Click® IRB: Ancillary Reviewer Manual

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Introduction

This guide covers information and tasks relevant to ancillary review activities (per Office for Human Subject Protection [OHSP] Policy 503 Ancillary Committee Reviews).

For information related to single-site study, multi-site study, and follow-on submissions, see Click® IRB: Study Staff Manual.

Note: A 1-page Quick Reference Guide summarizing Ancillary Reviewer activities is available on the final page of this manual.

Overview of the Click® IRB System

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

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<th>IRB Submission Types</th>
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<td><strong>Type</strong></td>
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<td><strong>Initial Submissions</strong></td>
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<td>Reportable New Information (RNI)</td>
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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:

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<th>Roles</th>
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<td>Ancillary Reviewer</td>
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<tr>
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Roles

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<tr>
<th>Position</th>
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<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)</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 a 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 Scientific Review Standards. 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: The system does not prevent a submission from being reviewed or approved by the RSRB if an ancillary review is outstanding. 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:

**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.
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:
- 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.

My Inbox

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

3. Submissions that require your action (i.e., submissions assigned for Ancillary Committee review). If an Ancillary Reviewer also conducts research, this will also include submissions that have been initiated but not yet submitted and submissions that have been submitted for review but have been sent back for clarification.
  - The type of submission can be identified by the ID prefix (e.g., a ‘STUDY’ prefix indicates the submission is a study, a ‘MOD’ prefix indicates the submission is a modification, etc.).

4. Actions you can perform, such as create a new study or report new information.

5. Shortcuts that provide access to other items, such as the submissions, meetings, and reports you can view.
Navigation and Basic Tasks (Continued)

Sort Submissions

To sort data on a page:

6. Prioritize submissions by sorting the headings provided (e.g., ID, date modified, or state).

7. Submissions can also be identified and/or sorted using the filter function (see additional information on filtering data below).

Filter Data

To filter data on a page:

8. Select the column to filter by.

9. 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).

10. Click Go to apply the filter.

11. To combine multiple filter criteria, click Add Filter.

12. To clear a filter, select Remove Filter or Clear All to remove all filters.

Open a Submission

From your inbox (or any other tab):

13. Click the submission name.

14. The submission workspace opens.

Get Help

15. Help text is available anytime you see a ? icon. Click on the icon to review the help text.
16. Click the **Submissions** shortcut or the **IRB** tab.

17. 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 submissions.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.
   - **New Information Reports**: All Reportable 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.

18. Click the name of the submission to open the submission workspace. To navigate within a submission, see the **Study & Follow-On Submission Workspace** below.
Navigation and Basic Tasks (Continued)

Study & Follow-on Submission Workspace

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

19. Submission state and details pertaining to the submission (e.g., submission date, initial approval date, approval end date)

20. Webpage breadcrumb
   - When reviewing follow-on submissions, the breadcrumb can be used to navigate to the related study’s workspace

21. 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)

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.

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 application as well as individuals with guest access.

- **Documents**: Identifies all study and site related documents, including final approved and watermarked versions.

- **Sites**: Identifies all participating sites undergoing single IRB review by the RSRB (for multi-site studies only).

- **Follow-On Submissions**: Lists all Mods, CRs, Mod/CRs, and RNIs related to the submission.

- **Reviews**: Identifies the status of Ancillary and IRB Reviews.

- **Department Reviews**: Identifies all requested and completed department 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).
Perform an Ancillary Review

Ancillary Committee reviews are facilitated by the IRBD and/or IRBC in accordance with OHSP Policy 503 Ancillary Committee Review: a quick reference guide identifying when Ancillary Review is required in relation to IRB review is available in the appendices.

When a study is submitted to the IRB for review, the IRBD will select the applicable Ancillary Committee, based on the information provided in the application, and submit for review. All assigned reviewers for the selected Ancillary Committee will receive an email notification alerting them to the submission. In some cases, in lieu of selecting a committee and notifying all reviewers of the submission, the IRBD can select one specific Ancillary Reviewer to conduct the review (in which case, only the selected reviewer will receive the email notification concerning the review). Additional or further Ancillary Review may also be requested by the IRBD or IRBC at any point during the review process, as well as at any point during the review process for follow-on submissions.

Find the Submission

To open a submission that requires Ancillary Review, you may:
1. Click the link in your notification email. You will be directed to log in and then automatically routed to the study workspace for the submission that requires review.

OR

2. If the submission requires Ancillary Review prior to IRB review or approval, you can access your submission via your Inbox. From your inbox, click the submission name and the study workspace will then open.

3. If the submission does not require a response to Ancillary Review prior to IRB review or approval (i.e., you receive notification only), the submission will not appear in your inbox. To access a submission:
   a. Click the Submissions shortcut or the IRB tab.
   b. Within the IRB module, select one of the following tabs:
      - In-Review: Submissions undergoing IRB review.
      - Active: All internally approved studies and exempt research (including projects deemed not research or not human subject research), as well as lapsed submissions.
      - All Submissions: All in-review, active and archived submissions, in any state.
Perform an Ancillary Review (Continued)

Perform a Review

From the study workspace, you can view the submission and its documents by selecting:

4. **View Study**: Opens the submission form. Click **Continue** to navigate through the pages.

5. **Printer Version**: Shows the submission in one scrollable page.

6. **Navigation Tabs**: Pulls specific information from the submission form and/or completed activities (e.g., Documents, Funding, Training Details).

**Note**: The Click® IRB Study Staff Manual provides detailed information on how each page of the submission form should be completed.

Submit Ancillary Review

After you have finished reviewing the submission, submit the Ancillary Review. Completing this form documents your review and approval of the research, commensurate with OHSP Policy 503 Ancillary Review Committees.

7. From the submission workspace, click **Submit Ancillary Review**.

8. In the corresponding pop-up box, select the Ancillary Committee for which you are reviewing.

9. Indicate whether you accept the proposed study.
   - If you answer no, comments should be provided in the field below. Alternately, comments can be provided via the **Add Comments** activity.

10. Insert any comments concerning the proposed study.

11. Upload any supporting documentation.

12. Click **OK**.

13. The Ancillary Review will be marked as completed on the Reviews navigation tab in the study workspace.
### Additional Activities

#### Add Comment

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

1. From the submission workspace, click **Add Comment**.
2. Insert your comment.
3. If applicable, add supporting documentation (e.g., a memo from the study team, supporting literature, email documentation).
4. If applicable, select the roles related to the submission that you want notified of the comment. Once the comment is submitted, those selected will receive an email notification concerning the comment.
5. 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.
**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** (new study submissions requiring Ancillary Committee approval prior to IRB review will generally not be assigned to an IRBC until the necessary Ancillary Committee approval has been granted). **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*.

*Study teams conducting research at Highland Hospital and FF Thompson must identify these sites as Research Locations; a separate question concerning review by these oversight committee does not appear on the Ancillary Committee page of the submission form. Nevertheless, these committees must still be notified of research conducted at their respective locations via the [Manage Ancillary Reviews](#) activity.

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<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</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>
</tr>
<tr>
<td>Study procedures on hospitalized newborns</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</td>
<td>Prior to IRB Review</td>
<td>N/A</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>
</tr>
<tr>
<td>• Cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects</td>
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<tr>
<td>• Introduction of genetically engineered micro-organisms into human subjects</td>
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<tr>
<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>
</tr>
<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; formerly RCBI)</td>
<td>Center for Advanced Brain Imaging &amp; Neurophysiology (CABIN; formerly RCBI)</td>
<td>Prior to IRB Approval</td>
<td>N/A</td>
</tr>
</tbody>
</table>

^When a study requires review by the PRC or EMRC and the PI’s primary appointment is the Cancer Center or Emergency Medicine, respectively, further review by the Ancillary Committee is not required; department review and approval is sufficient.
## Quick Reference Guide: Perform an Ancillary Review

### Log into 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).

### Perform a Review

From the submission workspace, you can view the proposal and its documents by selecting:

1. **View Study**: Opens the submission form; click Continue to move through the pages.
2. **Printer Version**: Shows the entire submission in one scrollable page.
3. Additional information is also available on the tabs provided in the navigation toolbar (e.g., Funding, Documents, Training Details, etc.).

### Find the Submission

1. From the Ancillary Review notification email, click the study link to open the submission workspace.

OR

If the submission requires Ancillary Review *prior to IRB review or approval*:

2. Log into Click® IRB and, from your inbox, click on the name of the submission.

If the submission does *not* require Ancillary Review *prior to IRB review or approval* (i.e., the Clinical Research Center, Investigational Drug Service, Highland Hospital or FF Thompson):

3. Log into Click® IRB and, from your inbox, click the **Submissions** shortcut or the **IRB** tab.
4. Within the IRB module, select one of the following tabs to locate the study: **In-Review, Active** or **All Submissions**.

### Submit Ancillary Review

From the submission workspace:

1. Click **Submit Ancillary Review**.
2. Select the Ancillary Committee for which you are reviewing.
3. Indicate whether you accept the proposed study
4. Insert any comments concerning the proposed study and/or upload supporting documentation, as applicable.
5. Click **OK**.