



Cayuse Human Ethics User Guide

Villanova's Office of
Research Protections

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Important Deadline Information

- Remember you need to schedule time for organizational approvals when submitting your applications.
- Monthly deadlines for the submission of protocols that will undergo Full Board review are available on the [IRB Website](#).

How do I log on to Cayuse?

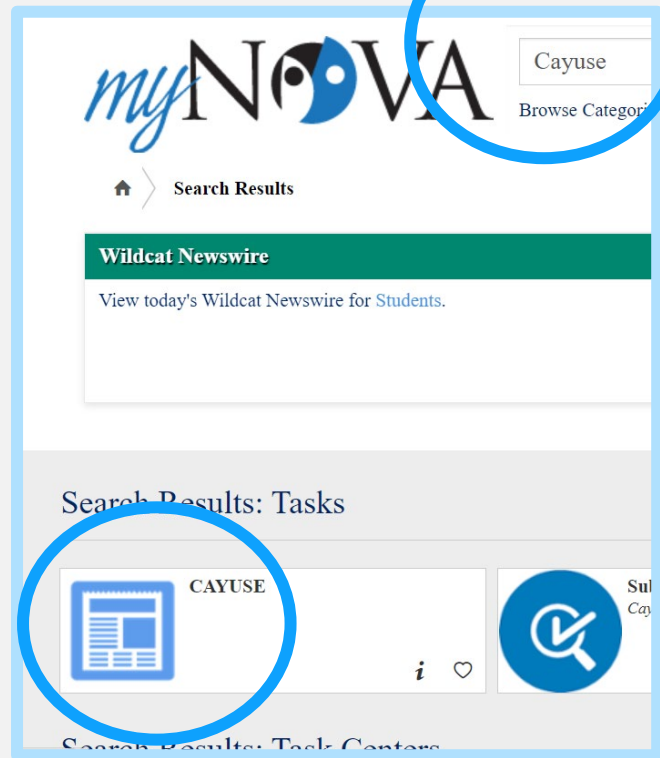
1. Email resadmin@villanova.edu to gain access to Cayuse.

2. Go to MyNova and search “Cayuse.”

3. Select the Cayuse link.

4. Sign on using Villanova username and password.

5. Select Cayuse IRB (Human Studies Compliance)

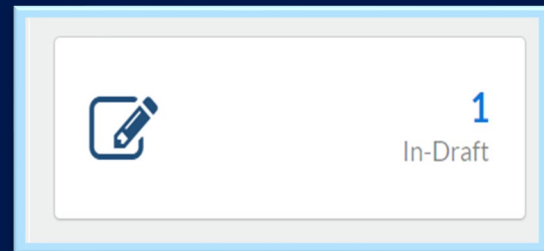


Research Administration Modules

- Cayuse SP (Sponsored Projects)
- Cayuse IRB (Human Studies Compliance)

How do I navigate the dashboard?

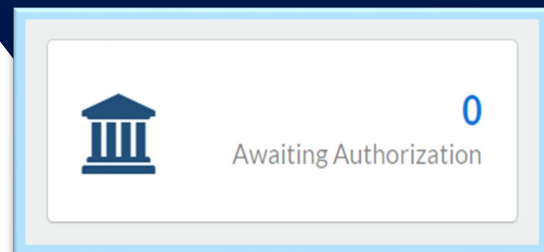
1. **In Draft:** includes studies PIs have not yet submitted and studies returned to PI with comments



1
In-Draft

The card features a pencil icon on the left and the text '1 In-Draft' on the right.

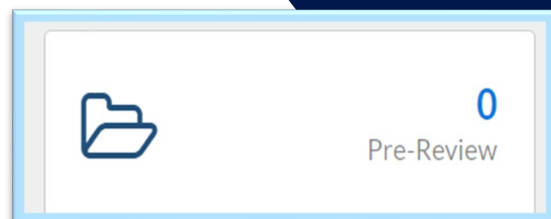
2. **Awaiting Authorization:** includes studies that are awaiting certification with organizational approver from department or college.



0
Awaiting Authorization

The card features a classical building icon on the left and the text '0 Awaiting Authorization' on the right.

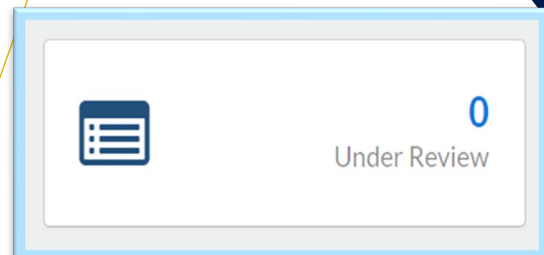
3. **Pre-Review:** includes studies that ORP are currently pre-reviewing before assigning to a reviewer.



0
Pre-Review

The card features a folder icon on the left and the text '0 Pre-Review' on the right.

4. **Under Review:** includes the studies that are currently with a reviewer.



0
Under Review

The card features a list icon on the left and the text '0 Under Review' on the right.

5. **Submission by Type:** to see the amount of submissions by type

6. **My Tasks:** see any outstanding tasks regarding active studies

7. **My Studies:** total amount of studies

Submissions by Type	
Initial	1
Withdrawal	0
Modification	0
Renewal	0
Incident	0
Closure	0
Legacy	0

My Tasks	
IRB-FY2019-49	Complete Submission

My Studies	
IRB-FY2019-49	test
IRB-FY2019-48	test

How do I check the status of my application?

Awaiting Certification

Incident

IRB-FY2022-166 - Cayuse

Routing:

Return

Certify

Awaiting Org Approval

Initial

IRB-FY2020-229 - EC

Approvals

Task History

Name

Caitlin St. Amour

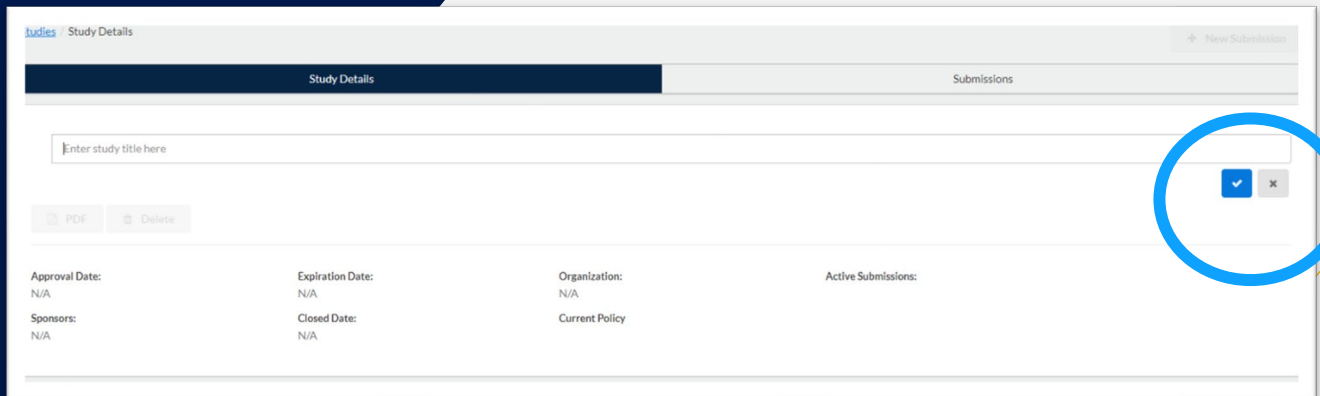
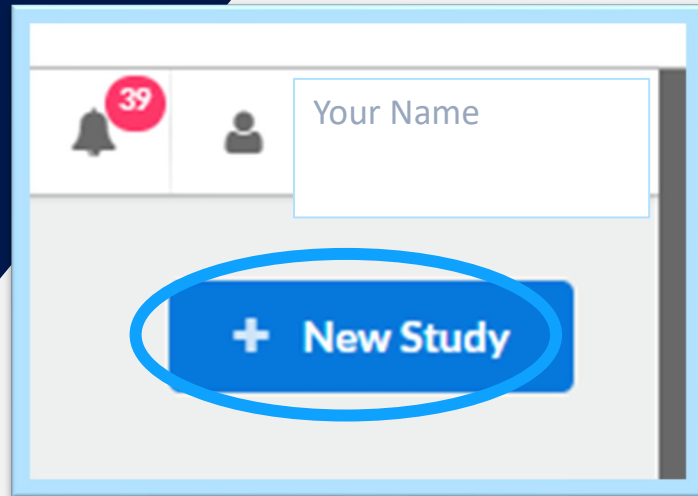
1. The “Awaiting Certification” icon means the submission needs to be certified by the PI. Click the blue “certify” button on the Submission Details page.

The “Awaiting Org Approval” icon means the submission needs to be approved by an organizational approver.

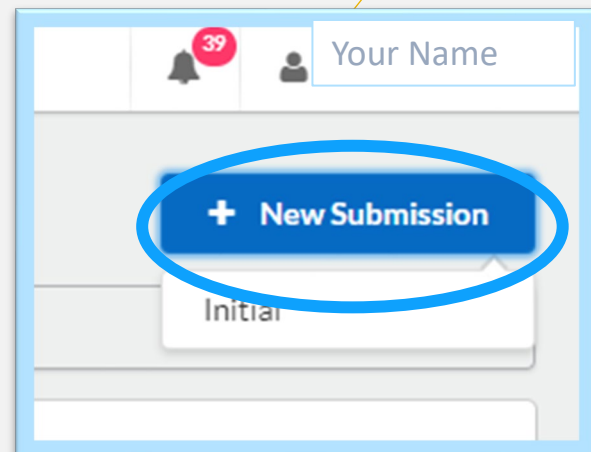
2. Select the Approvals tab to determine the status of the submission. The different sections (i.e. “research team” and “org approvers”) will list who needs to certify or approve the submission, respectively.

How do I create a study?

1. Click the blue “+ New Study” button in the upper right-hand corner. This will create a new folder. Enter the title in the text box then click on the blue check box.



2. Click the blue “+ New Submission” button in the top right-hand corner then select “Initial”. This will begin a new study submission.



3. The individual filling out the submission will automatically be assigned as the PC or Primary Contact, which is why the Assign PC button is crossed off. To access the full submission click the “Assign PI” button, or the “Edit” button in the study details page.

Required Tasks:

- [Assign PI](#)
- ✓ [Assign PC](#)
- [Complete Submission](#)

IRB NUMBER: IRB-FY2022-166
Cayuse User Guide - Initial

CREATE PDF COMPARE SAVE

Roles and Responsibilities of Investigators and Research Staff

* Roles and Responsibilities

The IRB holds the principal investigator of an approved research study responsible for below mentioned responsibilities. Please check all boxes as acknowledgement of these duties.

- * Obtaining prospectively written IRB approval prior to enrolling any participants in the study, abstaining from enrolling any individual in a research study during any period when the IRB or sponsor/principal investigator has suspended study activities; or following IRB or sponsor/principal investigator-directed termination of the study.
- * Ensuring that risks to research subjects are minimized by using procedures that are consistent with sound research design

4. The first page is the Roles and Responsibilities page. Read and acknowledge each statement. Red stars next to a question indicates that it is a required question.

TIP: Cayuse does not automatically save the form.

Please click the green save button at the top right and the bottom of the form at the end of each page. ORP also recommends drafting the main portions of the application in a word document, so the submission will be saved twice.

A Study Identification

* A.1 What type of submission is this?

- Help me determine whether my project fits the criteria for an official "Not Human Subjects Research" determination. Choose this option if you are not sure whether your project fits the criteria.

Research Study Involving Human Subjects (Exempt, Expedited or Full Board Review)

* A.1a What type of review is the Investigator seeking?

- Exempt Determination -Research involving minimal risk or approval
- Expedited review (Study involving more than minimal risk)
- Full Board Review (greater than minimal risk, not defined expedited categories). Submission deadlines.

5. Cayuse is an interactive form, meaning new questions will appear based on which answers are selected. Please reach out to ORP if you are unsure of which submission to select.

A Study Identification

* A.1 What type of submission is this?

- Help me determine whether my project fits the criteria for an official "Not Human Subjects Research" determination. Choose this option if you are not sure whether your project fits the criteria. Please answer questions in Sections E and F.

Research Study Involving Human Subjects (Exempt, Expedited or Full Board Review)

* A.2 Does your work take place exclusively in the United States?

6. When adding a Principal Investigator select the "Find People" button. PIs need to save the principal investigator entry before the submission can be sent to the organizational approver.

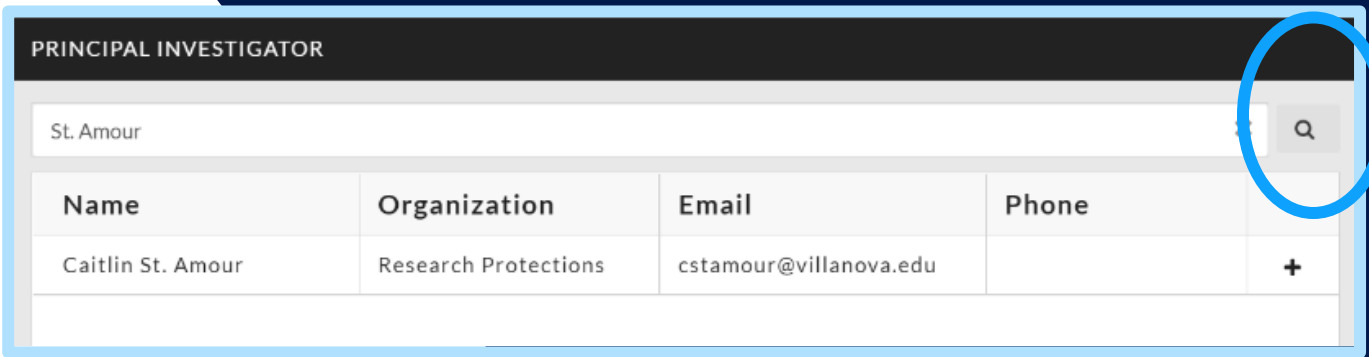
* B.1 Who is the Principal Investigator (PI)?

There can be only one PI listed on the study who is ultimately responsible for the conduct and oversight of the study including education of study staff, study management, record-keeping and the protection of study participants.

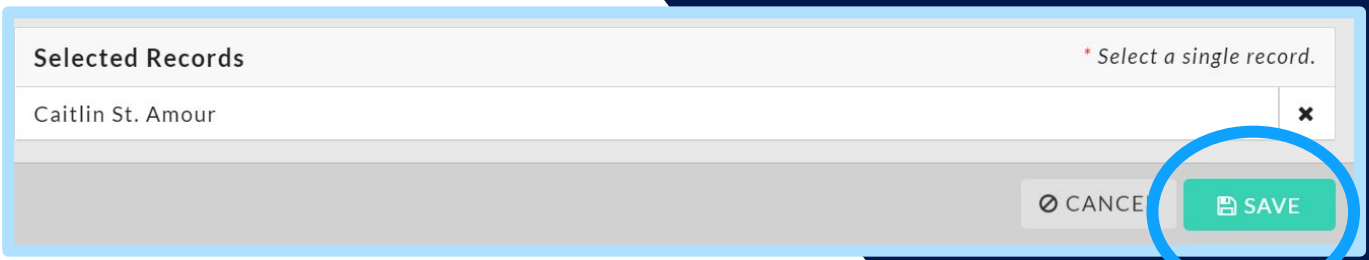
Note: The PI cannot be an undergrad or grad student. PhD and DNP candidates can be the PI, and should contact ORP to be added as a Cayuse user. (This is subject to change. Check ORP web page for most current VU policy.)

If you are completing this form and are NOT the PI, please ensure to make yourself either a Co-Investigator or the Primary Contact below so you maintain access to the Cayuse submission

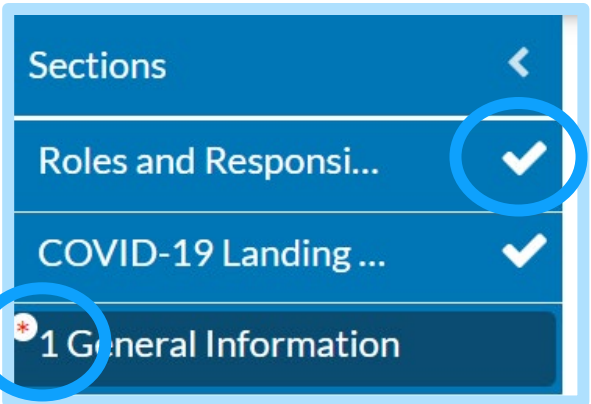
FIND PEOPLE



7. Enter a last name into the search box then click the magnifying glass button.



8. Select the name and click the green save button at the bottom of the box.



9. In the Sections tab, a red star indicates an unfinished page. A check mark indicates a finished page.

Continue to fill out the application. Please contact ORP with any questions about what information is required in each section if necessary.

How do I check CITI training for my personnel?

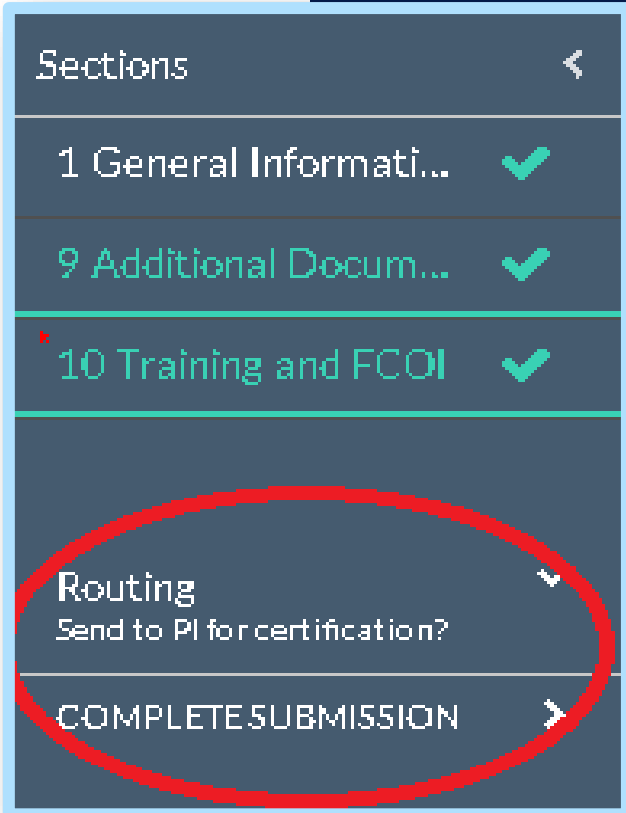
Name	Organization	Address	Phone	Email	Trainings
Caitlin St. Amour	Research Protections	800 Lancaster Avenue, Villanova, PA 19085-1603		cstamour@villanova.edu	View ✕

TRAININGS

Course Name	Group	Stage	Status	Completion Date	Expiration Date
Biomedical Data or Specimens Only Research - Basic/Refresher	Biomedical Data or Specimens Only Research - Basic/Refresher	1	Current	11/3/2021	11/2/2024
Personal Protective Equipment	Personal Protective Equipment	1	Current	10/26/2021	10/26/2022

Once personnel are saved into the application through the “Find People” buttons in sections B.1 – B.4. PI’s can check if those individuals’ CITI Trainings are up to date. Select “View” under Trainings in the personnel table. This will bring up a table of the required CITI trainings along with the completion and expiration dates. It is the PIs responsibility to ensure that the personnel listed on the protocol are trained. PIs should still double check CITI’s website in case there are missing or additional trainings listed on Cayuse.

How do I submit my initial application?



Sections <

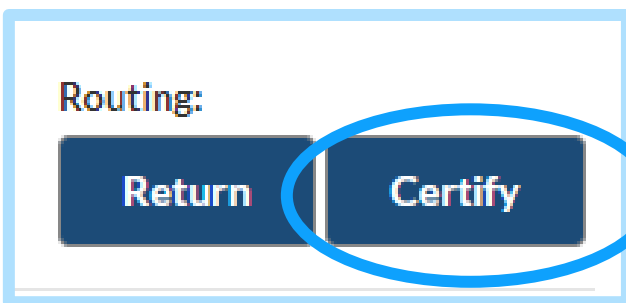
- 1 General Informati... ✓
- 9 Additional Docum... ✓
- 10 Training and FCOI ✓

Routing
Send to PI for certification? ✓

COMPLETE SUBMISSION >

1. Once the form is complete, a **Routing and Complete submission button** will appear. Select **“Complete Submission”**, then confirm. If a non-PI is completing the submission, this is the final step. PIs are required to certify the application.

2. If the PI is submitting the application, a **certify button** will appear in same place as the **“Complete Submission button** above. If the PI is not the individual submitting the application, they can enter the application separately and click the **“certify” button** on the study details page.

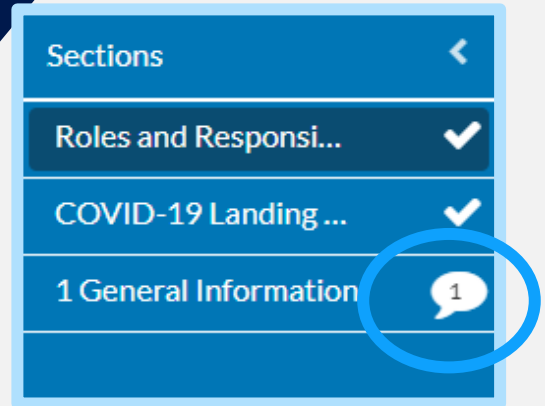


Routing:

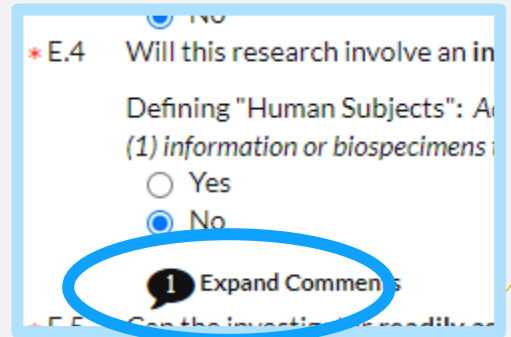
Return Certify

How do I resolve comments?

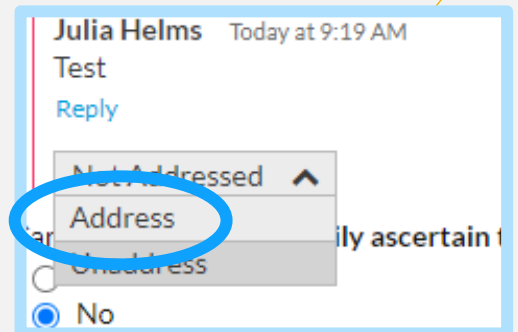
1. Comments from a reviewer or ORP will appear as a bubble next to the section the comments are located.



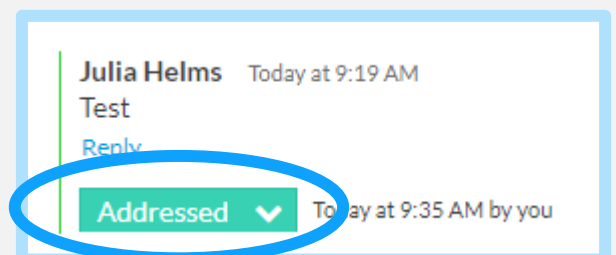
2. Type “Cntrl + F” and search for “expand” to locate all comments on the page. Click the “expand comment” button.



3. To address comments, reply to the comment and fix the issue in the actual submission.

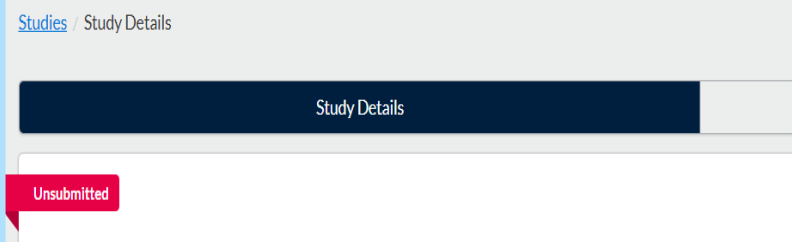
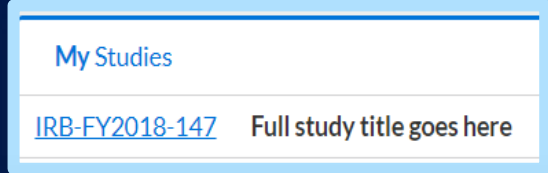


4. After replying to the comment, click the “Not Addressed” button then select “Addressed.” After all the comments have been addressed, resubmit to ORP.

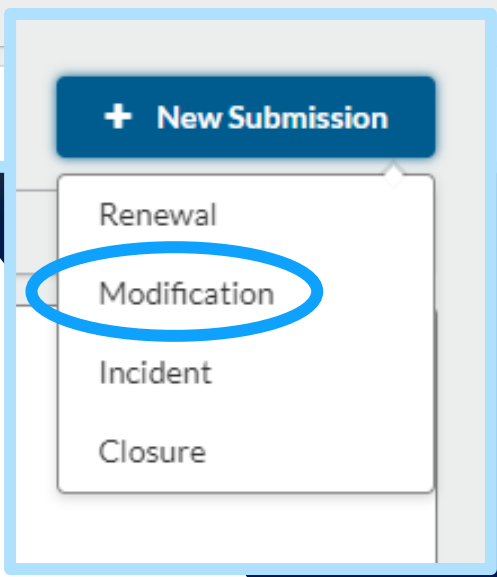


How do I submit a modification to my protocol?

1. Select the study to modify under the “My Studies,” box.

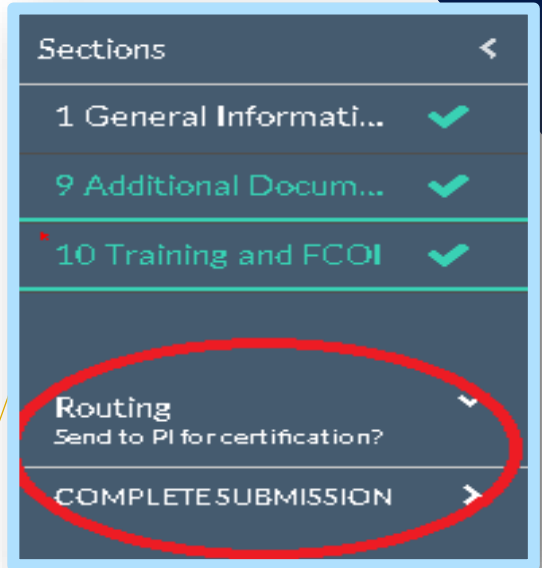
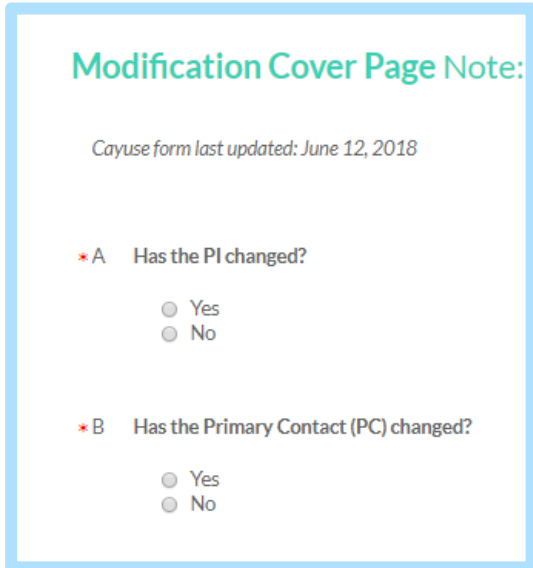


2. Click the blue “New Submission” button and select Modification.



3. Complete the modification cover page and change the appropriate sections in the original submission.

4. When the modifications are finished, submit the modification.



How do I renew my protocol?

My Studies

[IRB-FY2018-147](#) Full study title goes here

1. Select the study to renew under the “My Studies,” box.

[Studies](#) Study Details

Study Details

Submissions

Unsubmitted

+ New Submission

+ New Submission

Renewal

Modification

Incident

Closure

2. Click the blue “New Submission” button and select “Renewal” from the list.

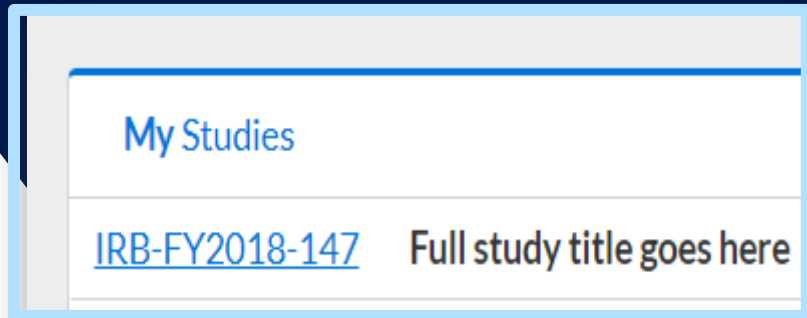
Was this study initially approved following full board review?

- Yes - Full Board
- No - Expedited or Exempt review

3. Complete the renewal or status update report form, depending on the study’s review level. Submit the renewal when it is complete.

How do I submit an incident report?

1. Select the study to submit an incident report for under the “My Studies,” box.



Studies / Study Details



+ New Submission

Study Details

Submissions

Unsubmitted

+ New Submission

Renewal

Modification

Incident

Closure

2. Click on the blue “New Submission” and select “Incident” from the list.

Report of Unanticipated Problems

The IRB must be promptly informed of any problem that suggests that the research plan breaches in confidentiality.

* Date of problem/event

MM-DD-YYYY



* Please describe the problem/event including any response to date.

B I U G :≡ ≡ ∞ 🖼

3. Complete the one-page incident report then submit to ORP.

How do I close my study?

1. Select the study to close under the “My Studies,” box.

My Studies

[IRB-FY2018-147](#) Full study title goes here

Studies / Study Details

+ New Submission

Study Details

Submissions

Unsubmitted

+ New Submission

Renewal

Modification

Incident

Closure

2. Click on “New Submission” and select “Closure” from the list.

Important Note

Please do NOT submit this form unless the study is absolutely ready to be closed. Once the closure is submitted it cannot be undone. In order to continue with the research, a brand-new submission would be required.

Closure

When all research-related interventions or interactions with human subjects have been considered as completed and the protocol may be closed. The Principal Investigator

A study is ready to be closed when the criteria below are met:

1. *The study is permanently closed to enrollment, AND*
2. *All subjects have completed research-related interventions or interactions, AND*
3. *All long-term subject follow-up activities are complete, AND*
4. *Identifiable data are no longer needed and all data have been de-identified*

In most circumstances, investigators may pursue publications and presentations derived

If you're not sure whether your protocol should be closed, **DO NOT SUBMIT THIS**

* A *Has subject accrual (enrollment) ended?*

- Yes
 No

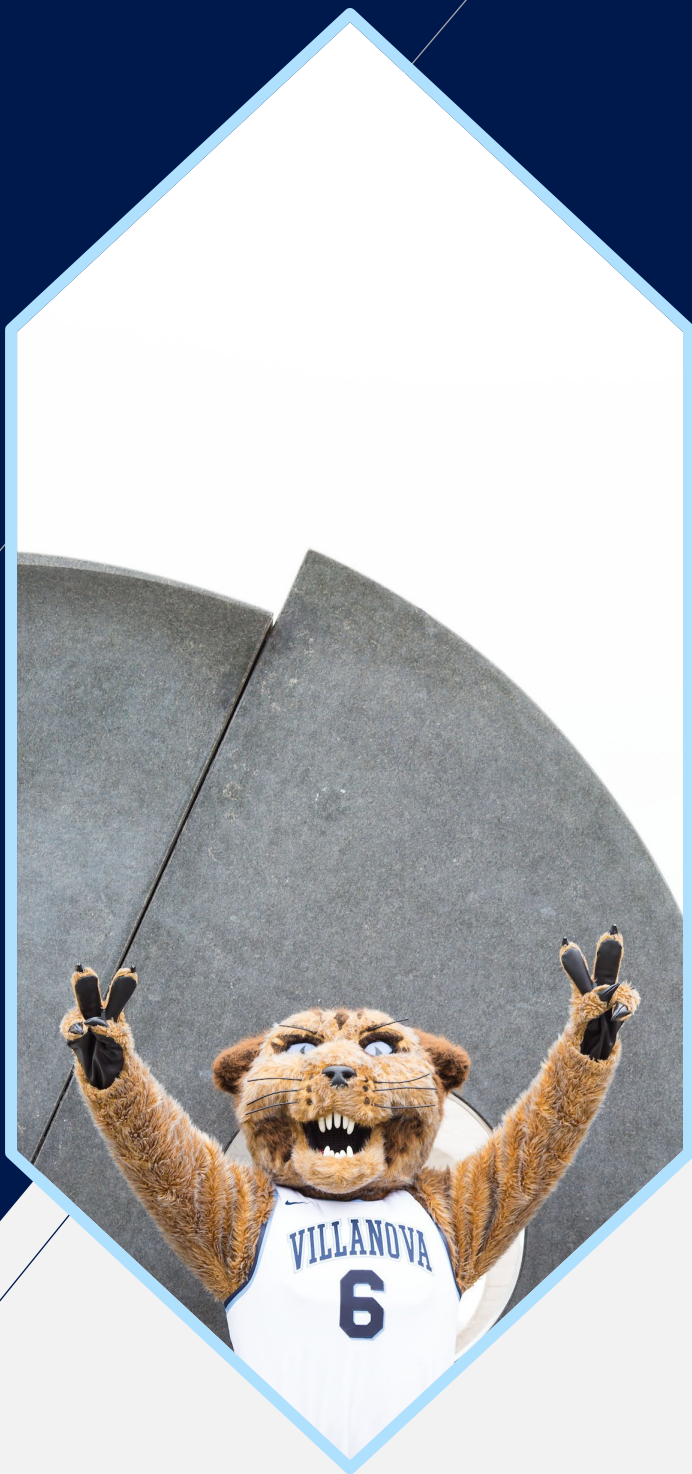
* B *Are research interactions, interventions, and data collection completed?*

- Yes
 No

* C *Have analyses of subject identifiable data been concluded and all data have been*

3. The closure report is one page. Complete the required questions and submit the closure report to ORP.

Contact Us



Office of Research
Protections

610-519-4250

irb@villanova.edu

irb.vllanova.edu