

Online Protocol Creation, Submission, and Management

IRB Member Guide

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Introduction

The Cayuse IRB Help is designed to answer questions about what certain items on a given screen are, what they do, how they function, and how you might use them. The content is intended to be functionally descriptive yet brief and to the point.

To access this help, click the **Help** link at the top of the screen in Cayuse IRB. You can search through the Help using the Contents and Index tabs, or type a search string in the box in the upper right.

If you cannot find an answer to your question here, you should review the [Cayuse IRB Support Resources](#) page, which contains links to many additional resources to help you with your questions and issues.

What is Cayuse IRB?

The Cayuse Institutional Review Board (IRB) module is an easy-to-use system for electronically preparing, submitting, and routing studies for IRB approval. All information is stored in the cloud and can be accessed securely from any location, making it simple for multiple simultaneous users to view and share documents. Users receive electronic notifications whenever an action is required on their part, allowing the study to proceed smoothly through each step of the process from study creation to final approval.

Cayuse IRB:

- Provides a comprehensive electronic compliance solution.
- Tracks and manages initial submissions, modifications, reportable events, and continuing reviews in a single location.
- Eliminates the need for paper forms.
- Is accessed using a secure connection via your web browser.
- Helps to ensure timely submissions by automatically generating reminder notices for continuing reviews.
- Allows institutions to design custom forms that request only the information that is relevant to the study, based on information provided by the researchers.
- Allows multiple researchers and administrators to view and work with forms at the same time.
- Tracks and compares changes between different versions of a submission.
- Enables convenient and efficient coordination of meetings and distribution of meeting minutes.
- Links IRB submissions to funding proposals in the Cayuse SP module, if licensed.

System Requirements

- Internet Explorer 9 or higher, Mozilla Firefox, Google Chrome, or Apple Safari. (**Note:** Safari is only provisionally supported at this time.)

Cayuse IRB Support Resources

Evisions provides several sources of support for Cayuse IRB users, including in-product Help, tutorials, and release notes, and a support website with many useful resources.

In-Product Help

The Cayuse IRB Help serves as a reference guide for all of the features in the software. You can access the help by going to **Help -> Open Help** in the menu. The Help contains a table of contents, an index, and a search feature.

Release Documentation

To view the release notes and release guides outlining the latest changes in Cayuse IRB, go to **Help -> Release Notes** within Cayuse IRB, or click [here](#).

Tutorials

To see a brief overview of the updated user interface introduced in Cayuse IRB 1.6, go to **Help -> View Dashboard Tutorial** or **Help -> View Visual Search Tutorial**.

Training Materials

Evisions provides many training resources for Cayuse IRB, intended to help meet your training needs.

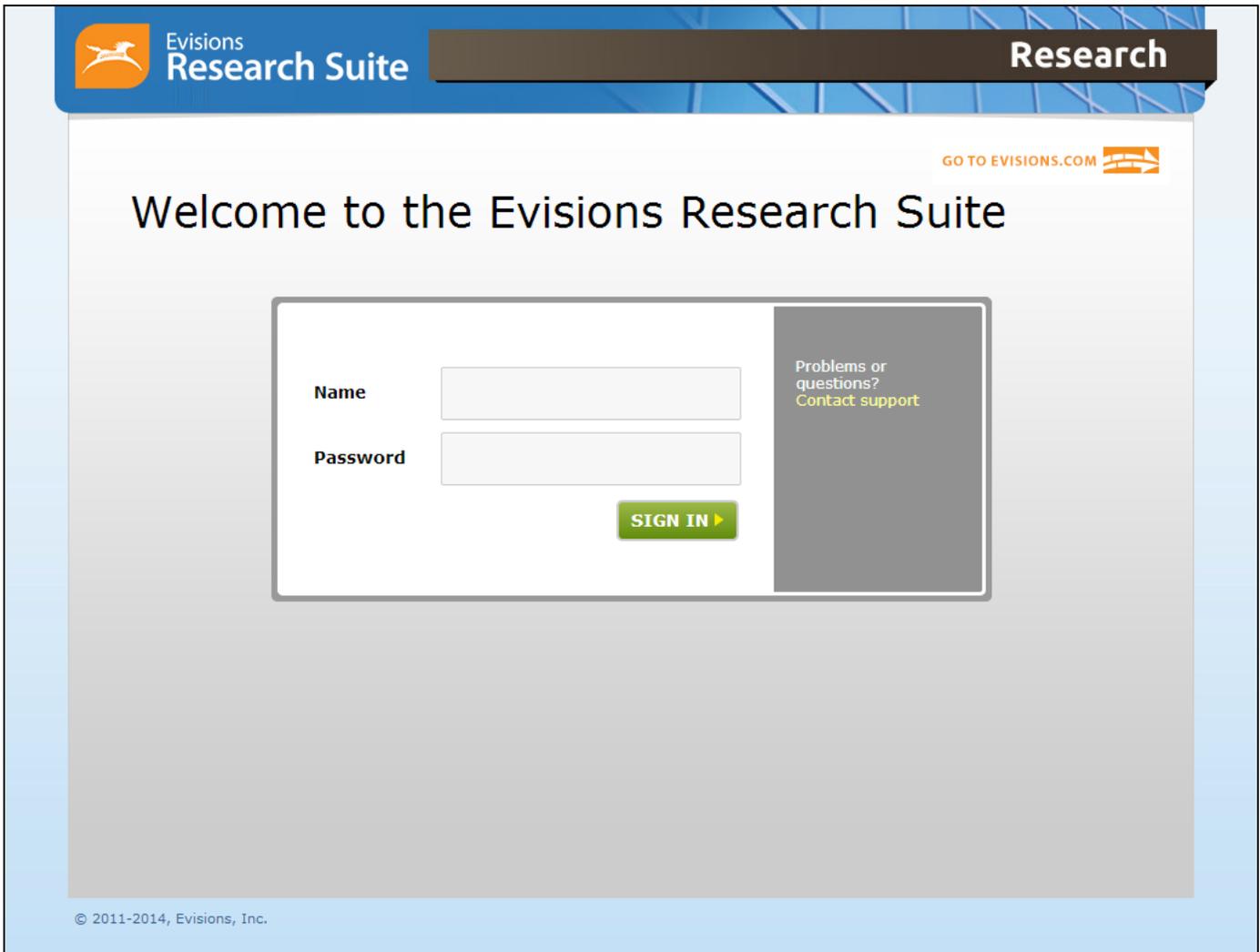
Additional Resources

The [Evisions Support Center](#) contains links to additional support resources:

- [HelpDesk](#) - Technical Support website where you can open a support ticket, or search the knowledgebase.
- [Knowledgebase](#) - Answers to common questions.
- [Browser Support and Configuration](#) - assistance using your favorite browser with the Evisions Research Suite.
- [IRB Support](#) - Provides links to this manual, the release guides, the Evisions blog, and the knowledgebase.

Logging In

This is the login screen for the Evisions Research Suite applications.



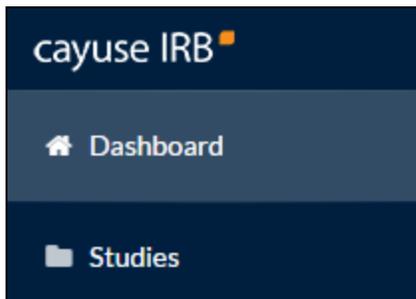
The screenshot shows the login interface for the Evisions Research Suite. At the top left, there is a logo for Evisions Research Suite. To the right of the logo, the word "Research" is displayed in a dark box. In the top right corner, there is a link "GO TO EVISIONS.COM" with a small icon. The main heading reads "Welcome to the Evisions Research Suite". Below this, there is a login form with two input fields: "Name" and "Password". A green "SIGN IN" button with a right-pointing arrow is positioned below the password field. To the right of the input fields, there is a grey box containing the text "Problems or questions?" and a link "Contact support". At the bottom left of the page, there is a copyright notice: "© 2011-2014, Evisions, Inc."

Enter your username and password at the prompt. Then, click **Sign In** to launch Cayuse IRB.

Navigating Cayuse IRB

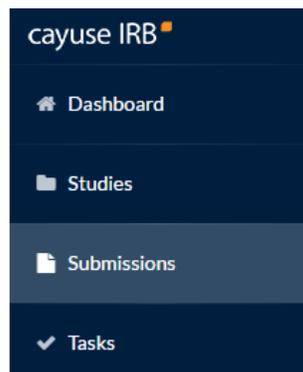
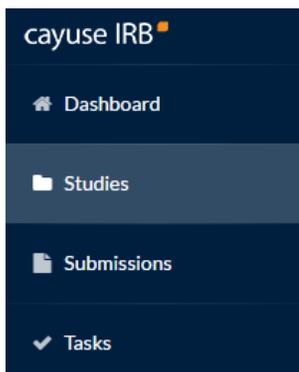
Dashboard

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

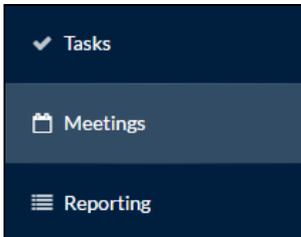
The [Studies](#) and [Submissions](#) screens list the studies and submissions that you have access to.



- **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

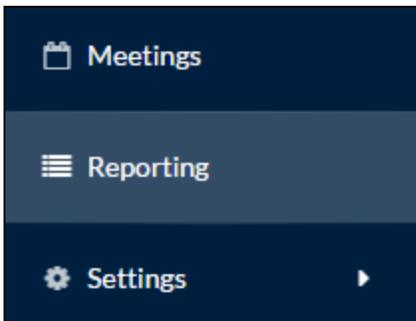
The [Meetings](#) section allows IRB Analysts, Admins, and Members to view the calendar of scheduled IRB meetings. *IRB Users do not see the Meetings section.*



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

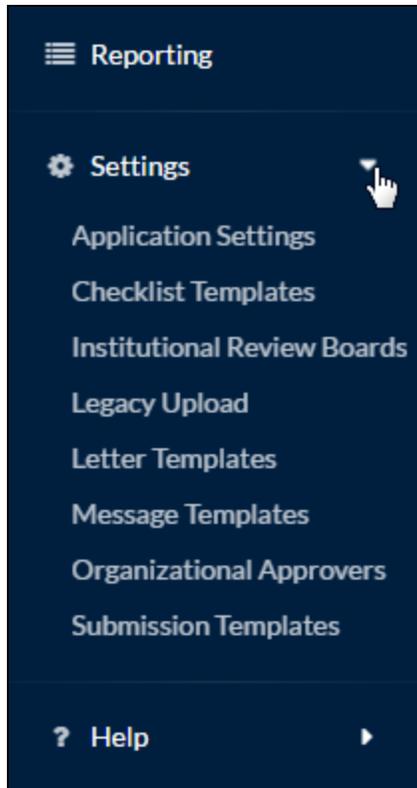
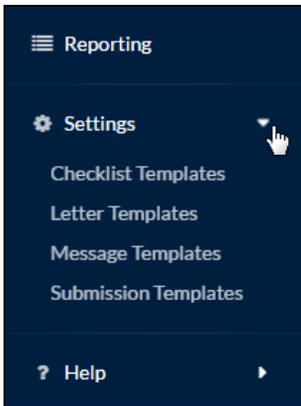
Reporting

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



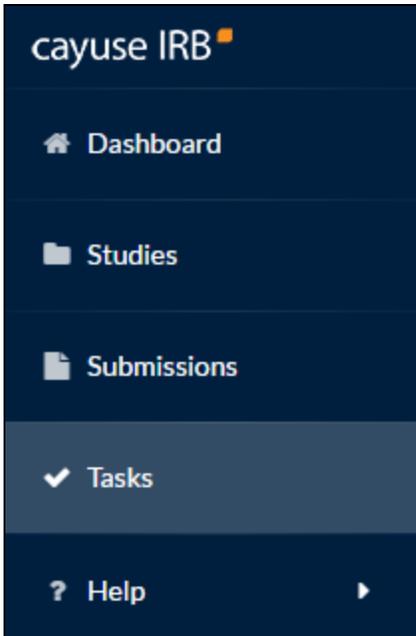
Settings

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.*



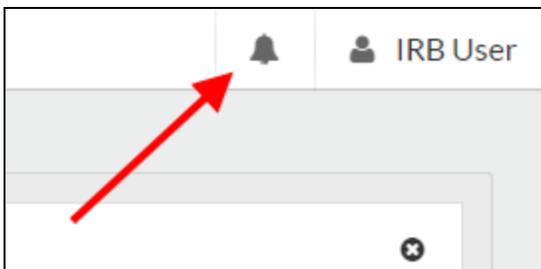
Tasks

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.



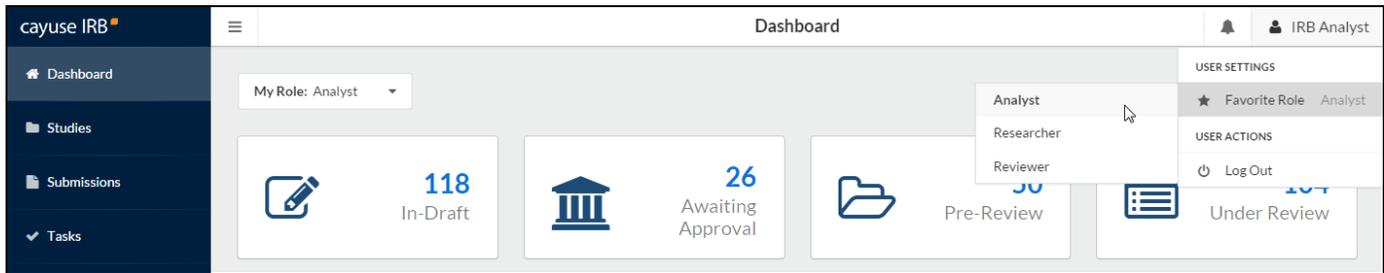
Notifications

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.

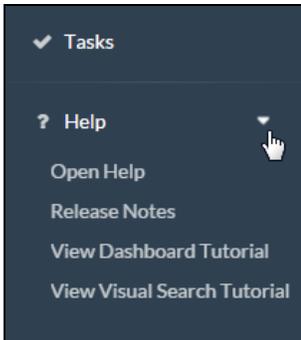


User Settings - Favorite Role - If you have more than one user role (such as *Analyst* and *Reviewer* for someone who is both an IRB Analyst and a member of a review board), certain screens (such as the dashboard) display different information depending on your role. These screens have a dropdown in 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 Cayuse IRB open the Help to the page with information relating to that part of the application.

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 dashboard looks different depending on your user role. An IRB User will see their studies, tasks and submissions:

The screenshot shows the Cayuse IRB Dashboard for a user with the role of Researcher. The interface includes a dark blue sidebar on the left with navigation options: Dashboard, Studies, Submissions, Tasks, Meetings, and Help. The main content area has a top bar with the user's role 'My Role: Researcher' and a '+ New Study' button. Below this are four summary cards: 'In-Draft' (9), 'Awaiting Approval' (4), 'Pre-Review' (10), and 'Under Review' (23). The dashboard is divided into several sections: 'My Studies' (listing 5 studies), 'My Tasks' (listing 3 tasks), 'Submissions by Type' (a table with 6 categories), 'Approved Studies' (listing 5 studies), 'Studies Expiring in 30 days' (showing 'No Expiring Studies'), and 'Expired Studies' (listing 1 study). Each section has a 'View All' button at the bottom.

Type	Count
Initial	10
Withdrawal	1
Modification	2
Renewal	9
Incident	1
Closure	1
Legacy	5

Instead of the list of their studies, the IRB Analyst can toggle between a list of all unassigned submissions, and all submissions that are assigned to them. The Analyst also has a list of all submissions that are currently under review, and can see a miniature meetings calendar.

The screenshot shows the 'cayuse IRB' Analyst Dashboard. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', 'Settings', and 'Help'. The main content area is titled 'Dashboard' and features a 'My Role: Analyst' dropdown and a '+ New Study' button. The dashboard is divided into several sections:

- Status Summary:** Four large buttons representing submission counts: In-Draft (118), Awaiting Approval (26), Pre-Review (49), and Under Review (105).
- Submissions that are Unassigned:** A list of unassigned submissions, currently showing one: IRB-2016-149, 'Use of compression in wound healing'.
- My Tasks:** A list of tasks for the analyst, including 'Complete Post Review' and 'Assign Analyst'.
- Submissions by Type:** A table showing the count of submissions for various review types.
- Submissions under review:** A summary of submissions currently under review, categorized by review type.
- Studies Expiring in 30 days:** A list of studies that are due for review within the next 30 days.
- My Meetings:** A calendar view for November 2015, showing scheduled meetings indicated by green dots on specific dates.

- 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:

- **Approved** - Study has been approved by the Compliance Office and/or Review Board.
- **Closed** - Study is no longer in progress.
- **Disapproved** - After being reviewed, the study was not approved by the Compliance Office/review board.
- **Expired** - The study has passed its expiration date without being renewed.
- **Legacy** - Optional status that can be used when importing [legacy submissions](#), in place of "Approved".
- **Requires Changes** - The Compliance Office has requested modifications to the study in order for it to be approved.
- **Submitted** - The PI has sent a submission to the Compliance Office and it is awaiting review.
- **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.
- **Under Review** - The Compliance Office and/or Review Board is currently reviewing the study.
- **Unsubmitted** - The study has not yet been sent to the Compliance Office for review.
- **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.

The screenshot shows the 'Studies' screen in the 'Archive' tab. A search filter 'Archived Within' is active, with a dropdown menu showing '1 year', '2 years', and '3 years'. The table below lists three archived studies:

IRB#	Submission	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

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.

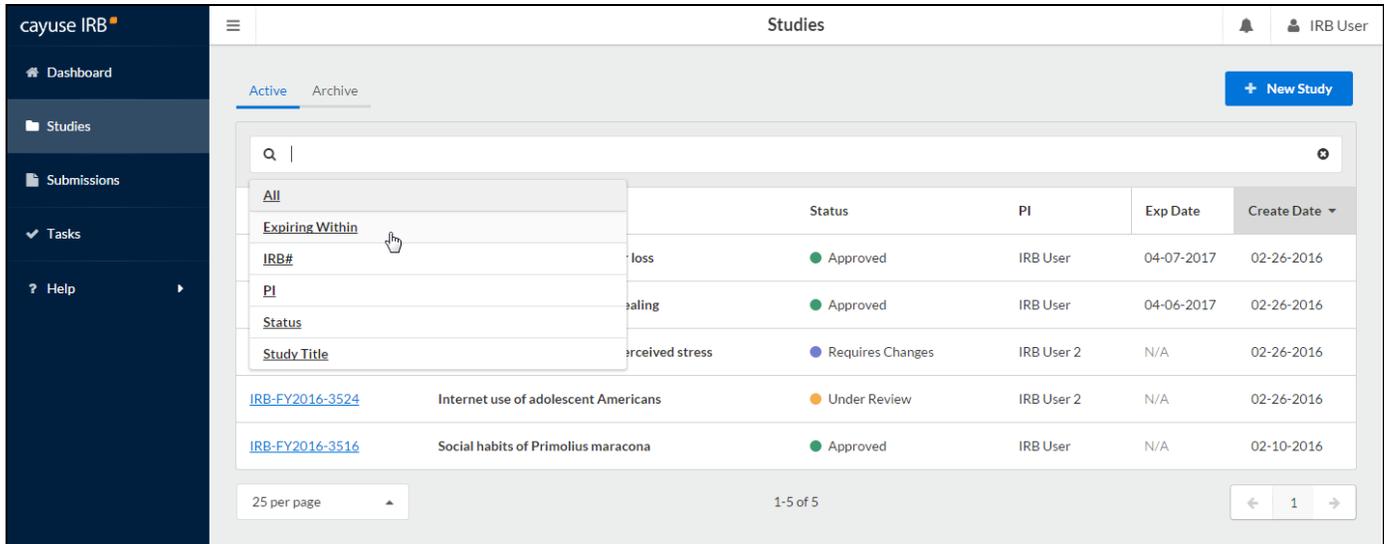
The screenshot shows the 'Submissions' screen. The table below lists six submissions:

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-FY2016-3557	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

You can resort the list of submissions by creation date in ascending or descending order by clicking on the column header.

Searching for Studies or Submissions

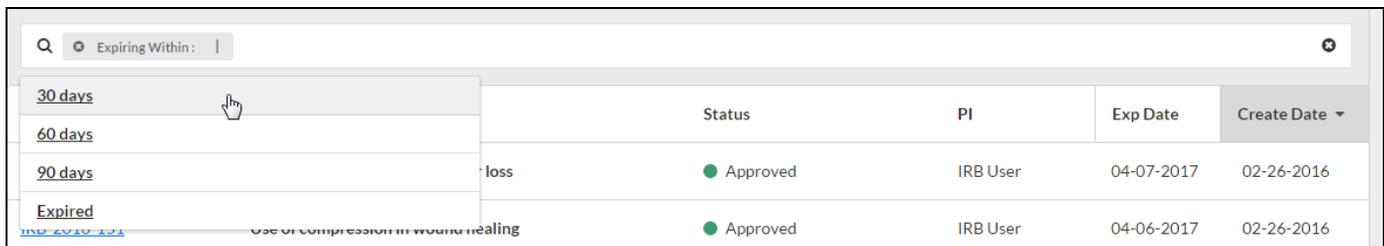
To filter the list of studies or submissions, click in the search box and select the attribute you wish to filter by. You can also simply enter your search term(s) to search all available fields.



The screenshot shows the 'Studies' page in the cayuse IRB system. A search box is active, and a dropdown menu is open, listing search attributes: All, Expiring Within, IRB#, PI, Status, and Study Title. The 'Expiring Within' option is highlighted. Below the dropdown, a table of studies is visible with columns for IRB#, Study Title, Status, PI, Exp Date, and Create Date. The table shows five rows of study data.

IRB#	Study Title	Status	PI	Exp Date	Create Date
	loss	Approved	IRB User	04-07-2017	02-26-2016
	healing	Approved	IRB User	04-06-2017	02-26-2016
	perceived stress	Requires Changes	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	N/A	02-10-2016

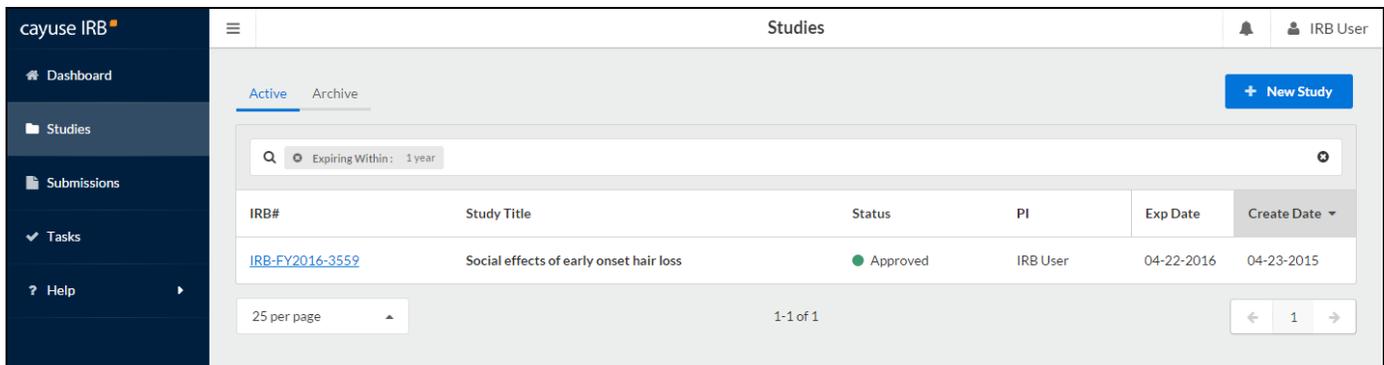
Once you select a value, you will see a second list of suggestions for values to search for. You can choose a value from this list, or free type your own.



This screenshot shows the search box with 'Expiring Within:' selected. A dropdown menu displays suggestions: 30 days, 60 days, 90 days, and Expired. The '30 days' option is highlighted. The table below shows the results of the search, with columns for IRB#, Study Title, Status, PI, Exp Date, and Create Date.

IRB#	Study Title	Status	PI	Exp Date	Create Date
	loss	Approved	IRB User	04-07-2017	02-26-2016
	Use of compression in wound healing	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 shows the 'Studies' page with the search filter 'Expiring Within: 1 year' applied. The search box contains the filter text. The table below shows the results, with columns for IRB#, Study Title, Status, PI, Exp Date, and Create Date.

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

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.

The screenshot shows the 'Tasks' screen in the Cayuse IRB system. The user is logged in as 'IRB Analyst'. The role is set to 'Analyst'. The table below shows the tasks assigned to the user:

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.

The screenshot displays the Cayuse IRB Dashboard. The top navigation bar includes the logo, a menu icon, the title 'Dashboard', a notification bell icon, and the user name 'IRB User'. The left sidebar contains navigation links for Dashboard, Studies, Submissions, Tasks, and Help. The main dashboard area features three summary cards: 'In-Draft' with a count of 3, 'Awaiting Approval' with a count of 1, and 'Review' with a count of 1. Below these are sections for 'My Studies' and 'My Tasks'. A 'Notifications' dropdown menu is open, showing a list of notifications with details such as study ID, PI, notification type, and timestamp. The notification types include 'Initial Submission Received', 'Incident Submission Received', 'Closure Submission Received', and 'Study has expired'. A 'New Study' button is visible in the top right corner.

Notifications are sent:

- To the PI when the submission has been sent to them for certification.
- To the PI and PC, when their submission has been received by the Compliance Office.
- To the Organizational Approver(s) when a submission requires approval.
- To the IRB Analyst when a new submission requires Analyst assignment.
- To the previous IRB Analyst, when a submission is reassigned to another Analyst
- To the IRB Analyst when an expedited review is complete.
- To the board members or reviewers when a submission requires their review.
- To the PI and PC when a study is expiring or has expired.
- 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.

Customizing Notifications

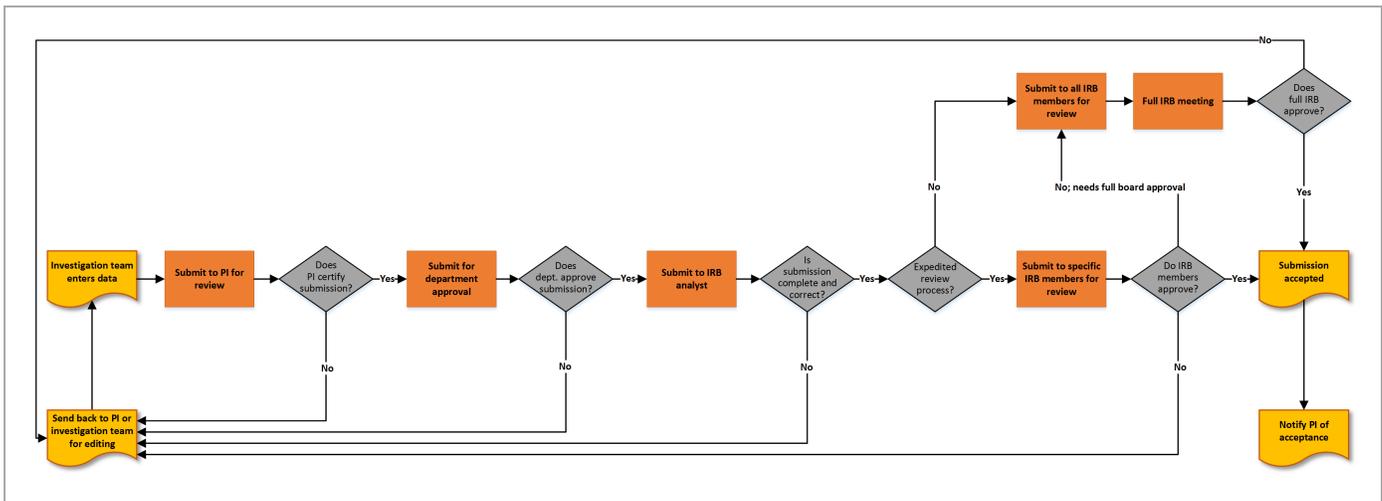
IRB Analysts and Admins have the ability to customize all of the notifications and emails that are sent out by Cayuse IRB via the [Message Templates](#) screen in the Settings section. Customization options include editing the text of the message, controlling which users receive it, or disabling certain types of notifications.

IRB Members

IRB Members may be asked to review a submission as part of a full board review, or may be selected to do an expedited/exempt review for submissions that meet these criteria.

The IRB Member's role is as follows:

1. [Review and comment on submissions](#) assigned to the IRB or to individual IRB Members.
2. Ensure reviewer [checklist](#) is complete, if checklists are enabled for your institution.
3. Discuss submission at a scheduled IRB meeting, or [make decisions for exempt/expedited reviews](#).



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

Stages: 1 In-Draft (Submission is with researchers), 2 Awaiting Approvals (Submission is awaiting certification or approval), 3 **Pre-Review** (Submission is being prepared for review), 4 Under-Review (Submission is with reviewers)

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

Buttons: Review, PDF, Delete, Checklist, Return, Proceed

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.

IRB NUMBER: IRB-FY2016-50

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

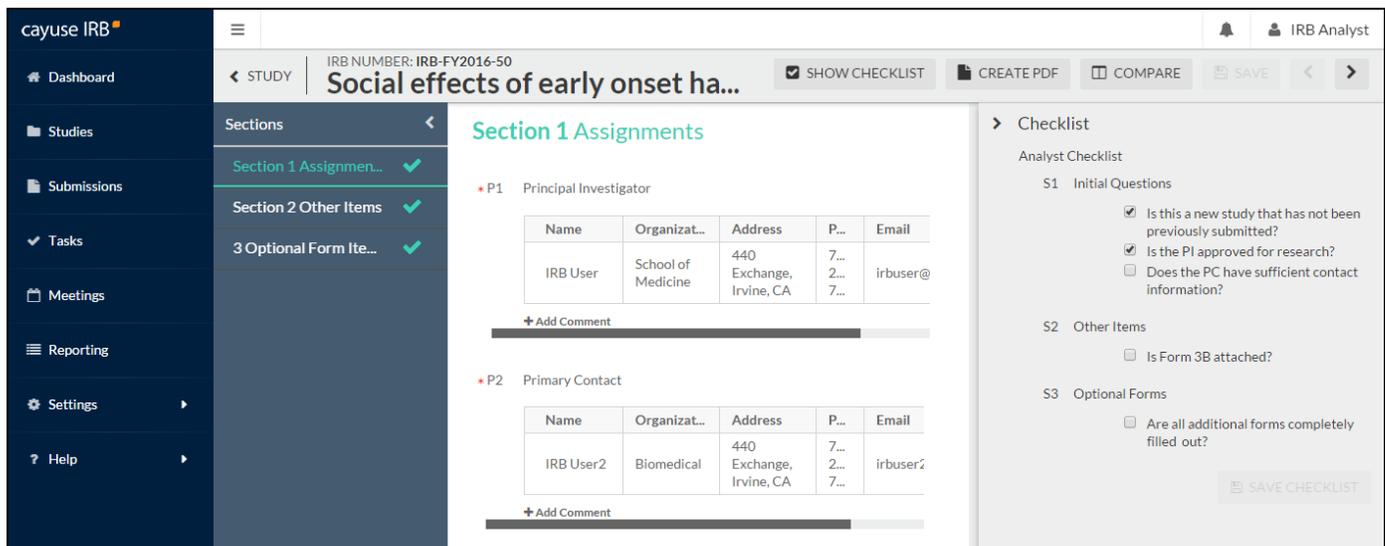
* P2 Primary Contact

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).



The screenshot shows the 'cayuse IRB' interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', 'Settings', and 'Help'. The main content area is titled 'STUDY' and 'IRB NUMBER: IRB-FY2016-50' with the study name 'Social effects of early onset ha...'. A 'SHOW CHECKLIST' button is highlighted. The 'Section 1 Assignments' table lists two users: P1 (Principal Investigator) and P2 (Primary Contact). The 'Checklist' section on the right contains three sections: S1 Initial Questions, S2 Other Items, and S3 Optional Forms, each with specific questions and checkboxes.

Name	Organizat...	Address	P...	Email
IRB User	School of Medicine	440 Exchange, Irvine, CA	7...	irbuser@

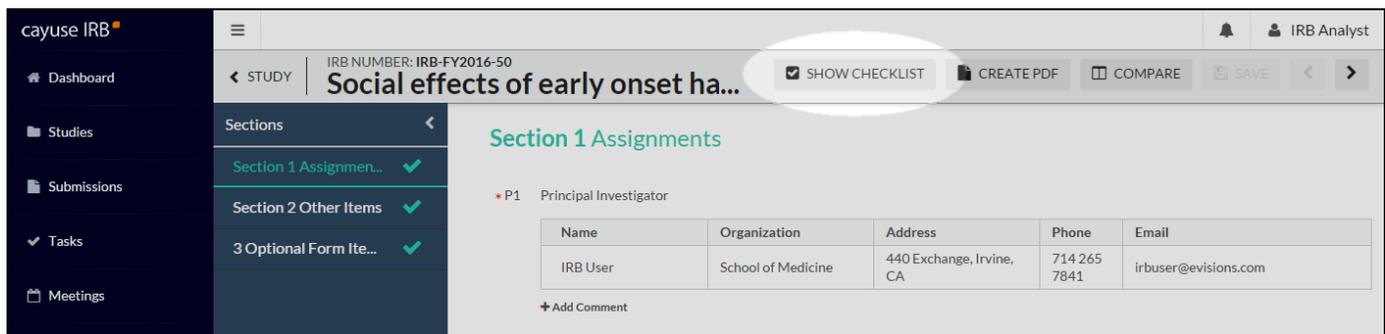
Name	Organizat...	Address	P...	Email
IRB User2	Biomedical	440 Exchange, Irvine, CA	7...	irbuser2

Checklist items:

- S1 Initial Questions
 - 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?

As you review the submission, mark off each item in the checklist when you have verified that it is complete. Click **Save Checklist** when you are finished making changes.

In addition to the Show Checklist button that opens the submission, you can toggle the checklist by using the Show Checklist button while you are reviewing a submission.



This screenshot is similar to the previous one, but the 'SHOW CHECKLIST' button in the top navigation bar is circled in white, indicating its function to toggle the checklist visibility.

Each submission for a study has its own Analyst and Reviewer checklists. When a review is complete, the Reviewer checklist(s) become read-only. Similarly, when a submission has been finalized, the Analyst can no longer modify the Analyst checklist for that submission.

The IRB Analyst can view all of the checklists associated with the submission. Submissions with multiple checklists have a dropdown at the top of the checklist that allows the Analyst to switch between them:

The screenshot shows the 'cayuse IRB' interface for a study titled 'Social Effects of Early Onset Hair Loss - Initial'. The top navigation bar includes 'STUDIES', 'MEETINGS', 'SETTINGS', and 'HELP'. The study ID is 'IRB-FY2015-390'. A checklist on the right side is open, showing a dropdown menu with options: 'IRB Analyst (Analyst Checklist)', 'IRB Member (Reviewer Checklist)', 'IRB Member 2 (Reviewer Checklist)', and 'IRB Member 3 (Reviewer Checklist)'. The 'IRB Analyst (Analyst Checklist)' option is selected. Below the dropdown, there are checkboxes for: 'Is this a new study that has not been previously submitted?' (checked), 'Is the PI approved for research?' (checked), and 'Does the PC have sufficient contact information?' (unchecked). The main content area shows two tables for assignments. The first table is for the Principal Investigator (PI) and the second is for the Primary Contact (PC). Both tables have columns for Name, Organization, Address, Phone, and Email.

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

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

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.

In addition to exporting submissions, the **PDF** dropdown on the Submission Details screen includes an option that allows the IRB Analyst to export individual checklists or all checklists for the submission into a PDF file.

The screenshot shows the 'Submission Details' screen for the study 'Initial' (IRB-FY2016-246 - Social Effects of Early Onset Hair Loss). The status is 'Under Pre-Review'. The 'PDF' dropdown menu is open, showing options: 'Submission', 'All Checklists', and 'Analyst Checklist IRB Analyst'. The 'Analyst Checklist IRB Analyst' option is highlighted. The screen also displays submission details: PI: IRB User, Review Type: N/A, Review Board: N/A, Decision: N/A, Meeting Date: N/A, and Required Tasks: Assign Review Type/Board. There are 'Return' and 'Proceed' buttons in the top right corner.

This option can be used for auditing purposes, or whenever an external copy of a checklist is required.

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.

The screenshot shows the cayuse IRB interface for a study titled "Social effects of early onset hair loss ...". The user is logged in as "IRB Analyst". The study ID is "IRB-FY2016-3559". The main content area is titled "Section 1 Assignments" and contains two contact entries:

- *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 [Rich text editor icons]

Are there any additional contacts for this study?

SAVE COMMENT

Enter the text of your comment in the box, then click **SAVE COMMENT** 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 sidebar on the left contains navigation options: Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, Settings, and Help. The main content area is titled 'Section 1 Assignments' and displays two tables. The first table, 'P1 Principal Investigator', lists IRB User from the School of Medicine at 440 Exchange, Irvine, CA, with phone 714 265 7841 and email irbuser@evisions.com. The second table, 'P2 Primary Contact', lists IRB User2 from Biomedical at the same address, with phone 714 265 7498 and email irbuser2@evisions.com. Below the tables are 'Add Comment' and 'Collapse Comments' buttons. A comment from 'IRB Analyst' is visible, asking 'Are there any additional contacts for this study?' with 'Edit' and 'Reply' links. A rich text editor with a 'SAVE COMMENT' button is at the bottom.

- 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 one or more files to upload.

Note: File attachments are limited to a maximum size of 20 MB.

IRB Analyst Today at 1:31 PM Visibility: Unrestricted 

Please fill out and upload this attachment.

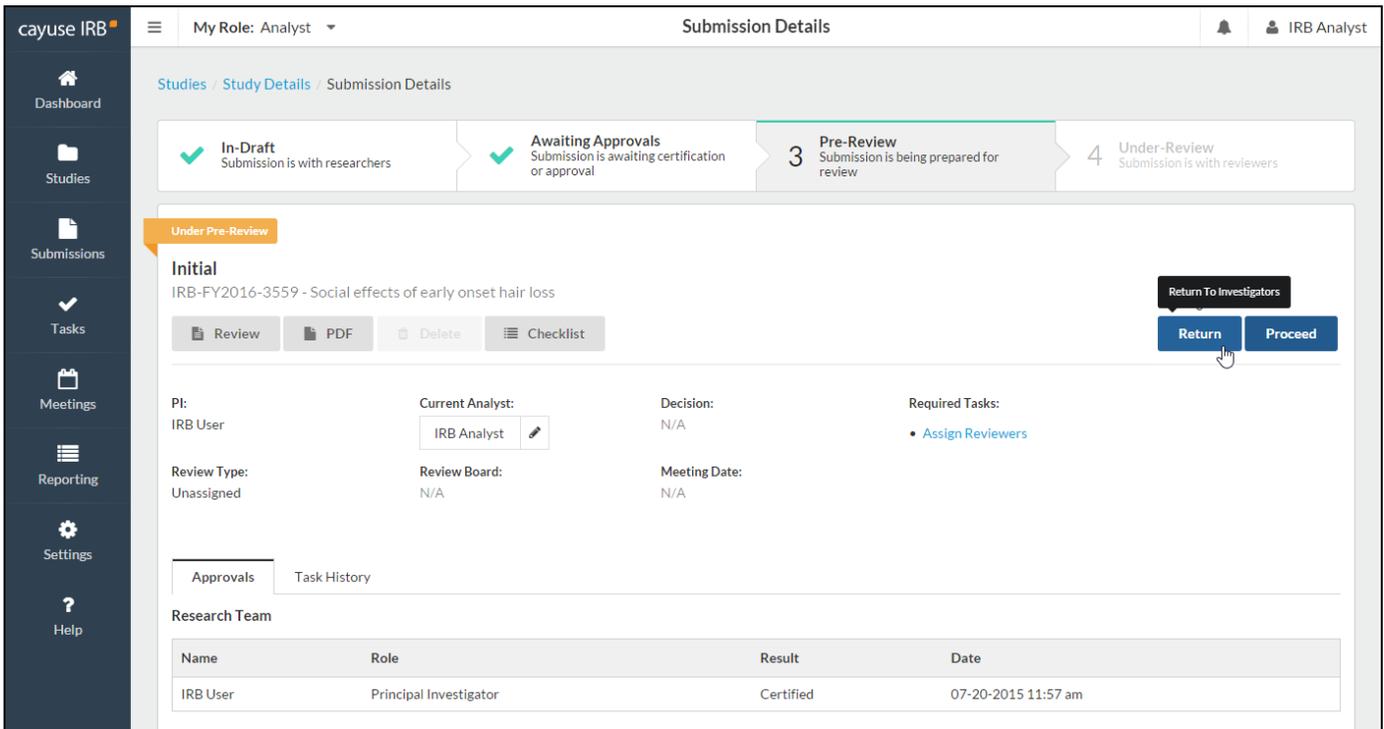
 Protocols.docx

[Edit Reply](#)

Feedback Requested

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.



The screenshot displays the 'Submission Details' page in the cayuse IRB system. The user is logged in as 'IRB Analyst'. The submission is currently in the 'Pre-Review' stage (Step 3), which is highlighted in teal. The submission title is 'Initial' for 'IRB-FY2016-3559 - Social effects of early onset hair loss'. The current analyst is 'IRB Analyst'. There are buttons for 'Return' and 'Proceed'. A tooltip 'Return To Investigators' is visible over the 'Return' button. The page also shows a 'Research Team' table with one member: IRB User, Principal Investigator, Certified, 07-20-2015 11:57 am.

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.

The screenshot displays the 'cayuse IRB' interface for an Analyst. The main window is titled 'Comparison: IRB-FY2016-3559 (Initial)'. It is split into two panes: 'PREVIOUS SUBMISSION' on the left and 'CURRENT SUBMISSION' on the right. The 'CURRENT SUBMISSION' pane shows a difference in the 'Section 1 Assignments' section, which is highlighted in light green. The difference is a change in the 'Primary Contact' table.

Section 1 Assignments

+ 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

Current Submission Difference:

+ P1 Principal Investigator

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

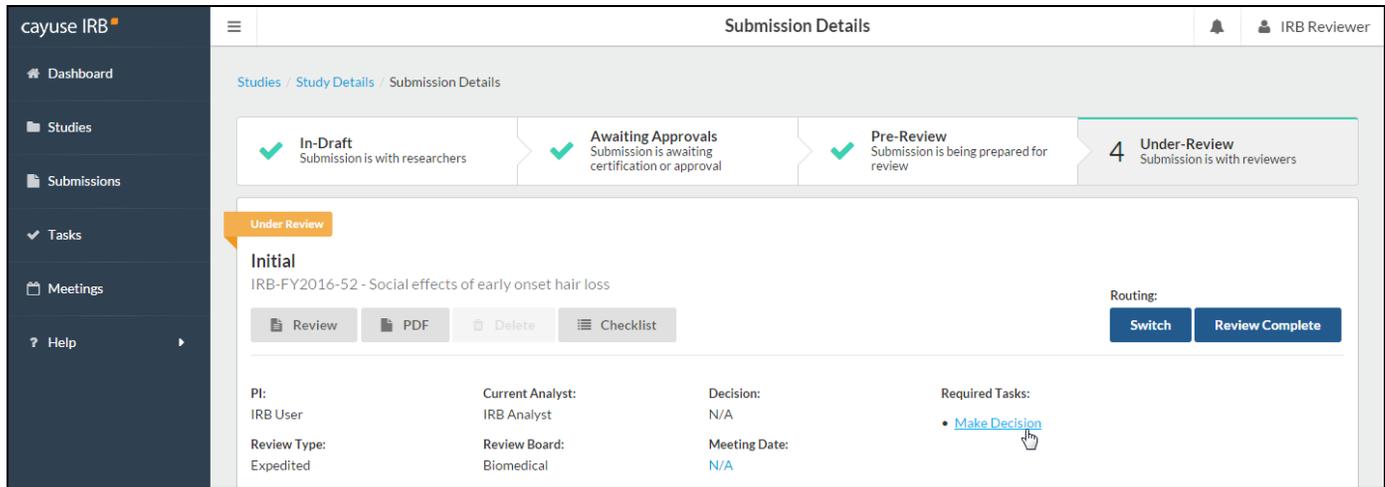
+ P2 Primary Contact

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

Making Decisions for Exempt and Expedited Reviews - Reviewers

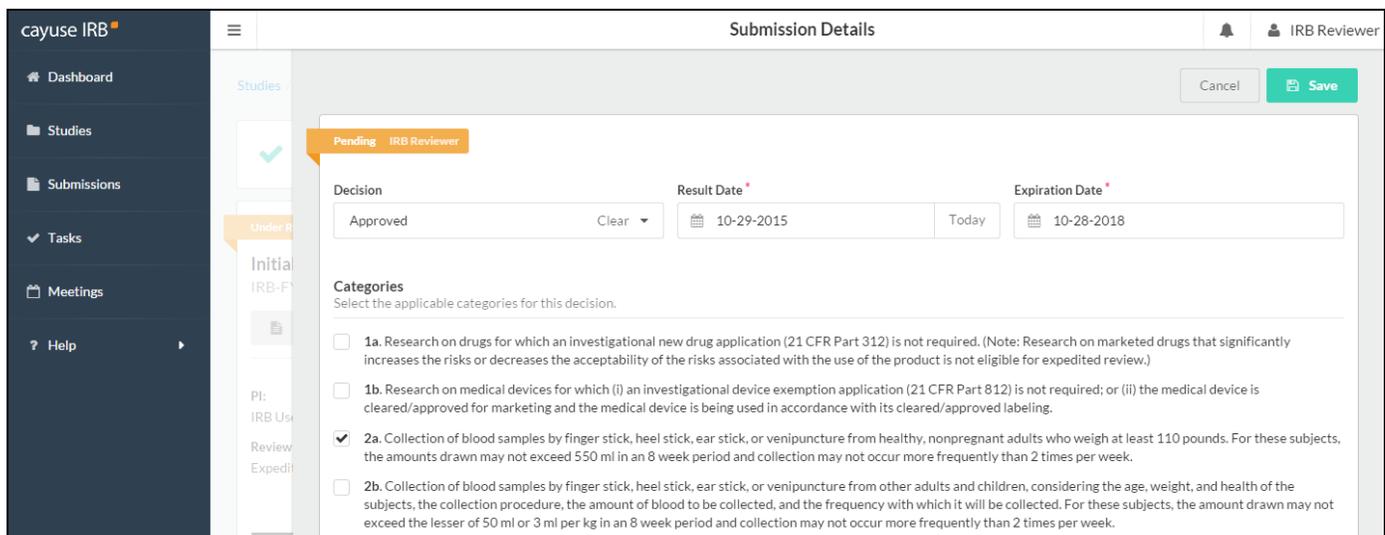
The IRB Analyst may assign submissions to one or more IRB Members for exempt and expedited reviews. If a primary reviewer has been assigned to a submission, they are tasked with making the decision based on their review and comments from any other reviewers assigned to the study. Otherwise, all reviewers 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 top navigation bar includes 'cayuse IRB', a menu icon, 'Submission Details', a notification bell, and the user 'IRB Reviewer'. The main content area displays 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, the submission is identified as 'Initial' for 'IRB-FY2016-52 - Social effects of early onset hair loss'. Action buttons include 'Review', 'PDF', 'Delete', and 'Checklist'. A 'Routing' section contains 'Switch' and 'Review Complete' buttons. A metadata table shows: PI: IRB User, Current Analyst: IRB Analyst, Decision: N/A, Review Type: Expedited, Review Board: Biomedical, Meeting Date: N/A. A 'Required Tasks' section lists 'Make Decision' with a mouse cursor hovering over 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.

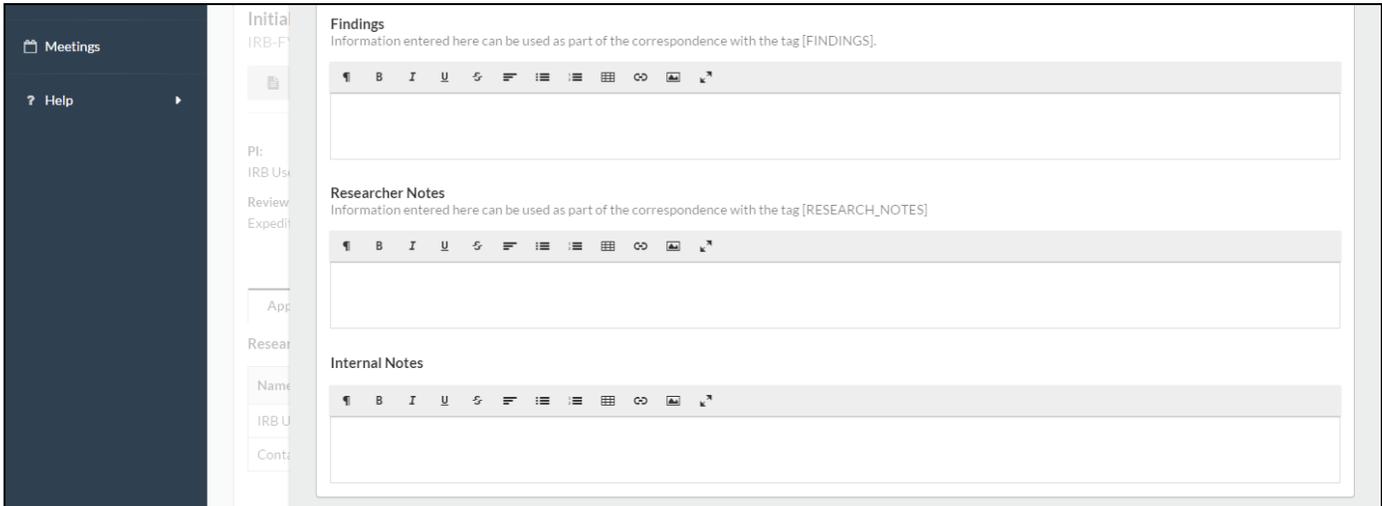


The screenshot shows the 'Decision' screen in the Cayuse IRB system. The top navigation bar is the same as the previous screenshot. The main content area shows a 'Pending' status for 'IRB Reviewer'. The 'Decision' dropdown is set to 'Approved'. The 'Result Date' is '10-29-2015' and the 'Expiration Date' is '10-28-2018'. Below this, there is a 'Categories' section with the instruction 'Select the applicable categories for this decision.' and a list of categories: '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...', '2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds...', and '2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children...'. The '2a' category is selected with a checked checkbox.

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

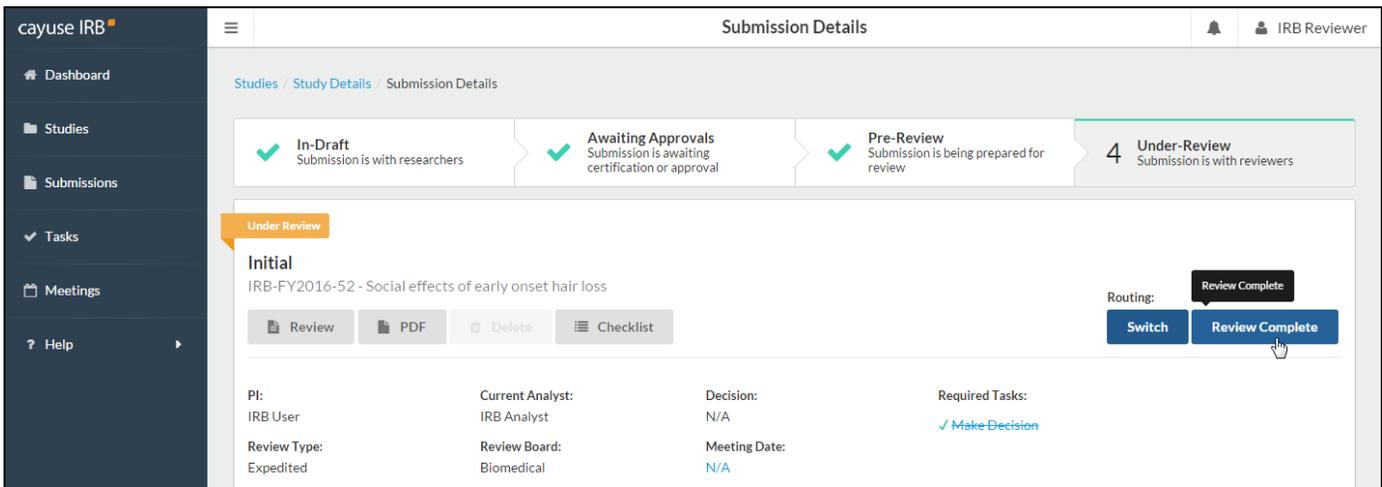
between exempt and expedited yourself using the **Switch to Exempt/Switch to Expedited** button on the submission dashboard. If you need to return the submission to the analyst to arrange a full board review, you should select *Not Exempt* or *Not Expedited* as the decision and complete the review.

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	<p>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.</p> <p>Suspension can only be lifted by selecting the "Suspension Removed" decision for a modification submission after it has had a full, full expedited, or expedited review. Lifting the suspension changes the study's status back to "Approved".</p> <p>Note: Renewal submissions for an expired suspended study can receive a decision of "Approved" in order to extend the date without lifting the suspension, or "Suspension Removed" in order to extend the date and lift the suspension.</p>	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.

Decision	Explanation	Resulting Study Status	Routing
Disapproved	The full board identified major issues with the study or submission and disapproved the research. In the case of a disapproved initial study, a new study and submission will need to be created. For disapproved renewal, modification, etc. submissions, the research team will need to create a new submission if they wish to proceed.	Disapproved	The submission and/or study are disapproved and no longer editable. Disapproving an initial submission archives the study.
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.	Requires Changes	Submission is returned to the PI and reopened for editing.
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.		
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.

Meetings

The **Meetings** tab allows IRB Analysts, Administrators, and Members to view the calendar of scheduled IRB meetings and to review the studies that are scheduled to be discussed at each meeting.

Board Members

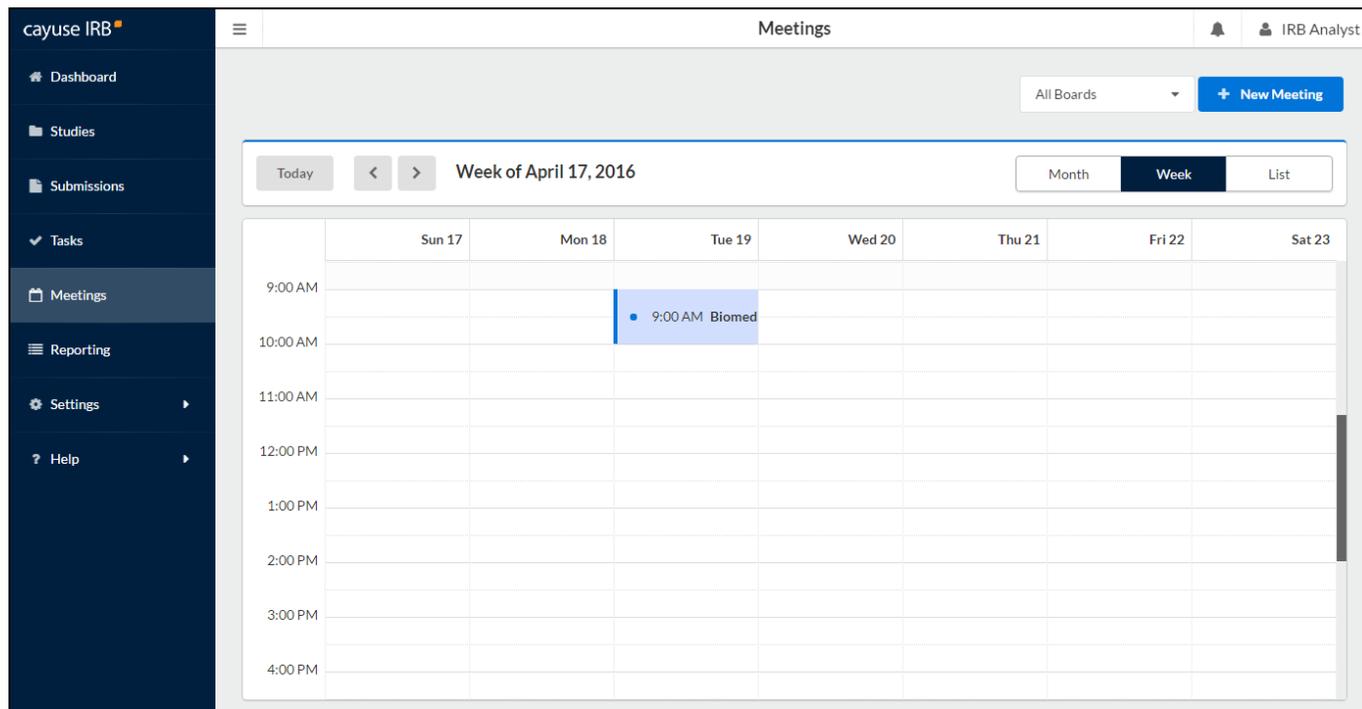
Using the Calendar

You can browse the calendar by clicking the < and > buttons at the top of the calendar. Use the **Boards** dropdown in the upper right to filter the meetings shown on the calendar to only displays meetings for the selected board.

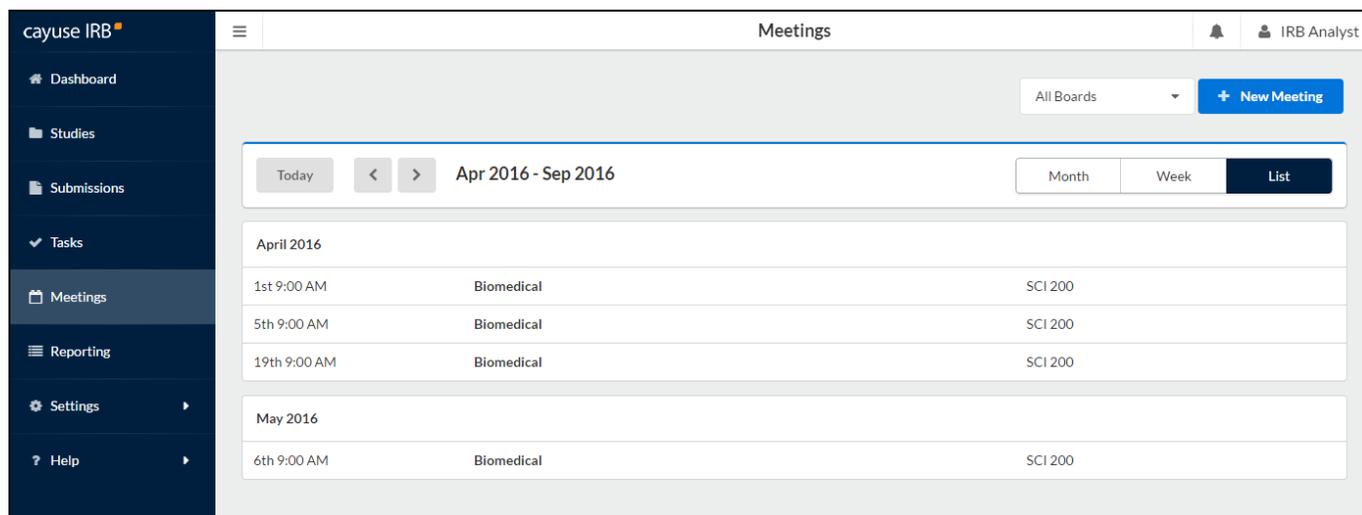
When in "Month" view, selecting the month or year at the top of the calendar brings up a menu to allow you to select a new month and/or year.

The screenshot shows the 'Meetings' calendar interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, Meetings (highlighted), Reporting, Settings, and Help. The main content area is titled 'Meetings' and shows a calendar for April 2016. At the top right of the calendar area, there is a dropdown menu for 'All Boards' and a '+ New Meeting' button. The calendar grid shows dates from 27 to 07. Meeting events are represented by blue dots with text: '9:00 AM Biom...' on April 01, 04, and 18. The calendar view is set to 'Month', with 'Week' and 'List' options also visible.

You can also choose to view the calendar by week. Select the **Week** button at the top of the screen to toggle the calendar view. When viewing the calendar by week, selecting the week starting date at the top of the calendar allows you to select a different week. You can browse through the weeks using the < and > buttons.

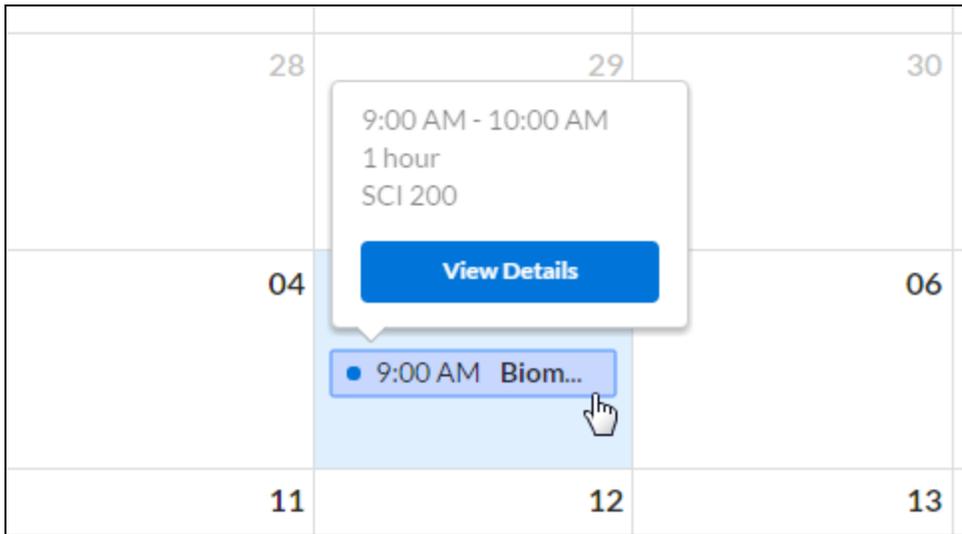


The third way of viewing the calendar is as a list of meetings. The **List** button displays the dates of all upcoming meetings, in date order.



Viewing Meeting Details

In month or week view, click on a meeting to see a brief overview.



For full meeting information, click **View Details**.

In list view, simply click on a meeting to open it.

Meeting Details

Send Agenda | Agenda | Minutes | **Start Meeting**

← Previous Board Meeting | Next Board Meeting →

Biomedical
Apr 01, 2016
9:00 AM - 10:00 AM
SCI 200

Edit | Delete

Agenda

- Review minutes of previous meeting
- Discuss IRB-FY2016-3531

Notes

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Attendees	Attachments	Full Board Reviews	Full Expedited Reviews	Expedited Reviews	Exempt Reviews	Closures	
Present	Name	Status	Representation	Affiliation	Office	Undo + Add	
Members	<input type="radio"/> No	IRB Member 2	--	--	Affiliated	--	✕
	<input type="radio"/> No	IRB Member 3	--	--	--	--	✕
Guests	<input type="radio"/> No	IRB Guest	--	--	Non-Affiliated	--	✕

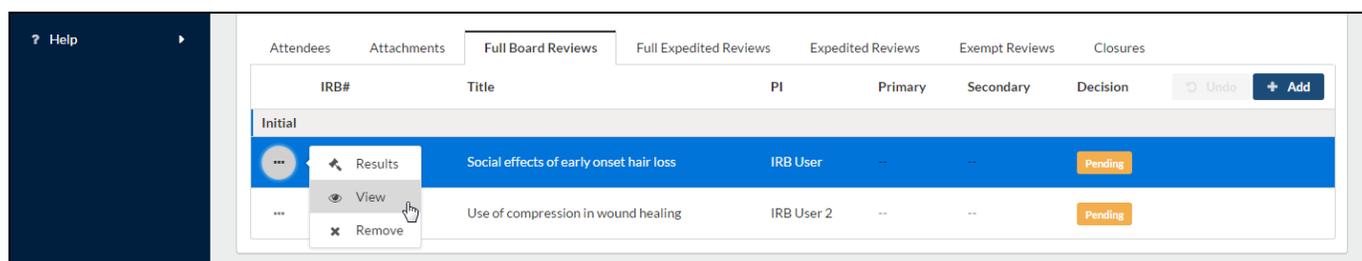
The top section of the Meeting Details screen contains information about the meeting, including its date, location, and start time. You can go to a previous or future meeting for this review board by clicking on the **Previous Board Meeting** or **Next Board Meeting** buttons.

Underneath that is an area for the IRB Analyst to enter an agenda for the meeting, and to enter any notes relating to the meeting or the submissions scheduled for discussion.

The bottom of the screen is divided into seven tabs. The first tab is the list of attendees. Once the meeting occurs, the IRB Analyst will use this list to indicate which board members were present at the meeting.

The second tab contains a list of attachments that have been added to the meeting. IRB Analysts can use this tab to include documents that they wish board members to review. Unlike study attachments, the attachments included here are not associated with any particular study.

The other tabs list the different types of submissions that are assigned to this meeting for review: **Full Board Reviews**, **Full Expedited Reviews**, **Expedited Reviews**, **Exempt Reviews**, and **Closures**. To view the details of a submission on any of these tabs, select the study, click the ellipsis button, and select **View**.



IRB Analysts and users who are assigned to review a submission can pull up the decision page for the submission by selecting **Results** to enter or edit the decision for this submission.