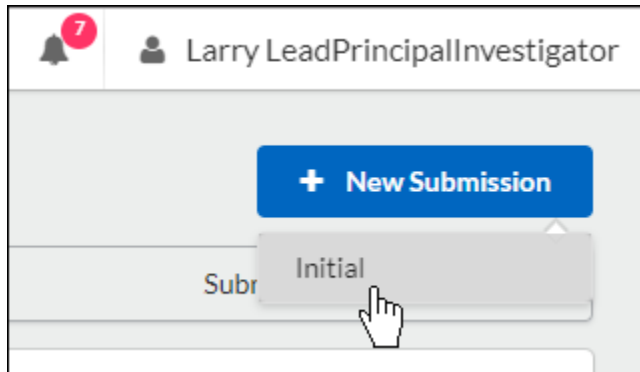
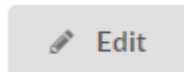


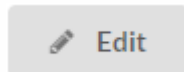
## Creating an Initial Submission

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 Save, or you will not be able to access your submission once you leave.**

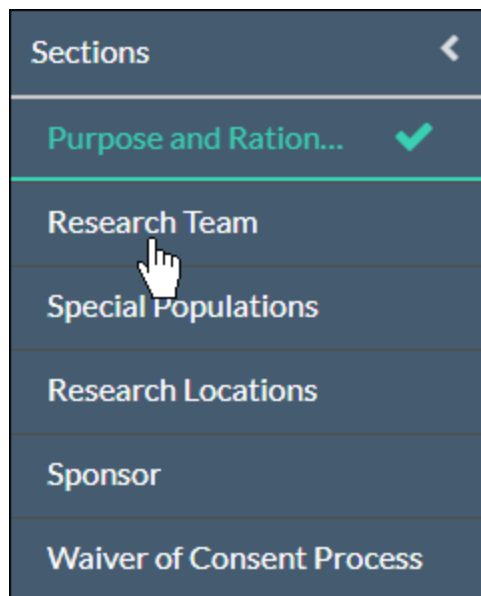


Click on  to begin your submission forms. You will always be able to return to your incomplete submission by click this button.

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.



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.

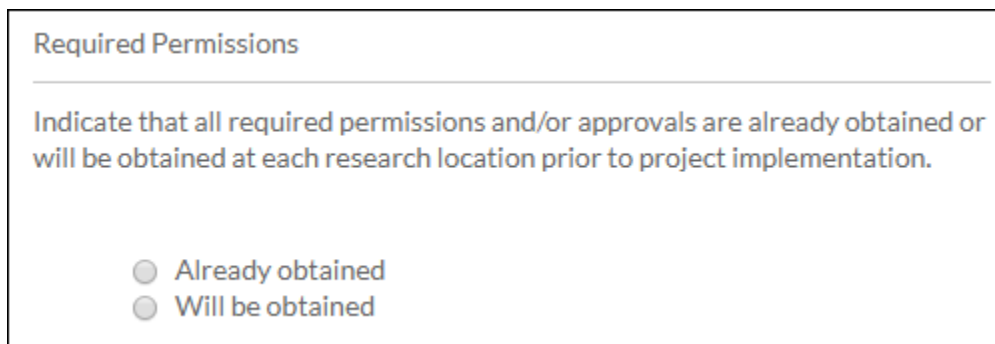


- Sections
- Purpose and Ration... ✓
- Research Team
- Special Populations
- Research Locations
- Sponsor
- Waiver of Consent Process

## Completing Submission Forms

There are several types of questions that you may see on the submission forms:

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



Required Permissions

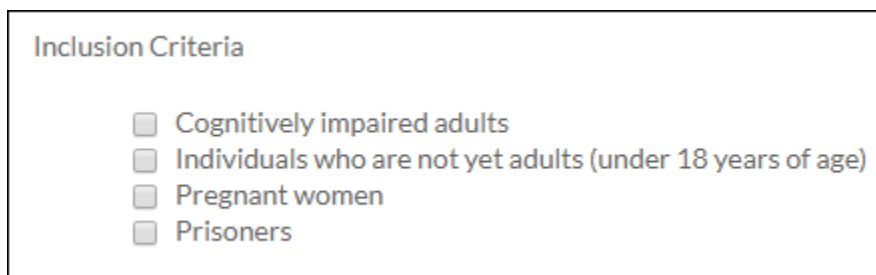
---

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

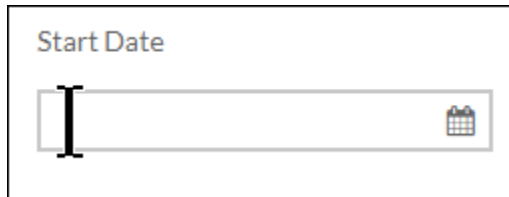
☐ Cognitively impaired adults

☐ Individuals who are not yet adults (under 18 years of age)

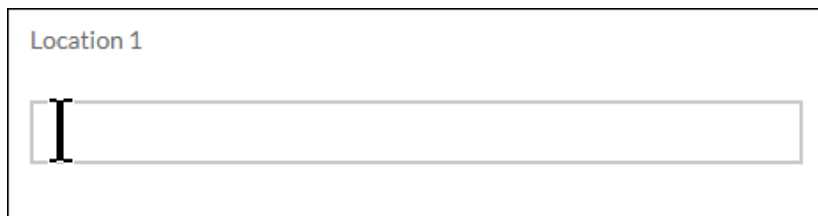
☐ Pregnant women

☐ Prisoners

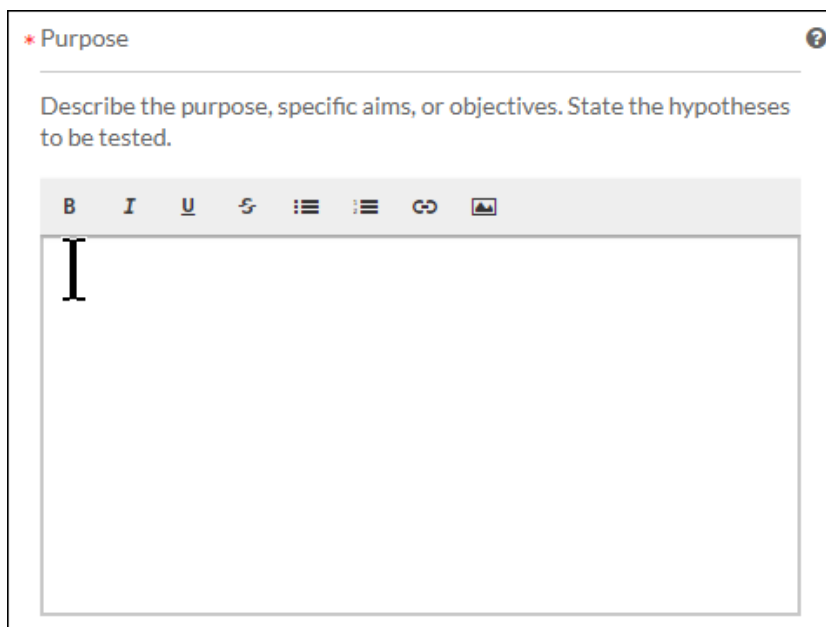
- **Date Picker:** Click within the field to browse for a date.


A form field labeled "Start Date" in blue text. Below the label is a text input box with a large black cursor at the start. To the right of the input box is a small calendar icon.

- **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.

A form field labeled "Location 1" in blue text. Below the label is a single-line text input box with a large black cursor at the start.

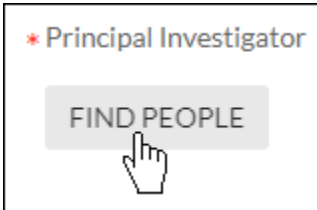
- **Text Area:** Provide a detailed answer to the stated question. You can use formatting such as bold, italics, underline, strikethrough, bulleted lists, numbered lists, and hyperlinks.

A form field titled "Purpose" with a red asterisk and a help icon. Below the title is a description: "Describe the purpose, specific aims, or objectives. State the hypotheses to be tested." Below the description is a rich text editor toolbar with icons for bold (B), italic (I), underline (U), strikethrough (ABC), bulleted list, numbered list, link, and image. Below the toolbar is a large text area with a large black cursor at the start.

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:** Every initial submission will require you to add a Primary Contact and Principal Investigator. Use this section to add other people or sponsors to different sections 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.

Name	Organization	Email	Phone	
Bella Bellason	Laboratory Medicine	bellason@cayuse.com	555-222-1111	+
Isabella Isabellason	Biochemistry	isabellason@cayuse.com	555-222-3333	+

**Selected Records** \* Select a single record.

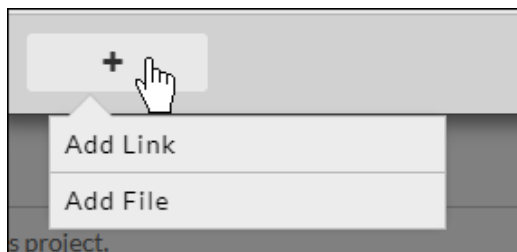
*No records selected. Select a record and click Save to apply.*

- **Attachments:** Upload one or more files to the study by clicking
- Human Ethics supports the following file types:

ATTACH

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

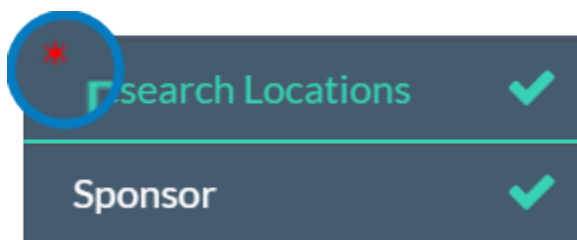
You can also include hyperlinks as "attachments" by choosing **Add Link** from the + drop-down menu.



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

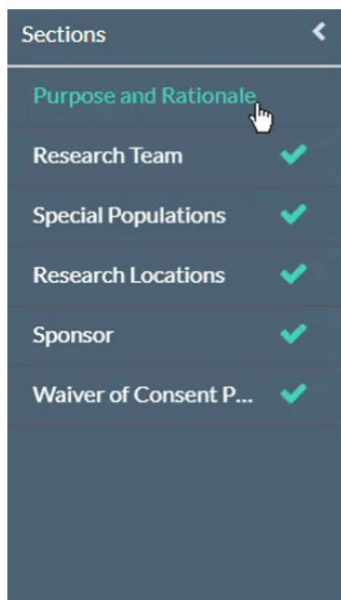
**Please note:** Some questions have \* next to the question number. This indicates a required question.

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



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

The **Complete Submission** button will only appear when you have 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.



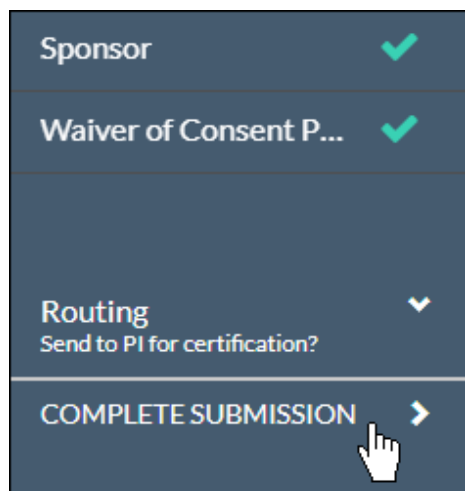
## Purpose and Rationale

### \* Purpose

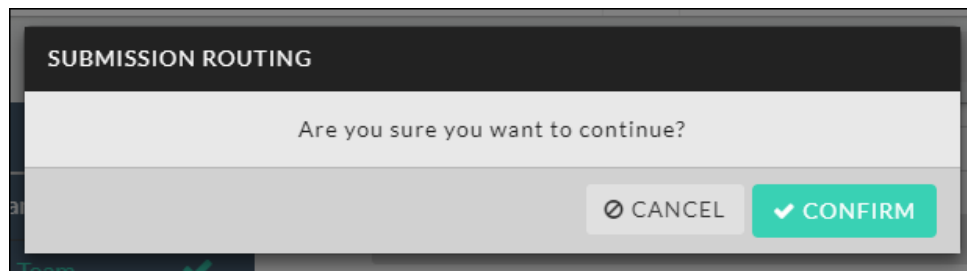
Describe the purpose, specific aims, or objectives. State the hypot

B I U

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



## 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.

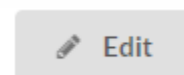
Once the PI has certified the submission, the submission will be routed to the IRB Administrator. The submission may be returned at any point for edits or clarification.

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

**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.

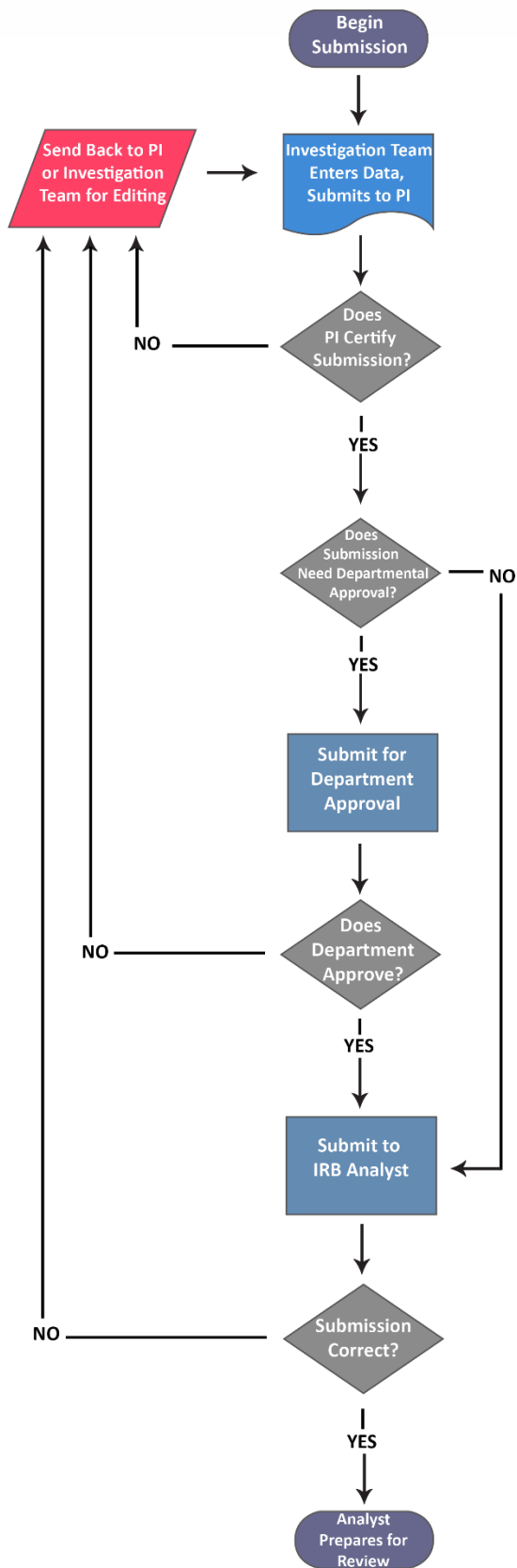
## Reopening Your Submission

To reopen the submission and make edits, click on the




button within Submission Details.

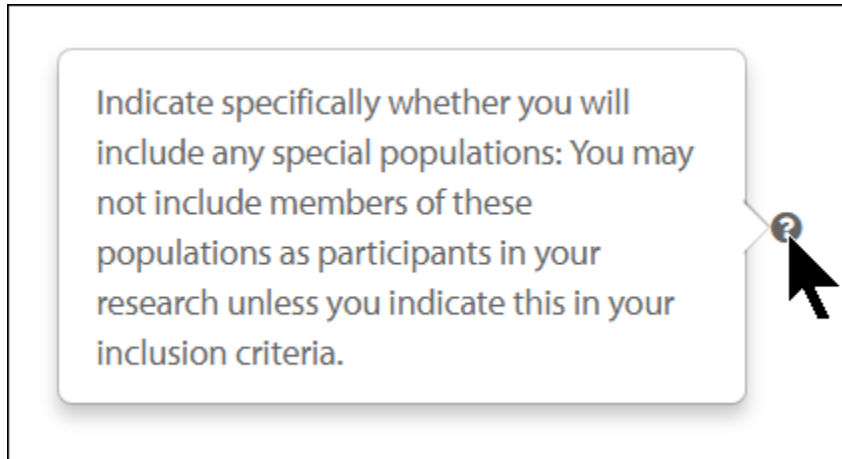
# Submission Routing





## Help with Questions

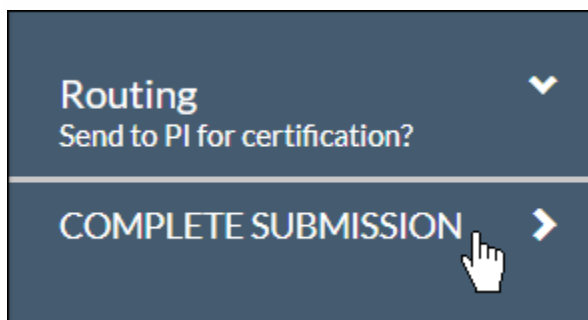
If there is help text for a question, you can click on the  button to view the additional information for that question.



Once there are 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.



**Please note:** Human Ethics 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.

## Sections



\* 1 General Information

3 Study Design



4 Recruitment and Compe...

6 Data Collection, St...



7 Consent and Debriefing

## Creating an Initial Submission

1. 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.
  - a. 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.**
2. Click on *Edit* to begin your submission forms. You will always be able to return to your incomplete submission by clicking this button.
  - a. 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.
  - b. 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.
3. Completing Submission Forms – there are several types of questions that you may see on the submission forms:
  - a. **Radio Buttons:** Select one of the available options.
  - b. **Check Boxes:** Select one or more of the available options.
  - c. **Date Picker:** Click within the field to browse for a date.
  - d. **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.
  - e. **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.
    - i. 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*.
  - f. **Person and Sponsor Finders:** Every initial submission will require you to add a Primary Contact and Principal Investigator. Use this section to add other people or sponsors to different sections within your submission. Click on the finder button to bring up a search dialogue.
    - i. Search for the individual or sponsor that you wish to add, select them, and click *Save*.
  - g. **Attachments:** Upload one or more files to the study by clicking 'ATTACH'. Human Ethics supports the following file types:

- i. **Text** – txt
- ii. **Adobe** – PDF
- iii. **Raster image formats** – png, bmp, gif, tif, tiff, jpg, jpeg, jp2, jpx
- iv. **Vector image formats** – wmf, emf, svg
- v. **Microsoft Word** – doc, docx, docm
- vi. **Microsoft Excel** – xls,xlsx, xlsxm
- vii. **Microsoft PowerPoint** – ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm
- viii. You can also include hyperlinks as "attachments" by choosing Add Link from the + drop-down menu.
  - 1. To delete an attachment, click the 'X' icon next to the attachment
- h. Please note: Some questions have \* next to the question number. This indicates a required question.
- i. Sections with unsaved changes have an asterisk next to the section name.
- j. To save your changes, click 'SAVE' in the upper right-hand corner.
- k. The *Complete Submission* button will only appear when you have 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.
- l. 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.
  - i. After clicking Complete Submission, you will be prompted to *Confirm or Cancel*.
  - ii. Upon confirmation, you will see the status of your submission change on the Submission Details page.

#### 4. Certification

- a. 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.
- b. 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.

- c. Once the PI has certified the submission, the submission will be routed to the IRB Administrator. The submission may be returned at any point for edits or clarification.
  - d. **Completing Submission as a PI:** If you are a PI completing your submission, you should be able to then certify the submission right away.
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- a. To reopen the submission and make edits, click on the 'Edit' button within Submission Details.
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- a. If there is help text for a question, you can click on the '?' button to view the additional information for that question.
  - b. Once there are check marks next to all of your sections, you have completed the submission forms and are ready for routing.
  - c. **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.
  - d. With every section completed, you can [complete your submission and send it to the PI for certification](#).
  - e. **Please note:** Human Ethics 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.