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Introduction

This guide covers information and tasks relevant to board chair and designated reviewer activities for committee and non-committee reviews.

Note: A 1-page Quick Reference Guide summarizing the review activities described in this manual is available in the appendices.

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:

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<th>IRB Submission Types</th>
<th>Description</th>
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<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:

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<th>Roles</th>
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<td><strong>Position</strong></td>
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<tr>
<td>Ancillary Reviewer</td>
</tr>
<tr>
<td>Committee Administrator</td>
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## Roles (Continued)

<table>
<thead>
<tr>
<th>Position</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<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 <a href="https://ohsp.rochester.edu/policies/">OHSP Policy 505 Departmental Scientific and Resource Review</a>).</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 <a href="https://ohsp.rochester.edu/policies/">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="https://ohsp.rochester.edu/policies/">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.</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>Site Manager</td>
<td>An individual who has system-wide access. This includes full access to security and system settings, and all data, workspaces, activities, and actions in the system.</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 a co-investigators, sub-investigators, statisticians, study coordinators, and other study personnel (see <a href="https://ohsp.rochester.edu/policies/">OHSP Guideline for Listing Research Personnel</a>) 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. The IRBC may also communicate questions and/or concerns related to the submission to the designated reviewer (e.g., board chair) via **Private Comment**. 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. Flow charts providing further detail of each review phase (Pre-Review, IRB Review, and Post-Review) are available in the **appendix**. **Note:** Department Review is programmed as a type of Ancillary Review and therefore not depicted separately in the diagram below.
**Modifications & Continuing Reviews:** 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. **Note:** Revisions identified in a modification are not applied to the parent study and active follow-on submissions until it has been approved.

**Reportable New Information:** 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 submission review process, including the roles and states involved in the review. Flow charts providing further detail of the RNI review pathway are available in the appendix.

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’; or
- Determine that review of the local site should remain in-house, regardless of whether other study sites will utilize a single reviewing IRB, e.g., when the project qualifies for exemption (see the Overview of the Submission Review Process).

Note: Per OHSP Policy 504 IRB Reliance and Collaborative Research, all studies that will utilize the RSRB as the sIRB or an External IRB require the execution of a reliance agreement (also referred to as an IRB authorization agreement). Submissions should not be initiated until a reliance agreement has been executed to accommodate review of the research by the sIRB or External IRB, as appropriate.

Overview of the Multi-Site sIRB Submission Process

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

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

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

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

1. The Lead PI (and study staff) creates a study, indicating that the study is multi-site and that the RSRB will serve as the sIRB of record for participating sites (pSites). The Lead PI is the individual with primary responsibility for oversight and management of the conduct of the study at all pSites. While the study team is working on the study application, it is in the Pre-Submission state. Once the submission form is complete, the PI submits the study to the RSRB for review.

2. Upon submission of the study to the RSRB, the study will move through the Department Review, Pre-Review, IRB Review and Post-Review processes, as described above for routine submissions.

3. During Post-Review, the IRBC prepares and sends the determination letter to the PI. If the study is approved, the IRBC creates a final version of the study documents and the submission moves to Review Complete (Approved state). If the committee/designated reviewer determines modifications are needed for the submission to be approved, the PI can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

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

1. The Lead PI (and study staff) or IRBC adds the pSite from the study workspace, resulting in the creation of a pSite workspace and corresponding submission. Upon creation, the pSite is in the Invitation Pending state. Once the IRBC validates the pSite’s eligibility to participate in the research, the pSite moves to an Awaiting Site Materials site.

2. Following receipt of the pSite’s study-specific documentation, the Lead PI, study staff or IRBC enter the pSite’s site-specific information and documents on their behalf and submit to the RSRB for individual review. **Note:** pSites cannot be submitted for review until the study submission has minimally reached the Pre-Review Complete.

3. Upon submission of the pSite to the RSRB, the pSite will move through a simplified version of the Pre-Review, IRB Review and Post-Review processes, as described above for routine submissions. **Note:** pSites cannot progress beyond the IRB Review point until the study submission has been approved.

4. As above, during Post-Review, the IRBC prepares and sends the determination letter to the Lead PI. If the study is approved, the IRBC creates a final version of the site documents and the pSite submission moves to Review Complete (Active state). If the committee/designated reviewer determines modifications are needed for the pSite to be approved, the Lead PI, study staff or IRBC can make changes to the study and re-submit the application. The IRBC will then review the changes and decide if the submission can be approved or must go back through an IRB review.

The following diagram illustrates the MSS submission review process, including the roles and states involved in the review:
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.
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? Contact OHSP at 273-4127.

Dashboard

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

3. My Inbox: Displays all items that require IRB action (inclusive of all boards). Sort Submissions or Filter Data, as needed.
4. Create Menu: Displays a menu of actions you can perform.
5. Study Expirations: Displays all studies (inclusive of all boards) that are within 60 days of their expiration date. Color coding indicates expiration proximity.
   - Lapsed studies will remain on the list for up to 5 days after expiration.
   - The search box can be used to further narrow results.
6. Recently Viewed: Displays the last 10 projects viewed, with the most recent on top.
7. **Assignments**: Displays workload volume for IRB Staff and Reviewers (determined by number of assigned submissions pending action by IRB staff/reviewers).

   - **Staff Assignments: Pending Staff Action** – Displays workload volume for IRB Staff. Click on the name of an IRB Staff member in the legend to exclude their assigned volume from the chart [7a]. Click on the chart wedge corresponding to an IRB Staff Member to view their assigned submissions and **Sort Submissions** or **Filter Data**, as needed. [7b].
   
   - **Staff Assignments: Pending Staff Action – Unassigned** – Displays submissions that have not been assigned an IRBC. Assign an IRBC directly from the list by selecting **Execute Activities** [7c].

   - **Reviewer Assignments: Pending Reviewer Action** – Displays Non-Committee Review workload volume for IRB Reviewers. Click on the name of an IRB Reviewer or corresponding chart wedge, as above [7a & 7b].
   
   - **Reviewer Assignments: Pending Reviewer Action – Unassigned** – Displays submissions in Non-Committee Review that have not been assigned an IRB Reviewer.

8. **In Process**: Summarizes volume by stages of review workflow. The number on a tile indicates how many submissions are in that stage. Click on a tile to view underlying submissions. **Sort Submissions**, as needed [8a].

**Get Help**

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

10. Select the IRB module (tab).

11. 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.

12. Click on a column heading to sort submissions by ID, name, PI last name, Coordinator last name, submission type, etc.

13. Select the column to filter by from the dropdown menu.

14. 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).

15. Click Go to apply the filter. Submissions can then be further sorted, as described above, if necessary.

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

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

#### Find Submissions

18. 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)

Find a Committee Meeting
19. Select the IRB module (tab).
20. Click on Meetings.
21. Select the meeting you wish to view. **Note:** Upcoming and prior meetings appear on separate tabs.

Find Checklists & Worksheets
To find protocol/consent checklists and reviewer worksheets:
22. Select the IRB module (tab).
23. Click on Library.
24. Select the Worksheets tab.
25. Click on the name of the document to download the worksheet.

Study & Follow-on Submission Workspace
As applicable to the submission type, you will find the following on study and follow-on submission workspaces:

26. Submission type
- 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; a MOD prefix indicates a modification submission). All prefixes abbreviations are identified in the **IRB Submission Types** table above.

27. 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).

28. Submission state and approval details (e.g., IRB submission date, initial approval and effective dates, approval end date, date the submission was last updated).
- If continuing review is not required, the Approval End data field will not be present.
Navigation and Basic Tasks (Continued)

29. Submission ID, short title and basic submission information (e.g., PI, Primary Contact, PI Proxies, IRBC, approval letter).

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

31. 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.
   - **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.
   - **Follow-On Submissions**: Lists all Mods, CRs, Mod/CRs, and RNIs related to the submission.
   - **Reviews**: Identifies determinations made during pre-review, designated/committee review, as well as completed Department and Ancillary Reviews. Review history is maintained for each review type. When a modification is approved, the latest pre-review information from that modification is copied to the parent submission.

32. Submission space navigation toolbar
   - **History**: Lists the actions taken on a submission including comments, attachments, or correspondence added.
   - **Determinations**: Lists the protocol/consent and regulatory determinations made by the IRBC and designated reviewer/committee.
   - **Snapshots**: Provides historical submission contents.
   - **Audits**: Lists internally-conducted audits and quality improvement reviews.
   - **Minutes**: Identifies all previously recorded minutes related to the submission.
   - **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).
   - **Sites** (if applicable): Identifies all participating sites undergoing single IRB review by the RSRB (for multi-site studies only).
Review an Assigned Submission

You will receive an email notification when a study, site, or follow-on submission has been assigned to you for review and the submission will appear in your IRB inbox. You may be assigned to review a submission as a Designated Reviewer via Non-Committee Review (i.e., expedited review) or as a Committee Reviewer via Committee Review (i.e., full board review).

Open the Submission

To open a submission, you may:

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

2. From your Inbox or Assignment tabs on the Dashboard, click on the name of the submission. OR

3. For items assign to a convened meeting:
   a. Select the IRB module.
   b. Click on Meetings.
   c. Select the meeting the submission has been assigned.
   d. Click on the submission ID or name.

Perform a Review

4. Click Review Study to open the submission form and review each section. You can scroll through the submission or use the left-hand navigation pane to jump to specific sections of the form.

5. To view revisions to previously submitted materials, use the Compare feature.

6. After reviewing each section, select the checkbox at the bottom of the section to confirm your review.
   - After confirmation, the section reviewed turns green and a green checkmark appears in the left-hand navigation pane.
   - If the submission is later edited, the green checkmark is removed and a pencil icon is added, indicating the section should be re-reviewed.

7. Click Exit to return to the submission workspace.

8. From the submission workspace, you may also use the navigation tabs to view specific information (e.g., documents, pending Ancillary Reviews, etc.) See the Study & Follow-On Submission Workspace for additional navigation information.

Next Steps

- If the submission has been assigned to you for Designated (Non-Committee) Review, see Designated Reviewer Activities.
- If the submission is scheduled for Committee Review, see Committee Reviewer Activities.
- If questions were submitted to you via Private Comment, respond via Private Comment.
Designated Reviewer Activities

Submissions that qualify for non-committee review (i.e., exempt or expedited review) will undergo Designated Review once an IRBC has submitted their Protocol Determinations and Pre-Review. After reviewing the assigned submission, the Designated Reviewer can a) move the submission forward via non-committee review by submitting their regulatory determinations and designated review; or b) assigning the submission for committee review. Note:

- If a submission requires clarification and/or revision, it is best practice to provide these to the IRBC via private comment prior to submitting the designated review rather than selecting ‘Request Clarification by Designated Reviewer’ (doing so will send requests DIRECTLY to the study team).
- If the submission is a follow-on submission, the determinations entered via the Submit Regulatory Determinations and Submit Designated Review activities will be pre-populated based on the previous review. Previously documented determinations should be updated/confirmed, as necessary, with the review of each follow-on submission.

Submit Regulatory Determination

Note: This activity is NOT REQUIRED for exemptions, projects deemed not human research, projects that are human research but the UR is not engaged, pSites undergoing MSS sIRB review, nor for study closures.

1. From the submission workspace, click Submit Regulatory Determination.

2. In the corresponding pop-up box, respond to all required fields, using the help text as needed.

3. If the submission is a MOD, CR or MOD/CR, an additional field [Field 1a] will be present to indicate whether non-compliance has been identified. Answering yes will provide an additional follow-up field [Field 1b] to indicate whether the non-compliance is serious or continuing.

4. In Field 2, indicate whether the submission is eligible for expedited review.
   - Answer yes, for: a) initial submissions that are minimal risk and fall into one of the expedited categories for review; b) follow-on submissions that are eligible for expedited review (irrespective of study risk level); or c) if the submission is a Concept, Umbrella or Coordinating Center study.
   - Answer no, if the submission requires committee review. [Although this form is not required for projects that qualify for exemption, do not involve human subject research, or is research but the UR is not engaged, if completed, answer no for these submissions.]
Designated Reviewer Activities (Continued)

5. *The following consent determination(s) apply to this submission:

- [ ] Consent will not be obtained / No subject enrollment
- [x] Informed consent obtained and documented
- [ ] Parent permission obtained and documented
- [ ] Waiver of written documentation of consent
- [ ] Waiver or alteration of consent process
- [ ] Waiver of parental permission
- [ ] Waiver of consent for deception study

a. "Is the consent process in accordance with the following criteria?"
   - Prospective subject/representative will have sufficient opportunity to consider whether to participate
   - The possibility of coercion or undue influence will be minimized
   - Information communicated to the subject/representative will be in language understandable to the subject/representative
   - Information communicated to the subject/representative will not include exculpatory language through which the subject/representative is made to waive or appear to waive any legal rights or appears to release the researcher, sponsor, institution, or its agents from liability or negligence
   - Yes [ ] No [ ] Clear

6. *Confirm HIPAA determination(s) appropriate to this review?:

- [ ] No subject enrollment
- [ ] No PHI
- [ ] HIPAA authorization obtained and documented
- [ ] Waiver or alteration of HIPAA
- [ ] HIPAA compliance using Limited Data Set or Data Use Agreement
- [ ] Partial waiver of HIPAA authorization for recruitment

7. *Are drugs included in this study?*

- [x] Yes [ ] No [ ] Clear

- [ ] IND
  - This research is conducted under an IND, and the FDA has agreed to let this research move forward.
  - Investigational drugs in this study are exempt from the IND regulations, as determined by the RSRB.
  - a. "Indicate the appropriate phase of the study:"

- [ ] Exempt

- [ ] IDE
  - This research is conducted under an IDE, with all the IDE regulations at 21 CFR 812.
  - Investigational device(s) in this study are significant risk; therefore, this research is conducted under an IDE and the FDA has agreed to let this research move forward. The study must follow all the IDE regulations at 21 CFR 812.

- [ ] HDE
  - This research is conducted under an HDE, with all the HDE regulations at 21 CFR 814.100.
  - Investigational device(s) in this study are significant risk; therefore, this research is conducted under an HDE. HDE regulations under 21 CFR 814.100 must be followed. Deaths & serious injury that the HDE has/have caused or was a contributing factor must be reported to FDA. These reports are coordinated.

8. *Are devices included in this study?*

- [ ] Yes [ ] No [ ] Clear

- [ ] IND
  - This research is conducted under an IND, and the FDA has agreed to let this research move forward.
  - Investigational devices in this study are exempt from the IND regulations, as determined by the RSRB.
  - a. "Indicate the appropriate phase of the study:"

- [ ] Exempt

- [ ] IDE
  - This research is conducted under an IDE, with all the IDE regulations at 21 CFR 812.
  - Investigational device(s) in this study are significant risk; therefore, this research is conducted under an IDE and the FDA has agreed to let this research move forward. The study must follow all the IDE regulations at 21 CFR 812.

- [ ] HDE
  - This research is conducted under an HDE, with all the HDE regulations at 21 CFR 814.100.
  - Investigational device(s) in this study are significant risk; therefore, this research is conducted under an HDE. HDE regulations under 21 CFR 814.100 must be followed. Deaths & serious injury that the HDE has/have caused or was a contributing factor must be reported to FDA. These reports are coordinated.

9. *Select risk level of vulnerable population(s) indicated below, if applicable?*

- [ ] Yes [ ] No [ ] Clear

- [ ] Pregnant Women & Fetuses

- [ ] Minimal Risk, all elements of 45CFR46.204 considered
- [ ] Greater than Minimal Risk, all elements of 45CFR46.204 considered

10. Below are the protocol and consent determinations for additional safeguards to protect the rights and welfare of vulnerable population(s), and the risk/benefit relationship, as applicable:

The vulnerable populations identified in the study protocol will be protected by:

a. Provide additional determinations as necessary

NOTE: Fields 5-10 apply to the study as a whole, not the individual follow-on submission alone (e.g., modification components). Determinations should only be updated during the review of a follow-on submission when the components of the follow-on submission change the prior determinations made on the research.

5. In Field 5, selecting ‘informed consent obtained…’, ‘parent permission obtained…’, and/or ‘waiver of written documentation of consent’, provides a follow-up Field 5a question (to confirm general regulatory requirements regarding consent have been met).

6. If HIPAA does not apply to the research, select ‘No PHI’ in Field 6.

7. Answering yes to either Field 7 or 8, provides follow-up determination options for drugs and devices, respectively.
   - Reminder: All new submissions involving an IND, IDE, Abbreviated IDE, or HDE require committee review.

8. FOR DESIGNATED, EXPEDITED REVIEWS ONLY (for research undergoing committee review, this information is documented via meeting minutes): If any vulnerable populations are included in the research, select the applicable risk determination for the population included in Field 9 and, if necessary, include any additional comments concerning safeguards in Field 10 (the IRBC’s comments concerning safeguards will pull through from their Protocol Determination smart form).
   - Children’s determinations appear on the Submit Designated Review activity described below, not the Submit Regulatory Determinations activity. If any vulnerable populations are missing from Field 9 (pregnant women, prisoners, adults with decision impairment), alert the IRBC to update their Pre-Review accordingly.
Designated Reviewer Activities (Continued)

9. If the submission is a MOD or MOD/CR, an additional field [Field 11] will be present to indicate what groups of subjects, if any, need to be notified of the revisions included within the modification. (If your determination differs from what the study team identified in the MOD submission form, the submission form should be updated accordingly prior to approval).

10. Click **OK**.

- The information entered here will pull through to future follow-on submissions. This will also appear on the Determinations tab (including text entries in the vulnerable populations and general comments fields).

Submit Designated Review

11. From the submission workspace, click **Submit Designated Review**.

12. In the corresponding pop-up box, respond to all required fields, using the help text as needed.

13. Select an approval determination.

14. Identify the risk level of the research. **Note:**

- This field applies to the study as a whole, not an individual follow-on submission (e.g., modification). The risk level should only be modified when the components of the follow-on submission change the risk level of the research.
- Answer ‘N/A’ only if the project is not human research or is human research but the UR is not engaged.

15. Selecting ‘Approved’ or ‘Modifications Required to Secure Approval’ in Field 1 provides follow-up fields that allow you to identify a review level and select applicable review categories (see **OHSP Policy 501 Levels of RSRB Review** and the associated guidelines on exempt status determinations and expedited reviews). For follow-on submissions:

- If the research involves minimal risk and is approved under an expedited or exempt review category (e.g., modification), confirm the review categories remain accurate (select or remove exempt categories 1-8 or expedited categories 1-9, as appropriate).
- If the research is greater than minimal risk research and the follow-on submission is undergoing designated review, select ‘mm’ (minor modification).
- The ‘other’ should only be selected for modifications undergoing designated review that involve administrative changes only – e.g., personnel changes other than the PI.
16. In Field 6, indicate whether continuing review is required for the submission. If yes, an additional field, requesting rationale for continuing review will be required.

17. Minimally, enter the approval date (this should default to the date you are completing the review).
   - The IRBC can fill in remaining dates, as necessary.
   - The last day of approval period field will only appear when continuing review is required.

18. If modifications are required to secure approval, enter the modifications required in Field 8.

19. Select the checkbox to confirm you do not have a conflict with the review of the submission.

20. Answer yes, if you are ready to submit your review (this will move the submission back into the IRBC’s inbox). If you are not ready to submit your review, answer no, and the information you entered will be saved. You can submit your review later.

21. Click OK.
   - The submission will move back into the IRBC’s inbox for post-review activities.
   - The information entered here will pull through to future follow-on submissions.

### Assign to Committee Review

22. If a submission in non-committee review requires committee review, click Assign to Committee Review.

23. Indicate the reason the submission requires committee review.

24. Click OK.
   - The submission will move back into the IRBC’s inbox for meeting assignment. If necessary, provide comments and/or directions to the IRBC via private comment.
Committee Reviewer Activities

Once a submission has been assigned to Committee Review, the IRBC will assign the submission to a Committee Reviewer (i.e., primary reviewer). Prior to the committee meeting, the Committee Reviewer, as well as any Committee Members, can record their review comments for other Committee Members to view before and during the meeting.

**Note:** If a Committee Reviewer or Committee Member identifies missing information or clarifications that require action prior to committee review, the Committee Reviewer/Member should communicate such issues to the IRBC via private comment. Committee Reviewers/Members should not select ‘Request Clarification by Committee Member’. Doing so will send requests DIRECTLY to the study team. Furthermore, this activity only allow study team members to provide a written response; it does not allow them to edit the submission.

### Add Review Comments

1. From the submission workspace, click **Add Review Comments**.
2. Type your notes for other committee members and/or the IRBC/IRBD.
3. Click **Add** to attach any review checklists and/or supporting documents (e.g., existing literature, tracked consent documents, etc.) you want to share.
   - **Primary Reviewer worksheets** are available for use in the IRB Library.
4. Click **OK**.
   - The review comments and attachments will then appear on both the **History** and **Reviews** tabs of the submission workspace. Once the review of the submission is complete, comments will be removed from the Reviews tab but will remain accessible via the History log.
   - All committee members and IRB staff will be able to view your comments.

### Next Steps

Following committee review of the submission at the convened meeting:

- The Committee Chair will submit Regulatory Determinations.
- The IRBC will submit additional determination’s on behalf of the committee via the **Submit Committee Review** activity.
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.

1. From the submission workspace, click **Review Study**.
2. The versions of the submission being compared will appear at the top of the left-hand navigation pane. To change version the current submission is being compared to, click the down arrow to show the submission versions and select the version desired version.
3. Click the pencil icon(s) to view the change(s) made.
4. Revisions are indicated within the SmartForm by a blue ‘Differences’ box that can be expanded/contracted.
5. ‘Changed’ or ‘Added’ can also be expanded/contracted to provide revision details.
6. 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].
Review a Report of New Information

When an RNI is first submitted to the IRB for review, it will appear in the IRBD inbox. The IRBD will assign the RNI to an IRBC based on the RNI’s related submissions. Once a study has been assigned to an IRBC, they will complete an initial review and based on the information provided, either: a) acknowledge the event (with no further review necessary) or b) move the event forward in the review process by assigning it to either Designated or Committee Review.

You will receive an email notification when a RNI has been assigned to you for review and the submission will appear in your IRB inbox. You may be assigned to review a RNI as a Designated Reviewer via Non-Committee Review (i.e., expedited review) or as a Committee Reviewer via Committee Review (i.e., full board review).

Perform a RNI Pre-Review

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

1. **Review RNI**: Opens the RNI submission form. To view revisions to a previously submitted RNI, use the Compare feature.
2. **Printer Version**: Shows the submission in one scrollable page.
3. **Documents Tab**: Shows all attached RNI documents.
4. **Related Submissions Tab**: Shows all submissions related to the RNI.

Next Steps

Once you’ve completed your review, you can do one of the following:

5. **Submit RNI Designated Review** to document your determinations and move the submission forward in the review process. In the corresponding pop-up box: select the applicable determination [5a]; confirm you do not have a conflict with the submission [5b]; indicate whether you are ready to submit the review [5c]; and click OK [5d]. (See the overview of RNI review process for a description of how the determination selected will move the submission forward.)

6. **Assign to Committee Review** to move the RNI back into the IRBC’s inbox for assignment to a board meeting.

7. **Add a Private Comment to the IRBC** if you have questions or need to request changes. **Note:** Selecting ‘Request Clarification by Designated Reviewer’ will send requests DIRECTLY to the study team.
Additional Committee Member Activities

You will receive an email notification when: a) you are assigned to act as primary reviewer of a submission or review item; and b) when a committee meeting agenda has been sent.

Find the Meeting Materials

To open the meeting workspace, you may:

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

OR

2. From your dashboard, select the IRB module (tab).
3. Click on Meetings.
4. Select the upcoming meeting you wish to review materials for.

Confirm / Decline Attendance

To confirm or decline attendance, from the meeting workspace:

5. From the meeting workspace, select Confirm Attendance or Decline Attendance, as applicable.
6. Click OK (for confirmations only).

Find the Agenda

7. Click on the agenda link in your notification email.

OR

8. From the meeting workspace, select the hyperlink for the agenda in the workspace heading. The agenda will open as a Microsoft Word document.

Review the Expedited Report

9. From the meeting workspace, select the link for ‘Expedited Submissions Approved in the Last 45 Days’ in the workspace heading.

Review Previous Minutes

10. Select the previous meeting with pending minutes. The original meeting’s workspace will open in a new tab of your web browser.
11. From the original meeting’s workspace, select the minutes link in the header.
Review Meeting Materials (Continued)

Review Other Agenda Items

‘Other Agenda Items’ allow for materials external to a study or follow-on submission to be reviewed by the board. A description of the materials and how to locate applicable documents should be included in the agenda. Routinely, this will include audit/quality improvement reports but other materials may also be added via this activity.

To access audit/quality improvement reports:

12. Click on the study ID listed under ‘Other Agenda Items’.
13. From the study workspace, click the ellipses on the navigation toolbar.
14. Select the Audits tab.
15. Click on the report identified on the agenda to open and review the report.

Add Private Comment

Private comments may be added at any time by IRB Staff and Committee Members, to any type of submission. Private comments are only visible to IRB Staff and Committee Members who are not on the study team.

16. From the submission workspace, click Add Private Comment.
17. Insert your comment.
18. Select the roles and/or specific individuals to be notified of the comment.
19. Click OK. The private comment will appear on the History tab and the individuals selected in Fields 3 and/or 4 will be sent an email notification alerting them to the comment.

Request Clarification by Committee Member: DO NOT select ‘Request Clarification by Committee Member’. Doing so will send requests directly to the study team.
Appendices & Quick Reference Guides

The following appendices and quick reference guides are provided to supplement the information provided in the preceding pages of this manual.

- Detailed IRB Submission Review Workflow: Pre-Review
- Detailed IRB Submission Review Workflow: IRB Review
- Detailed IRB Submission Review Workflow: Post-Review
- Detailed RNI Submission Review Workflow
- Detailed MSS siRB Submission Review Workflow
- Quick Reference Guide: Ancillary Committee Review
- Quick Reference Guide: Approval, Effective & Expiration Dates
- Quick Reference Guide: Regulatory Oversight
- Quick Reference Guide: Conducting Designated & Committee Reviews
IRB Submission Review Workflow: Pre-Review

New Studies, Modifications, Continuing Reviews & Mod/CRs

**PI/Proxy**
- Submit New Study
- Submit Follow-On Submission
  - Review Clarification Requests & Revise Submission
    - Re-submit?
    - No → Discard
  - IRBD Review
  - IRBC Review
- Dept Review
  - Send to & Manage Department Review
  - Request Clarifications?
    - Yes → Submit Department Review
    - No → Send to Pre-Review
  - IRBD Review

**IRB Director (IRBD)**
- Review Submission
  - Request Clarifications?
    - Yes → Send to Pre-Review
    - No → Assign IRB Coordinator
  - Ancillary Review Required?
    - Yes →IRBD Review
    - No → IRBC Review
- IRBD Review

**Department Reviewer**
- Review Submission
  - Request Clarifications?
    - Yes → Submit Department Review
    - No → Send to Pre-Review

**Ancillary Reviewer**
- Review Submission
  - Submit Ancillary Review
    - Note: The Submit Ancillary Review activity does not move a submission back into an IRBD/IRBC inbox. Rather, the submission is marked as acceptable or unacceptable by the Ancillary Committee on the Reviews tab. Comments for IRB review consideration and management should be provided by the Ancillary Reviewer for those marked unacceptable.

**IRB Coordinator (IRBC)**
- Review Submission (See details in IRB Submission Review Workflow for IRBC Role)
  - Request Clarifications?
    - Yes → Submit Protocol Determination
    - No → Submit Pre-Review
  - Note: The Submit Ancillary Review activity does not move a submission back into an IRBD/IRBC inbox. Rather, the submission is marked as acceptable or unacceptable by the Ancillary Committee on the Reviews tab. Comments for IRB review consideration and management should be provided by the Ancillary Reviewer for those marked unacceptable.

**Note:**
- The IRBD will generally not assign new submissions requiring Ancillary Committee approval prior to IRB review to an IRBC until the necessary Ancillary Committee approval has been granted.

**Note:**
- The Submit Ancillary Review activity does not move a submission back into an IRBD/IRBC inbox. Rather, the submission is marked as acceptable or unacceptable by the Ancillary Committee on the Reviews tab. Comments for IRB review consideration and management should be provided by the Ancillary Reviewer for those marked unacceptable.

**Note:**
- The Submit Protocol Determination activity is only required for: 1) new study submissions undergoing expedited or full board review; 2) follow-on submissions that change the information originally documented within the Submit Protocol Determination activity.
Exempt or Expedited IRB Submission Review Workflow: IRB Review

New Studies, Modifications, Continuing Reviews & Mod/CRs

P/P Proxy

Pre-Review

Review Level? No

Request Clarifications?

Exempt or Expedited Full Board

Assign Designated Reviewer

Assign to Meeting

Add Review Comments

Assign Reviewers

Review Submission

Assign to Non-Committee Review

Assign Designated Reviewer to IRBC

Request Clarifications by DR

Re-submit?

Yes

No

Withdraw/ Discard

IRB Coordinator (IRBC)

IRB Coordinator (IRBC)

PI/PI Proxy

Designated Reviewer (DR)

Primary Reviewer

Committee Chair

Yes

Yes

No

No

Yes

Yes

*Note: The Submit Regulatory Determination activity is not required for exemptions, projects deemed not human subject research, projects that are human subject research but the UR is not engaged, pSites undergoing MSS sIRB review, nor for study closures.
IRB Submission Review Workflow: Post-Review

New Studies, Modifications, Continuing Reviews & Mod/CRs

PI/PI Proxy

IRB Review → Determination?
- Approved
- Modifications Required to Secure Approval, Deferred
- Disapproved

IRB Coordinator (IRBC)

Review & Verify:
- Department Review
- Ancillary Review
- Protocol Determinations
- Regulatory Determinations
- Vulnerable Population Safeguards
- Approval Dates

Prepare Letter → Modifications Required to Secure Approval or Deferred
- Approved or Disapproved

Send Letter → Review Complete

Re-submit?
- Yes
- No

Review Submission → Ready for approval?
- Yes
- No, Send to PI
- No, Send to DR
- No, Send to Committee

Review Required Modifications; Answer Yes to Q4
- Review Required Modifications; Answer No to Q4; Edit ‘Notes’ to Clarify/Add Required Modifications

Assign Designated Reviewer
- Assign to Committee Meeting
- IRB Review
IRB Submission Review Workflow: Reportable New Information

**Pre-Review**
- Submit
  - Assign IRB Coordinator
    - Review Submission*
      - Submit Pre-Review
        - Additional Review Required
          - Potentially Serious*
          - No Further Review*
        - Assign Designated Reviewer
        - Assign to Committee Review
      - No Further Review*
    - No Further Review*

**IRB Review**
- Review Submission; Add Review Comments; Assign Reviewers
  - Assign to Meeting; Add Review Comments; Assign Reviewers
  - Submit RNI; Committee Review
  - Present at Convened Meeting
  - Potentially Serious*
    - Review Required
    - Committee Review
    - Designated Review
  - No Further Review*

**Post-Review**
- Prepare & Send Letter
  - Action Required
  - No Further Review*
    - Yes
      - Further Review Required
      - Review Required Actions
      - Actions Completed?
    - No
      - Yes
        - Re-submit RNI
      - No Further Review%
        - No Further Review%
        - Regulatory Reporting Required
          - Yes
          - No
          - Actions Completed?

*Clarifications may be requested, if necessary
*Serious = UPIRTSO; suspension or termination of IRB approval; serious or continuing non-compliance
*No Further Review = Not serious or continuing; no basis in fact; none of the above

% No Further Review = Not serious or continuing; no basis in fact; none of the above
Multi-Site, Single IRB Submission Review Workflow

New MSS sIRB Studies, New Participating Sites (pSite) & Follow-On Submissions

Lead PI/PI Proxy

- Submit New MSS sIRB Study
- Add pSite*
- Request Addition of pSite PI Contact in Click® IRB
- Submit Invitation Decision
  - Request Addition of pSite PI Contact in Click® IRB

sIRB (RSRB)

- Create pSite Institutional Profile
- Pre-Review
- IRB Review*
- Post-Review
- Review Complete

- Edit pSite Submission* (Update with Site-Specific Materials)
- Submit pSite Materials*
- Submit Study Modification
- Submit Site Modification
- Submit Study Continuing Review
- Report Site Continuing Review Data*
- Submit RNI
- Record pSite CR Data*

*Activity may be performed by the IRBC on behalf of the PI/PI Proxy.
*See Detailed IRB or RNI Submission Review Workflows for Pre-Review, IRB Review and Post-Review workflows for additional details.
# 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.

<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>
</tr>
<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>
</tbody>
</table>
| • Introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.) into human subjects  
• Cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects  
• Introduction of genetically engineered micro-organisms into human subjects  
• Biohazardous organisms or materials handled at Biosafety Level 2 or higher | Institutional Biosafety Committee | Prior to IRB Approval | N/A |
| Obtaining fresh, banked or archived human tissue | Surgical Pathology | Prior to IRB Approval | N/A |
| Radioisotopes or radiation-generating devices used for research purposes | Human Use of Radiation Committee (HURC) / Radiation Safety | Prior to IRB Approval | Annual re-approval |
| Access to the Center for Advanced Brain Imaging & Neurophysiology (CABIN) | Center for Advanced Brain Imaging & Neurophysiology (CABIN) | Prior to IRB Approval | N/A |

^When a study requires review by the PRC, DROIPR or EMRC and the PI’s primary appointment is the Cancer Center, Radiation Oncology, or Emergency Medicine, respectively, further review by the Ancillary Committee is not required; Department Review and approval is sufficient.
Quick Reference Guide: Approval, Effective & Expiration Dates

During Post-Review, the **Submit Designated Review** and **Submit Committee Review** activities provide fields to enter approval, effective and expiration dates. Depending on the approval determination made within the activity form, date-related field requirements differ. The guidance provided below clarifies when date-related fields are required and what dates should be entered into respective fields, based on the approval determination.

<table>
<thead>
<tr>
<th>Approval Determination</th>
<th>Required Date Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mods Required to Secure ‘Not Human Research’</td>
<td>Approval Date</td>
</tr>
<tr>
<td>Mods Required to Secure ‘Human Research, Not Engaged’</td>
<td>Approval Date</td>
</tr>
<tr>
<td>Mods Required to Secure Approval</td>
<td>Approval Date</td>
</tr>
<tr>
<td>Not Human Research</td>
<td>Approval Date, Effective Date</td>
</tr>
<tr>
<td>Human Research, Not Engaged</td>
<td>Approval Date, Effective Date</td>
</tr>
<tr>
<td>Exemption Determination</td>
<td>Approval Date, Effective Date</td>
</tr>
<tr>
<td>Approved (Committee or Non-Committee Review)</td>
<td>Approval Date, Effective Date</td>
</tr>
</tbody>
</table>

**Date Descriptions**

**Approval Date**: The date the regulatory determination was made by the designated review/committee indicating all requirements of the approval criteria were met (i.e., the date the designated review submitted their regulatory determination form or the date of the committee meeting).

- If the designated review/committee determined that modifications were required to secure approval, this date only gets updated when/if the submission returns to the designated reviewer/committee and a new determination is made.

**Effective Date**: The date the regulatory determination (IRB decision) takes effect (i.e., the date the final approval/exemption letter is sent; the first possible date the research can be performed).

- If the regulatory determination is outright approval, the approval and effective date are the same.
- If the regulatory determination requires modifications to secure approval, the effective date is date the modifications are reviewed and accepted.
- If the research is deferred, enter the date of the committee meeting.
- If the research is disapproved, enter the date of the committee meeting.

**Last Day of Approval Period**: The last day of study approval and the last date on which research activities can be performed (the following day the submission approval lapses).

- For submissions approved for 1 year, enter 1 year following the approval date minus one day.
  - E.g., if a designated reviewer recorded their regulatory determination on 10/15/2018, the last day of approval would be 10/14/2019.
  - E.g., if a committee voted on their regulatory determination on 10/15/2018, the last day of approval would be 10/14/2019.
- For all other submissions (i.e., submissions approved for less than 1 year), enter the date determined by the designated reviewer/committee.
- For all modifications, ensure the date entered is consistent with the expiration date listed at the time of the last continuing review (this should populate automatically).
### Quick Reference Guide: Regulatory Oversight

The following is a list of entities that provide regulatory oversight and their applicable scopes.

<table>
<thead>
<tr>
<th>Select this regulatory body…</th>
<th>When…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Defense (DOD)</td>
<td>Research is funded by DoD</td>
</tr>
<tr>
<td>Department of Energy (DOE)</td>
<td>Research is funded by DoE</td>
</tr>
<tr>
<td>Department of Justice (DOJ)*</td>
<td>Research is funded by DoJ</td>
</tr>
<tr>
<td>Department of Education (ED)</td>
<td>Research is funded by ED</td>
</tr>
<tr>
<td>Environmental Protection Agency (EPA)</td>
<td>Research is funded by EPA</td>
</tr>
</tbody>
</table>
| Food & Drug Administration (FDA)* | - Research involves a test article (drug, biologic, device [including in vitro diagnostic devices], or supplement) subject to regulation by the FDA  
- Research funded by the FDA |
| General Data Protection Regulation (GDPR) | Research involves data collection from subjects located in the European Economic Area (EEA) |
| Department of Health & Human Service (HHS) | Activities involve human subjects and meet HHS’s definition of research (including exempt determinations) |
| International Conference for Harmonization of Good Clinical Practice (ICH GCP) | Study protocol specifically cites compliance with ICH GCP guidelines |
| National Science Foundation (NSF) | Research is funded by National Science Foundation |
| Office of Civil Rights (OCR) | Research is subject to HIPAA regulations (i.e., research involves the use and/or disclosure of protected health information by a covered entity; the study team includes members of a covered entity)  
Note: Proposals deemed exempt, not human research or projects that are human research but the UR is engaged are still subject to HIPAA regulations if the proposal involves the use/disclosure of protected health information by a covered entity. |
| Other federal agency | Research is subject to other federal regulations based on the study population, funding source, etc (e.g., Family Education Rights and Privacy Act, Protection of Pupil Rights Amendment) |
| Tribal law | Research is conducted in a setting governed by tribal law |
| None of the above | Activities that do not meet the definition of research or do not involve human subjects |

* If FDA or DOJ is selected, the study will automatically fall under the Pre-2018 Common Rule requirements, even if it falls after the effective date setting of the 2018 requirements.
## Quick Reference Guide: Conducting Designated & Committee Reviews

### 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).

### Conduct a Designated (Expedited or Exempt) Review

Following review of the submission, you may:

1. Request clarifications by sending the IRBC a **Private Comment**. Alternately, if revisions are minor, clarifications/revisions may be requested via the **Submit Designated Review Activity** (select ‘Modifications required to Secure Approval’).
   - **DO NOT SELECT** ‘Request Clarification by Designated Review’. Doing so will send requests directly to the study team.

2. **Assign to Committee Review**, if the submission requires review by the full board.

3. Move the submission forward in the review process (back to the IRBC) by: a) clicking **Submit Regulatory Determinations** (i.e., chair’s checklist) to document findings; and b) clicking **Submit Designated Review** to document your approval determinations. **Note:** The Submit Regulatory Determinations activity is not required for exemptions, projects deemed not human subject research, projects that are research but the UR is not engaged, nor for study closures.

### Locate Submissions & Meetings

1. Click the link in your notification email.
2. Log into Click® IRB and locate the submission from your inbox or assignments tab on the Dashboard.
3. Log into Click® IRB and the **IRB** module.
4. Click on **Meetings**.
5. Select the meeting the submission has been assigned to.
6. Click on the submission or submission ID to open the submission.

### Conduct a Committee (Full Board) Review

If you are assigned the Primary Reviewer role, prior to the committee meeting, document your review notes by:

1. Clicking **Add Review Comments** from the submission workspace.
   - **DO NOT SELECT** ‘Request Clarification by Committee Member’. Doing so will send requests directly to the study team.

2. Type your notes in the comments field and/or attach supporting documents (e.g., reviewer checklist, tracked consent forms, etc.). Click **OK**.

During/after the committee meeting, document findings (i.e., complete the chair’s checklist) by:

3. Clicking **Submit Regulatory Determinations** to document findings.

### Review a Submission

From the submission workspace you may:

1. **Review Study/Mod/CR/RNI**: 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.
   - Use the **Compare** feature to review revisions to previously reviewed materials. The versions of the submission compared will appear at the top of the left-hand navigation pane when **Compare** is selected (click the down arrow to change the versions being compared). Click on the pencil icon(s) to view the change(s) made. Revisions will be indicated by ‘Differences’ boxes that may be expanded/contracted for additional revision details

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

3. Additional information is also available in the navigation toolbar (e.g., funding, contacts, documents, reviews, determinations, training details, etc.)

### Review a Report of New Information

Following review of the RNI, you may:

1. **Submit RNI Designated Review** to document your determination and move the submission forward in the review process. Depending on your determination, the submission will either move to Review Complete or be assigned for committee review.

2. Request clarifications by sending the IRBC a **Private Comment**.
   - **DO NOT SELECT** ‘Request Clarification by Designated Reviewer’. Doing so will send requests directly to the study team.