



Electronic Proposal Development and Submission

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

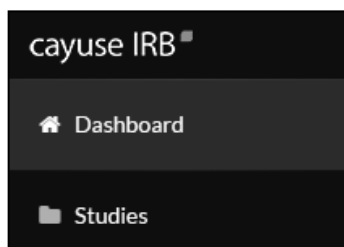
The [Cayuse Support Center](#) contains links to additional support resources:

- [Help Center](#) - Technical Support website where you can open a support ticket, or search the knowledgebase.

Navigating Cayuse IRB

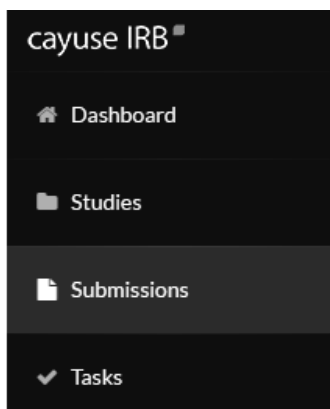
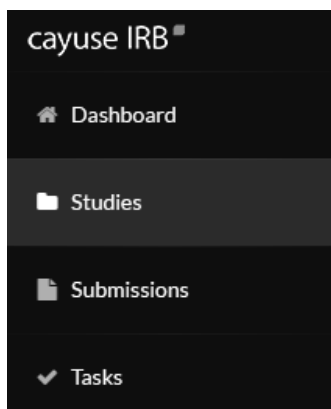
Dashboard

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



Studies and Submissions

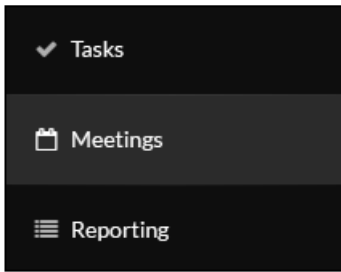
The **Studies** and **Submissions** screens list the studies and submissions that you have access to.



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

Meetings

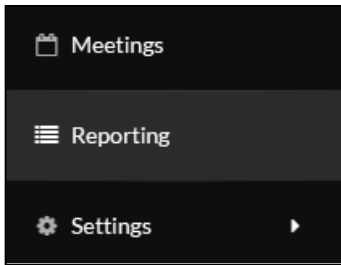
The **Meetings** section allows IRB Analysts, Admins, and Members to view the calendar of scheduled IRB meetings. *IRB Users do not see the Meetings section.*



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

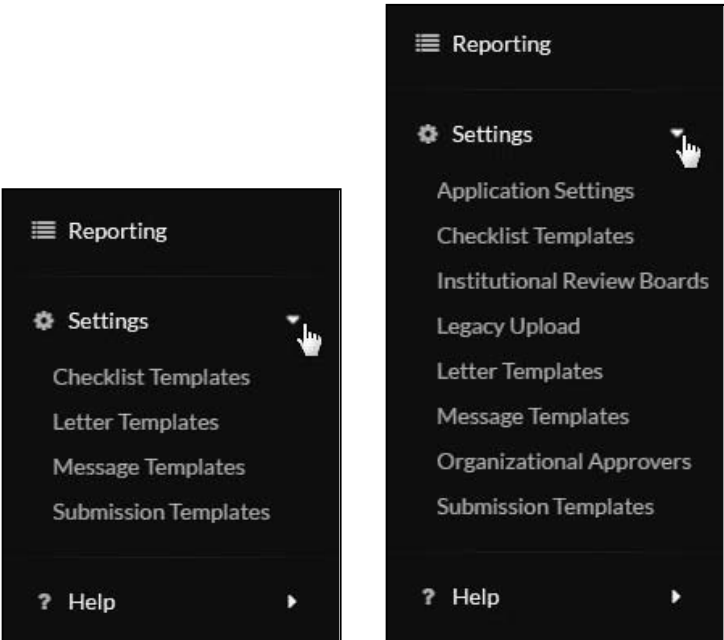
Reporting

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



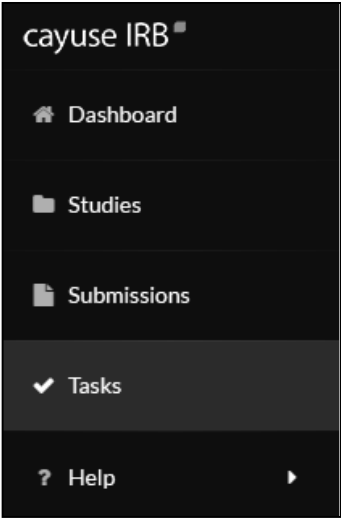
Settings

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



Tasks

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



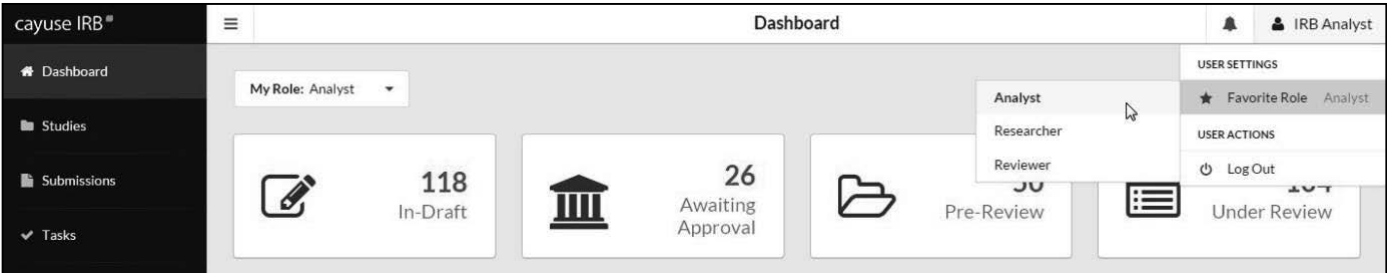
Notifications

The **Notifications** icon at the top of the screen lets you see the system messages that have been sent to you regarding the submissions you are involved with. Click on the icon to display the list of notifications.



User Settings and Actions

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

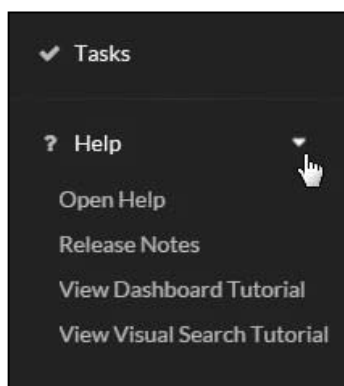


User Settings - Favorite Role: If you have more than one user role (such as *Analyst* and *Reviewer* for someone who is both an IRB Analyst and a member of a review board), certain screens (such as the dashboard) display different information depending on your role. These screens have a dropdown in the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

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

Help

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



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

Dashboard

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

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

The screenshot shows the Cayuse IRB Dashboard for a user with the role of 'Researcher'. The interface includes a sidebar with navigation links for Dashboard, Studies, Submissions, Tasks, Meetings, and Help. The main content area features a top section with four summary cards: In-Draft (9), Awaiting Approval (4), Pre-Review (10), and Under Review (23). Below these are three tables: 'My Studies' listing five studies, 'My Tasks' listing three tasks, and 'Submissions by Type' showing counts for various submission types. At the bottom, there are three more sections: 'Approved Studies' (listing the same five studies), 'Studies Expiring in 30 days' (showing no expiring studies), and 'Expired Studies' (listing one expired study).

My Studies
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

My Tasks
IRB-FY2016-91 Complete Submission
IRB-FY2016-84 View Submission
IRB-FY2016-84 Certify Submission

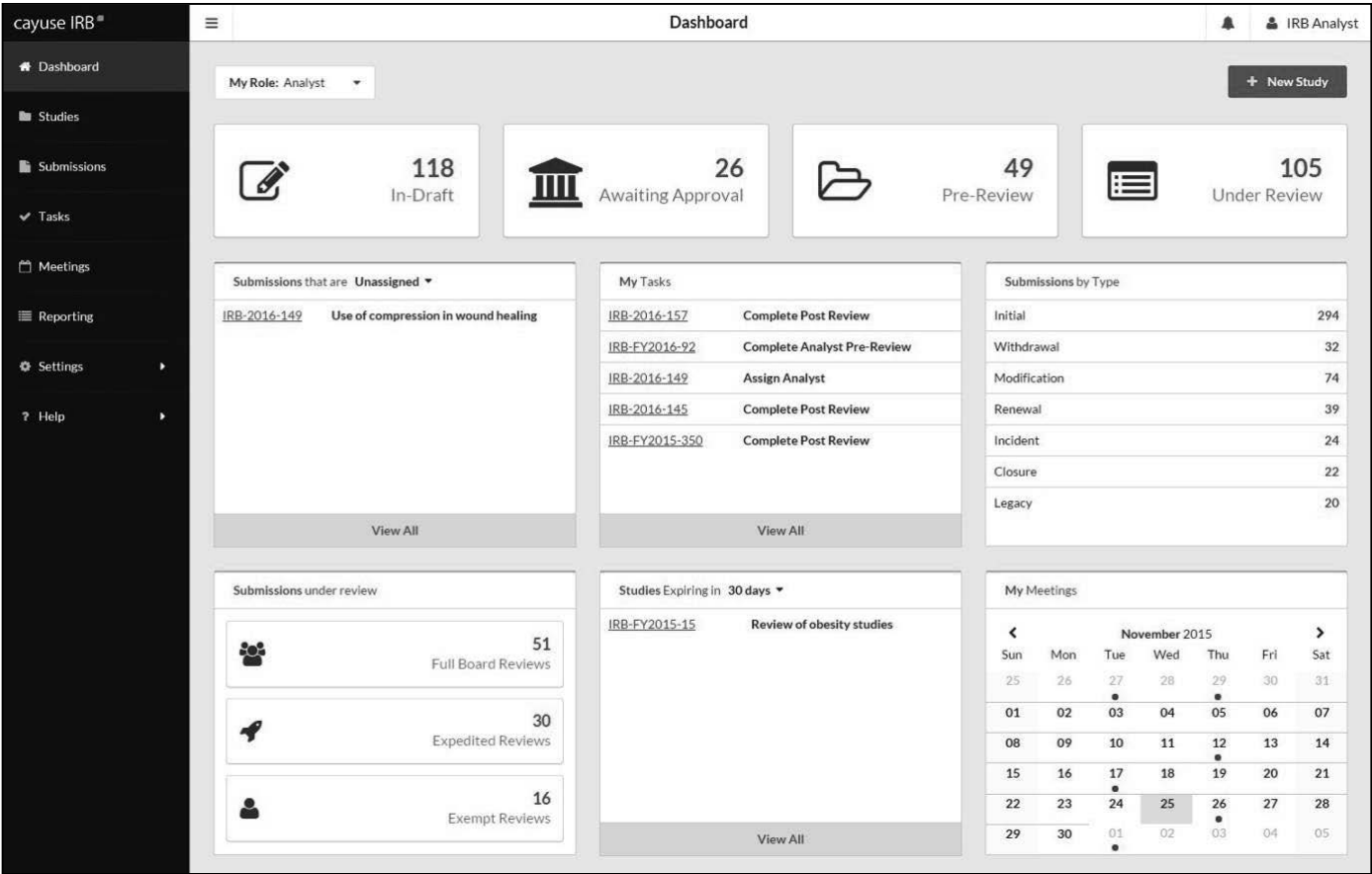
Submissions by Type	
Initial	10
Withdrawal	1
Modification	2
Renewal	9
Incident	1
Closure	1
Legacy	5

Approved Studies
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

Studies Expiring in 30 days
No Expiring Studies

Expired Studies
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 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.

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Dashboard

Studies

Submissions

Tasks

Help

Studies

ActiveArchive

Q Archived Within :

1 year2 years3 years

		Status	PI	Archive Date	Create Date
IRB-FY2014-1113	Effects of sunlight on seasonal affective disorder	Closed	IRB User	01-05-2016	02-26-2014
IRB-FY2014-2884	Depression in first-year college students	Closed	IRB User	01-26-2016	01-26-2014

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1

Submissions

Each study can have one or more submissions associated with it. When you first create a study, you must begin by creating an *Initial* submission (or a *Legacy* submission if the study was imported from a previous system). The **Submissions** screen lists all of the submissions relating to the studies that you have access to.

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

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Dashboard

Studies

Submissions

Tasks

Help

Submissions

Click to search

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

25 per page

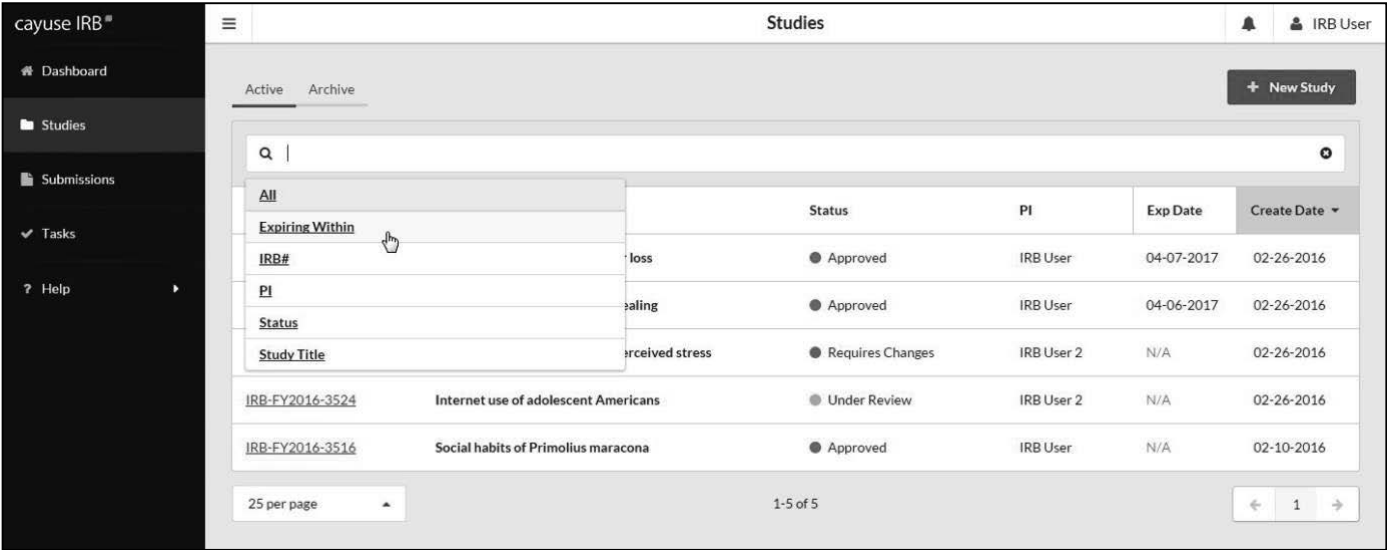
1-6 of 6

1

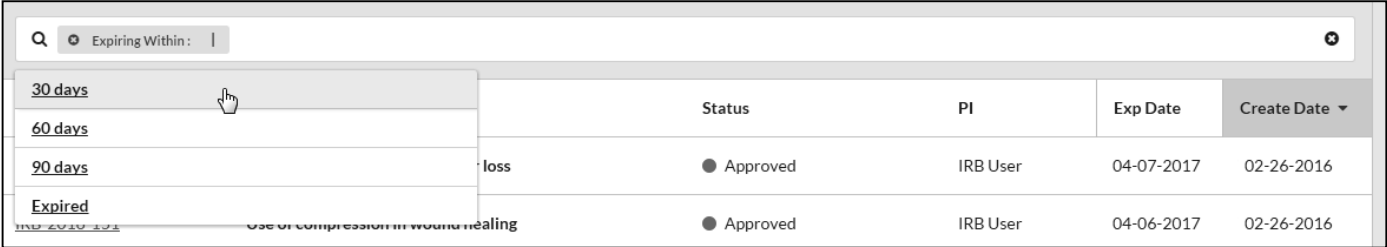
You can resort the list of submissions by creation date in ascending or descending order by clicking on the column header.

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.



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



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



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

Tasks

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

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

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

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

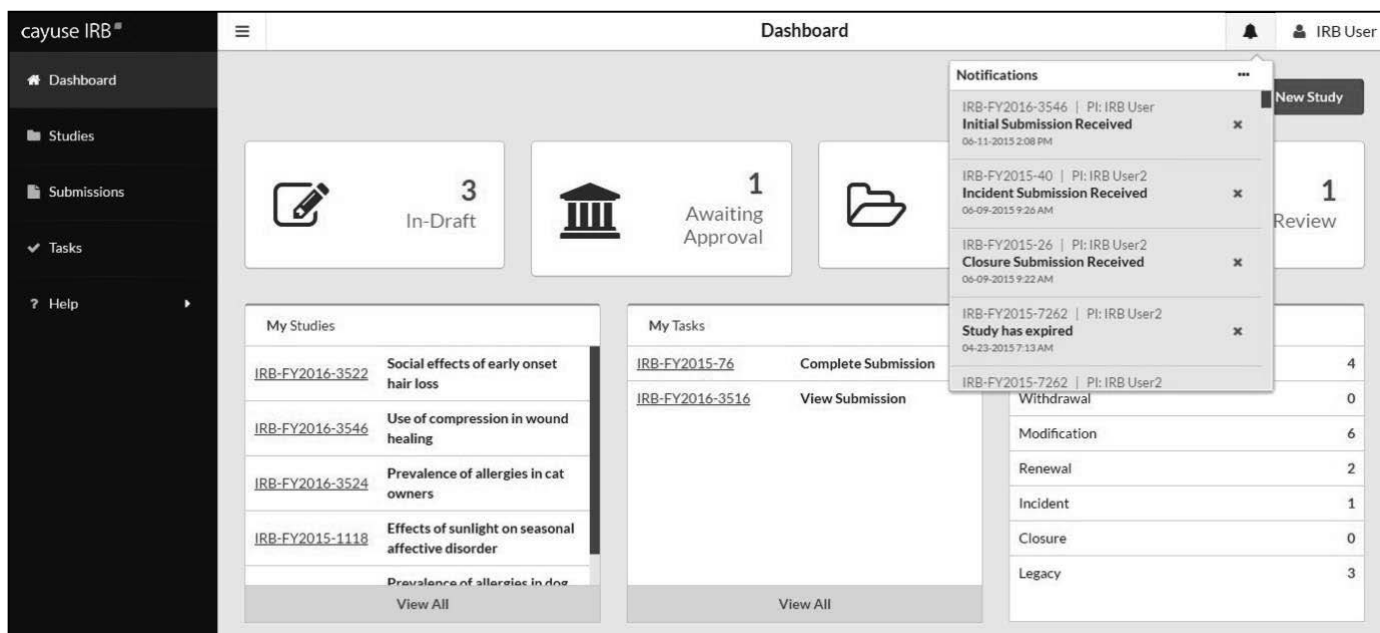
When you complete a task, it is removed from your task list. You may then see another task assigned to you for the next step in the process, or another user may receive a task depending on where the submission is in the workflow.

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

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

Notifications

The **Notifications** icon shows you a list of all the messages you have received regarding one of your studies. In the example below, this IRB User has received notifications for several studies. The notifications for the first three studies indicate that various submissions have been received by the IRB office. The fourth notification pertains to a study that has expired. You will get a notification whenever one of your studies requires some action by a different user or user role.



Notifications are sent:

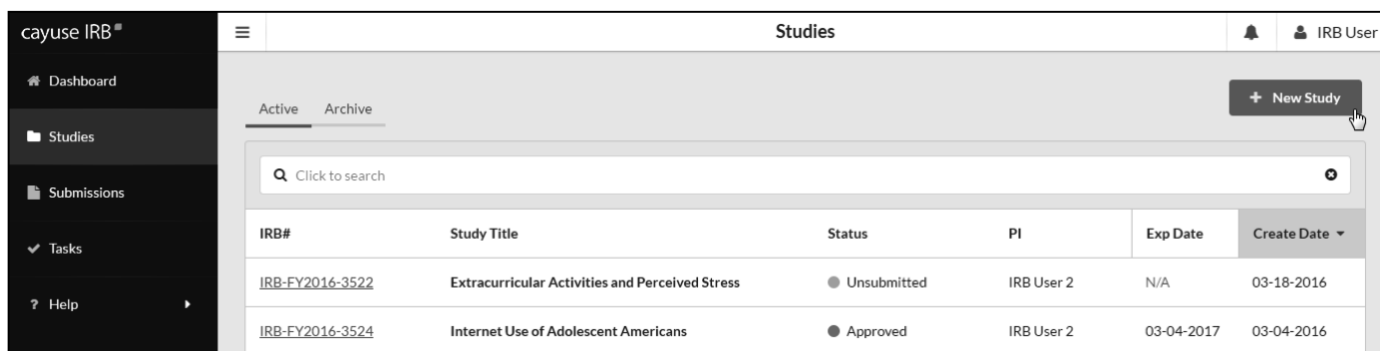
- ☐ To the PI when the submission has been sent to them for certification.
- ☐ To the PI and PC, when their submission has been received by the Compliance Office.
- ☐ To the Organizational Approver(s) when a submission requires approval.
- ☐ To the IRB Analyst when a new submission requires Analyst assignment.
- ☐ 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.).

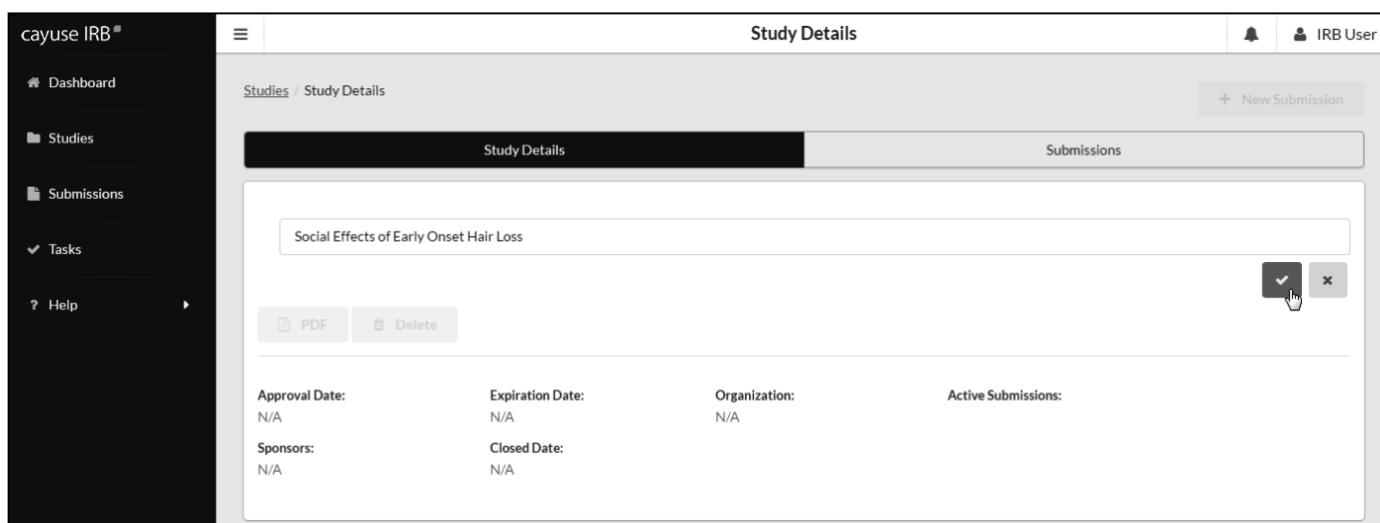
Note on Customizing Notifications: IRB Analysts and Admins have the ability to customize all of the notifications and emails that are sent out by Cayuse IRB via the Message Templates screen in the Settings section. Customization options include editing the text of the message, controlling which users 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.

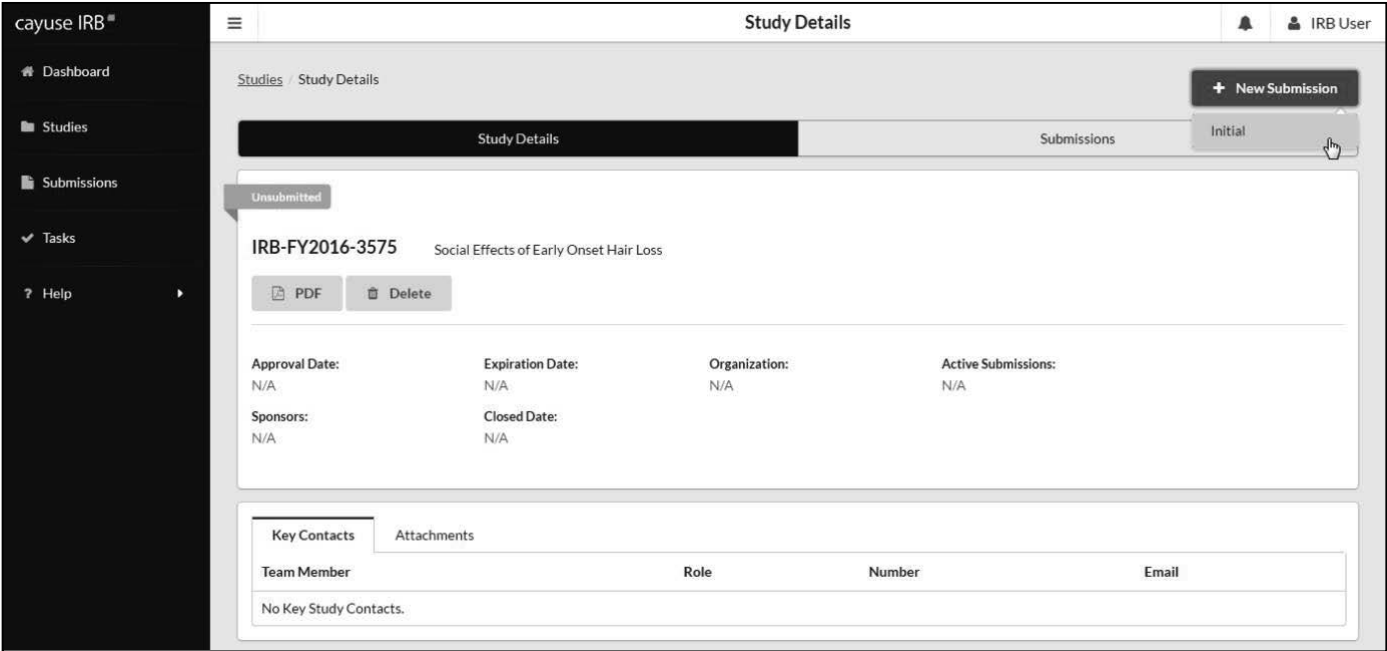


After creating the new study, you will be taken to the Study Details page for that study, which displays important information regarding the study.

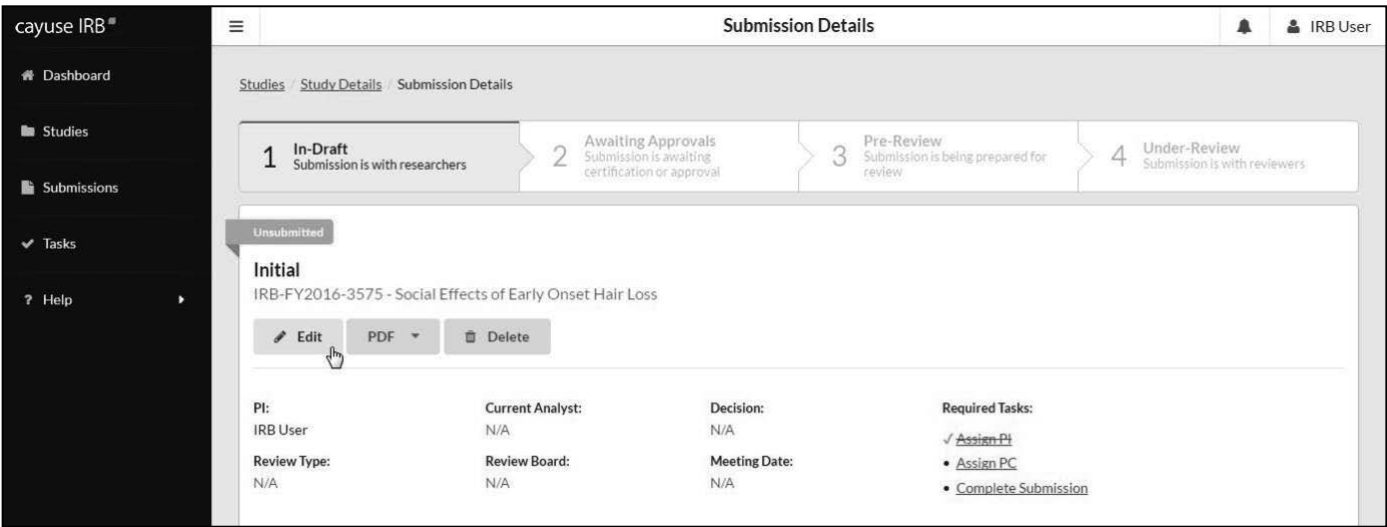
Note on Editing Study Titles: You can choose to rename your study at any point up until the initial (or a withdrawal) submission has finished being reviewed. From the Study Details screen, click anywhere within the study title field to edit the title.

Creating the Initial Submission

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



The 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 anytime by clicking on the < **STUDY** link in the upper left of the screen.

cayuse IRB®

Dashboard

Studies

Submissions

Tasks

Help

STUDY

IRB NUMBER: IRB-FY2016-3575

Social Effects of Early Onset Hair Loss - Init...

CREATE PDF

COMPARE

SAVE

<

>

Sections

Section 1 Assignments

Section 2 Other Items

Section 3 Optional Forms

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	x

* P2 Primary Contact

FIND PEOPLE

<

>

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 top navigation bar includes the logo, a hamburger menu, the role 'My Role: Researcher', a notification bell, and the user 'IRB User'. Below this is a study header with a back arrow, the text 'STUDY', the IRB number 'IRB-FY2016-3576', the study title 'Social effects of early onset hair loss - Initial', and buttons for 'CREATE PDF', 'COMPARE', 'SAVE', and navigation arrows. A left sidebar contains icons for Dashboard, Studies, Submissions, Tasks, and Help. A central 'Sections' menu lists 'General Information' (highlighted in green), 'Location of Research', 'Study Information', 'Subject Information', and 'Advertisements'. The main content area is titled 'General Information' and contains three sections: 1. Principal Investigator (a table with one row), 2. Primary Contact (a text input field and a 'FIND PEOPLE' button), and 3. Anticipated Start Date (a date picker).

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

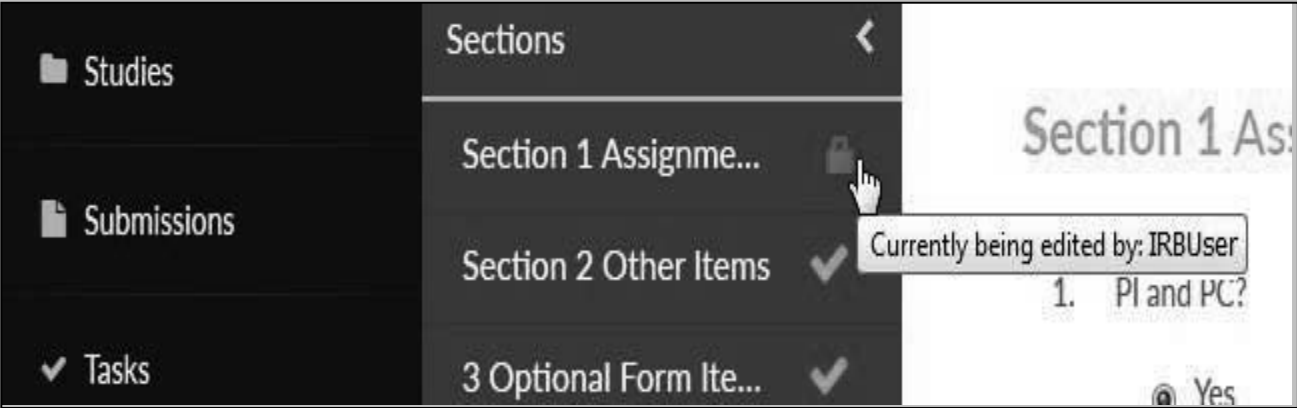
The section you are currently working on appears in the menu in green text. As you provide information, the status bar underneath the section turns green. When complete, the section name has a green check mark to its right. Sections with no required questions are marked complete when you visit the section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

This screenshot shows the same interface but with the 'Location of Research' section selected in the menu and active in the main content area. The 'General Information' section in the menu now has a green checkmark. The 'Location of Research' section contains a question: '1. Will your research be conducted on campus?' with radio buttons for 'Yes' and 'No' (selected). Below this is a sub-question 'a. Select the type of facility where the research will be conducted.' with radio buttons for 'Correctional Facility', 'Home Health Agency', 'Veterans Hospital', 'Health Clinic', and 'Other'. Navigation arrows are at the bottom right.

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.

Note on 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 811hmi88ion r::innot hP. r.omnIP.tP.rl whilP. :.inothP.r 118P.r

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)

Text Box

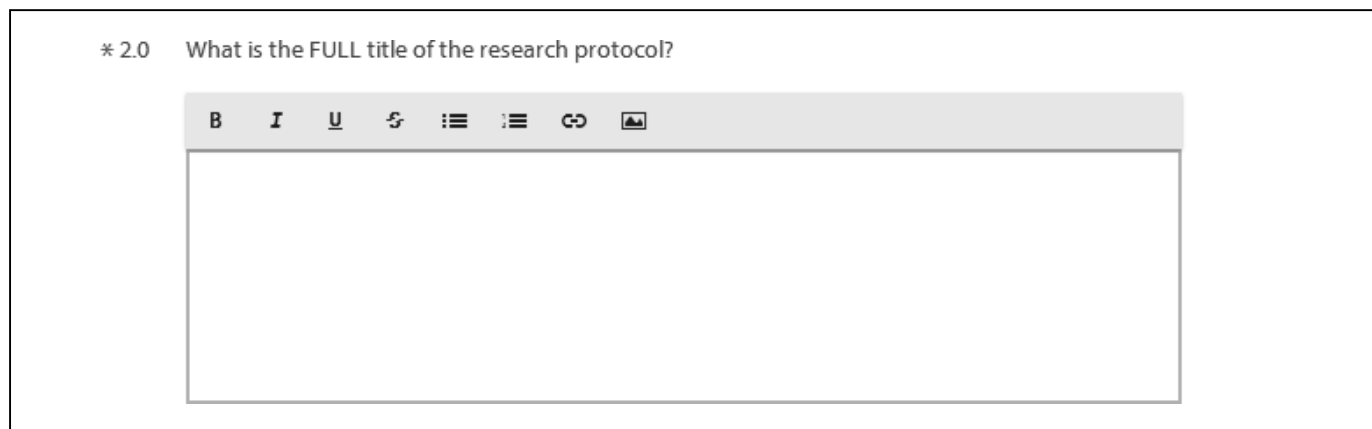
A text box provides space for a short answer that does not require a lot of explanation. You can enter multiple lines of text here if needed; the box will expand to fit the text.

* 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?

The screenshot shows a text editor with a toolbar containing icons for bold (B), italic (I), underline (U), strikethrough (ABC), bulleted list, numbered list, link, and image. Below the toolbar is a large, empty text input area.

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

The screenshot shows a search field with the label "Who is the Primary Contact?" and a button labeled "FIND PEOPLE".

Click **FindPeople** to bring up the **Primary Contact** search dialog:

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.

PRIMARY CONTACT

Mark

×

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

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.

INVESTIGATOR

Mark

×

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

Mark Williams	×
Mark Klein	×

⌵ CANCEL

💾 SAVE

Attachments

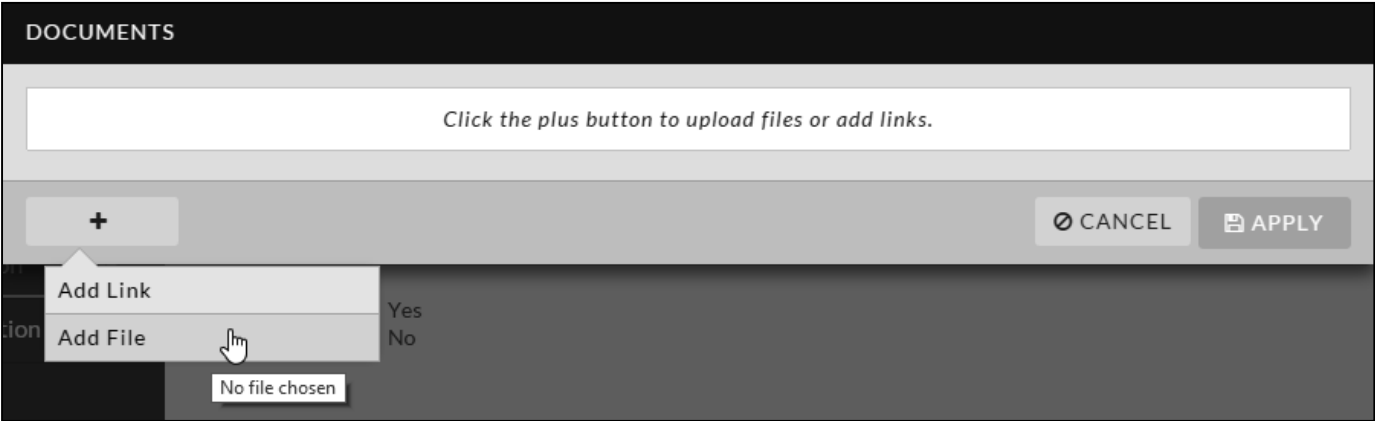
Attachment fields allow you to upload one or more files to the study, or to include hyperlinks as "attachments".

4.0

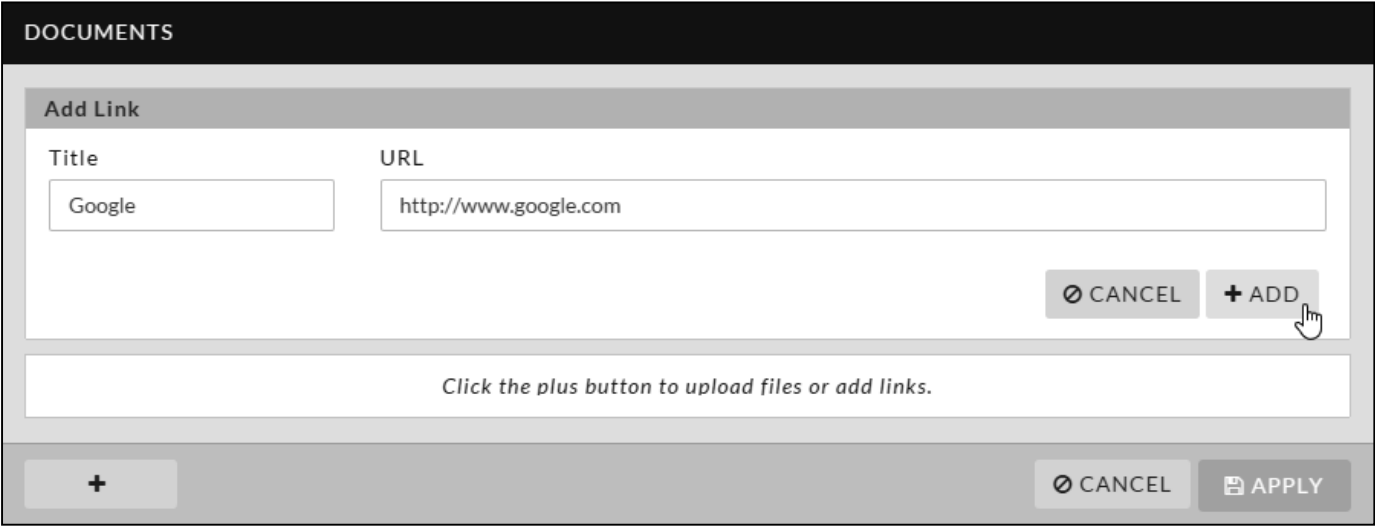
Attach the Letters of Support from the respective Department/Division.

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.

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.

The screenshot displays the Cayuse IRB web application. On the left is a dark sidebar with icons for Dashboard, Studies, Submissions, and Tasks. The top navigation bar shows 'My Role: Researcher' and 'IRB NUMBER: IRB-FY2016-3576'. The main content area is titled 'Social effects of early onset hair loss - Initial' and includes buttons for 'CREATE PDF', 'COMPARE', and 'SAVE'. A 'Sections' menu on the left lists 'General Information', 'Location of Research', 'Study Information', 'Subject Information', and 'Advertisements', each with a checkmark. The form contains two required questions marked with a red asterisk: '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 upload area showing 'Study Protocol.pdf' with a delete icon.

Note on 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.

Note on 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

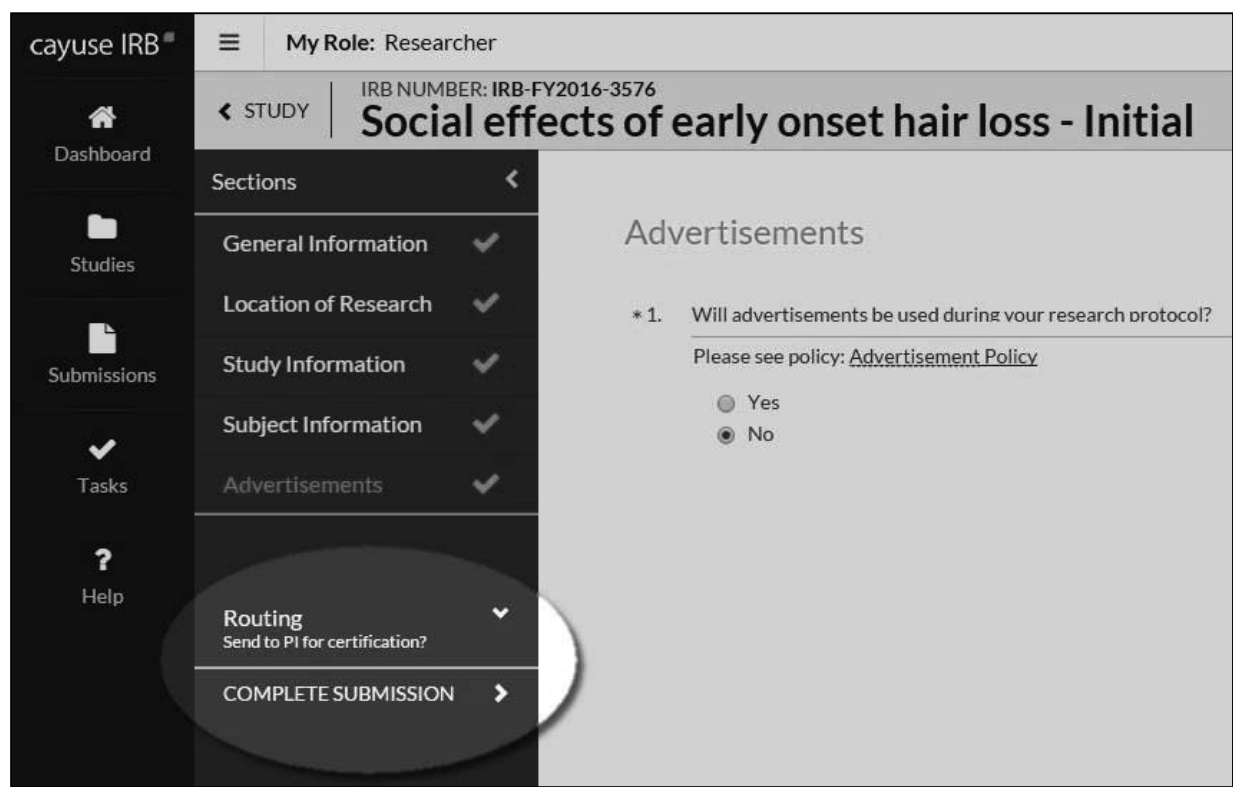
When you have responded to a comment, change the dropdown from to . Unaddressed comments have a red bar to their left, and display the comment count in the comment bubble icon for that question. You can toggle comments between addressed and unaddressed as needed.

Routing

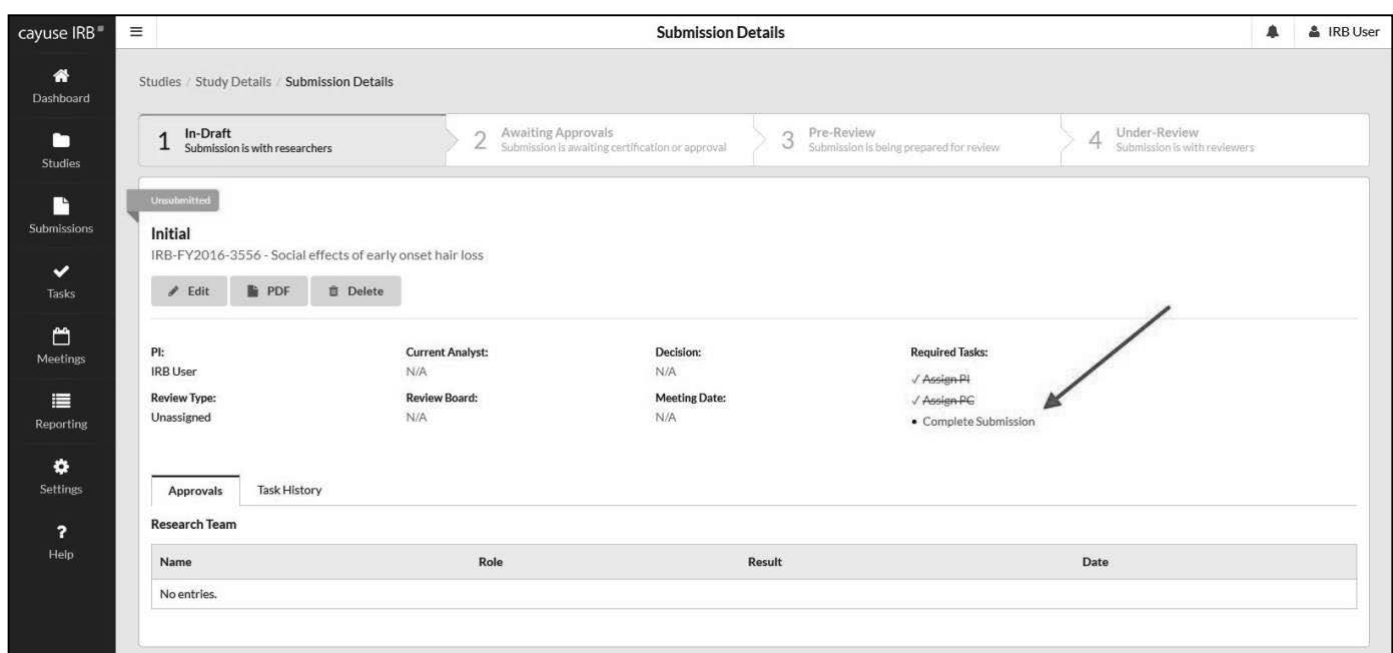
If there are available actions that you can perform, the **Routing** menu appears prompting you to perform the action. For example, when you finish filling out all parts of the submission, a "Complete Submission" link appears in the Routing menu. Completing the submission will send it to the PI for certification,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

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:



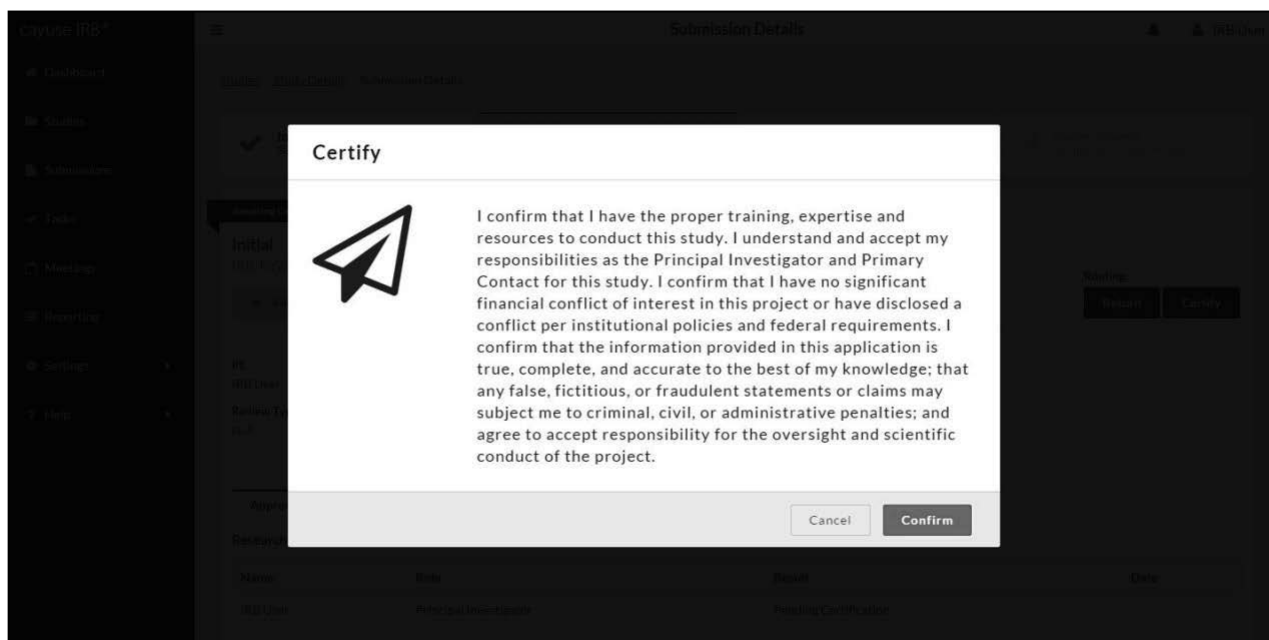
If you are on the Submission Details screen, you will also see the Complete Submission link indicating the next step in the routing process:



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.

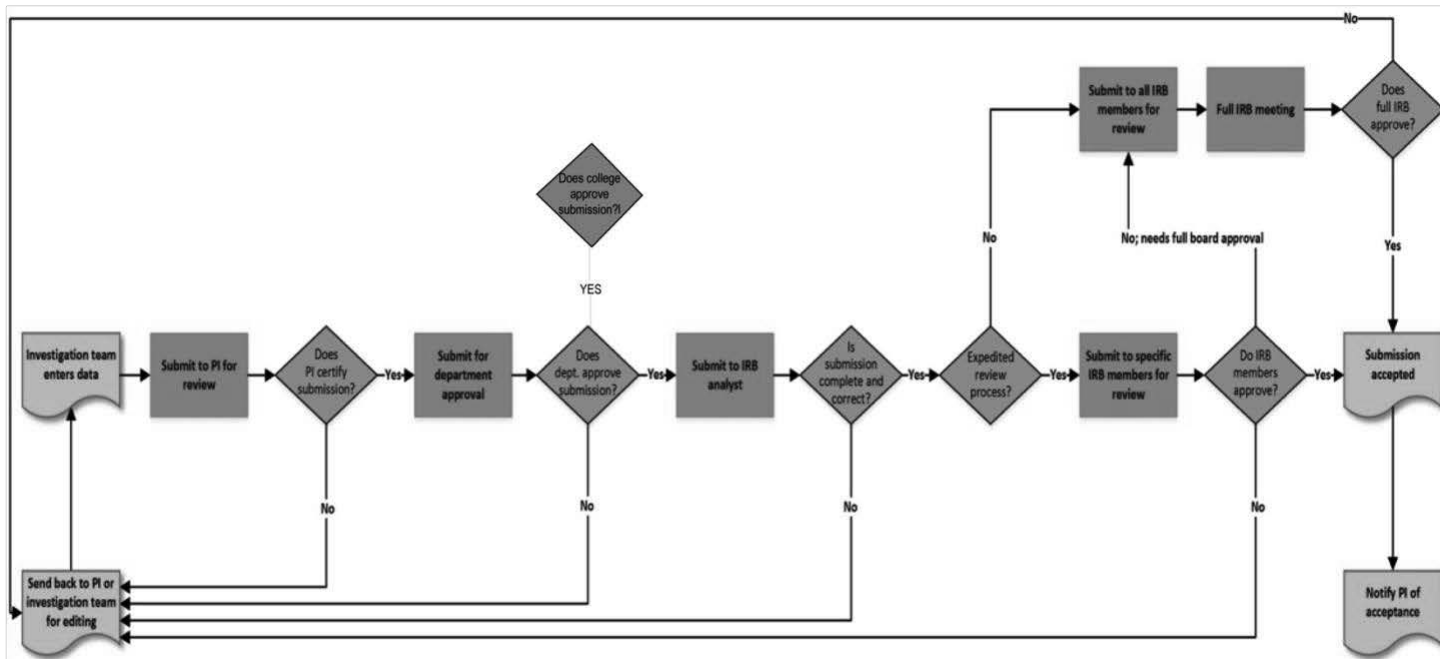
If everything is correct, the PI can then **Certify** the submission. By certifying the submission, the PI asserts that the submission is complete and accurate, and that they accept their responsibilities as PI of the study.

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 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.

cayuse IRB™

Dashboard

Studies

Submissions

Tasks

Help

Submission Details

IRB User

Studies / Study Details / Submission Details

In-Draft
Submission is with researchers

Awaiting Approvals
Submission is awaiting certification or approval

Pre-Review
Submission is being prepared for review

Under-Review
Submission is with reviewers

Review Complete

Initial
IRB-FY2016-55 - Social effects of early onset hair loss

View

PDF

Delete

PI:
IRB User

Current Analyst:
IRB Analyst

Decision:
Approved

Review Type:
Full

Review Board:
Biomedical

Approvals

Task History

Letters

Meetings

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.

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 **SavePageAs** (Firefox), or go to **Tools->File->SaveAs** (Internet Explorer).

www.cayuse.com

CayuseIRB User Guide

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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. The user is logged in as 'IRB User' and is viewing the 'Social effects of early onset hair loss - Initial' submission. The 'Section 1 Assignments' section is highlighted, and a comment bubble icon with the number '1' is visible next to the section title. The table below lists the assignments for Section 1.

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

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 user is logged in as 'IRB User' and is viewing the 'Social effects of early onset hair loss - Initial' submission. The 'Section 1 Assignments' section is highlighted, and a comment bubble icon with the number '1' is visible next to the section title. The table below lists the assignments for Section 1.

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

Below the table, there is a comment from the IRB Analyst. The comment is titled 'Collapse Comments' and contains the text: 'IRB Analyst Today at 1:21 PM Are there any additional contacts for this study?'. Below the comment, there is a reply box with the text: 'No, there are no additional contacts.' and a 'REPLY' button.

Enter your reply and then click to save it.

Once you've 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.

cayuse IRB®

Dashboard

Studies

Submissions

Tasks

Help

My Role: Researcher

IRB NUMBER: IRB-FY2016-3559

STUDY

Social effects of early onset hair loss - Initial

CREATE PDF

COMPARE

SAVE

IRB User

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.

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.

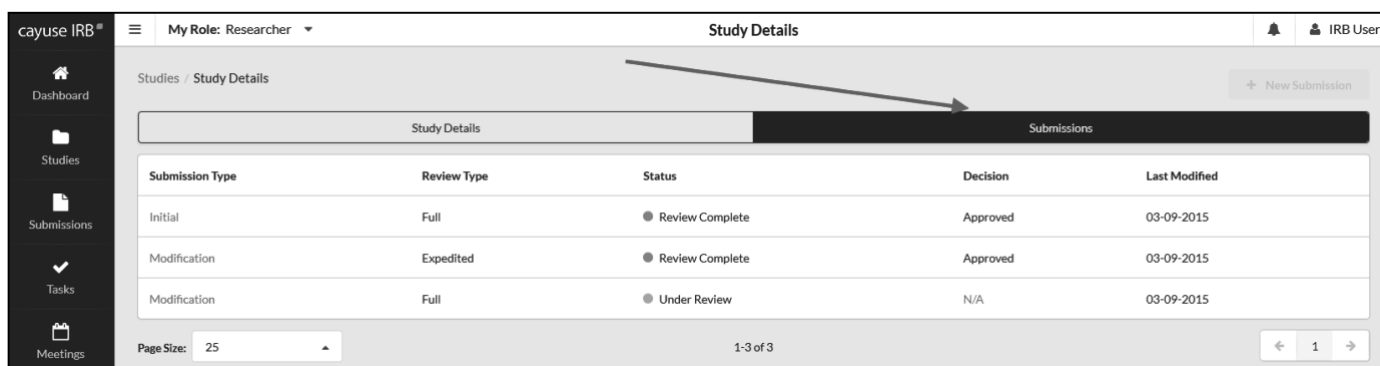
There are two additional submission types that are only available to IRB Analysts and Admins:

- ❑ **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 **Submission** tab:

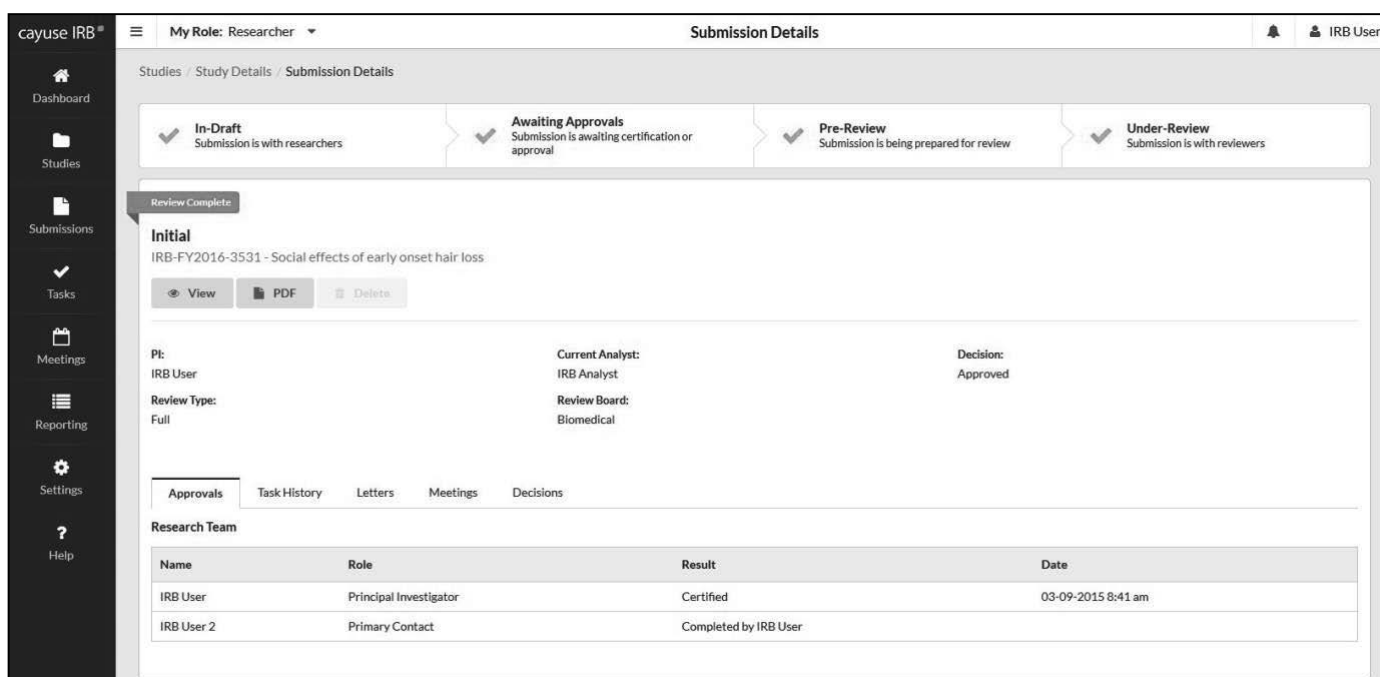


The screenshot shows the 'Study Details' page in the cayuse IRB system. The 'Submissions' tab is selected, displaying a table of submission history. An arrow points to the 'Submissions' tab.

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

Page Size: 25 1-3 of 3

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 in the cayuse IRB system. The submission is in the 'Initial' state, with a 'Full' review type and an 'Approved' decision. The Research Team table is also displayed.

Review Complete

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

[View](#) [PDF](#) [Delete](#)

Pt: 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.

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 'Study Details' page in the Cayuse IRB system. The left sidebar contains navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area has tabs for 'Study Details', 'Submissions', and 'Legacy'. The 'Legacy' tab is active, showing details for submission 'IRB-FY2011-126' titled 'Use of Compression in Wound Healing'. Below the title are 'PDF' and 'Delete' buttons. A metadata section lists: Approval Date (11-15-2011), Expiration Date (N/A), Organization (N/A), Active Submissions (N/A), Sponsors (N/A), and Closed Date (N/A). At the bottom, there are tabs for 'Key Contacts' and 'Attachments'. The 'Key Contacts' tab shows a table with columns: Team Member, Role, Number, and Email.

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.

The screenshot shows the 'Submission Details' page for a 'Legacy' submission (IRB-FY2011-126). The left sidebar is the same as the previous screenshot. The main content area shows a progress bar with four steps: 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 the progress bar is the 'Unsubmitted' status. The submission title 'Legacy' and ID 'IRB-FY2011-126' are shown, followed by 'Edit', 'PDF', and 'Delete' buttons. A metadata section lists: PI (IRB User), Current Analyst (N/A), Decision (N/A), Required Tasks (Complete Submission), Review Type (N/A), Review Board (N/A), and 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.