



Hazard Safety

IBC Researcher Manual

Office of Research Integrity
(540) 568-7025
researchintegrity@jmu.edu


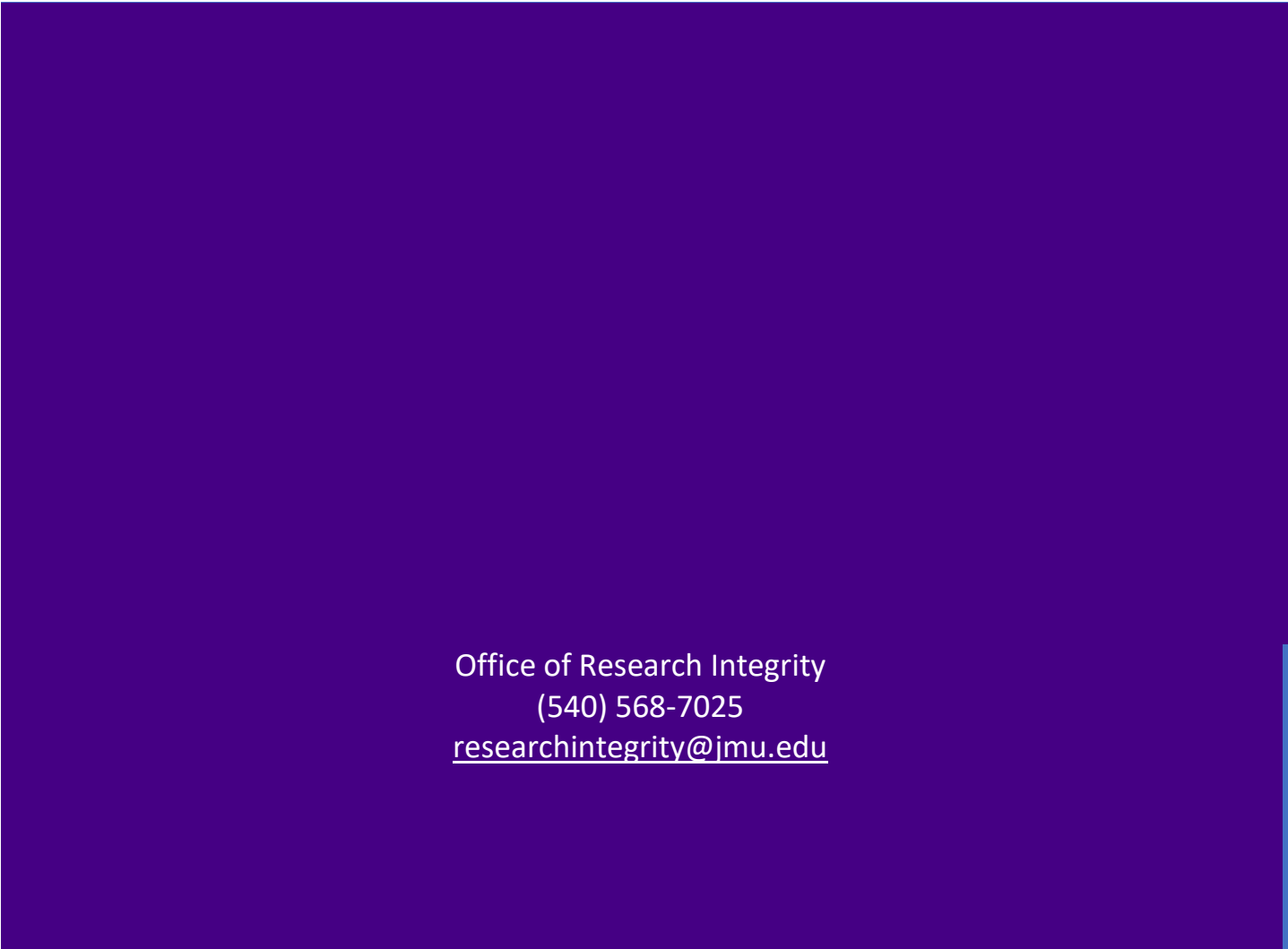


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Accessing Cayuse

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:

My Tasks

Assigned to Me Created by Me Open All

| Task | Task Type | From | Assigned To | Created | Last Active |
|----------------|-----------|------|-------------|---------|-------------|
| No Saved Tasks | | | | | |

Products dropdown menu options: Home, Human Ethics, Animal Oversight, Outside Interests, Hazard Safety.

You will be taken to your Researcher Staff Members dashboard:

Protocol Actions Draft Protocols

+ Start a New IBC Application ! Copy IBC Protocol to New Protocol Start IBC Amendment

IBC Versions Preview

| PI | Protocol # | Version | Protocol Title |
|----|------------|---------|----------------|
| | | | |

Find Page 1 of 1 20 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**.

| Protocol Actions | |
|-------------------------------|------------|
| + Start a New IBC Application | |
| Q Find ↺ | |
| PI | Protocol # |
| Trey Jehan | IBC-000025 |

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

Start a New IBC 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.

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.

Start a New IBC Application IBC-00002227 1

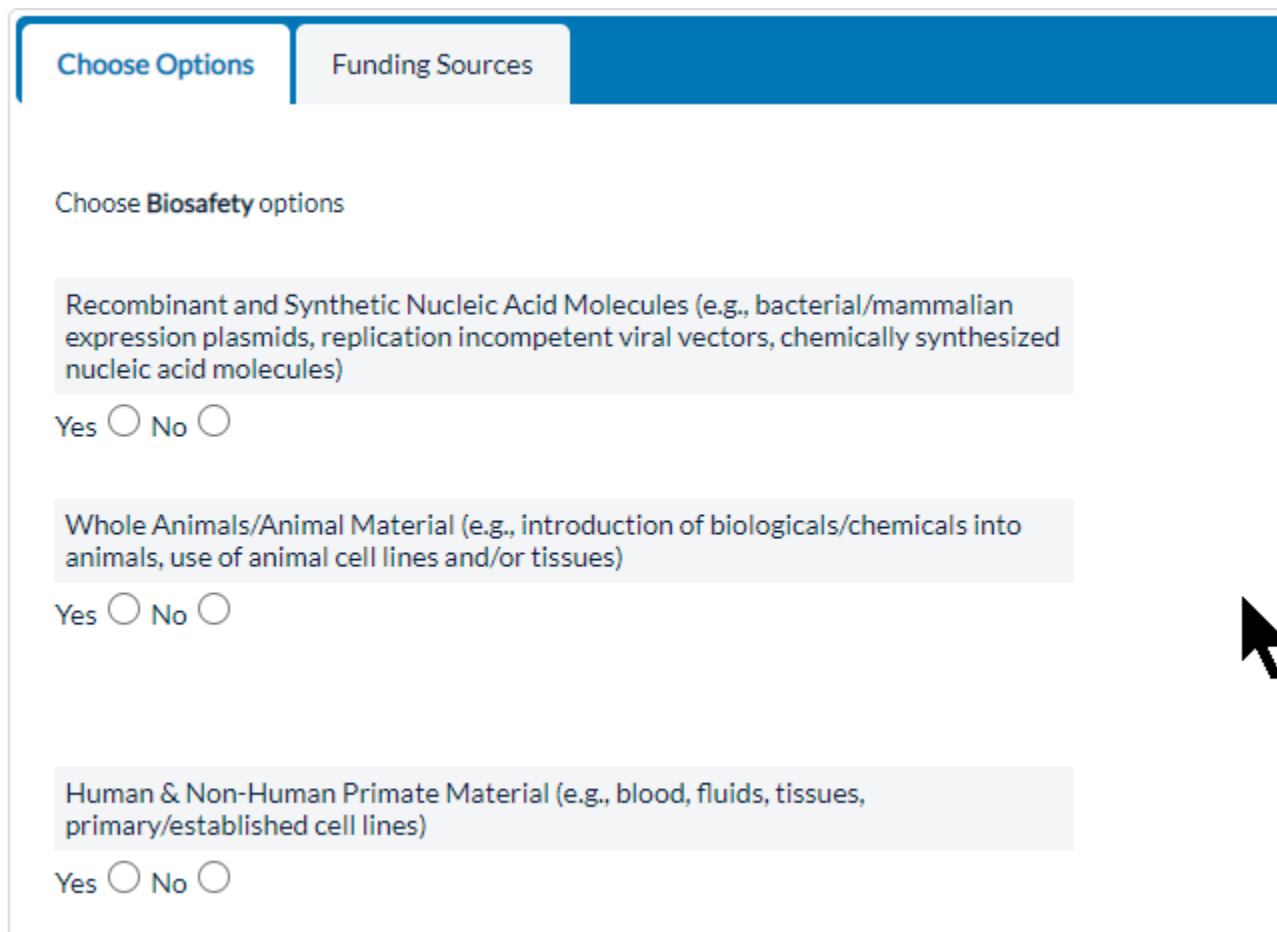
Table of Contents ?

☐ Options

IBC Protocol Application

Completing Your Table of Contents

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



Choose Options | Funding Sources

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.

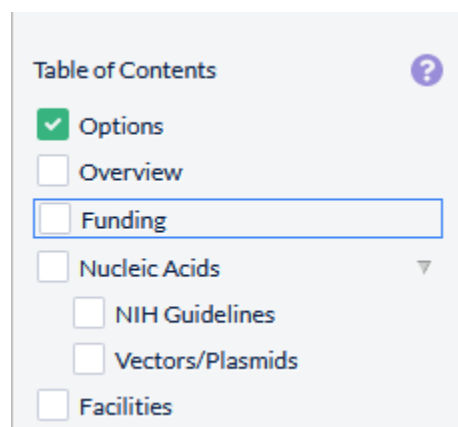


Table of Contents ?

- ☒ 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.

☒ Options

Text Fields

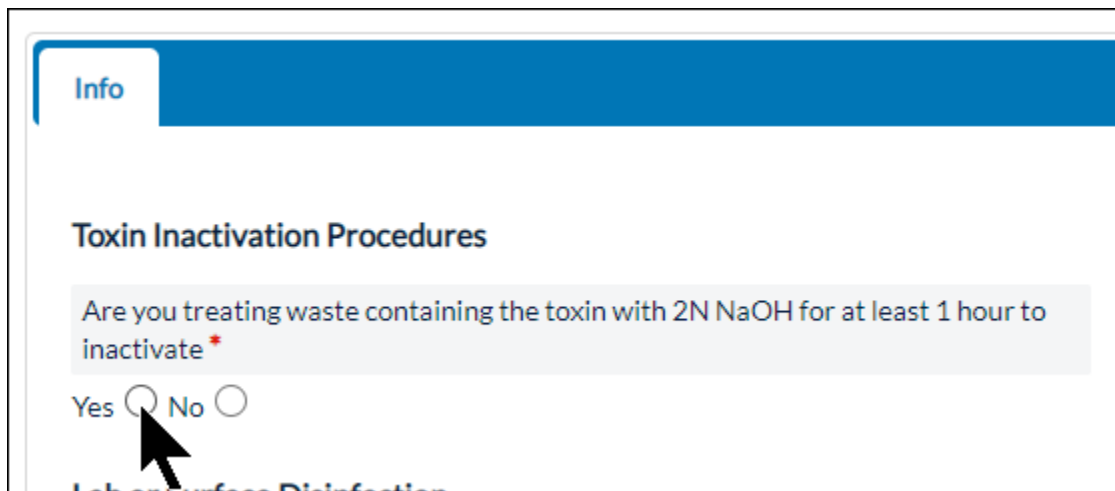
Text fields are provided when you need to input a custom response. If the text field has a toolbox, then you will be able to input rich text, such as bolded or italicized text, custom alignment, or bullet points.

Scientific Benefits

| | | | | | | | | | | | | | | |
|---|---|----------|-------------|----------|--------------|----------------|----------------|----------|-----------|---|---|--|--|--|
| ↶ | ↷ | B | <i>I</i> | <u>U</u> | S | X ₂ | X ² | <u>A</u> | ▼ | | ▼ | | | |
| ≡ | ≡ | ≡ | System Font | ▼ | 10pt | | | ▼ | Paragraph | ▼ | | | | |
| ≡ | ≡ | ≡ | ▼ | ≡ | ▼ | | | ▼ | Ω | — | | | | |
| | | | | | | | | | | | | | | |

Radio Buttons

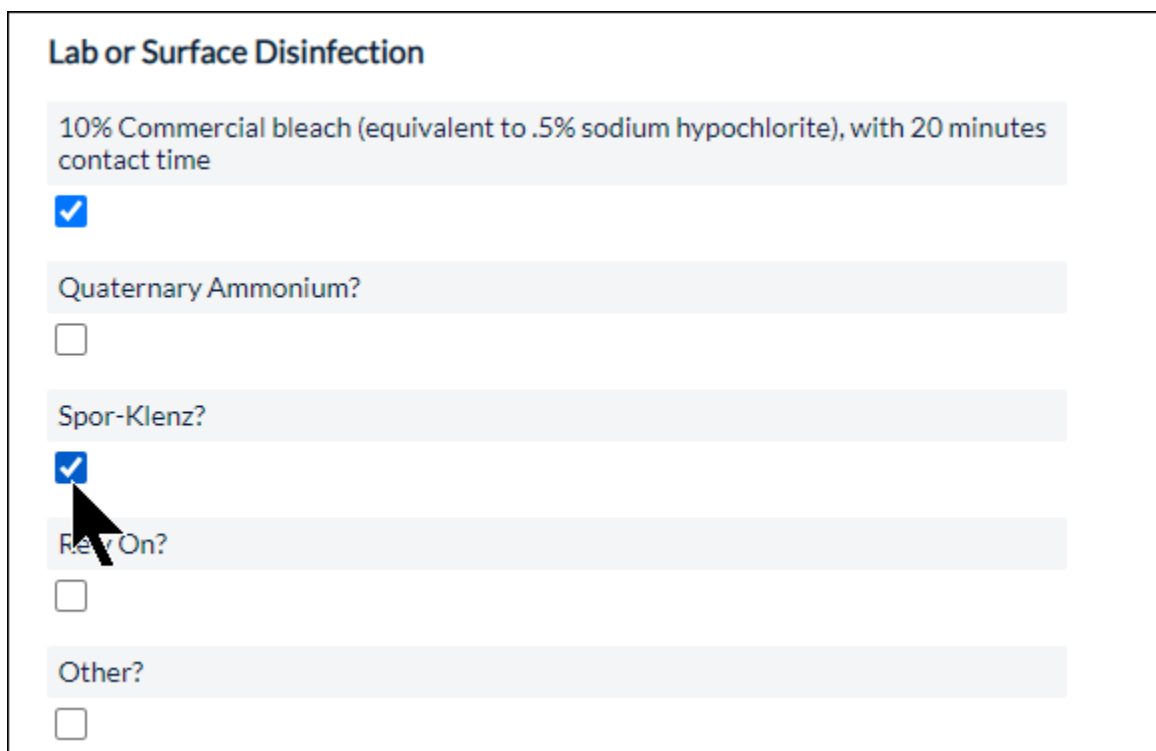
Radio button questions appear when only one choice is allowed from a set of configured choices.



The screenshot shows a form with a blue header bar containing the word 'Info'. Below the header, the title 'Toxin Inactivation Procedures' is displayed. A text input field contains the question: 'Are you treating waste containing the toxin with 2N NaOH for at least 1 hour to inactivate *'. Below the text field, there are two radio buttons labeled 'Yes' and 'No'. A mouse cursor is pointing at the 'Yes' radio button, which is currently selected.

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 titled 'Lab or Surface Disinfection'. It contains several check box questions. The first question is '10% Commercial bleach (equivalent to .5% sodium hypochlorite), with 20 minutes contact time', which is checked. The second question is 'Quaternary Ammonium?', which is unchecked. The third question is 'Spor-Klenz?', which is checked. The fourth question is 'Re-Ton?', which is unchecked. The fifth question is 'Other?', which is unchecked. A mouse cursor is pointing at the 'Re-Ton?' check box, which is currently selected.

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.

The screenshot shows a form with a label 'Facility/Room *'. Below it is a dropdown menu. The dropdown is open, displaying a list of items. The first item, 'Cayuse National Primate Research Center', is highlighted in blue. A mouse cursor is pointing at this item. To the right of the dropdown is another dropdown menu, which is currently closed. Below the dropdowns, there is a label 'is Location *'.

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.

The screenshot shows the 'Agency Funding List' page. At the top, there is a heading 'Agency Funding List' and a subheading 'Please enter all granting Agency information.' Below this are three buttons: '+ Add from my List of Funds', '+ Add Agency Fund', and 'Edit Agency Fund'. The first button is highlighted with a mouse cursor. Below the buttons is a table with columns 'Fund Source', 'Grant Title', and 'Funde'. At the bottom of the table, there is a pagination bar showing 'Page 1 of 0' and a dropdown menu for '20'.

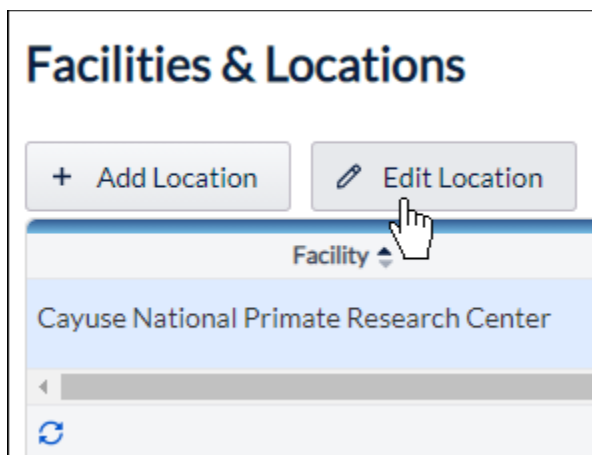
Add New

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

The screenshot shows the 'Facilities & Locations' page. At the top, there is a heading 'Facilities & Locations'. Below this are three buttons: '+ Add Location', 'Edit Location', and 'Delete Location'. The first button is highlighted with a mouse cursor. Below the buttons is a table with columns 'Facility' and 'Room'. At the bottom of the table, there is a pagination bar showing 'Page 1 of 0' and a dropdown menu for '20'.

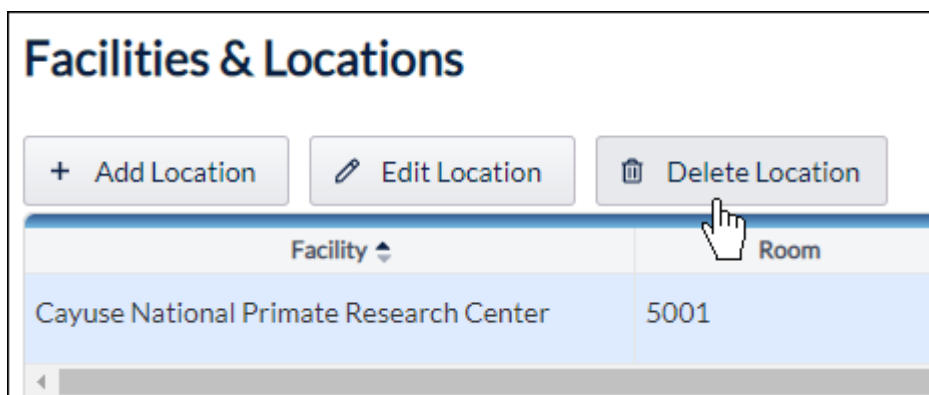
Edit

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. *

2

?

Once obtained, upload it to the Attachments section.

Submit Protocol

Attachments

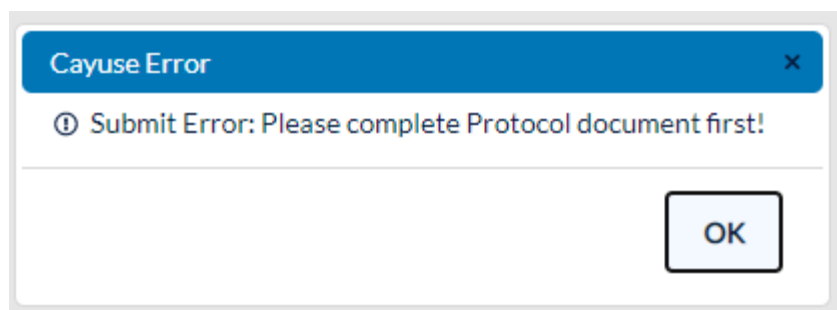
Cancel Draft Protocol

Preview Protocol

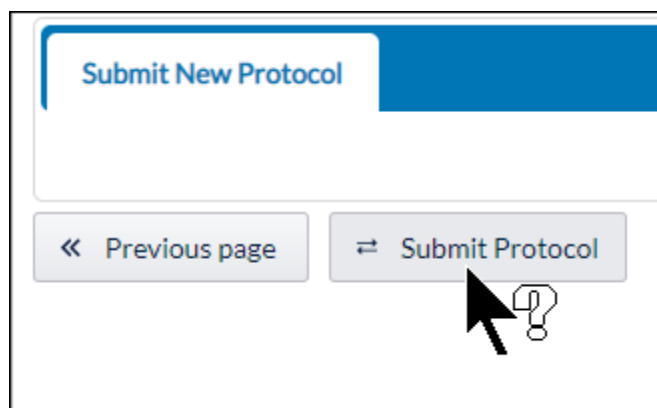
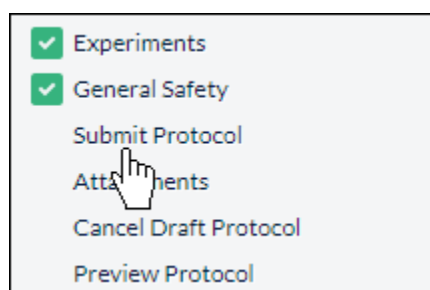
Submitting Your Protocol

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.

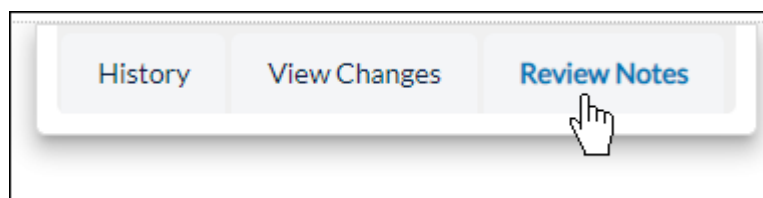
| | | | |
|-------------------------|-------|-------|-----|
| Animal Oversight | | | ... |
| Hazard Safety | | | ... |
| Alert | Inbox | Total | |
| Protocol Actions | 0 | 2 | |
| Draft Protocols | 3 | 3 | |
| Protocols in Review | | | |
| De Novo Reviews | 0 | 0 | |
| Continuing Reviews | | | |
| Draft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

Revising Your Protocol in Hazard Safety

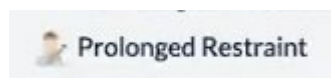
If a protocol is returned with recommendations from reviewers, the PI will receive an email notification. The PI can re-open the protocol by clicking on the protocol number within the email, or within Draft Protocol Alerts.

| | | | | | |
|---------------------|-------|-------|------------|--------------|---|
| Service Charges ... | | | Find Find | | |
| Vet Care ... | | | | | |
| Hazard Safety ... | | | | | |
| Alert | Inbox | Total | PI | Protocol # | Title |
| Protocol Actions | 0 | 2 | Trey Jehan | IBC-00002227 | Bacterial growth in natural aquatic systems |
| Draft Protocols | 1 | 1 | Find Find | | |

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



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



Within each section requiring review, you can make a revision to your protocol, respond to the reviewer with a rebuttal, or both. Information must be added to each section of the protocol in order to complete the page and get the green box. In some cases, you may have to respond to a reviewer remark in the rebuttal field to make this change.

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**.

Protocol Actions ?
 Draft Protocols ×
 Protocols in Review ×
 Draft Amendment ×

+ Start a New Protocol Application
 Copy Protocol to New Document

Highlight a protocol to start a new protocol copy of the selected

Find ↻

| 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**.

Protocol Actions ?
 Draft Protocols ×
 Protocols in Review ×
 Draft Amendment ×

+ Start a New Protocol Application
 Copy Protocol to New Document
 Start an Amendment

Find ↻

| 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**.

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


Amend Protocol

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.


Continuing Reviews

If you need to submit a continuing review, you can do so from the Continuing Reviews inbox.



| | |
|-------------------------|--------------------|
| Animal Oversight | ... |
| Hazard Safety | ... |
| Alert | Inbox Total |
| Protocol Actions | 0 3 |
| Draft Protocols | 4 4 |
| Protocols in Review | 0 1 |
| De Novo Reviews | 0 0 |
| Continuing Reviews | 2 2 |
| Draft IBC Amendments | 1 1 |
| Continuations in Review | |
| Reports | |

Click on the protocol you wish to continue:



Site: JMU
Role: Researcher Staff Members
P


Animal Oversight
Hazard Safety
Alert
Protocol Actions
Draft Protocols
Protocols in Review
De Novo Reviews
Continuing Reviews
Draft IBC Amendments
Continuations in Review
Reports

Protocol Actions
Draft Protocols
De Novo Reviews
Continuing Reviews
Draft IBC Amendments

Preview Protocol

| PI | Protocol # | Version | Title | Date Approved | Review Date | Expiration Date | Due Days | Status |
|----|------------------------------|---------|--------|---------------|-------------|-----------------|----------|----------------------------|
| | IBC-00000008 | 1 | TEST | 03/19/2024 | 03/19/2025 | 03/19/2027 | 30 | Approved (w/o Stipulation) |
| | IBC-00000006 | 2 | Exempt | 03/20/2024 | 03/20/2025 | 03/20/2027 | 31 | Approved (w/o Stipulation) |

Click on the Progress Report tab, select an option from the drop-down menu, and provide a brief summary of progress to date.



Site: JMU

Continuing Review

IBC-00000008 1

Table of Contents

- ☒ Continuing Review
- [Submit Continuing Review](#)
- [Preview Protocol](#)

Continuing Review

Please answer the questions on the Progress Report tab, answer any additional questions, and submit for IBC review.

As a reminder, if there are any changes in agents, procedures, locations, or personnel, an amendment to the protocol must be submitted to the IBC for review and approval prior to initiation of Adverse events, spills, and exposures must be promptly reported to the IBC.

Info

Progress Report

Project Personnel

Status

You must choose Continue As Is to keep your protocol active. If you want to close your protocol, choose Withdrawn. *

Progress Report

Provide brief update on the progress made in achieving the specific aims of the protocol. *

Continue As Is ▼

Continue As Is

Withdrawn

I U ~~S~~ X_2 X^2

A
B
C

D
E
F


System Font
10pt
Paragraph

≡
≡
≡

Save changes

Cancel changes

If continuing the study, indicate if personnel will continue on the study:



Site: JMU Role: Researcher Staff Member

Continuing Review

IBC-00000008 1

Table of Contents

- ☒ Continuing Review
- [Submit Continuing Review](#)
- [Preview Protocol](#)

Continuing Review

Please answer the questions on the Progress Report tab, answer any additional questions, and submit for IBC review.

As a reminder, if there are any changes in agents, procedures, locations, or personnel, an amendment to the protocol must be submitted to the IBC for review and approval prior to initiation of Adverse events, spills, and exposures must be promptly reported to the IBC.

Info

Progress Report

Project Personnel

| Carry Forward to Next Year? | Name | Role | Phone | Email | Organization |
|-------------------------------------|------------|--------------------------|-------|------------|--------------|
| <input checked="" type="checkbox"/> | [REDACTED] | | | [REDACTED] | |
| <input checked="" type="checkbox"/> | [REDACTED] | Researcher Staff Members | | | CoS |

Once all questions have been answered, submit the Continuing Review form:



Continuing Review

IBC-00000008 1

Table of Contents

☒ Continuing Review

[Submit Continuing Review](#)

[Preview Protocol](#)

Submit Continuing Review

[Submit New Protocol](#)

[↔ Submit Protocol](#)

De Novo Reviews

If your protocol is due for a De Novo Review, you can do so from the De Novo Reviews inbox.



| | |
|-------------------------|---------------------------|
| Animal Oversight | ... |
| Hazard Safety | ... |
| Alert | Inbox Total |
| Protocol Actions | 0 4 |
| Draft Protocols | 4 4 |
| Protocols in Review | |
| De Novo Reviews | 1 1 |
| Continuing Reviews | 2 2 |
| Draft IBC Amendments | 1 1 |
| Continuations in Review | |
| Reports | |

Click on the protocol you wish to continue:



Site: JMU

Role: Researcher Staff Members

PI Group: 1

| | |
|-------------------------|---------------------------|
| Animal Oversight | ... |
| Hazard Safety | ... |
| Alert | Inbox Total |
| Protocol Actions | 0 4 |
| Draft Protocols | 4 4 |
| Protocols in Review | |
| De Novo Reviews | 1 1 |
| Continuing Reviews | 2 2 |
| Draft IBC Amendments | 1 1 |
| Continuations in Review | |
| Reports | |

Protocol Actions Draft Protocols x De Novo Reviews x Continuing Reviews x Draft IBC Amendments x

Preview Protocol

| PI | Protocol # | Version | Title | Date Approved | Review Date | Expiration Date | Due Days | Protocol Status | Document |
|----|------------------------------|---------|-------|---------------|-------------|-----------------|----------|----------------------------|----------|
| | IBC-00000018 | 1 | | 03/18/2022 | 03/18/2025 | 03/18/2025 | 28 | Approved (w/o Stipulation) | New |

Provide a brief summary of progress to date and select an option from the drop-down menu:

De Novo Review Form

IBC-00000018 1

Phone

Progress Report

Provide a brief update on the progress made in achieving the specific aims of the protocol. *

| | | | | | | | | | | | | |
|--|--|----------|-------------|----------|--|-------|-------|----------|-----------|--|--|--|
| | | B | <i>I</i> | <u>U</u> | | X_2 | X^2 | <u>A</u> | | | | |
| | | | System Font | 10pt | | | | | Paragraph | | | |
| | | | | | | | | | | | | |

Please choose De Novo Review Action

- To close the protocol, please choose Lapse upon expiration.

- To renew the protocol, select Protocol will be renewed. The renewal protocol will be reviewed as if it is a new submission. If you need assistance, please reach out to the IBC office.

Instructions:

1. Complete the page and click Save.
2. Then click 'Start De Novo Review' at the bottom of the page. The system will open the currently approved protocol for editing. The system will prompt you to edit the details of each page to receive the green checkmark.
3. Please feel free to edit the form as needed to update information and include new work and justification for changes in animal numbers. **If no edits are needed, simply click in a text box or open a grid entry and resave to get the green checkmark.**
4. After all pages have green checkmarks, please submit for review. *

Protocol will be renewed

Lapse upon expiration

Cancel changes

If protocol will be renewed, click on “Start De Novo Review” at the bottom of the page:



De Novo Review Form

IBC-00000018 1

Phone

Progress Report

Provide a brief update on the progress made in achieving the specific aims of the protocol. *

| | | | | | | | | | | | | | | | |
|------|---|----------|-------------|----------|------|----------------|----------------|----------|---|---|---|--|---|--|--|
| ↶ | ↷ | B | <i>I</i> | <u>U</u> | ⌂ | X ₂ | X ² | <u>A</u> | ▼ | | ▼ | | ▼ | | |
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| test | | | | | | | | | | | | | | | |

Please choose De Novo Review Action

- To close the protocol, please choose Lapse upon expiration.

- To renew the protocol, select Protocol will be renewed. The renewal protocol will be reviewed as if it is a new submission. If you need assistance, please reach out to the IBC office.

Instructions:

1. Complete the page and click Save.
2. Then click 'Start De Novo Review' at the bottom of the page. The system will open the currently approved protocol for editing. The system will prompt you to edit the details of each page to receive the green checkmark.
3. Please feel free to edit the form as needed to update information and include new work and justification for changes in animal numbers. **If no edits are needed, simply click in a text box or open a grid entry and resave to get the green checkmark.**
4. After all pages have green checkmarks, please submit for review. *

Protocol will be renewed ▼

Start DeNovo Review


Update the protocol with any changes then click on Submit Protocol.

Closing a Protocol

If your protocol needs to be closed, follow the steps for Continuing Review or De Novo Review.

Continuing Review

On the Progress Report tab, select “Withdrawn,” provide a progress report, and choose an option of what will happen to the animals. Save changes once complete.


Site: JMU Role

Continuing Review
IBC-00000008 1

Table of Contents

- ✓ Continuing Review
- Submit Continuing Review
- Preview Protocol

Continuing Review

Please answer the questions on the Progress Report tab, answer any additional questions, and submit for IBC review.

As a reminder, if there are any changes in agents, procedures, locations, or personnel, an amendment to the protocol must be submitted to the IBC for review and approval.

Adverse events, spills, and exposures must be promptly reported to the IBC.

Info
Progress Report
Project Personnel

Status

You must choose Continue As Is to keep your protocol active. If you want to close your protocol, choose Withdrawn. *

Progress Report

Provide brief update on the progress made in achieving the specific aims of the protocol. *

Withdrawn

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System Font 10pt Paragraph

Save changes

Cancel changes

De Novo Review

Provide a progress report then select "Lapse Upon Expiration." Save changes once complete.



De Novo Review Form

IBC-00000018 1

Phone

Progress Report

Provide a brief update on the progress made in achieving the specific aims of the protocol. *

| | | | | | | | | | | | | | | |
|---|---|----------|-------------|----------|---|------------|------------|----------|---|-----------|---|---|---|--|
| ↶ | ↷ | B | <i>I</i> | <u>U</u> | ☹ | \times_2 | \times^2 | <u>A</u> | ▼ | | ▼ | | ▼ | |
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| | | | | | | | | | | | | | | |

Please choose De Novo Review Action

- To close the protocol, please choose Lapse upon expiration.

- To renew the protocol, select Protocol will be renewed. The renewal protocol will be reviewed as if it is a new submission. If you need assistance, please reach out to the IBC office.

Instructions:

1. Complete the page and click Save.
2. Then click 'Start De Novo Review' at the bottom of the page. The system will open the currently approved protocol for editing. The system will prompt you to edit the details of each page to receive the green checkmark.
3. Please feel free to edit the form as needed to update information and include new work and justification for changes in animal numbers. **If no edits are needed, simply click in a text box or open a grid entry and resave to get the green checkmark.**
4. After all pages have green checkmarks, please submit for review. *

Lapse upon expiration ▼

Save changes

Cancel changes

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](#).

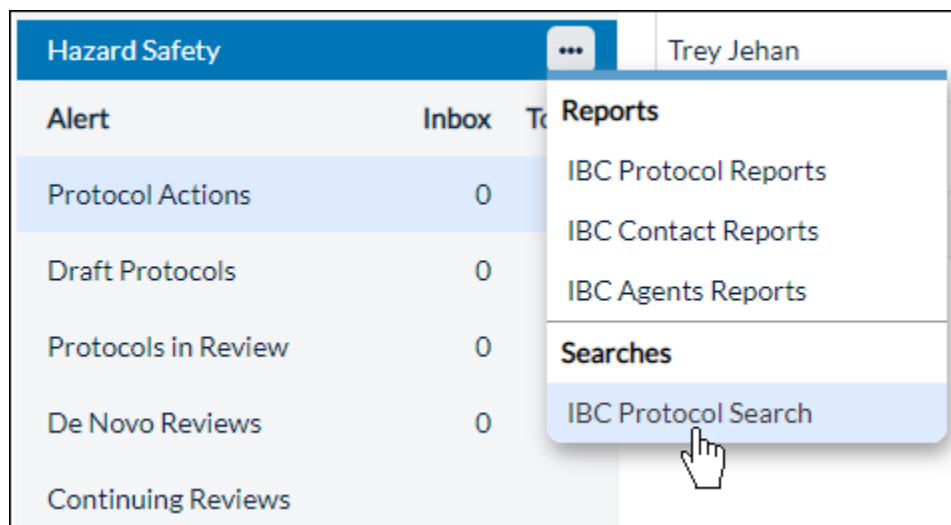
Continuations in Review

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

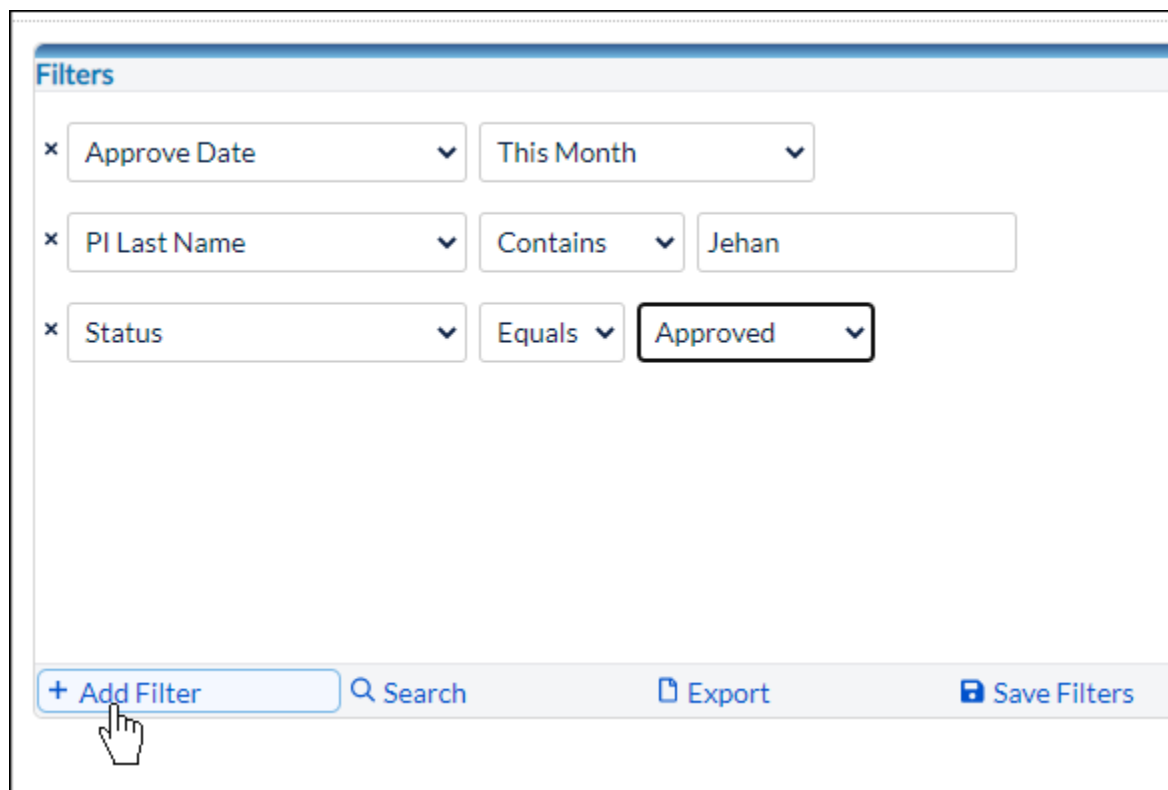
Running a Search in Hazard Safety

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

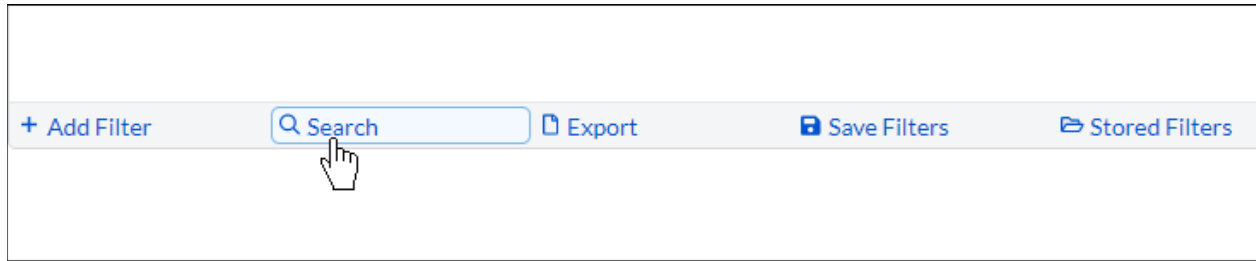
1. Click the menu next to the Hazard Safety header.
2. Click on **IBC Protocol Search**.



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.

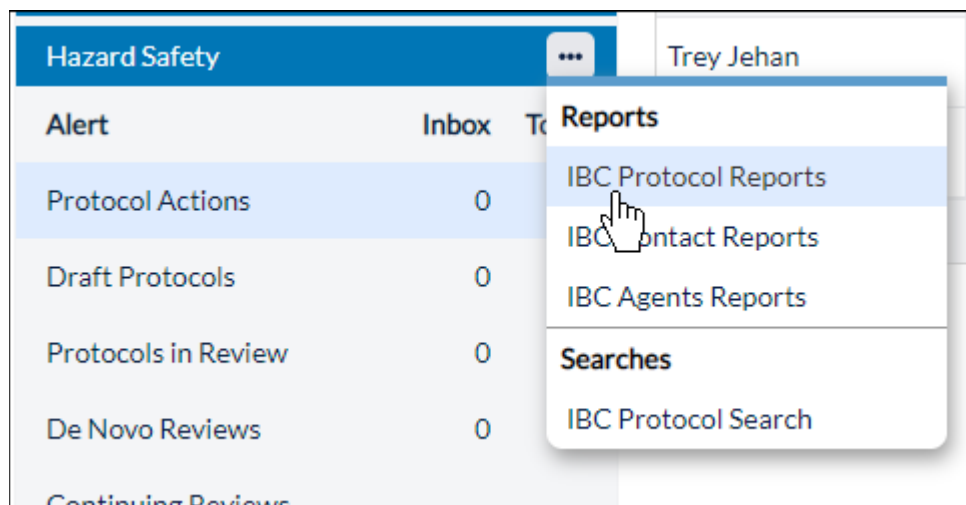


Running Reports in Hazard Safety

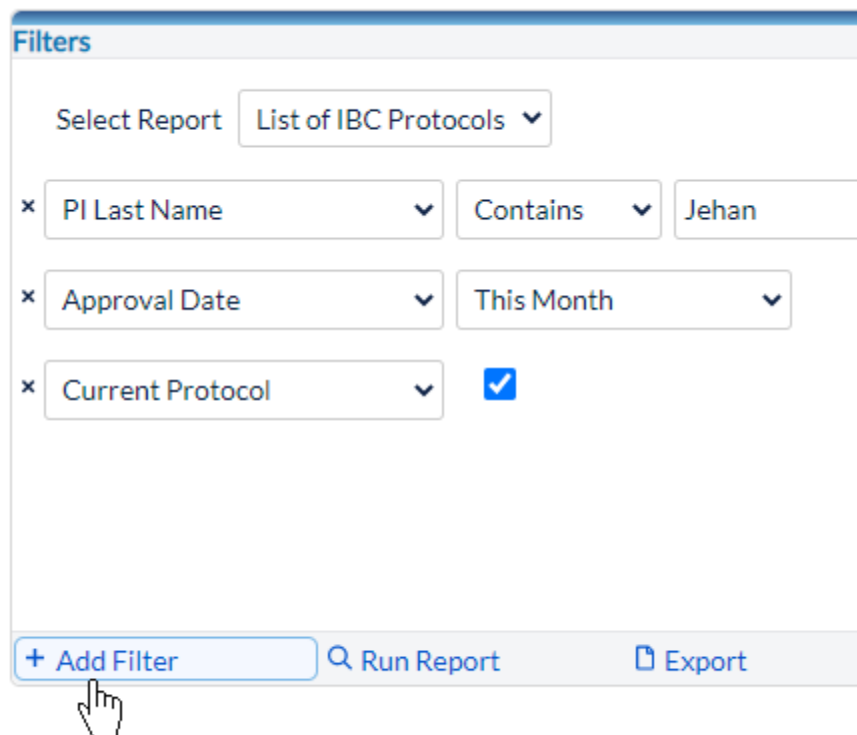
At some point, you may need to run reports in Cayuse IBC. You can run three different kinds of reports:

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

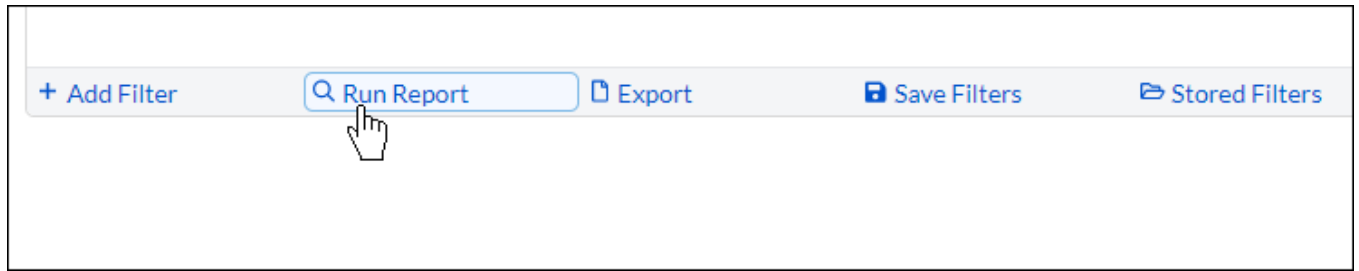
1. Click the menu next to the Hazard Safety header.
2. Click on the type of report or search you wish to run.



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



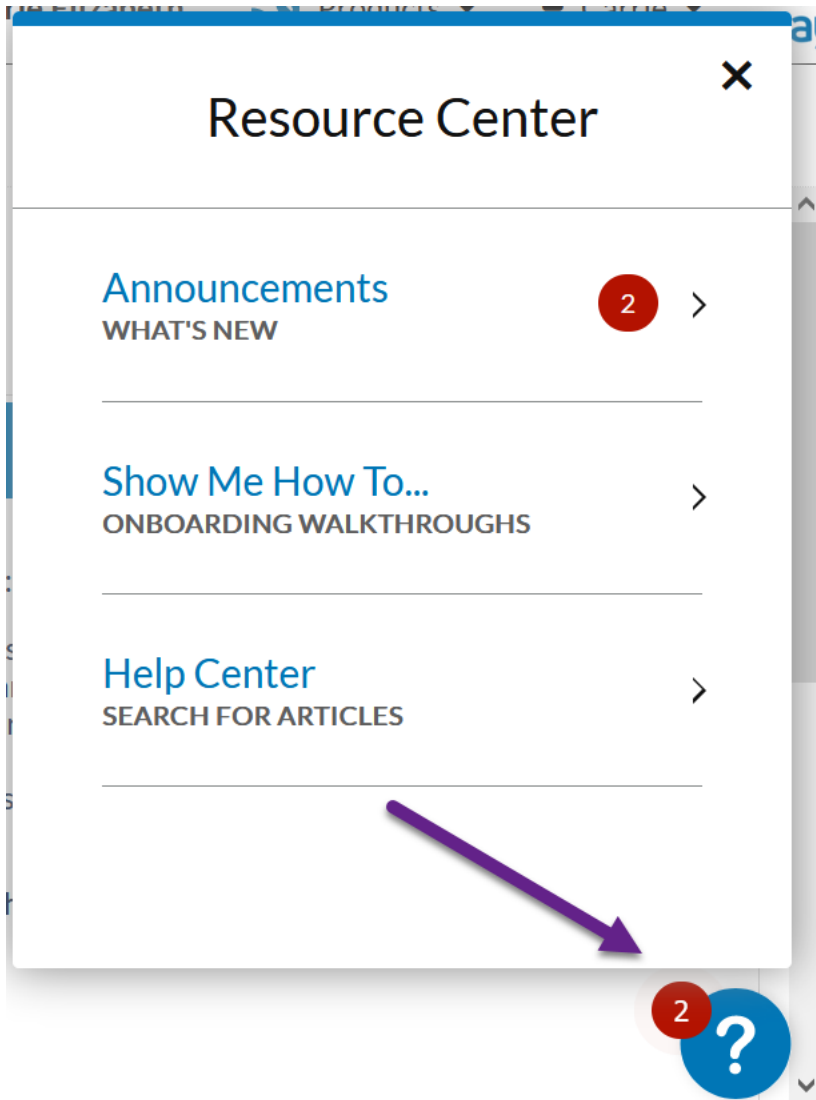
4. When you've chosen your filters, click **Run Report**. The report will populate in a new window.



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.

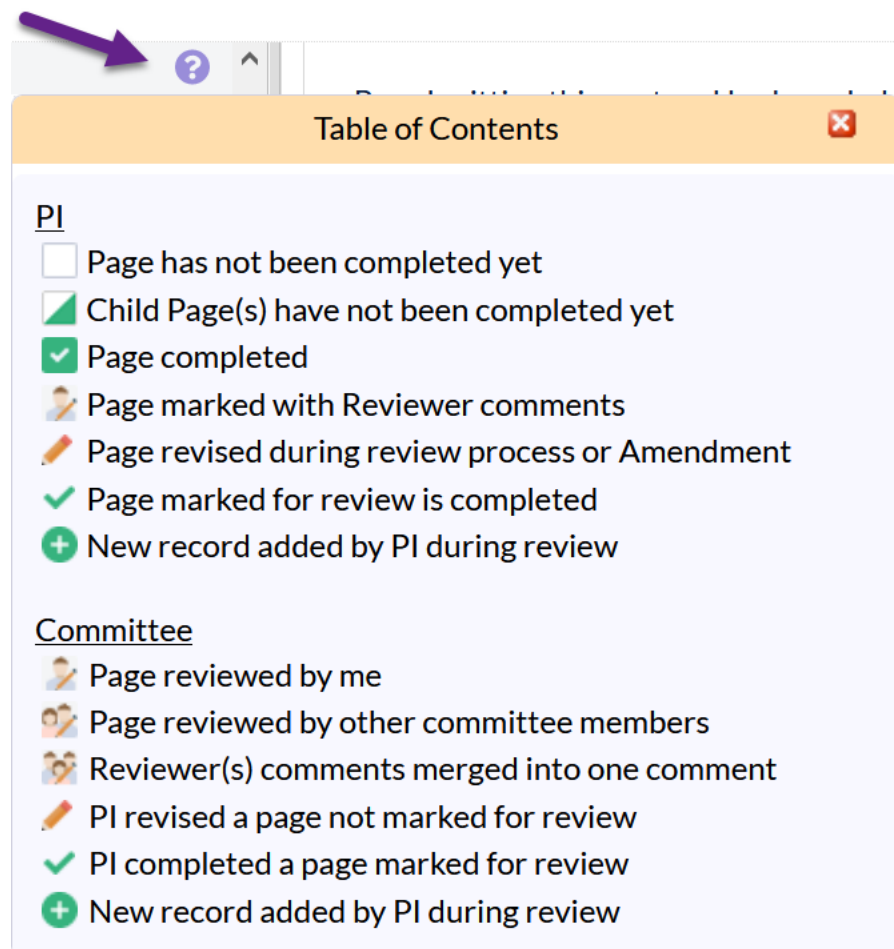


Table of Contents

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.