

Online Protocol Creation, Submission, and Management

Cayuse IRB User Guide

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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.

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**.

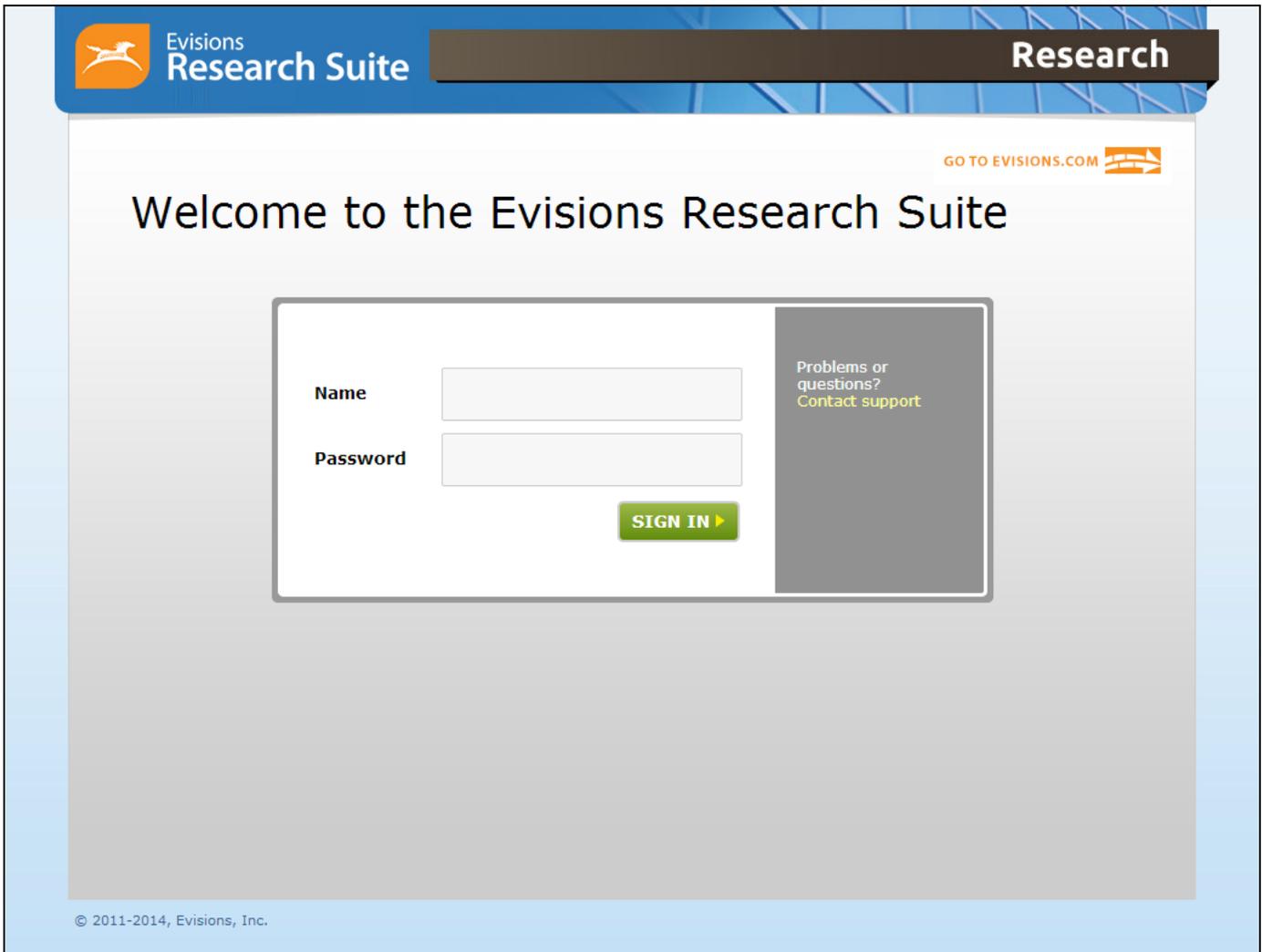
Additional Resources

The [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.



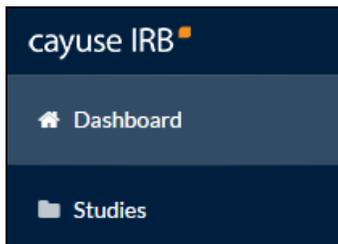
The screenshot shows the login interface for the Evisions Research Suite. At the top left, there is a logo for Evisions Research Suite. To the right of the logo, the word "Research" is displayed in a dark box. In the top right corner, there is a link "GO TO EVISIONS.COM" with a small icon. The main heading 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

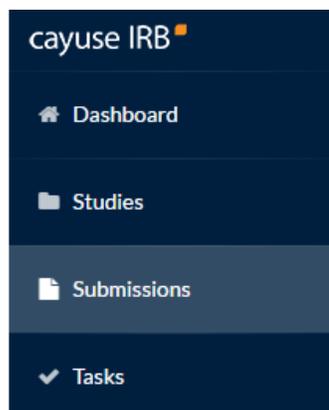
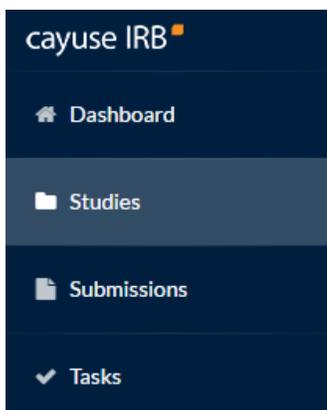
Dashboard

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

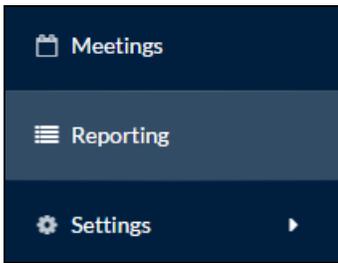
The [Studies](#) and [Submissions](#) screens list the studies and submissions that you have access to.



- **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.

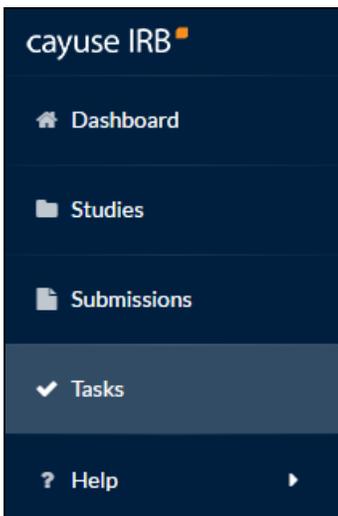
Reporting

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



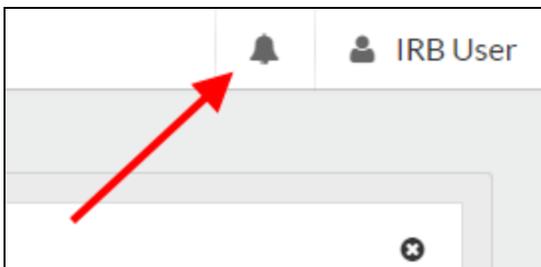
Tasks

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.



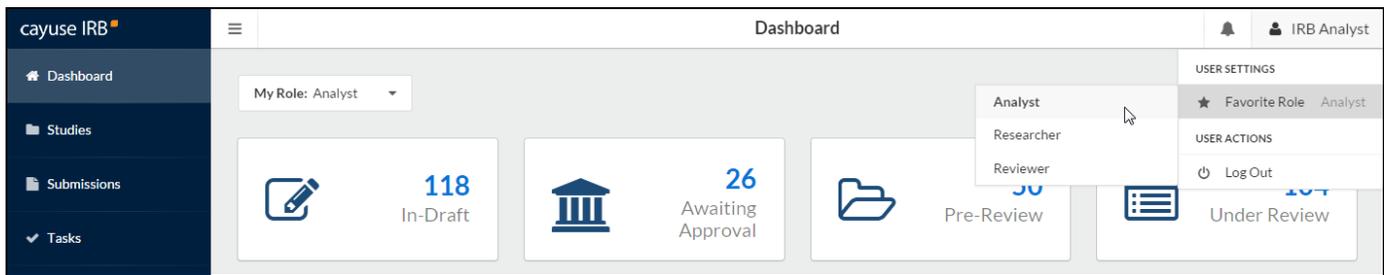
Notifications

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.

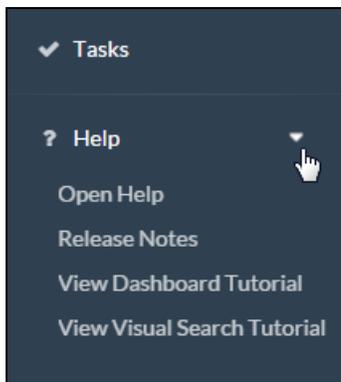


User Settings - Favorite Role - If you have more than one user role (such as *Analyst* and *Reviewer* for someone who is both an IRB Analyst and a member of a review board), certain screens (such as the dashboard) display different information depending on your role. These screens have a dropdown in 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' (listing 6 types), '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.

Category	Count
In-Draft	9
Awaiting Approval	4
Pre-Review	10
Under Review	23

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

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

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

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

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

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 displays the Cayuse IRB Analyst Dashboard. At the top, there is a navigation bar with the Cayuse IRB logo, a hamburger menu, the title 'Dashboard', a notification bell, and the user's name 'IRB Analyst'. Below the navigation bar, there is a dropdown menu for 'My Role: Analyst' and a '+ New Study' button. The main content area is divided into several sections:

- Status Summary:** Four large cards showing submission counts by status: 'In-Draft' (118), 'Awaiting Approval' (26), 'Pre-Review' (49), and 'Under Review' (105).
- Submissions that are Unassigned:** A list of unassigned submissions, including one for 'IRB-2016-149' titled 'Use of compression in wound healing'.
- My Tasks:** A list of tasks assigned to the analyst, such as 'Complete Post Review' for 'IRB-2016-157' and 'Assign Analyst' for 'IRB-2016-149'.
- Submissions by Type:** A table showing the count of submissions for various review types: Initial (294), Withdrawal (32), Modification (74), Renewal (39), Incident (24), Closure (22), and Legacy (20).
- Submissions under review:** A section showing counts for different review types: Full Board Reviews (51), Expedited Reviews (30), and Exempt Reviews (16).
- Studies Expiring in 30 days:** A list of studies that are due for review, such as 'IRB-FY2015-15' for 'Review of obesity studies'.
- My Meetings:** A calendar 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 maraona	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.

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.

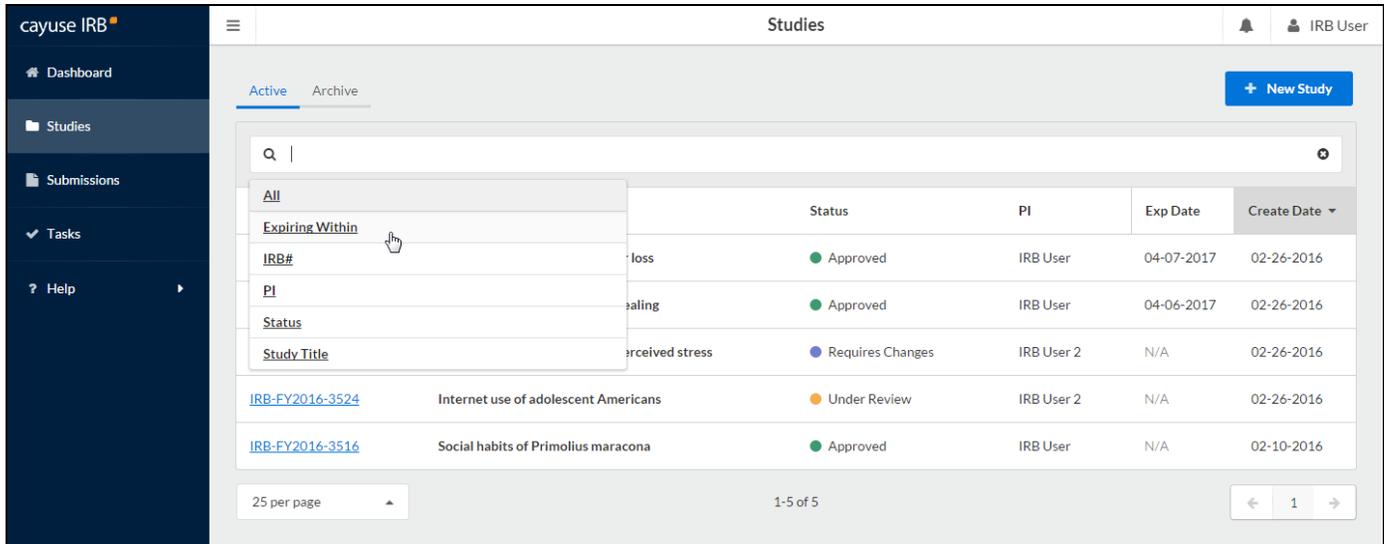
Note that some of the submissions are different types of submissions for the same study. For instance, an initial submission that was later followed up by a modification submission for that study.

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

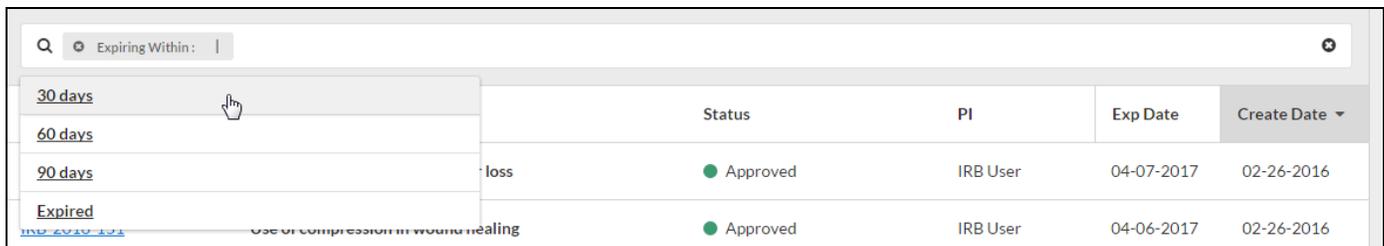
To filter the list of studies or submissions, click in the search box and select the attribute you wish to filter by. You can also simply enter your search term(s) to search all available fields.



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
		Approved	IRB User	04-07-2017	02-26-2016
		Approved	IRB User	04-06-2017	02-26-2016
		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 dropdown menu with 'Expiring Within' selected. A second dropdown menu is open, showing suggestions: 30 days, 60 days, 90 days, and Expired. The '30 days' option is highlighted. The table of studies from the previous screenshot is partially visible behind the dropdown.

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 bar now contains the text 'Expiring Within: 1 year'. The table of studies is filtered to show only one row: IRB-FY2016-3559, titled 'Social effects of early onset hair loss', with a status of 'Approved'.

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.

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 shows the Cayuse IRB Dashboard with a notifications dropdown menu open. The dashboard has a dark blue sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Dashboard' and features three summary cards: 'In-Draft' with 3 items, 'Awaiting Approval' with 1 item, and 'Review' with 1 item. Below these are 'My Studies' and 'My Tasks' sections. The 'My Studies' section lists four studies with their titles and IRB numbers. The 'My Tasks' section lists two tasks. The notifications dropdown menu is positioned over the 'My Tasks' section and lists five notifications with their dates and times. A 'New Study' button is located in the top right corner of the dashboard.

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.).

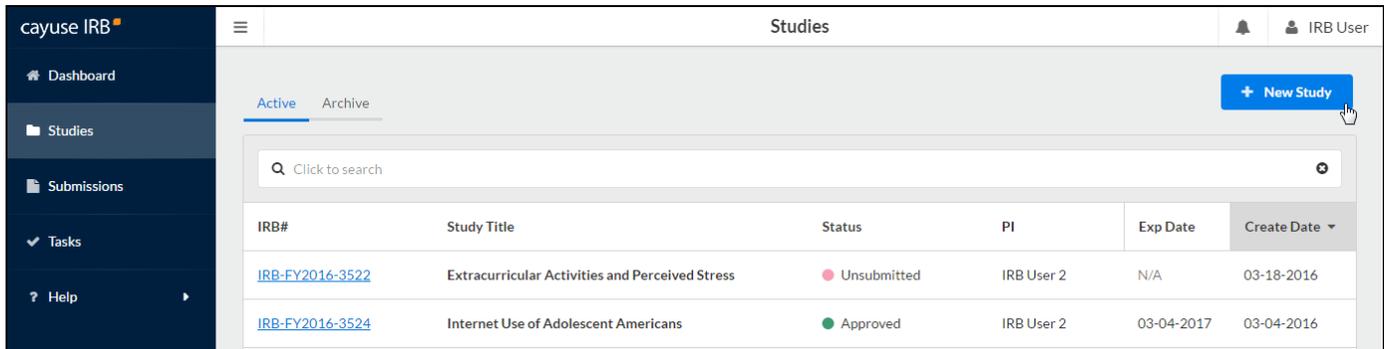
Clicking on a notification takes you to the submission that notification pertains to. Viewed notifications are no longer highlighted in the Notifications list. You can delete notifications from the list by clicking the **X** icon next to that notification, or use the ... menu to mark all notifications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

Customizing Notifications

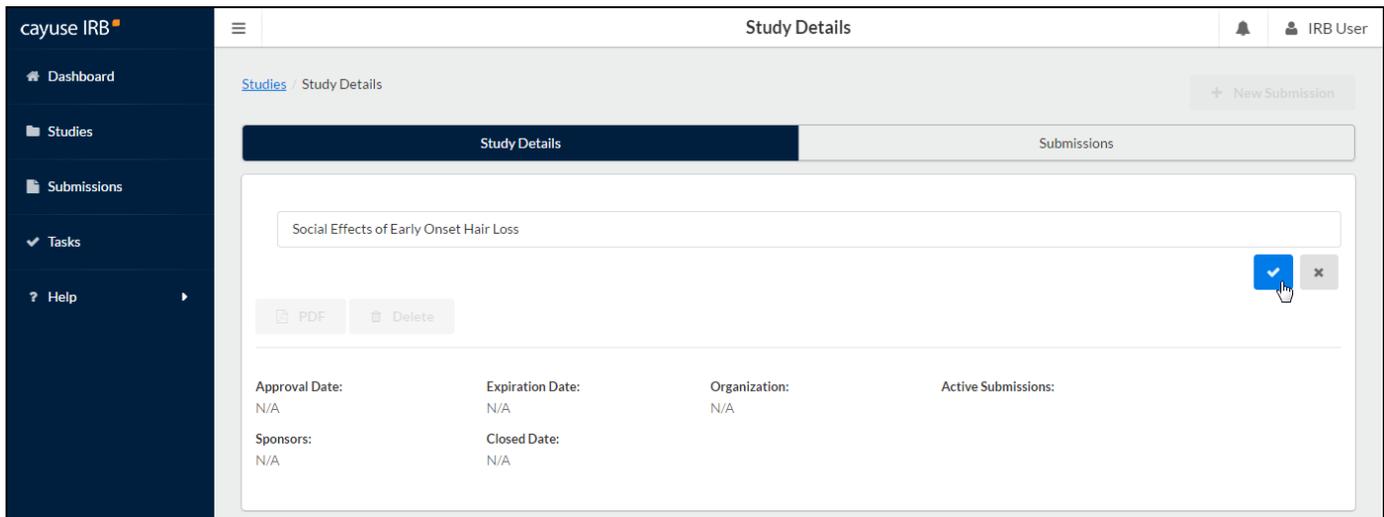
IRB Analysts and Admins have the ability to customize all of the notifications and emails that are sent out by Cayuse IRB via the [Message Templates](#) screen in the Settings section. Customization options include editing the text of the message, controlling which users receive it, or disabling certain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

Creating a New Study

To create a new study, click the **New Study** button in the upper right of either the [Studies](#) page or your [Dashboard](#).



Enter a title for your study (up to 600 characters). Then, click the **Save** button.



After creating the new study, you will be taken to the Study Details page for that study, which displays important information regarding the study.

Editing Study Titles

You can choose to rename your study at any point up until the initial (or a withdrawal) submission has finished being reviewed. From the Study Details screen, click anywhere within the study title field to edit the title.

Creating the Initial Submission

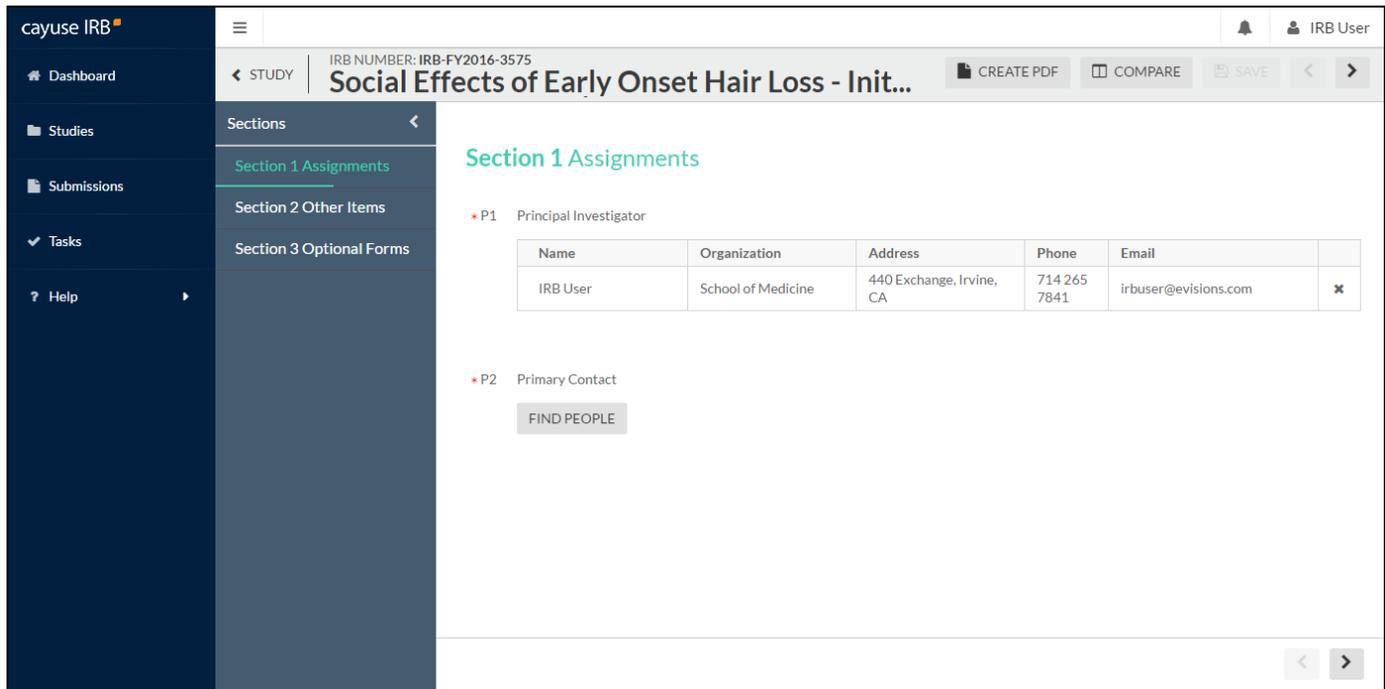
To begin working on your study, click **New Submission** to add the Initial submission for your study.

The screenshot shows the 'Study Details' page in the Cayuse IRB system. The sidebar on the left contains navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and includes a 'New Submission' button. Below this, there's a section for 'IRB-FY2016-3575 Social Effects of Early Onset Hair Loss' with 'PDF' and 'Delete' buttons. A metadata table shows fields like Approval Date, Expiration Date, Organization, Active Submissions, Sponsors, and Closed Date, all with 'N/A' values. At the bottom, there's a 'Key Contacts' section with a table header for Team Member, Role, Number, and Email, currently showing 'No Key Study Contacts'.

The initial submission appears below the study details. The person who creates the study is added as the PI by default. You can change this when editing the submission, if needed. Click the **Edit** button to begin working on the initial submission.

The screenshot shows the 'Submission Details' page in the Cayuse IRB system. The sidebar on the left contains navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Submission Details' and includes a progress bar with four 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), and 4 Under-Review (Submission is with reviewers). Below this, there's a section for 'Initial IRB-FY2016-3575 - Social Effects of Early Onset Hair Loss' with 'Edit', 'PDF', and 'Delete' buttons. A metadata table shows fields like PI (IRB User), Current Analyst (N/A), Decision (N/A), Review Type (N/A), Review Board (N/A), Meeting Date (N/A), and Required Tasks (Assign PI, Assign PC, Complete Submission).

You will now be taken to your institution's initial submission form, where you can begin filling out information. Your study is saved, and you can return to the Study Details page at any time by clicking on the < **STUDY** link in the upper left of the screen.



The screenshot shows the Cayuse IRB interface. On the left is a dark blue sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area has a top header with the study title "Social Effects of Early Onset Hair Loss - Init..." and the IRB number "IRB NUMBER: IRB-FY2016-3575". Below the header is a "Sections" menu with "Section 1 Assignments" selected. The main content area is titled "Section 1 Assignments" and contains two sections: "P1 Principal Investigator" and "P2 Primary Contact". The P1 section includes a table with the following data:

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

Below the P1 section is the "P2 Primary Contact" section, which includes a "FIND PEOPLE" button. At the bottom right of the main content area are navigation arrows.

Completing Forms

When you create a new submission for your study, the submission prompts you for the information required by your institution's template for that particular submission type. There may be multiple sections in the template, as well as actions and attachments that you can provide.

The screenshot shows the 'General Information' section of a form. The left sidebar contains navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Social effects of early onset hair loss - Initial' and includes a 'FIND PEOPLE' button. The form is currently in the 'General Information' section, which is highlighted in green. The form includes a table for Principal Investigator information and a 'FIND PEOPLE' button for Primary Contact.

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

The section you are currently working on appears in the menu in green text. As you provide information, the status bar underneath the section turns green. When complete, the section name has a green check mark to its right. Sections with no required questions are marked complete when you visit the section for the first time.

The screenshot shows the 'Location of Research' section of the form. The left sidebar now shows 'Location of Research' with a green checkmark. The main content area is titled 'Location of Research' and includes a question about whether research will be conducted on campus. The 'SAVE' button is now green. The form includes a question about whether research will be conducted on campus.

1. Will your research be conducted on campus?

Yes
 No

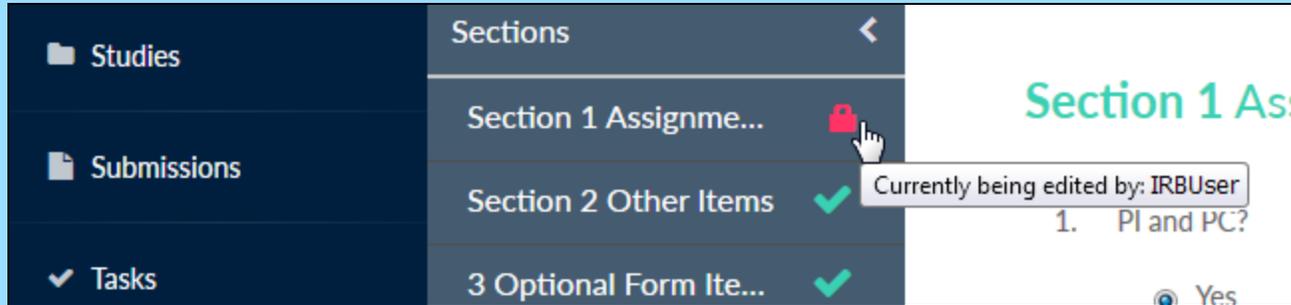
a. Select the type of facility where the research will be conducted.

- Correctional Facility
- Home Health Agency
- Veterans Hospital
- Health Clinic
- Other

Use the < and > buttons to navigate to the previous and next sections. You can also click on a section name in the menu at left to jump to that section.

Simultaneous Users

More than one member of the research team (PI, Co-PI, Primary Contact, or another authorized Investigator) can be working on different sections of a submission at the same time. When another user is currently working on a section, that section will have a red lock icon in the section menu and you will not be able to make edits to that section. You can still work on other sections that are not locked. To see who is currently editing a locked section, hover over the lock icon in the section menu.



A submission cannot be completed while another user is still editing it.

Types of questions

There are several types of questions that you may see on a submission form:

Radio Buttons

Select one of the available options.

* 1.0 What type of submission is this? 

- Research Study Involving Human Subjects (Exempt, Expedited, Full Board Review) oversight by the Cayuse University IRB
- Research Study involving an Outside IRB of Record or NCI PCIRB
- Emergency Use of Investigational Agent
- Request for Determination of the Need for IRB Review

Check Boxes

Select one or more of the available options.

* 3.0 In which locations will the research take place? (Check all that apply.)

- Inpatient Location
- Outpatient Location
- Community Settings
- Subject's Home
- N/A (limited to review of records, data and analysis)

Date Picker

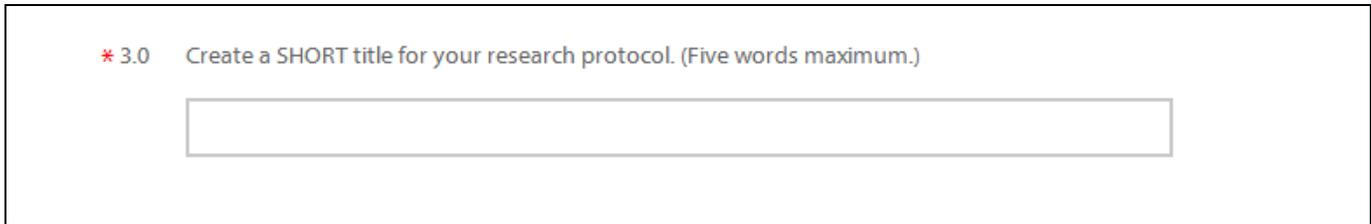
Click the calendar icon to browse for a date.

7.2 Date the event started:



Text Box

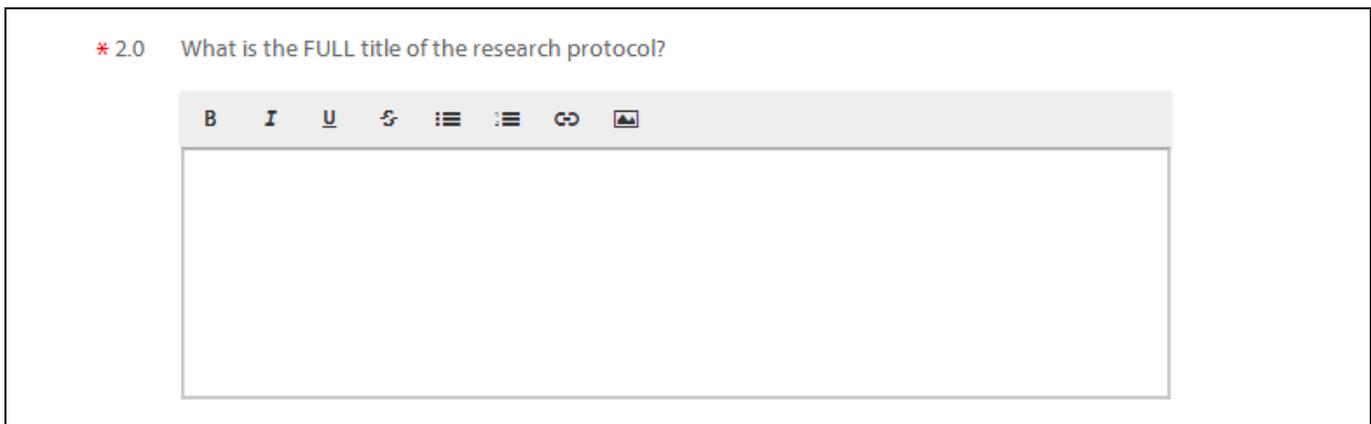
A text box provides space for a short answer that does not require a lot of explanation. You can enter multiple lines of text here if needed; the box will expand to fit the text.



* 3.0 Create a SHORT title for your research protocol. (Five words maximum.)

Text Area

The multi-line text editor allows you to apply simple text formatting such as bold, italics, underline, strikethrough, bulleted lists, numbered lists, and hyperlinks.



* 2.0 What is the FULL title of the research protocol?

B **I** U ~~ABC~~

-

- 1

[Link](#) 

You can also add PNG or JPG images using the image browser. To add an image to the text area, click the  icon in the toolbar.



Add Image

Choose source:

Upload

Web URL

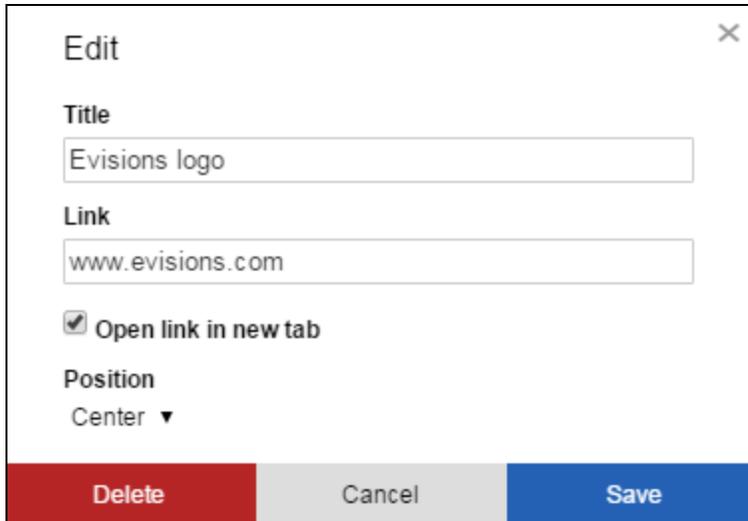
Clipboard

Depending on your browser, you have a choice of three possible image sources:

- **Upload** - Use the **Choose File** button to browse for an image on your computer or from a network location.
- **Web URL** - Paste the URL to an image that is hosted online.
- **Clipboard** - Paste an image that you have copied to your clipboard. Due to browser limitations, this option is only available to Chrome users.

Click **Confirm** to import the image.

Once the image is inserted, you can resize it as needed by clicking and dragging on the corners. When you hover over the image, an **Edit** button appears that opens a dialog where you can add a title for the image, turn the image into a hyperlink, or adjust the image position relative to the flow of text.



Edit ×

Title
Evisions logo

Link
www.evisions.com

Open link in new tab

Position
Center ▾

Delete Cancel Save

Person and Sponsor Finders

Some fields require a single person, such as the Primary Contact for a study:

* 1.0 Who is the Primary Contact?

Click **Find People** to bring up the **Primary Contact** search dialog:

PRIMARY CONTACT

✕ 🔍

Name	Organization	Email	Phone	
Mark Williams	Biomedical	mwilliams@evisions.com	714 824 5678	+
Mark Klein	Biomedical	mklein@evisions.com	714 824 1234	+

Selected Records * Select a single record.

No records selected. Select a record and click **Save** to apply.

Type the name or part of the name of the person you are looking for in the search box and click the **Search** icon. Locate the desired person in the list, then click the + button next to their name to add them to the selection. Click **Save** to return to the form.

Other People fields allow you to select more than one person. For example, when you click Find People, the **Investigator** search dialog allows you to select any number of investigators using the + buttons. When you add a person to the selection, the + button changes to a check mark.

INVESTIGATOR

Mark x 🔍

Name	Organization	Email	Phone	
Mark Williams	Biomedical	mwilliams@evisions.com	714 824 5678	✓
Mark Klein	Biomedical	mklein@evisions.com	714 824 1234	✓

Selected Records

Mark Williams	x
Mark Klein	x

⌂ CANCEL SAVE

When you have added all the people you wish to include, click Save.

Sponsor finders work exactly the same way as Person finders, except that the search returns matching sponsors instead of people.

Attachments

Attachment fields allow you to upload one or more files to the study, or to include hyperlinks as "attachments".

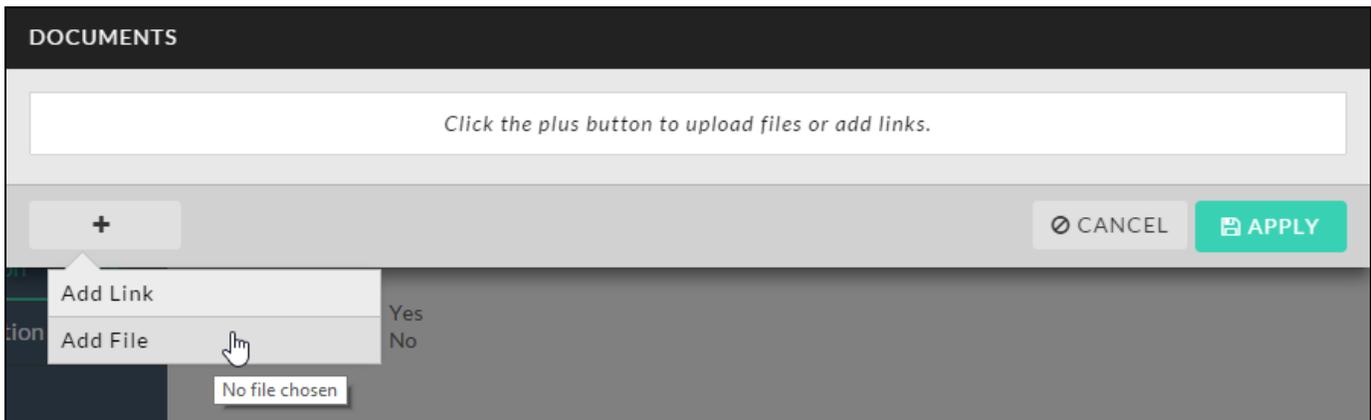


4.0 Attach the Letters of Support from the respective Department/Division.

ATTACH

A mouse cursor is positioned over the ATTACH button.

Click **Attach** to open the **Documents** window. To add a file or link, click the + button and choose to add a URL or file.



DOCUMENTS

Click the plus button to upload files or add links.

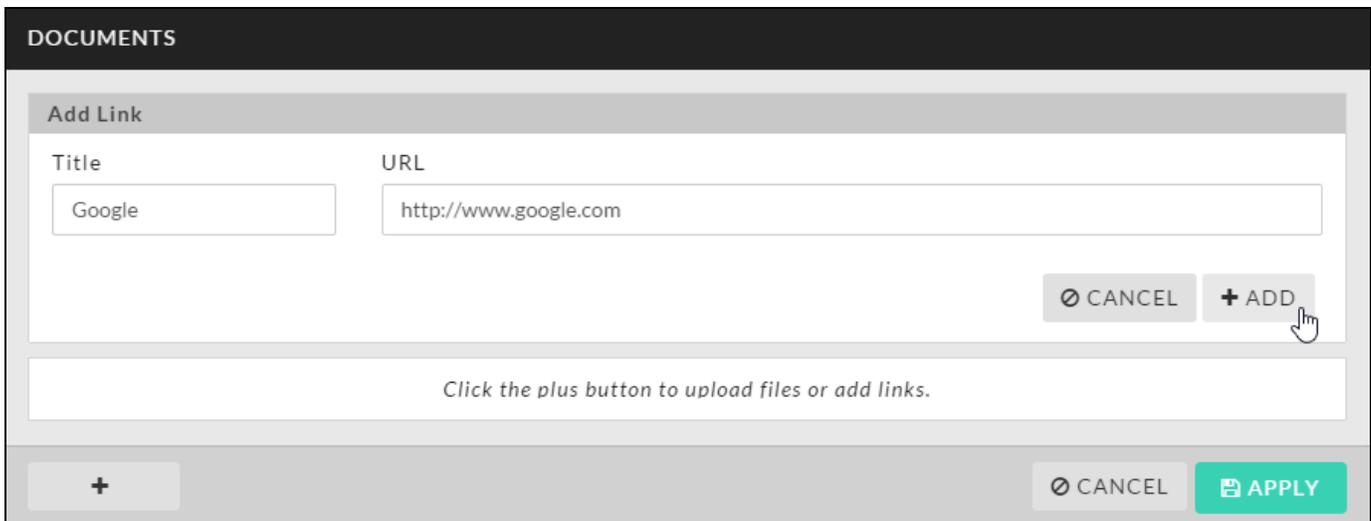
+ CANCEL APPLY

Add Link
Add File

No file chosen

Yes No

Choosing **Add File** launches the default file browser on your system. Choosing **Add Link** opens a text area where you can enter the URL and a title for the page:



DOCUMENTS

Add Link

Title URL

Google http://www.google.com

CANCEL + ADD

Click the plus button to upload files or add links.

+ CANCEL APPLY

Enter the desired URL or select the desired file, then click **Apply**.

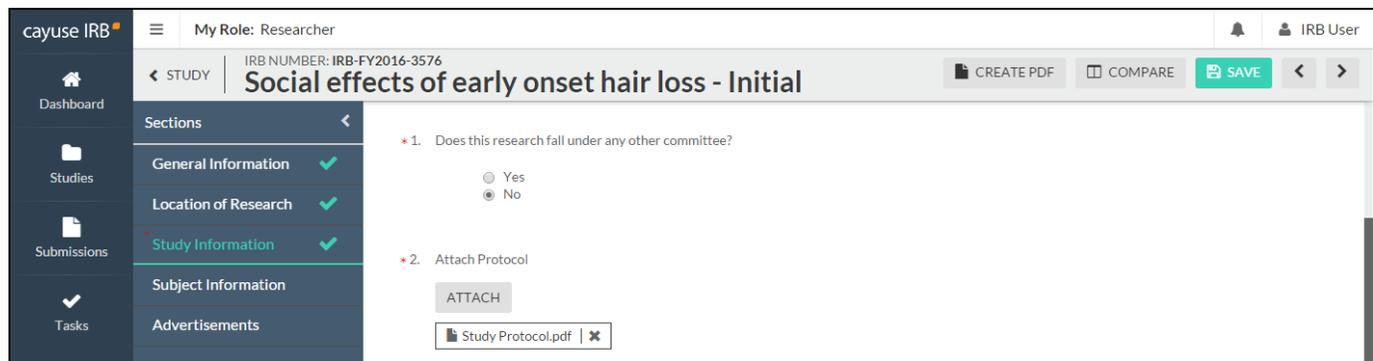
Supported File Types

Cayuse IRB supports the following file types. Each file can be a maximum of 20 MB in size.

File Type	Extension
Text	txt
Adobe	pdf
Raster image formats	png, bmp, gif, tif, tiff, jpg, jpeg, jp2, jpx
Vector image formats	wmf, emf, svg
Microsoft Word	doc, docx, docm
Microsoft Excel	xls, xlsx, xlsxm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

Deleting Attachments

To delete an attachment, click the **X** icon next to the attachment. You can also download file attachments by clicking on the filename.



Required Questions

Some questions have a red asterisk (*) next to the question number. This indicates a required question that must be answered before you can submit.

Saving Your Changes

Sections that have unsaved changes have an asterisk next to the section name in the menu. To save your changes, click the Save button in the upper right.

Help with questions

A question may provide additional information in case you need assistance with that particular question. If there is help text for a question, you can click on the (?) button to the right of the question to view the additional information for that question.

* 1.0 What type of submission is this? This is some help text. ?

- Research Study Involving Human Subjects (Exempt, Expedited, Full Board Review) oversight by the Cayuse University IRB
- Research Study involving an Outside IRB of Record or NCI PCIRB
- Emergency Use of Investigational Agent

Comments

When the IRB Office is reviewing a submission, the IRB Analyst or Members may have questions regarding some of your answers. If the submission gets returned to you, you will see a comment icon in the sidebar next to each section that contains comments, and a similar icon underneath the questions that have comments on them. Click the  [Expand Comments](#) link to see and respond to these comments.

* PC Primary Contact

FIND PEOPLE

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

 Collapse Comments

IRB Analyst Today at 2:05 PM
Are there any additional contacts for this study?
Reply

IRB User Today at 5:39 PM
No, there are no additional contacts.
Addressed Today at 5:39 PM by you

IRB Reviewer Today at 6:01 PM
I think there should be more contacts. What if the first one is out of the office?
Reply
Not Addressed

When you have responded to a comment, change the dropdown from **Not Addressed** to **Addressed**. Unaddressed comments have a red bar to their left, and display the comment count in the comment bubble icon for that question. You can toggle comments between addressed and unaddressed as needed.

Routing

If there are available actions that you can perform, the **Routing** menu appears prompting you to perform the action. For example, when you finish filling out all parts of the submission, a "Complete Submission" link appears in the Routing menu. Completing the submission will send it to the PI for certification, which is the next step in the submission workflow.

The screenshot displays the cayuse IRB web application interface. At the top, the user is identified as 'My Role: Researcher' and the study title is 'Social effects of early onset hair loss - Initial'. The IRB number is 'IRB-FY2016-3576'. The interface includes a sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The 'Routing' menu is expanded, showing 'Send to PI for certification?' and a 'COMPLETE SUBMISSION' button. The main content area is titled 'Advertisements' and contains a question: '1. Will advertisements be used during your research protocol?'. Below the question, there is a link to 'Advertisement Policy' and two radio button options: 'Yes' and 'No'. The 'No' option is selected. At the bottom of the page, there is a footer with the Evisions Research Suite logo and contact information.

Submission Workflow

Once you have completely filled out every section in the study and included all required attachments, a **Complete Submission** option appears under **Routing** in the menu when inside the submission:

The screenshot displays the Cayuse IRB interface for a researcher. The top navigation bar shows 'My Role: Researcher' and the study title 'Social effects of early onset hair loss - Initial' with IRB number 'IRB-FY2016-3576'. A left sidebar contains navigation options: Dashboard, Studies, Submissions, Tasks, and Help. A central 'Sections' menu lists 'General Information', 'Location of Research', 'Study Information', 'Subject Information', 'Advertisements', 'Routing', and 'COMPLETE SUBMISSION'. The 'Advertisements' section is active, showing a question: '* 1. Will advertisements be used during your research protocol?' with a link to 'Advertisement Policy' and radio buttons for 'Yes' and 'No'. A blue oval highlights the 'Routing' and 'COMPLETE SUBMISSION' options in the sidebar menu.

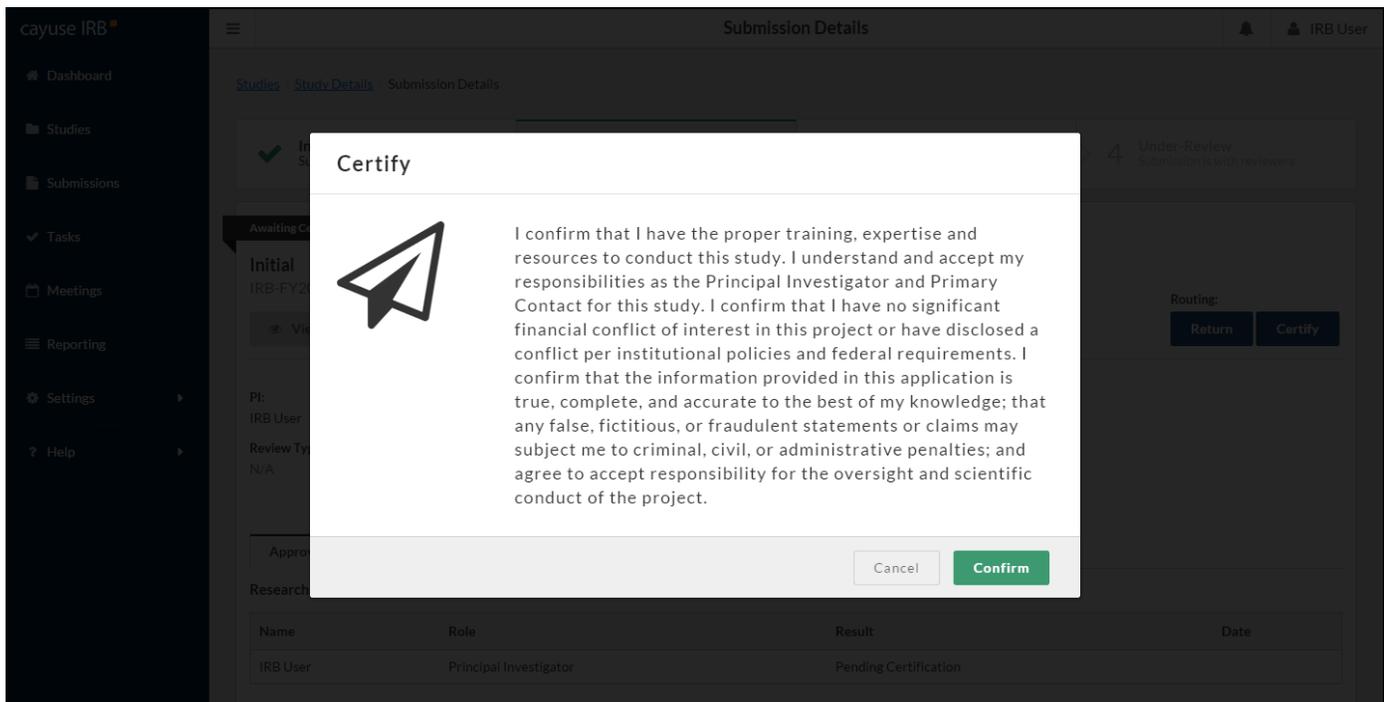
If you are on the Submission Details screen, you will also see the Complete Submission link indicating the next step in the routing process:

The screenshot displays the 'Submission Details' page in the Cayuse IRB system. At the top, a progress bar indicates the submission's status through four 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), and 4. Under-Review (Submission is with reviewers). The current stage is 'In-Draft'. Below the progress bar, the submission is identified as 'Initial' for 'IRB-FY2016-3556 - Social effects of early onset hair loss'. A red arrow points to the 'Complete Submission' link in the 'Required Tasks' section, which also includes 'Assign PI' and 'Assign PC' with checkmarks. The 'Research Team' table below is currently empty.

After clicking Complete Submission in the study sidebar, you will be prompted to confirm or cancel. Confirming marks the submission as completed and sends it to the PI (and possibly to any Co-PIs, depending on your institution's settings) for certification. It sends an email to the PI and places the study in their inbox to be addressed.

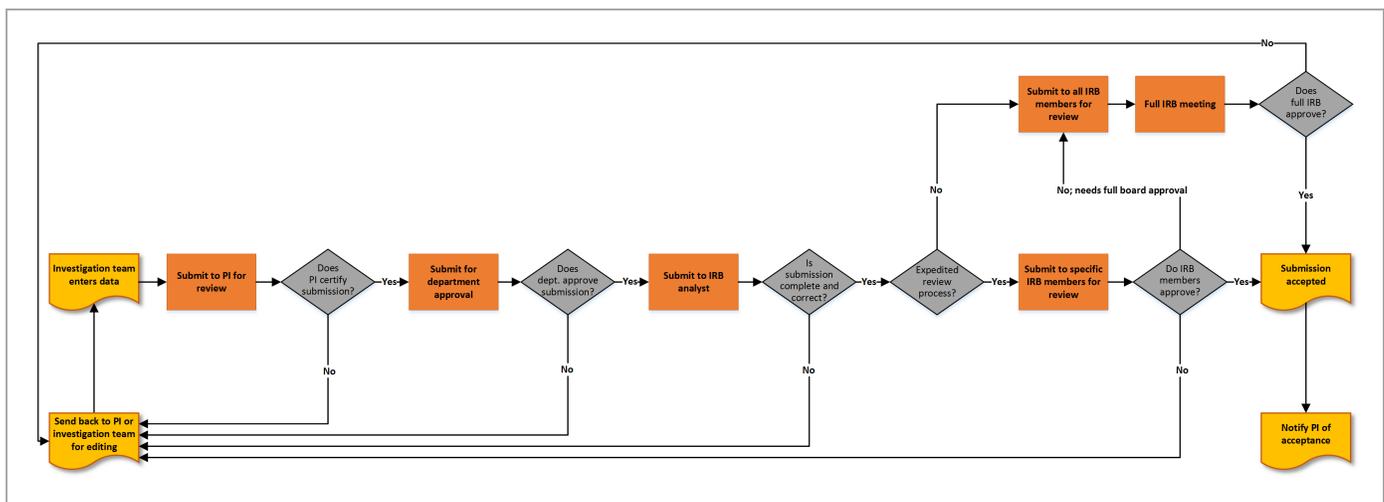
If everything is correct, the PI can then **Certify** the submission. By certifying the submission, the PI asserts that the submission is complete and accurate, and that they accept their responsibilities as PI of the study.

Note: Your institution's settings may require that any Co-PIs on the study also certify it, in addition to the PI's certification. IRB Administrators can specify this behavior in the Application Settings.



Alternatively, if the PI decides that changes need to be made, they can send the submission back to the research team by clicking **Return to Investigators**. The research team members will receive an email notification of the change in status so they can make the necessary edits before marking it complete again.

Once the PI has certified the submission, it goes to the departmental approver for review, and from there goes down the chain to the IRB analyst and members. At any point the submission may be returned to the investigation team to answer questions or to make changes.



Letters

At certain points in the workflow, the compliance office may send communication to the Principal Investigator in the form of a letter notifying them of status changes, approvals, information required, etc. Letters are sent via email, and are also available to download from the submission in Cayuse IRB.

The **Letters** tab appears for a submission when there is at least one letter associated with that submission. Click on the Letters tab to view the letters associated with the submission.

The screenshot shows the 'Submission Details' page for 'IRB-FY2016-55 - Social effects of early onset hair loss'. The page has a dark sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area 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 Under-Review (Submission is with reviewers). Below the progress bar, a green 'Review Complete' badge is visible. The submission title is 'Initial' and the subject is 'IRB-FY2016-55 - Social effects of early onset hair loss'. There are buttons for 'View', 'PDF', and 'Delete'. Below this, key information is displayed: PI: IRB User, Current Analyst: IRB Analyst, Decision: Approved, Review Type: Full, and Review Board: Biomedical. At the bottom, there are tabs for 'Approvals', 'Task History', 'Letters', and 'Meetings'. The 'Letters' tab is active, showing a table with columns for Subject, Recipients, and Sent Date.

Subject	Recipients	Sent Date
IRB-FY2016-55 - Initial: Approval - Full Board	IRBUser@evisions.com	11-09-2015
IRB-FY2016-55 - Initial: Revision Needed	IRBUser@evisions.com	09-01-2015

Each line contains the subject, send date, and recipient(s) of a letter. You can click anywhere on the line to open a PDF of the letter in a new browser window.

The screenshot shows an email letter with the following content:

To: IRB User
School of Medicine
Approval Date: Thu, 27 Feb 2014
Expiration Date of Approval: Fri, 27 Feb 2015

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Initial
Study #: IRB-FY2015-390
Study Title: Social Effects of Early Onset Hair Loss

This submission has been approved by the above IRB for the period indicated.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

When applicable, enclosed are stamped copies of approved consent documents and other recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

To save the letter to a file, right-click within the opened PDF and select **Save As** (Chrome) or **Save Page As** (Firefox), or go to **Tools -> File -> Save As** (Internet Explorer).

Addressing Comments

When a submission has been certified and sent to the IRB Analyst, the Analyst may comment on various questions on the form. The Analyst will return the submission to the investigators with any comments if you need to correct an issue, add additional information, etc.

Sections with unresolved comments have a comment bubble icon to their right indicating the total number of unresolved comments in that section. Questions with new comments show a gray comment bubble and the number of comments for that particular item underneath the question:

The screenshot shows the 'cayuse IRB' interface for a researcher. The study title is 'Social effects of early onset hair loss - Initial'. The 'Section 1 Assignments' section is active, showing two tables of contact information. 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'. A comment bubble icon with the number '1' is next to the section header, and an 'Expand Comments' link is below the second table.

You may see comments from the IRB Analyst, your Organizational Approver, or from the IRB member(s) reviewing the submission, depending on how far the submission progressed through the approval process.

Click on the **Expand Comments** link to view the comments associated with each question. You can then reply to the comment below.

The screenshot shows the 'cayuse IRB' interface with the 'Section 1 Assignments' section expanded. A comment from the 'IRB Analyst' is displayed, asking 'Are there any additional contacts for this study?'. The comment was made 'Today at 1:21 PM'. Below the comment is a text input field with the text 'No, there are no additional contacts.' and buttons for 'REPLY' and 'CANCEL'. A 'Not Addressed' status indicator is visible at the bottom of the comment area.

Enter your reply and then click **REPLY** to save it.

Once you have resolved an issue, change the status dropdown from **Not Addressed** to **Addressed**. Addressed comments have a green sidebar and the comment count no longer appears on the comment bubble icon for that question (unless there are other unaddressed comments for that question). You must mark all comments as addressed before the submission can be re-certified.

The screenshot displays the Cayuse IRB interface for a submission titled "Social effects of early onset hair loss - Initial". The interface includes a sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area shows a table for "Primary Contact" with columns for Name, Organization, Address, Phone, and Email. Below the table, there are comments from "IRB Analyst" and "IRB User" regarding additional contacts for the study. A green "Addressed" dropdown is visible at the bottom of the comment thread.

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

Comments:

- IRB Analyst** (Today at 1:21 PM): Are there any additional contacts for this study? [Reply](#)
- IRB User** (Today at 2:09 PM): No, there are no additional contacts. [Reply](#)
- Addressed** (Today at 2:08 PM by you)

Once all comments on the submission have been addressed, the PI (or Co-PI, depending on your institution's settings) will need to re-certify the submission to return it to the IRB Analyst.

Submission Types

When you first create a study, you also create the initial submission outlining the purpose of that study. In addition to this initial submission, there are five other types of submissions that IRB Users may submit during the course of your research. The available submission types include:

- **Initial** - This is the first submission that you create when you enter a new study in the system. The initial submission describes the research you intend to do and the methodology you intend to use. The initial submission must be approved before any research can begin.
- **Modification** - If you wish to change any of the details of the study after it has been approved, you must submit a modification which must be approved before you can proceed with the changes.
- **Renewal** - When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research. The renewal will need to be approved before you can continue with the study.
- **Incident** - You must submit an incident report to inform the Compliance Office of any adverse incidents, as required by your institution. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. More than one incident report may be created for a given study, as needed.
- **Withdrawal** - A withdrawal submission notifies the Compliance Office that you no longer wish to submit your initial submission and want to withdraw the study. Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal submission at any point once an initial submission has been created, until it has been approved. If the initial submission has been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research.
- **Closure** - A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified.
- **Legacy** - Used for studies imported from previous systems. The legacy submission replaces the initial submission for imported studies. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. An IRB Analyst must create and publish a legacy template before users can create legacy submissions or work with studies that have been imported from other systems.

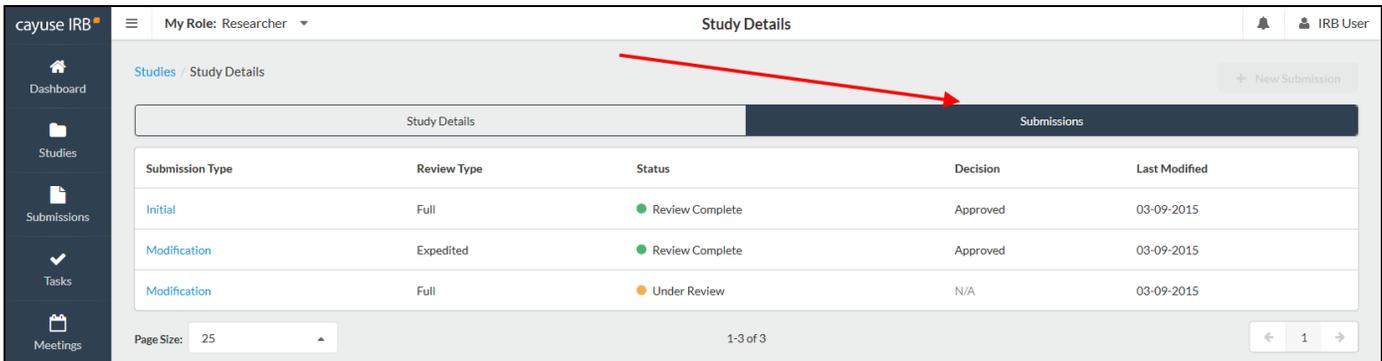
There are two additional submission types that are only available to IRB Analysts and Admins:

- **Admin Closure** - Allows a study to be administratively closed when needed, for example when the PI leaves the institution or chooses to let a study expire.
- **Admin Withdrawal** - Allows a study to be administratively withdrawn when needed, for example when the PI leaves the institution.

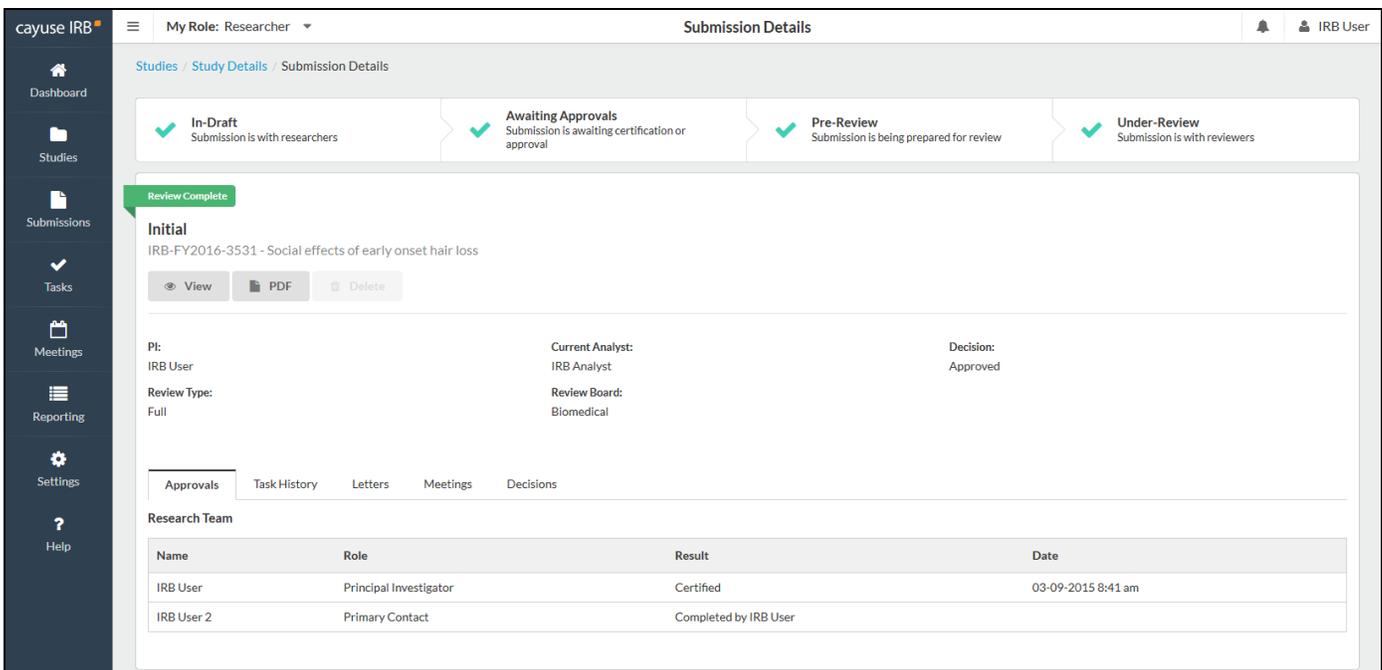
Each submission type has its own template that the IRB Analyst or Admin configures via the Manage Submission Templates screen.

Viewing Submission History

To view the submission history for a study, go to the Study Details page and click on the **Submissions** tab:



The Submissions tab shows the list of submissions associated with the study, including the submission type, review type and status, decision, and last modified date. Click on any submission in the list to go to its Submission Details screen:



Notice the Approvals, Task History, Letters, Meetings, and Decisions tabs showing for the initial submission. Click on the desired tab to locate the information you require.

Working with Legacy Submissions

When a study is first imported from a previous IRB system into Cayuse IRB, the study does not have any submissions associated with it. If an investigator wishes to continue working with the study, they (or an IRB Analyst) must first create a **Legacy** submission for the study. The Legacy submission is used in place of the Initial submission. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. and work with the study as you would any other study in Cayuse IRB.

Note: An IRB Analyst or Admin must set up and publish a template for Legacy submissions on the Submission Templates screen before you can create a Legacy submission.

When you first open an imported study, the only available submission type is legacy submission. Click **New Submission -> Legacy** to proceed.

The screenshot shows the Cayuse IRB interface. On the left is a dark blue sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and shows a breadcrumb trail 'Studies / Study Details'. A '+ New Submission' button is visible in the top right. Below it, a 'Legacy' tab is selected, showing details for a submission with ID 'IRB-FY2011-126' and title 'Use of Compression in Wound Healing'. There are 'PDF' and 'Delete' buttons. Below this, a grid of key information is displayed:

Approval Date: 11-15-2011	Expiration Date: N/A	Organization: N/A	Active Submissions: N/A
Sponsors: N/A	Closed Date: N/A		

Below the key information, there are two tabs: 'Key Contacts' and 'Attachments'. The 'Key Contacts' tab is active, showing a table with the following data:

Team Member	Role	Number	Email
IRB User	Principal Investigator		
IRB User 2	Primary Contact		

The legacy submission is added in a similar manner to the first initial submission, but using the Legacy template instead of the Initial template. Click **Edit** to see the data on the legacy submission form.

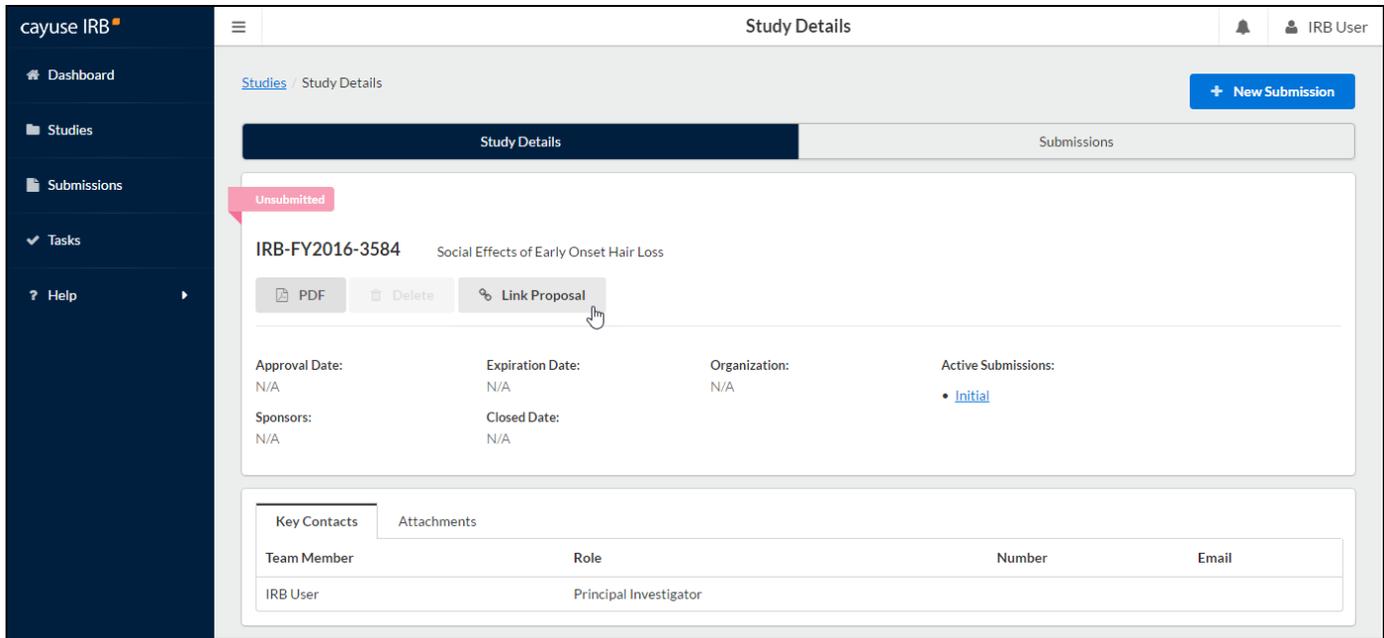
PI: IRB User	Current Analyst: N/A	Decision: N/A	Required Tasks: • Complete Submission
Review Type: N/A	Review Board: N/A	Meeting Date: N/A	

Note: Some of the data, such as the Principal Investigator, may be prepopulated into the submission form. You must save the form in order for these changes to be remembered.

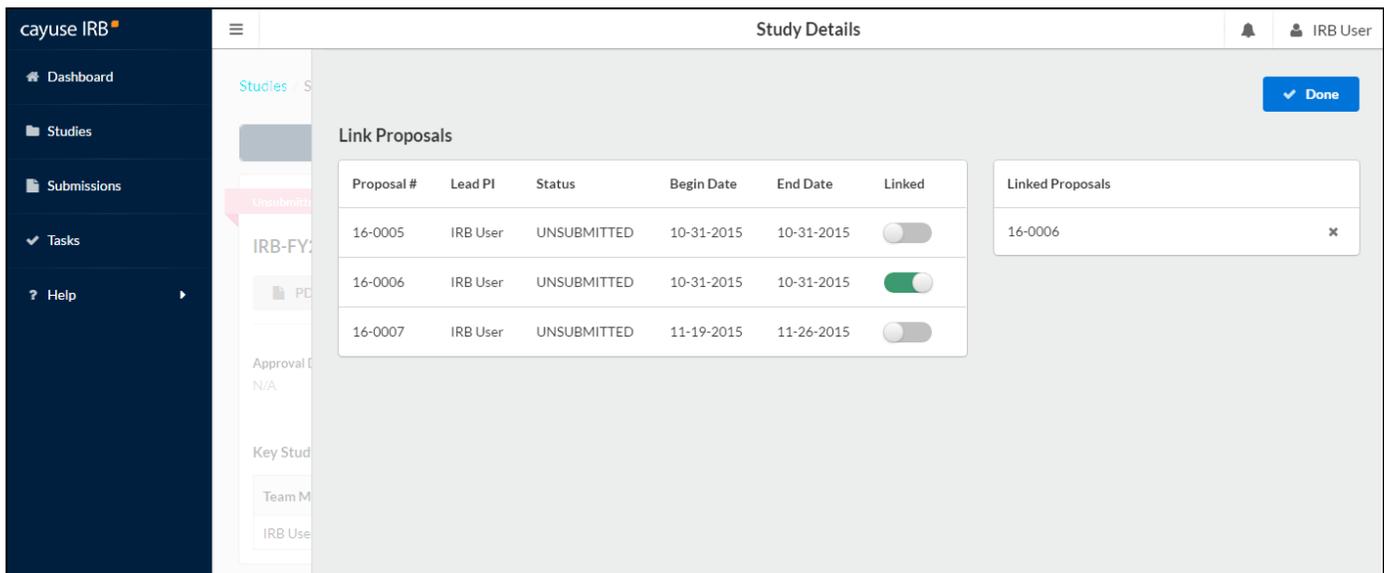
When you are finished editing the form, click **Complete** to finalize the legacy submission. You then have the option to create additional submissions for this study, such as renewal, modification, incident, or closure submissions.

Linking a Study to Cayuse SP

If your institution has purchased Cayuse SP, any Cayuse IRB user now has the option to link each study in Cayuse IRB with one or more proposals in Cayuse SP.



Click the **Link Proposal** button on the Study Details screen to launch the **Proposal Finder**.



Cayuse IRB automatically searches for SP proposals associated with the researchers assigned to the study in Cayuse IRB. If you are not seeing the proposal you want to link, make sure that you have created an initial submission and assigned a PI and the researcher(s) associated with the Cayuse SP proposal.

Select the study or studies you wish to link using the green **Linked** toggle, then click **Done**.

The linked proposal(s) appear above the Key Study Contacts on the Study Details screen:

The screenshot shows the 'Study Details' page in the Cayuse IRB system. The left sidebar contains navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and includes a 'New Submission' button. Below this, there is a section for 'IRB-FY2016-3584' with a status of 'SP Link test'. This section includes buttons for 'PDF', 'Delete', and 'Link Proposal'. Below the buttons, there are fields for 'Approval Date', 'Expiration Date', 'Organization', and 'Active Submissions'. The 'Active Submissions' field contains a link to 'Initial'. At the bottom, there is a 'Linked Proposals' tab with a table showing one proposal.

Proposal #	Lead PI	Status	Begin Date	End Date
16-0006	IRB User	UNSUBMITTED	10-31-2015	10-31-2015

You can now click on the proposal number to view the proposal in Cayuse SP.

To remove the link to the proposal, click the Link Proposal button to open the Proposal Finder again, and remove the link by clicking the **X** next to the linked proposal..