Animal Oversight
IACUC Researcher Manual

Table of Contents

Accessing Cayuse

To access Cayuse, go to: https://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!

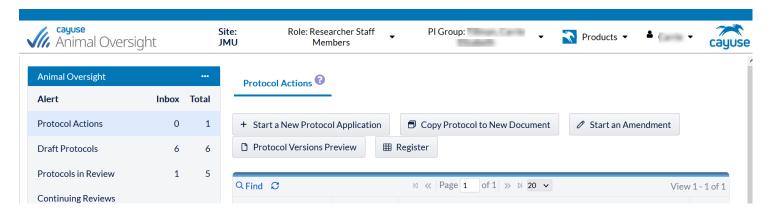Be sure to log out of this system by completely closing your web browser when finished. If you do not, someone else could use your web browser to login as you.
- Windows users: Close all web browser windows.
- Mac users: Quit your web browser

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

You will be taken to your Researcher Staff Members dashboard:

Starting and submitting your protocol

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

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

On the new page, click **Yes** next to **Will your research involve vertebrate animals or products of vertebrate animals?**

Clicking **No** will take you back to the homepage.

Click **Start New Application**.

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

Please Note: You can exit the protocol document at any time and continue working on it later by clicking **Animal Oversight** 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.

Completing Your Table of Contents Options

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

Protocol Introduction

Choose Options

Funded?	☐
Will you be collaborating with an outside institution?	Yes ◯ No ◯
Will field studies be conducted?	Yes ◯ No ◯
Will animals be moved through public access areas or taken outside of the vivarium?	Yes ◯ No ◯

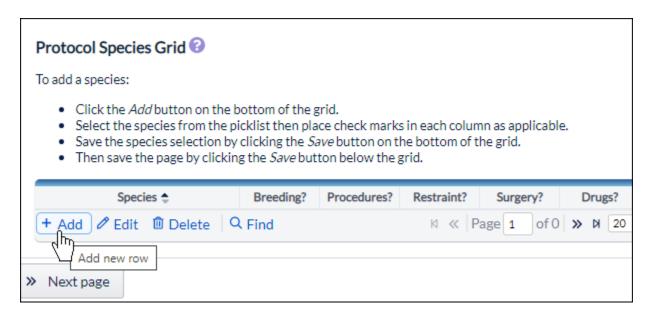The Options section is the first section in the protocol's Table of Contents. You will also need to update your Protocol Species Grid by clicking **Add**.

Protocol Species Grid ❓

To add a species:

- Click the *Add* button on the bottom of the grid.
- Select the species from the picklist then place check marks in each column as applicable.
- Save the species selection by clicking the *Save* button on the bottom of the grid.
- Then save the page by clicking the *Save* button below the grid.

Species ⬍	Breeding?	Procedures?	Restraint?	Surgery?	Drugs?

➕ Add   ✏ Edit   🗑 Delete   🔍 Find   ⏮ ≪ Page 1 of 0 ≫ ⏭ 20

Add new row

≫ Next page

Select your species from the dropdown, select which procedures the animal will undergo, and click **Save**. You can do this for multiple species within a protocol.

When you click **Save**, the selections made in the Options page determine which sections are added to the Table of Contents.

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

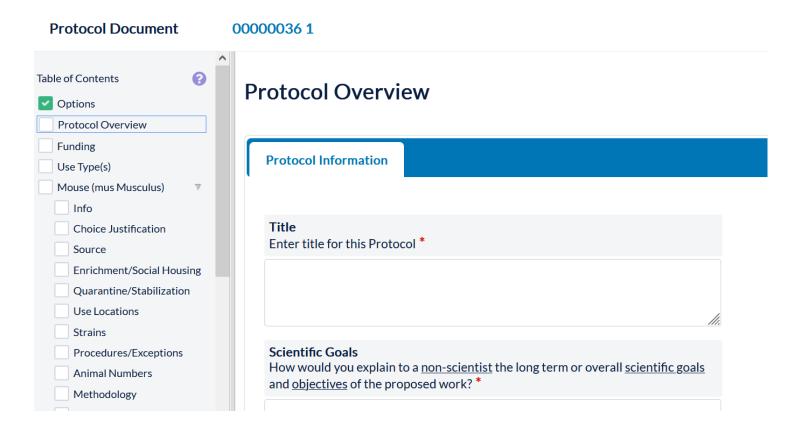A green check in the box next to a section means that all required fields within the section have been filled out. All sections must have a check mark before you can submit the protocol.

Default Sections

The default sections within all protocols are as follows:

- Options
- Protocol Overview
- Use Type(s)
- Personnel
- Databases Searched
- Endpoints

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.
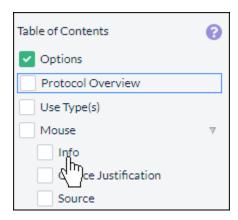
Tabs

Different pages may have multiple tabs with required questions you will need to fill out before a section can be marked as complete.

Required Questions

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

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.

Scientific Goals

How would you explain to a <u>non-scientist</u> the long term or overall <u>scientific goals</u> and <u>objectives</u> of the proposed work? *

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.

Radio Buttons

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

Enrichment

Will animals be socially housed?
The *Guide* states on p. 64 that *Single housing of social species should be the exception and justified based on experimental requirements or veterinary-related concerns about animal well-being.* *

Yes ○ No ○

Will environment enrichment be provided? *

Yes ○ No ○

Check Boxes

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

Type of Animal Use

Use Type(s)

Research Type *	Research ⌄
Other?	☐

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.

Type of Animal Use
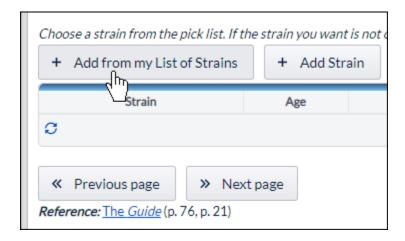
Use Type(s)

Research Type *	Research ⌄
Other?	

Research
Teaching
Wildlife
Holding

💾 Save changes ⊘ es

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**. The list item will show up as red if it needs your attention.

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/iacuc/forms/academic-unit-head-approval.docx.
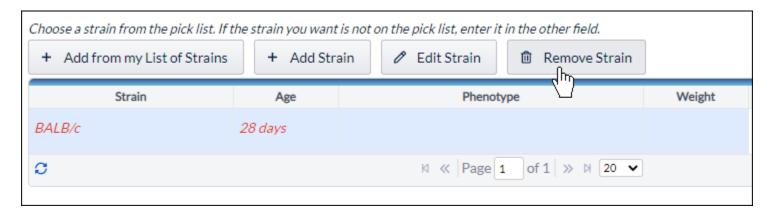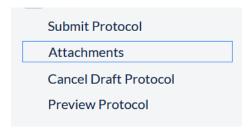
research and/or teaching, including PHS policies, USDA regulations, all federal, state, and local laws and regulations.

- I certify that all individuals working on this protocol will read and understand the approved procedures described in this protocol, prior to initiating any animal work on this project.
- I certify that all individuals working on this protocol will read and understand the approved procedures described in all future modifications to this protocol, prior to initiating any work covered by the modification.
- I certify that all personnel will be made aware of the various health hazards they may encounter while working on this protocol, complete applicable training, and will be trained on the appropriate steps to mitigate any risks.
- I certify that all personnel will be provided with sufficient time to obtain the training necessary for their participation in this project.
- I certify that all animals will be lawfully acquired and that the animal activities approved in this protocol will not begin until required permits and committee approvals are obtained.
- I certify that the committee will be notified regarding any unexpected study results or incidents that cause more than slight or momentary pain or distress to animals, including unexpected morbidity and mortality.
- I understand that failure to comply with any of the above conditions is a matter of non-compliance and can result in approval delays and/or suspension of any or all animal-related activities associated with this protocol.

Please download the Academic Unit Head Approval **form. Complete this form with your academic unit head and then upload it under the attachments section.**

Once obtained, upload it to the Attachments section.

Submit Protocol

Attachments

Cancel Draft Protocol

Preview Protocol

Important Note: ORI will obtain the Attending Veterinarian's verification once the protocol has been submitted.

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.

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

If a section is missing a green checkmark, 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:

If you filled out everything correctly, you will return to the dashboard and your protocol will now be routed to the IACUC office for review and approval, and the protocol will appear in your Protocols in Review inbox.

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

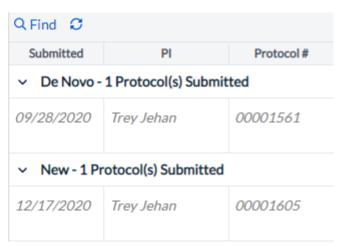| Protocols in Review	0	2
Continuing Reviews		
Continuations in Review		
De Novo Reviews		
Draft Amendment	2	2
Transfer Ownership	0	0

🔍 Find ↻

Submitted	PI	Protocol #
⌄ De Novo - 1 Protocol(s) Submitted		
09/28/2020	Trey Jehan	00001561
⌄ New - 1 Protocol(s) Submitted		
12/17/2020	Trey Jehan	00001605

Important Note: ORI will route to the Attending Veterinarian for verification before it is assigned to the IACUC for review.

Revising Your Protocol in Animal Oversight

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 Protocols in Review Alerts.

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.

When you are finished revising your protocol, click **Submit Protocol**, 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.

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

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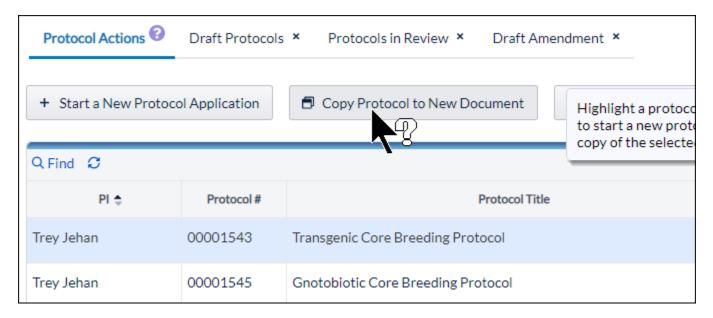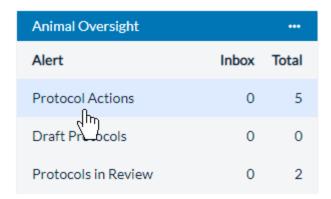
Animal Oversight		•••
Alert	**Inbox**	**Total**
Protocol Actions	0	5
Draft Protocols	0	0
Protocols in Review	0	2

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 *	Subject quantity needs adjustment

✏ 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.

Click on the protocol you wish to continue:

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

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

On the next tab, indicate if there have been any adverse events within the past year:

cayuse Animal Oversight

Continuing Review   00000003 3

Table of Contents
Continuing Review
Submit Continuing Review
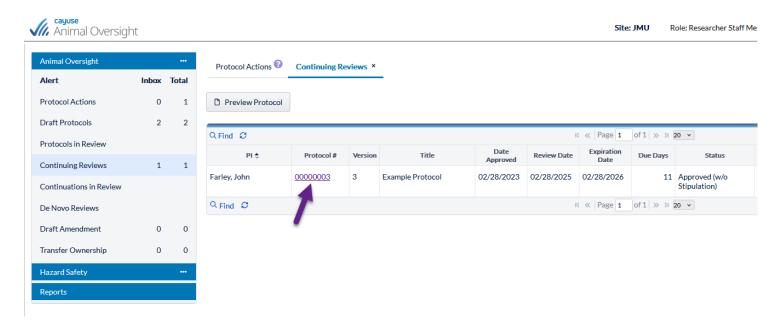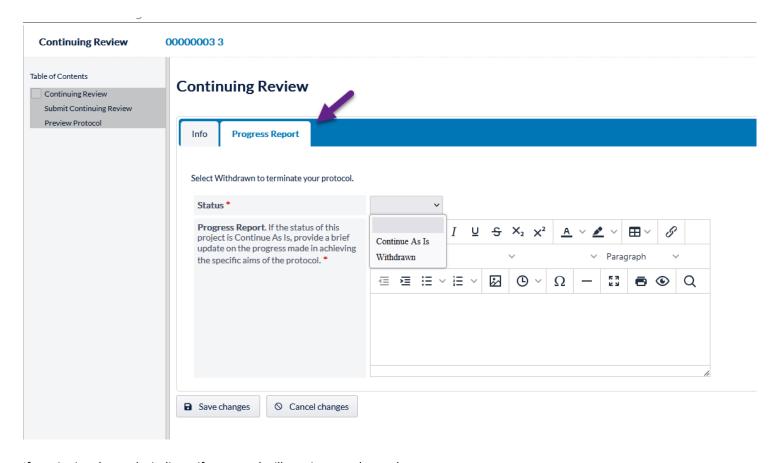Preview Protocol

Continuing Review

| Info | Progress Report | Project Personnel | **Adverse Events** |

Have you experienced any adverse events or unexpected outcomes in the past year? *

Yes ○ No ○

💾 Save changes   ⊘ Cancel changes

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

cayuse Animal Oversight

Continuing Review   00000003 3

Table of Contents
✔ Continuing Review
Submit Continuing Review
Preview Protocol

Submit

Submit New Protocol

By submitting this protocol, I acknowledge and agree to the following terms.

⇄ 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.

Click on the protocol you wish to continue:

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

cayuse
Animal Oversight

De Novo Review Form 00000029 1

Progress Report. If the status of this project is Renewal, provide a brief update on the progress made in achieving the specific aims of the protocol. *

[Rich text editor toolbar]

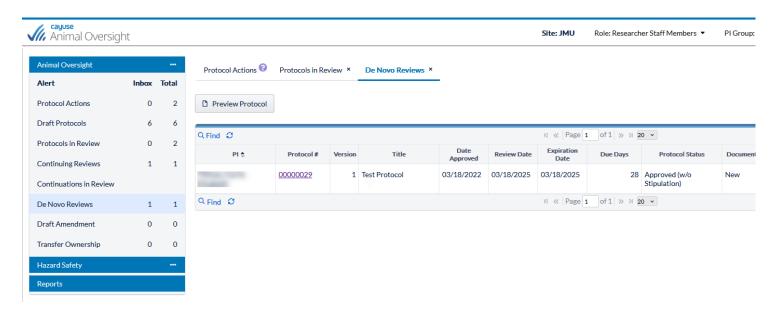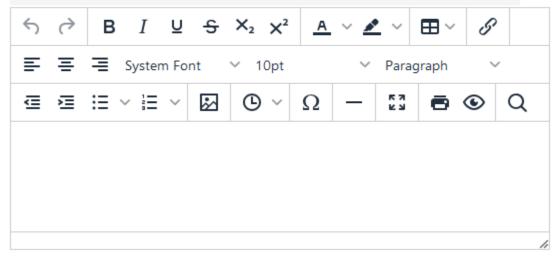↶ ↷ **B** *I* U S X₂ X² A ∨ ✎ ∨ ⊞ ∨ 🔗

≡ ≡ ≡ System Font ∨ 10pt ∨ Paragraph ∨

⇤ ⇥ ☰ ∨ ☰ ∨ 🖼 🕐 ∨ Ω — ⤢ 🖨 👁 🔍

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 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. *

[Drop-down menu options:]
Protocol will be renewed
Lapse upon expiration

	gory	Total # Approved	Balance	Approve Date
Musculus)		50	50	03/18/2022

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

Fund Source	Fund Title
National Science Foundation	

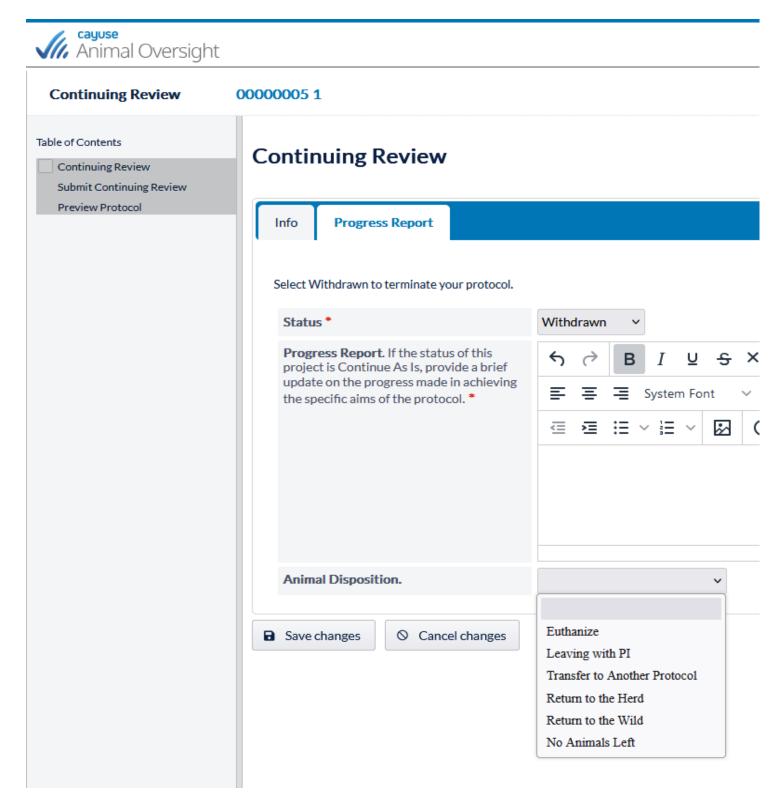Q Find ↻

□ 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.
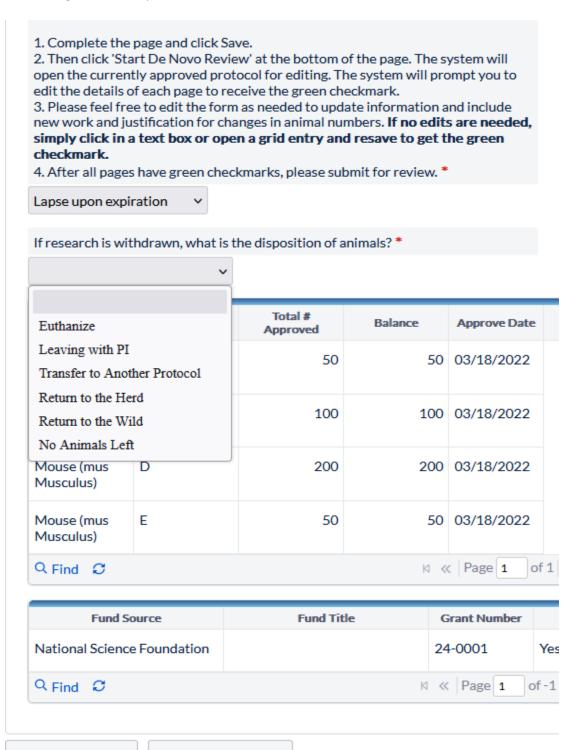
Continuing Review

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.

De Novo Review

Provide a progress report then select "Lapse Upon Expiration" and choose an option of what will happen to the animals. Save changes once complete.
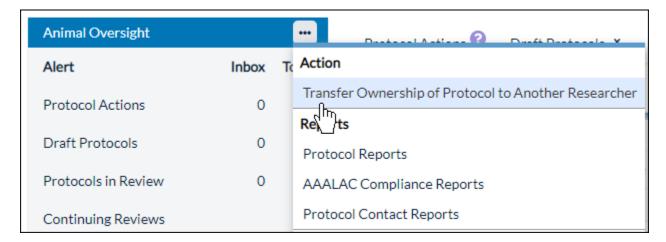
1. Complete the page and click Save.
2. Then click 'Start De Novo Review' at the bottom of the page. The system will open the currently approved protocol for editing. The system will prompt you to edit the details of each page to receive the green checkmark.
3. Please feel free to edit the form as needed 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 ⌄

If research is withdrawn, what is the disposition of animals? *

⌄

		Total # Approved	Balance	Approve Date
Euthanize				
Leaving with PI		50	50	03/18/2022
Transfer to Another Protocol				
Return to the Herd		100	100	03/18/2022
Return to the Wild				
No Animals Left				
Mouse (mus Musculus)	D	200	200	03/18/2022
Mouse (mus Musculus)	E	50	50	03/18/2022

🔍 Find ⟳   ◁ « Page 1 of 1

Fund Source	Fund Title	Grant Number	
National Science Foundation		24-0001	Yes

🔍 Find ⟳   ◁ « Page 1 of -1
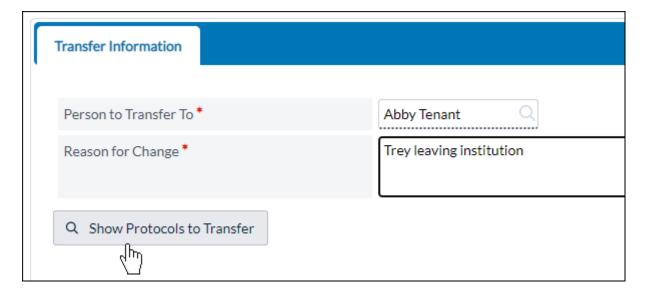
💾 Save changes   ⊘ Cancel changes

Transferring a Protocol

If you need to transfer the ownership of your protocol to another researcher, you can do so within the Actions menu.
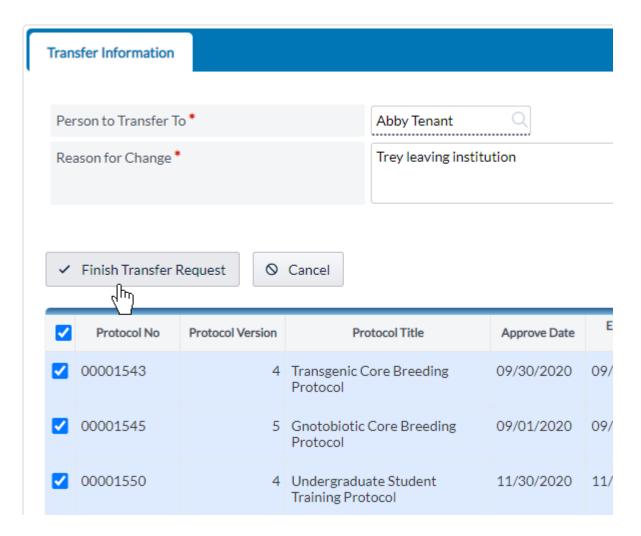
1. Click on the menu next to Animal Oversight.

2. Click **Transfer Ownership of Protocol to Another Researcher**.

3. Select the new owner of the protocol. Contacts are defined within Contact Management by the IACUC office.
4. Enter the reason for the transfer, and click **Show Protocols to Transfer**.
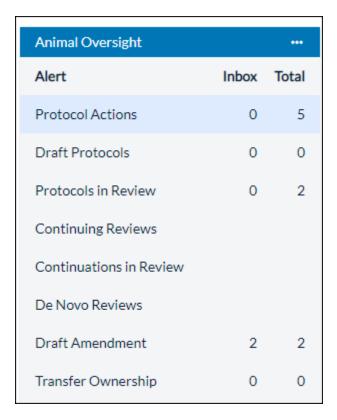
5. Select the protocol(s) you wish to transfer, and click **Finish Transfer Request**.

The protocol will remain in the Transfer Ownership inbox beneath the alerts on your dashboard until the transfer has been approved by the IACUC office.

Understanding Alerts in Animal Oversight

In Cayuse Animal Oversight, 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.

Animal Oversight	•••	
Alert	**Inbox**	**Total**
Protocol Actions	0	5
Draft Protocols	0	0
Protocols in Review	0	2
Continuing Reviews		
Continuations in Review		
De Novo Reviews		
Draft Amendment	2	2
Transfer Ownership	0	0

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.

Continuations in Review

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

De Novo Reviews

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

Draft Amendment

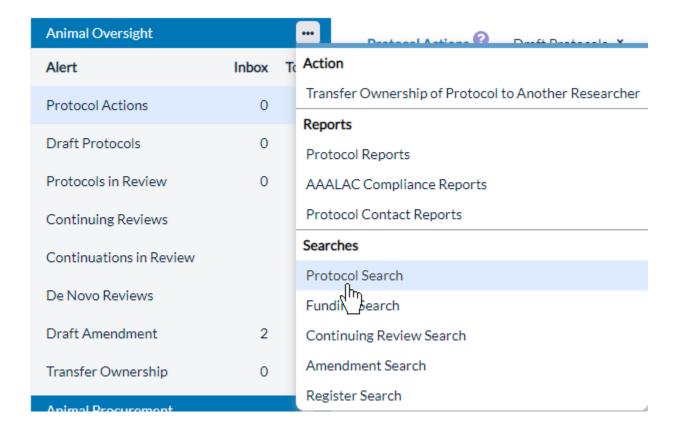This alert will show draft amendments.

Transfer Ownership

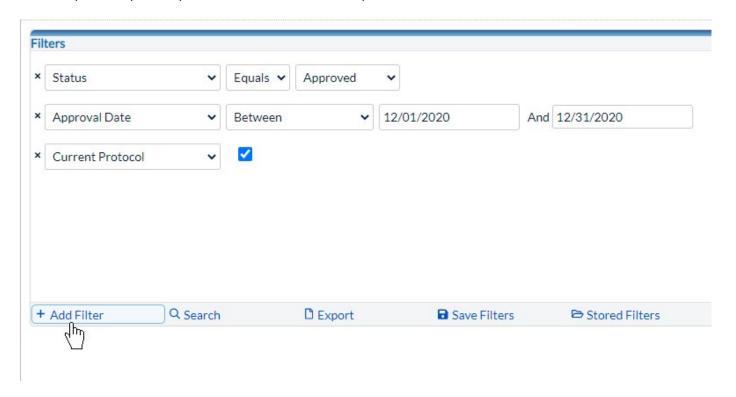This alert shows all protocols where the transfer of ownership is pending.

Running a Search in Animal Oversight

You can run four different kinds of searches in Cayuse Animal Oversight from the Actions menu:

- Protocol Search
- Funding Search
- Continuing Review Search
- Register Search

1. Click the menu next to the Animal Oversight header in the left-hand menu.

2. Click on the type of search you wish to run.

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.
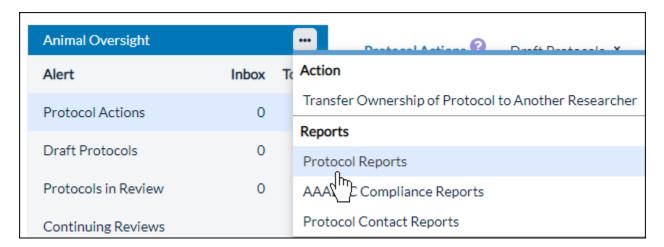

You can also **Export** the report to a .CSV, **Recall Filters**, or **Save Filters** for later.
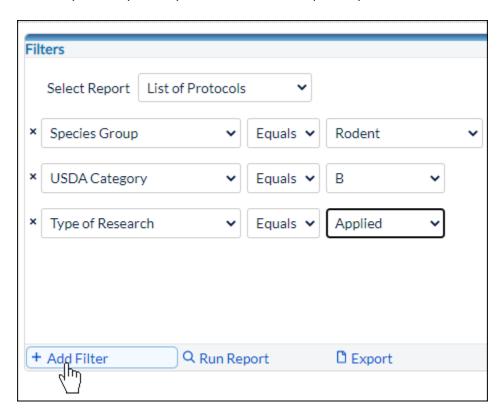
Running Reports in Animal Oversight

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

- Protocol Reports
- AAALAC Reports
- Protocol Contact Reports

1. Click the menu next to the Animal Oversight header in the left-hand menu.

2. Click on the type of report you wish to run.

3. On the Protocol Reports Filters page, select the type of report you wish to run.
4. Select any filters by which you wish to limit the report. If you need to add additional filters, click **Add Filter**.

5. 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.

Frequently Asked Questions

What is Cayuse Animal Oversight?
Cayuse Animal Oversight is a web-based application used to draft, review, approve, and manage Institutional Animal Care and Use Committee (IACUC) 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 Animal Oversight?
Users will need to be granted access by the IACUC 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 Animal Oversight?
Users with the Researcher Staff Members role that have PI eligibility may submit protocols. In addition, only JMU faculty may serve as PI. Please see the guidance on Principal Investigator Eligibility.

How do I receive updates regarding my Cayuse IACUC submissions?
The application will send users emails when action is required on submissions. For example, the Cayuse Animal Oversight application will send users notifications when a protocol has questions from the IACUC 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 Procedure, Species, Drug, etc. is not available in the protocol.
Data dictionaries were created based on current information. If your proposed procedure, species, etc. is not listed, please complete the following form and ORI will add them to the system: https://forms.office.com/r/nXU1WLArvs.

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

How will Cayuse Animal Oversight 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.