

# Click® IRB: Department & Ancillary Reviewer Manual

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# Introduction

This guide covers information and tasks relevant to Department and Ancillary review activities (per Office for Human Subject Protection [OHSP] Policies [505 Departmental Scientific and Resource Review](#) and [503 Ancillary Committee Reviews](#), respectively).

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 Department and 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) overview. Click® IRB supports the following submission types:

IRB Submission Types	
Type	Description
<b>Initial Submissions</b>	
<b>Study</b>	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.
<b>Site</b>	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.
<b>Follow-on Submissions</b>	
<b>Modification (Mod)</b>	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.
<b>Continuing Review (CR)</b>	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.
<b>Modification and Continuing Review (Mod/CR)</b>	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.
<b>Reportable New Information (RNI)</b>	A report of new information about an approved study or active research (e.g., new risk information, breaches in confidentiality, subject complaints or reports of non-compliance).

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

Roles	
Position	Typical Activities
<b>Ancillary Reviewer</b>	An individual responsible for evaluating study submissions against the requirements set forth for their specific Ancillary Committee (in accordance with <a href="#">Office for Human Subject Protection [OHSP] Policy 503 Ancillary Committee Reviews</a> ).

Roles	
Position	Typical Activities
<b>Department Reviewer</b>	A type of Ancillary Reviewer responsible for evaluating study submissions against their department-specific scientific review policy (in accordance with <a href="#">OHSP Policy 505 Departmental Scientific and Resource Review</a> ).
<b>Designated Reviewer (DR)</b>	An IRB chair or experienced IRB committee member, designated by the chair, to conduct reviews of newly submitted studies and follow-on submissions.
<b>IRB Coordinator (IRBC)</b>	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.
<b>IRB Director (IRBD)</b>	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.
<b>Guest</b>	Study staff may add guests to a study to permit read-only access.
<b>Primary Contact</b>	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.
<b>Principal Investigator (PI)</b>	The Principal Investigator has full and final responsibility for the conduct of the research (see <a href="#">OHSP Policy 901 Investigator Responsibilities</a> ). Each study and pSite requires a single PI to be identified on the submission. All PIs must meet the <a href="#">University of Rochester [UR] PI Eligibility Policy</a> . 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.
<b>PI Proxy</b>	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.
<b>Registered User</b>	Users authorized to create submissions.
<b>Study Staff (SS) / Study Team (ST)</b>	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 <a href="#">OHSP Guideline for Listing Research Personnel</a> for additional information).

## Overview of the Submission Review Process

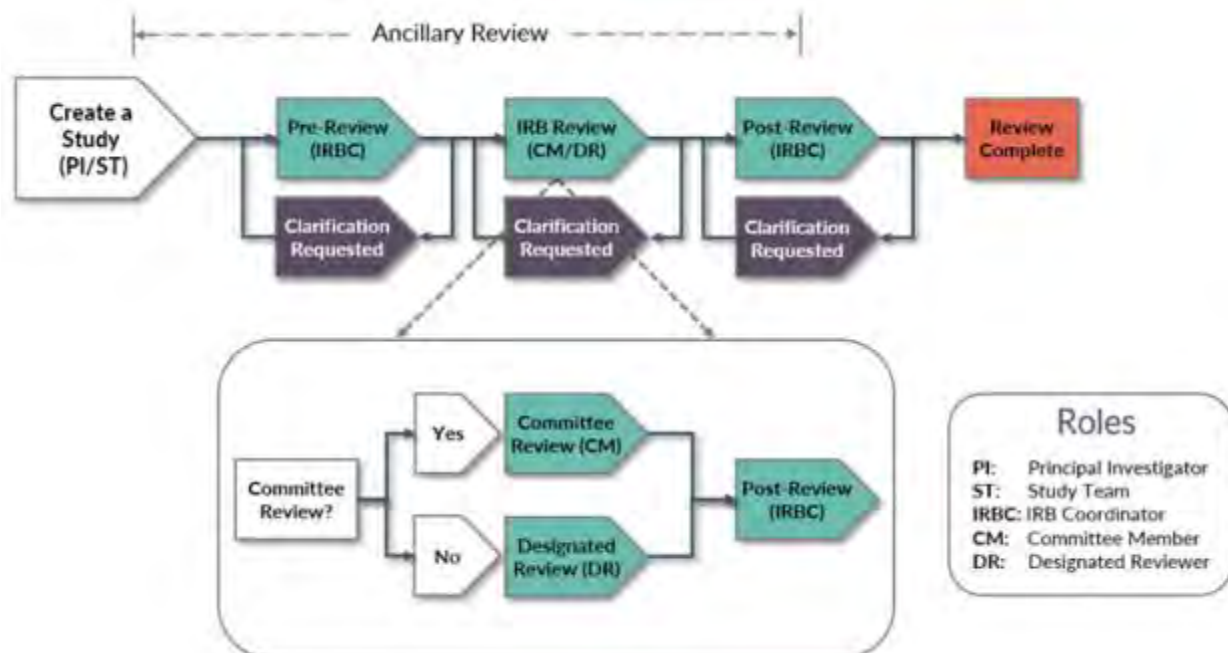
**New Studies:** The basic review process for a new study submitted to the Research Subjects Review Board (RSRB), the University of Rochester's local IRB, is as follows:

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

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

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

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



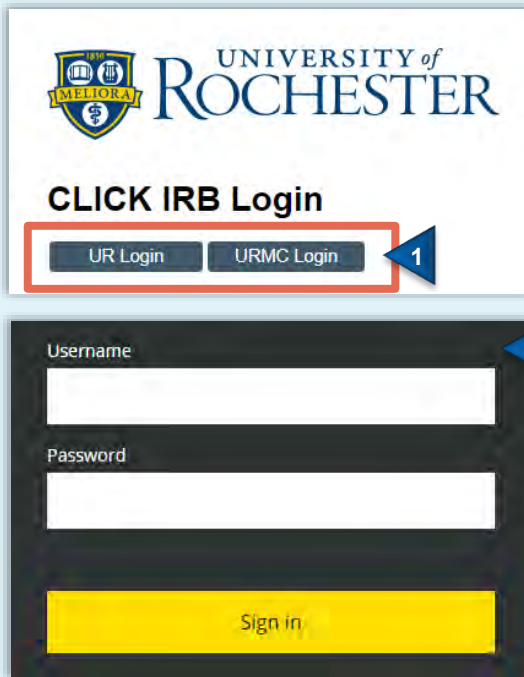
**Modifications (Mod) & Continuing Reviews (CR):** Modifications are required anytime previously approved submission materials require updating (e.g., the study submission form, study protocol, consent forms, recruitment materials, study measurements, etc.). Modifications can be submitted once a study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

Continuing review (i.e., a progress report) is required at least annually for all research deemed greater than minimal risk and may be required for minimal risk research. Study closure is required once the research is complete for all research other 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



UNIVERSITY of ROCHESTER

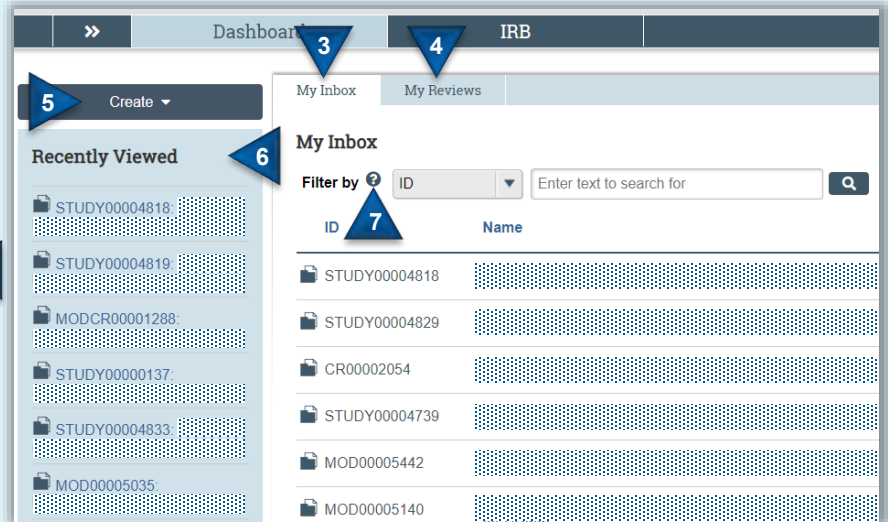
**CLICK IRB Login**

UR Login UPMC Login

Username

Password

Sign in



Dashboard IRB

Create

My Inbox My Reviews

My Inbox

Filter by ID Enter text to search for

ID	Name
STUDY00004818	
STUDY00004819	
MODCR00001288	
STUDY00000137	
STUDY00004833	
MOD00005035	

### Log In

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

1. Select your UR affiliation.
2. Use your UR active directory credentials to log in (i.e., the credentials used to log into your computer and/or access your UR email account).

#### Note:

- Users will not be able to log in to Click® IRB until they receive a user account confirmation email (approximately 1-2 business days following completion of the UR's required [human subjects training](#)).
- If you are logging in remotely, [two-factor authentication](#) is required. To facilitate this process, OHSP recommends enrolling in [Duo using a mobile phone](#).

Need help logging in? Use the contact information on the log in page to contact the help desk.

### Get Help

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

### Dashboard

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

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

## Navigation and Basic Tasks (Continued)

The screenshot shows the IRB system interface. At the top, there is a navigation bar with 'Dashboard' and 'IRB' tabs. Below this, there are several tabs for different submission states: 'In-Review', 'Department Review', 'Active', 'New Information Reports', 'External IRB', 'Relying Sites', 'All Submissions', and 'Archived'. A search bar is located below the tabs, with a 'Filter by' dropdown menu set to 'ID'. A table of submissions is displayed, with columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, and Coordinator Last Name. A filter bar at the bottom allows for selecting a filter column (ID), entering search text, and clicking 'Go', '+ Add Filter', or 'x Clear All'.

### Find Submissions

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

### Sort Submissions

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

### Filter Data

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

### Open a Submission

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

## Navigation and Basic Tasks (Continued)

### Study & Follow-on Submission Workspace

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

19. Submission ID, short title and basic submission information (e.g., PI, submission type, Primary Contact, PI Proxies, IRB Coordinator, approval letter, and legacy study link, if applicable).

- The submission type is identified in the heading of the workspace, as well as in the prefix of the submission ID (e.g., a STUDY prefix indicates the study submission). See [IRB Submission Types](#) for prefix abbreviations.

20. Submission state and approval details (e.g., IRB submission date, initial approval date, approval end date)

- If continuing review is not required, the Approval End data field will not be present.

21. Webpage breadcrumb

When reviewing follow-on submissions, the breadcrumb can be used to navigate to the related study's workspace (i.e., the study homepage)

22. Review workflow, indicating where the submission is in the review process.

- When submissions appear on the bottom row of the workflow (e.g., clarifications requested), action is required by the study team.

23. Smart forms and activities:

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

24. Submission space navigation toolbar:

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



## Perform a Department or Ancillary Committee Review

Department and Ancillary Committee Reviews are facilitated by the IRBD and/or IRBC in accordance with [OHSP Policy 505 Departmental Scientific and Resource Review](#) and [OHSP Policy 503 Ancillary Committee Review](#), respectively (a [quick reference guide](#) identifying when Ancillary Committee Review is required in relation to IRB review is available in the appendices).

When a study is submitted to the IRB, the IRBD will select the applicable Department and Ancillary Committee(s), based on the information provided in the submission, and submit for review. All assigned reviewers for the selected Department/ Ancillary Committee(s) will receive an email notification alerting them to the submission. In some cases, in lieu of selecting a department or committee and notifying all reviewers of the submission, the IRBD can select one specific Department/ Ancillary Committee Reviewer to conduct the review (in which case, only the selected reviewer will receive the email notification concerning the review). Additional or further Department/Ancillary Committee 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 of a follow-on submissions.

The image shows a composite of three screenshots illustrating the process of finding a submission for review. 
   
1. A notification email titled 'Notification of Ancillary Review' with a link to 'STUDY00003250'.
   
2. The IRB system's 'Dashboard' with the 'My Inbox' tab selected, showing a submission 'STUDY00004860' with the title 'Training Manual Demo E'.
   
3. The 'IRB' module selected, with the 'In-Review' tab active, showing a list of submissions including 'STUDY00004821'.

### Find the Submission

To open a submission that requires Department/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 has been submitted for Department Review or requires Ancillary Committee Review *prior* to IRB review or approval of the submission, you can access your submission via your [Dashboard](#). From your dashboard, click the submission name and the study workspace will then open (the submission will appear on both your My Inbox and My Reviews tabs).
  3. If the submission has been submitted for Ancillary Committee Review and does *not* require a response an Ancillary Committee response 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. Select the **IRB** module (tab).
    - b. Find the submission under one of the following tabs (the location will depend on the current state of the submission). See instructions on how to [Sort Submissions](#) and [Filter Data](#) for additional help.
      - **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 a Department or Ancillary Committee (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. You can scroll through the submission or use the left-hand navigation pane to jump to specific sections of the form.
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.

### Next Steps

- **FOR DEPARTMENT REVIEWERS ONLY:** If you have questions or changes for the PI, see [Request Clarification on a Submission](#).
- If you are finished reviewing the submission, see [Submit Department and/or Ancillary Review](#).

### Request Department Reviewer Clarification

**Note:** This activity is only available to reviewers conducting [Department Reviews](#).

7. From the study workspace, click **Request Department Reviewer Clarification**.
8. In the corresponding pop-up box, type your request in the text box.
9. If you require more space for your request, add a memo identifying your requests as a supporting document. Instruct the PI to refer to the memo in the textbox in Field 1. Additional supporting documentation may also be uploaded here.
10. Click **OK**.
  - The PI, PI Proxy and Primary Contact will receive an email notification about your request.
  - The submission state will change to 'Clarifications Requested by Department'.
  - When the study team submits their revisions to the submission, applicable Department Reviewers will receive an e-mail notification. Use the [Compare](#) feature to review revisions to the submission.

## Perform a Department or Ancillary Committee (Continued)

**Next Steps**

View Study

Printer Version

---

Request Department Review Clarification

Submit Ancillary Review 1

Add Comment

**Submit Ancillary Review**

**1. \* Select the review you are submitting:**

**2** Organization      Person      Review Type      Required

Obstetrical Research Committee yes

**2. \* Do you accept the proposed study?**

**3**  Yes  No [Clear](#)

**3. Comments:**

**4**

**4. Supporting documents:**

**5** + Add

Name

There are no items to display

**6** OK Cancel

## Submit Department and/or Ancillary Review

After you have finished reviewing the submission, submit the Department/Ancillary Review. Completing this form documents your review and approval of the research, commensurate with [OHSP Policy 505 Departmental Scientific and Resource Review](#) and/or [OHSP Policy 503 Ancillary Review Committees](#), as applicable.

1. From the study workspace, click **Submit Ancillary Review**.
2. In the corresponding pop-up box, select the Department or Ancillary Committee for which you are reviewing.
3. Indicate whether you accept the proposed study.
  - If you answer no, comments should be provided in the following Comments field. Alternately, comments can be provided via the [Add Comments](#) activity.
4. Insert any comments concerning the proposed study, as applicable.
5. Upload any supporting documentation.
  - **DEPARTMENT REVIEWERS: Upload your completed scientific review checklist** (refer to [OHSP Policy 505 Departmental Scientific and Resource Review](#), the [Guideline for Scientific and Resource Review of Human Subject Research](#), and the [Scientific and Resource Review Checklist](#)).
6. Click **OK**.
  - The review will be marked as completed on the Reviews navigation tab in the study workspace.

## Review Requested Changes

Once the study team has responded to changes and/or clarifications that have been requested. Use the [Compare](#) feature to review the revisions.

**Next Steps**

View Study **1**

Printer Version

**2** Compare

You Are Here: Training Manual

Reading: STUDY00004818

Compare current state of version: 0.4 Changes submitted to IRB with 0.2 Submit to IRB 5/5/2020 11:37:05 AM **3**

Version	Description	Date
0.4	Changes submitted to IRB	5/7/2020 2:14:09 PM
0.3	Changes submitted to IRB	5/7/2020 1:01:47 PM
0.2	Submit to IRB	5/5/2020 11:37:05 AM
0.1	[No description]	5/4/2020 12:48:23 PM

**4**

**5** \* Attach the protocol:

Document	Category	Date Modified	Document History
View Protocol(0.02)	IRB Protocol	5/7/2020	History <b>7c</b>

**6** Differences

modified 2 hours ago • version 0.3 (Changes submitted to IRB)

**7** Changed: Protocol

Property: Protocol.Draft.targetURL  
New Value: View  
Old Value: View

Property: Protocol.Draft.version  
New Value: 0.01 **7**  
Old Value: 0.01

File Tools View Protocol REVISED (3) (Protected View) - Word **7a** Enable Editing

File Home Insert Design Layout References Mailings Review View Developer Tell me what you want to do...

Track Changes **7b** Show Markup - Reviewing Pane - Accept Reject

**3** \* Brief description: This is a [vaccine questionnaire stu

**4** \* What kind of study: Single-site study

**5** \* Will an external IRB:  Yes  No

**6** \* Local principal inv

**Final Page**

You have reached the end of the IRB submission form. Read the next steps carefully. **8**

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

**Exit**

## Compare

1. From the submission workspace, click **View Study**.
2. Click **Compare** on the left-hand navigation pane.
3. Click the down arrow to show the submission versions and select the version you wish to compare the current version against.
4. Click the pencil icon(s) to view the change(s) made.
5. Revisions are indicated within the SmartForm by a blue 'Differences' box that can be expanded/contracted.
6. 'Changed' or 'Added' can also be expanded/contracted to provide revision details.
7. If a document was revised, select the **Compare** activity to view tracked changes. **Note:** In order to view the tracked changes in the Word document, you may need to: a) Select **Enable Editing** (in the yellow toolbar) when the document is first opened [7a]; and b) Select the **Review** tab and then All Markup in the Tracking Options pane of the Review tab [7b]. Documents can also be compared by viewing the **Document History** [7c].
8. Click **Close** to exit.

## Additional Activities

**Next Steps**

[View Study](#)

[Printer Version](#)

[Request Department Review Clarification](#)

[Submit Ancillary Review](#) 1

[Add Comment](#)

**Add Comment**

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

**1. Comment:**

2

**2. Supporting documents:**

3

[+ Add](#)

Name	Description
There are no items to display	

**3. Who should receive an e-mail notification? ?**

4

PI/PI Proxy/Primary Contact

Study Team

IRB Coordinator

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

### Add Comment

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

1. From the submission workspace, click **Add Comment**.
2. Insert your comment.
3. If applicable, add supporting documentation.
4. 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. 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.

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

<sup>^</sup>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: Perform a Department or Ancillary Review

### Log into Click® IRB

1. Go to <http://rochesterirb.huronresearchsuite.com/>
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).

### Find the Submission

1. Click the link in your notification email. You will be directed to log in and then automatically routed to the study workspace.

OR

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

2. Log into Click® IRB and, from your dashboard, click on the name of the submission (the submission will appear on both your My Inbox and My Reviews tabs).

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

3. Log into Click® IRB and select the **IRB** module (tab).
4. Find the submission under one of the following tabs: **In-Review**, **Active** or **All Submissions**.

### Perform a Review

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

1. **View Study:** Opens the submission form. You can scroll through the submission or use the left-hand navigation pane to jump to specific sections of the form.
2. **Printer Version:** Shows the entire submission in one scrollable page.
3. **Navigation Tabs:** Pulls specific information from the submission form and/or completed activities (e.g., Funding, Documents, Training Details, etc.).

### Request Department Reviewer Clarification

**Note: This activity is only available to reviewers conducting Department Reviews.**

4. From the study workspace, click **Request Department Reviewer Clarification**.
5. In the corresponding pop-up box, type your request in the text box, uploaded additional supporting documentation if necessary.
6. Click **OK**.

### Submit Department and/or Ancillary Review

1. From the study workspace, click **Submit Ancillary Review**.
2. Select the Department/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.
  - **DEPARTMENT REVIEWERS: Upload your completed scientific review checklist.**
5. Click **OK**.