

Animal Oversight & Hazard Safety Committee Reviewer Manual



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Understanding the Protocol Workflow

Each institution has a unique protocol review workflow process. For example, some IBC programs send all new protocols to the IBC meeting for Full Committee Review. Some IACUC programs send submissions to all members to poll the committee to determine if items should be called to a full committee meeting. The Cayuse Animal Oversight and Hazard Safety applications rely on the IACUC or IBC office role to route the submission through the applicable review workflow.

When submissions are assigned to committee members, the system will send an email to alert the reviewer of the assignment. To view and complete assignments, reviewers will log into the system under the applicable committee member role, IACUC Committee Member or IBC Member.

The inbox will display submissions for review under the Alert called 'Protocols in Review.' In the inbox, reviewers will see a table with different columns. The definitions of these columns are below.

- **PI:** PI name
- **Protocol Number:** Protocol Number
- **Date and Time Sent:** These columns display when the submission was assigned to the committee member. It is important to note that some programs sent deadlines for review assignments.
- **Title:** Protocol Title
- **From and To:** These columns indicate that the submission was sent from the IACUC or IBC office to the members for review.
- **Action:** This is a very important column. It displays what type of review the submission is under. As mentioned previously, all institutions have unique submission workflows. Please refer to the institutional IACUC or IBC office if there are questions about the specific action assigned in the system.
- **Type:** This column displays the submission type. It may display Amendment, New protocol, or De Novo protocol. It is critical for members to note the submission type. ***If an amendment is assigned, it is strongly recommended that members use the Protocol Versions compare function to review all changes that have occurred in the amendment.*** This function is discussed in a different section of this guide.


Role: IACUC Committee Member

Animal Oversight	Inbox	Total
Protocols in Review	2	2

PI	Document Status	Protocol #	Date Sent	Time Sent	Title	From	To	Action	Orig. Submission	Type	Primary/Secondary Reviewers
04/07/2022 - 2 Protocol(s)											
Account3, Test	IACUC Office	2022-0122	04/07/2022	10:57:41	The power analysis appears to be based on 6 different conditions (3 technologies and two surgery types). However, the experimental model appears to indicate that all rabbits will undergo bilateral sciatic nerve cuff implantation, without any mention of the other electrode types to be tested. Clarify what is meant by Different rabbits will have different nerve electrode technologies implanted on the sciatic nerves from. The methodology lacks any description of implanting any electrode other than nerve cuffs. Clarify the extra testing to be carried out in the non-survival procedure.	IACUC Office	Member(s)	FCR Polling	04/02/2022	New	
Mourad's, Najit		2021-0057	04/07/2022	10:58:28	tiger testing	IACUC Office	Member(s)	Designated Review	11/15/2021	Amendment	Josway, Sarah (P)

Reviewing an Assigned Submission

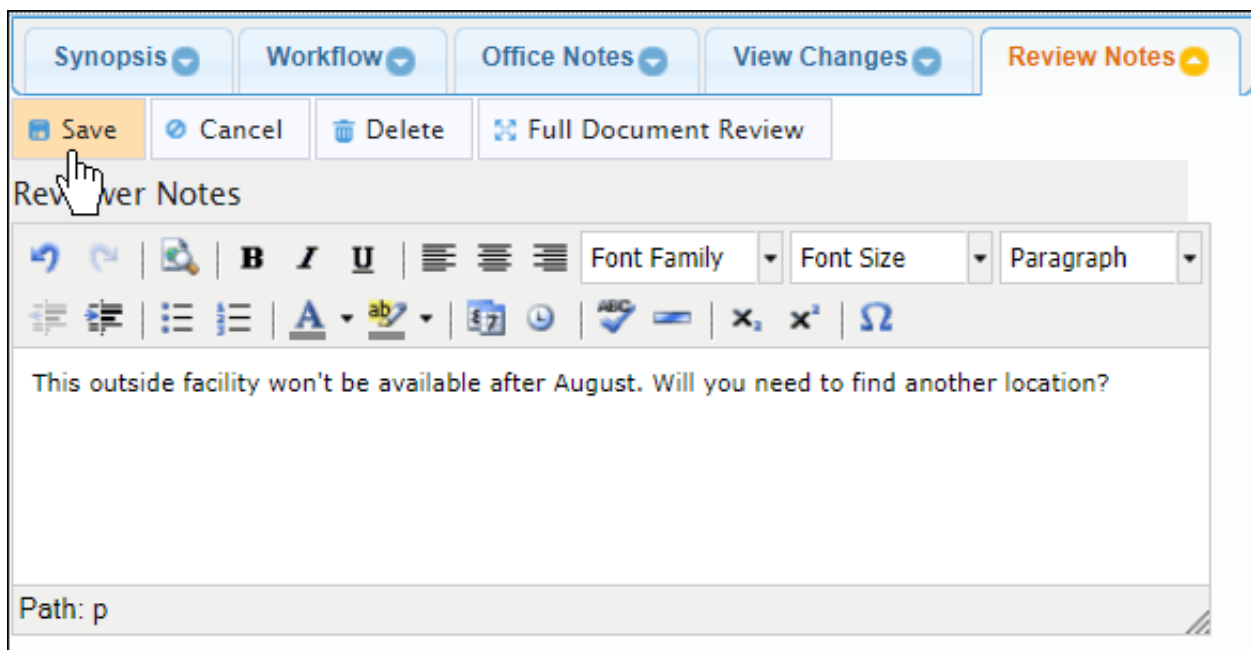
To access the submission, click on the protocol number hyperlink from the inbox. This will open the submission. The Review pane displays in the top right-hand corner of the protocol form. Click the tabs to expand or minimize the review tools.

1. **Office Notes:** Displays Designated reviewer's comments as well as IACUC coordinator merged comments. All previous revision comments are available for viewing here.
2. **View Changes:** Displays the previous contents of the field and current changes made by the PI.
3. **Review Notes:** Shows all comments made by the reviewers. IACUC coordinator can also add comments and merge comments. Only merged comments and Designated Reviewer comments are viewable to the PI.

Adding Comments

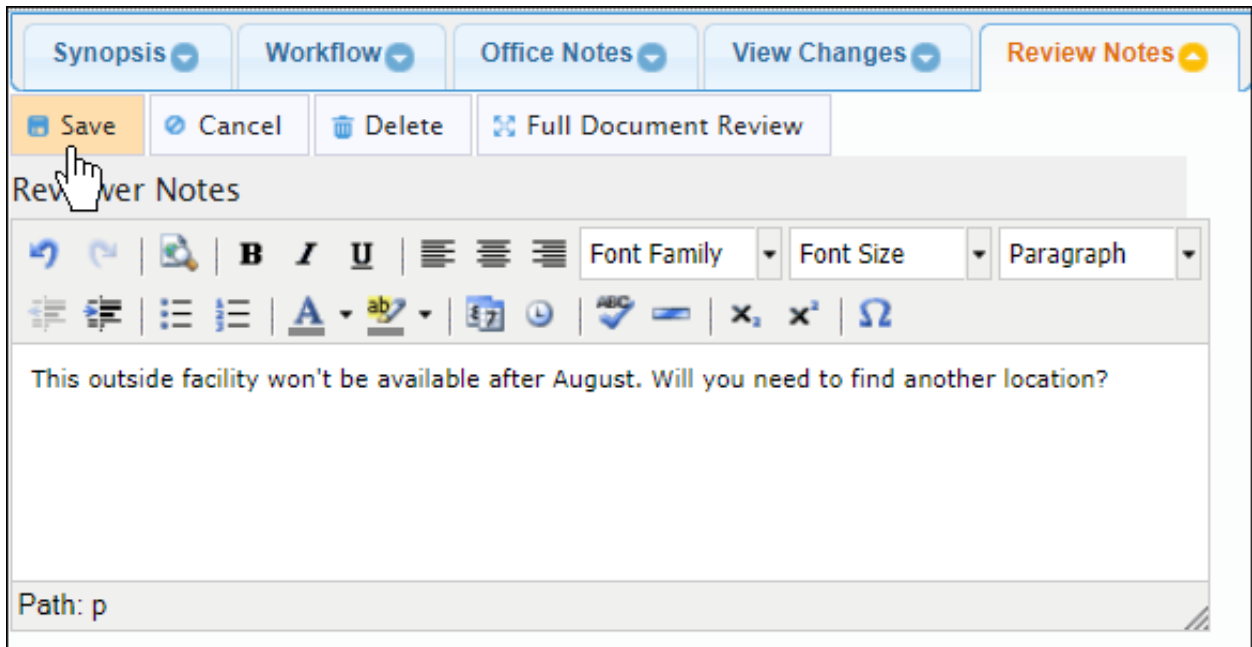
Click on the Review Notes tab to enter comments. You can also click on a Text or Word editor field to enable the review pane.

Enter your notes in the Reviewer Notes section and click **Save**



All IACUC review notes are automatically displayed in the Office Notes tab. Each revision is identified by its Review Number. When IACUC merges all of the reviewer's comments, they also display on this tab. The PI sees only the notes found in the Office Notes tab.

You can view all of the revision notes regardless of the current revision. The Revision Number is automatically updated when the PI submits the protocol to the IACUC office.



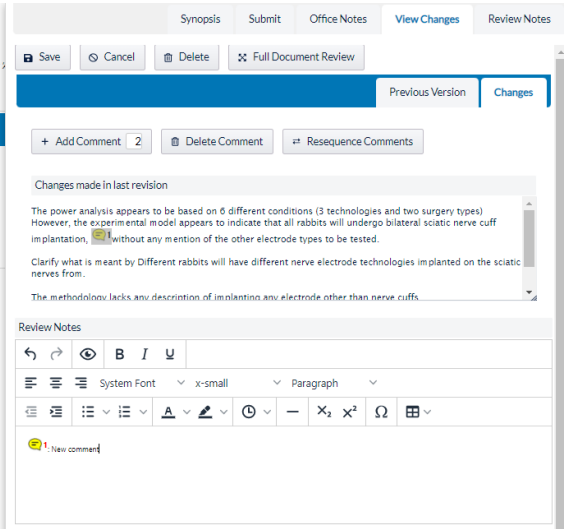
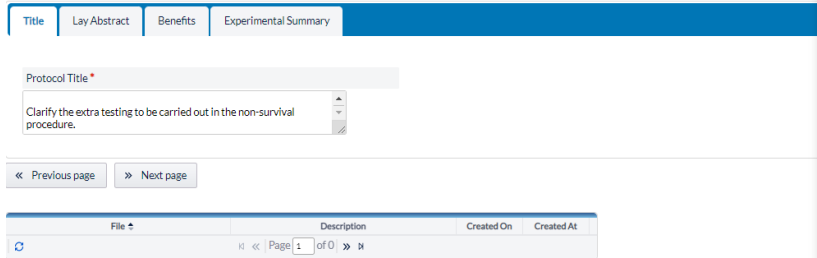
Adding Footnotes

Reviewers can add footnotes in text fields or word editor fields.

1. Click within the text response in the protocol form to enable the Changes tab in the Review pane. This is useful when reviewers need to reference an exact location in the text.
2. Click the Add Comment button, then click in the location of the text needed to reference
3. Click by the comment bubble in the Review Notes section below to add your comments
4. Click Save

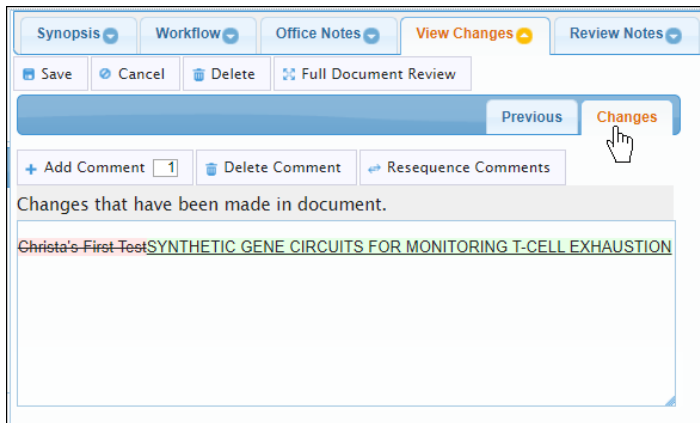
Protocol Overview

Enter the requested information into the designated text boxes across each of the tabs below. You may click and drag the bottom right corner of any text area to resize it. To attach documents, click...



View Changes

The Changes tab displays what the PI changed. The items crossed out in red indicate what was removed. The underlined text highlighted in green reflect the new text.



The IACUC or IBC office can choose to edit these notes prior to submitting the protocol to the investigator.

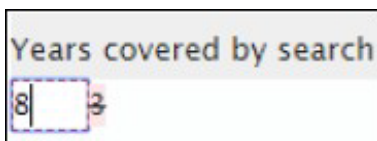
Reviewing PI Responses to Committee Responses

When the investigator submits a protocol back to the IACUC office, the pages in the TOC are marked with icons. The green check marks indicate the PI reviewed the recommendations. Any pages marked with a notepad and a pencil are pages the investigator modified which were not flagged for change.

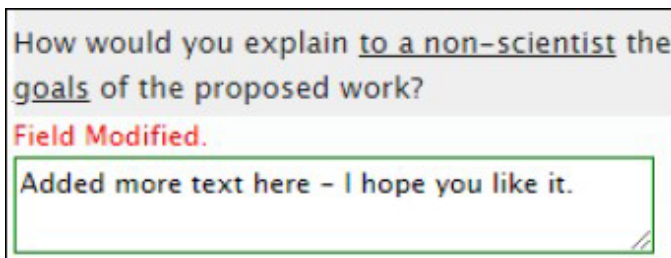
As the IACUC office reviews the changes made by the PI, the review pane helps to see the changes made to the large text-area and word-editor fields.

Modified Field Representations

Text and Numeric



Text Area and Word Editor



Radio Buttons

Will you be using animal tissues?
Yes No **no**

A **No** is switched to **Yes**.

Drop-down Lists

Research Type (Basic, Applied, Field) Applied ▼ **Research**

Research is replaced with **Applied**.

Checkboxes

Not Funded?
 no

A **No** is switched to **Yes**.

New Record

Icon indicates record has been added.

Record Removed

Deleted Records	
NTM University	

Records which have been removed from a grid are indicated in a Deleted Records grid, right below the original grid.

Changes to USDA

Revised Records	
USDA Category	# of Anim
B	+1000 0
C	- 1000

Any changes to the USDA Categories grid are reflected in a new grid named Revised Records. This grid displays under the USDA Categories grid and indicates what has been removed, changed and added.

Page Removed

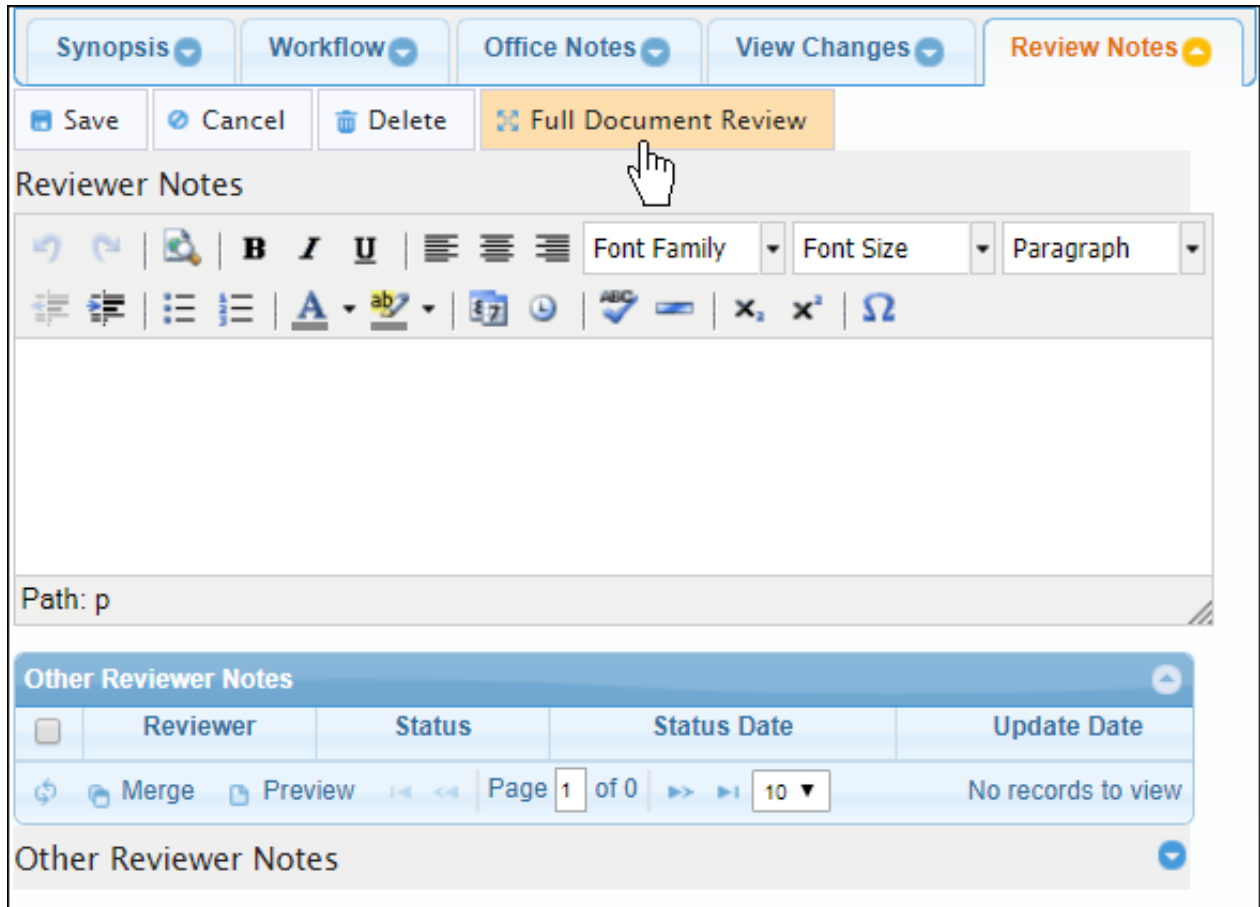
X	Mousechangethename
X	Info
X	Choice Justification
X	Source
X	Housing/Use Labs

Pages deleted from a protocol are reflected with a red X in the TOC.

Using Full Document Review

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. Click Save if available.


Protocol Introduction

My Notes 

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.

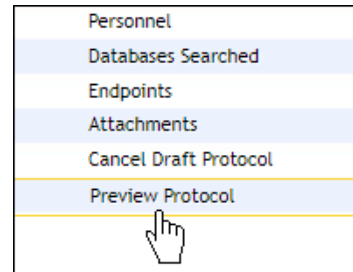
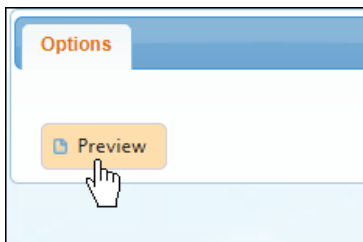
Review Icons

-  **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.

Comparing Protocol Versions (Important for Amendments)

For amendments, it is important to view all changes that have occurred during the amendment cycle. The Review mode and Full Document Review only display the last round of PI edits, or revisions. Most reviewers prefer to have this side-by-side comparison open in a separate window or on a separate screen while conducting the review. Reviewers can add comments within the Review mode on the amendment while looking at this on another screen.

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** drop-down menu to choose the two versions to compare. To compare the current version of the amendment with the last approved version of the protocol, select 'Approved' and then select the highest version available. The highest approved version is the latest approved version of the protocol.



Previous Version	Changes																								
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>PI :</td><td>Mourad's, Najj T</td></tr> <tr><td>Protocol #</td><td>2021-0057</td></tr> <tr><td>Status :</td><td>Approved (w/o Stipulation)</td></tr> <tr><td>Approved :</td><td>11/15/2021</td></tr> <tr><td>Expires :</td><td>11/15/2024</td></tr> <tr><td>Title :</td><td>tiger testing</td></tr> </table> <p>Table of Contents</p> <ul style="list-style-type: none"> Protocol Introduction Protocol Overview Protocol Federal/Foundation Funding Type of Animal Use Mouse <ul style="list-style-type: none"> Species Information Species Source Use Locations Strain Information Animal Subjects and Pain Categories Methodology Pain Category E Justification Reduce, Refine, Replace Adverse Consequences Exemptions Personnel List Databases Searched Endpoints and Assurances Protocol Attachments <p>Protocol Introduction</p> <p><i>Tips to Complete this Protocol Form:</i></p>	PI :	Mourad's, Najj T	Protocol #	2021-0057	Status :	Approved (w/o Stipulation)	Approved :	11/15/2021	Expires :	11/15/2024	Title :	tiger testing	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>PI :</td><td>Mourad's, Najj T</td></tr> <tr><td>Protocol #</td><td>2021-0057</td></tr> <tr><td>Status :</td><td>Pending</td></tr> <tr><td>Approved :</td><td>11/15/2021</td></tr> <tr><td>Expires :</td><td>11/15/2024</td></tr> <tr><td>Title :</td><td>tiger testing</td></tr> </table> <p>Table of Contents</p> <ul style="list-style-type: none"> Protocol Introduction Protocol Overview <li style="border: 1px solid orange;">Protocol Federal/Foundation Funding <li style="border: 1px solid orange;">Type of Animal Use Mouse <ul style="list-style-type: none"> Species Information Species Source <li style="border: 1px solid orange;">Use Locations Strain Information Animal Subjects and Pain Categories Methodology Pain Category E Justification Reduce, Refine, Replace Adverse Consequences Exemptions <li style="border: 1px solid orange;">Personnel List <li style="border: 1px solid orange;">Databases Searched <li style="border: 1px solid orange;">Endpoints and Assurances <li style="border: 1px solid orange;">Protocol Attachments <li style="border: 1px solid orange;">Amendment Reason <p>Protocol Introduction</p> <p><i>Tips to Complete this Protocol Form:</i></p>	PI :	Mourad's, Najj T	Protocol #	2021-0057	Status :	Pending	Approved :	11/15/2021	Expires :	11/15/2024	Title :	tiger testing
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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.

<p>Type of Animal Use</p> <p><i>Identify all types of animal use for this protocol.</i></p> <p>Which of the following describe the type of animal use proposed in this application? (check all that apply)</p> <p>Activity Location</p> <p><input type="checkbox"/> On Campus</p> <p>Instructional or Training</p> <p><input type="checkbox"/></p> <p>Testing (e.g., toxicology screening)</p> <p><input type="checkbox"/></p> <p>Surveillance (e.g., sentinel health monitoring, wildlife surveillance, field study)</p> <p><input type="checkbox"/></p> <p>Research</p> <p><input type="checkbox"/></p> <p>Other</p> <p><input type="checkbox"/></p> <p style="text-align: right;">TOC</p>	<p style="text-align: right;">TOC</p> <p>Type of Animal Use</p> <p><i>Identify all types of animal use for this protocol.</i></p> <p>Which of the following describe the type of animal use proposed in this application? (check all that apply)</p> <p>Activity Location</p> <p><input type="checkbox"/> On Campus</p> <p>Instructional or Training</p> <p><input type="checkbox"/></p> <p>Testing (e.g., toxicology screening)</p> <p><input type="checkbox"/></p> <p>Surveillance (e.g., sentinel health monitoring, wildlife surveillance, field study)</p> <p><input type="checkbox"/></p> <p>Research</p> <p><input checked="" type="checkbox"/> No previous value.</p> <p>Other</p> <p><input type="checkbox"/></p> <p style="text-align: right;">TOC</p>
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