cayuse IRB

Cayuse IRB Guide for Reviewers

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Login Information

I.   Navigate to https://ucmerced-cayuse424.com/rs/irb/ on a web browser - Google Chrome, Firefox, Safari, and Internet Explorer.

II.   Use your UCM Net ID and password.

Navigating Cayuse IRB

Dashboard

When you first log in to Cayuse IRB, the **Dashboard** screen presents you with a quick overview of any studies you are involved with or that require your attention.
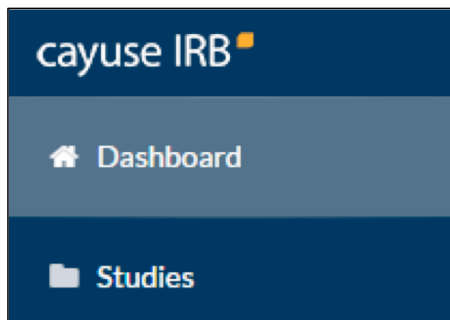
Studies and Submissions

The **Studies** and **Submissions** screens list the studies and submissions that you have access to.
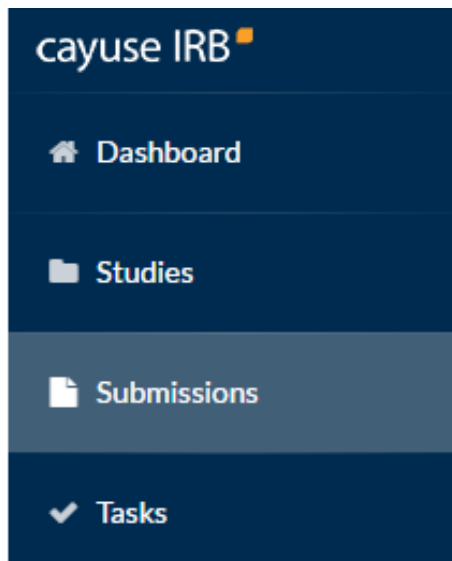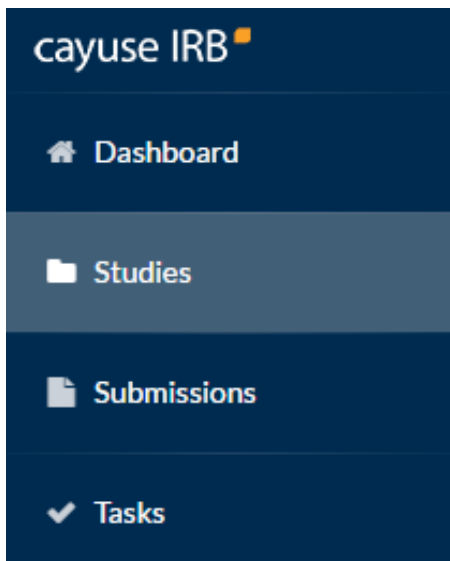
- **IRB Users** see all studies that they are involved with as PI, PC, Researcher, etc.
- **Organizational Approvers** see the studies that require their approval before proceeding.
- **IRB Members** see all studies that are or were assigned to them, or to the review board(s) they are a member of, for review.
- **IRB Analysts** and **Admins** can see all studies in the system.

Meetings

The **Meetings** section allows IRB Analysts, Admins, and Members to view the calendar of scheduled IRB meetings. *IRB Users do not see the   Meetings section.*
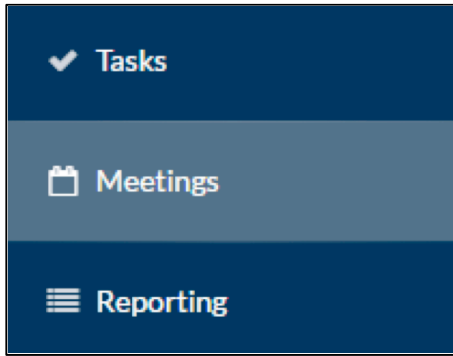
IRB Members can use the Meetings screen to access the studies that are assigned to their review board(s).

Reporting

The **Reporting** section lets IRB Analysts and Admins create and download custom CSV reports containing various study details and audit   information.
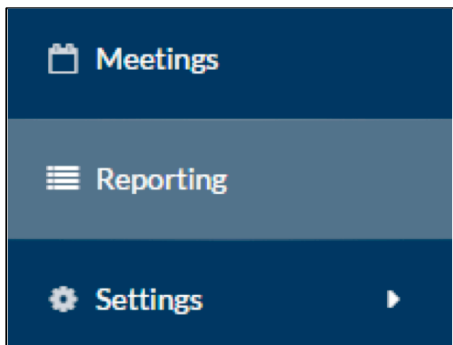
Settings

The **Settings** section contains options for IRB Analysts and Admins to configure settings in the Cayuse IRB application, and to create templates for submissions, messages, and letters. Admins see additional areas of configuration that Analysts do not have. *IRB Users do not see the Settings   section.*
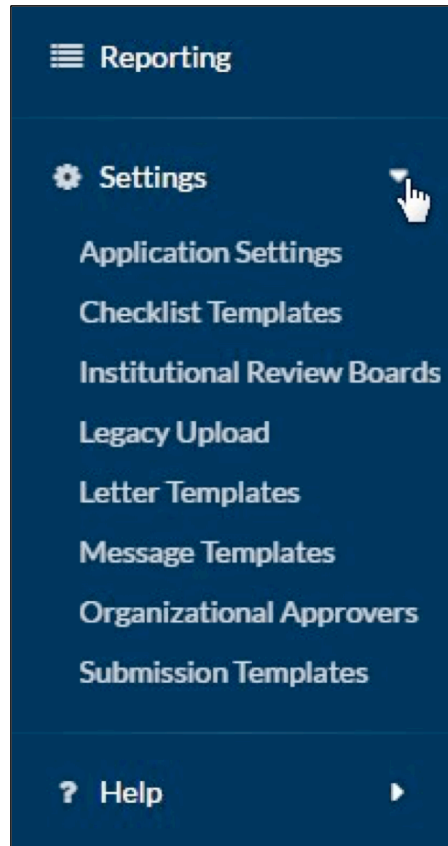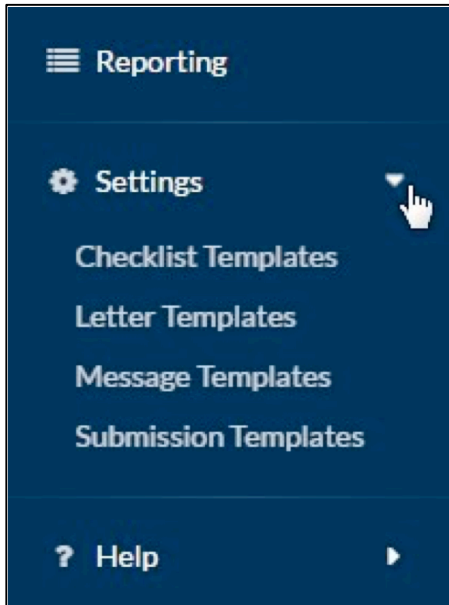
Tasks

The **Tasks** screen lists the studies that are assigned to you, along with the task that you are responsible for. Completing a task advances a   submission through the workflow.
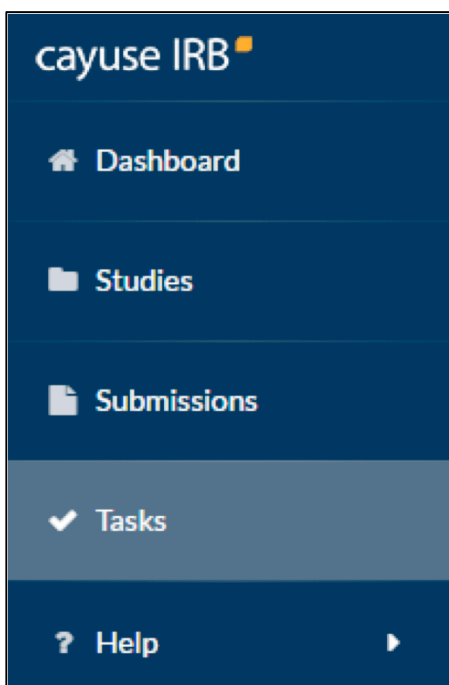
Notifications

The **Notifications** icon at the top of the screen lets you see the system messages that have been sent to you regarding the submissions you are   involved with. Click on the icon to display the list of notifications.

User Settings and Actions

Clicking on your name in the upper right corner of Cayuse IRB displays a dropdown menu with two options.

User Settings - Favorite Role - If you have more than one user role (such as *Analyst* and *Reviewer* for someone who is both an IRB Analyst   and a member of a review board), certain screens (such 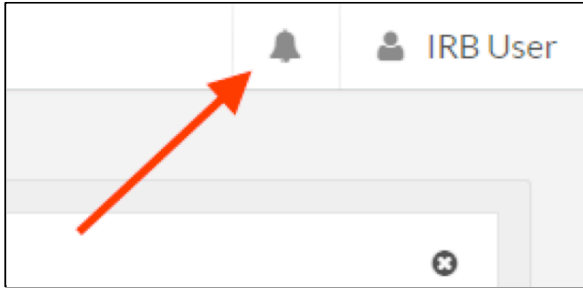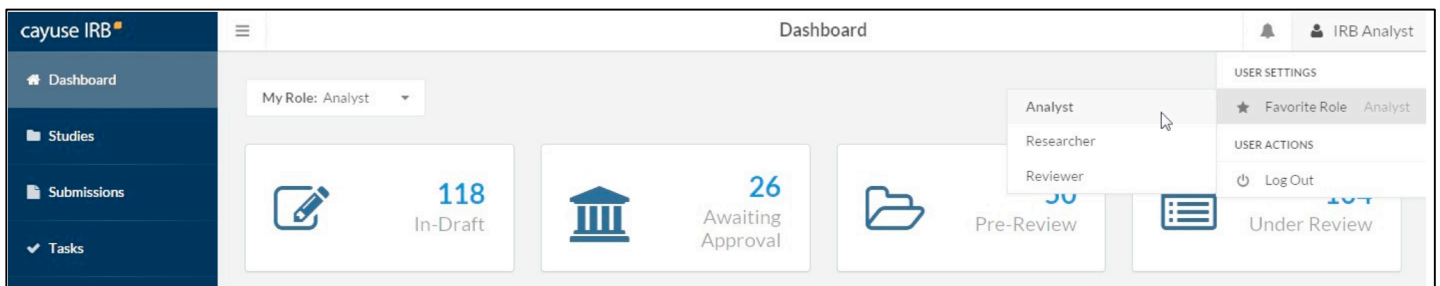as the dashboard) display different information depending on your role. These screens   have a dropdown in the upper left that allows you to select which user role you are currently working as. The Favorite Role option in the user   menu allows you to specify a default role which will be selected each time you log in to IRB.

User Actions - Log Out - Log out of Cayuse IRB.

Help

You can click on the **Help** menu at any time to launch this in-product Help, or to view the release notes for this and all previous versions of   Cayuse IRB. The Help menu also contains tutorials that explain the Dashboard screen, and how to search for studies and submissions.
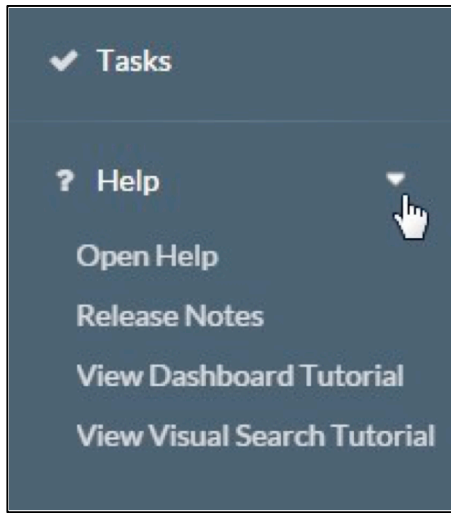
Clicking the small icons throughout Cayu

Dashboard

When you first log in to Cayuse IRB, you will be taken to your **Dashboard**. This screen displays an overview of all the studies you are involved w i t h or that require your attention, and offers a quick way to view and filter studies, submissions, and tasks.

- The four status buttons across the top allow you to run quick filters on submissions which have the selected status. For instance, clicking on the **In Draft** button takes you to the Submissions page and displays all of the submissions that are currently in draft (status = Unsubmitted or status = Reopened).
- Clicking on a review type in the Analyst's **Submissions under review** pane takes you to the Submissions screen and automatically searches for submissions with the selected review type.
- Clicking on the IRB number for a submission, study, or task takes you to the Submission or Study Details screen for that submission or study.
- The **Submissions by Type** pane displays the counts of each submission type for all active studies. It does not include submissions for archived studies, or administrative closure/withdrawal submissions.
- Calendar dates with a green dot have a meeting scheduled on that date. Click on the date to bring up the details of the meeting(s) scheduled on that day.

Studies and Submissions

Studies

The **Studies** screen lists all of the studies that you have access to. For IRB Users, this means all of the studies that you have created or are involved in as a researcher. Organizational Approvers see the studies that have been assigned to them for review. IRB Members see the studies that have been assigned to them or to their review board(s). IRB Analysts and Admins can view all studies in the system.

You can sort the list of studies by expiration date or creation date. To sort on a column, click on its header.

Study Statuses

There are 11 different statuses that a study can be in:

I. **Approved** - Study has been approved by the Compliance Office and/or Review Board.

II. **Closed** - Study is no longer in progress.

III. **Disapproved** - After being reviewed, the study was not approved by the Compliance Office/review board.

IV. **Expired** - The study has passed its expiration date without being renewed.

V. **Legacy** - Optional status that can be used when importing legacy submissions, in place of "Approved".

VI. **Requires Changes** - The Compliance Office has requested modifications to the study in order for it to be approved.

VII. **Submitted** - The PI has sent a submission to the Compliance Office and it is awaiting review.

VIII. **Suspended** - Used when an incident has occurred to place the study on hold until further notice. The research team must submit a modification in order to remove the suspension.

IX. **Under Review** - The Compliance Office and/or Review Board is currently reviewing the study.

X. **Unsubmitted** - The study has not yet been sent to the Compliance Office for review.

XI. **Withdrawn** - The research team has submitted a withdrawal for this study and no longer wishes to pursue it.

The Studies screen is divided into two tabs, **Active** and **Archive**. The Active tab displays all of the studies that are currently active within Cayuse IRB. The Archive tab lists studies that have been closed, disapproved, or withdrawn.

cayuse IRB

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- **Tasks**
- **? Help** ▶

Studies

🔔 👤 IRB User

Active Archive

+ New Study

🔍 ⚙ Archived Within :   ⊗

		Status	PI	Archive Date	Create Date ▼
1 year		● Closed	IRB User	01-05-2016	02-26-2014
2 years					
3 years					
IRB-FY2014-1113	Effects of sunlight on seasonal affective disorder	● Closed	IRB User	01-05-2016	02-26-2014
IRB-FY2014-2884	Depression in first-year college students	● Closed	IRB User	01-26-2016	01-26-2014

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Submissions

Each study can have one or more submissions associated with it. When you first create a study, you must begin by creating an *Initial* submission (or a *Legacy* submission if the study was imported from a previous system). The **Submissions** screen lists all of the submissions relating to the studies that you have access to.
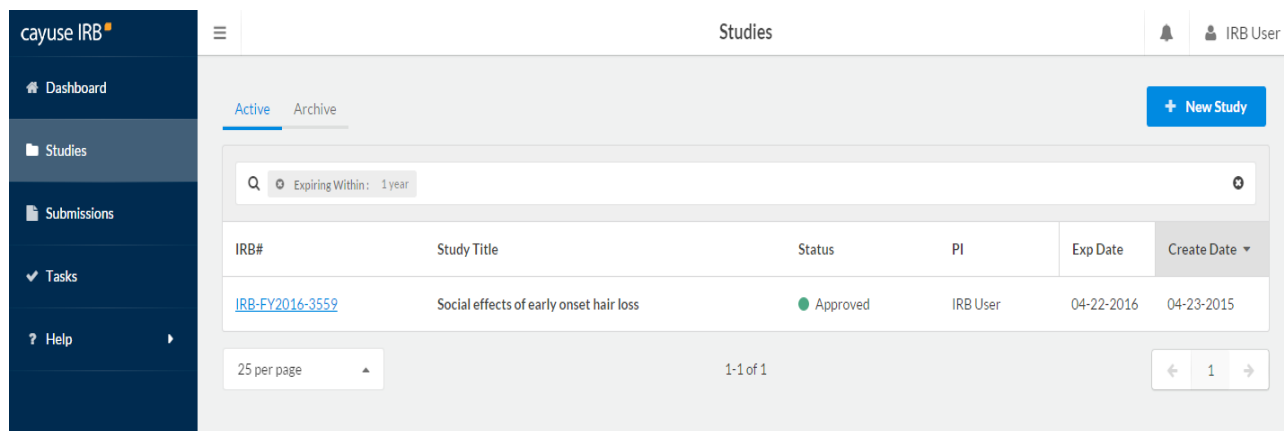
Note that some of the submissions are different types of submissions for the same study. For instance, an initial submission that was later followed up by a modification submission for that study.

Once you select a value, you will see a second list of suggestions for values to search for. You can choose a value from this list, or free type your own.

If desired, you can add additional search filters by clicking in the white space in the search bar. When finished, press enter to search.

To go to a study or submission, click anywhere in that row.

Tasks

Whenever a study changes state, Cayuse IRB assigns one or more *tasks* to various users. For example, when a researcher first saves a new submission, the system assigns them a "complete submission" task. The task assignments tell you what you need to do next in order to proceed with the submission.

The **Tasks** screen lists all of the tasks that are currently assigned to you. Click on any task to open the submission associated with that task.

If you have more than one user role-- for instance, you are an IRB Analyst but sometimes review submissions as well-- the task list only shows tasks that pertain to your currently-selected role. To change your user role, use the Role dropdown at the top of the screen.

When you complete a task, it is removed from your task list. You may then see another task assigned to you for the next step in the process, or another user may receive a task depending on where the submission is in the workflow.

Depending on how your IRB Administrator has configured the application, you may receive email notifications for tasks at periodic intervals. Administrators can specify how frequently to send reminder emails for outstanding tasks via the Application Settings screen.

The task list for the IRB Analyst above shows several studies that are waiting to be assigned to an Analyst. Assigning the study to a particular Analyst for review is the next step, and these tasks will appear in all IRB Analysts' task lists until this is done.

Notifications

The **Notifications** icon shows you a list of all the messages you have received regarding one of your studies. In the example below, this IRB User has received notifications for several studies. The notifications for the first three studies indicate that various submissions have been received by the IRB office. The fourth notification pertains to a study that has expired. You will get a notification whenever one of your studies requires some action by a different user or user role.
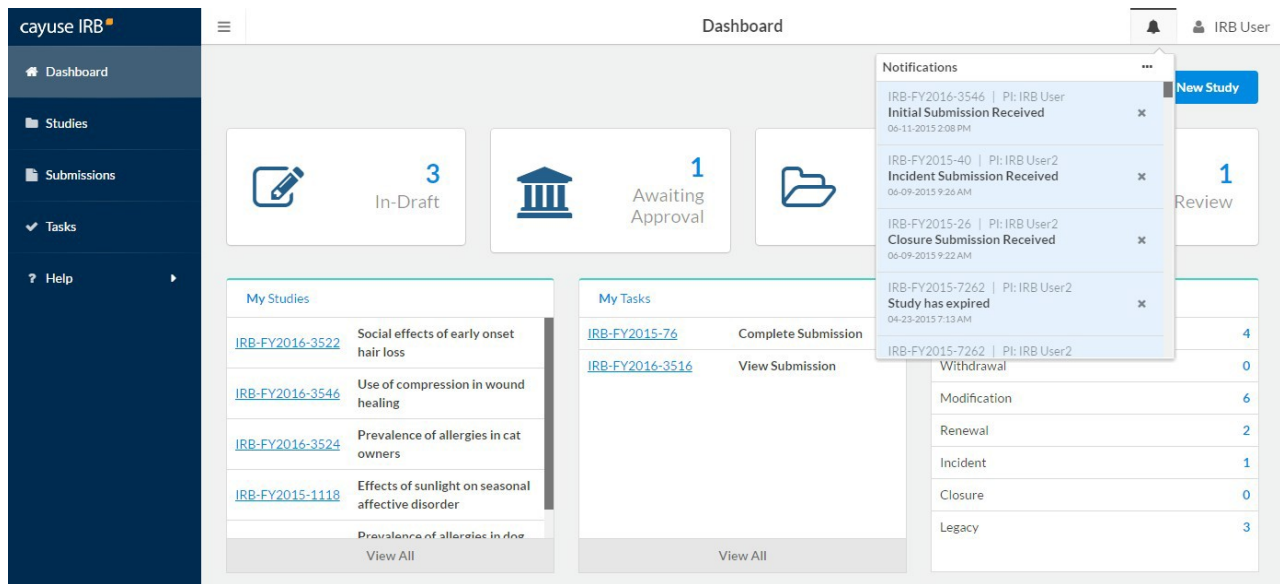
Notifications are sent:

XII. To the PI when the submission has been sent to them for certification.

XIII. To the PI and PC, when their submission has been received by the Compliance Office.

XIV. To the Organizational Approver(s) when a submission requires approval.

XV. To the IRB Analyst when a new submission requires Analyst assignment.

XVI. To the previous IRB Analyst, when a submission is reassigned to another Analyst

XVII. To the IRB Analyst when an expedited review is complete.

XVIII. To the board members or reviewers when a submission requires their review.

XIX. To the PI and PC when a study is expiring or has expired.

XX. To the primary and/or secondary reviewer(s), when an Analyst has added a comment to the submission.

Many of these notifications are also sent via email to ensure the recipient sees the message in a timely manner. In particular, the PI and other contacts listed on the submission receive emailed notifications whenever the submission moves to a new step in the workflow (when it is reviewed and approved, returned to the PI, etc.).

Clicking on a notification takes you to the submission that notification pertains to. Viewed notifications are no longer highlighted in the Notifications list. You can delete notifications from the list by clicking the **X** icon next to that notification, or use the **...** menu to mark all notifications read or to delete all notifications.

Reviewing and Commenting on Submissions

The **Review** button lets the IRB Analyst or Member whom the submission is assigned to view the submission and add any notes or attachments necessary. Comments can be used to communicate with the investigation team and request changes or additional information, or they can be hidden so that only the compliance office and IRB members can see them.

Both the **Review** button and the **Checklist** button open the submission form for review. Checklist opens the submission form with the checklist expanded.

Note: You may not see the Checklist button if no checklists are configured for your institution.

Using Checklists

Checklists are designed to help the analyst or reviewer verify that the form questions have been answered in a manner that satisfies your institution's specific requirements. IRB Analysts and Administrators can configure the checklist questions via the Settings menu. There are two different checklists used for all submissions-- one checklist for the IRB Analyst, and a different checklist used by each of the submission's reviewer(s).

The IRB Analyst has read-only access to the reviewers' checklists, allowing the Analyst to see which items have or have not been completed during the review.

Adding Comments

Each question on the form has an **Add Comment** link below it that you can use to add a comment regarding that question. Click Add Comment button to open a text-entry field.

Enter the text of your comment in the box, then click **SAVE COMMENT** to insert the comment.

- By default, new comments are visible only to IRB Analysts, Members, and Administrators. To make a comment visible to the research team, use the dropdown in the upper right of the comment to change the visibility from *Restricted* to *Unrestricted*.

- To insert additional comments, enter the text of the new comment and then click the [SAVE COMMENT] button at the bottom of the list of existing comments.

- The total number of unresolved comments for each section appears in the sidebar next to that section.

- If the submission is returned to the research team, they can reply to any visible comments and/or mark them as **addressed**. Analysts and reviewers can enter and reply to comments and mark them as resolved when the submission is assigned to them.

- Replies entered by the research team are visible to everyone.

- The research team must address all visible comments before they can re-certify the submission.

Inserting Attachments

When you are entering the text of a comment, you can include an attachment in the comment. Use the 🔗 icon in the text editor to browse for a file to upload.
Note: File attachments are limited to a maximum size of 20 MB.

Returning Submissions to the PI for Modifications

If the IRB Analyst or reviewers determine that the investigation team must make changes to the submission or would like them to address comments made on the submission, the Analyst can return the submission to the PI using the **Return** button. Once the investigation team has made the requested changes, the PI will then need to recertify the submission.

Comparing Two Versions of a Submission

If a submission has been returned to the investigators for them to make changes or corrections, once they resubmit it you can compare the new version to the previous version by clicking the **Compare** button at the top of the review window. The sidebar shows the number of differences found in each section. Within each section, each difference is highlighted for you to review. Click the **Previous** or **Next Diff** buttons at the top of the comparison window to jump to the previous/next difference.

Making Decisions for Exempt and Expedited Reviews - Reviewers

The IRB Analyst may assign submissions to one or more IRB Members for exempt and expedited reviews. If a primary reviewer has been assigned to a submission, they are tasked with making the decision based on their review and comments from any other reviewers assigned to the study. Otherwise, all reviewers assigned to the submission may enter their decision, and the IRB analyst will choose which decision to accept. All exempt submissions have a primary reviewer, but expedited submissions may or may not have a primary specified. **Note:** Studies under full review are discussed at a scheduled IRB meeting, and the analyst handles the decision based on the results of the meeting.

All reviewers can review/comment on submissions that have been assigned to them. Once the review is complete, the primary reviewer, or all reviewers if there is no designated primary, can select **Make Decision** to enter the results.

On the **Decision** screen, select the decision for this submission, and the date of the result. The expiration date is automatically calculated based on your system settings, but you can change it if needed. **Note:** The expiration date is only set for Initial and Renewal submissions that have been approved. Modification, Incident, and Closure submissions will display the expiration date set in the most recent Initial or Renewal submission for the study. You can also manually edit the expiration date for "Rely on NCI-CIRB" and "Rely on External IRB" decisions. The expiration date is optional for exempt studies.

You can also select a category that explains why this study qualifies for an expedited or exempt decision. Depending on your institution's requirements, if the study does not fall into any of these categories, it may not qualify as exempt/expedited. You can toggle the submission between exempt and expedited yourself using the **Switch to Exempt**/**Switch to Expedited** button on the submission dashboard. If you need to

return the submission to the analyst to arrange a full board review, you should select *Not Exempt* or *Not Expedited* as the decision and complete the review.

There are three optional note fields that you can fill out with additional information regarding your review:

- **Findings** - Any text entered in the Findings box may be used as part of the letter(s) sent to the research team in relation to this submission.
- **Researcher Notes** - Notes that are intended for the research team and can be used as part of the letters(s) sent in relation to this submission.
- **Internal Notes** - Private notes that will not be visible to the research team.

Once you have recorded the decision, return to the Study Overview and select **Review Complete** to return the submission to the IRB Analyst.

Decision Types

When entering decisions, you can choose from the following selections. You will see different options depending on the type of review.

Decision	Explanation	Resulting Study Status	Routing
Approved	The study is approved.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
No Engagement in Research	The study does not constitute research and therefore does not require IRB approval.		
No Human Subjects Research	The study does not include human subjects research and therefore does not require IRB approval.		
Noted	The incident report has been noted by the IRB.		
Rely on External IRB	The study and submission were reviewed and approved by an external IRB and their decision has been recorded by the IRB.		
Rely on NCI-CIRB	The study and submission were reviewed and approved by an NCI-CIRB and their decision has been recorded by the IRB.		
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Exempt	
Suspended	A study is suspended when the IRB decides that the research needs to stop until changes have been made to the research. A suspended decision is available on Incident Reports, Modifications, and Renewals.	Suspended	Submission is returned to the PI and is no longer editable.
Closed	A closure submission is created and submitted when the research is done and the study can be closed.	Closed	The study is closed and no further research can be done.
Withdrawn	The research team decided not to proceed with the initial submission. This decision is only available for withdrawal submissions. The research team can choose to withdraw the study at any point until the initial submission has been approved. If the initial submission has been approved, the research team must create a closure submission instead.	Withdrawn	The study is closed and no further research can be done.
Disapproved	The full board identified major issues with the study and submission and disapproved the research. A new study and submission will need to be created.	Disapproved	The submission and study are disapproved and no longer editable.
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.		Submission is returned

Minor[12] Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	Requires Changes	to the PI and reopened for editing.
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.		
Not Expedited/Not Exempt	The study will be returned to the IRB Analyst to reassign it to the correct review type.		Submission is returned to the Analyst to reassign the review type and reviewers.
Not Reviewed	Documents that the submission was unable to be discussed at the meeting. The "Not Reviewed" decision is logged in the decision history so that a new decision can be made at a subsequent meeting. This decision type is only available for full board reviews of initial, modification, incident, and renewal submissions.		Submission is returned to the Analyst to assign to a new meeting.