

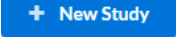
Cayuse How-Tos

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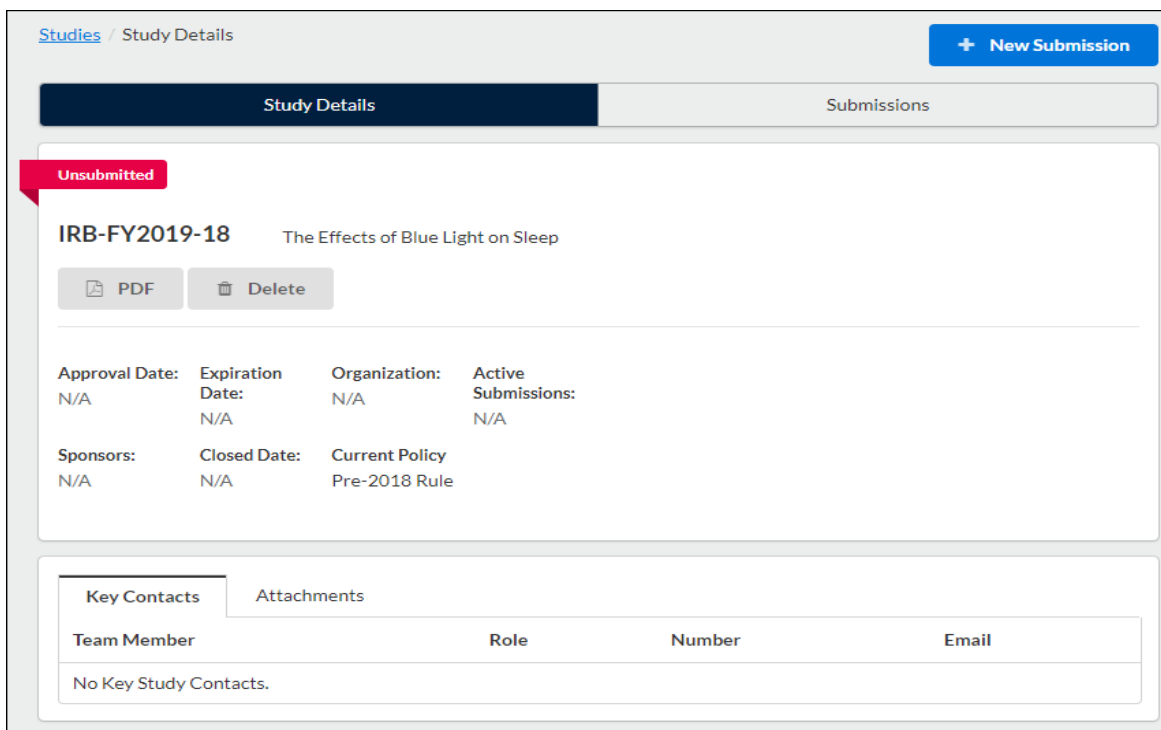
Creating an IRB Application (New Study)


1. Click  in the upper right-hand corner of your Dashboard *or* the Studies page.
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 populate once you begin your submission:





Studies / Study Details 

Study Details Submissions

Unsubmitted

IRB-FY2019-18 The Effects of Blue Light on Sleep

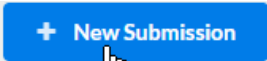
 PDF  Delete

| | | | |
|----------------|------------------|----------------|---------------------|
| Approval Date: | Expiration Date: | Organization: | Active Submissions: |
| N/A | N/A | N/A | N/A |
| Sponsors: | Closed Date: | Current Policy | |
| N/A | N/A | Pre-2018 Rule | |

Key Contacts Attachments

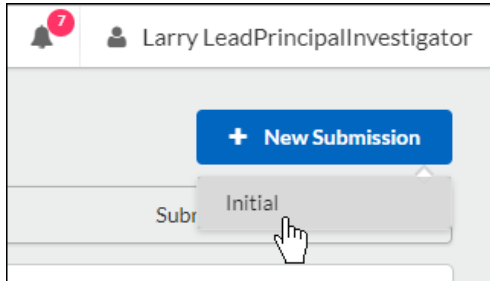
| Team Member | Role | Number | Email |
|------------------------|------|--------|-------|
| No Key Study Contacts. | | | |

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

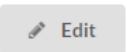
Once you create your study, you can [begin your initial submission](#). Click on  in the upper right-hand corner to start completing your forms.

Filling out an IRB Application (Initial Submission)



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.

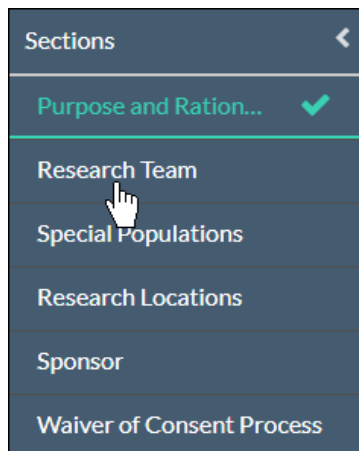


Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission. **Make sure to not remove yourself from all roles and to Save, or you will not be able to access your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

Click on  to begin your submission forms. You will always be able to return to your incomplete submission by clicking this button. Once on the initial submission form, you can return to the Submission Details page by clicking on **Study** in the upper left-hand corner of the screen.



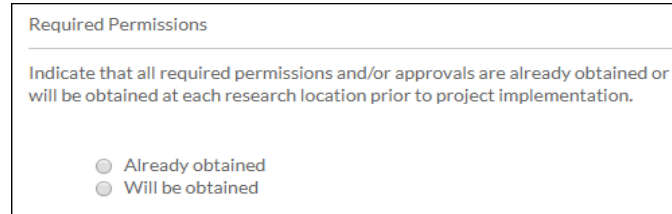
Use the   buttons to toggle between sections. You can also click on a section name in the menu at left to jump to that section:



Application Question Types

There are several types of questions that are included on the submission forms:

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

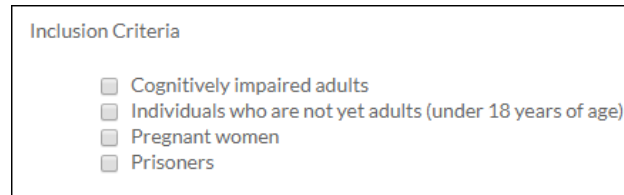


Required Permissions

Indicate that all required permissions and/or approvals are already obtained or will be obtained at each research location prior to project implementation.

Already obtained
 Will be obtained


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




Inclusion Criteria

Cognitively impaired adults
 Individuals who are not yet adults (under 18 years of age)
 Pregnant women
 Prisoners

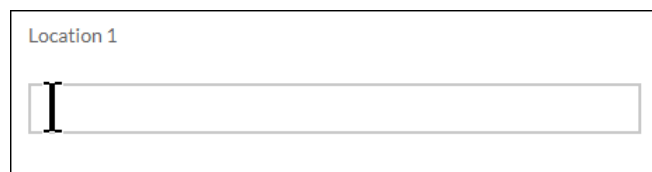
- **Date Picker:** Click within the field to browse for a date.



Start Date

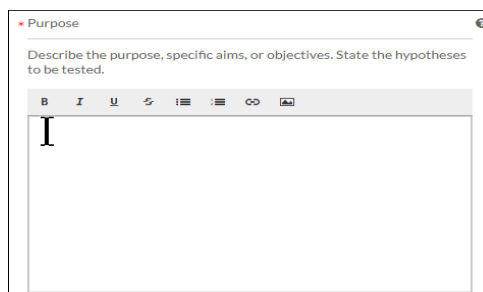


- **Text Box:** Provide a short answer to the stated question (200-character limit). If you need to enter multiple lines of text, the box will expand to fit.



Location 1

- **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.






Purpose

Describe the purpose, specific aims, or objectives. State the hypotheses to be tested.

B *I* U ~~S~~

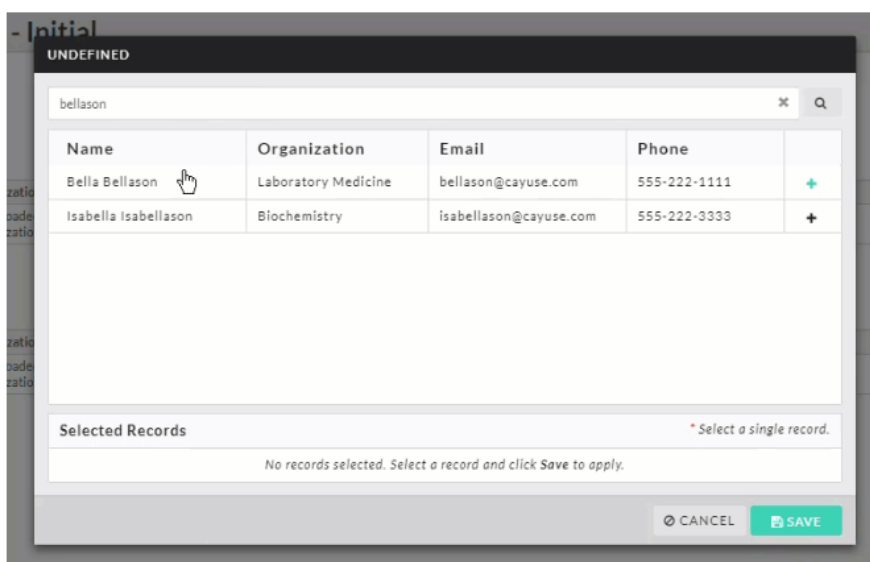
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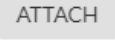
 

- You can also add PNG or JPG images using the image button . Once your image is inserted, you can edit the image by clicking on the image and then clicking **Edit**.
- Person and Sponsor Finders:** While every initial submission will require you to add a Primary Contact and Principal Investigator, you may need to add a faculty sponsor or other people within your submission. Click on the finder button to bring up a search dialogue.



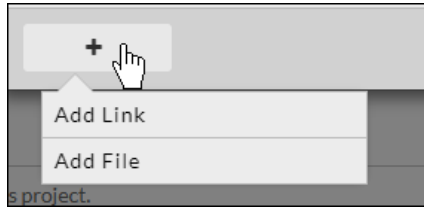
Search for the individual or sponsor that you wish to add, select them, and click **Save**.



- Attachments:** Upload one or more files to the study by clicking . 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, xlsxm |
| Microsoft PowerPoint | ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm |

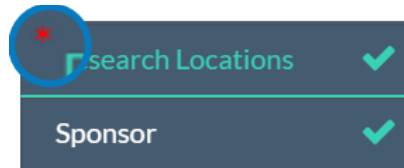
You can also include hyperlinks as "attachments" by choosing **Add Link** from the + drop-down menu.



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:

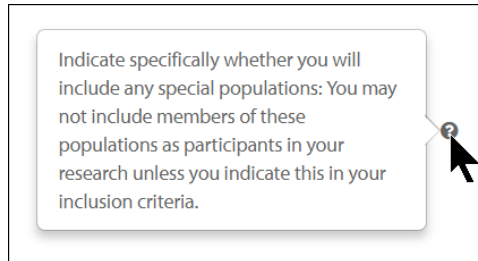


To save your changes, click  **SAVE** in the upper right-hand corner.

General How-To Questions

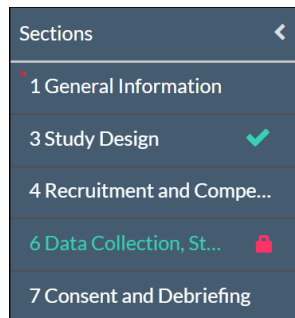
How do I find help within the application?

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



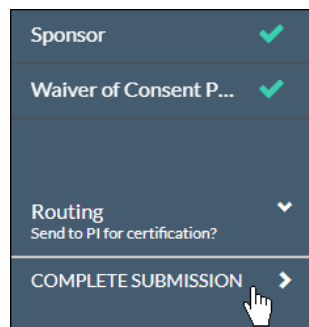
Why is there a red lock on a section?

Please note: Cayuse IRB will warn you with a red lock icon if another user is currently editing a section. You won't be able to edit that section until they're done with their edits.

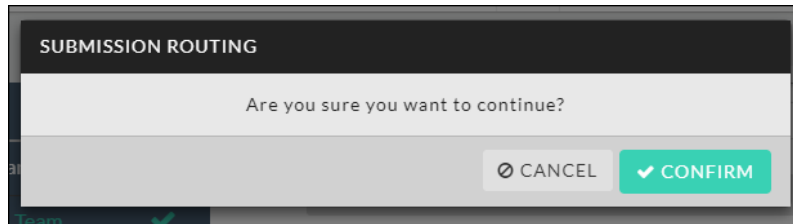


How do I submit my application?

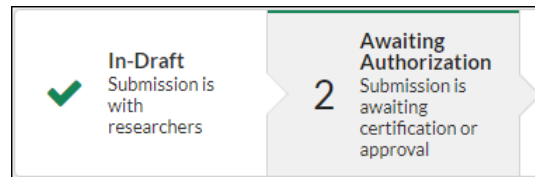
The **Complete Submission** button will only appear when you have green check marks next to all of your sections. If one of your sections doesn't have a check mark and you aren't sure why, click on the section to search for any required questions you may have missed. Once you have filled out every section of your submission and have added all required attachments, a **Complete Submission** option appears beneath **Routing** within the menu:



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

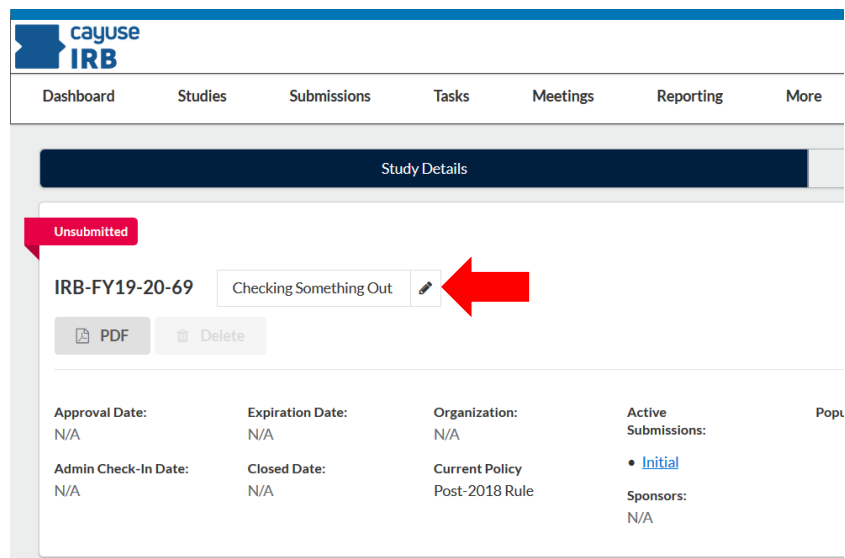


Upon confirmation, the status of your submission will change on the Submission Details page:



How do I change my study title?

To change your study title, you will need to go to the study details page and click on the pencil to the right of the existing title. Then, make your edits, and click the green check:



Certifying and Returning an Application

Once you have clicked “complete submission,” your application is sent to the PI and other study personnel for certification. Research team members will receive an email letting them know that the submission needs to be certified. When a researcher or faculty sponsor certifies the submission, they are asserting the submission is complete and accurate and are accepting their researcher/faculty sponsor responsibilities.

If the PI or the faculty sponsor 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 all study personnel have certified the submission, the submission will be routed to the IRB. The submission may be returned at any point for edits or clarification.

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: Liberty University requires 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.

Faculty Sponsor: Liberty University requires that the faculty sponsor on the study also certifies the submission. These individuals also have the ability to return to the submission to the researcher/research team.

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.

How to **review** and **certify** a submission:

You should receive an email instructing you to certify the submission (remember to check your junk folder if you do not see an email):

DATE: Jan 13, 2020 3:33 PM EST

RE: Initial Submission Requires Certification

STUDY #: IRB-FY19-20-73

STUDY TITLE: Certify this Study!

The Initial submission for the above-referenced study has been completed. This submission requires your approval as a member of the research team before it can be submitted to the Liberty University IRB. Please log into Cayuse IRB [Cayuse IRB](#); review and certify this submission.

Thank you,
Research Ethics Office
434-592-5530

If you click the link, you will be prompted to log in to Cayuse IRB. Log in and navigate to the dashboard.

You can then access the study by selecting the task in your **notifications** or by clicking on the study in the “**My Tasks**” tab:

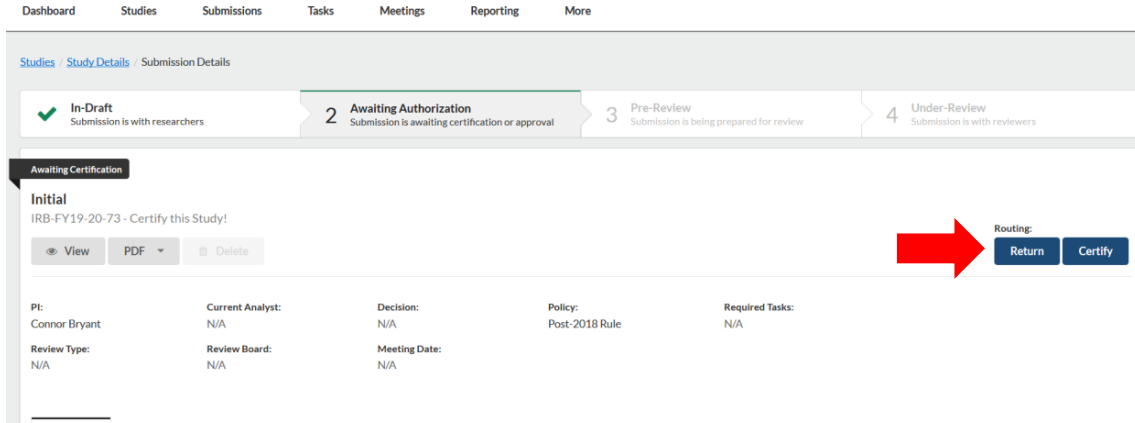
The screenshot shows the Cayuse IRB dashboard. At the top right, there is a 'Role:' label with a red arrow pointing to a notification icon with a '10' badge. Below the navigation tabs (Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, More), there are four task cards: 'In-Draft' (2), 'Awaiting Authorization' (1), 'Pre-Review' (1), and a partially visible 'U' card. Below these are three panels: 'My Studies' with a list of studies, 'My Tasks' with a list of tasks, and 'Submissions by Type' with a list of submission types. A red arrow points from the 'Certify this Study!' task in the 'My Tasks' panel to the 'Certify this Study!' study in the 'My Studies' panel.

Select the study that needs to be reviewed and certified. You will then be taken to the submission details page. Once on the submission details page, you will need to review the study. You can do this by clicking **view** or by downloading a **pdf** version of the application:

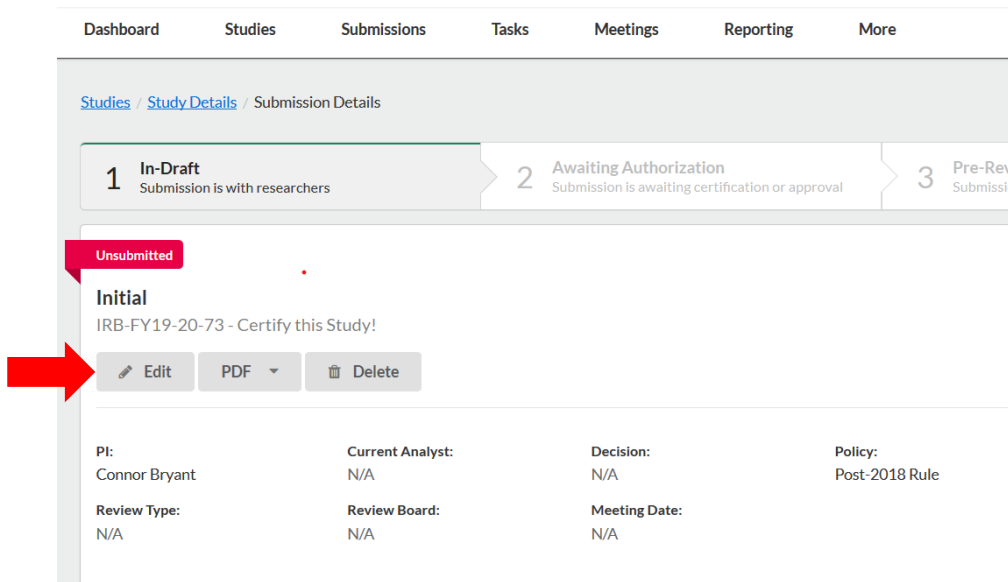
The screenshot shows the submission details page. At the top, there is a progress bar with four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Authorization (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). Below the progress bar, there is a section for 'Awaiting Certification' with the study title 'Initial IRB-FY19-20-73 Certify this Study!'. A red arrow points to the 'View' button, and another red arrow points to the 'PDF' button. To the right, there are 'Return' and 'Certify' buttons. Below this, there is a table of metadata:

| | | | | |
|----------------------|-------------------------|----------------------|---------------------------|------------------------|
| PI: Connor Bryant | Current Analyst: N/A | Decision: N/A | Policy: Post-2018 Rule | Required Tasks: N/A |
| Review Type: N/A | Review Board: N/A | Meeting Date: N/A | | |

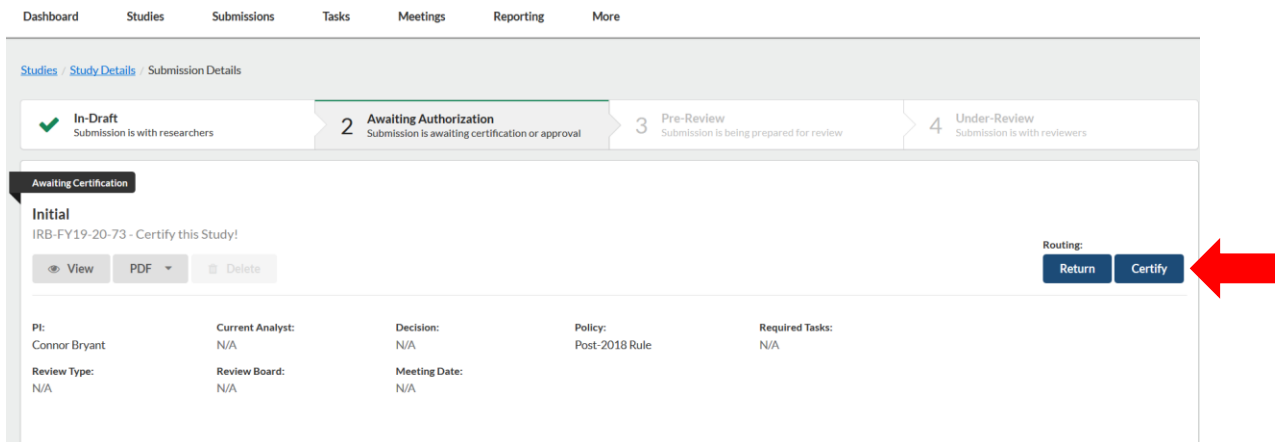
If after reviewing the study you find that edits need to be made, click **return**:



Once **return** is selected, any member of the study team will be able to make edits to the application:




If after reviewing the study you find that it is ready for submission to the IRB, click **certify**:

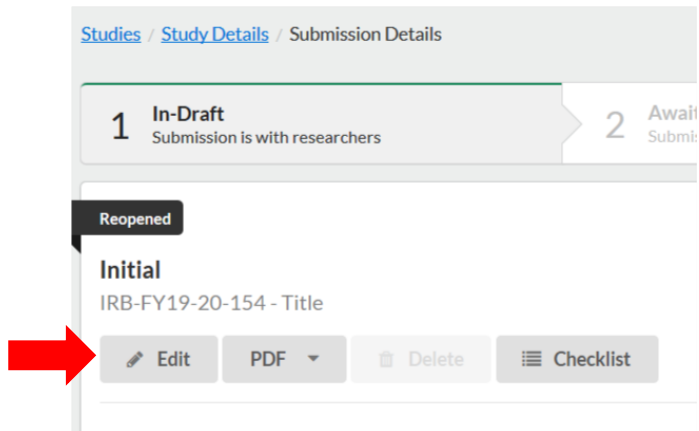


How to Find and Respond to Revision Requests

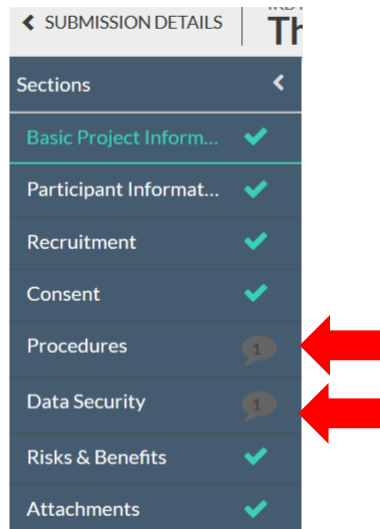
When your study is returned to you in Cayuse IRB, you will need to re-open your study and find the revision request comments. To re-open your study, go to your Cayuse dashboard, and click on “My Tasks.” Your study should appear in this tab. The task should state “Complete Submission.” **Click on the study in need of revisions:**

| IRB# | Task | Study Title |
|-------------------------------------------------------------------------------------------------------------------|---------------------|--------------|
| IRB-FY19-20-97 | Certify Submission | MPH Training |
|  IRB-FY19-20-127 | Complete Submission | Test Study |

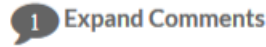
Once you are on the study details page, **click on “edit” to re-open your study:**



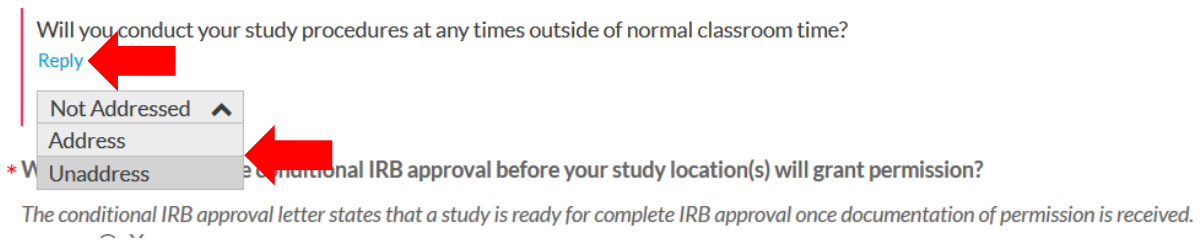
Once you have opened your study, **revision comments appear to the right of the sections** with a comment bubble and the number of revisions requests in that section:



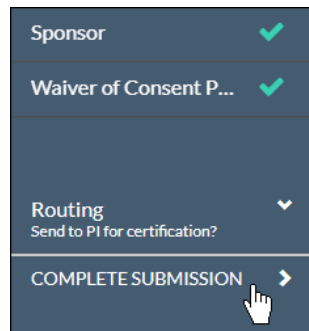
To make revisions, **click on the section with the revision request comments**. You should then be able to see where exactly a revision was requested by looking for the numbered comment bubble:



You will then have the option to **make the change within the application itself, or reply to the reviewer's comment** directly. Once you have addressed the revision request, you can mark the revision request as "Addressed."

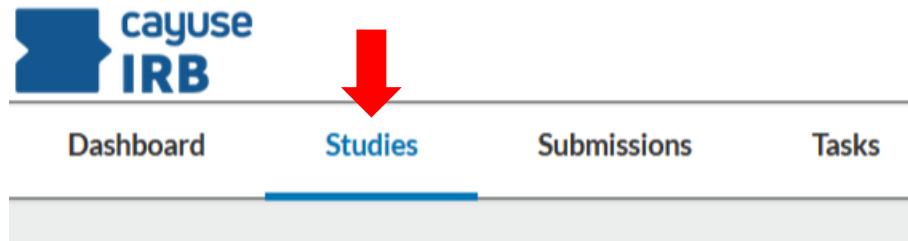


Once all revision requests have been addressed, each section should have a green check mark, and the "Complete Submission" button should appear underneath the application sections. Click **complete submission to re-submit the application**. You and your faculty chair (*if applicable*) will once again be asked to **certify the submission**. Once certified, the IRB receives the revised application for review:

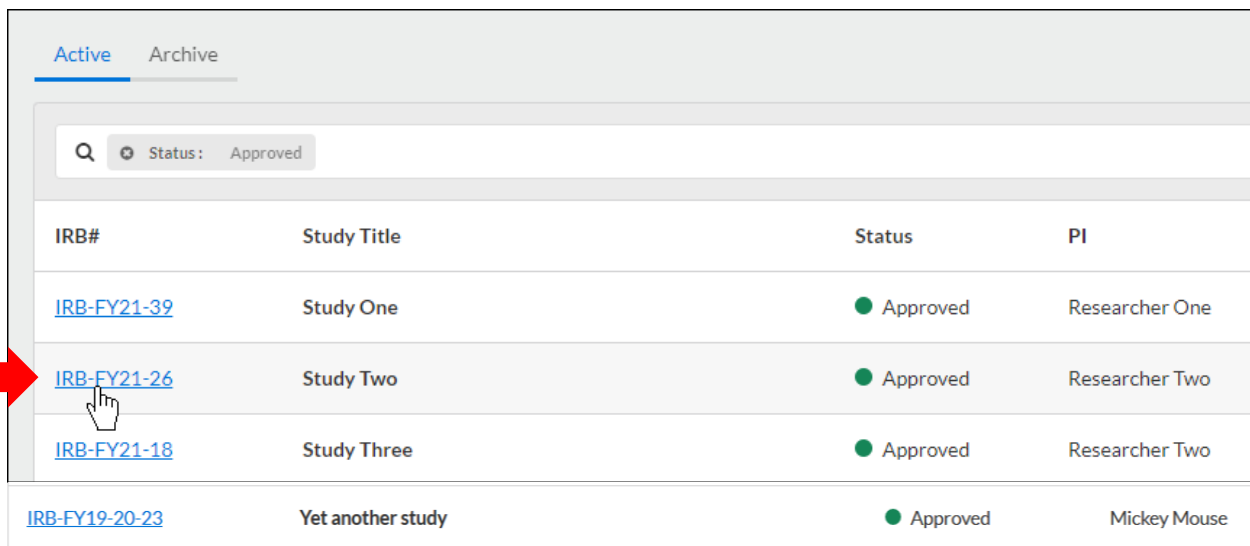


How to Make Changes to an Approved Study (Modification)

To make changes to an approved study, you will need to create and submit a modification submission. To start, find the study that you need to make changes to by **clicking on the studies tab**:



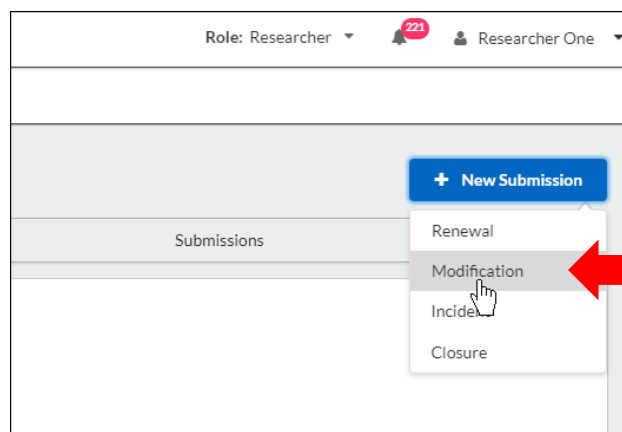
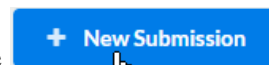
Next, **click on the specific study** you need to change:



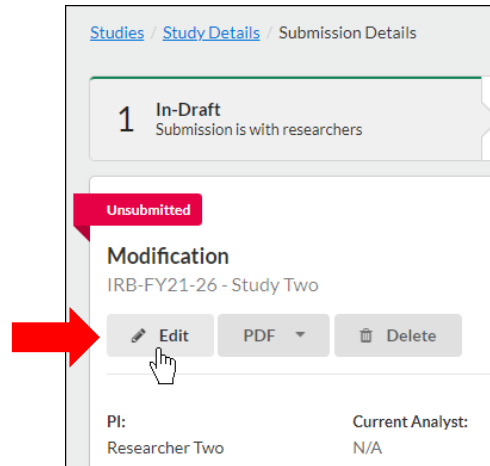
The screenshot shows the 'Active' tab of the Cayuse IRB interface. A search bar contains 'Status: Approved'. A table lists several studies. A red arrow points to the study with IRB# 'IRB-FY21-26'.

| IRB# | Study Title | Status | PI |
|--------------------------------|-------------------|------------|----------------|
| IRB-FY21-39 | Study One | ● Approved | Researcher One |
| IRB-FY21-26 | Study Two | ● Approved | Researcher Two |
| IRB-FY21-18 | Study Three | ● Approved | Researcher Two |
| IRB-FY19-20-23 | Yet another study | ● Approved | Mickey Mouse |

This takes you to the **study details** page. Once on this page, click the **New Submission** button. You will then want to select **modification**:



Click on **Edit** to begin your submission:



Once you click **edit**, you will be asked whether or not a modification is *actually* required (based on a list of provided examples). If after reviewing the list, you determine that a modification is **not** necessary, **please select “No”** and delete the modification submission.

*** Based on the above information, do you need to make changes to the project?**

Yes
 No

If you determine that a modification **is necessary**, you will need to answer “Yes.” You will then be provided with an exact copy of your original, approved submission. You will then be able to click through the application to make any changes to this copy.

*** Based on the above information, do you need to make changes to the project?**

Yes
 No

Once you have made the necessary changes, you will need to **click “Complete Submission”** and then **certify your submission**:

