Watermarked with Approval Date Only

- Assent Form
- Assent Script
- Consent Addendum
- Information Sheet
- Verbal Script
- Recruitment Brochure
- Recruitment Flyer
- Recruitment Email
- Recruitment Poster
- Radio/TV/Newspaper Ad
- Recruitment/Information Letter
- Research Match
- Social Media Post
- SON
- Telephone or Announcement Script
- Other Recruitment Materials

Watermark Example (Consent Form)

OFFICE FOR HUMAN SUBJECT PROTECTION
Research Subjects Review Board

UNIVERSITY OF ROCHESTER

CONSENT FORM

Test Study Title

Principal Investigator: Test Principal Investigator

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because...
- The purpose of this study is...
- Your participation in this study will last for about...
- Procedures will include... Some of these procedures may be optional.
- There are risks from participating.
 - The most common risk is...
 - One of the most serious risks is ... See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You might not benefit from being in this research study. The potential benefit to you might be...

Purpose of Study
The purpose of this study is to...

Description of Study Procedures
If you decide to take part in this study, you will be asked to...

Information health reco
with the stu

RSRB Approval Date: 10/12/2018
Expiration Date: 10/11/2019

Number of
Approximately x subjects will take part in this study.

Risks of Participation
The risks...

Study#12345 Page 1 of 5

RSRB Approval Date: 10/12/2018
Expiration Date: 10/11/2019

Quick Reference Guide: Submitting to the RSRB

Obtain Access to Click IRB®

- Complete human subject protection training via CITI.
 - Internal research personnel must use their UR email to register for CITI account.**
- Approximately 1-2 business days, UR faculty, staff & students will receive a user account confirmation email approximately 1-2 business days.

Log In to Click IRB®

- Go to <http://rochesterirb.huronresearchsuite.com/>.
- Select your UR affiliation.
- User your UR active directory credentials to log in (i.e., the credentials used to log into your computer/access your email).

Create & Submit a New Study

- From your dashboard, click **Create**, expand the IRB section (if applicable) and select **Create New Study** under the IRB heading.
- Complete the submission form.
 - Programming within the form will add/remove questions based on preceding responses.
 - Complete all required (*) fields.
 - Navigate through the submission form using the 'Back' and 'Continue' buttons.
 - Use the help text (? icon), when indicated, for additional guidance.
- On the final page of the submission form, click **Finish** to exit.
- To edit a form prior to submission, from the study workspace, click **Edit Study**.

Adding & Updating Study Documents

To add documents:

- Within the submission form, as directed, click **Add**.
- In the pop-up box, click **Choose File** to find and attach the applicable file.
- Insert a document name. **Do not rely on the file name to adequately identify the document.** Click **OK**.

To update existing documents:

- Find the existing document within the submission form and click **Update** (to the left of the document name). **Do not add the updated file as an additional document.**
- In the pop-up box, click **Choose File** to find the updated document and attach the applicable file. Click **OK**.

Submitting a New Study

Once the study submission form is completed, it must be submitted for review. **Submissions can only be submitted by Principal Investigators (PI) and PI Proxies.**

- From the study workspace, click **Submit**.
- Read the terms provided and click **OK** to agree.

Respond to Clarification Requests

- From the study workspace, review the requested clarifications in the **History** tab.
- Click **Edit Study** and make the requested changes.
- Once all requested changes have been made, click **Submit Response**.
- Provide a response to the reviewer in the Notes box and click **OK**.

Assign a PI Proxy & Primary Contact

PI Proxies can perform PI activities in Click® IRB on the PI's behalf (e.g., submit studies). Only the PI can assign PI Proxies and only study team members identified within a study can be assigned this role.

- To assign a PI Proxy, click **Assign PI Proxy** in the study workspace.

A Primary Contact acts as the study's main point of contact and receives notifications from the IRB in addition to the PI and assigned PI Proxies. Only one Primary Contact can be identified per study.

- To assign a Primary Contact, click **Assign Primary Contact** in the study workspace.

Find Approved Study Documents

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

Draft	Category	Final	Last Finalized	Document History
Protocol Revised Enrollment	IRB Protocol	Final	9/25/2018 9:32 AM	History

Draft	Category	Final	Last Finalized	Document History
Consent Revised Enrollment	Consent Form	Final	9/25/2018 9:32 AM	History
Data Collection Sheet	Data Collection/Abstraction Sheet			

Submit a Follow-On Submission

Once a study has been approved, from the study workspace you may submit:

- Modification (Mod) – changes or updates approved studies
- Continuing Review (CR) – routine review (progress report) of approved studies
- Mod/CR – a combined modification and continuing review
- Reportable New Information – reports new information on approved studies