




Hazard Safety

IBC Researcher Manual



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Accessing Cayuse

To access Cayuse, go to: jmu.app.cayuse.com/

It will redirect you to Duo:

JAMES MADISON UNIVERSITY

Log in to Cayuse Research Suite
- Live

ATTENTION:

- **Duo two-factor authentication is now required** for this and many other JMU systems. See [here](#) for a complete list.
- **If you have not yet enrolled with Duo**, find instructions [here](#). For assistance, contact the IT Help Desk at 540-568-3555, or email helpdesk@jmu.edu

JMU eID

Password

Log in

Protect Your Privacy!

Be sure to log out of this system by completely closing your web browser when finished. If you do not, someone else could use your web browser to login as you.

- **Windows users:** Close all web browser windows.
- **Mac users:** Quit your web browser

You will be brought to the My Tasks dashboard. Under Products, click on Hazard Safety:

The screenshot shows the 'My Tasks' dashboard. At the top left is the 'cayuse platform Home' logo. On the right, there is a 'Products' dropdown menu with a red notification icon. The dropdown menu is open, showing the following options: Home, Human Ethics, Animal Oversight, Outside Interests, and Hazard Safety. A purple arrow points to the 'Hazard Safety' option. Below the dropdown, there are filter buttons: 'Assigned to Me', 'Created by Me', 'Open', and 'All'. A table header is visible with columns: 'Task', 'Task Type', 'From', 'Assigned To', 'Created', and 'Last Active'. The table content is empty, displaying 'No Saved Tasks'.

You will be taken to your Researcher Staff Members dashboard:

The screenshot shows the 'Researcher Staff Members' dashboard. The top navigation bar includes the 'cayuse Hazard Safety' logo, 'Site: JMU', 'Role: Researcher Staff Members', 'PI Group: [redacted]', and 'Products' dropdown. The main content area is titled 'Protocol Actions' and includes a 'Draft Protocols' tab. There are three buttons: '+ Start a New IBC Application', '! Copy IBC Protocol to New Protocol', and 'Start IBC Amendment'. Below these is a button for 'IBC Versions Preview'. A search bar is present with 'Find' and a refresh icon. A table at the bottom shows protocol details:

PI	Protocol #	Version	Protocol Title

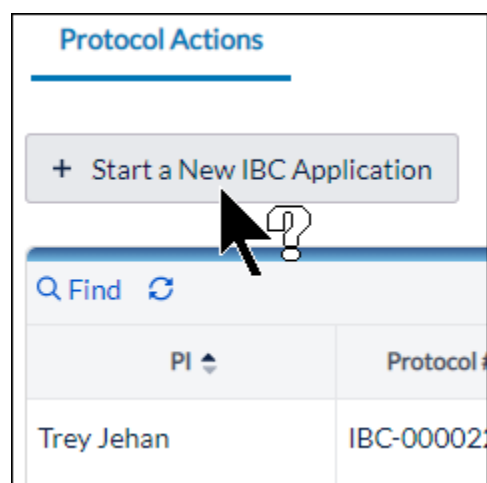
The table is currently empty. The page also shows a pagination control: 'Page 1 of 1' and 'View 1 - 2 of 2'.

Starting and submitting your protocol

Within IBC, a new protocol can be started from the Protocol Actions inbox.

Hazard Safety		
Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	0	0
Protocols in Review	0	2
De Novo Reviews	0	0
Continuing Reviews		
Draft IBC Amendments	0	0
Continuations in Review		

1. Beneath Protocol Actions, click **Start a New Protocol Application**.



2. After reading the protocol information, click **Start a new IBC Protocol**.

cayuse Hazard Safety Site: JMU Role: Researcher Staff Members PI Group: Products

Start a New IBC Application

Start a New IBC Protocol Application

IBC Protocols must be approved by the Institutional Biosafety Committee (IBC) prior to the initiation of research.

The protocol will undergo annual renewal with a Continuing Review form and De Novo review every three years. The Hazard Safety application will send an email reminder and automatically generate the Continuing Review and De Novo Review forms, which will display in your Mailbox Alerts until submission.

As a reminder, spills, exposures, and adverse events must be promptly reported to the IBC office.

Resources:

- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules - 2019](#)
 - Section 1-B, Definition of Recombinant and Synthetic Nucleic Acid Molecules In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:
 - (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
 - (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or
 - (iii) molecules that result from the replication of those described in (i) or (ii) above.
- [Biosafety in Microbiological and Biomedical Laboratories - 6th edition](#)
 - Biosafety Level 1 (BSL-1) is the basic level of protection and is appropriate for defined and characterized strains of viable biological agents that are not known to cause disease in immunocompetent adult humans.
 - Biosafety Level 2 (BSL-2) is appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure.
 - Biosafety Level 3 (BSL-3) is appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections, and that are indigenous or exotic in origin.
 - Exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available are restricted to high containment laboratories that meet Biosafety Level 4 (BSL-4) guidelines.
- [American Biological Safety Association - Risk Group Database](#)
- [CDC Federal Select Agent Program - Select Agents and Toxins](#)
- [US Department of Health and Human Safety - Dual Use Research of Concern](#)
- [CDC Guidelines for Biosafety Laboratory Competency](#)

Start a new IBC Protocol Home Page

3. Protocol Introduction Options will generate. Cayuse IBC will generate the protocol number automatically, which is available at the top left-hand side of the page.

cayuse Hazard Safety

Start a New IBC Application IBC-00002227 1

4. **Please Note:** You can exit the protocol document at any time and continue working on it later by clicking **Hazard Safety** in the top left-hand corner. The Protocol will be saved in the Draft Protocols tab and you will be taken back to your dashboard.

cayuse Hazard Safety

Start a New IBC Application IBC-00002227 1

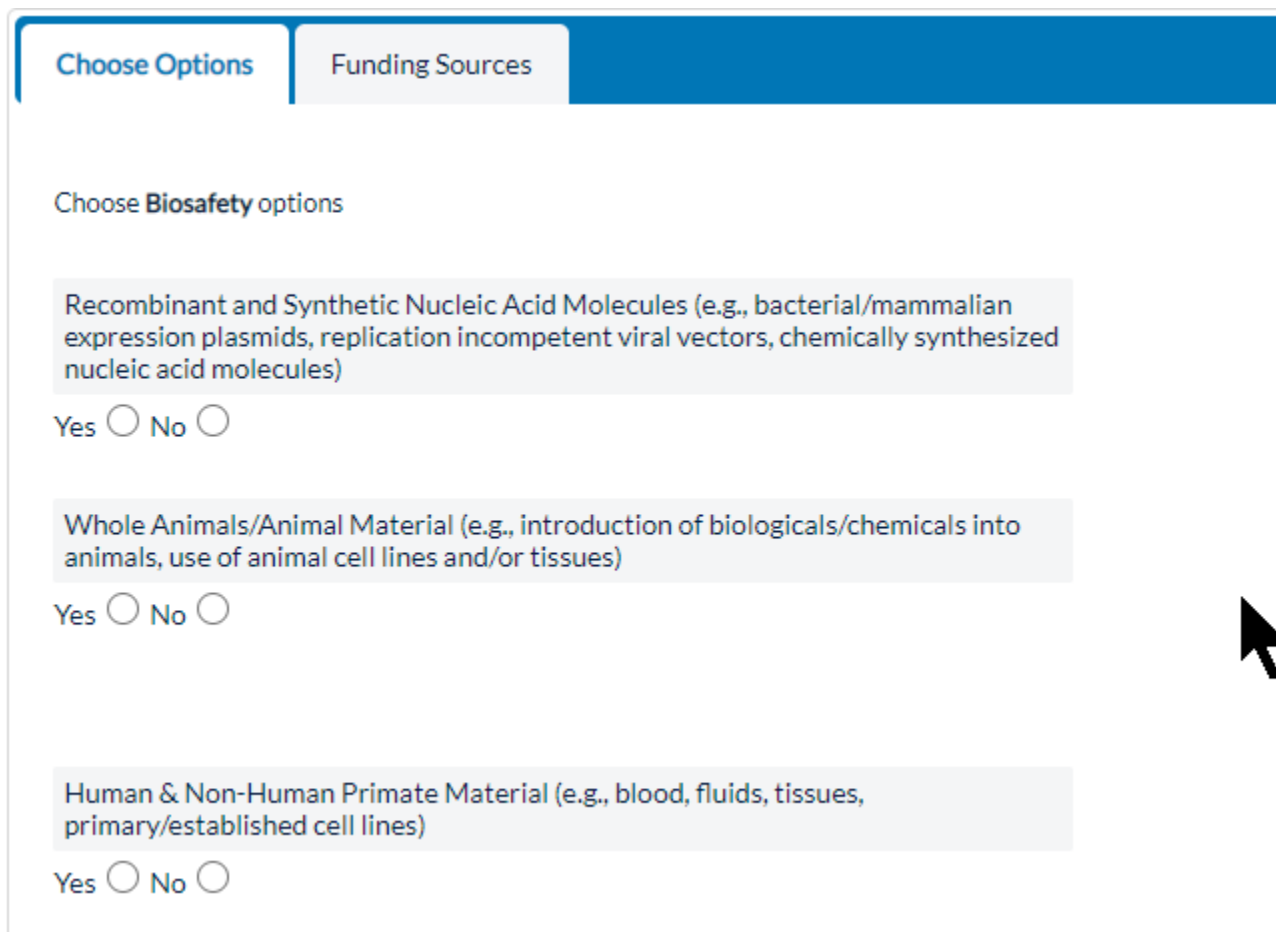
Table of Contents ?

Options

IBC Protocol Application

Completing Your Table of Contents

After you create your protocol, you will be directed to an Options page.



Choose **Biosafety** options

Recombinant and Synthetic Nucleic Acid Molecules (e.g., bacterial/mammalian expression plasmids, replication incompetent viral vectors, chemically synthesized nucleic acid molecules)

Yes No

Whole Animals/Animal Material (e.g., introduction of biologicals/chemicals into animals, use of animal cell lines and/or tissues)

Yes No

Human & Non-Human Primate Material (e.g., blood, fluids, tissues, primary/established cell lines)

Yes No

The Options section is the first section in the protocol's Table of Contents.

When you click **Save**, the selections made in the Options page determine which sections are added to the Table of Contents. Each Yes answer will populate a separate section.

You can navigate to any section by clicking on the section name within the Table of Contents.

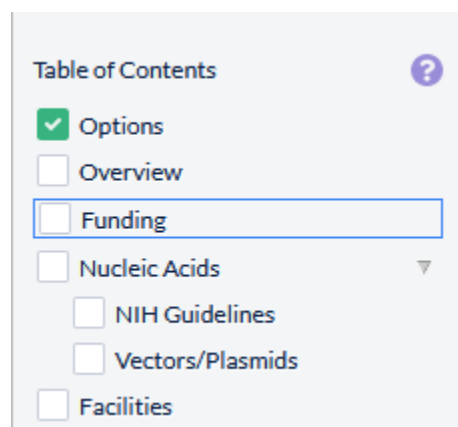


Table of Contents ?

Options

Overview

Funding

Nucleic Acids ▼

NIH Guidelines

Vectors/Plasmids

Facilities

A green check in the box next to a section means that all required fields within the section have been filled out. All sections must have a check mark before you can submit the protocol.

Filling Out Your Protocol

Once you've completed all of your options for your table of contents, you can begin filling out your protocol by clicking on sections within your table of contents.

The following sections explain the types of questions you may be asked within your protocol.

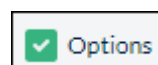
The following sections explain the types of questions you may be asked within your protocol.

Required Questions

Required questions have a red dotted border around them. These questions must be answered before you submit your protocol.

Protocol Title *

If all required questions are answered within a section, a green checkmark will appear next to the section within the table of contents.



Text Fields

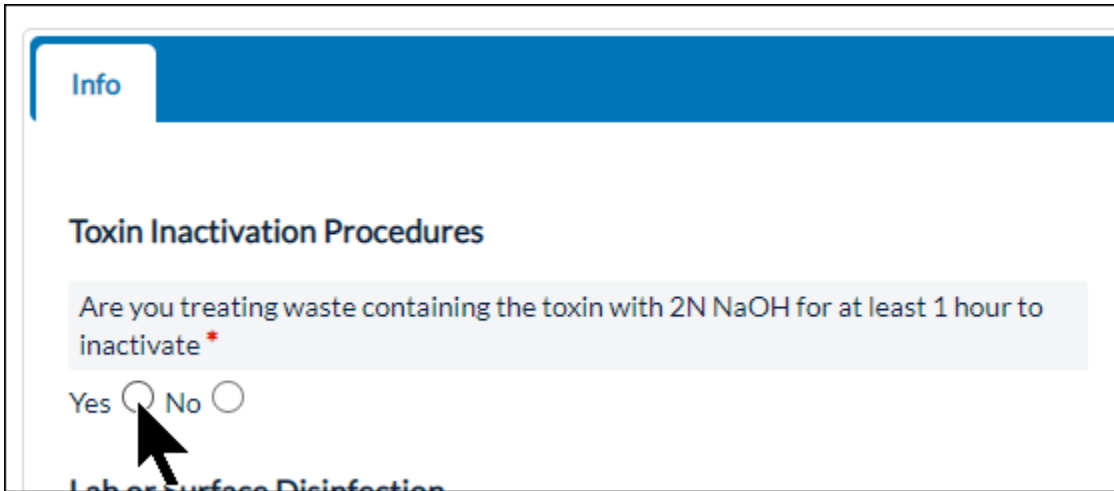
Text fields are provided when you need to input a custom response. If the text field has a toolbox, then you will be able to input rich text, such as bolded or italicized text, custom alignment, or bullet points.

Scientific Benefits

↶	↷	B	<i>I</i>	<u>U</u>	S	X_2	X^2	<u>A</u>	v		v			
≡	≡	≡	System Font		v	10pt				v	Paragraph	v		
≡	≡	≡	v	≡	v		⌚	v	Ω	—				Q

Radio Buttons

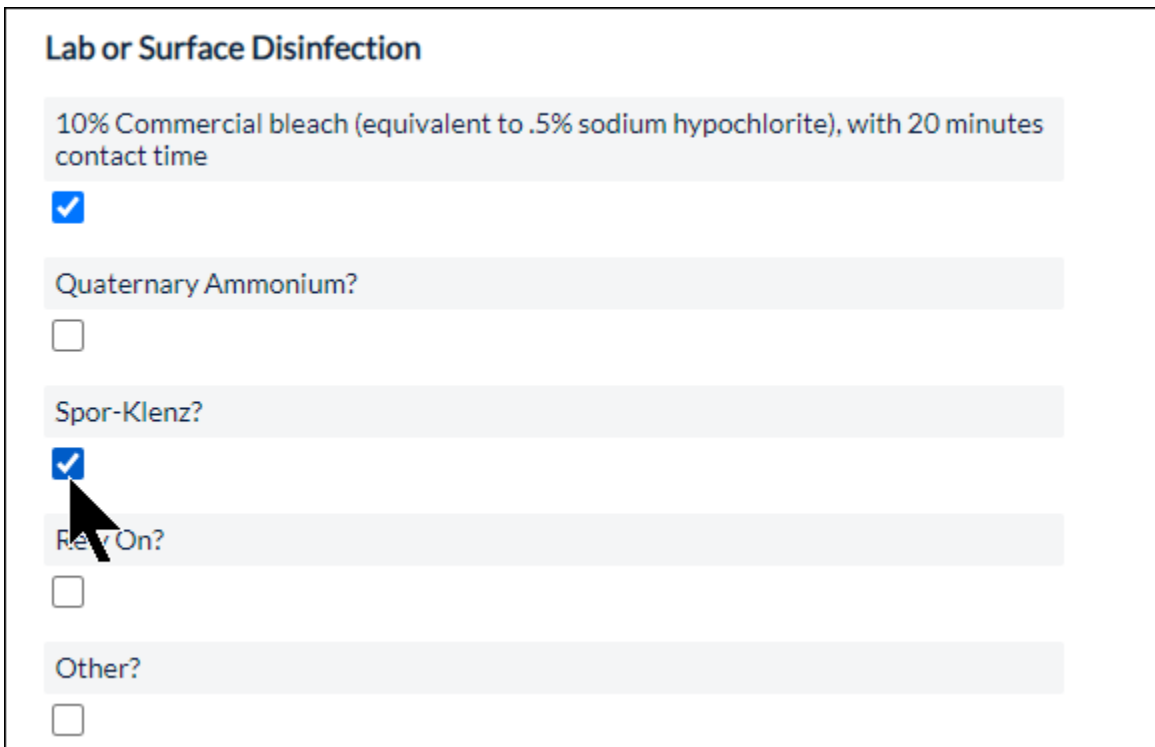
Radio button questions appear when only one choice is allowed from a set of configured choices.



The screenshot shows a form with a blue header bar containing the word "Info". Below the header is a section titled "Toxin Inactivation Procedures". A question is displayed in a light gray box: "Are you treating waste containing the toxin with 2N NaOH for at least 1 hour to inactivate *". Below the question are two radio button options: "Yes" and "No". A mouse cursor is pointing at the "Yes" radio button. Below the question, the text "Lab or Surface Disinfection" is partially visible.

Check Boxes

Check box questions appear when you can choose more than one choice from a set of configured choices.



The screenshot shows a form with a section titled "Lab or Surface Disinfection". Below the title is a light gray box containing the text "10% Commercial bleach (equivalent to .5% sodium hypochlorite), with 20 minutes contact time". Below this box is a checked checkbox. Below the checked checkbox are four more questions, each with an unchecked checkbox: "Quaternary Ammonium?", "Spor-Klenz?", "Re-Ton?", and "Other?". A mouse cursor is pointing at the checked checkbox for "Spor-Klenz?".

Drop-Down Menus

Questions with drop-down menus are similar to radio button questions, and will let you select one answer from a set of configured choices.

Add From List

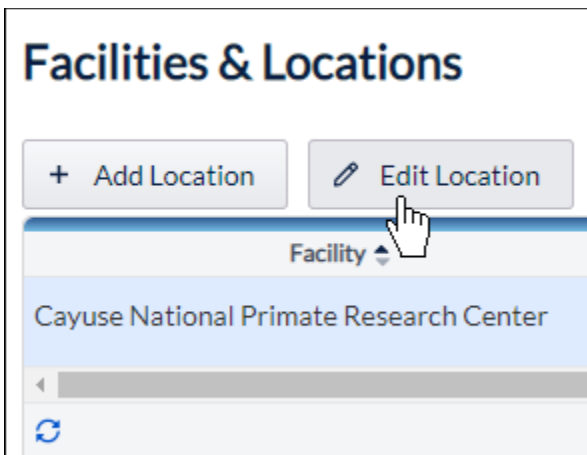
The Add From List option allows you to choose from data that you have inputted previously. For example, if you are a PI, you may be able to add funding from your current list of funds, depending on your approved protocols.

Add New

The Add New option allows you to add new data into the system, such as a new funding source, location, or strain.

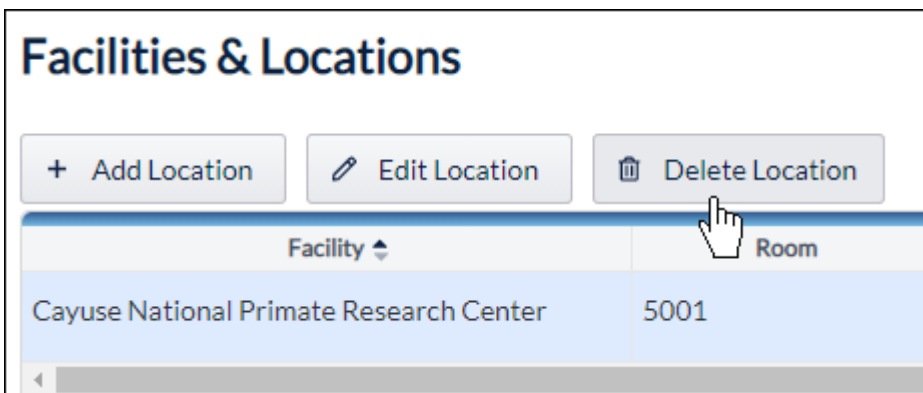
Edit

When adding from a list or adding new data, you can edit the data by clicking on the list item, and then clicking **Edit**.



Delete or Remove

You can delete or remove an item from a list by clicking on the item, and then clicking **Remove**.



Academic Unit Head Approval

Before you submit your protocol, complete the Academic Unit Head Approval form available on the ORI website: <https://www.jmu.edu/researchintegrity/biosafety/forms/academic-unit-head-approval.docx>.


Signature

By submitting this protocol I acknowledge and agree to all of the following statements:

- I certify that all personnel on this protocol will abide by all applicable regulations, policies, and guidelines.
- I agree to obtain Institutional Biosafety Committee approval prior to initiating any changes to the work described in this protocol.
- I certify that all personnel will be informed of the various applicable health hazards, complete required training modules, and will be trained on risk mitigation.
- I certify that the Institutional Biosafety Committee will be notified of any adverse events, exposures, or spills per institutional guidance.

Please download the [Academic Unit Head Approval](#) form. Complete this form with your department head and then upload it under the attachments section.

By signing below I certify that I have had the appropriate conversations with my academic unit head and the AUH Approval form has been uploaded to this application. *



Once obtained, upload it to the Attachments section.

Submit Protocol

Attachments

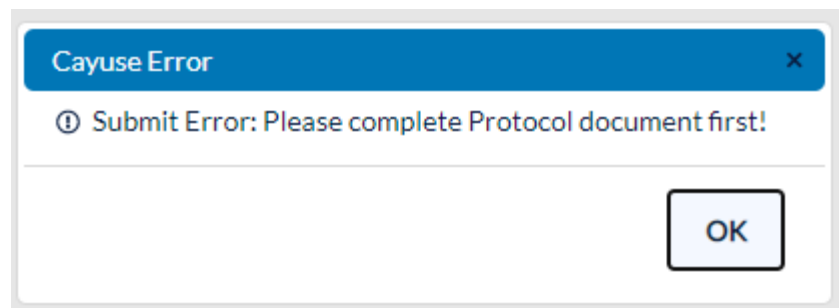
Cancel Draft Protocol

Preview Protocol

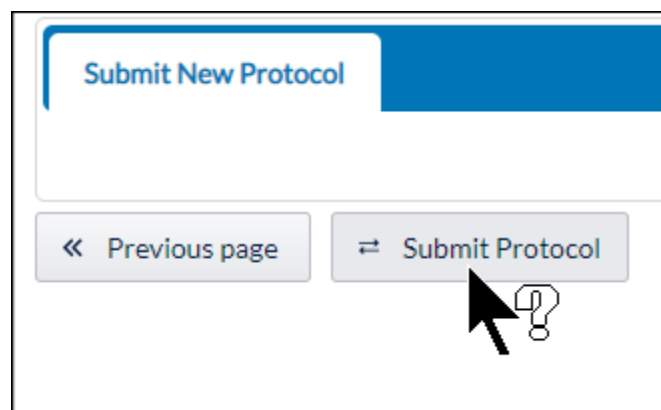
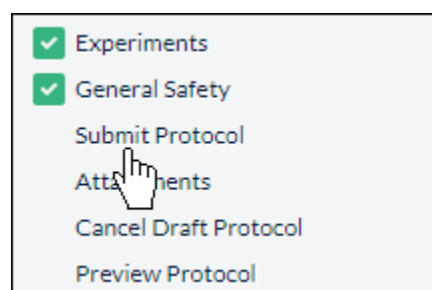
Submitting Your Protocol

If green checkmarks appear next to every section within the table of contents of your protocol, then you are ready to submit.

If a section is missing a green check mark, it means that you still need to answer a required question. If you try submitting without answering all the required questions, you will see this message:



To submit your protocol, click on **Submit Protocol** within your table of contents, and then click **Submit Protocol**.



Your protocol will now be routed to the IBC office for review and approval, and the protocol will appear in your Protocols in Review inbox.

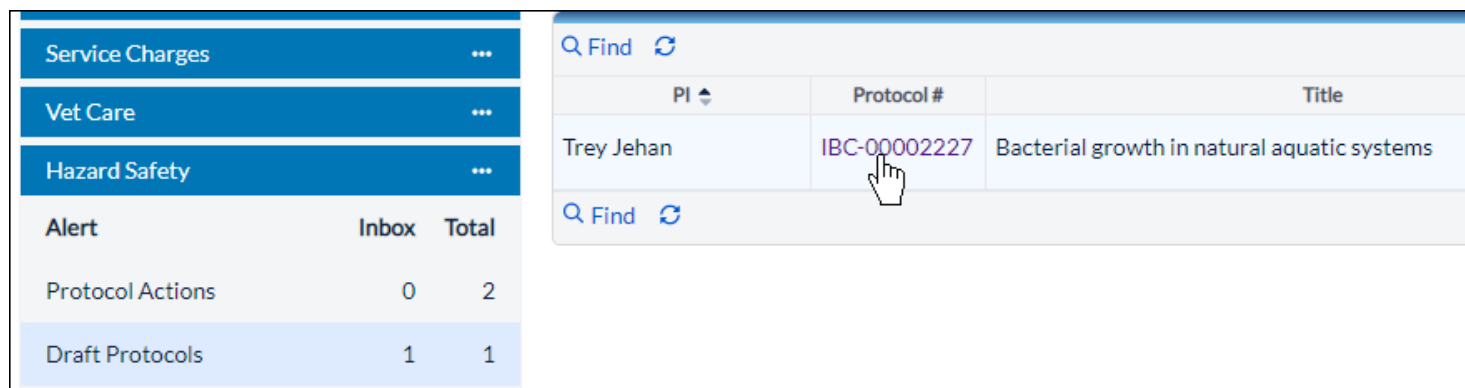
Animal Oversight		
Hazard Safety		
Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	3	3
Protocols in Review		
De Novo Reviews	0	0
Continuing Reviews		
Draft IBC Amendments	0	0
Continuations in Review		
Reports		

When your protocol has been reviewed and approved, it will appear in your Protocol Actions inbox.

Animal Oversight		
Hazard Safety		
Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	3	3
Protocols in Review		
De Novo Reviews	0	0
Continuing Reviews		
Draft IBC Amendments	0	0
Continuations in Review		
Reports		

Revising Your Protocol in Hazard Safety

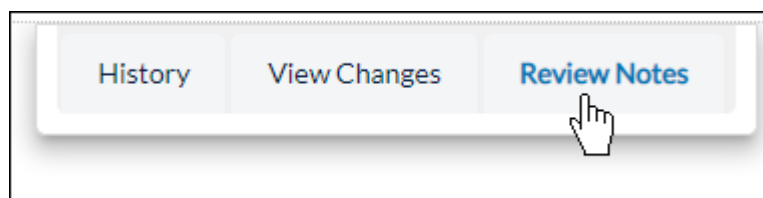
If a protocol is returned with recommendations from reviewers, the PI will receive an email notification. The PI can re-open the protocol by clicking on the protocol number within the email, or within Draft Protocol Alerts.



Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	1	1

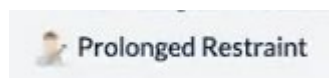
PI	Protocol #	Title
Trey Jehan	IBC-00002227	Bacterial growth in natural aquatic systems


Within the protocol, the reviewer pane will be displayed on the right-hand side. Click on a tab to expand the pane.



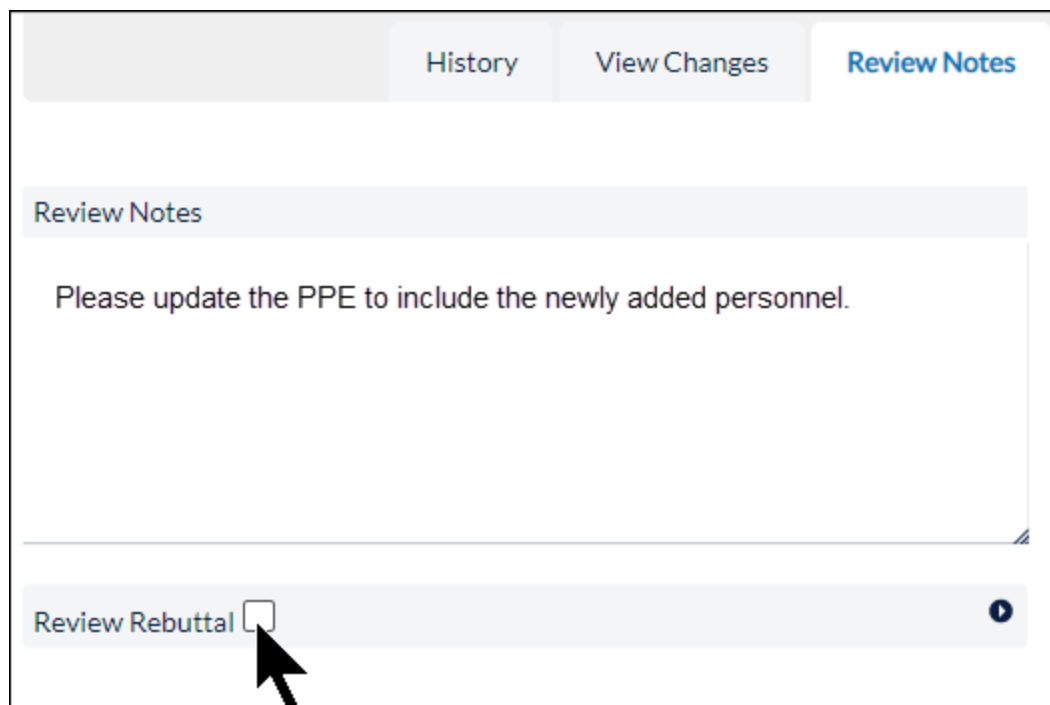
History View Changes **Review Notes**

You will see a pencil icon next to any sections where reviewers are requesting a revision.



 Prolonged Restraint

Within each section requiring review, you can make a revision to your protocol, respond to the reviewer with a rebuttal, or both. To make a rebuttal, click the checkbox next to **Review Rebuttal**, and type your response.



History View Changes **Review Notes**

Review Notes

Please update the PPE to include the newly added personnel.

Review Rebuttal

When you are finished revising your protocol, click **Submit Protocol**, type in your password, and click **Submit**.

Copying an Approved Protocol

If you would like to use an approved protocol as a base for a new protocol, you can copy the protocol from the Protocol Actions inbox.

Hazard Safety		
Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	1	1
Protocols in Review	0	2
De Novo Reviews	0	0

Click on the protocol you wish to copy, and then click **Copy Protocol to New Document**.

The screenshot shows the 'Protocol Actions' interface. At the top, there are tabs for 'Protocol Actions', 'Draft Protocols', 'Protocols in Review', and 'Draft Amendment'. Below the tabs are two buttons: '+ Start a New Protocol Application' and 'Copy Protocol to New Document'. A mouse cursor is pointing at the 'Copy Protocol to New Document' button, which has a question mark icon next to it. A tooltip is visible next to the button, stating: 'Highlight a protocol to start a new protocol copy of the selected'. Below the buttons is a search bar with 'Find' and a refresh icon. Underneath is a table with columns 'PI', 'Protocol #', and 'Protocol Title'. The table contains two rows of data.

PI	Protocol #	Protocol Title
Trey Jehan	00001543	Transgenic Core Breeding Protocol
Trey Jehan	00001545	Gnotobiotic Core Breeding Protocol

You will be directed to your new protocol application.

Amending a Protocol

If you need to amend a protocol, you can do so from the Protocol Actions inbox.

Animal Oversight		
Alert	Inbox	Total
Protocol Actions	0	5
Draft Protocols	0	0
Protocols in Review	0	2

Click on the protocol you wish to amend, and then click **Start an Amendment**.

The screenshot shows the 'Protocol Actions' interface. At the top, there are tabs for 'Protocol Actions', 'Draft Protocols', 'Protocols in Review', and 'Draft Amendment'. Below the tabs are three buttons: '+ Start a New Protocol Application', 'Copy Protocol to New Document', and 'Start an Amendment'. A mouse cursor is pointing at the 'Start an Amendment' button. Below the buttons is a search bar with 'Find' and a refresh icon. Below the search bar is a table with columns 'PI', 'Protocol #', and 'Protocol Title'. The table contains two rows of data:

PI	Protocol #	Protocol Title
Trey Jehan	00001543	Transgenic Core Breeding Protocol
Trey Jehan	00001545	Gnotobiotic Core Breeding Protocol

Enter a reason for amending the protocol, and click **Amend Protocol**.

The screenshot shows the 'Amend Protocol' form. It has several fields:

- Approve Date: 09/01/2020
- Expiration Date: 09/01/2023
- Full Name: Trey Jehan
- Reason for Change: Need to update PPE

At the bottom of the form is a button labeled 'Amend Protocol' with a pencil icon. A mouse cursor is pointing at this button.

You will be redirected to the protocol draft. When you are finished with your amendment, you can re-submit your protocol.

Please note: Only one amendment can be in process at a time.

Understanding Alerts in Hazard Safety

In Cayuse IBC, the left-hand menu contains different sections for alerts regarding your protocols. You can refer to these alerts to understand where your protocols are within the routing process.

Hazard Safety		
Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	0	0
Protocols in Review	0	3
De Novo Reviews	0	0
Continuing Reviews		
Draft IBC Amendments	0	0
Continuations in Review		

Draft Protocols

This alert displays the protocols that have yet to be submitted. You can continue to edit the protocol by clicking on the protocol number.

Protocols in Review

This alert displays the workflow process, showing both the sender and recipient of the protocol. If a protocol appears in italics, it means the protocol hasn't yet been submitted to the PI.

If a protocol is returned with recommendations from reviewers, the PI will receive an email notification. The PI can re-open the protocol by clicking on the protocol number within the email, or within Draft Protocol Alerts.

Continuing Review

This alert shows protocols that have come up for the first year review.

De Novo Reviews

This alert will show protocols up for their three year review.

IBC Amendments

This alert will show draft amendments. Learn more about amending your protocol [here](#).

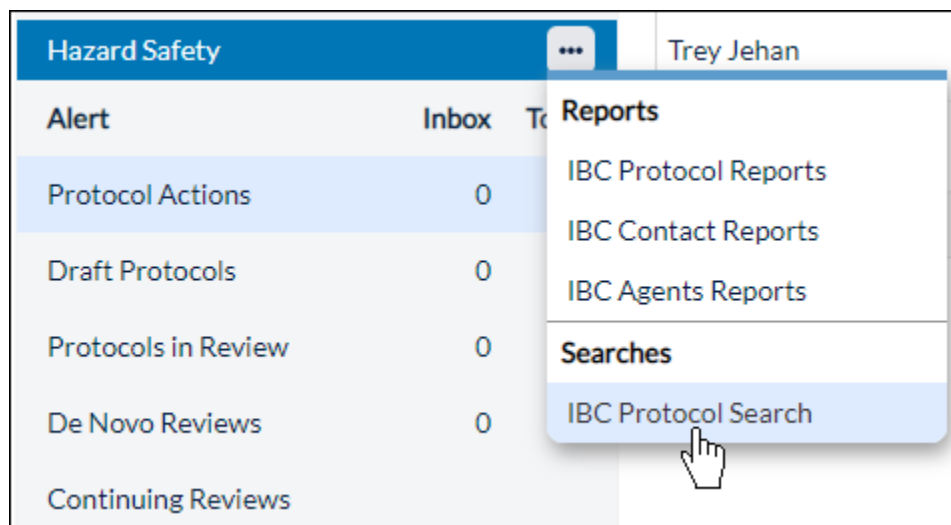
Continuations in Review

This alert shows first year review protocols that are in review by the IBC committee.

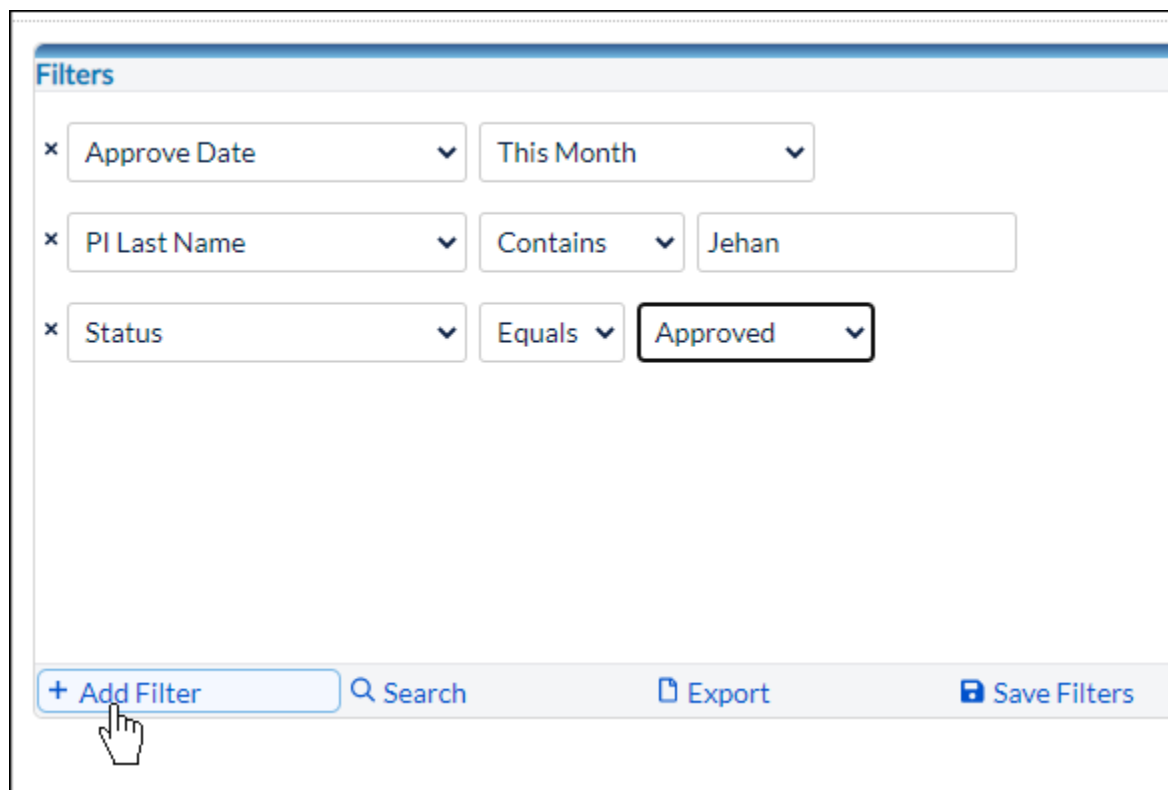
Running a Search in Hazard Safety

In Cayuse IBC, you are able to search for protocols from the Actions menu

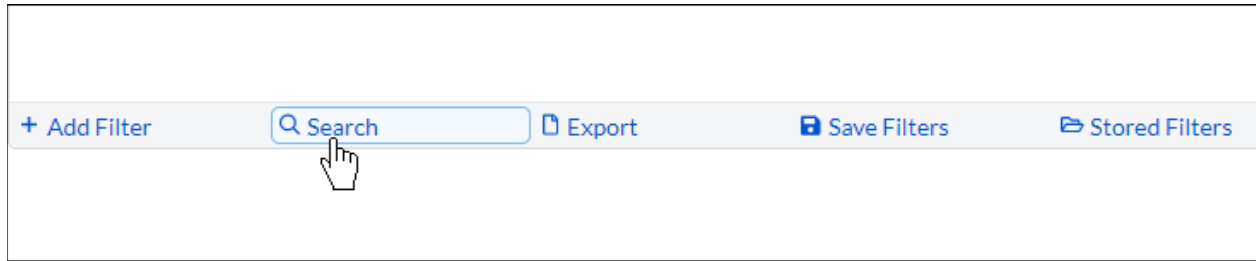
1. Click the menu next to the Hazard Safety header.
2. Click on **IBC Protocol Search**.



3. Select any filters by which you wish to limit the search. If you need to add additional filters, click **Add Filter**.



4. When you've chosen your filters, click **Search**. Your search results will populate.

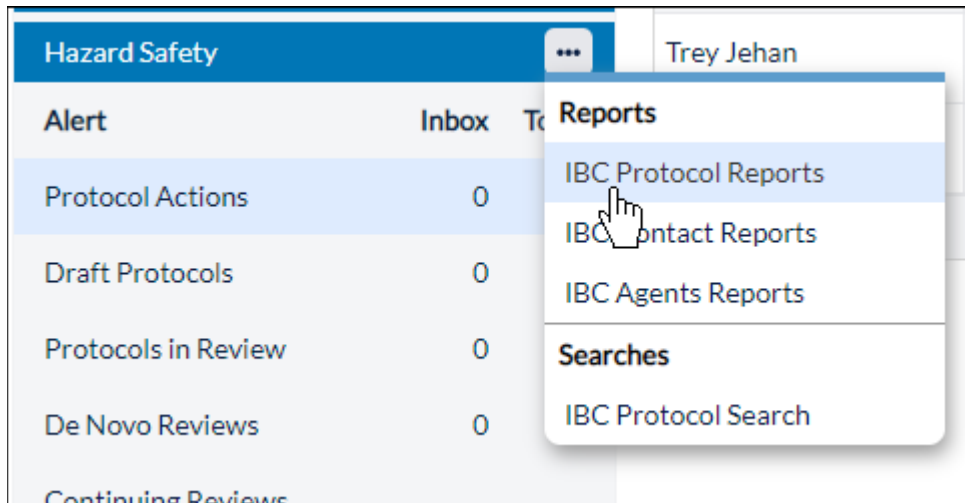


Running Reports in Hazard Safety

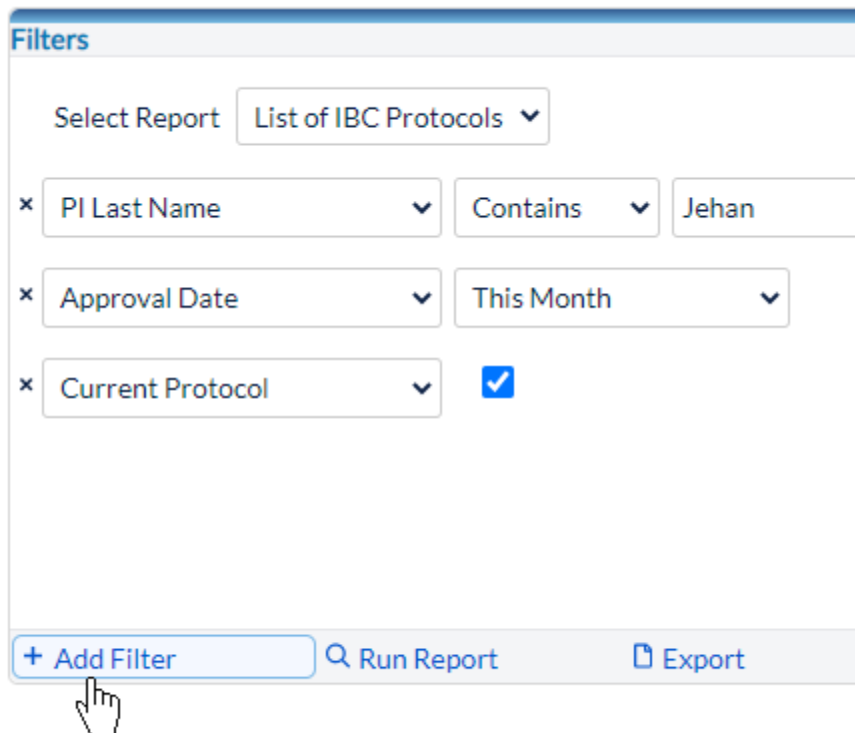
At some point, you may need to run reports in Cayuse IBC. You can run three different kinds of reports:

- IBC Protocol Reports
- IBC Contact Reports
- IBC Agents Reports

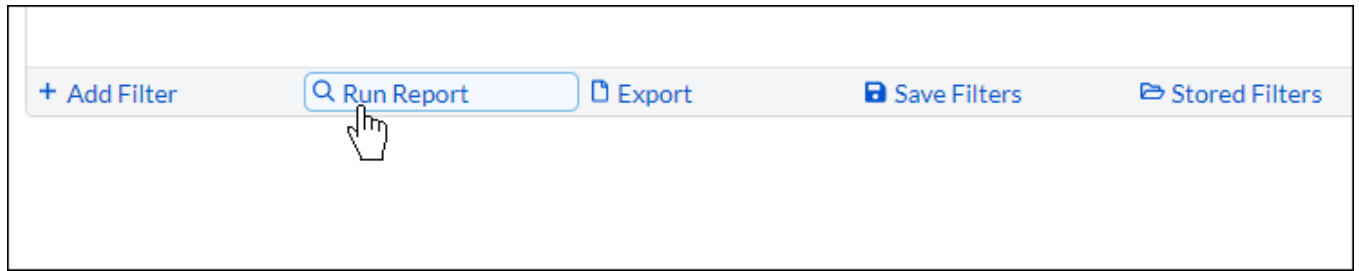
1. Click the menu next to the Hazard Safety header.
2. Click on the type of report or search you wish to run.



3. Select any filters by which you wish to limit the report. If you need to add additional filters, click **Add Filter**.



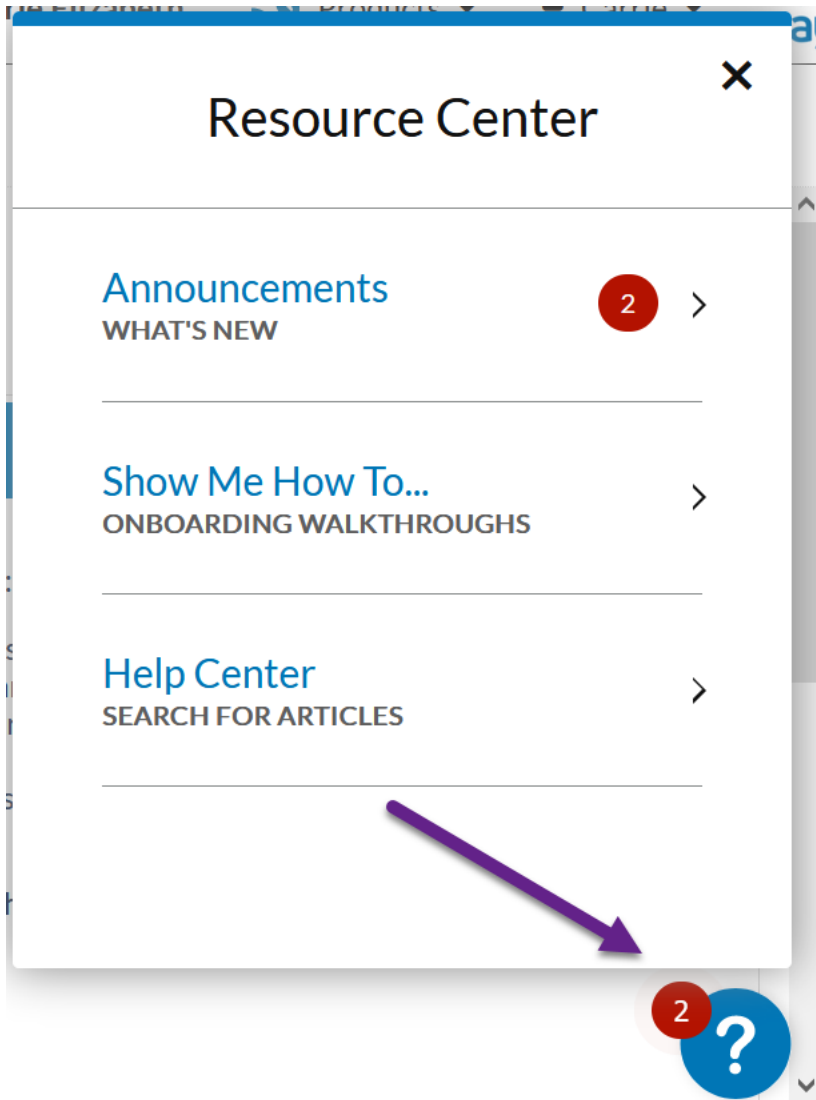
- When you've chosen your filters, click **Run Report**. The report will populate in a new window.



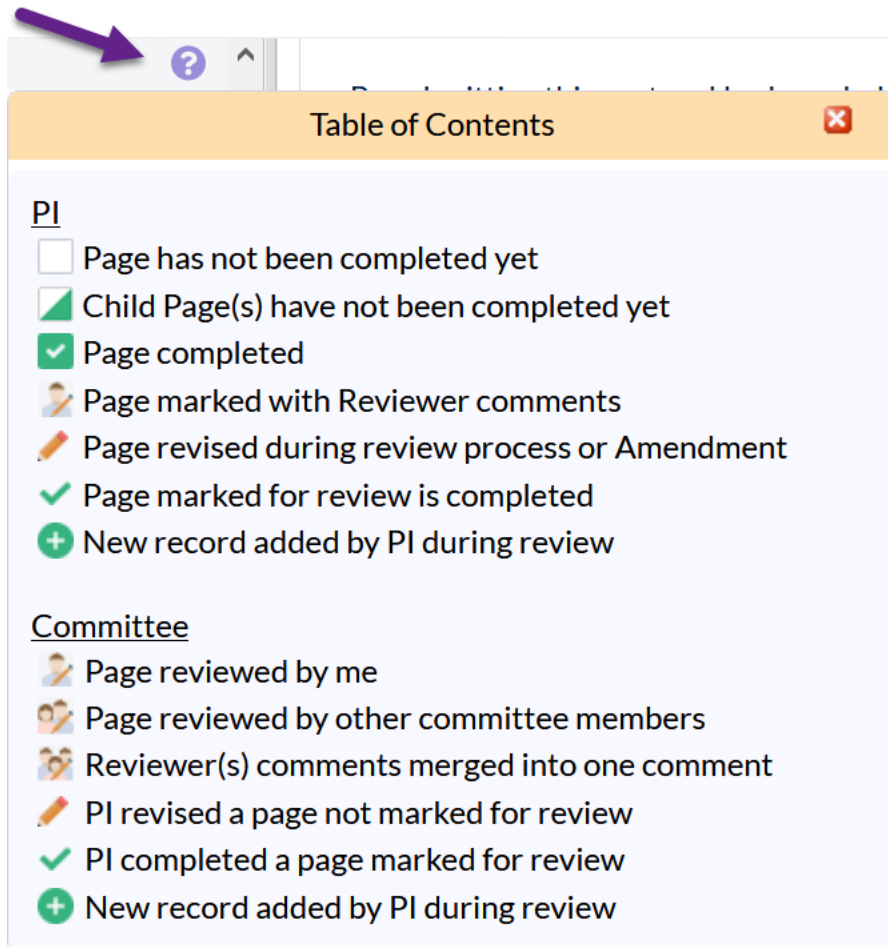
You can also **Export** the report to a .CSV, **Recall Filters**, or **Save Filters** for later.

Additional Help

A blue question mark is at the bottom of each screen, which will open up the Cayuse Resource Center. You can use it for “Show Me How To...” or link to the Cayuse Help Center for articles.





Click on the purple question mark in the left-hand navigation menu for an explanation of the Table of Contents symbols.







The screenshot shows a software interface with a purple arrow pointing to a question mark icon in the left-hand navigation menu. Below this, a 'Table of Contents' dialog box is open, displaying a list of symbols and their meanings, categorized under 'PI' and 'Committee'.

Table of Contents

PI

- Page has not been completed yet
- Child Page(s) have not been completed yet
- Page completed
-  Page marked with Reviewer comments
-  Page revised during review process or Amendment
- Page marked for review is completed
- New record added by PI during review

Committee

-  Page reviewed by me
-  Page reviewed by other committee members
-  Reviewer(s) comments merged into one comment
-  PI revised a page not marked for review
- PI completed a page marked for review
- New record added by PI during review

Frequently Asked Questions

What is Cayuse Hazard Safety?

Cayuse Hazard Safety is a web-based application used to draft, review, approve, and manage Institutional Biosafety Committee (IBC) protocols. All submissions can be accessed via the website on any device linked to the internet. Users will receive emails from the Cayuse system when action is required on a protocol, such as at the annual renewal or De Novo (3-year) renewal.

Who has access to Cayuse Hazard Safety?

Users will need to be granted access by the IBC administrators. If you need to access the application, please reach out to the [Office of Research Integrity \(ORI\)](#) for assistance.

Who can submit protocols in Cayuse Hazard Safety?

Users with the Researcher Staff Members role that have PI eligibility may submit protocols. In addition, only JMU faculty may serve as PI.

How do I receive updates regarding my Cayuse IBC submissions?

The application will send users emails when action is required on submissions. For example, the Cayuse Hazard Safety application will send users notifications when a protocol has questions from the IBC that need to be addressed or when a protocol is due for renewal.

Is there a character limit?

There is no known character limit. If you run out of space, you may upload as an Attachment.

My Biological Material, Toxins, Room Number is not available in the protocol.

Data dictionaries were created based on current information. If your proposed material, toxin, etc. is not listed, please complete the following form and ORI will add them to the system: <https://forms.office.com/r/U02CNt1CR7>.

Can I initiate multiple submissions (e.g., Amendment and Renewal) for the same study at the same time?

The system does not allow multiple amendments on a single protocol at one time.

Where can I get help with Cayuse Hazard Safety?

Cayuse Hazard Safety offers an in-application resource center. Please click the question mark in the bottom right of your screen when you are in the Hazard Safety application. For additional resources, reach out to ORI.

How will Cayuse Hazard Safety help researchers?

The application offers many benefits to researchers.

- Transparency: view protocol status at all times;
- Improved Compliance: renewal reminders are automated and submissions requiring action will display in your inbox;
- Web-Based: submissions can be accessed on any device with an internet connection; and
- Reduced Administrative Burden: the smart-form technology will simplify the protocol drafting process by only displaying the questions that apply to your project.

Question not listed? Please reach out to researchintegrity@jmu.edu or call (540) 568-7025.