

Electronic Proposal Development and Submission



Cayuse IRB Organizational Approver Guide

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www.cayuse.com Page 2 of 24

Table of Contents

Electronic Proposal Development and Submission	1
Trademark, Publishing Statement, and Copyright Notice	2
Table of Contents	3
WhatisCayuseIRB?	4
System Requirements	
Cayuse IRB Support Resources	5
Online Help	
Tutorials	5
Additional Resources	5
Logging In	6
Navigating Cayuse IRB	7
Dashboard	
Studies and Submissions	7
Meetings	7
Reporting	8
Settings	8
Tasks	9
Notifications	9
User Settings and Actions	9
Help	10
Dashboard	11
Studies and Submissions	13
Studies	13
Study Statuses	13
Submissions	14
Searching for Studies or Submissions	15
Tasks	16
Notifications	17
Organizational Approvers	18
ReviewingandCommentingonSubmissions	10
Using Checklists	
Adding Comments	
Inserting Attachments	
Comparing Two Versions of a Submission	
Companing I wo versions of a Submission	23
ApprovingandRejectingSubmissions	

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

- Display with 1024x768 or higher resolution.
- Internet Explorer 11, Mozilla Firefox, or Google Chrome for PC; Safari, Firefox, or Chrome for Mac.
- Microsoft Edge is provisionally supported for Windows.

www.cayuse.com Page 4 of 24

Cayuse IRB Support Resources

Cayuse provides several sources of support for Cayuse IRB users, including online help and user guides, release notes, and a support website where you can browse the Knowledge Base, participate in customer forums, or open a support ticket.

Online 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.

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**.

Additional Resources

The Cayuse 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 Cayuse Research Suite.
- IRB Support Provides links to this manual, the release guides, the Cayuse blog, and the knowledgebase.

www.cayuse.com Page 5 of 24

Logging In

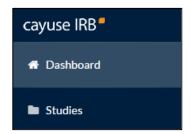
Enter your username and password at the prompt. Then, click **Sign In** to launch Cayuse IRB.

www.cayuse.com Page 6 of 24

Navigating Cayuse IRB

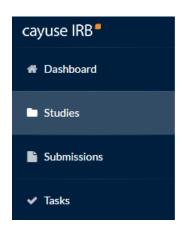
Dashboard

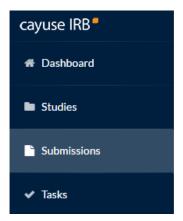
When you first log in to Cayuse IRB, the <u>Dashboard</u> screen presents you with a quick overview of any studies you are involved with or that require your attention.



Studies and Submissions

The **Studies** and **Submissions** screens list the studies and submissions that you have access to.



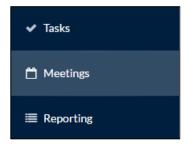


- IRB Users see all studies that they are involved with as PI, PC, Researcher, etc.
 - o **Organizational Approvers** see the studies that require their approval before proceeding.
- **IRB Members** see all studies that are or were assigned to them, or to the review board(s) they are a member of, for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

Meetings

The <u>Meetings</u> section allows IRB Analysts, Admins, and Members to view the calendar of scheduled IRB meetings. *IRB Users do not see the Meetings section.*

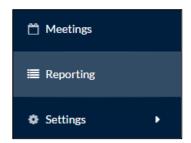
www.cayuse.com Page 7 of 24



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

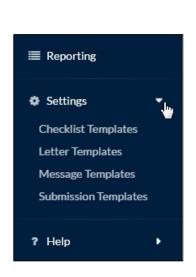
Reporting

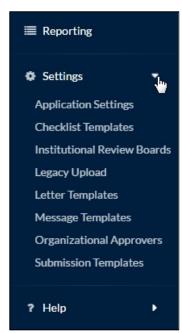
The <u>Reporting</u> section lets IRB Analysts and Admins create and download custom CSV reports containing various study details and audit information.



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.

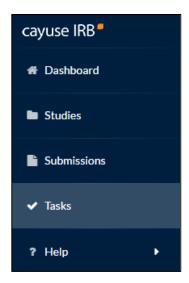




www.cayuse.com Page 8 of 24

Tasks

The <u>Tasks</u> 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.



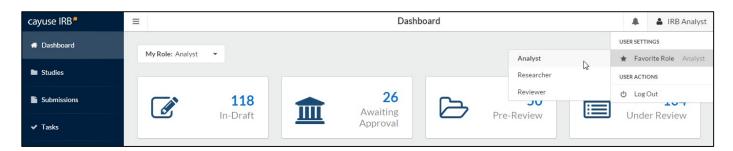
Notifications

The <u>Notifications</u> 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.



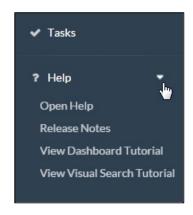
www.cayuse.com Page 9 of 24

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.



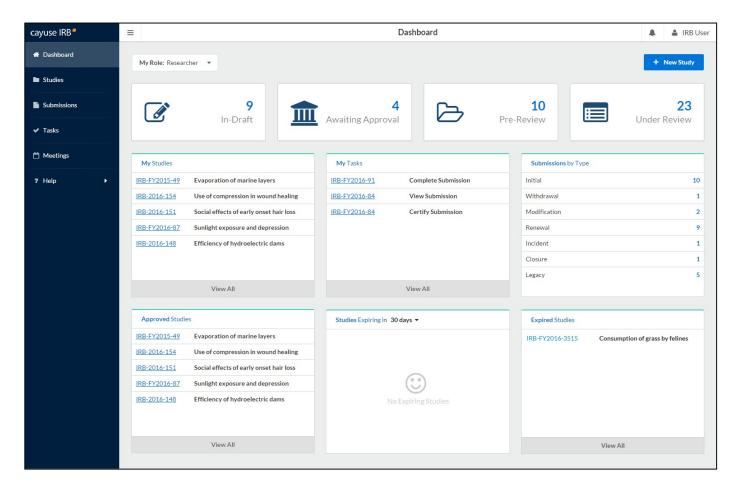
Clicking the small icons throughout Cayuse IRB open the Help to the page with information relating to that part of the application.

www.cayuse.com Page 10 of 24

Dashboard

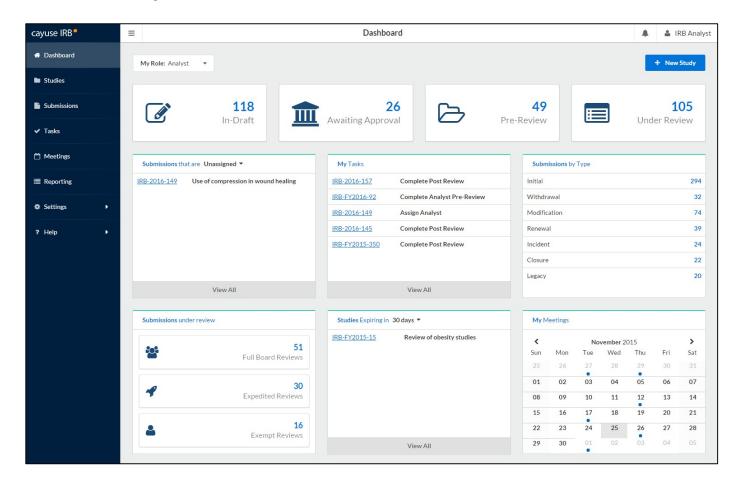
When you first log in to Cayuse IRB, you will be taken to your **Dashboard**. This screen displays an overview of all the studies you are involved with or that require your attention, and offers a quick way to view and filter studies, submissions, and tasks.

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



www.cayuse.com Page 11 of 24

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.



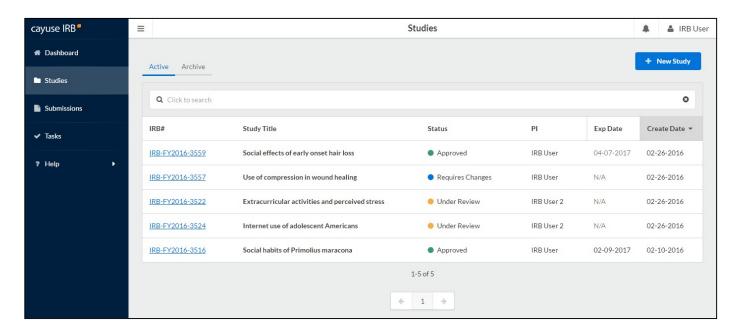
- The four status buttons across the top allow you to run quick filters on submissions which have the selected status. For instance, clicking on the **In Draft** button takes you to the Submissions page and displays all of the submissions that are currently in draft (status = Unsubmitted or status = 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.

www.cayuse.com Page 12 of 24

Studies and Submissions

Studies

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



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

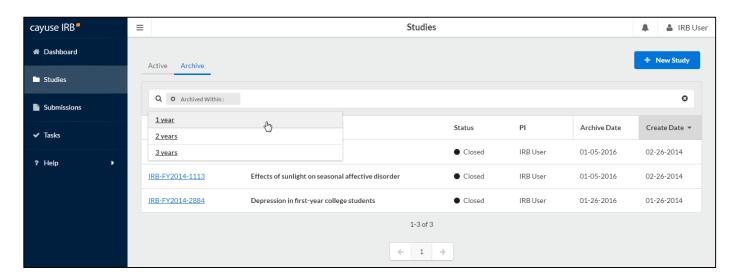
Study Statuses

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

- 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.

www.cayuse.com Page 13 of 24

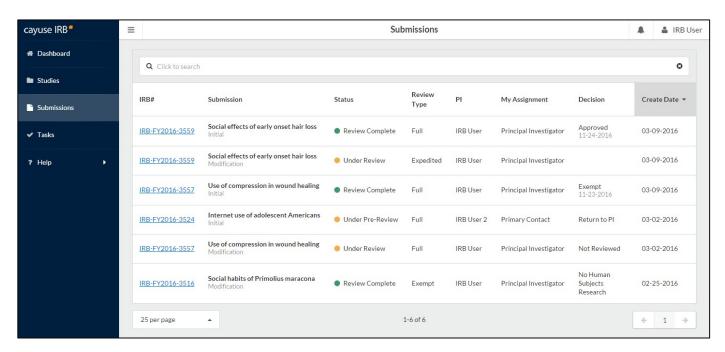
The Studies screen is divided into two tabs, **Active** and **Archive**. The Active tab displays all of the studies that are currently active within Cayuse IRB. The Archive tab lists studies that have been closed, disapproved, or withdrawn.



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.

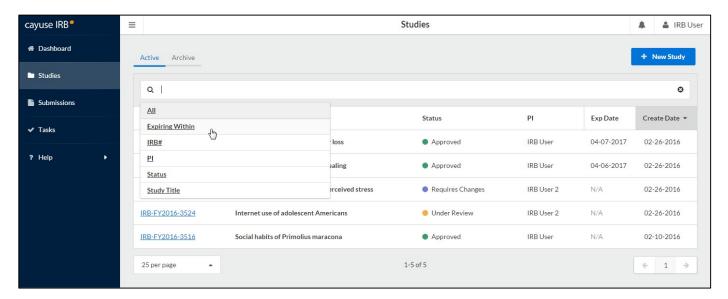


You can resort the list of submissions by creation date in ascending or descending order by clicking on the column header.

www.cayuse.com Page 14 of 24

Searching for Studies or Submissions

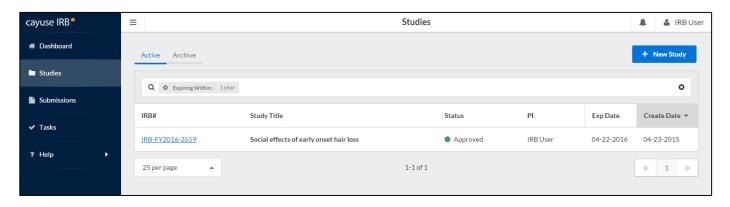
To filter the list of studies or submissions, click in the search box and select the attribute you wish to filter by. You can also simply enter your search term(s) to search all available fields.



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



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



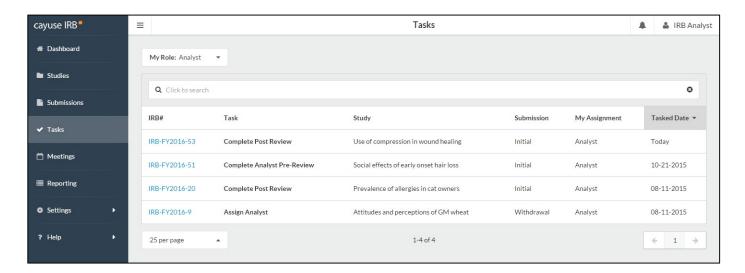
To go to a study or submission, click anywhere in that row.

www.cayuse.com Page 15 of 24

Tasks

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

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



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

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

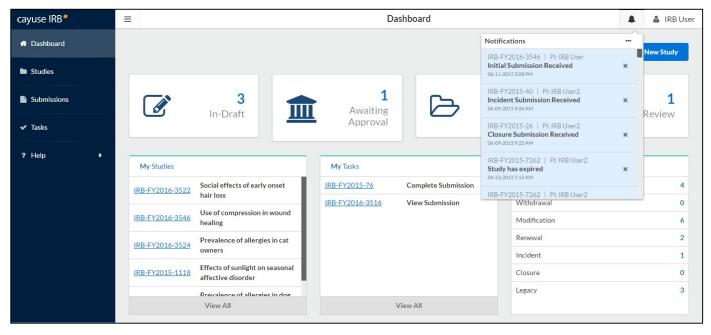
Depending on how your IRB Administrator has configured the application, you may receive email notifications for tasks at periodic intervals. Administrators can specify how frequently to send reminder emails for outstanding tasks via the Application Settings_screen.

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

www.cayuse.com Page 16 of 24

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:

- 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.

www.cayuse.com Page 17 of 24

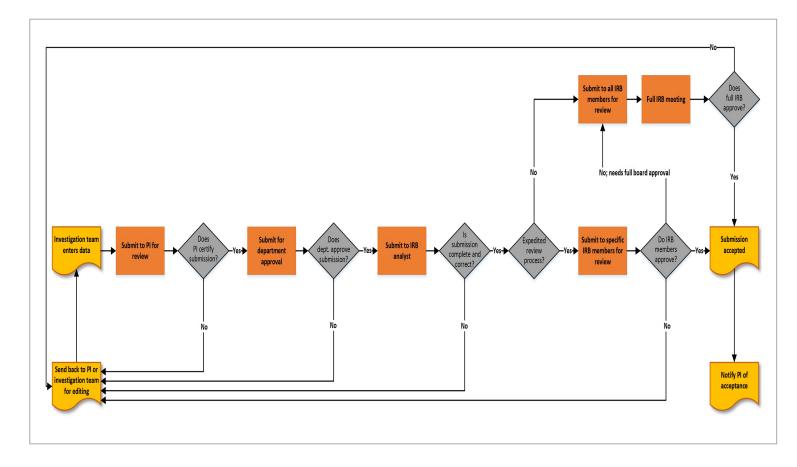
Organizational Approvers

The Organizational Approver is responsible for making sure that the submission meets departmental standards and that it is OK to proceed with sending the submission to the Compliance Office for review. Your institution may or may not require the organizational approval step, and there may be more than one person who needs to sign off on each submission for a given department. Any one of the designated Organizational Approvers for an organization can approve submissions for that organization and level.

IRB Administrators can specify the Organizational Approvers for each department and change the organizational approval settings for your institution as needed.

The Organizational Approver's role is as follows:

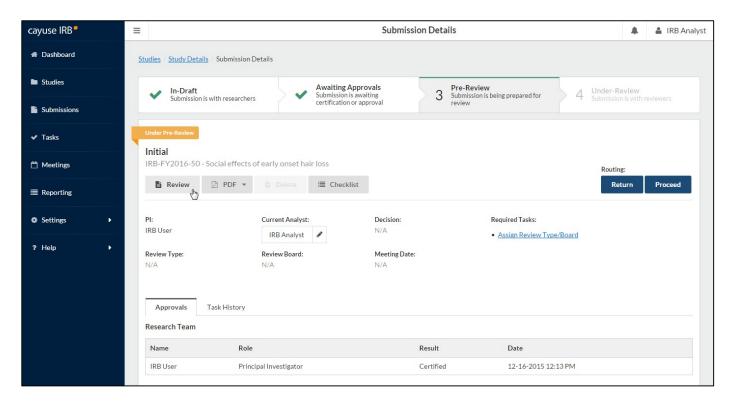
- Review the submission once it has been certified by the PI.
- Route the submission by returning it to the PI for changes, or approving it and sending it to an IRB Analyst for review.



www.cayuse.com Page 18 of 24

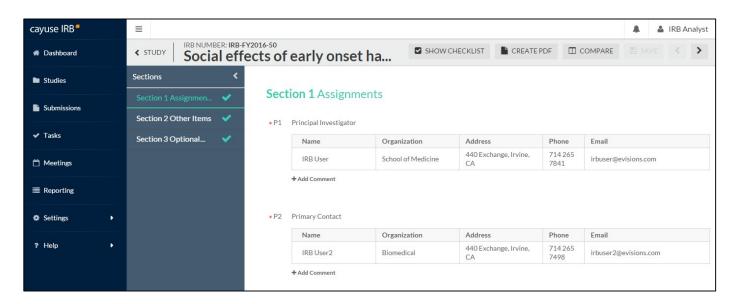
Reviewing and Commenting on Submissions

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



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

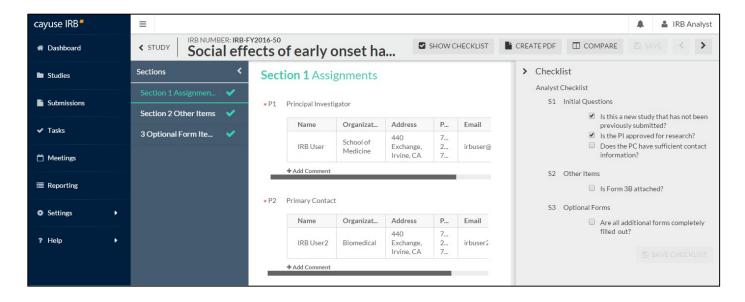
Note: You may not see the Checklist button if no checklists are configured for your institution.



www.cayuse.com Page 19 of 24

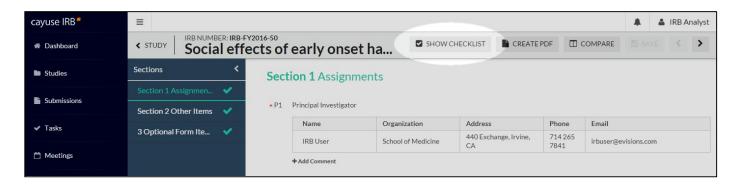
Using Checklists

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 <u>Settings</u> 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).



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.



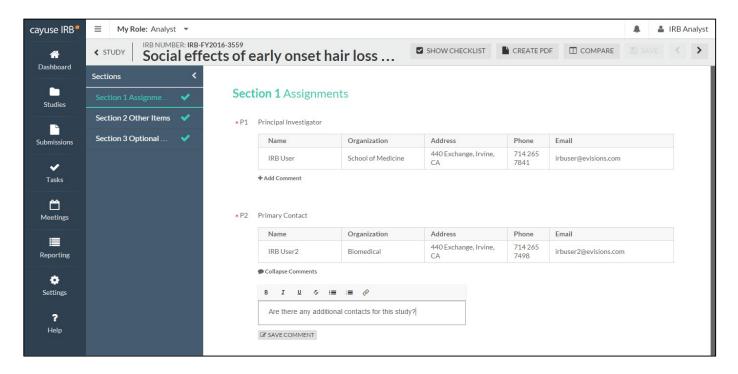
Each submission for a study has its own Analyst and Reviewer checklists. When a review is complete, the Reviewer checklist(s) become read- only. Similarly, when a submission has been finalized, the Analyst can no longer modify the Analyst checklist for that submission.

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

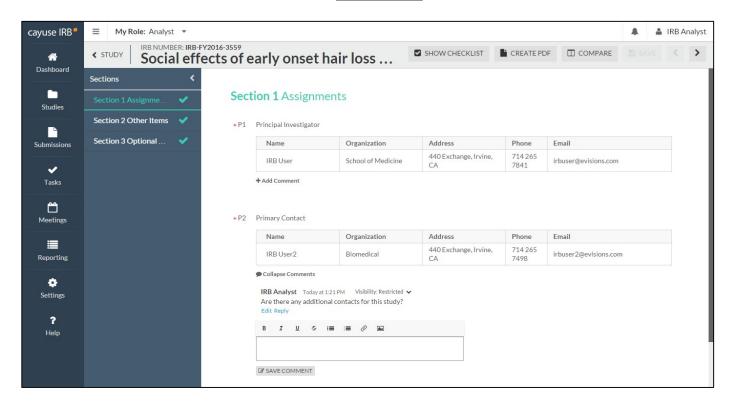
www.evisions.com Page 20 of 24

Adding Comments

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



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



www.evisions.com Page 21 of 24

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.

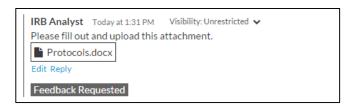
If the submission is returned to the research team, they can reply to any visible comments and/or mark them as **addressed**. Analysts and reviewers can enter and reply to comments and mark them as resolved when the submission is assigned to them.

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

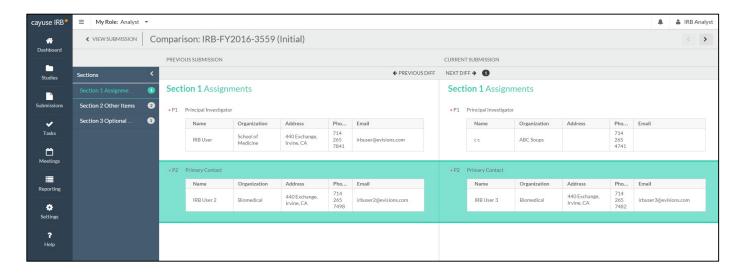
When you are entering the text of a comment, you can include an attachment in the comment. Use the *⊘* icon in the text editor to browse for one or more files to upload. **Note:** File attachments are limited to a maximum size of 20 MB.



www.evisions.com Page 22 of 24

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.

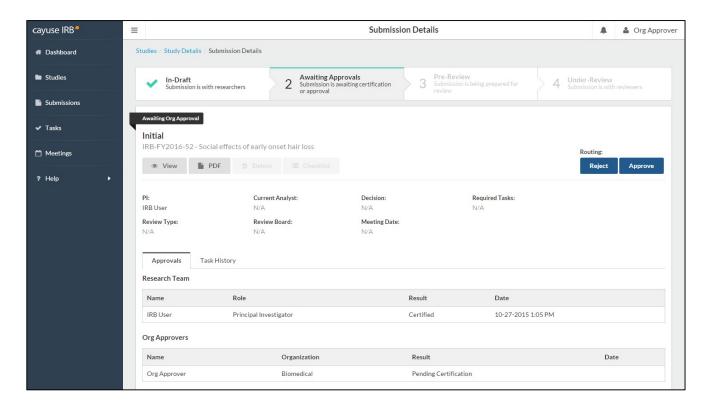


www.evisions.com Page 23 of 24

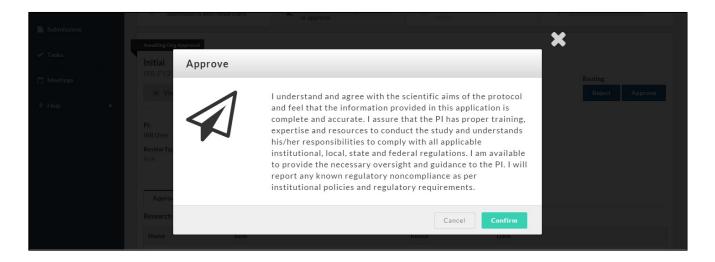
Approving and Rejecting Submissions

After reviewing the submission, you can either **Reject** or **Approve** it. Rejecting the submission returns it to the PI. If you approve the submission, you will be asked to confirm that you believe it is complete and accurate, and complies with all relevant regulations.

Select the **View** button to open the submission for review. Then, select either Reject or Approve under the Routing section.



If you are approving the submission, you must confirm your approval in order to proceed:



The submission is then routed to an IRB Analyst for review.

www.evisions.com Page 24 of 24