*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.

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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)
How do I navigate the dashboard?

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

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

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

4. **Under Review**: includes the studies that are currently with a reviewer.
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
How do I check the status of my application?

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.

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.

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.
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.

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*
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?

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.
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 the 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.
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?

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

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

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.

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

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.

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

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