

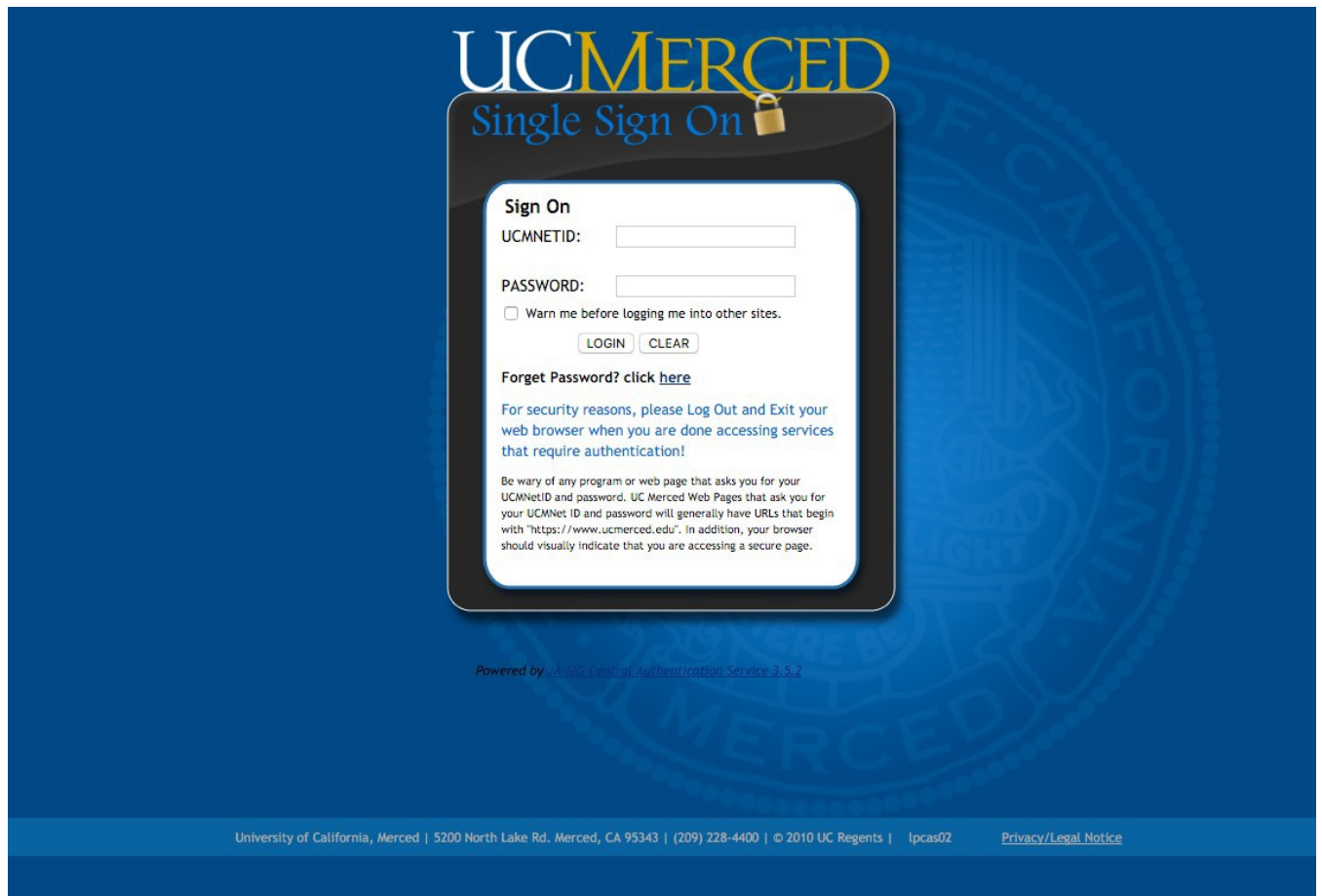


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Login Information

- 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.



The image shows the UC Merced Single Sign On login page. The background is a solid blue color with a large, faint, circular seal of the University of California, Merced, in the background. The seal features a building and the text "UNIVERSITY OF CALIFORNIA" and "MERCED".

At the top center, the text "UCMERCED" is displayed in a large, yellow, serif font. Below it, the text "Single Sign On" is displayed in a smaller, blue, sans-serif font, followed by a small yellow padlock icon.

The login form is a white rectangular box with a black border and a drop shadow, centered on the page. It contains the following elements:

- Sign On**: A heading in bold black text.
- UCMNETID:**: A label followed by a white text input field.
- PASSWORD:**: A label followed by a white text input field.
- ☐ Warn me before logging me into other sites.
- LOGIN** and **CLEAR**: Two small, rounded rectangular buttons.
- Forget Password? click [here](#)**: A link in blue text.
- For security reasons, please Log Out and Exit your web browser when you are done accessing services that require authentication!**: A paragraph of text in blue.
- Be wary of any program or web page that asks you for your UCMNetID and password. UC Merced Web Pages that ask you for your UCMNet ID and password will generally have URLs that begin with "https://www.ucmerced.edu". In addition, your browser should visually indicate that you are accessing a secure page.**: A paragraph of text in black.

Below the login form, the text "Powered by [A-SIS Central Authentication Service 3.5.2](#)" is displayed in a small, blue, sans-serif font.

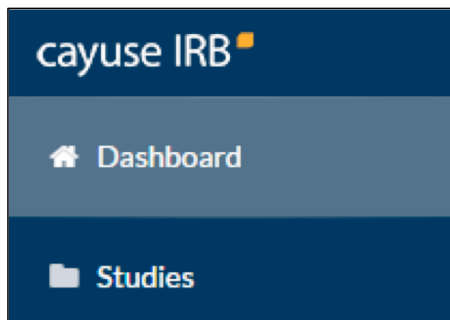
At the bottom of the page, a dark blue horizontal bar contains the following text in a small, white, sans-serif font:

University of California, Merced | 5200 North Lake Rd. Merced, CA 95343 | (209) 228-4400 | © 2010 UC Regents | lpcas02 [Privacy/Legal Notice](#)

Navigating Cayuse IRB

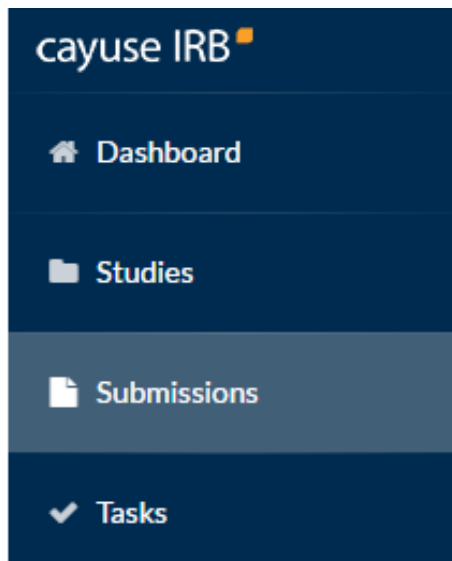
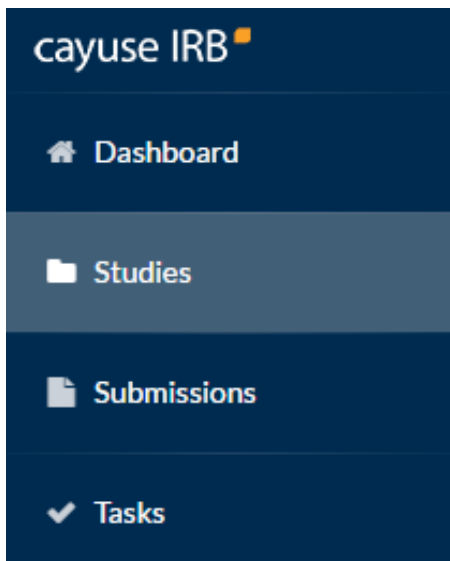
Dashboard

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

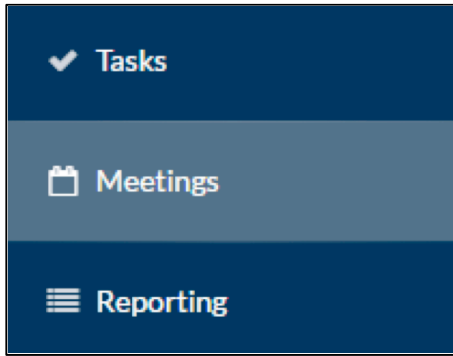
The [Studies and Submissions](#) screens list the studies and submissions that you have access to.



- **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

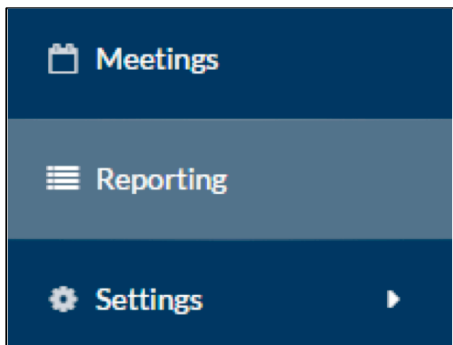
The [Meetings](#) section allows IRB Analysts, Admins, and Members to view the calendar of scheduled IRB meetings. *IRB Users do not see the Meetings section.*



IRB Members can use the Meetings screen to access the studies that are assigned to their review board(s).

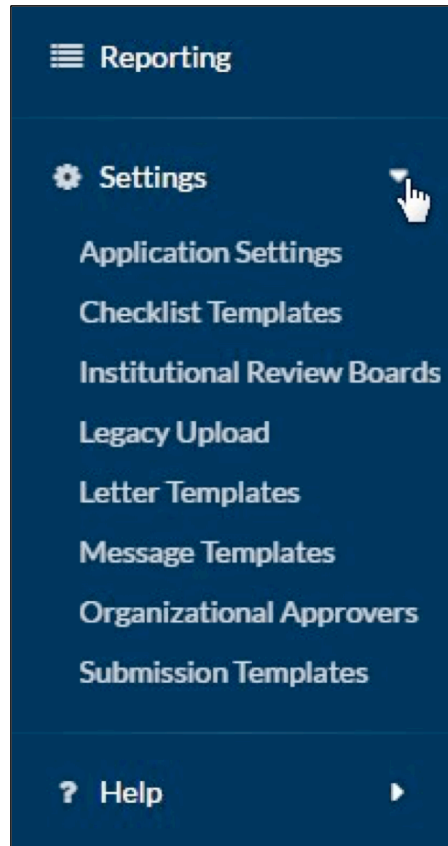
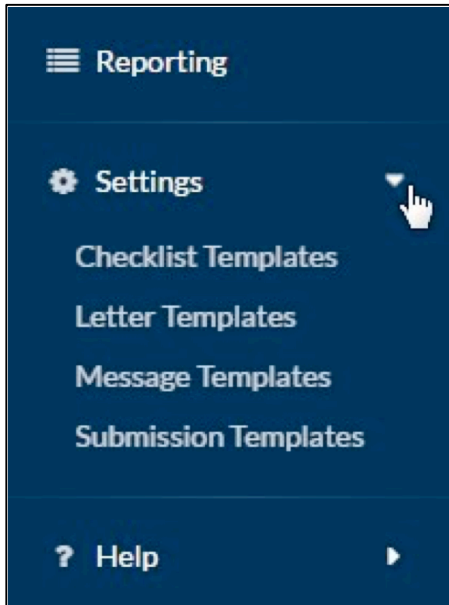
Reporting

The [Reporting](#) section lets IRB Analysts and Admins create and download custom CSV reports containing various study details and audit information.



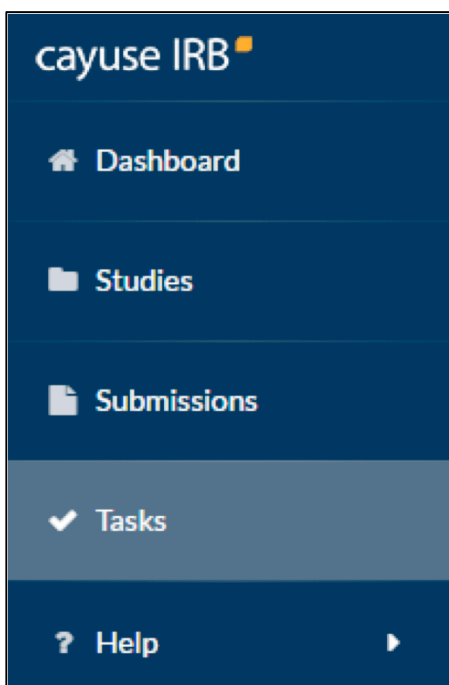
Settings

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.*



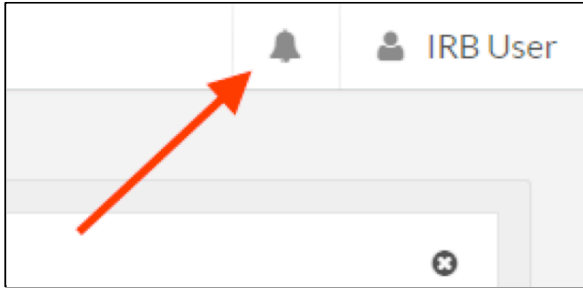
Tasks

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.



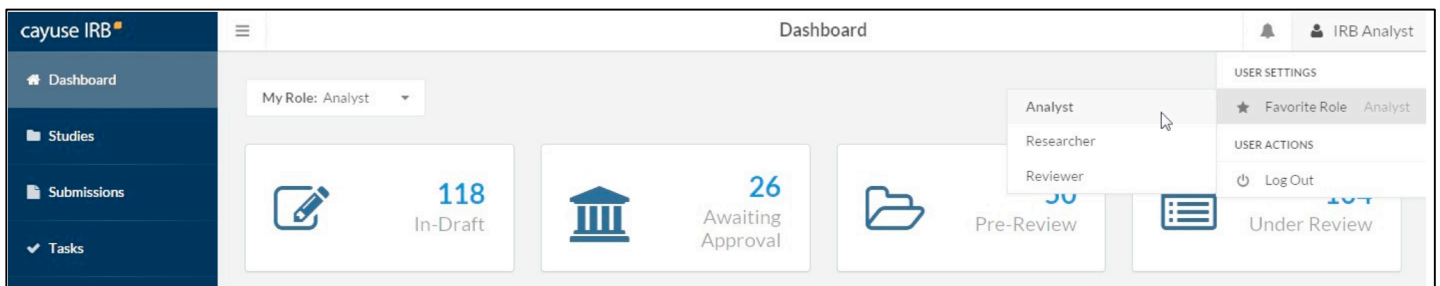
Notifications

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.

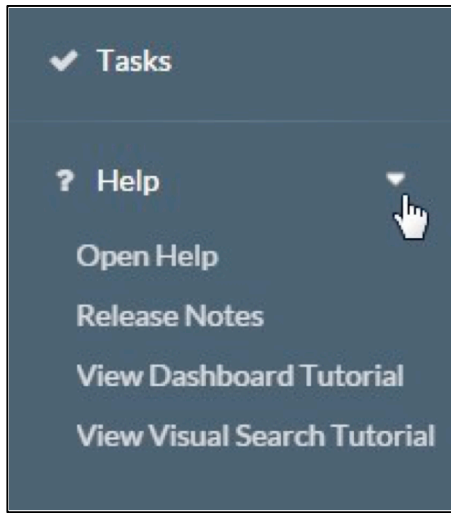



User Settings - Favorite Role - If you have more than one user role (such as *Analyst* and *Reviewer* for someone who is both an IRB Analyst and a member of a review board), certain screens (such as the dashboard) display different information depending on your role. These screens have a dropdown in 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 with or that require your attention, and offers a quick way to view and filter studies, submissions, and tasks.

The screenshot shows the Cayuse IRB Dashboard for a user with the role of 'Researcher'. The dashboard provides a comprehensive overview of the user's studies, tasks, and submissions.

Dashboard Overview:

- My Role:** Researcher
- + New Study** button
- Study Status Summary:**
 - In-Draft:** 9
 - Awaiting Approval:** 4
 - Pre-Review:** 10
 - Under Review:** 23

Main Content Sections:

- My Studies:** A list of studies with links to their details.

Study ID	Study Title
IRB-FY2015-49	Evaporation of marine layers
IRB-2016-154	Use of compression in wound healing
IRB-2016-151	Social effects of early onset hair loss
IRB-FY2016-87	Sunlight exposure and depression
IRB-2016-148	Efficiency of hydroelectric dams

[View All](#)
- My Tasks:** A list of tasks with links to their details.

Task ID	Task Title
IRB-FY2016-91	Complete Submission
IRB-FY2016-84	View Submission
IRB-FY2016-84	Certify Submission

[View All](#)
- Submissions by Type:** A table showing the count of submissions for each type.

Submission Type	Count
Initial	10
Withdrawal	1
Modification	2
Renewal	9
Incident	1
Closure	1
Legacy	5
- Approved Studies:** A list of approved studies with links to their details.

Study ID	Study Title
IRB-FY2015-49	Evaporation of marine layers
IRB-2016-154	Use of compression in wound healing
IRB-2016-151	Social effects of early onset hair loss
IRB-FY2016-87	Sunlight exposure and depression
IRB-2016-148	Efficiency of hydroelectric dams

[View All](#)
- Studies Expiring in 30 days:** A section indicating no studies are currently expiring.

No Expiring Studies
- Expired Studies:** A list of expired studies with links to their details.

Study ID	Study Title
IRB-FY2016-3515	Consumption of grass by felines

[View All](#)

The screenshot shows the 'cayuse IRB' Dashboard for a user named 'IRB User'. The dashboard includes a sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, Meetings, and Help. The main content area features a 'My Role: Researcher' dropdown and a '+ New Study' button. Below these are four status filters: In-Draft (9), Awaiting Approval (4), Pre-Review (10), and Under Review (23). The dashboard is divided into several panels: 'My Studies' (listing studies like IRB-FY2015-49, IRB-2016-154, etc.), 'My Tasks' (listing tasks like Complete Submission, View Submission, etc.), 'Submissions by Type' (a table showing counts for Initial, Withdrawal, Modification, etc.), 'Approved Studies' (listing approved studies), 'Studies Expiring in 30 days' (showing 'No Expiring Studies'), and 'Expired Studies' (listing expired studies like IRB-FY2016-3515).

- 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.

IRB#	Study Title	Status	PI	Exp Date	Create Date
IRB-FY2016-3559	Social effects of early onset hair loss	Approved	IRB User	04-07-2017	02-26-2016
IRB-FY2016-3557	Use of compression in wound healing	Requires Changes	IRB User	N/A	02-26-2016
IRB-FY2016-3522	Extracurricular activities and perceived stress	Under Review	IRB User 2	N/A	02-26-2016
IRB-FY2016-3524	Internet use of adolescent Americans	Under Review	IRB User 2	N/A	02-26-2016
IRB-FY2016-3516	Social habits of Primolius maracona	Approved	IRB User	02-09-2017	02-10-2016

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

Dashboard

Studies

Submissions

Tasks

Help

Studies

ActiveArchive

+ New Study

Archived Within:

1 year2 years3 years

		Status	PI	Archive Date	Create Date
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

1-3 of 3

1

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.

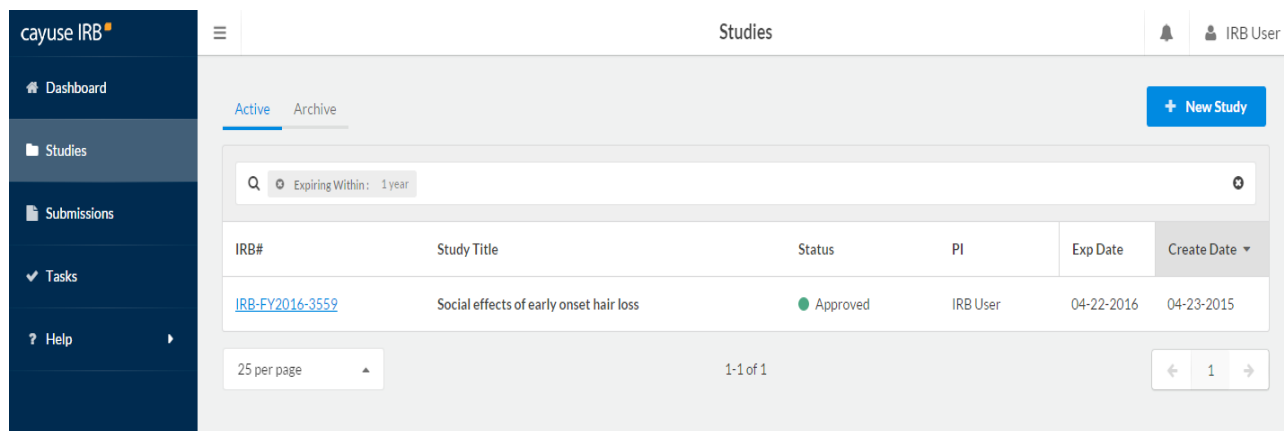
Note that some of the submissions are different types of submissions for the same study. For instance, an initial submission that was later followed up by a modification submission for that study.

IRB#	Submission	Status	Review Type	PI	My Assignment	Decision	Create Date
IRB-FY2016-3559	Social effects of early onset hair loss Initial	Review Complete	Full	IRB User	Principal Investigator	Approved 11-24-2016	03-09-2016
IRB-FY2016-3559	Social effects of early onset hair loss Modification	Under Review	Expedited	IRB User	Principal Investigator		03-09-2016
IRB-FY2016-3557	Use of compression in wound healing Initial	Review Complete	Full	IRB User	Principal Investigator	Exempt 11-23-2016	03-09-2016
IRB-FY2016-3524	Internet use of adolescent Americans Initial	Under Pre-Review	Full	IRB User 2	Primary Contact	Return to PI	03-02-2016
IRB-FY2016-3527	Use of compression in wound healing Modification	Under Review	Full	IRB User	Principal Investigator	Not Reviewed	03-02-2016
IRB-FY2016-3516	Social habits of Primolius maracona Modification	Review Complete	Exempt	IRB User	Principal Investigator	No Human Subjects Research	02-25-2016

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.

Status	PI	Exp Date	Create Date
Approved	IRB User	04-07-2017	02-26-2016
Approved	IRB User	04-06-2017	02-26-2016

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



The screenshot displays the 'cayuse IRB' interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Studies' and features a 'New Study' button in the top right. Below the title are tabs for 'Active' and 'Archive', with 'Active' selected. A search bar contains the filter 'Expiring Within: 1 year'. A table lists the following study:

IRB#	Study Title	Status	PI	Exp Date	Create Date
IRB-FY2016-3559	Social effects of early onset hair loss	Approved	IRB User	04-22-2016	04-23-2015

At the bottom, there is a pagination control showing '25 per page' and '1-1 of 1'.

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.

IRB#	Task	Study	Submission	My Assignment	Tasked Date
IRB-FY2016-53	Complete Post Review	Use of compression in wound healing	Initial	Analyst	Today
IRB-FY2016-51	Complete Analyst Pre-Review	Social effects of early onset hair loss	Initial	Analyst	10-21-2015
IRB-FY2016-20	Complete Post Review	Prevalence of allergies in cat owners	Initial	Analyst	08-11-2015
IRB-FY2016-9	Assign Analyst	Attitudes and perceptions of GM wheat	Withdrawal	Analyst	08-11-2015

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.

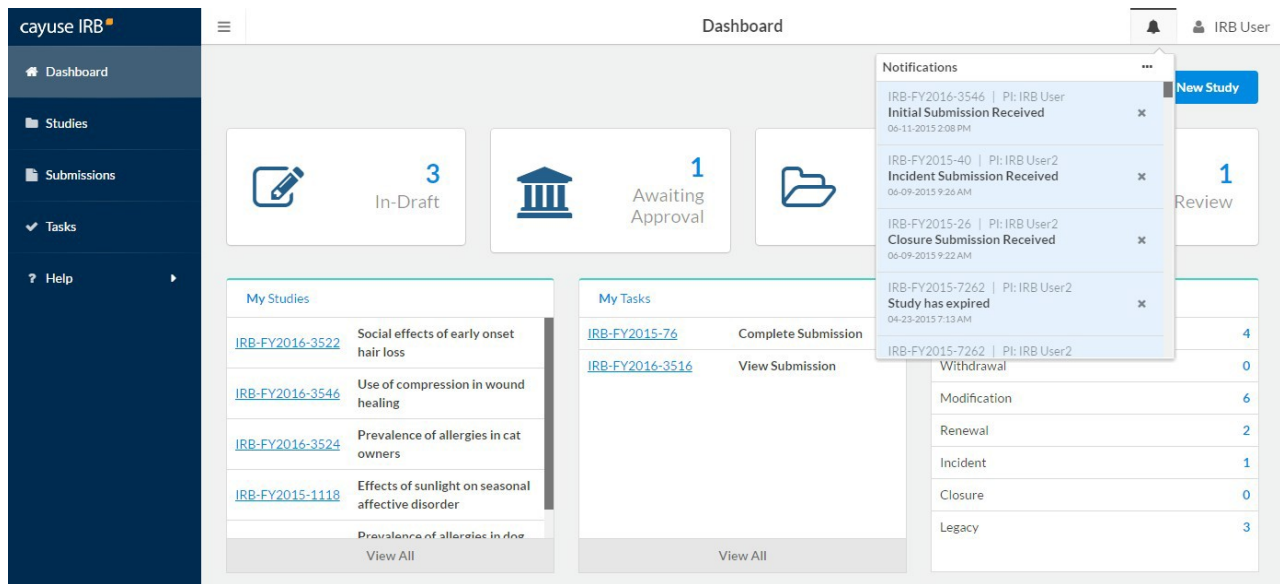
When you complete a task, it is removed from your task list. You may then see another task assigned to you for the next step in the process, or another user may receive a task depending on where the submission is in the workflow.

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.

Submission Details

Studies / Study Details / Submission Details

In-Draft Submission is with researchers

Awaiting Approvals Submission is awaiting certification or approval

3 Pre-Review Submission is being prepared for review

4 Under-Review Submission is with reviewers

Under Pre-Review

Initial
IRB-FY2016-50 - Social effects of early onset hair loss

Review **PDF** **Delete** **Checklist**

Routing:
Return **Proceed**

PI: IRB User
Current Analyst: IRB Analyst
Decision: N/A
Required Tasks:
• [Assign Review Type/Board](#)

Review Type: N/A
Review Board: N/A
Meeting Date: N/A

Approvals **Task History**

Research Team

Name	Role	Result	Date
IRB User	Principal Investigator	Certified	12-16-2015 12:13 PM

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.

STUDY IRB NUMBER: IRB-FY2016-50 **Social effects of early onset ha...** **SHOW CHECKLIST** **CREATE PDF** **COMPARE** **SAVE** **<** **>**

Sections

- Section 1 Assignment... ✓
- Section 2 Other Items ✓
- Section 3 Optional... ✓

Section 1 Assignments

*** P1 Principal Investigator**

Name	Organization	Address	Phone	Email
IRB User	School of Medicine	440 Exchange, Irvine, CA	714 265 7841	irbuser@evisions.com

+ Add Comment

*** P2 Primary Contact**

Name	Organization	Address	Phone	Email
IRB User2	Biomedical	440 Exchange, Irvine, CA	714 265 7498	irbuser2@evisions.com

+ Add Comment

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).

Sections

- Section 1 Assignments ✓
- Section 2 Other Items ✓
- Section 3 Optional F... ✓

1 Assignments

* PI Principal Investigator

Name	Organization	Address	Phone	Email
Joe Smith	School of Medicine	440 Exchange, Irvine, CA	714 265 7841	jsmith@evisions.com

+ Add Comment

* PC Primary Contact

Name	Organization	Address	Phone	Email
Bob Rawley	School of Medicine	440 Exchange, Irvine, CA	714 265 7498	brawley@evisions.com

+ Add Comment

Checklist

IRB Analyst (Analyst Checklist)

- ☒ Is this a new study that has not been previously submitted?
- ☒ Is the PI approved for research?
- ☐ Does the PC have sufficient contact information?

S2 Other Items

- ☐ Is Form 3B attached?

S3 Optional Forms

- ☐ Are all additional forms completely filled out?

SAVE CHECKLIST

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.

Sections

- Section 1 Assignme... ✓
- Section 2 Other Items ✓
- Section 3 Optional ... ✓

Section 1 Assignments

* P1 Principal Investigator

Name	Organization	Address	Phone	Email
IRB User	School of Medicine	440 Exchange, Irvine, CA	714 265 7841	irbuser@evisions.com

+ Add Comment

* P2 Primary Contact


Name	Organization	Address	Phone	Email
IRB User2	Biomedical	440 Exchange, Irvine, CA	714 265 7498	irbuser2@evisions.com

⌵ Collapse Comments

B I U ↺ ⌵ ⌵ ⌵

Are there any additional contacts for this study?

SAVE COMMENT

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

The screenshot shows the 'cayuse IRB' interface. The top navigation bar includes 'My Role: Analyst', 'IRB NUMBER: IRB-FY2016-3559', and buttons for 'SHOW CHECKLIST', 'CREATE PDF', 'COMPARE', and 'SAVE'. The left sidebar lists various functions: Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, Settings, and Help. The main content area is titled 'Section 1 Assignments' and lists two roles: P1 Principal Investigator and P2 Primary Contact. Each role has a table with contact information. Below the tables are comment sections with a text editor and a 'SAVE COMMENT' button.

- 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 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.

The screenshot shows a comment from an 'IRB Analyst' posted 'Today at 1:31 PM' with 'Visibility: Unrestricted'. The comment text is 'Please fill out and upload this attachment.' Below the text is a file attachment icon and the filename 'Protocols.docx'. There are links for 'Edit' and 'Reply', and a 'Feedback Requested' button.

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.

cayuse IRB

My Role: Analyst

Submission Details

IRB Analyst

Dashboard

Studies

Submissions

Tasks

Meetings

Reporting

Settings

Help

Studies / Study Details / Submission Details

In-Draft

Submission is with researchers

Awaiting Approvals

Submission is awaiting certification or approval

3 Pre-Review

Submission is being prepared for review

4 Under-Review

Submission is with reviewers

Under Pre-Review

Initial

IRB-FY2016-3559 - Social effects of early onset hair loss

Review

PDF

Delete

Checklist

Return To Investigators

Return

Proceed

PI:

IRB User

Current Analyst:

IRB Analyst

Decision:

N/A

Required Tasks:

Assign Reviewers

Review Type:

Unassigned

Review Board:

N/A

Meeting Date:

N/A

Approvals

Task History

Research Team

Name	Role	Result	Date
IRB User	Principal Investigator	Certified	07-20-2015 11:57 am

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.

cayuse IRB

My Role: Analyst

Comparison: IRB-FY2016-3559 (Initial)

IRB Analyst

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Comparison: IRB-FY2016-3559 (Initial)

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Section 1 Assignments

Section 1 Assignments

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• P1 Principal Investigator

Name	Organization	Address	Pho...	Email
IRB User	School of Medicine	440 Exchange, Irvine, CA	714 265 7841	irbuser@evisions.com

• P2 Primary Contact

Name	Organization	Address	Pho...	Email
IRB User 2	Biomedical	440 Exchange, Irvine, CA	714 265 7498	irbuser2@evisions.com

• P1 Principal Investigator

Name	Organization	Address	Pho...	Email
c c	ABC Soups		714 265 4741	

• P2 Primary Contact

Name	Organization	Address	Pho...	Email
IRB User 3	Biomedical	440 Exchange, Irvine, CA	714 265 7482	irbuser3@evisions.com

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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.

The screenshot shows the 'Submission Details' page in the Cayuse IRB system. The left sidebar contains navigation links: Dashboard, Studies, Submissions, Tasks, Meetings, and Help. The main content area shows the submission status as 'Under Review' with a progress bar indicating four steps: In-Draft, Awaiting Approvals, Pre-Review, and Under-Review (current step). Below the progress bar, the submission is titled 'Initial' with the study name 'IRB-FY2016-52 - Social effects of early onset hair loss'. There are buttons for 'Review', 'PDF', 'Delete', and 'Checklist'. A 'Routing' section shows 'Switch' and 'Review Complete' buttons. A table of metadata includes PI (IRB User), Current Analyst (IRB Analyst), Decision (N/A), Review Type (Expedited), Review Board (Biomedical), and Meeting Date (N/A). A 'Required Tasks' section lists a single task: 'Make Decision' with a hand cursor icon pointing to it.

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.

The screenshot shows the 'Decision' screen in the Cayuse IRB system. The left sidebar is the same as the previous screenshot. The main content area shows the 'Decision' form. At the top, there are buttons for 'Cancel' and 'Save'. The form has three main sections: 'Decision', 'Result Date', and 'Expiration Date'. The 'Decision' section has a dropdown menu with 'Approved' selected. The 'Result Date' section has a date picker with '10-29-2015' selected. The 'Expiration Date' section has a date picker with '10-28-2018' selected. Below these sections is a 'Categories' section with the instruction 'Select the applicable categories for this decision.' There are four checkboxes: '1a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.', '1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.', '2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.', and '2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.' The '2a' checkbox is checked.

You can also select a category that explains why this study qualifies for an exempt or expedited 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:

The screenshot shows the 'Submission Details' page in the Cayuse IRB system. On the left is a dark blue sidebar with navigation links: Meetings, Help, Dashboard, Studies, Submissions, Tasks, and Meetings. The main content area is titled 'Submission Details' and shows a progress bar with four stages: In-Draft (Submission is with researchers), Awaiting Approvals (Submission is awaiting certification or approval), Pre-Review (Submission is being prepared for review), and 4 Under-Review (Submission is with reviewers). Below the progress bar, there's a section for 'Initial' information, including the submission ID 'IRB-FY2016-52 - Social effects of early onset hair loss'. There are buttons for 'Review', 'PDF', 'Delete', and 'Checklist'. At the bottom, there's a table with fields for PI, Current Analyst, Decision, Required Tasks, Review Type, Review Board, Meeting Date, and a 'Review Complete' button.

- **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.

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Decision Types¹¹

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	
Exempt	The study is exempt because it fits into one of the specified categories for exemption.		
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.