cayuse Help Center

Se rch

Articles in this section m

Creating a New Study m

Sarah Raynor

19 days ago · Updated m

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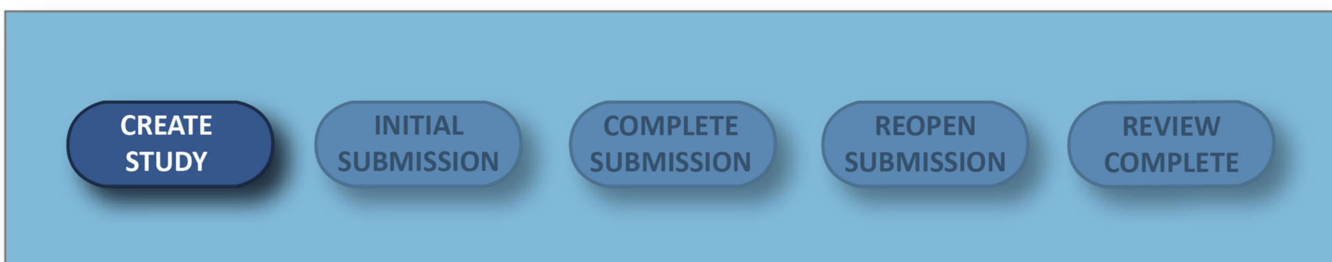
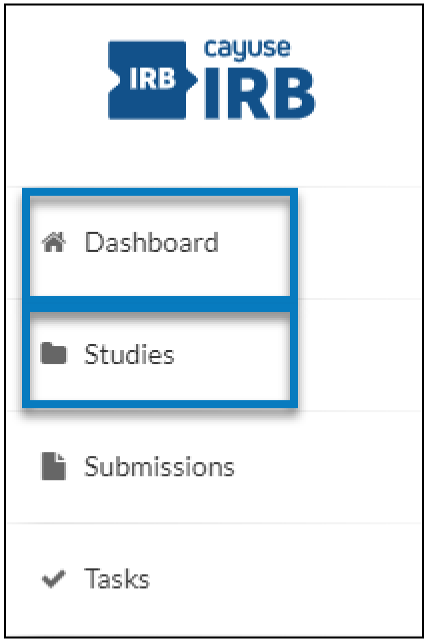


As an IRB Researcher, you can create a new study from your Dashboard or the Studies page within Cayuse IRB. m

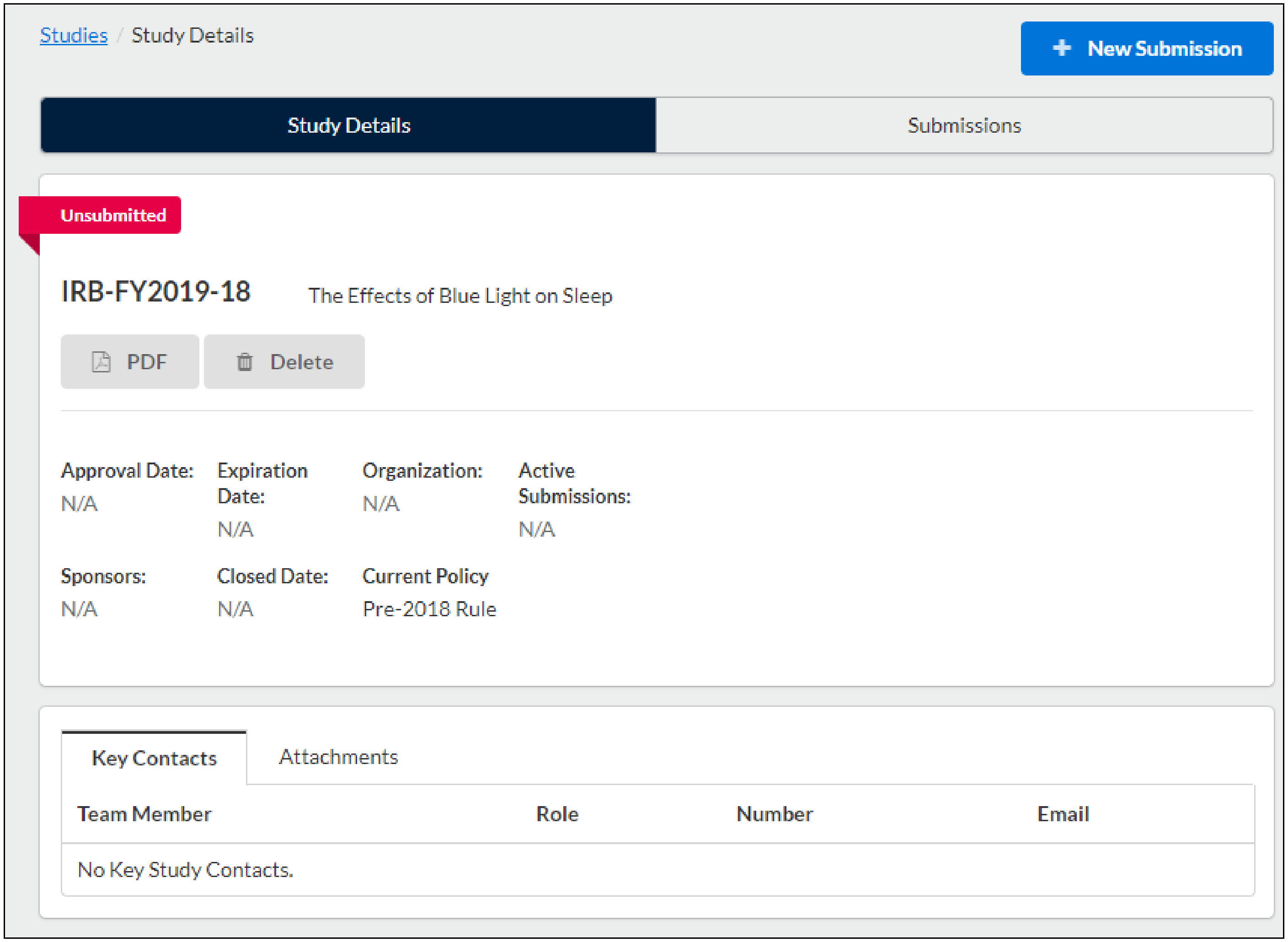


Creating a Study

1. Click **+ New Study** in the upper right-hand corner of your Dashboard or the Studies page. m
2. Enter the title of your study. The title can be up to 600 characters long.

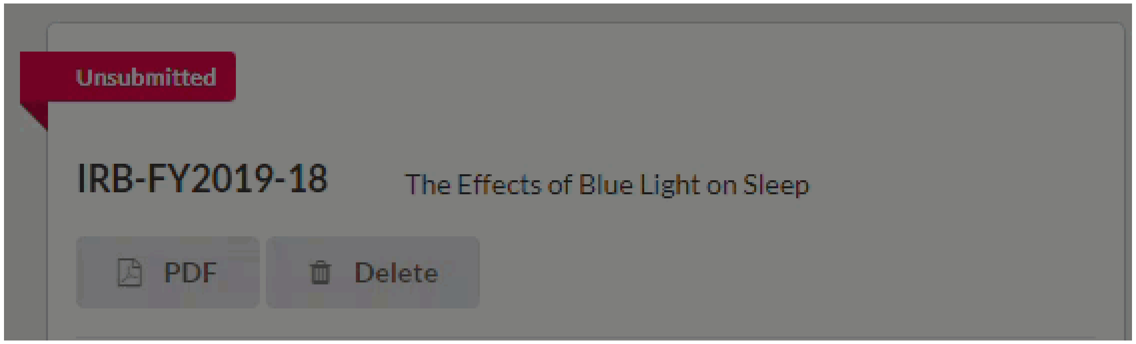
3. Click  to save your study.

After creating your study, you will be taken to the Study Details page. Here, you will see where important study information will m populate once you begin your submission.

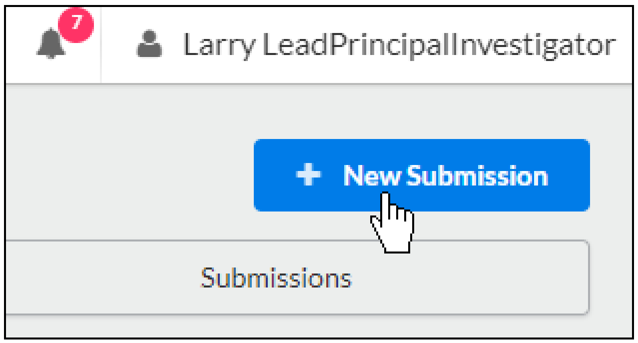


The person who creates the study is added as the primary contact by default. You can change this when editing the submission.

You can rename your study up until the completion of the initial (or withdrawal) submission. From the Study Details screen, hover over the study title and click within the field to edit.



Once you create your study, you can begin your initial submission. Click on **New Submission** in the upper right-hand corner to start m completing your forms.



m

Was this article helpful? m

✓ Yes ✕ No

22 out of 25 found this helpful m

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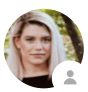
Ca use Help Center -> Ca use IRB > Researchers: Studies and Submissions

S arch

Articles in this section

Creating an Initial Submission



Sarah Raynor

9 days ago · Updated

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Initial_Submission_Workflow_-_Initial_Submission.png

After you create a new study, you can begin completing forms for your initial submission by clicking on **New Submission**, and then clicking **Initial** from the drop-down menu.

2018-12-13_9-56-43.png

Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission. **Make sure to not remove yourself from all roles and Save, or you will not be able to access your submission once you leave.**

Cl ck on 2018-12-13_11-23-07.png to beg n your submiss on forms. You w ll always be able to return to your ncomplete submission by clicking this button. -

Once on your institution's initial submission form, you can return to the Submission Details page by clicking on **Study** in the upper left-hand corner of the screen.

2018-12-13_10-21-46.png

Use the 2018-12-13_11-15-07.png buttons to toggle between sections. You can also click on a section name in the menu at left to jump to that section. -

2018-12-13_10-24-49.png

Completing Submission Forms

There are several types of questions that your institution may have chosen to include on the submission forms:

- **Radio Buttons:** Select one of the available options.

  2018-12-13_11-21-31.png -

- **Check Boxes:** Select one or more of the available options.

  2018-12-13_12-02-33.png -

- **Date Picker:** Click within the field to browse for a date.

  2018-12-13_12-22-32.png

- **Text Box:** Provide a short answer to the stated question (200-character limit). If you need to enter multiple lines of text, the box will expand to fit.

  -

20 8- 2--3_ 2-49-26.png -

- **Text Area:** Provide a detailed answer to the stated question. You can use formatting such as bold, italics, underline, - strikethrough, bulleted lists, numbered lists, and hyperlinks.

  2018-12-13_12-24-12.png

  You can also add PNG or JPG images using the image button 2018-12-13_13-33-56.png. Once your image is inserted, you can edit the image by clicking on the image and then clicking **Edit**.

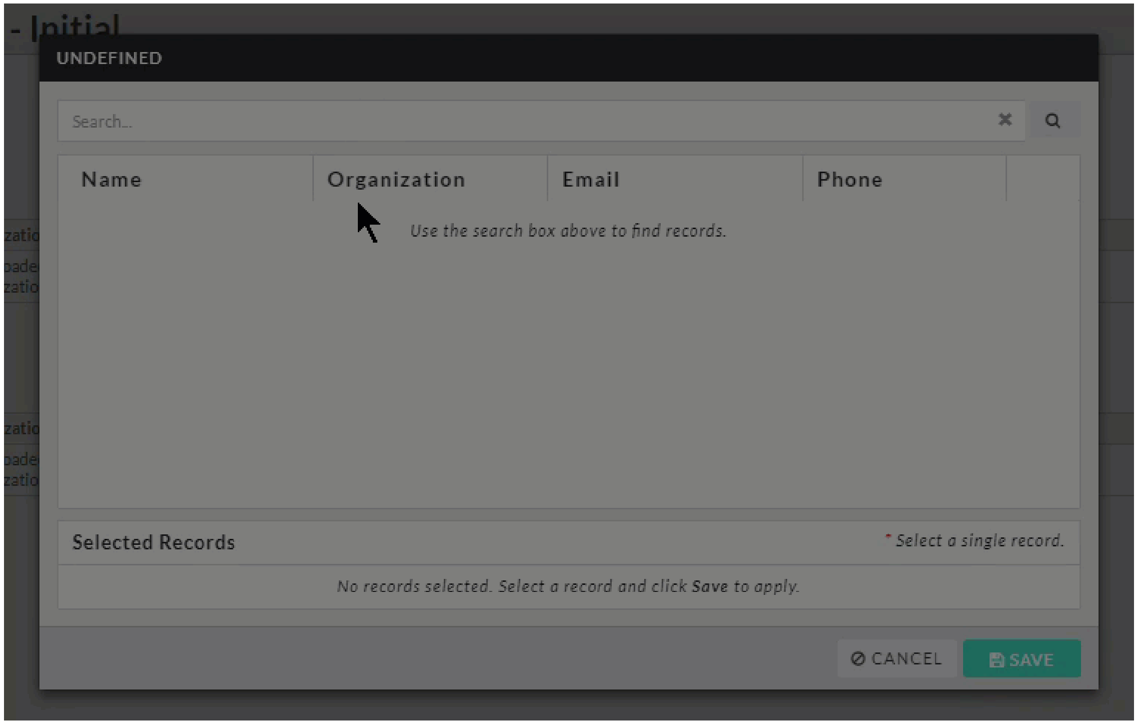
  2018-12-13_13-35-54.png

- **Person and Sponsor Finders:** While every initial submission will require you to add a Primary Contact and Principal Investigator, your institution may have you add other people or sponsors to different sections within your submission. Click on the finder button to bring up a search dialogue.

  2018-12-13_12-22-02.png

  Search for the individual or sponsor that you wish to add, select them, and click **Save**.

  -



- **Attachments:** Upload one or more files to the study by clicking ATTACH . Cayuse IRB supports the following file types:

-

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, xlsm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

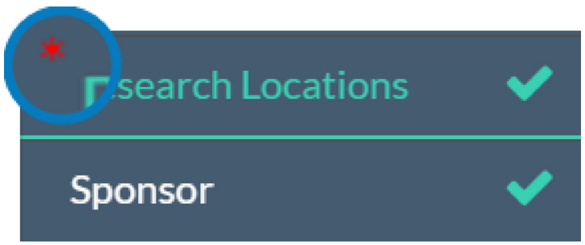
You can also include hyperlinks as "attachments" by choosing **Add Link** from the **+** drop-down menu. -

-

To delete an attachment, click the icon next to the attachment.

Please note: Some questions have * next to the question number. This indicates a required question. -

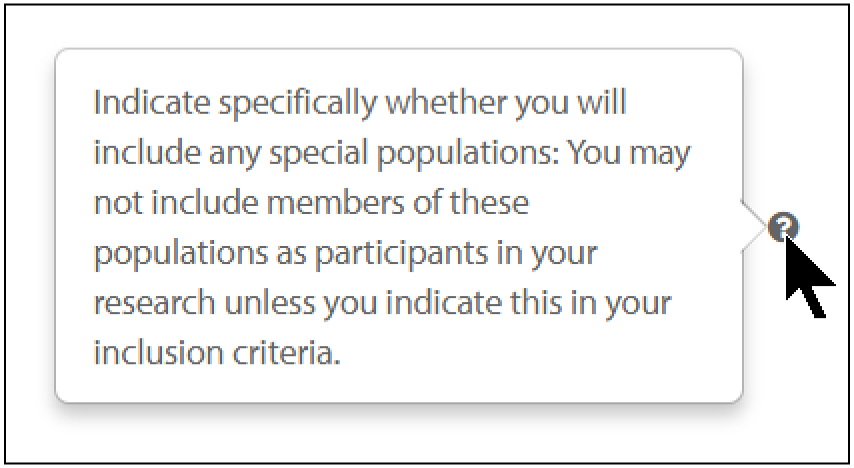
Sections with unsaved changes have an asterisk next to the section name.



To save your changes, click SAVE in the upper right-hand corner.

Help with Questions -

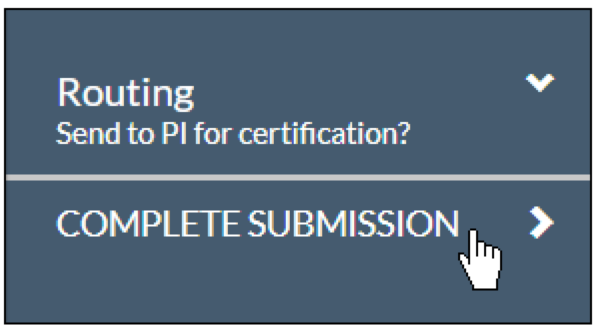
If there is help text for a question, you can click on the button to view the additional information for that question.



Once there are green check marks next to all of your sections, you have completed the submission forms and are ready for routing.

Please note: If one of your sections doesn't have a check mark and you aren't sure why, search the section for any required questions you may have missed. -

With every section completed, you can complete your submission and send it to the PI for certification.



Was this article helpful? -

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Articles in this section 5

Completing a Submission 5

Sarah Raynor

2 months ago · Updated 5

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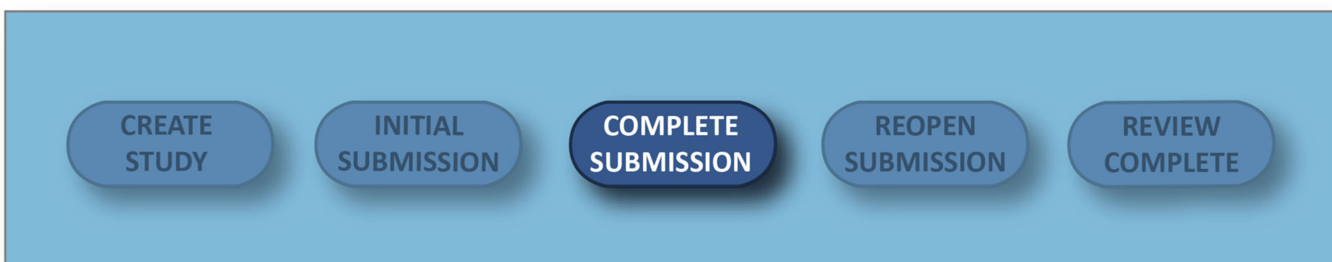
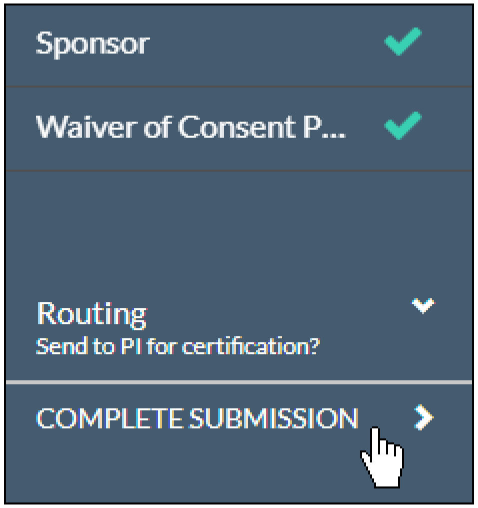


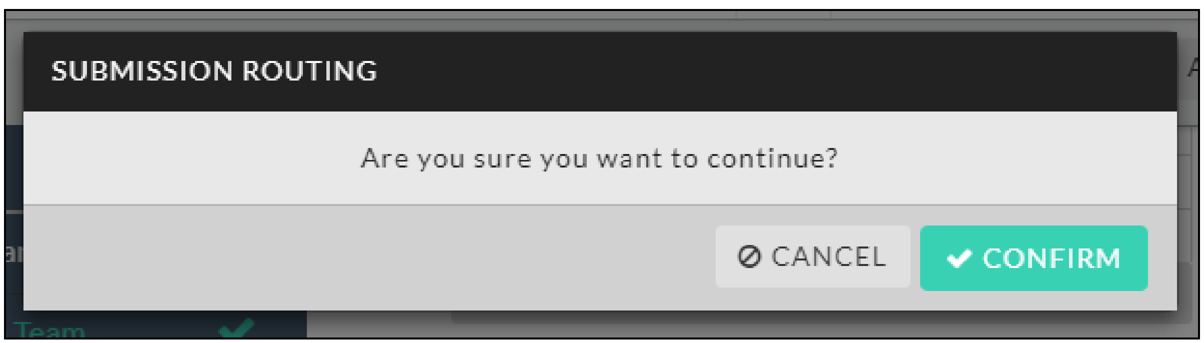
The **Complete Submission** button will only appear when you have green check marks next to all of your sections,. If one of your sections doesn't have a check mark and you aren't sure why, click on the section to search for any required questions you may have 5 mi ed. 5

2018-12-17_9-47-20.gif

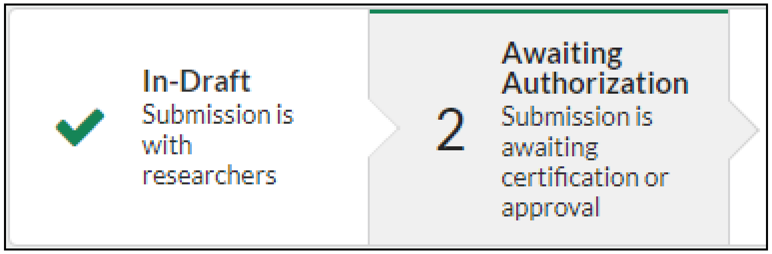
Once you have filled out every section of your submission and have added all required attachments, a **Complete Submission** option appears beneath **Routing** within the menu. 5



After clicking Complete Submission, you will be prompted to **Confirm** or **Cancel**. 5



Upon confirmation, you will see the status of your submission change on the Submission Details page. 5



Certification

Your completed submission is sent to the PI for certification. The PI will receive an email letting them know that the submission needs to be certified. When the PI certifies the submission, they are asserting the submission is complete and accurate and are accepting their PI responsibilities.

If the PI decides that changes need to be made, they will send the submission back. All research team members will receive an email notifying them of the change in status so they can make the necessary edits and complete the submission once more.

Once the PI has certified the submission, the submission will be reviewed by the organizational approver and routed to the IRB Analyst. The submission may be returned at any point for edits or clarification. **Please note:** If your institution does not have an approver, the submission may be routed directly to the IRB Analyst.

Completing Submission as a PI: If you are a PI completing your submission, you should be able to then certify the submission right away.

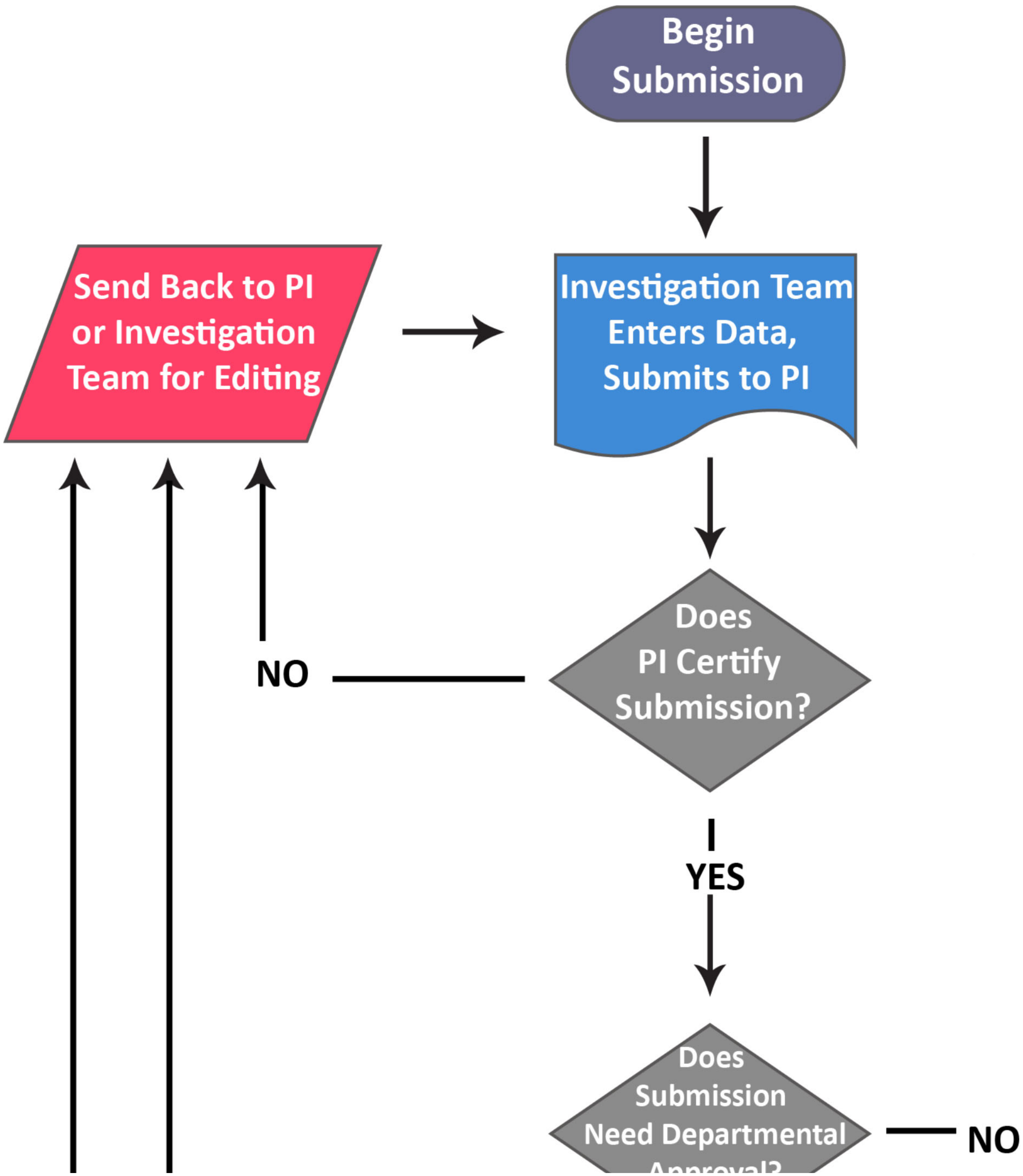
Co-PIs: Your institution's settings may require that any Co-PIs on the study also certify the submission. These individuals also have the ability to return to the submission to the research team. IRB Administrators can specify this behavior in the Application Settings. 5

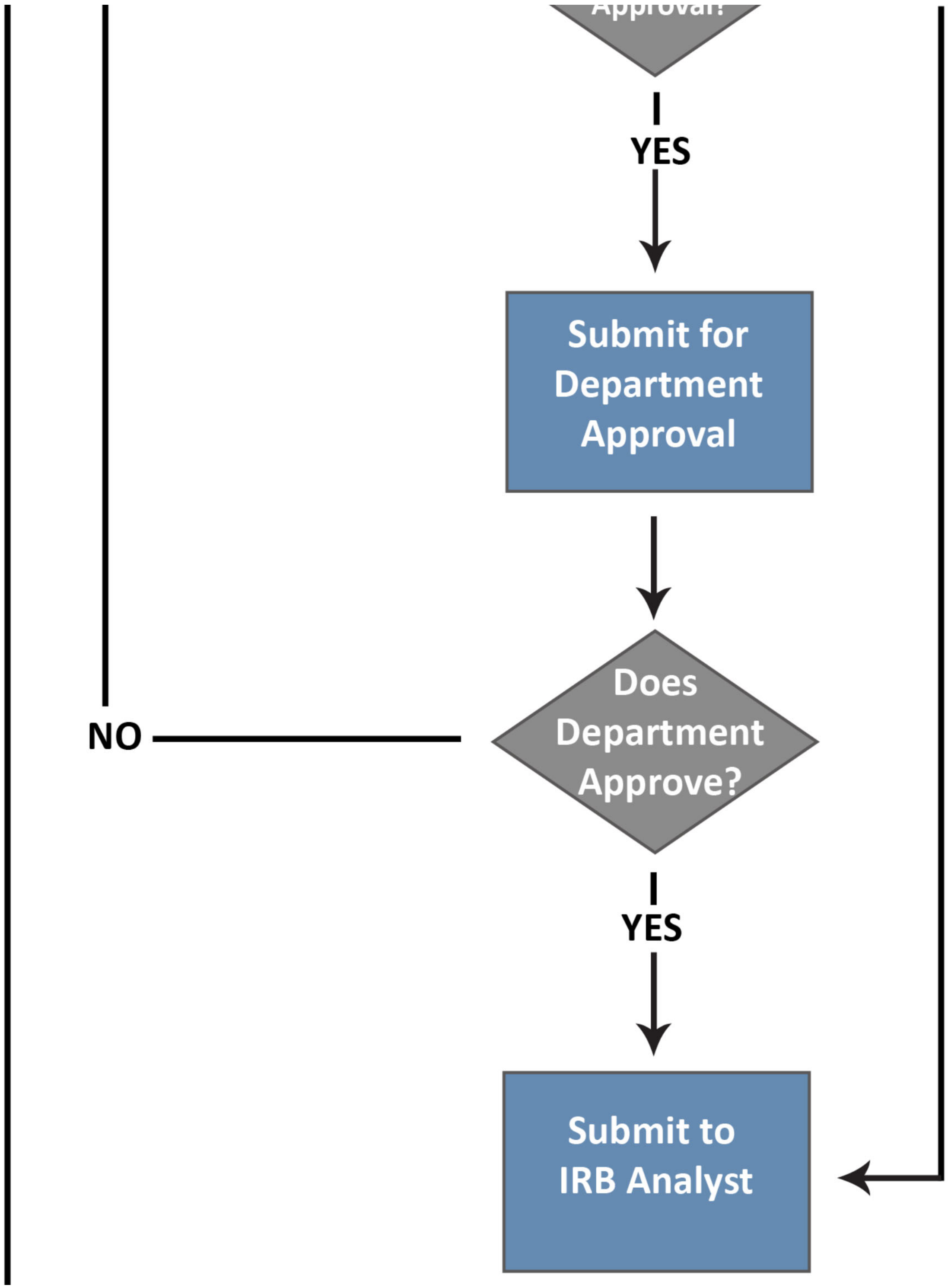
Recertification: If the submission does get returned to the research team, all previous certifications are cleared. All individuals who were required to certify the submission in previous rounds of routing must recertify every time the submission is returned before it can move forward. 5

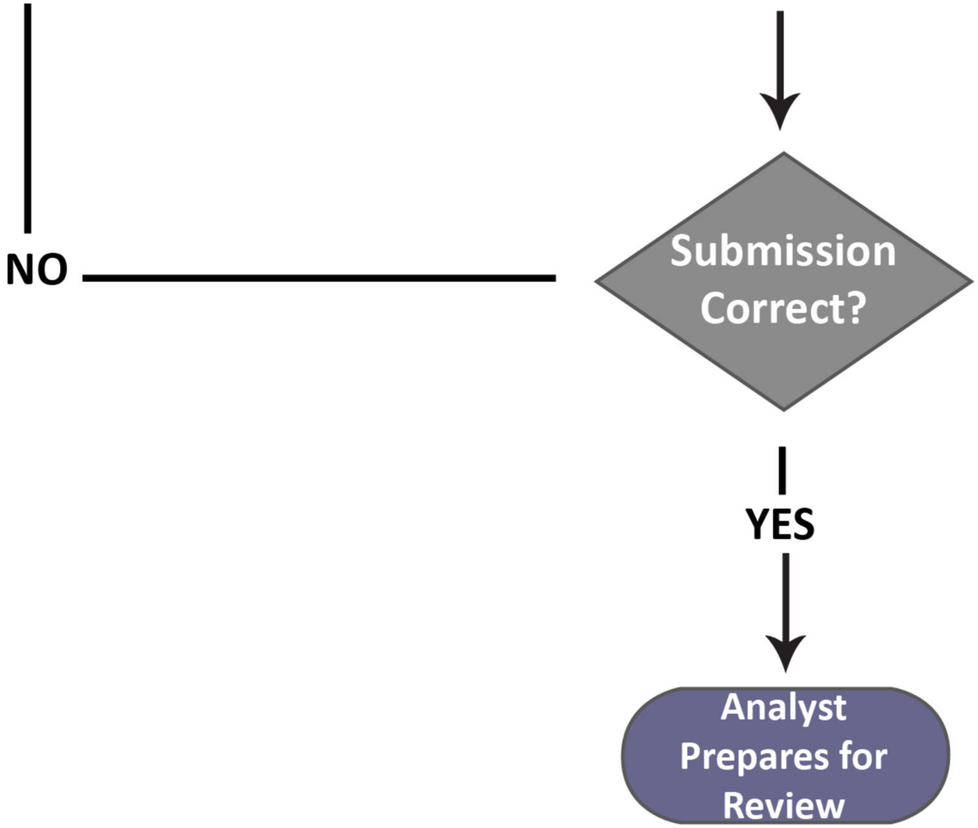
Reopening Your Submission

To reopen the submission and make edits, click on the 5 Edit button within Submission Details. 5

Su mi ion outing 5




Approval?
YES
Submit for Department Approval
NO
Does Department Approve?
YES
Submit to IRB Analyst



5

Was this article helpful?

✓ Yes ✕ No

1 out of 4 found this helpful

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Sarah Raynor
2 months ago · Updated c

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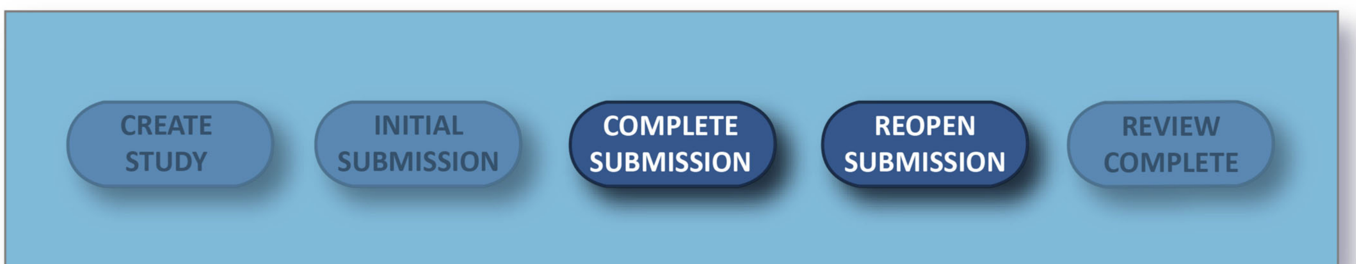
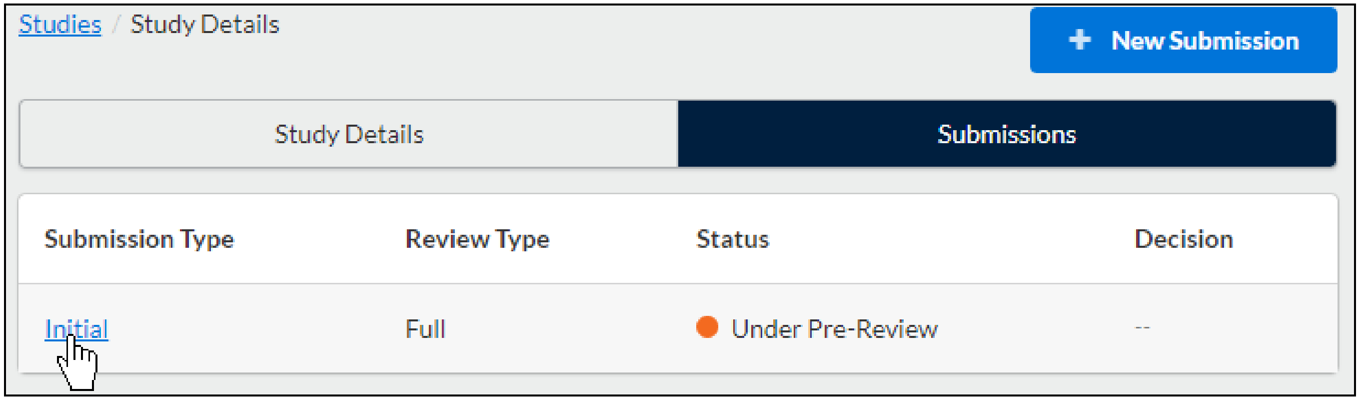
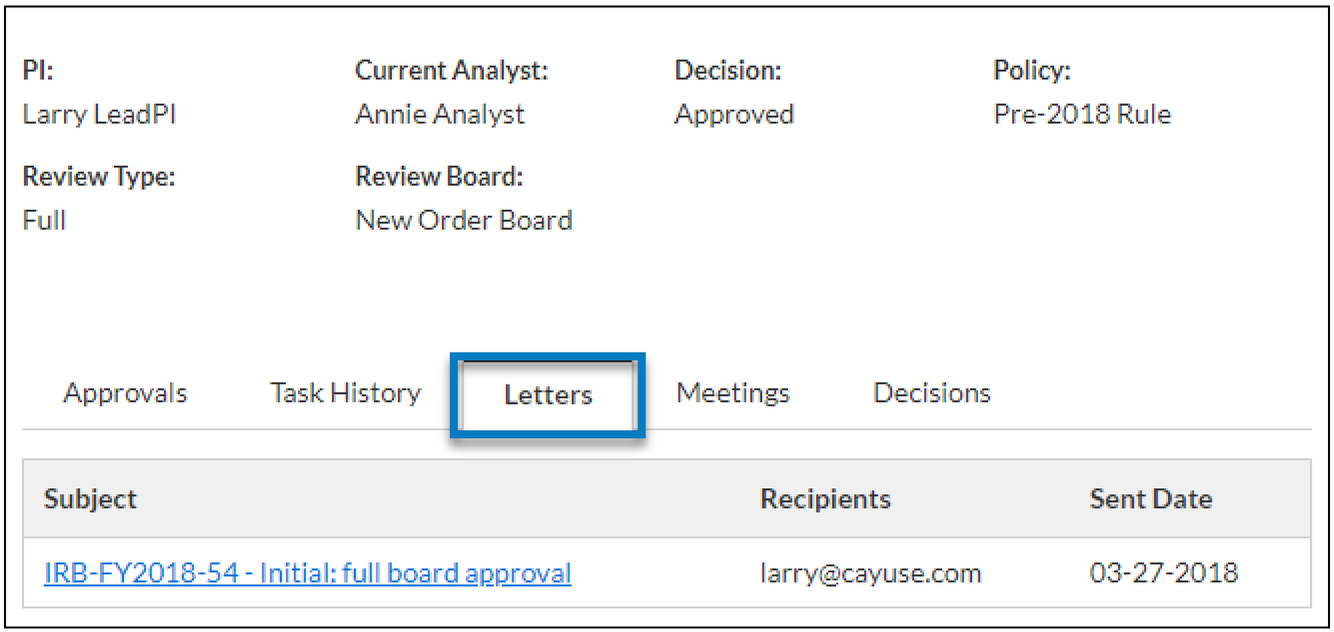


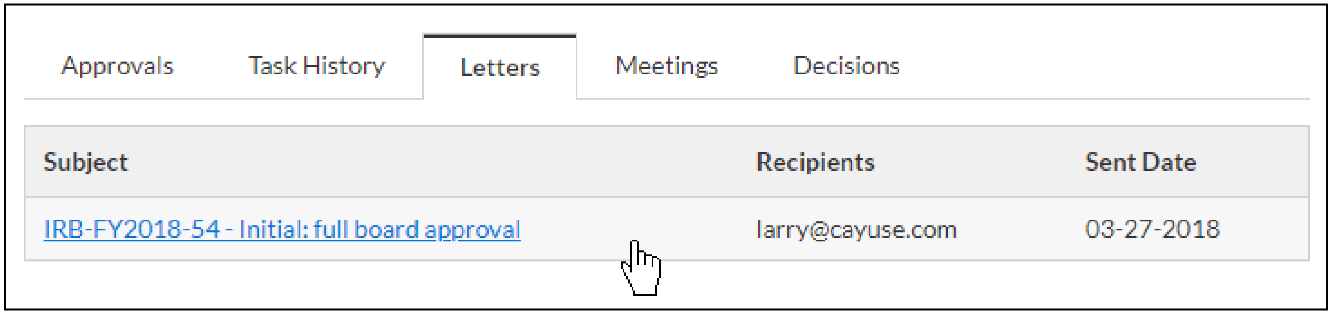
During the submission process, the compliance office may send communication to the PI in the form letters notifying the PI of status changes, approvals, and needed information. Letters are sent via email and are available to download directly from Submission etails in Cayuse IRB. c



The Letters tab appears for a submission when there is at least one letter associated with that submission. To view a letter, click on c the letter tab. c

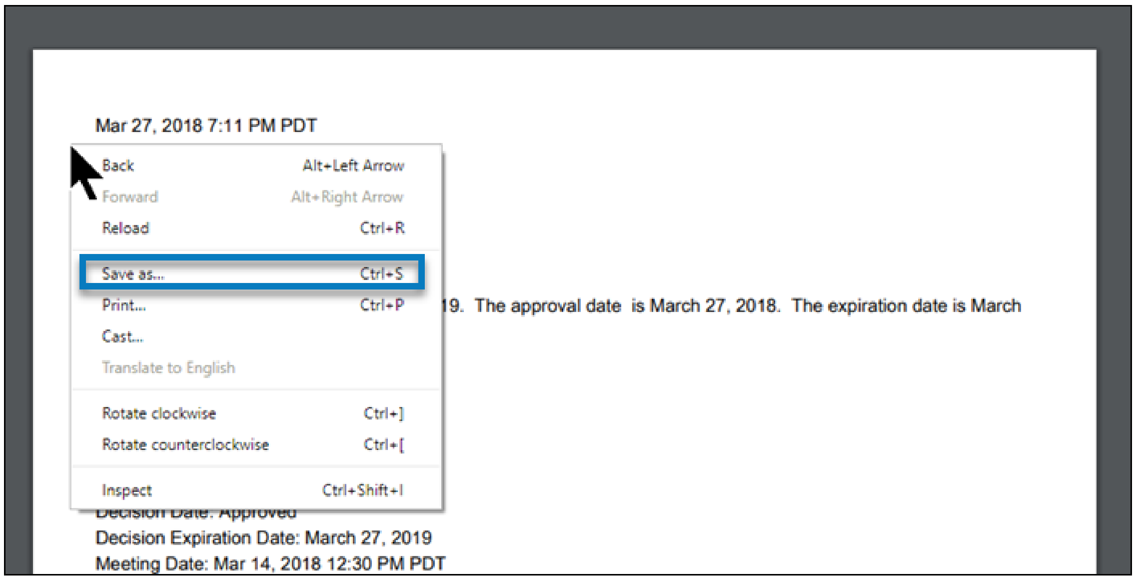


You will be able to view the subject, send date, and recipient(s) for each letter. You can click anywhere on the line to open a PDF of c the letter in a new window.

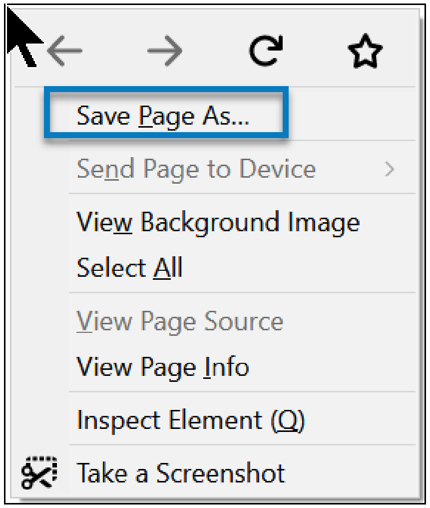


To save the letter to a file: c

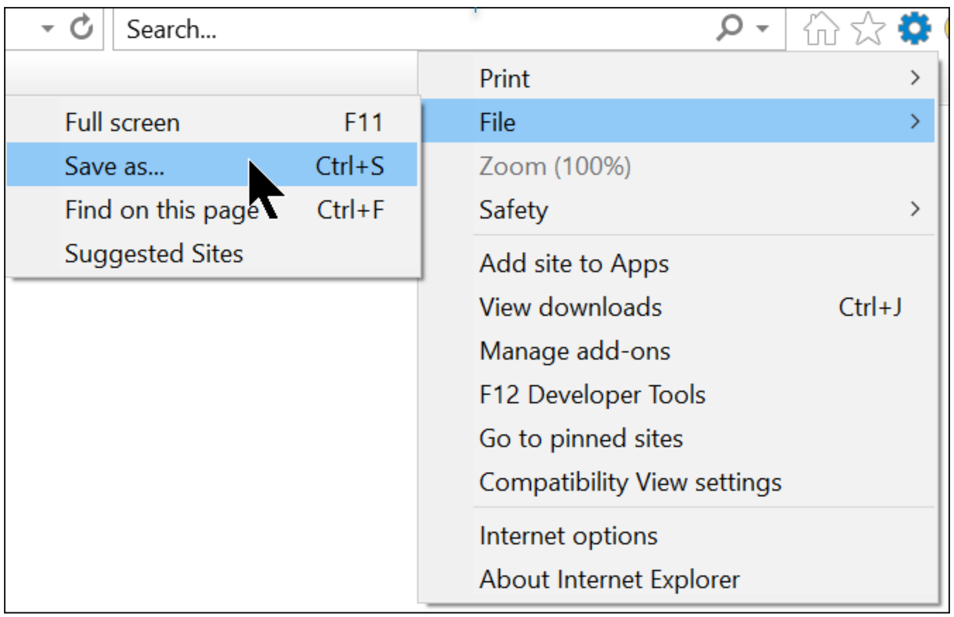
- **Chrome:** Right-click within the opened PDF and select **Save As**. c



- **Firefox:** Right-click within the opened PDF and select **Save Page As**.



- **Internet Explorer:** In the menu bar, click on **> File > Save As**. c



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Cayu e Help Center 5 Cayu e IRB > Re earchers: Studies and Submissions

Articles in this section 5

Addressing Comments

Sarah Raynor

1 month ago · Updated

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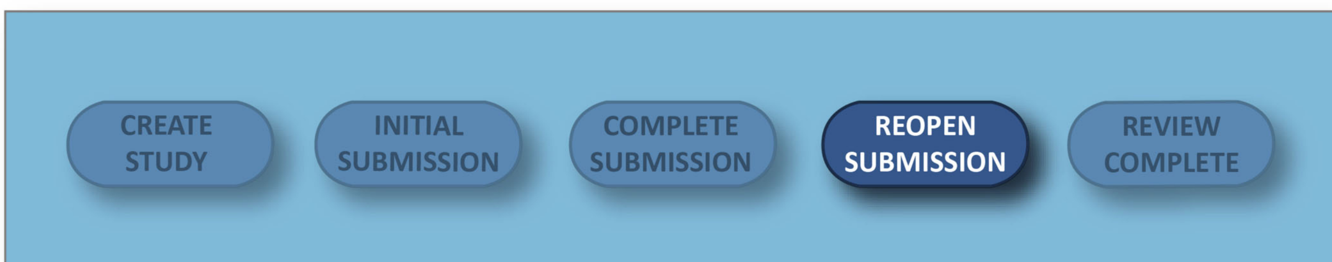
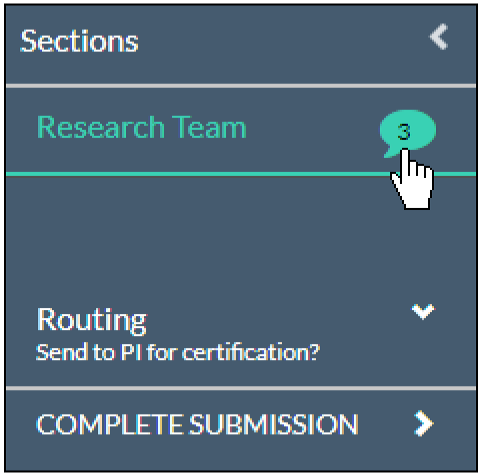


When a submission has been certified by a PI and sent to the IRB Analyst, the Analyst or other individuals reviewing the submission may comment on various questions within the submission forms. The Analyst will return the submission to the investigators, and the inve tigator will need to addre an5y of the comment .

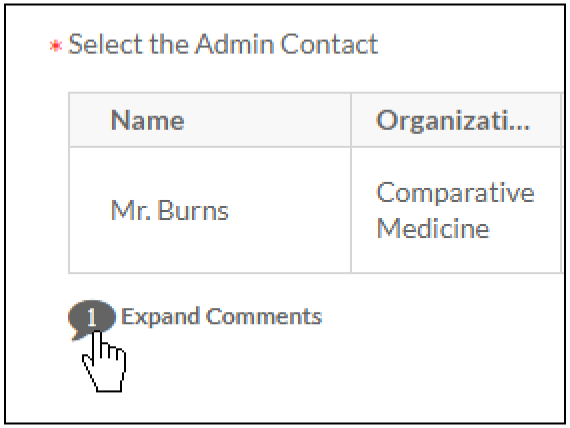
Se5tions with unresolved comments have a comment bubble icon indicating the total number of unresolved comments in that 5 section. Click on the section to see which questions have a comment attached. 5



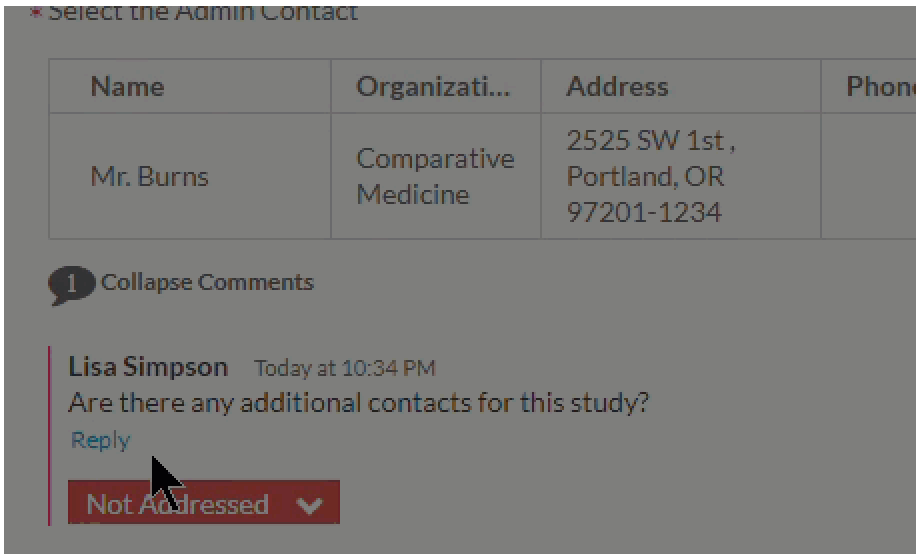
Depending on how far the submission progressed, you may see comments from the IRB Analyst, your Organizational Approver, or 5 from the IRB member(s) reviewing the submission.

Addressing Comments

1. Click on the numbered comment bubble to view the unaddressed comments associated with each question. 5



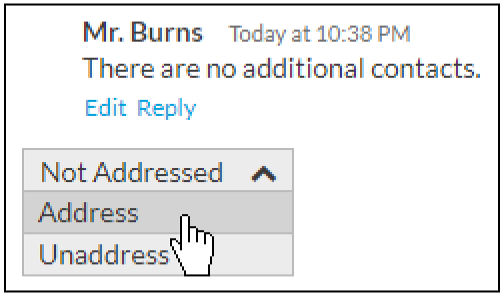
2. Click **Reply**. Enter your reply and click **Save**. 5



3. Once you have resolved an issue, change the status drop-down from 

to 

. 5



You must mark all comments as addressed before the submission can be completed.

Once all comments on the submission have been addressed and the submission has been completed, the PI will need to re-certify the submission to return it to the IRB Analyst. 5

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✓ Yes ✕ No

1 out of 3 found this helpful

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Viewing Submission Details and History :

Sarah Raynor

2 months ago · Updated :

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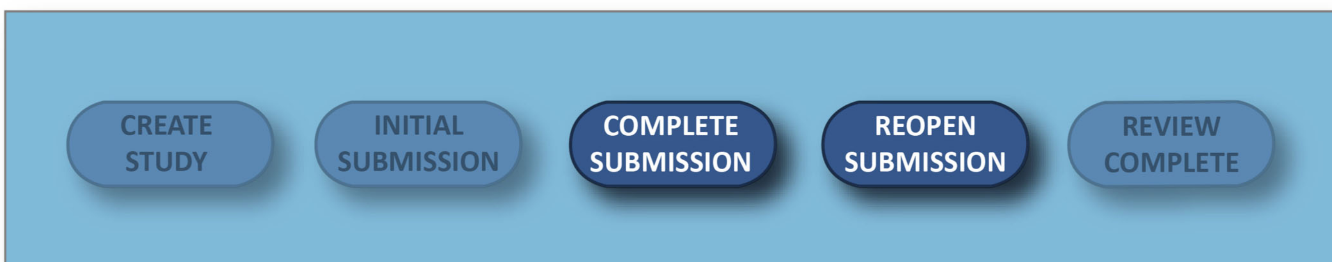
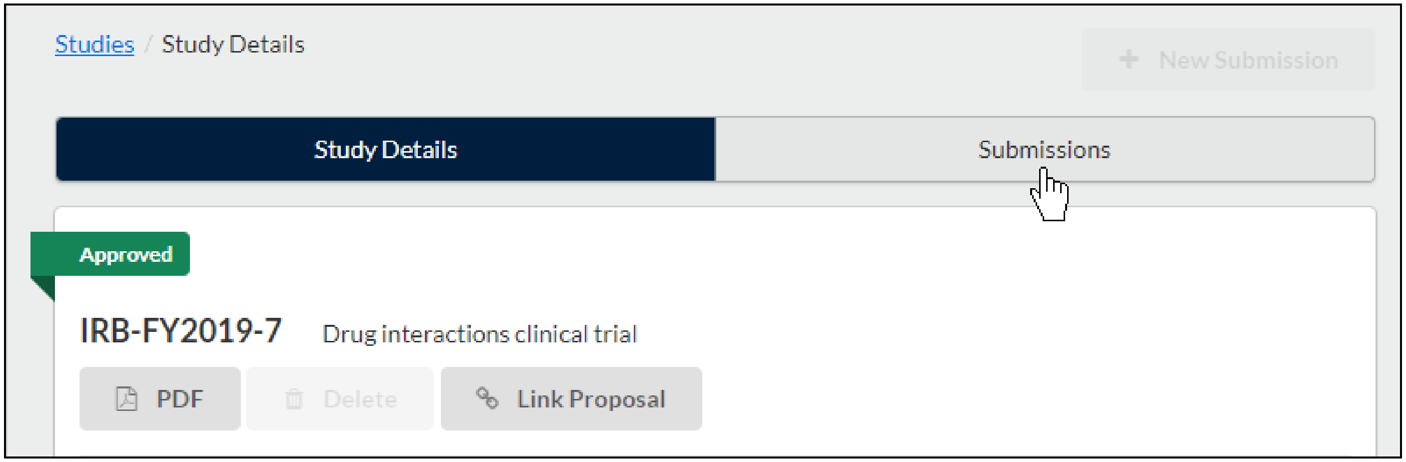


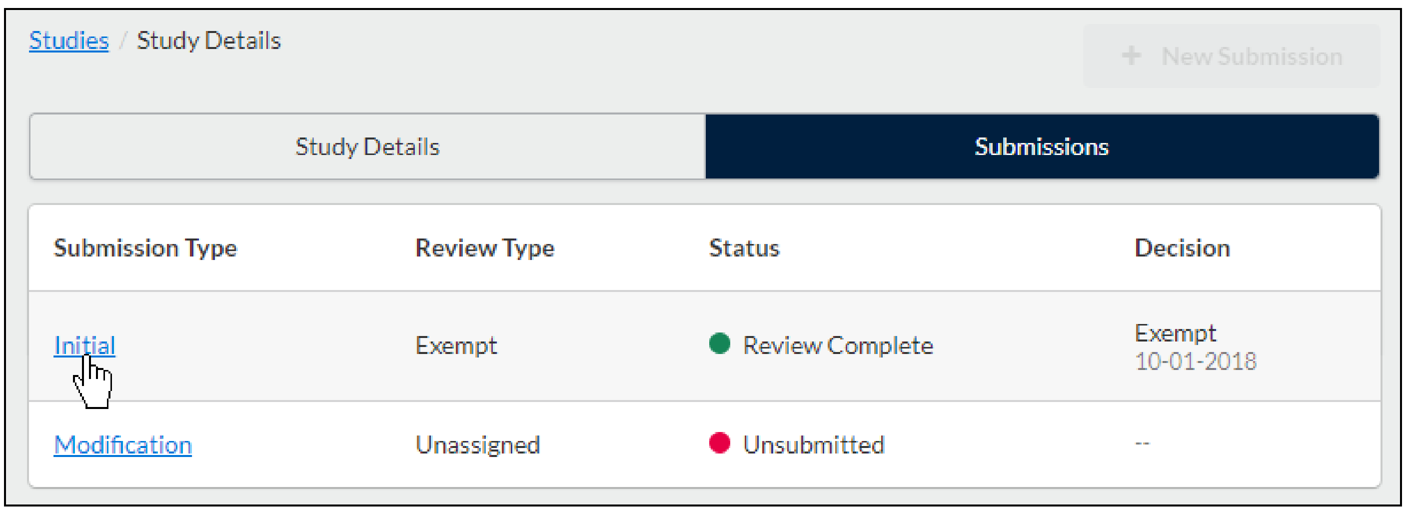
You can access all details and history for a submission within the **Submissions** tab on the **Study Details** page, or from the menu on : your Dashboard.

Fr m S udy De ails

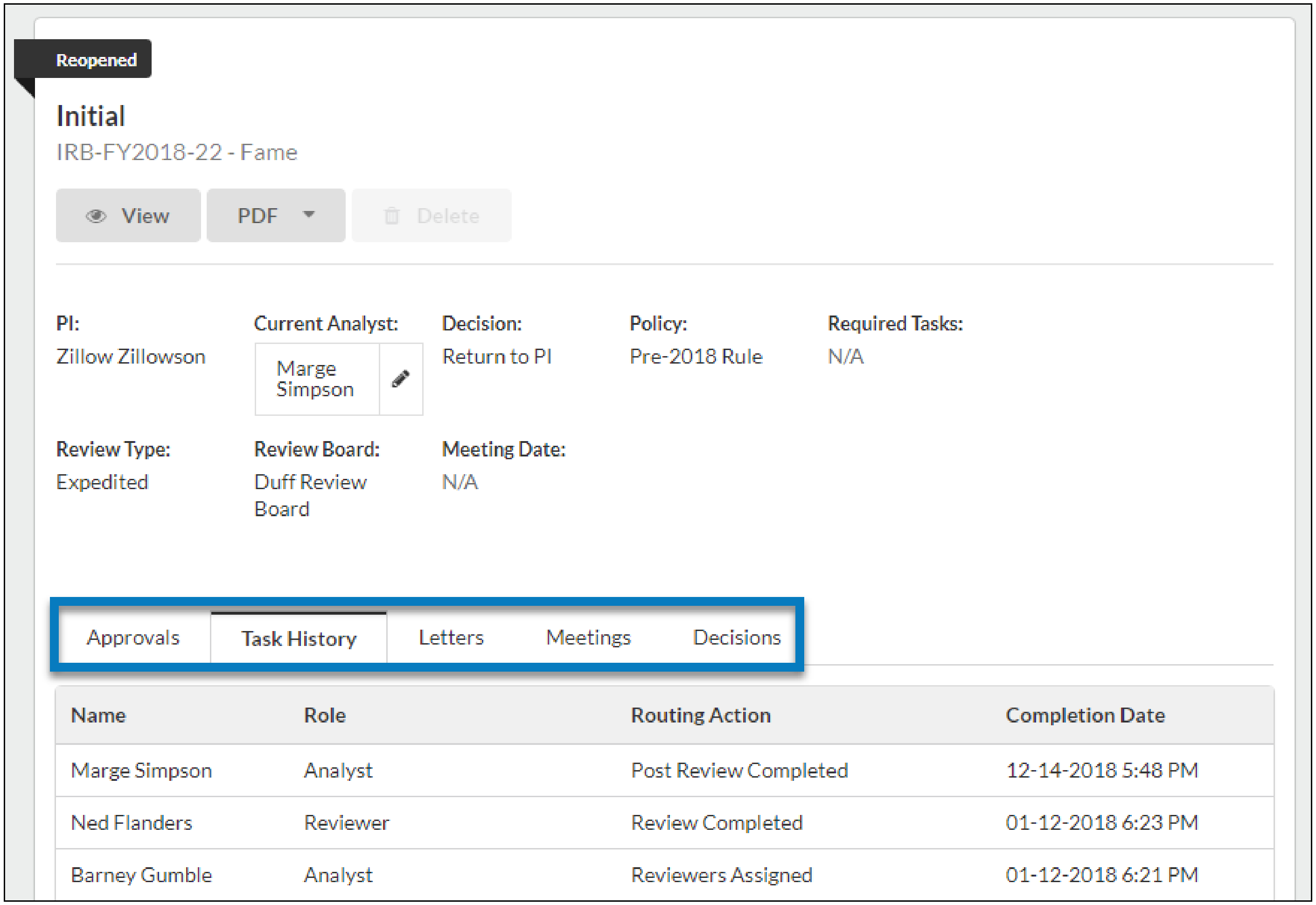
From the **Study Details** page, click on the **Submissions** tab. :



The Submissions tab shows the list of submissions associated with the study, including the submission type, review type and status, : decision, and last modified date. Click on the submission you wish to view. :



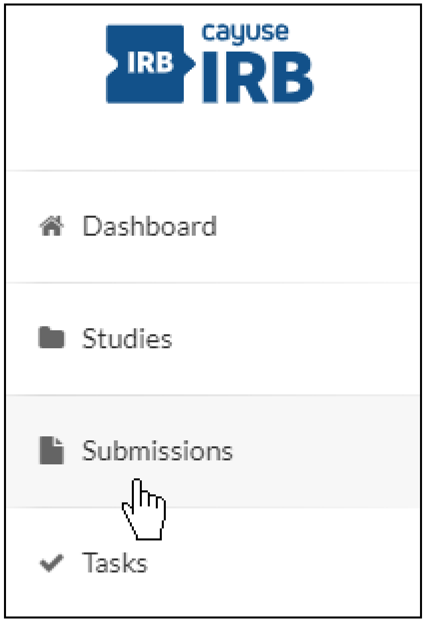
At the bottom of the Submission Details screen, you'll see tabs that vary depending on the submission stage. Tabs may include : **Approvals**, **Task History**, **Letters**, **Meetings**, **Decisions**, and **Linked Proposals**. :



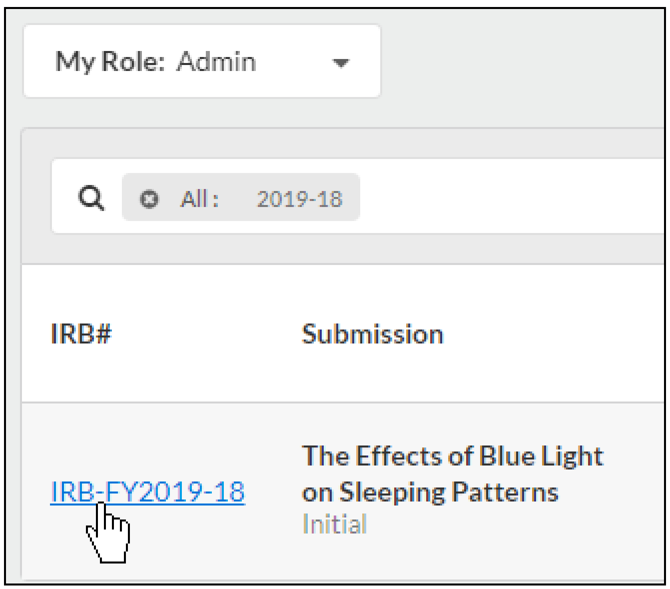
Click on the desired tab to locate the required information.

From Your Dashboard

Click on **Submissions** in the left-hand menu.   :



Search for the: submission you wish to view, and then click on the submission. :



This will bring you to the Submission Details page. :

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Articles in this section c

Linking a Study to Cayuse SP c

Sarah Raynor

2 months ago · Updated c

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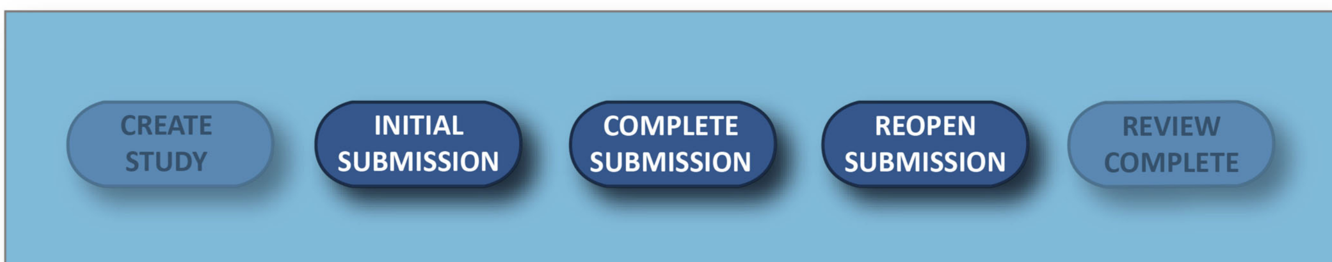
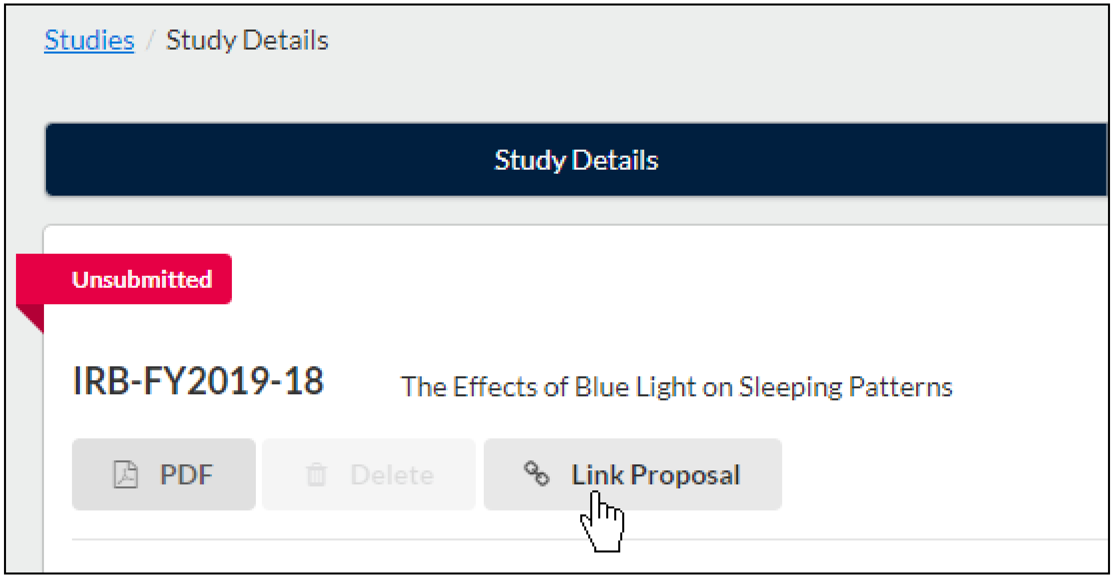


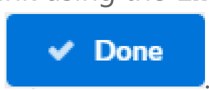
If your institution has purchased Cayuse SP, any Cayuse IRB user now has the option to link each study in Cayuse IRB with one or more proposals in Cayuse SP. c

L nk n cYo r Cay se SP Proposal c

From the Study Details page, click the **Link Proposal** button to launch the **Proposal Finder.** c



Cayuse IRB will automatically search for Cayuse SP proposals associated with the researchers assigned to the study in Cayuse IRB. If c you don't see the proposal you want to link, make sure you have created an initial submission and assigned the PI and researcher(s) c associated with the Cayuse SP proposal. c

Select the study or studies you wish to link using the **Linked** toggle. The toggle will change from  to . When you've linked the appropriate proposal(s), click 

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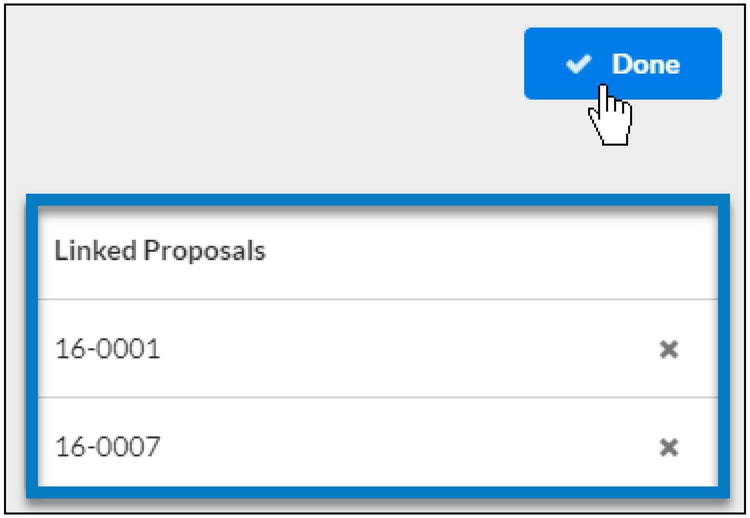
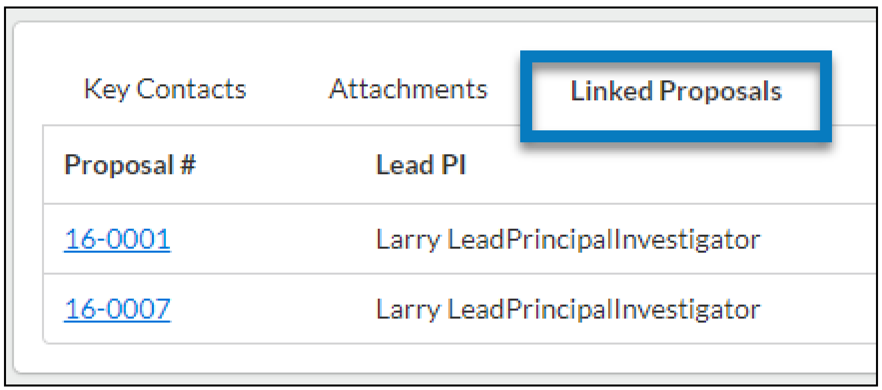
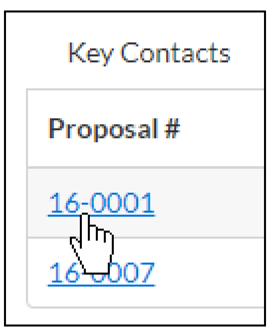


The linked proposal(s) will now appear within the tab on the Study Details page. c



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



nl nk ng our Cayuse SP Proposal

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

c

Was this article helpful? c

✓ Yes ✕ No

2 out of 3 found this helpful

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Search

Articles in this section .

Understanding Submission Types .

Sarah Raynor

2 months ago · Updated .

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When you first create a study, you also create the initial submission outlining the purpose of that study by clicking on **+ New Submission** on the Study Details page.

In addition to this initial submission, there are five other types of submissions that you may submit during the course of your research.

Please note: Each submission type has its own template that the IRB Analyst or Admin needs to configure via the Manage Submission Templates page before the submission type can be created. .

va labl Submiss on Typ s

- **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.

Submission Types 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. .