




Hazard Safety

IBC Reviewer Manual



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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 “**Hazard Safety**”:

The screenshot shows the 'My Tasks' dashboard. The top navigation bar includes 'Products' with a dropdown menu. The dropdown menu is open, showing options: Home, Human Ethics, Animal Oversight, Outside Interests, and Hazard Safety. A purple arrow points to 'Hazard Safety'. Below the navigation bar, there are filter buttons: 'Assigned to Me', 'Created by Me', 'Open', and 'All'. The main content area is a table with columns: Task, Task Type, From, Assigned To, Created, and Last Activity. Below the table, it says 'No Saved Tasks'.

Verify that your dashboard is correct. You may need to select “**Role**” then “**IBC Member**.”

The screenshot shows the 'Hazard Safety' dashboard. The top navigation bar includes 'Site: Root', 'Role: IBC Member' (with a dropdown arrow), 'Products', and the 'cayuse' logo. A purple arrow points to the 'Role: IBC Member' dropdown. Below the navigation bar, there is a sidebar with 'Hazard Safety' and 'Alert' sections. The main content area shows a table with columns: Full Name, Protocol No, Step Start Date, Step Start Time, Protocol Title, Previous Workflow User Status, Work Flow User Status, Trans Detail, Submit Date, Document Number, and Primary Secondary Reviewers. The table is currently empty.

Reviewing a Protocol

Click on the protocol number to begin your review.

The screenshot shows the Hazard Safety system interface. On the left is a sidebar with a 'Table of Contents' menu. The main area displays 'Protocols in Review IBC' with a 'Preview Protocol' button. Below this is a table with columns: Full Name, Protocol No, Step Start Date, Step Start Time, Protocol Title, Previous Workflow User Status, Work Flow User Status, Trans Detail, Submit Date, and Document Number. A purple arrow points to the protocol number 'IBC-0000019' in the 'Protocol No' column. The table also shows a date filter for '04/01/2024 - 1 Protocol(s)' and a 'test 3/27/24' protocol title.

Navigating the Protocol and Adding Comments

1. Use the Table of Contents (TOC) on the side bar to jump from page to page by clicking on the page title.

The screenshot shows the 'Table of Contents' sidebar menu. The menu items are: Options, Overview (highlighted with a blue border), Nucleic Acids (with a dropdown arrow), NIH Guidelines, Vectors/Plasmids, Facilities, Transport/Shipping, Dual Use, Personnel, Safety, Assurance, Attachments, Preview Protocol, and Agents on IACUC Protocols.

2. Use the previous or next buttons at the bottom of the page to navigate through the protocol form.
3. Click on the “**Review Notes**” tab to expand the toolbox. To leave a note at the **page level**, type the comment in the Reviewer Notes box and click Save.

Table of Contents

- Options
- Protocol Overview
- Funding
- Use Type(s)
- Mice
- Info
- Choice Justification
- Source
- Enrichment/Social Housing
- Quarantine/Stabilization
- Use Locations
- Strains
- Procedures/Exceptions
- Vet Drugs
- Animal Numbers
- Methodology**
- Unrelieved Pain/Distress
- 3Rs
- Adverse Consequences
- Personnel
- Databases Searched
- Endpoints
- Attachments
- Review Protocol

Methodology

- Please list the interventions/procedures in chronological order, indicating the time interval between each procedure.
- All procedures listed in the table on the procedures page must be included.**
- Include the rationale for use of tissues in vitro but do not describe in vitro procedures performed on tissues in vivo.
- Flowcharts or other graphical representations of the methodology can be very helpful. This text box allows for a maximum of 10,000 characters.

Animal Use Procedure Description

Species	Type	Description
Mice	Procedures	Behavior Modification

Find Page 1 of 1 of 1 View 1 - 1 of 1

Procedure Description *

- Describe the statistical method (or other method) used to justify the number of animals per group.
- Federal guidance states that statistical methods must be used in order to justify the number of animals requested.
- Describe mortality or exclusion rates if applicable.

Synopsis Submit Office Notes View Changes **Review Notes**

Save Cancel Delete Full Document Review

Review Notes

Committee Member comment goes here!

Reviewer	Status	Status Date	Update Date
Preview			

No records to view

Reviewer Notes

5. To leave a reviewer comment within a **specific text response**, click the response. The text will display in the review toolbox. Click +Add Comment and then click the text to add a footnote. Then add the comment in the Reviewer Notes box below. Click Save.

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Justification for Choice of Species

Justify the choice of species by stating why a species lower on the phylogenetic scale is not appropriate.

Justification

Justification for choice of species. *

Toxicity studies using mammalian species are generally required to provide safety data to support clinical development and licensing registration for potential new pharmaceuticals. International regulatory guidelines outline recommendations for the order (rodent and/or non-rodent) and number of species, retaining flexibility for development of a diverse range of drug modalities in a manner relevant for each specific new medicine. Selection of the appropriate toxicology species involves consideration of scientific, ethical and practical factors, with individual companies likely having different perspectives and preferences regarding weighting of

« Previous page » Next page »

Synopsis Submit Office Notes **View Changes** Review Notes

Save Cancel Delete Full Document Review

Previous Version Changes

+ Add Comment 2 Delete Comment Resequence Comments

Changes made in last revision

Toxicity studies using mammalian species are generally required to provide safety data to support clinical development and licensing registration for potential new pharmaceuticals. International regulatory guidelines outline recommendations for the order (rodent and/or non-rodent) and number of species, retaining flexibility for development of a diverse range of drug modalities in a manner relevant for each specific new medicine. Selection of the appropriate toxicology species involves consideration of scientific, ethical and practical factors, with individual companies likely having different perspectives and preferences regarding weighting of various aspects dependent upon molecule characteristics and previous experience.

Review Notes

Footnote comment within a block of text to better guide the PI to the sentence in question

6. To add a comment on an item in a **grid** (e.g. Drug Information, Personnel, etc.), click the entry to highlight it and then click View. Expand the Reviewer toolbox and add the comment. Click Save. After a reviewer comment is saved, a Reviewer Icon will display by the item needing revision.

Table of Contents ?

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- Mice ▼
 - Info
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 - Adverse Consequences
 - Personnel
 - Databases Searched

Drug Information

For assistance in determining species-appropriate drugs and dosages, contact one of our veterinarians.

View Drug

Drug	Type	Dosage	Route of Administration	Frequency	Reason for Administration	Pharma Grade?
Meloxicam	Analgesic	0.2 mg/kg	INJ	SID	Meloxicam is indicated for relief of pain and inflammation due to osteoarthritis. It is taken as a single dose of 7.5 mg/day, and it is considered to have a better safety profile than older nonsteroidal anti-inflammatory agents Engelhardt (1996).	Yes
<input type="checkbox"/> Pyrantel pamoate	Anesthetic	2.0 to 4% for induction	INJ	Test	to treat pinworms (enterobiasis; oxyuriasis). This medicine may also be used for other worm infections as determined by your doctor. Pyrantel works by paralyzing the worms. They are then passed in the stool.	Yes

Page of 1
View 1 - 2 of 2

Submitting the Review

1. Click on the Submit tab and select a status.

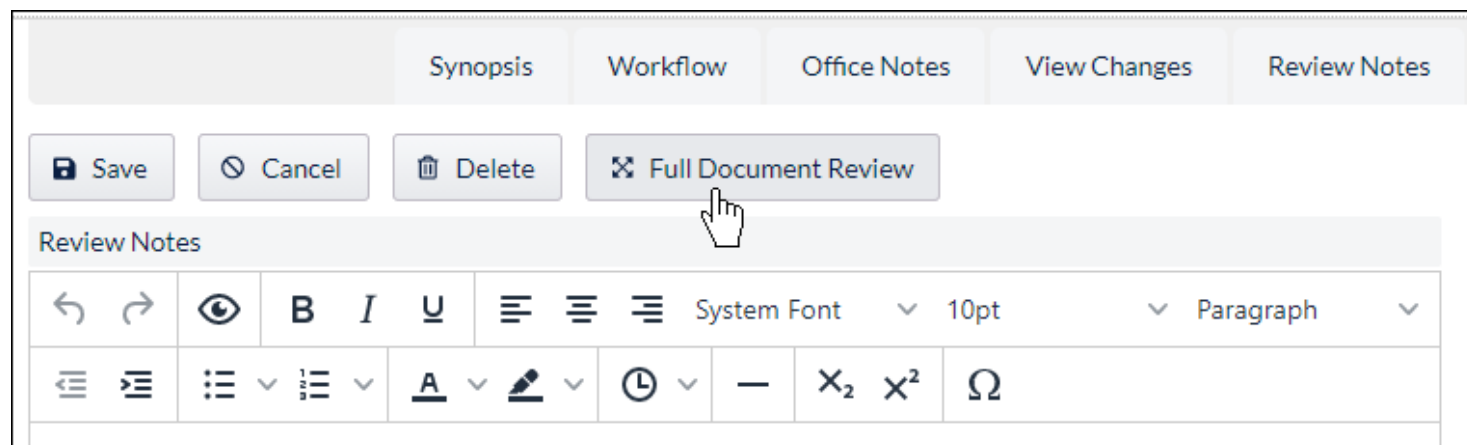
- Full Committee Review – the IBC Office will be notified to add the item to the agenda
- Reviewed, no Questions – the review was completed without any questions for the PI
- Reviewed, w/Questions – the IBC Office will be notified that questions were entered for the PI

The screenshot shows a software interface with a top navigation bar containing tabs: Synopsis, **Submit**, Office Notes, View Changes, and Review Notes. Below the tabs is a 'Submit' button with a right-pointing arrow. Underneath is a 'Status:' dropdown menu currently set to 'Full Committee Review'. A dropdown menu is open, showing three options: 'Full Committee Review' (highlighted in blue), 'Reviewed, no Questions', and 'Reviewed, w/Questions'. Below the status dropdown is a rich text editor toolbar with icons for undo, redo, bold, italic, underline, link, bulleted list, numbered list, text color, background color, link, unlink, subscript, superscript, insert link, and table. The main text area is empty.

2. Use the General Notes text box to document your review decision.
1. Designated Member Review – Log your decision (Modifications Required, FCR or Approved)
 2. Full Committee Review – provide your review summary and recommendation to the committee
3. Click Submit to return the protocol to the office. Once submitted, the protocol will disappear from your alerts.

Using Full Document Review in Hazard Safety

The Full Document Review (FDR) allows the reviewer to view the entire protocol at once. While in review mode, click on the Full Document Review button found in the Review Pane.



A new window will open the full document review:

- Multiple reviewers can use the FDR feature simultaneously.
- As reviewer's comments are saved on the FDR, reviewers can see these comments via the protocol. In other words, all comments made via Full Document Review are synchronously available to view via the protocol review.
- As reviewer's comments are saved on the protocol, reviewers using the Full Document Review feature can view them by refreshing the page.
- Icons display indicating where revisions and updates have been made.
- Footnotes can only be used in the protocol, not in Full Document Review.

Document Layout

Full Document Review will open to the Table of Contents.

PI :	Principal, Penny
Protocol #	00001033
Status :	Pending
Approved :	07/31/2019
Expires :	07/31/2022
Title :	SYNTHETIC GENE CIRCUITS FOR MONITORING T-CELL EXHAUSTION

Table of Contents

[Protocol Introduction](#)
[Protocol Overview](#)
[Protocol Federal/Foundation Funding List](#)
[Protocol Internal Funding](#)
[Foundation Funding](#)
[Protocol Other Funding](#)
[Protocol Private/Commercial Funding](#)
[Off-campus Animal Work](#)
[Outside Collaboration](#)
[Inside Collaboration](#)
[Antibodies Source](#)
[Animal Tissues Info](#)
[Type of Animal Use](#)
[Housing Outside Central Facility](#)

Enter review notes in the My Notes area within every section.

Protocol Introduction

My Notes

↶ ↷ **B** *I* A A ~~S~~ U
Font Sizes ▾
Formats ▾
Font Family ▾

Federal/Foundation funded?

Internally funded?

Private/Commercially funded?

Reviewer notes are automatically saved. The pin icon is used to pin the note to the top of the document. These icons allow the user to view and write on the review section as they scroll through the document.

As different reviewers enter their review notes, the notes display in the Reviewer's Notes tab.

Review Icons

- **One head:** Page has only been reviewed by you.
- **Two heads:** Page has been reviewed by other committee members.
- **Three heads:** Reviewer's comments have been merged by IACUC coordinator into one comment.
- **Pencil:** PI has revised a page which was not marked for review.
- **Check mark:** PI has completed a page marked for his review.
- **New record:** PI added a new record to a multi-grid page during review.

Hover over the purple question mark in the Table of Contents any time you need to remember what each review icon means.

The screenshot shows the Cayuse Hazard Safety application interface. At the top, there is a header with the Cayuse logo and the text "Hazard Safety". Below the header, there are two main sections: "Start a New IBC Application" and "IBC-00000019 1". The main content area is titled "Protocol Overview" and contains a "Table of Contents" sidebar on the left. A purple question mark icon is visible in the sidebar. A pop-up window titled "Table of Contents" is open, displaying a legend for review icons.

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

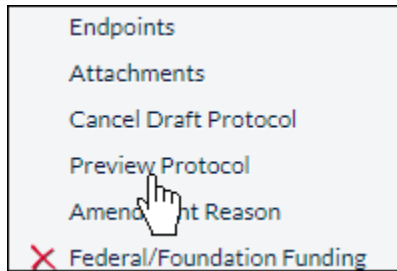
Committee

- 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

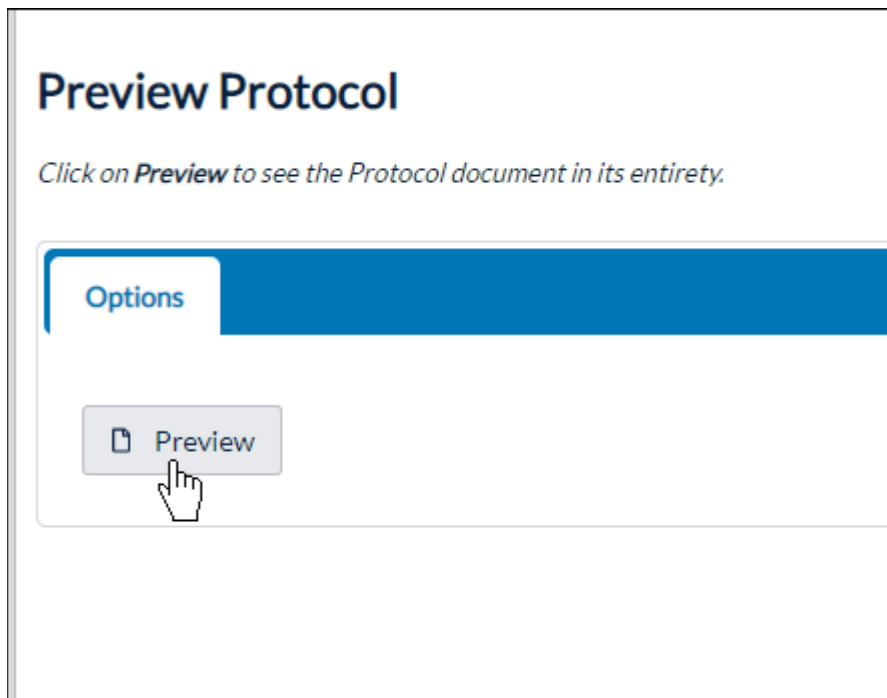
Comparing Protocol Versions in Hazard Safety

If you'd like to compare versions of a protocol side-by-side, you can do this within a revised protocol.

1. In the Table of Contents, click on **Preview Protocol**.



2. Beneath Options, click on **Preview**.



3. A new window will pop up containing the protocol. At the top of the protocol, use the **Compare to previous** dropdown menu to choose the two versions to compare.

Compare to previous Revisions: 0004 Hide previous Show Main
 Text Style: On 0004 Font size: 12

Previous Version	Changes																								
<table border="1"> <tr><td>PI :</td><td>Trey Jehan</td></tr> <tr><td>Protocol #</td><td>00001543</td></tr> <tr><td>Status :</td><td>Approved</td></tr> <tr><td>Approved :</td><td>09/30/2020</td></tr> <tr><td>Expires :</td><td>09/30/2023</td></tr> <tr><td>Title :</td><td>Transgenic Core Breeding Protocol</td></tr> </table> <p>Table of Contents</p> <ul style="list-style-type: none"> Protocol Introduction Protocol Overview Protocol Federal/Foundation Funding List Type of Animal Use Mouse <ul style="list-style-type: none"> Species Information Justification for Choice of Species Species Source Enrichment and/or Exercise Use Locations Strain Information Breeding Information Non-Surgical Procedures Prolonged Restraint Surgical Procedures Multiple Major Survival Surgeries Veterinary Drug Information Experimental Agents Euthanasia Method Information Humane Use Animal Categories Methodology Unrelieved Pain or Distress Reduce, Refine, Replace Adverse Consequences SOP Exemptions Personnel List Databases Searched Research Endpoints Protocol Attachments Amendment Reason <p>Protocol Introduction</p>	PI :	Trey Jehan	Protocol #	00001543	Status :	Approved	Approved :	09/30/2020	Expires :	09/30/2023	Title :	Transgenic Core Breeding Protocol	<table border="1"> <tr><td>PI :</td><td>Trey Jehan</td></tr> <tr><td>Protocol #</td><td>00001543</td></tr> <tr><td>Status :</td><td>Pending</td></tr> <tr><td>Approved :</td><td>09/30/2020</td></tr> <tr><td>Expires :</td><td>09/30/2023</td></tr> <tr><td>Title :</td><td>Transgenic Core Breeding Protocol</td></tr> </table> <p>Table of Contents</p> <ul style="list-style-type: none"> Protocol Introduction Protocol Overview Protocol Internal Funding Type of Animal Use Mouse <ul style="list-style-type: none"> Species Information Justification for Choice of Species Species Source Use Locations Strain Information Breeding Information <ul style="list-style-type: none"> Non-Surgical Procedures Prolonged Restraint Surgical Procedures Multiple Major Survival Surgeries Veterinary Drug Information Experimental Agents Euthanasia Method Information Humane Use Animal Categories Methodology Unrelieved Pain or Distress Reduce, Refine, Replace Adverse Consequences SOP Exemptions Enrichment and/or Exercise Non-Surgical Procedures Personnel List Databases Searched Research Endpoints Protocol Attachments Amendment Reason Protocol Federal/Foundation Funding List 	PI :	Trey Jehan	Protocol #	00001543	Status :	Pending	Approved :	09/30/2020	Expires :	09/30/2023	Title :	Transgenic Core Breeding Protocol
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Title :	Transgenic Core Breeding Protocol																								

A side-by-side view of the previous version and changes will populate. Sections that have been changed will be bordered by orange, and specific changed will be highlighted red and green.

Procedure Description

2019-07-30 10:25:09 Methodology
 For each species, describe in narrative form all experimental or ~~instructional procedures~~ instructional procedures to be performed on the animals (e.g. blood collection, surgery, behavioral training, administration of substances or test compounds, breeding, tumor induction, etc.). Include the time frames and intervals and describe the procedures in the order in which they will be performed. Include a description of procedures performed on anesthetized animals. All procedures ~~checked~~ checked on the procedures page should be described ~~below~~ below. ~~Include~~ add ~~below~~ Include the rationale for use of tissues in vitro but do not describe in vitro procedures performed on tissues taken from animals or procedures performed on animals after they are euthanized. add some text

TOC