Click® IRB: Study Staff Manual

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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:

<table>
<thead>
<tr>
<th>IRB Submission Types</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Submissions</strong></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>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.</td>
</tr>
<tr>
<td>Site</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Follow-on Submissions</strong></td>
<td></td>
</tr>
<tr>
<td>Modification (Mod)</td>
<td>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.</td>
</tr>
<tr>
<td>Continuing Review (CR)</td>
<td>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.</td>
</tr>
<tr>
<td>Modification and Continuing Review (Mod/CR)</td>
<td>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.</td>
</tr>
<tr>
<td>Reportable New Information (RNI)</td>
<td>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).</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Position</th>
<th>Typical Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancillary Reviewer</td>
<td>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 Policy 503 Ancillary Committee Reviews).</td>
</tr>
<tr>
<td>Committee Administrator</td>
<td>An individual responsible for managing committee meetings.</td>
</tr>
<tr>
<td>Committee Chair (CC)</td>
<td>An IRB committee member assigned to chair the committee.</td>
</tr>
<tr>
<td>Committee Member (CM)</td>
<td>Individuals on an IRB committee that are responsible for reviewing submissions.</td>
</tr>
<tr>
<td>Committee Reviewer (CR)</td>
<td>The individuals assigned to review and present a submission at a committee meeting (i.e., primary reviewer).</td>
</tr>
<tr>
<td>Department Reviewer</td>
<td>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).</td>
</tr>
<tr>
<td>Designated Reviewer (DR)</td>
<td>An IRB chair or experienced IRB committee member, designated by the chair, to conduct reviews of newly submitted studies and follow-on submissions.</td>
</tr>
<tr>
<td>IRB Coordinator (IRBC)</td>
<td>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.</td>
</tr>
<tr>
<td>IRB Director (IRBD)</td>
<td>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.</td>
</tr>
<tr>
<td>Guest</td>
<td>Study staff may add guests to a study to permit read-only access.</td>
</tr>
<tr>
<td>Primary Contact</td>
<td>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.</td>
</tr>
<tr>
<td>Principal Investigator (PI)</td>
<td>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.</td>
</tr>
<tr>
<td>PI Proxy</td>
<td>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.</td>
</tr>
<tr>
<td>Registered User</td>
<td>Users authorized to create submissions.</td>
</tr>
<tr>
<td>Study Staff (SS) / Study Team (ST)</td>
<td>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).</td>
</tr>
</tbody>
</table>
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 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:

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

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

Overview of the External IRB Submission Process

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

1. The study is submitted to Click® IRB for institutional review (as described below). This process ensures compliances with institutional policies and allows the institution to track research that isn’t reviewed locally.

2. Once the RSRB’s institutional review is complete, the study is submitted to the External IRB for review and approval per their standard operating procedures. Upon approval of the research, all further review of the research (modifications and continuing review) is deferred to the External IRB.

Note: It is best practice to wait to initiate 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

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.

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.

Get Help

7. Help text is available anytime you see a ? icon. Click on the icon to review the help text.
Navigation and Basic Tasks (Continued)

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 refer 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

21. Dashboard

20. Measurments

19. IRB

18. Library

17. Help Center

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.
   - **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 RNI 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).

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)
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 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.

Create a 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. Within the submission form:
   a. Navigate through the form using the ‘Continue’ button on the floating navigation bar.
   b. 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.
   c. All * fields are required.
   d. Help text is available anytime you see a ? icon. Click on the icon to review the help text

Basic Study Information

3. 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.

4. Indicate the study type.

5. 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. Click on the ellipses to enter a Principal Investigator. **Note:** This field defaults to whomever creates the submission.

7. 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.

8. Click **Add** to attach the study protocol.

9. 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.

- The version number entered into Field 3 must be numeric (no dates). If your protocol version includes a date or other version format, leave the field blank (a default version will be set).

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

### Study Funding Source

11. 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.

12. 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**.

13. Enter sponsor funding ID, grants office ID and attach grant applications, as applicable.

14. Click **OK**.

15. Click **Continue** to proceed to the next page of the application.
Create and Submit a Study (Continued)

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)

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.
   - Enter numerical information only; including the ‘NCT’ prefix will prevent the entire identification number from being entered.

30. Click Continue to proceed to the next page of the application.

Local Research Locations

31. Click Add to add research locations.
   - **If there are no additional research locations, SKIP this section.**
   - Include Highland Hospital & FF Thompson, if applicable.
   - See the Help Text (?) icon for additional information on what constitutes a research location.

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

**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

**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

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

49. Click **Add** in the section that corresponds to the type of document being attached.

50. 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.

51. Select the category (type) of document uploaded.

52. Click **OK**.

53. Once all documents have been added, click **Continue** to proceed to the next page of the application.

Ancillary Committee Review

54. Indicate whether the research requires review by any of the UR Ancillary Committees listed (see quick reference guide for additional information).

- **a.** Answering yes, will provide several follow-up questions that correspond to each type of Ancillary Committee. **All** questions require a response.

- **b.** 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).

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

Final Page

56. Click **Finish** to exit the form.

- **This does not submit the application.**
Create and Submit a Study (Continued)

Submit a Study Submission

57. Once an application has been completed, you may edit the application prior to submission by clicking 

58. 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
- Add Related Grant
- Add Comment

59. When you’re ready to submit the study, click Submit from the study workspace.

- Only PIs and PI Proxies can submit new study applications.

60. 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 ≠ 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 require 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.
5. Selecting Mod or Mod & CR will provide a follow-up question regarding the modification scope, select the checkboxes that apply.
   - 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.
Create and Submit a Modification or Continuing Review (Continued)

**Complete a CR Form**

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

11. 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.

12. 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.

7. **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).

8. 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.

9. **Identify whether any new subjects have enrolled since the previous review that required a signed consent document?** 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.

10. 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)

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; Devices; Local Site Documents; Ancillary Committees.

   • To add/edit study documents, see Update Study Documents.
Create and Submit a Modification or Continuing Review (Continued)

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.

Create an RNI

1. 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.

2. Enter a RNI short title.

3. Enter the date you became aware of the event/new information.

4. Select they type(s) of event/new information.

5. Provide a description of the event/new information. **Note:** A memo and/or other supporting documentation may also be uploaded into Field 7.

6. 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.

7. 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.

8. Click Continue when done.
   - **This does not submit the RNI.**

9. Once the form has been completed, you may edit it prior to IRB submission by clicking Edit RNI.

10. When you’re ready to submit the form, click Submit RNI from the submission workspace.

11. 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.

Create a Multi-Site 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.
   - 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.

3. Click Continue to proceed to the next page of the application.

4. Identify funding sources by click Add and click Continue to proceed to the next page of the application.

5. 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)

6. Complete the Study Scope page and click Continue to proceed to the next page of the application.

7. 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.

8. 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.

9. 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.

10. 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.

11. Indicate whether the research requires review by any of the UR Ancillary Committees. Click Continue to proceed to the next page of the application.

12. 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.

16. 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;
   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

17. 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)

18. 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.
   - If the Institutional Profile and/or PI do not appear in the database contact the IRBC.

19. 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**

20. From the study workspace, select the ‘Sites’ tab.

21. To open the pSite submission form:
   a. Click on the name of the pSite submission. The pSite workspace will open. Click Edit Site. OR
   b. To jump to the pSite submission, click on the icon under the ‘SmartForm’ heading and select the Basic Site Information page.

22. 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.

23. 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)

Submit Site Materials

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

25. Confirm that all site-specific materials have been received by selecting the checkbox in Field 2.

26. 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.

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)

3. From the site workspace, click **Create Site Modification**.
   
a. **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.

4. Indicate the status of local subject enrollment.

5. 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.

6. 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.

7. Click **Continue** to proceed.

8. 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**.

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

10. Once the form has been completed you may edit it prior to IRB submission by clicking **Edit Modification**.

11. When you’re ready to submit the form, click **Submit** from the submission workspace.
   
   - **Only PIs and PI Proxies can submit Site Modifications**.

12. READ the terms provided and click **OK** to agree.
   
   - The modification has now been submitted.
Update a Multi-Site Study with Single IRB Review (Continued)

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 whichever 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.
Create and Submit an External IRB Study (Continued)

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) should 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.

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.
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)

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 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.

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.

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.

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.
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

1. 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.

2. From the submission workspace, click Edit Study.

3. To add an additional document (i.e., a new document), find the appropriate location within the submission form and click Add.

4. 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.

5. 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

6. 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

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.

10. From the submission workspace, click Add Comment.

11. Insert your comment.

12. If applicable, add supporting documentation.

13. Select the roles related to the submission that you want notified of the comment.

14. 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.

15. From the study submission workspace, click Copy Submission.

16. Enter the name of the new submission.

17. Click OK.

18. 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.
### Additional Activities (Continued)

#### Add Related Grant
Grants may be added or removed from study submissions.

19. From the submission workspace, click **Add Related Grant**.
20. Click **Add**.
21. Enter the grant ID and title and click **OK**.
22. Click **OK**.
23. To updated associated grants, click **Update**.
24. 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).

25. From the submission workspace, click **Withdraw**.
26. Enter a comment, providing the reason for withdrawal and attach any applicable supporting documents.
27. 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.

28. From the submission workspace, click **Discard**.
29. 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, contact 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

- **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
  - 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

- **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
  - Any additional instructions/information sheets concerning drug administration that will be provided to the subject

- **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
  - Any additional instructions/information sheets concerning use of the device that will be provided to the subject
**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*.

<table>
<thead>
<tr>
<th>If the study involves…</th>
<th>Approval is required by…</th>
<th>When…</th>
<th>Additional review(s)…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolling individuals with cancer or reviewing patient health information generated by the Cancer Center^</td>
<td>Cancer Center Peer Review Committee (PRC)</td>
<td>Prior to IRB Review</td>
<td>Modifications, as appropriate</td>
</tr>
<tr>
<td>Pregnant to post-partum women</td>
<td>Obstetrical Research Committee (ORC)</td>
<td>Prior to IRB Review</td>
<td>N/A</td>
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<tr>
<td>Study procedures on hospitalized newborns in the Birth Center, Newborn Nursery, or Neonatal Intensive Care Unit</td>
<td>Neonatal Clinical Trials Group (NCTG)</td>
<td>Prior to IRB Review</td>
<td>N/A</td>
</tr>
<tr>
<td>Administration of radiation therapy at UMRC &amp; Affiliates^</td>
<td>Department of Radiation Oncology Review Committee (DROIPR)</td>
<td>Prior to IRB Review</td>
<td>Modifications, as appropriate</td>
</tr>
<tr>
<td>Enrolling patients in the Emergency Department^</td>
<td>Emergency Medicine Research Committee (EMRC)</td>
<td>Prior to IRB Approval</td>
<td>Modifications Annual re-approval</td>
</tr>
<tr>
<td>• Introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.) into human subjects</td>
<td>Institutional Biosafety Committee</td>
<td>Prior to IRB Approval</td>
<td>N/A</td>
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<tr>
<td>• Cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects</td>
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<td>• Introduction of genetically engineered micro-organisms into human subjects</td>
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<td>• Biohazardous organisms or materials handled at Biosafety Level 2 or higher</td>
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<tr>
<td>Obtaining fresh, banked or archived human tissue</td>
<td>Surgical Pathology</td>
<td>Prior to IRB Approval</td>
<td>N/A</td>
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<tr>
<td>Radioisotopes or radiation-generating devices used for research purposes</td>
<td>Human Use of Radiation Committee (HURC) / Radiation Safety</td>
<td>Prior to IRB Approval</td>
<td>Annual re-approval</td>
</tr>
<tr>
<td>Access to the Center for Advanced Brain Imaging &amp; Neurophysiology (CABIN)</td>
<td>Center for Advanced Brain Imaging &amp; Neurophysiology (CABIN)</td>
<td>Prior to IRB Approval</td>
<td>N/A</td>
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</table>

^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).

<table>
<thead>
<tr>
<th>Documents Watermarked with Approval &amp; Expiration Dates</th>
<th>Watermark Example (Consent Form)</th>
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<tbody>
<tr>
<td>• Consent Form</td>
<td>![Watermarked Consent Form]</td>
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<tr>
<td>• Parental Permission Form</td>
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<td>• Consent to Procedures; Consent to Data Use (Deception Studies)</td>
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<tr>
<td>• Short Form</td>
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<tr>
<th>Documents Watermarked with Approval Date Only</th>
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<tbody>
<tr>
<td>• Assent Form</td>
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<td>• Assent Script</td>
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<td>• Consent Addendum</td>
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<td>• Information Sheet</td>
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<td>• Verbal Script</td>
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<td>• Recruitment Brochure</td>
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<td>• Recruitment Flyer</td>
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<td>• Recruitment Email</td>
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<td>• Recruitment Poster</td>
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<td>• Radio/TV/Newspaper Ad</td>
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<td>• Recruitment/Information Letter</td>
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<td>• Research Match</td>
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<td>• Social Media Post</td>
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<td>• SON</td>
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<td>• Telephone or Announcement Script</td>
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<td>• Other Recruitment Materials</td>
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</table>
### Quick Reference Guide: Submitting to the RSRB

#### Obtain Access to Click IRB®

1. Complete human subject protection training via CITI.
   - Internal research personnel must use their UR email to register for CITI account.
2. 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®

2. Select your UR affiliation.
3. Use 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

1. From your dashboard, click **Create**, expand the IRB section (if applicable) and select **Create New Study** under the IRB heading.
2. 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.
3. On the final page of the submission form, click **Finish** to exit.
4. To edit a form prior to submission, from the study workspace, click **Edit Study**.

#### Adding & Updating Study Documents

**To add documents:**

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

**To update existing documents:**

4. 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.**
5. In the pop-up box, click **Choose File** to find the updated document and attach the applicable file. 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.

1. 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.

1. 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.

#### 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.**

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

#### Respond to Clarification Requests

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

#### 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