

cayuse IRB 

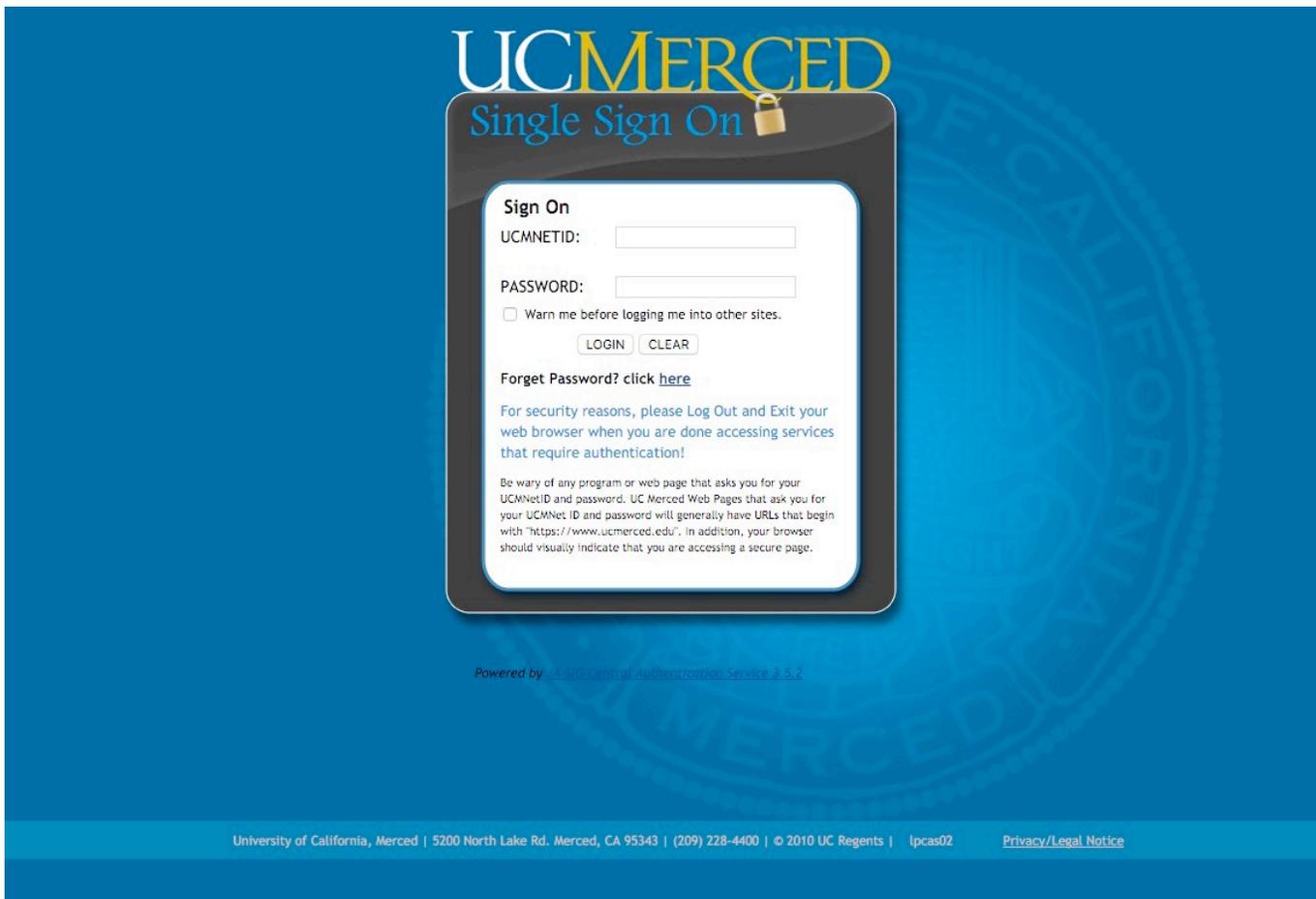
*Cayuse IRB Guide for Investigators*

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# Login Information

- I. Navigate to <https://ucmerced-cayuse424.com/rs/irb/> on a web browser - Google Chrome, Firefox, Safari, and Internet Explorer.
- II. Use your UCM Net ID and password.

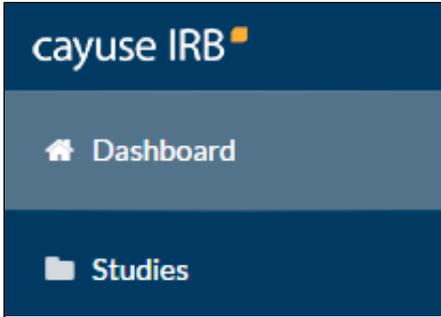


The image shows the UC Merced Single Sign On login page. The page has a blue background with the UC Merced seal faintly visible. At the top, the text "UCMERCED" is in large yellow letters, and "Single Sign On" is in blue with a padlock icon. Below this is a white login box with a dark border. Inside the box, there are two input fields: "UCMNETID:" and "PASSWORD:". Below the password field is a checkbox labeled "Warn me before logging me into other sites." and two buttons: "LOGIN" and "CLEAR". Below the login box, there is a link "Forget Password? click here" and a security warning: "For security reasons, please Log Out and Exit your web browser when you are done accessing services that require authentication!" and "Be wary of any program or web page that asks you for your UCMNetID and password. UC Merced Web Pages that ask you for your UCMNet ID and password will generally have URLs that begin with 'https://www.ucmerced.edu'. In addition, your browser should visually indicate that you are accessing a secure page." At the bottom of the page, there is a footer with the text: "University of California, Merced | 5200 North Lake Rd. Merced, CA 95343 | (209) 228-4400 | © 2010 UC Regents | lpcas02 [Privacy/Legal Notice](#)"

# Navigating Cayuse IRB

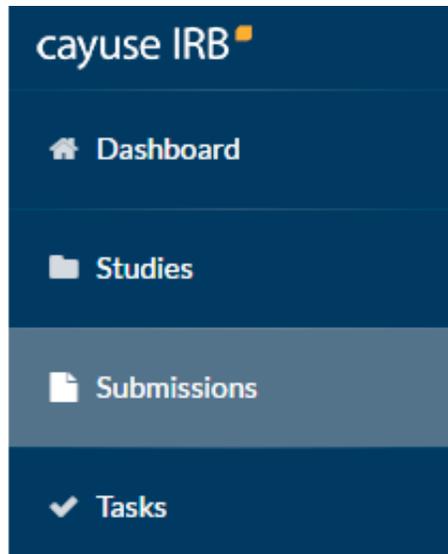
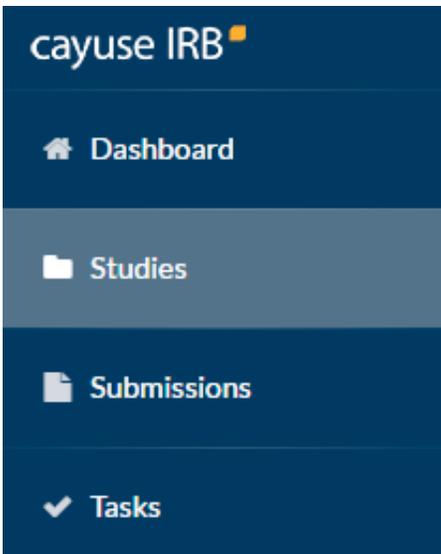
## Dashboard

When you first log in to Cayuse IRB, the [Dashboard](#) screen presents you with a quick overview of any studies you are involved with or that require your attention.



## Studies and Submissions

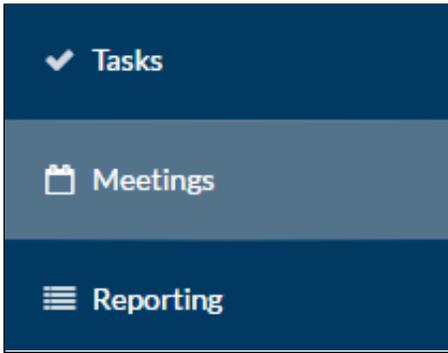
The [Studies and Submissions](#) screens list the studies and submissions that you have access to.



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

## Meetings

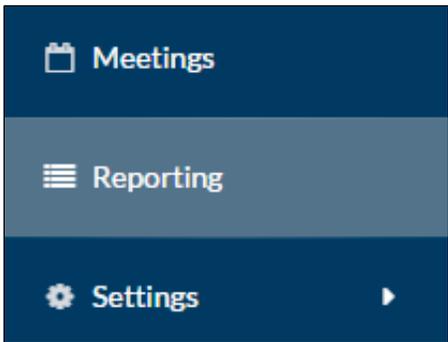
The [Meetings](#) section allows IRB Analysts, Admins, and Members to view the calendar of scheduled IRB meetings. *IRB Users do not see the Meetings section.*



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

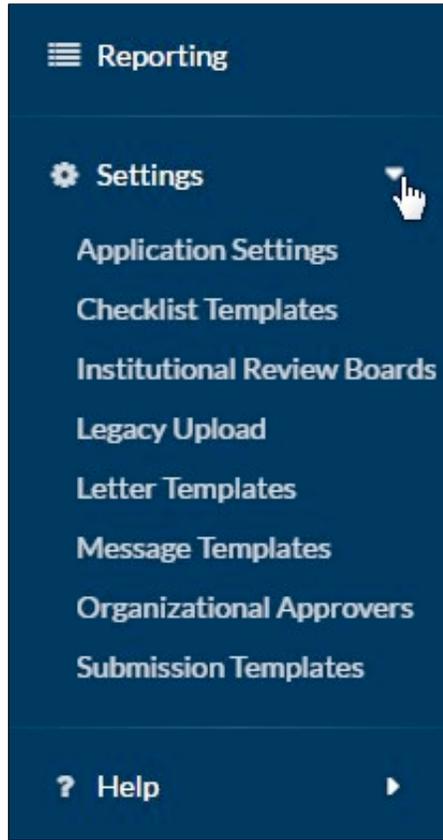
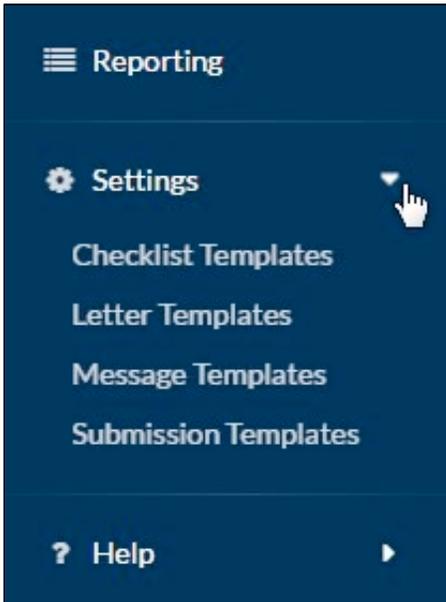
## **Reporting**

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



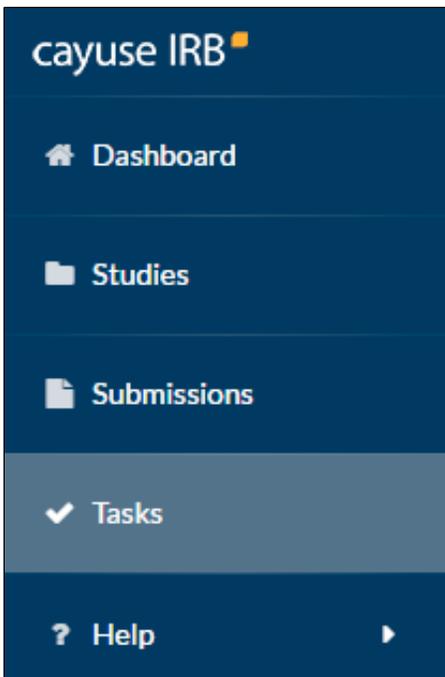
## **Settings**

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



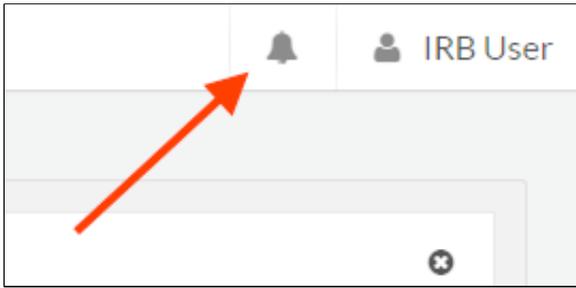
## Tasks

The [Tasks](#) screen lists the studies that are assigned to you, along with the task that you are responsible for. Completing a task advances a submission through the workflow.



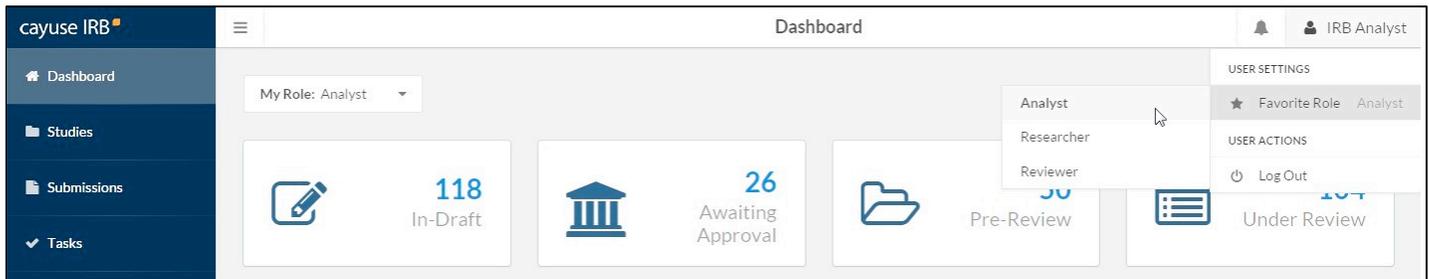
## Notifications

The [Notification](#) icon at the top of the screen lets you see the system messages that have been sent to you regarding the submissions you are involved with. Click on the icon to display the list of notifications.



## User Settings and Actions

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

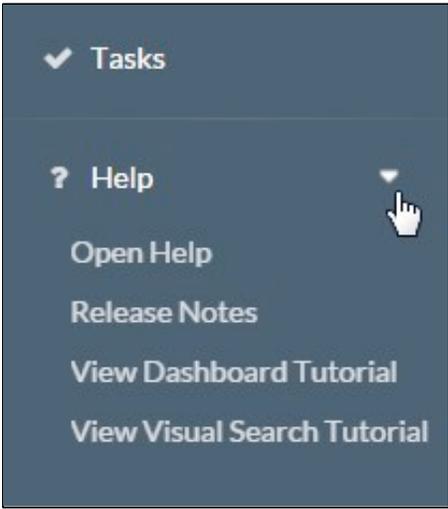


**User Settings - Favorite Role** - If you have more than one user role (such as *Analyst* and *Reviewer* for someone who is both an IRB Analyst and a member of a review board), certain screens (such as the dashboard) display different information depending on your role. These screens have a dropdown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

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

## Help

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



Clicking the small  icons throughout Cayu

# Dashboard

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

The screenshot shows the Cayuse IRB Dashboard interface. At the top left is the 'cayuse IRB' logo. The main header area includes a search bar, the title 'Dashboard', and a user profile for 'IRB User'. A navigation sidebar on the left contains links for Dashboard, Studies, Submissions, Tasks, Meetings, and Help. The dashboard content is organized into several sections:

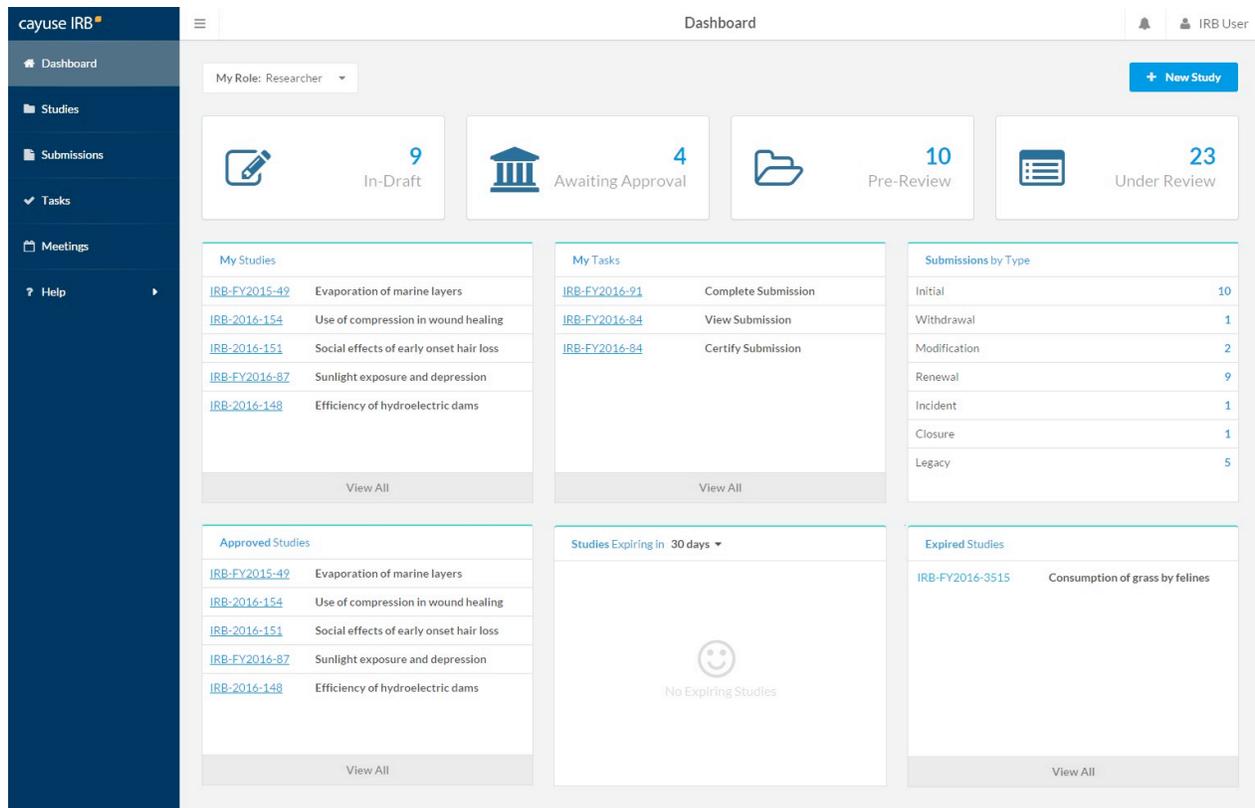
- Summary Cards:** Four cards at the top show key metrics: 'In-Draft' (9), 'Awaiting Approval' (4), 'Pre-Review' (10), and 'Under Review' (23). Each card includes an icon representing the category.
- My Studies:** A table listing active studies with columns for ID and title.
 

| Study ID                      | Title                                   |
|-------------------------------|---|
| <a href="#">IRB-FY2015-49</a> | Evaporation of marine layers            |
| <a href="#">IRB-2016-154</a>  | Use of compression in wound healing     |
| <a href="#">IRB-2016-151</a>  | Social effects of early onset hair loss |
| <a href="#">IRB-FY2016-87</a> | Sunlight exposure and depression        |
| <a href="#">IRB-2016-148</a>  | Efficiency of hydroelectric dams        |
- My Tasks:** A table listing tasks with columns for ID and description.
 

| Task ID                       | Description         |
|-------------------------------|---------------------|
| <a href="#">IRB-FY2016-91</a> | Complete Submission |
| <a href="#">IRB-FY2016-84</a> | View Submission     |
| <a href="#">IRB-FY2016-84</a> | Certify Submission  |
- Submissions by Type:** A table showing the count of submissions for different categories.
 

| Type         | Count |
|--------------|-------|
| Initial      | 10    |
| Withdrawal   | 1     |
| Modification | 2     |
| Renewal      | 9     |
| Incident     | 1     |
| Closure      | 1     |
| Legacy       | 5     |
- Approved Studies:** A table listing approved studies, identical in structure to the 'My Studies' table.
- Studies Expiring in 30 days:** A section showing a smiley face icon and the text 'No Expiring Studies'.
- Expired Studies:** A table listing expired studies.
 

| Study ID                        | Title                           |
|---------------------------------|---------------------------------|
| <a href="#">IRB-FY2016-3515</a> | Consumption of grass by felines |



- 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.

The screenshot displays the 'Studies' page in the cayuse IRB system. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area has a header with 'cayuse IRB' logo, a hamburger menu, the title 'Studies', a notification bell, and the user 'IRB User'. Below the header are tabs for 'Active' and 'Archive', and a '+ New Study' button. A search bar is present above a table of studies. The table has columns: IRB#, Study Title, Status, PI, Exp Date, and Create Date. There are 5 rows of data. At the bottom, it shows '1-5 of 5' and a pagination control with '1' in the center.

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

Active Archive

+ New Study

Q Archived Within:

|                                 |  | Status | PI       | Archive Date | Create Date |
|---------------------------------|--|--------|----------|--------------|-------------|
| <a href="#">1 year</a>          |  |        |          |              |             |
| <a href="#">2 years</a>         |  |        |          |              |             |
| <a href="#">3 years</a>         |  |        |          |              |             |
| <a href="#">IRB-FY2014-1113</a> | Effects of sunlight on seasonal affective disorder | Closed | IRB User | 01-05-2016   | 02-26-2014  |
| <a href="#">IRB-FY2014-2884</a> | Depression in first-year college students          | Closed | IRB User | 01-26-2016   | 01-26-2014  |

1-3 of 3

## 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 |
|---------------------------------|---|------------------|-------------|------------|------------------------|----------------------------------|-------------|
| <a href="#">IRB-FY2016-3559</a> | Social effects of early onset hair loss<br>Initial      | Review Complete  | Full        | IRB User   | Principal Investigator | Approved<br>11-24-2016           | 03-09-2016  |
| <a href="#">IRB-FY2016-3559</a> | Social effects of early onset hair loss<br>Modification | Under Review     | Expedited   | IRB User   | Principal Investigator |                                  | 03-09-2016  |
| <a href="#">IRB-FY2016-3557</a> | Use of compression in wound healing<br>Initial          | Review Complete  | Full        | IRB User   | Principal Investigator | Exempt<br>11-23-2016             | 03-09-2016  |
| <a href="#">IRB-FY2016-3524</a> | Internet use of adolescent Americans<br>Initial         | Under Pre-Review | Full        | IRB User 2 | Primary Contact        | Return to PI                     | 03-02-2016  |
| <a href="#">IRB-FY2016-3557</a> | Use of compression in wound healing<br>Modification     | Under Review     | Full        | IRB User   | Principal Investigator | Not Reviewed                     | 03-02-2016  |
| <a href="#">IRB-FY2016-3516</a> | Social habits of Primolius maracona<br>Modification     | Review Complete  | Exempt      | IRB User   | Principal Investigator | No Human<br>Subjects<br>Research | 02-25-2016  |

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

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

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

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

| IRB#                            | Study Title                             | Status   | PI       | Exp Date   | Create Date |
|---------------------------------|---|----------|----------|------------|-------------|
| <a href="#">IRB-FY2016-3559</a> | Social effects of early onset hair loss | Approved | IRB User | 04-22-2016 | 04-23-2015  |

At the bottom of the table, there is a '25 per page' dropdown, '1:1 of 1' pagination, and navigation arrows.

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 Cayuse IRB 'Tasks' screen. On the left is a dark sidebar with navigation links: Dashboard, Studies, Submissions, Tasks (selected), Meetings, Reporting, Settings, and Help. The main area has a header with 'My Role: Analyst' and a search bar. Below is a table of tasks:

| 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  |

At the bottom of the table, there is a '25 per page' dropdown and a pagination indicator '1-4 of 4' with navigation arrows.

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 for an IRB User. The dashboard includes a sidebar with navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area features three summary cards: 'In-Draft' (3), 'Awaiting Approval' (1), and 'Review' (1). Below these are sections for 'My Studies' and 'My Tasks'. A 'Notifications' dropdown menu is open, showing a list of messages with details such as study ID, user role, and the type of notification (e.g., 'Initial Submission Received', 'Incident Submission Received', 'Closure Submission Received', 'Study has expired').

| Study ID        | User Role     | Notification Type            | Date               |
|-----------------|---------------|------------------------------|--------------------|
| IRB-FY2016-3546 | PI: IRB User  | Initial Submission Received  | 08-11-2015 2:08 PM |
| IRB-FY2015-40   | PI: IRB User2 | Incident Submission Received | 08-09-2015 9:26 AM |
| IRB-FY2015-26   | PI: IRB User2 | Closure Submission Received  | 08-09-2015 9:22 AM |
| IRB-FY2015-7262 | PI: IRB User2 | Study has expired            | 04-23-2015 7:13 AM |
| IRB-FY2015-7262 | PI: IRB User2 | Withdrawal                   |                    |
|                 |               | Modification                 | 6                  |
|                 |               | Renewal                      | 2                  |
|                 |               | Incident                     | 1                  |
|                 |               | Closure                      | 0                  |
|                 |               | Legacy                       | 3                  |

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.).

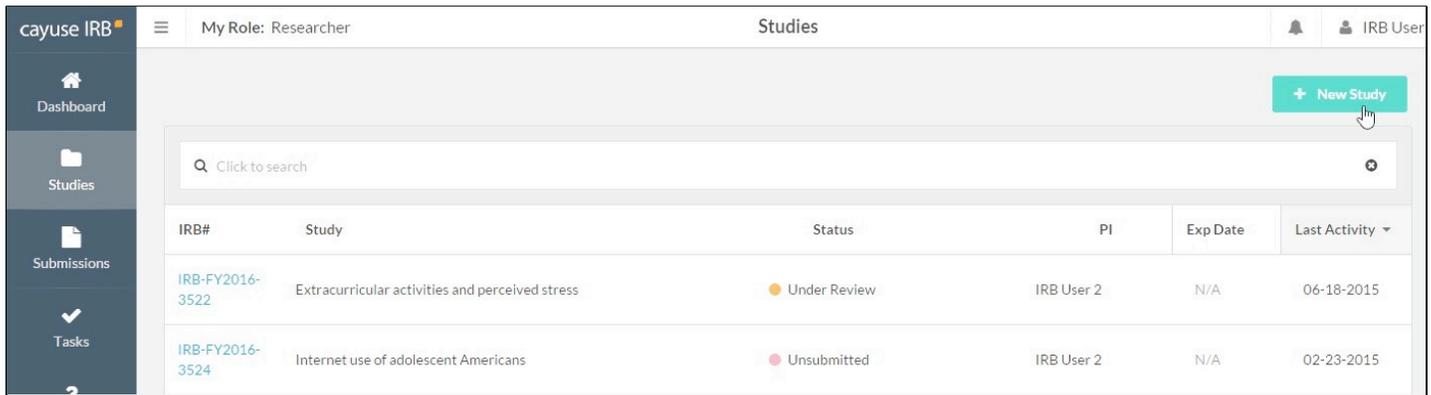
Clicking on a notification takes you to the submission that notification pertains to. Viewed notifications are no longer highlighted in the Notifications list. You can delete notifications from the list by clicking the **X** icon next to that notification, or use the ... menu to mark all notifications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

### ***Customizing Notifications***

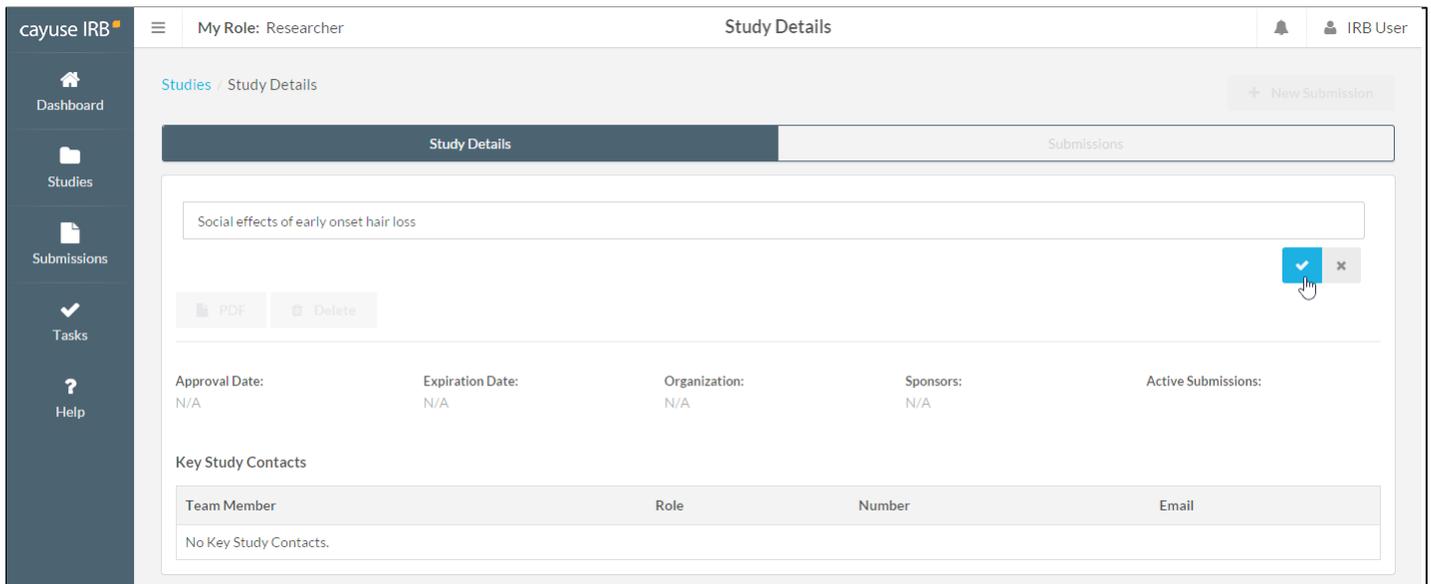
IRB Analysts and Admins have the ability to customize all of the notifications and emails that are sent out by Cayuse IRB via the [Message Templates](#) screen in the Settings section. Customization options include editing the text of the message, controlling which users receive it, or disabling certain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

## Creating the Initial Submission

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

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.

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.

cayuse IRB ☰ My Role: Researcher 🔔 IRB User

STUDY IRB NUMBER: IRB-FY2016-3575 **Social effects of early onset hair loss - Initial** 📄 CREATE PDF 🔍 COMPARE 💾 SAVE ⏪ ⏩

Dashboard

Sections

- Section 1 Assignments
- Section 2 Other Items
- Section 3 Optional Forms

Studies

Submissions

Tasks

Help

### 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 | ✕ |

\* P2 Primary Contact

⏪ ⏩

# 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 'cayuse IRB' interface. The user is logged in as 'My Role: Researcher' and is viewing the 'Social effects of early onset hair loss - Initial' study. The 'General Information' section is active, indicated by a green checkmark in the sidebar. The form contains the following sections:

- 1. Principal Investigator:** A table with columns for Name, Organization, Address, Phone, and Email. The entry for 'IRB User' is shown with details: School of Medicine, 440 Exchange, Irvine, CA, 714 265 7841, and irbuser@evisions.com.
- 2. Primary Contact:** A search field with the text 'Please select the Primary Contact for this Protocol.' and a 'FIND PEOPLE' button.
- 3. Anticipated Start Date:** A date selection field.

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.

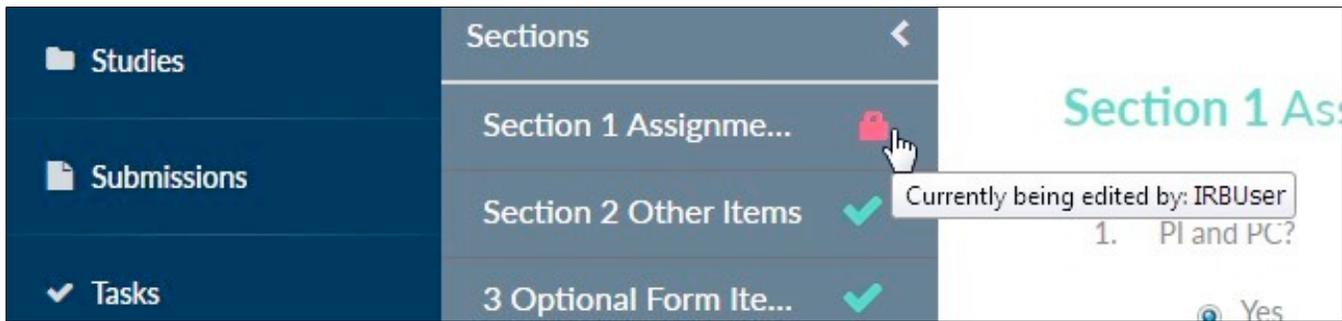
The screenshot shows the 'cayuse IRB' interface. The user is logged in as 'My Role: Researcher' and is viewing the 'Social effects of early onset hair loss - Initial' study. The 'Location of Research' section is active and marked as complete, indicated by a green checkmark in the sidebar. The form contains the following sections:

- 1. Will your research be conducted on campus?** Radio buttons for Yes and No.
- a. Select the type of facility where the research will be conducted.** Radio buttons for Correctional Facility, Home Health Agency, Veterans Hospital, Health Clinic, and 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:

02/27/2014 

### 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?

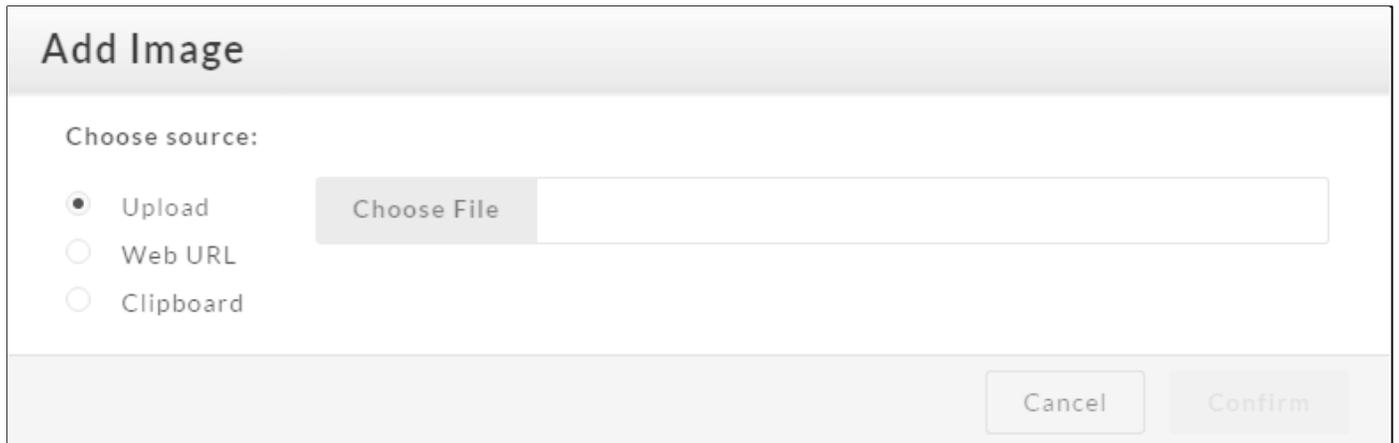
**B** **I** U ~~S~~

- ☰

- ☰

[G](#) 

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.



The image shows a dialog box titled "Add Image". It has a header bar with the title. Below the header, there is a section labeled "Choose source:". Under this section, there are three radio button options: "Upload" (which is selected), "Web URL", and "Clipboard". To the right of the "Upload" option is a "Choose File" button and a text input field. At the bottom right of the dialog box, there are two buttons: "Cancel" and "Confirm".

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?

FIND PEOPLE

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

**PRIMARY CONTACT**

Mark x Q

| 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.*

⊘ CANCEL
SAVE

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 ✕ 🔍

| 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 | ✕ |
| Mark Klein    | ✕ |

⊗ 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.

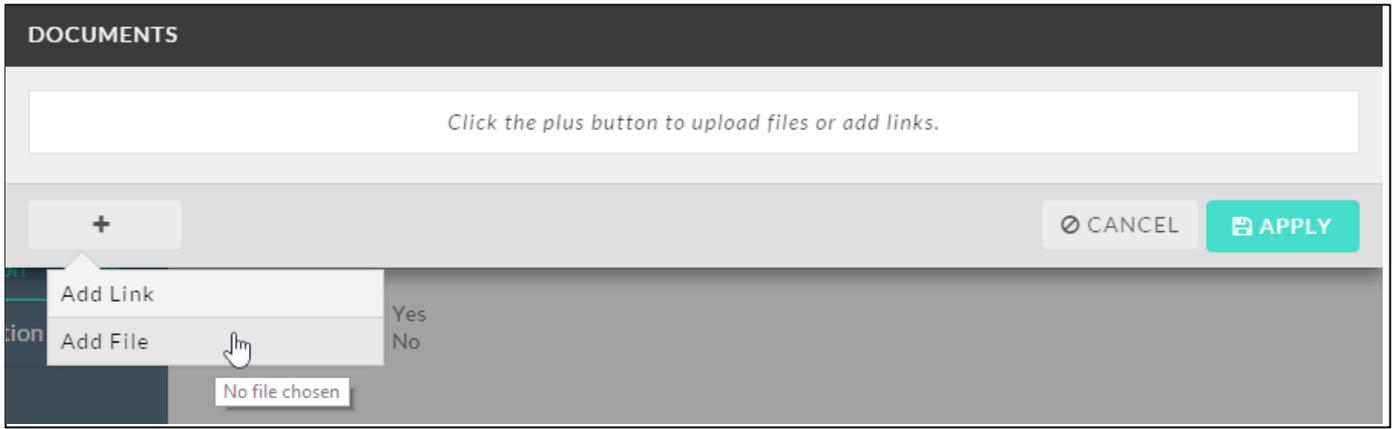
### Attachments

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

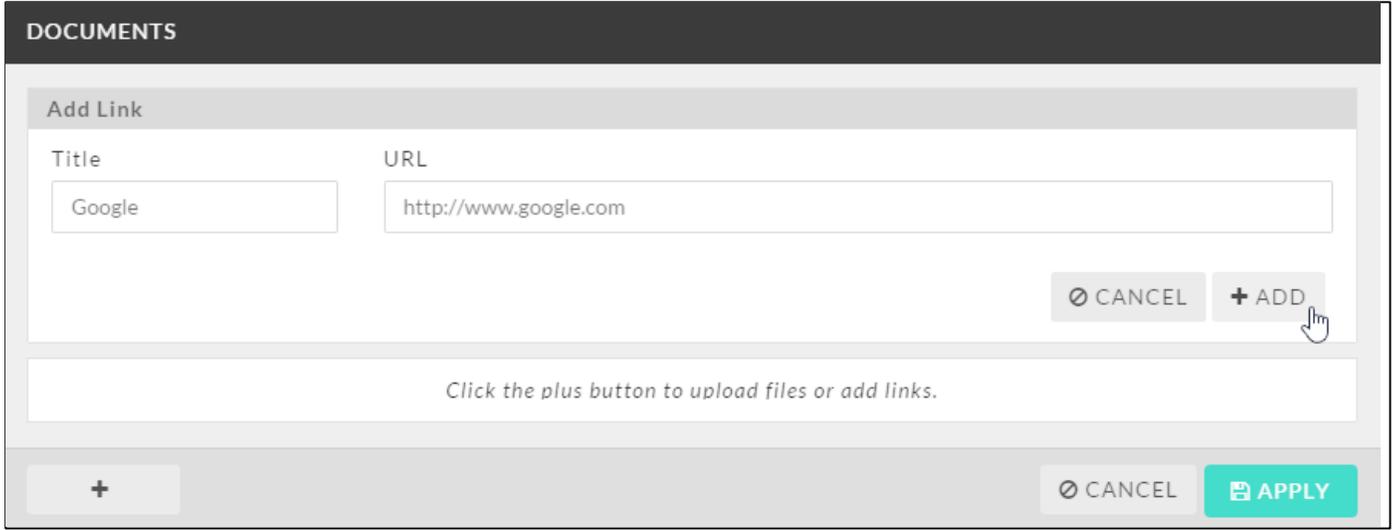
4.0 Attach the Letters of Support from the respective Department/Division.

ATTACH
🖱️

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



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:



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

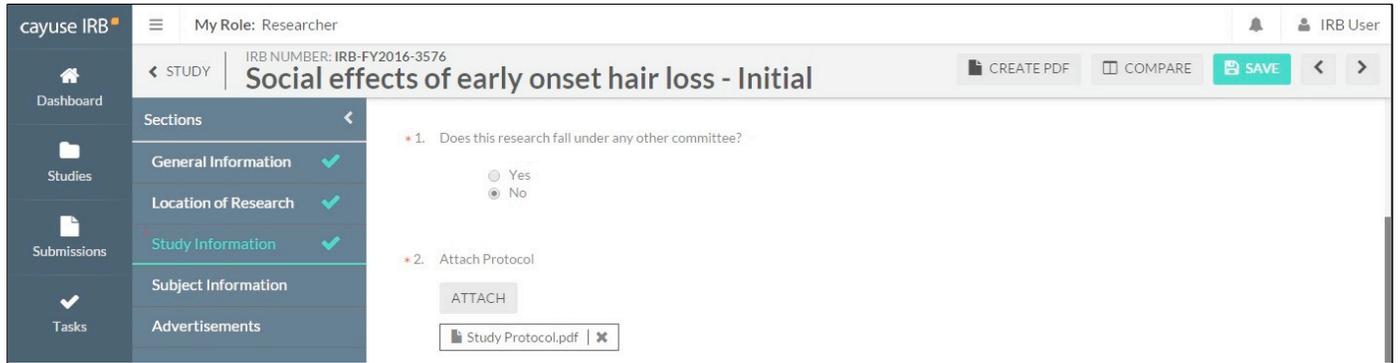
**Supported File Types**

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

|                      |   |
|----------------------|---|
| 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.



The screenshot displays the cayuse IRB interface for a researcher. The top navigation bar includes the logo, a hamburger menu, the role 'My Role: Researcher', a notification bell, and the user 'IRB User'. The main header shows the study title 'Social effects of early onset hair loss - Initial' and the IRB number 'IRB-FY2016-3576'. Action buttons for 'CREATE PDF', 'COMPARE', and 'SAVE' are visible. A left sidebar contains navigation options: Dashboard, Studies, Submissions, and Tasks. A 'Sections' menu on the left lists 'General Information', 'Location of Research', 'Study Information', 'Subject Information', and 'Advertisements', with green checkmarks indicating completion. The main content area contains two questions: '1. Does this research fall under any other committee?' with radio buttons for 'Yes' and 'No' (selected), and '2. Attach Protocol' with an 'ATTACH' button and a file attachment 'Study Protocol.pdf' with a close (X) icon.

### ***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

### 1 Expand 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 underneath the questions that have comments on them. Click the [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

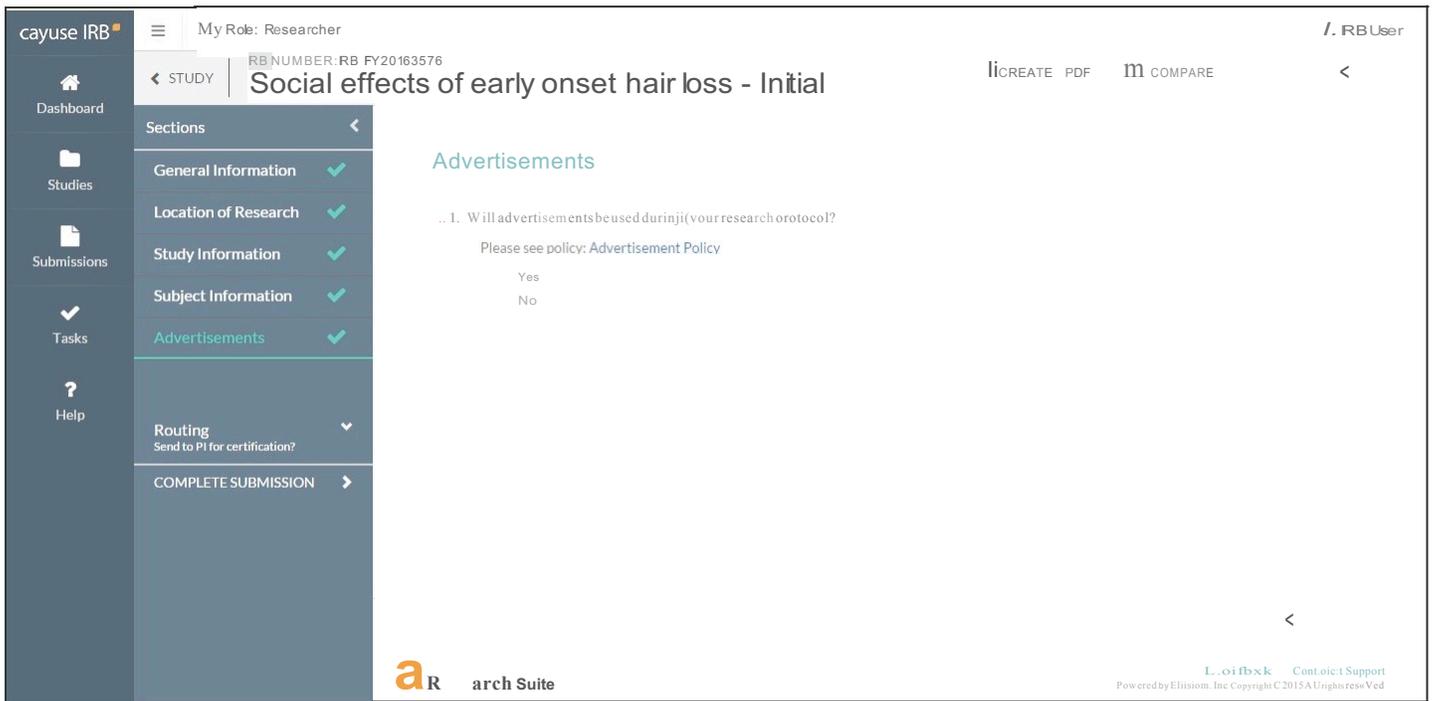
Not Addressed ▾

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.

You will see a comment icon in the sidebar next to each section that contains comments, and a similar ic

# 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.



# Letters

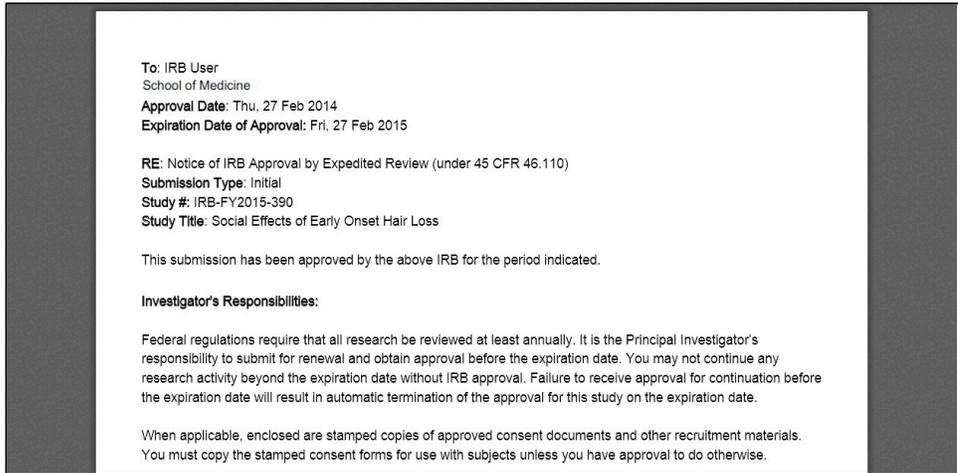
At certain points in the workflow, the compliance office may send communication to the Principal Investigator in the form of a letter notifying them of status changes, approvals, information required, etc. Letters are sent via email, and are also available to download from the submission in Cayuse IRB.

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 displays the 'Submission Details' page in the Cayuse IRB system. The left sidebar contains 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 'Review Complete' notification is shown. The submission title is 'Initial' for 'IRB-FY2016-55 - Social effects of early onset hair loss'. Action buttons for View, PDF, Delete, and Checklist are available. Metadata includes PI: IRB User, Current Analyst: IRB Analyst, Decision: Approved, Review Type: Full, and Review Board: Biomedical. At the bottom, the 'Letters' tab is active, displaying a table of sent letters.

| Subject  | Recipients           | Sent Date  |
|--|----------------------|------------|
| <a href="#">IRB-FY2016-55 - Initial: Approval - Full Board</a> | IRBUser@evisions.com | 11-09-2015 |
| <a href="#">IRB-FY2016-55 - Initial: Revision Needed</a>       | 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.



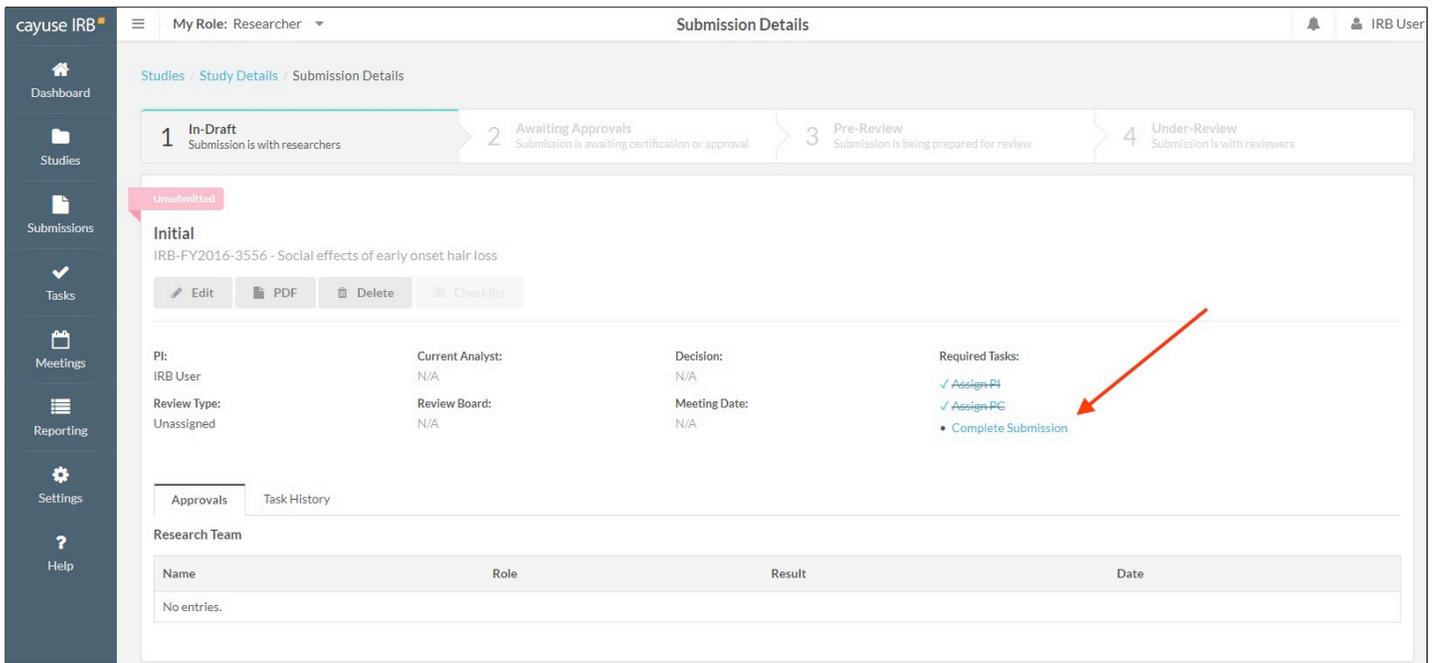
To save the letter to a file, right-click within the opened PDF and select **Save As** (Chrome) or **Save Page As** (Firefox), or go to **Tools -> File -> Save As** (Internet Explorer).

# 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 shows the cayuse IRB interface for a researcher. The top navigation bar includes the logo, a hamburger menu, and the role 'My Role: Researcher'. Below this, the study title 'Social effects of early onset hair loss - Initial' is displayed, along with the IRB number 'IRB-FY2016-3576'. A sidebar on the left contains navigation icons for Dashboard, Studies, Submissions, Tasks, and Help. The main content area shows a list of sections: General Information, Location of Research, Study Information, Subject Information, Advertisements, and Routing. The 'Routing' section is highlighted with a blue oval, and a 'COMPLETE SUBMISSION' link is visible below it. The 'Advertisements' section contains a question: 'Will advertisements be used during your research protocol?' with radio buttons for 'Yes' and 'No'.

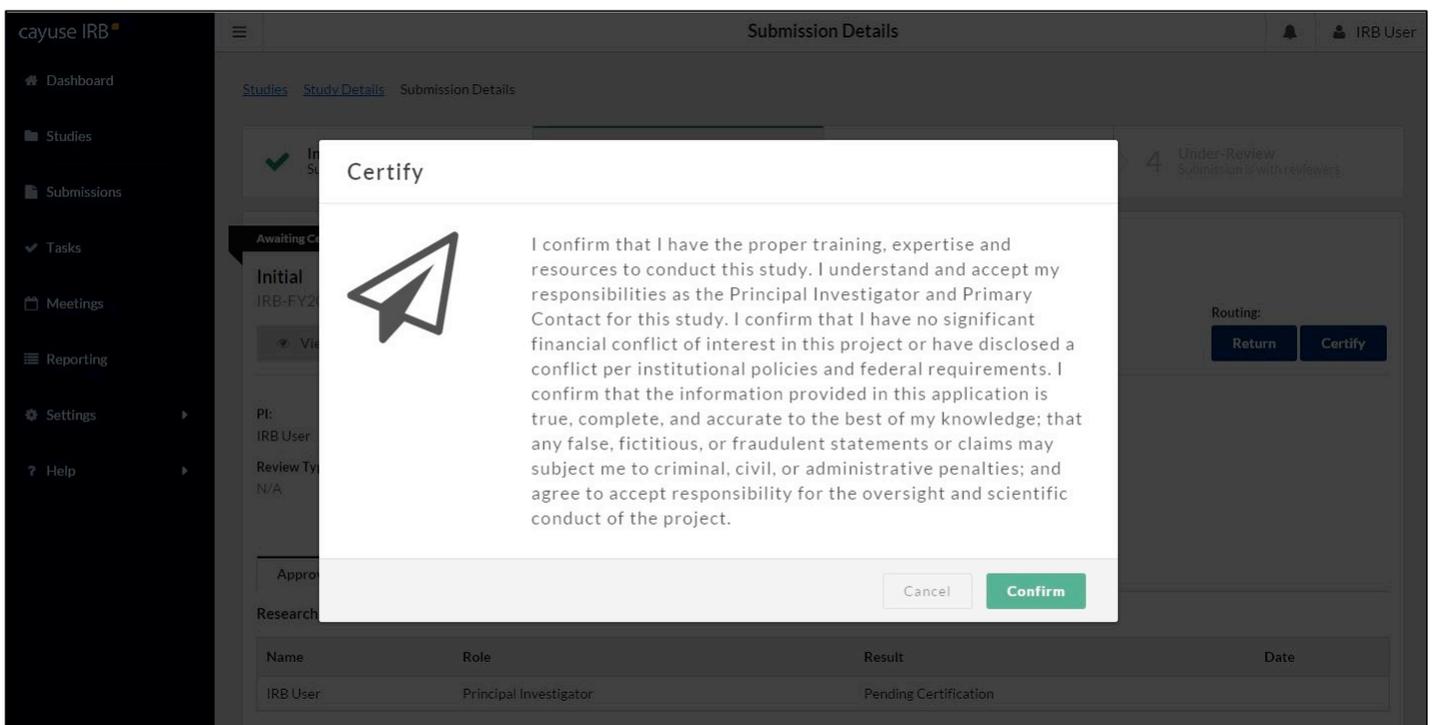
If you are on the Submission Details screen, you will also see the Complete Submission link indicating the next step in the routing process:



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**

# 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 system interface. The user is logged in as 'IRB User' and is viewing a study 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 displays 'Section 1 Assignments' with two tables:

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

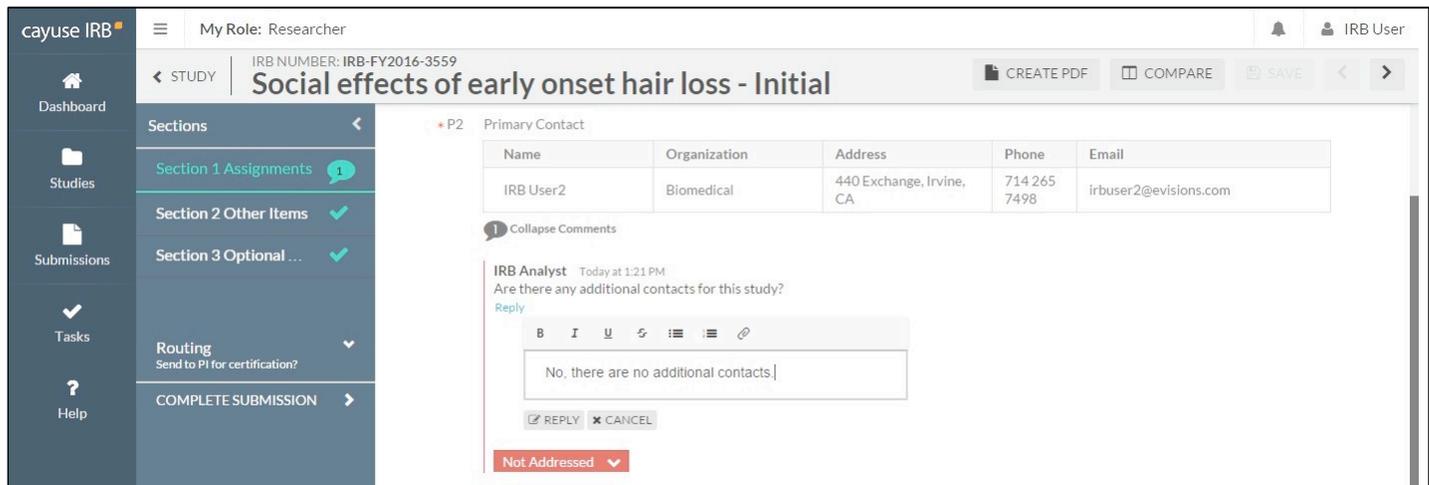
  

| Name      | Organization | Address                  | Phone        | Email                 |
|-----------|--------------|--------------------------|--------------|-----------------------|
| IRB User2 | Biomedical   | 440 Exchange, Irvine, CA | 714 265 7498 | irbuser2@evisions.com |

Below the tables, there is a comment bubble icon and the text 'Expand Comments'.

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. The top navigation bar includes the logo, a menu icon, the role 'My Role: Researcher', a notification bell, and the user 'IRB User'. The main header displays the study title 'Social effects of early onset hair loss - Initial' and the IRB number 'IRB NUMBER: IRB-FY2016-3559'. Below the header, there are buttons for 'CREATE PDF', 'COMPARE', and 'SAVE'. The left sidebar contains navigation options: Dashboard, Studies, Submissions, Tasks, and Help. The main content area shows a 'Primary Contact' table with one entry: IRB User2, Biomedical, 440 Exchange, Irvine, CA, 714 265 7498, irbuser2@evisions.com. Below the table is a comment from 'IRB Analyst' asking 'Are there any additional contacts for this study?'. A reply box contains the text 'No, there are no additional contacts.' and a 'REPLY' button is highlighted.

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

Enter your reply and then click  to save it.

Once you have resolved an issue, change the status dropdown from  to . 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.

cayuse IRB My Role: Researcher IRB User

STUDY **Social effects of early onset hair loss - Initial** CREATE PDF COMPARE SAVE

IRB NUMBER: IRB-FY2016-3559

Sections

- Section 1 Assignme... ✓
- Section 2 Other Items ✓
- Section 3 Optional ... ✓
- Routing Send to PI for certification? ▾
- COMPLETE SUBMISSION >

\* P2 Primary Contact

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

Collapse 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.

# Viewing Submission History<sup>37</sup>

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

The screenshot shows the 'Study Details' page in the cayuse IRB system. The 'Submissions' tab is selected, and a red arrow points to it from the left. The page displays a table of submission records.

| Submission Type | Review Type | Status          | Decision | Last Modified |
|-----------------|-------------|-----------------|----------|---------------|
| Initial         | Full        | Review Complete | Approved | 03-09-2015    |
| Modification    | Expedited   | Review Complete | Approved | 03-09-2015    |
| Modification    | Full        | Under Review    | N/A      | 03-09-2015    |

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:

The screenshot shows the 'Submission Details' page for an initial submission. The submission is titled 'Initial' and has the ID 'IRB-FY2016-3531 - Social effects of early onset hair loss'. The submission is in the 'Review Complete' status.

**Review Complete**

**Initial**  
IRB-FY2016-3531 - Social effects of early onset hair loss

View PDF Delete Checklist

**PI:** IRB User  
**Current Analyst:** IRB Analyst  
**Decision:** Approved

**Review Type:** Full  
**Review Board:** Biomedical

Approvals Task History Letters Meetings Decisions

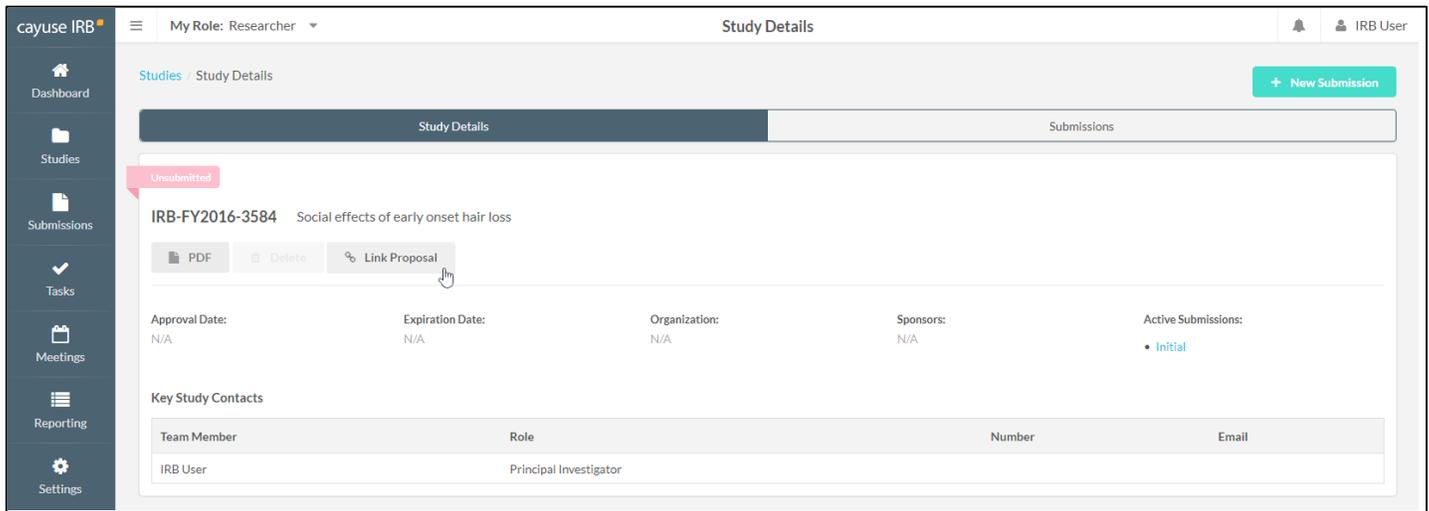
**Research Team**

| Name       | Role                   | Result                | Date               |
|------------|------------------------|-----------------------|--------------------|
| IRB User   | Principal Investigator | Certified             | 03-09-2015 8:41 am |
| IRB User 2 | Primary Contact        | Completed by IRB User |                    |

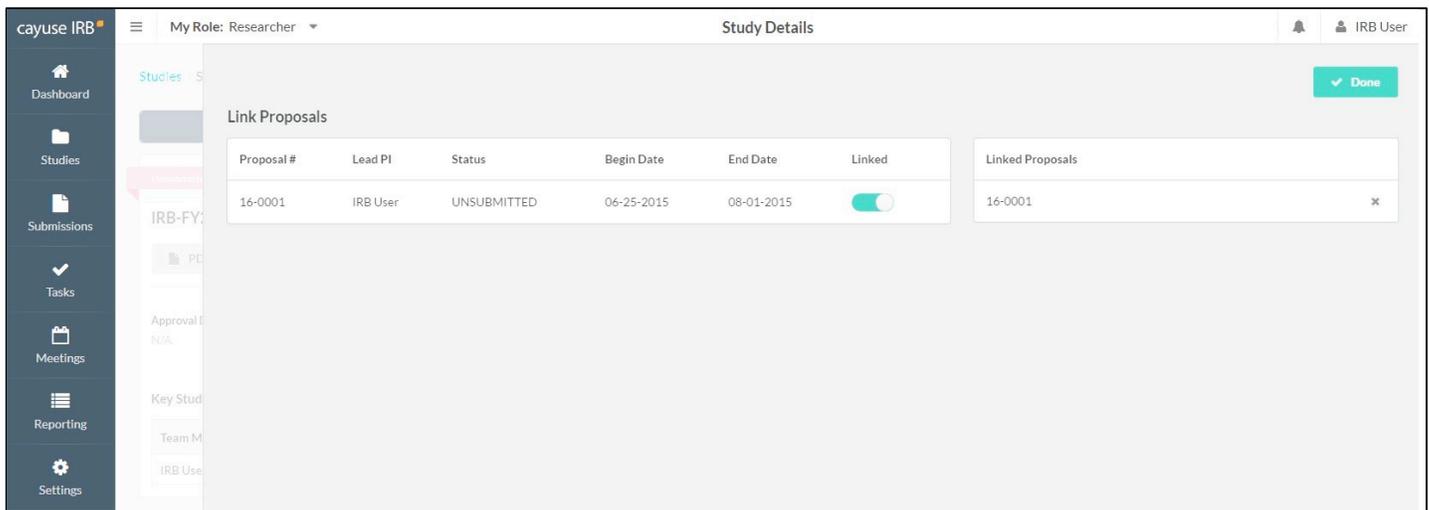
Notice the Approvals, Task History, Letters, Meetings, and Decisions tabs showing for the initial submission. Click on the desired tab to locate the information you require.

# 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

The screenshot displays the 'Study Details' page in the Cayuse IRB system. The page is for a study titled 'IRB-FY2016-3584 Social effects of early onset hair loss', which is currently 'Unsubmitted'. The interface includes a sidebar with navigation options like Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, Settings, and Help. The main content area shows the study title, a 'New Submission' button, and a 'Link Proposal' button. Below this, there are fields for Approval Date, Expiration Date, Organization, Sponsors, and Active Submissions. A table lists 'Linked Proposals' with columns for Proposal #, Lead PI, Status, Begin Date, and End Date. A 'Key Study Contacts' table is also present, showing the IRB User as the Principal Investigator.

| Proposal # | Lead PI  | Status      | Begin Date | End Date   |
|------------|----------|-------------|------------|------------|
| 16-0001    | IRB User | UNSUBMITTED | 06-25-2015 | 08-01-2015 |

| Team Member | Role                   | Number | Email |
|-------------|------------------------|--------|-------|
| IRB User    | Principal Investigator |        |       |

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.

Study Contacts on the Study Details screen