CAYUSE IACUC - REVIEWER/ MEMBER MANUAL

CAYUSE IACUC

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Understanding the Protocol Workflow

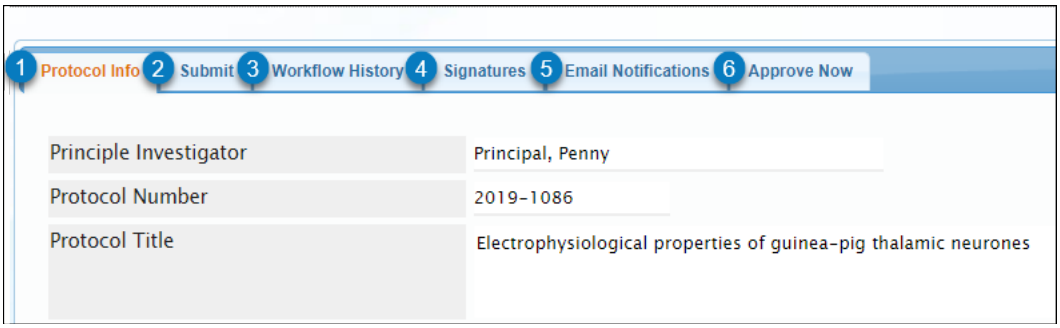
The IACUC coordinator has complete control over the protocol workflow. IACUC's flexibility allows you to perform any of the following actions without any pre-set order:

- return the protocol to unfinished status (only applies to New and De Novo protocols)
- conduct an IACUC review (review by coordinator)
- edit the protocol (only applies to New and De Novo protocols)
- submit the protocol to the veterinarian for a vet review and recommendations
- submit the protocol to the IACUC Chair for review and recommendations
- submit to one or multiple committee members for review and recommendations
- move a protocol to a meeting agenda for discussion
- approve the protocol

IACUC sends an email each time a protocol is submitted.

To open the IACUC workflow, click on the hyperlink found on the protocol number in either the Protocols in Review or Continuations in Review alert.

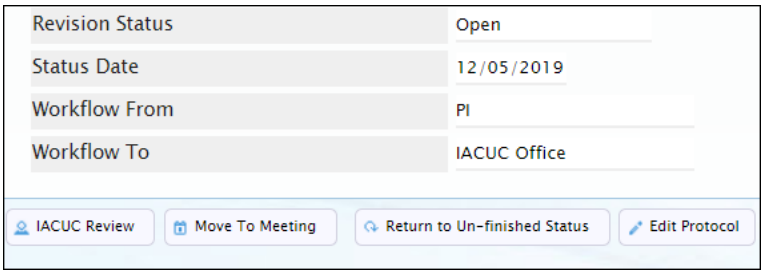
Workflow Tabs



1. **Protocol Info:** Information about the protocol submission. The Revision Number indicates the current revision. This number is advanced each time the PI responds to recommendations and returns the protocol to the IACUC office. The Workflow From/To indicates who submitted the protocol and where it is in the IACUC workflow.
2. **Submit:** IACUC submits the protocol to PI, Member(s), Chairperson(s) or Vet(s) for review. Only available when the protocol is in the IACUC office.
3. **Workflow History:** The first grid, Revision Reviewers, documents the reviewers, the status of their review and the general comments they may have entered. The Workflow History grid displays the date/time stamp for each cycle of the review.
4. **Signatures:** Stores the date/time stamp each time the PI, IACUC Coordinator, Vet or Reviewers enter their password to submit the protocol.
5. **Email Notifications:** Stores the date/time stamp of each email notification that was sent out during the review process. Every time a protocol is submitted, Cayuse IACUC sends an email notification.

6. **Approve Now:** The IACUC coordinator approves the protocol from here.

Other Workflow Actions

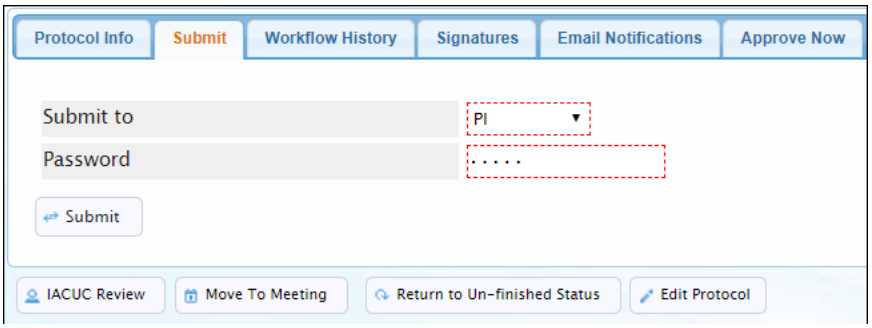


- **IACUC Review:** Coordinator reviews protocol and provides comments. Available when protocol is IN IACUC coordinator workflow.
- **Move to Meeting:** Puts protocol on the upcoming meeting agenda. Available when protocol is IN IACUC coordinator workflow.
- **Return to Unfinished Status:** Coordinator may send protocol back to PI without committee review or recommendations. Available when protocol is IN IACUC coordinator workflow and no recommendations have been made.
- **Edit Protocol:** Opens protocol for editing by coordinator. Available when protocol is IN IACUC coordinator workflow. Not available on Amendments or Continuing Reviews.

Submitting Protocols for Review

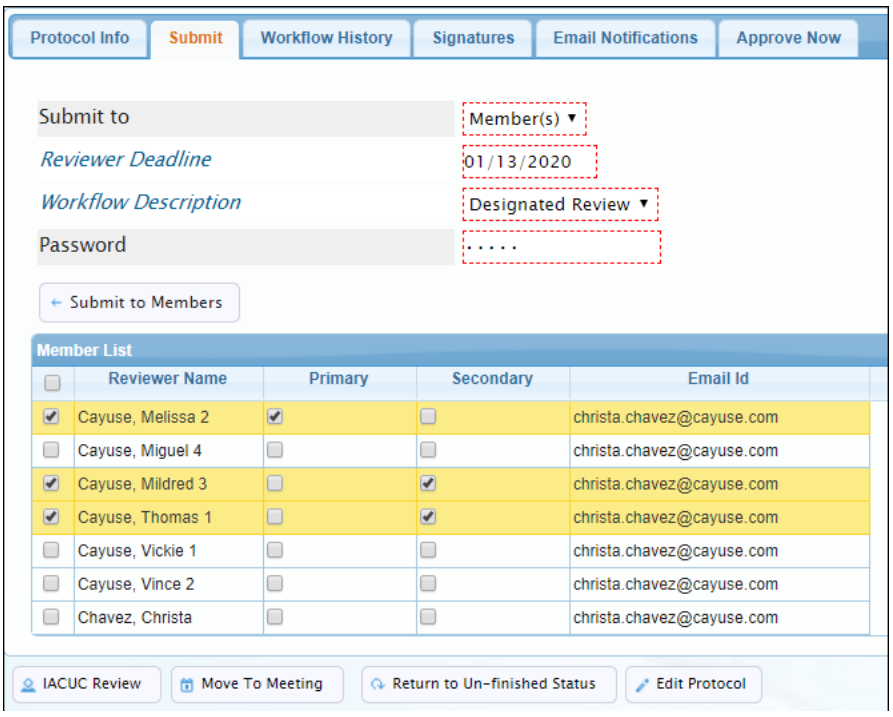
Using the Submit tab, the IACUC Coordinator can submit the protocol to the IACUC Members, the PI, the Vet(s) or the IACUC Chair for review.

PI



The protocol can be submitted back to the PI only if and when there are pages marked for review.

Members

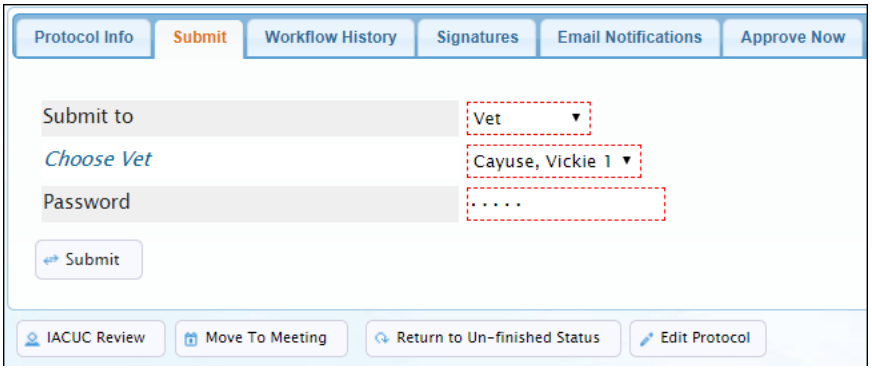


When submitting to the Members, the list of members will display in the Member List grid. The list of members displayed are those defined in the IACUC Members list from the IACUC dictionary. These members must have the IMBR role to access IACUC.

The Primary and Secondary selections are optional. If Primary and Secondary members are selected, their names will display in the Review alerts. Additionally, the Primary reviewer has the ability of writing a Synopsis when reviewing the protocol.

The Workflow Description options are Designated Review and Member(s) Review. When a Designated Review Workflow is selected and a Primary Reviewer is also selected, the protocol is automatically returned to the IACUC office when the primary reviewer has reviewed and the due date has arrived, regardless if any other reviewers have submitted their review.

Vet



When submitting a protocol for a Vet review, select Submit to Vet and choose the Vet you want to send the protocol to. The list of Vets available in the dropdown will be those listed in the IACUC Members dictionary which have a VET role to access IACUC.

The protocol will display on the Vet's Protocols in Review alert or Continuations in Review, depending on the type of submission.

IACUC Chair

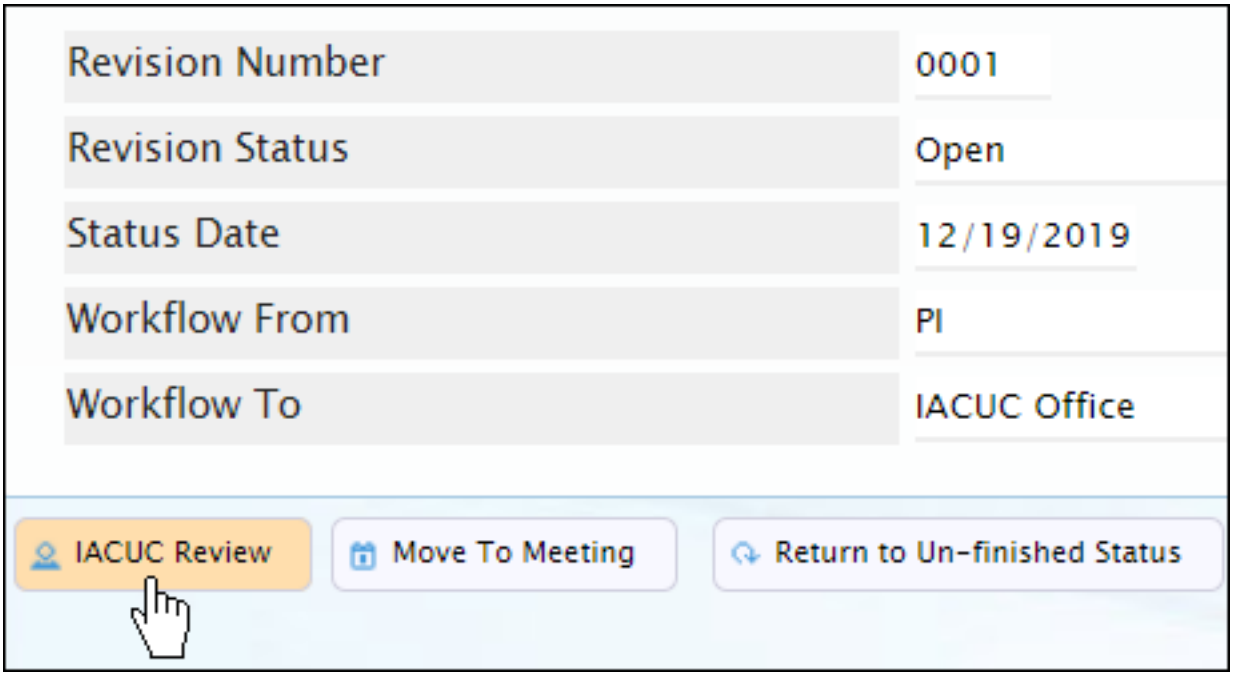
Select the Chairperson you wish to submit the protocol to. The list of chairpersons available in the dropdown need to be defined in the IACUC Members list and also need to have the ICHAIR role to access IACUC.

The protocol will display on the Chairperson's Protocols in Review alert or Continuations in Review, depending on the type of submission.

Reviewing as an IACUC Coordinator

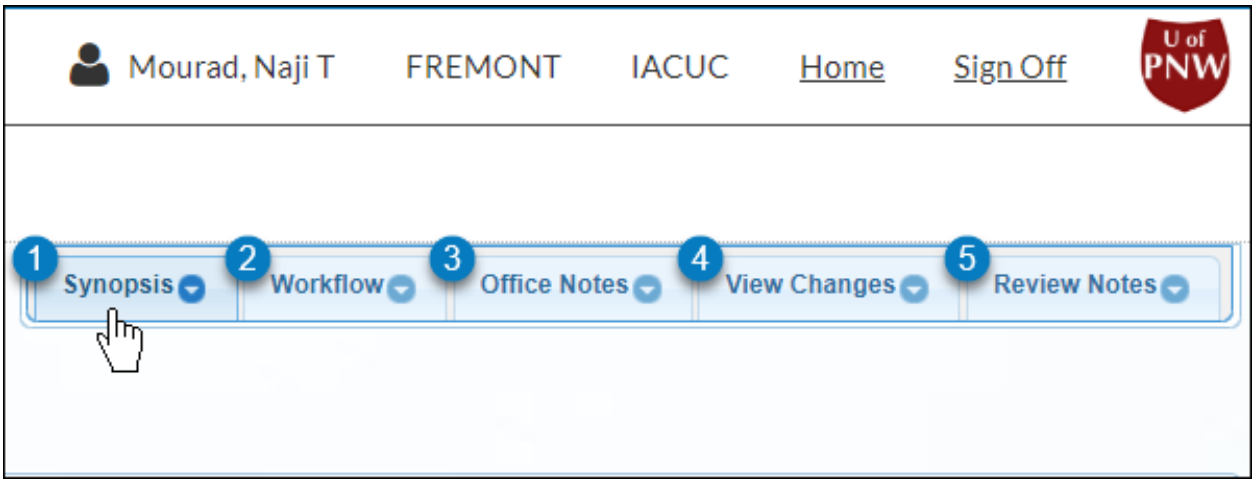
The IACUC Coordinator may choose to review the protocol prior to submitting it for review, or after.

To review a protocol from the IACUC workflow page, click on IACUC Review.



The Review pane displays in the top right-hand corner of the protocol form. Click the tabs to expand the pane.

Tabs



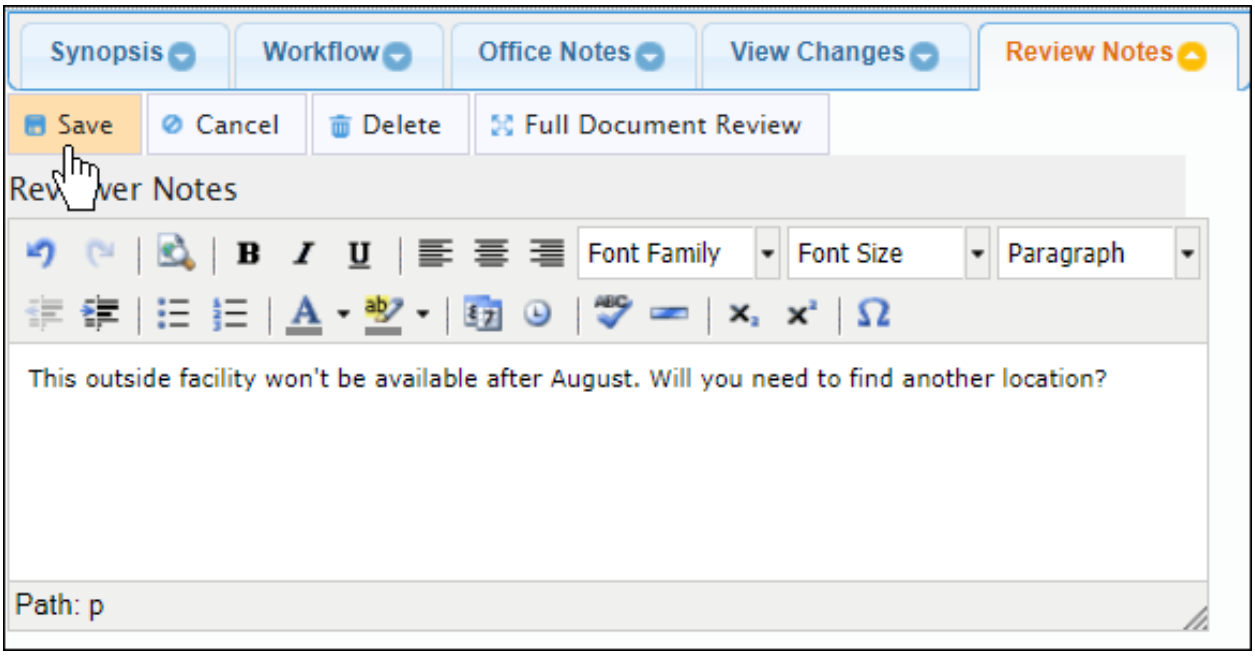
1. **Synopsis:** Available for the Primary reviewer to add a synopsis.
2. **Workflow:** Return to the IACUC Workflow page.

3. **Office Notes:** Displays Designated reviewer's comments as well as IACUC coordinator merged comments. All previous revision comments are available for viewing here.
4. **View Changes:** Displays the previous contents of the field and current changes made by the PI.
5. **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

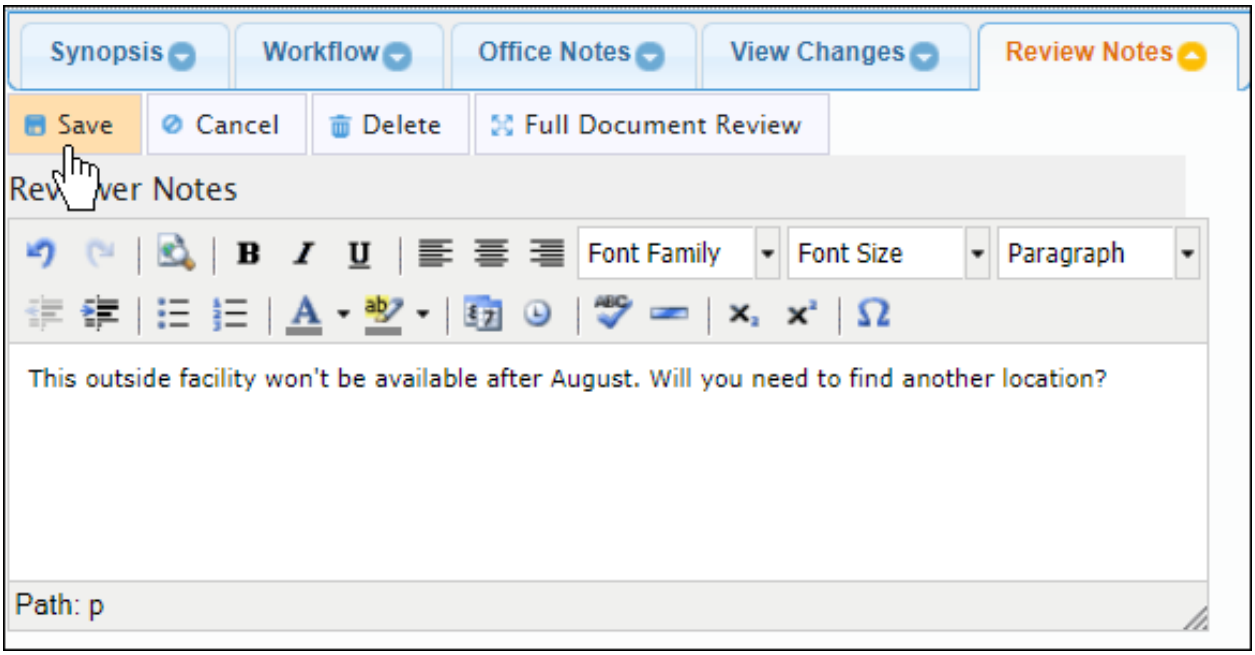
Click on the Review Notes tab to enter comments. You can also click on a Text or Word editor field to enable the review pane.

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.

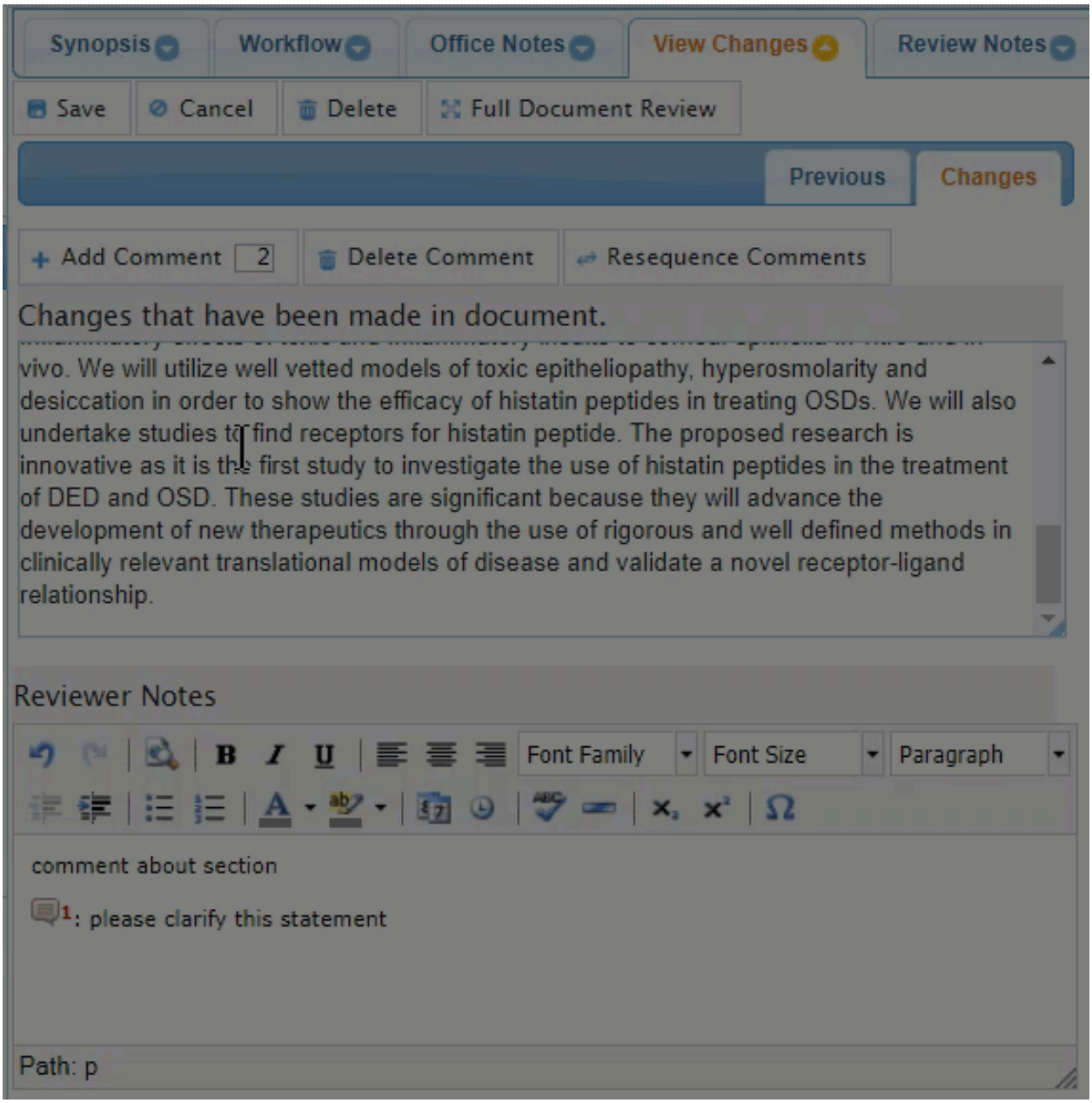
You can view all of the revision notes regardless of the current revision. The Revision Number is automatically updated when the PI submits the protocol to the IACUC office.



Adding Footnotes

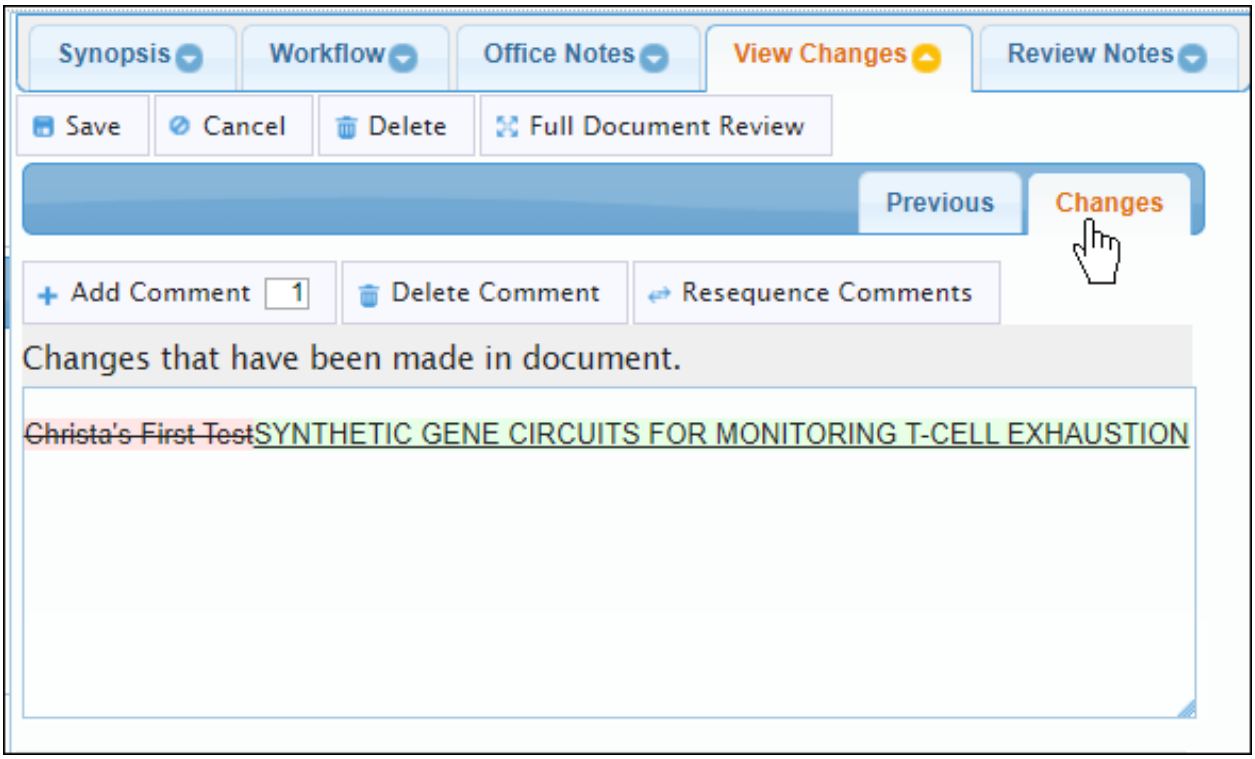
Reviewers can add footnotes in text fields or word editor fields by clicking on the field in the protocol form to enable the Changes tab in the Review pane. This is useful when reviewers need to reference an exact location in the text.

To add a footnote comment, click the Add Comment button, then click in the location of the text needed to reference, and add your comments in the Reviewers Notes section.



View Changes

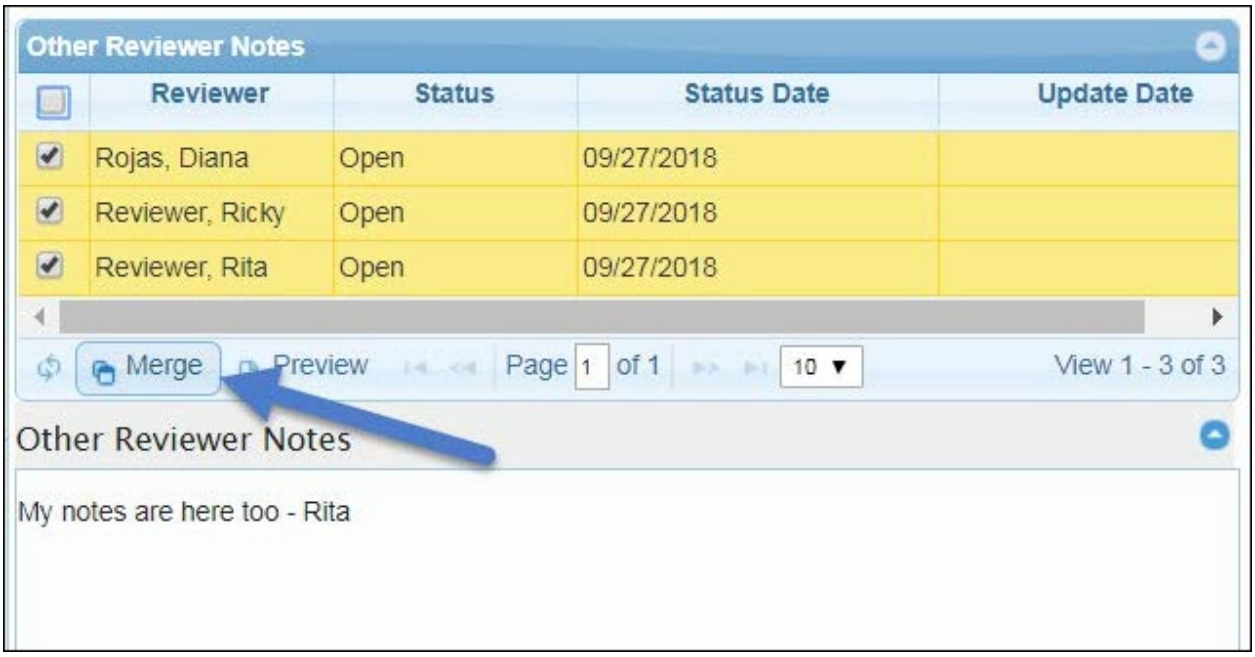
The Changes tab displays what the PI changed. The items crossed out in red indicate what was removed. The underlined text highlighted in green reflect the new text.



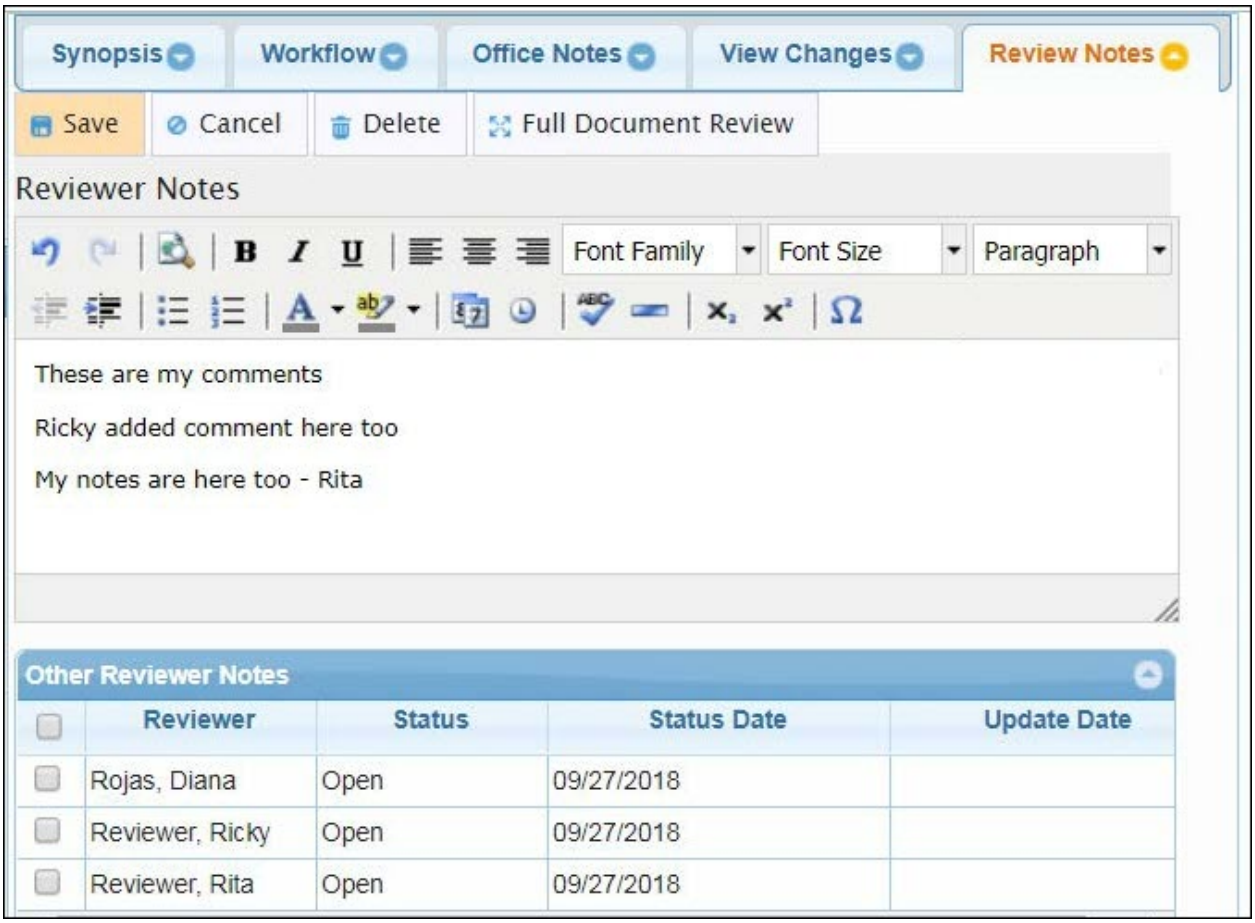
Merging Comments

When all reviewers' comments are returned to the IACUC office, the IACUC coordinator can choose which comments to merge prior to submitting the protocol to the investigator.

Click on the Reviewer beneath Other Reviewer Notes to view their comments. To merge all comments or a selection of comments, click on the reviewer checkbox and click **Merge**.



All of the notes are merged to the Reviewer Notes section. IACUC can choose to edit these notes prior to submitting the protocol to the investigator. Save the update.



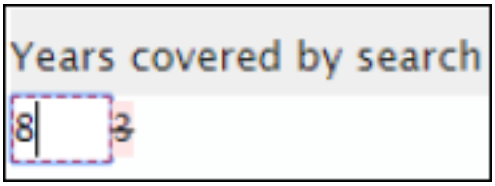
Reviewing PI Responses to Committee Responses

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 all of the recommendations. Any pages marked with a notepad and a pencil are pages the investigator modified which were not flagged for change.

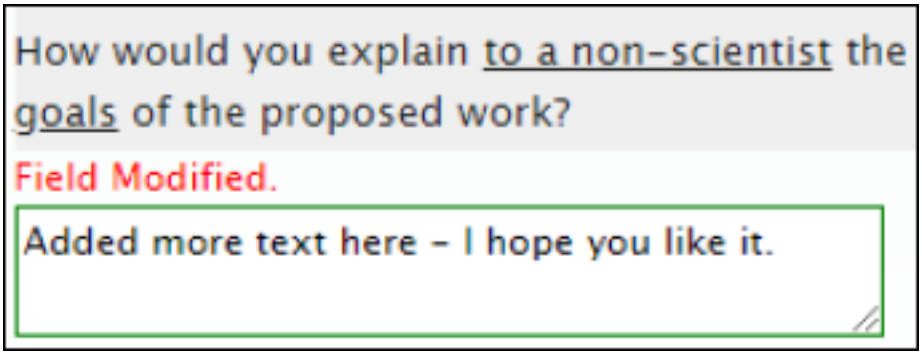
As the IACUC office reviews the changes made by the PI, the review pane helps to see the changes made to the large text-area and word-editor fields.

Modified Field Representations

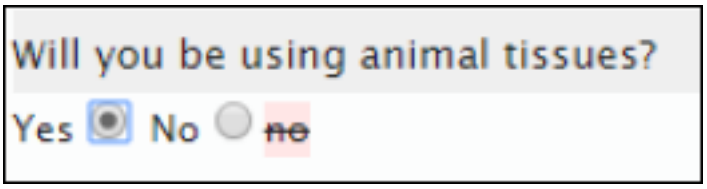
Text and Numeric



Text Area and Word Editor



Radio Buttons



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

Drop-down Lists

Research is replaced with **Applied**.

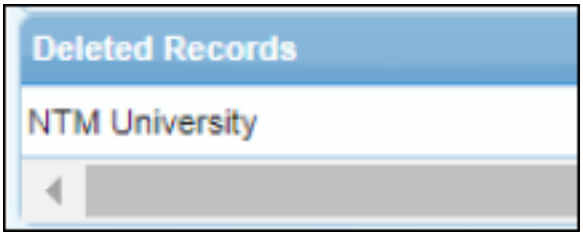
Checkboxes

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

New Record

Icon indicates record has been added.

Record Removed

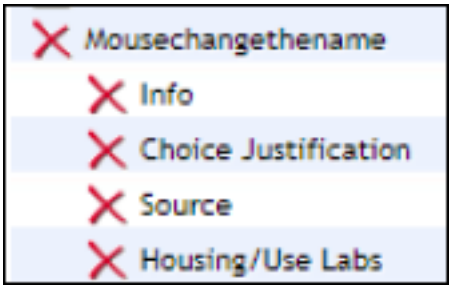


Records which have been removed from a grid are indicated in a Deleted Records grid, right below the original grid.

Changes to USDA

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

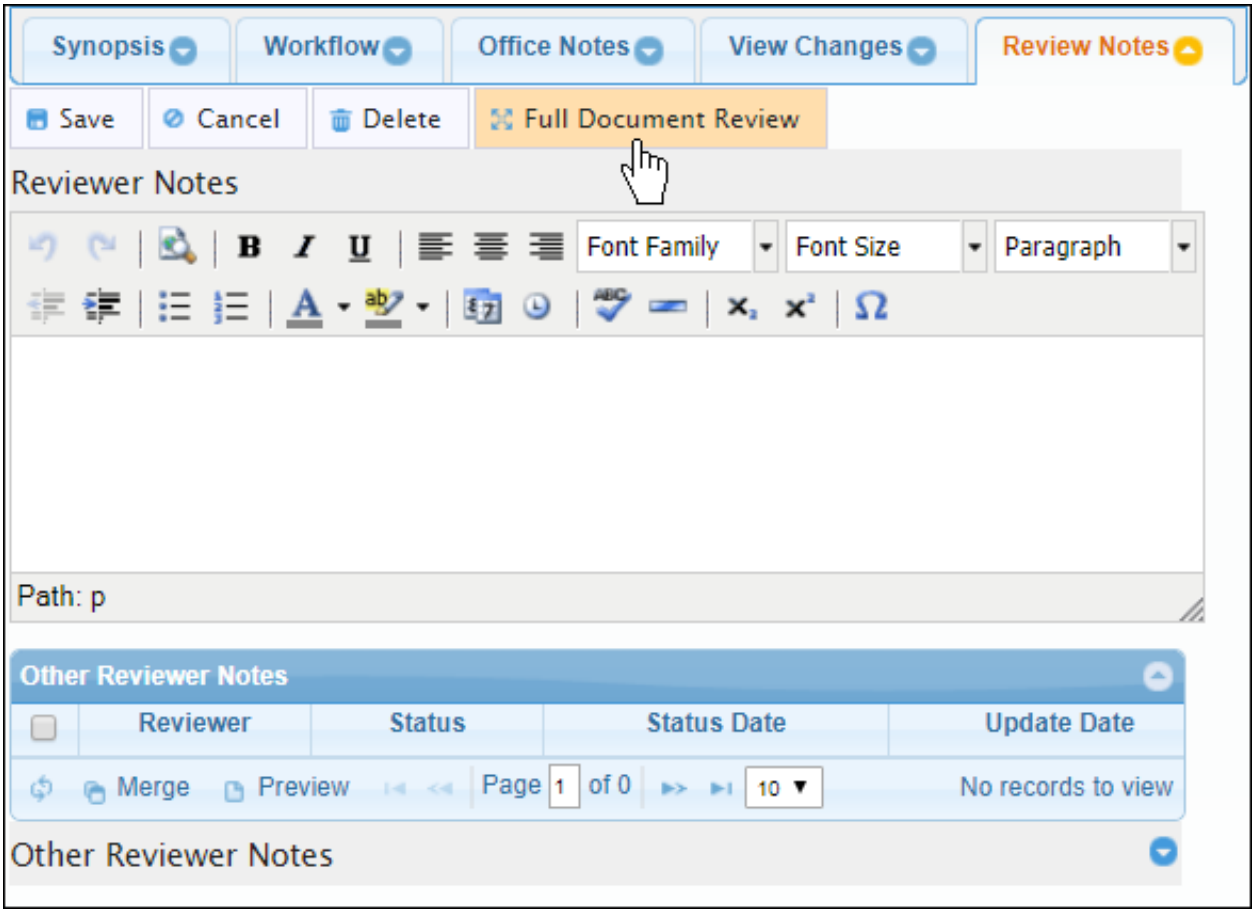


Pages deleted from a protocol are reflected with a red X in the TOC.

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.

cayuse IACUC

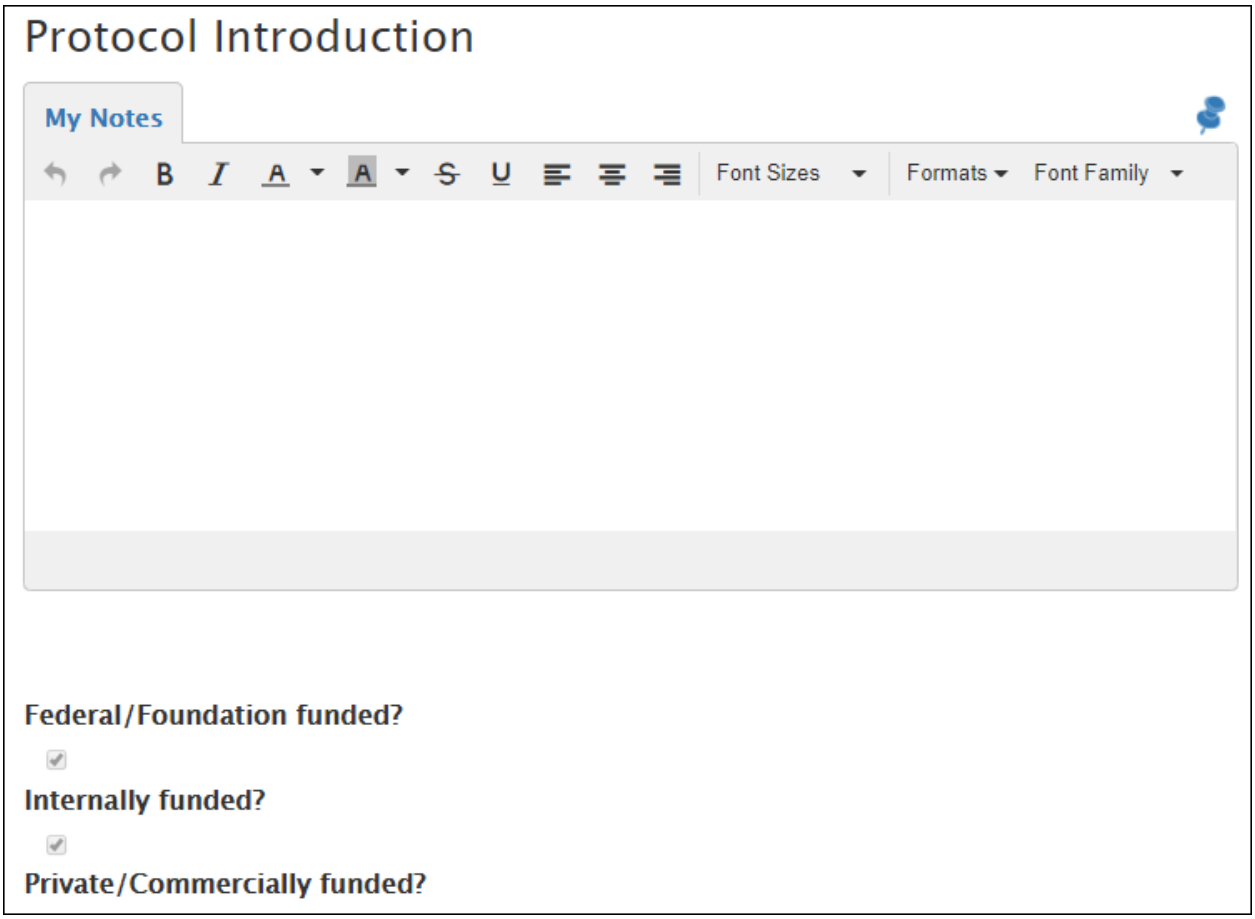
U of PNW

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

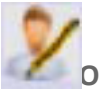
Enter review notes in the My Notes area within every section.



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.

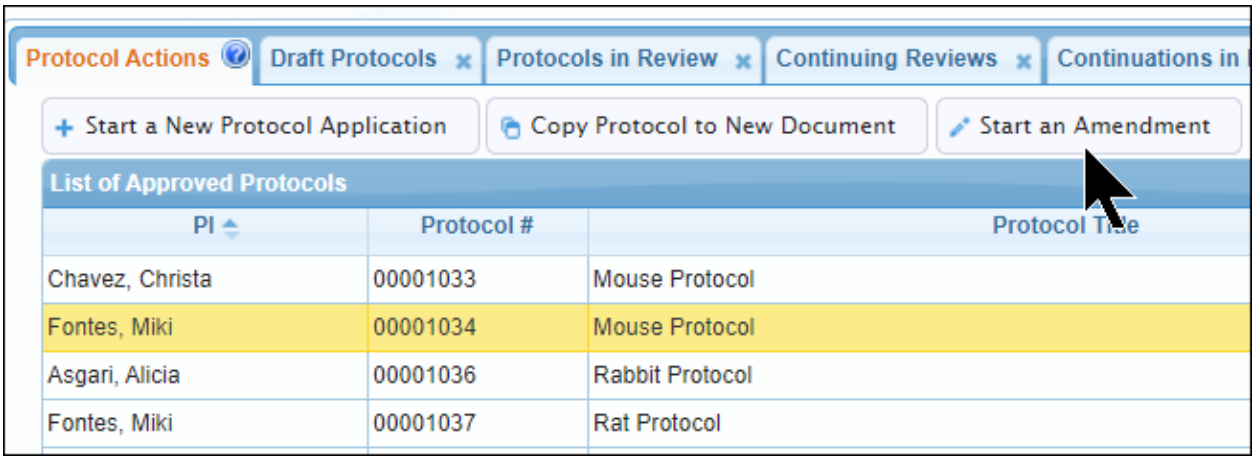
Review Icons

-  **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.

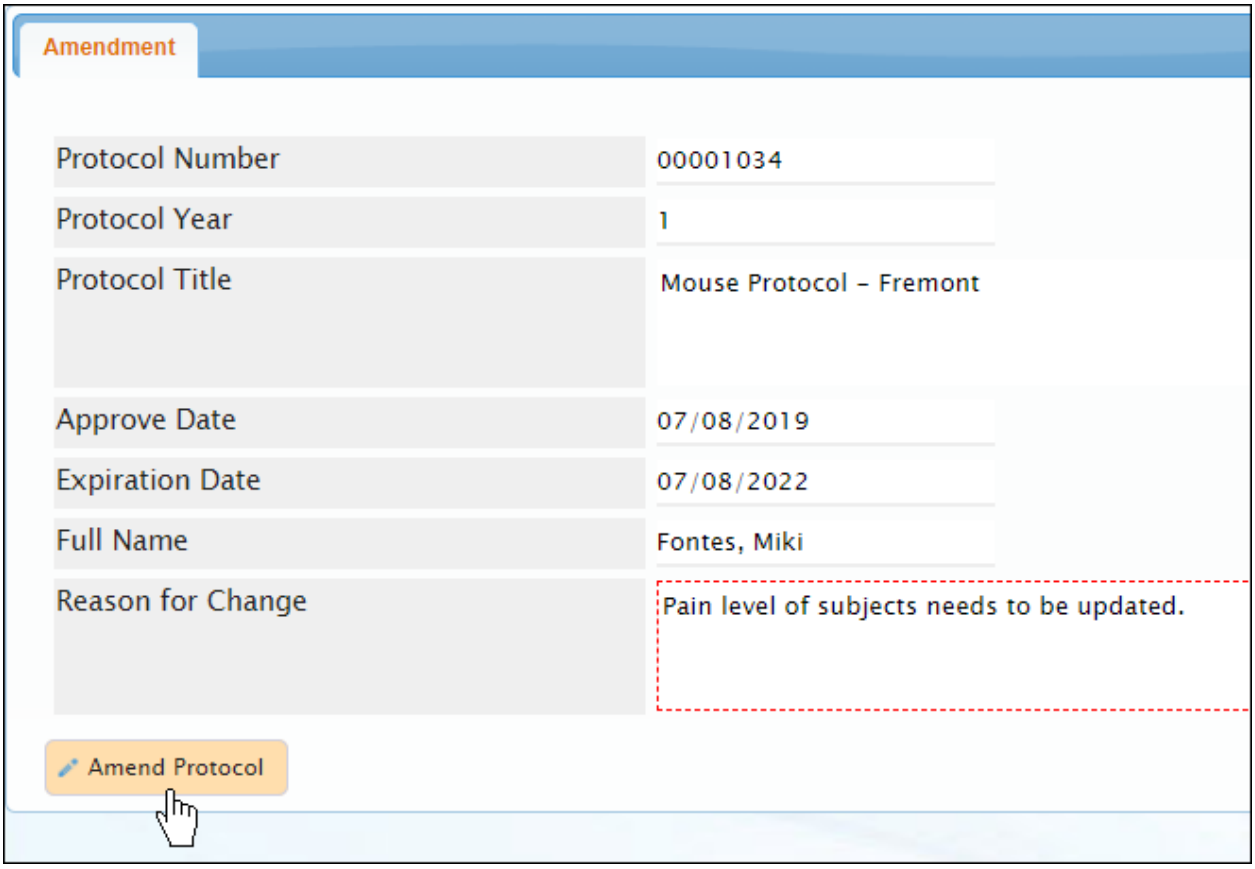
- **Check mark:** PI has completed a page marked for his review.
- **New record:** PI added a new record to a multi-grid page during review.

Managing Amendments

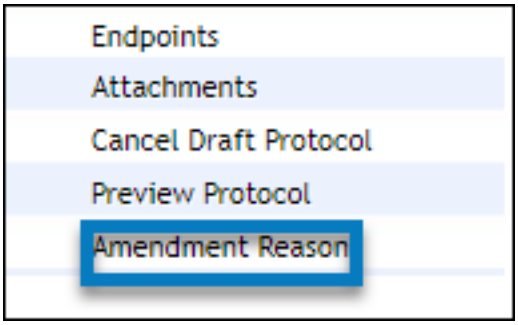
The IACUC office can perform an amendment on behalf of the PI. To start an amendment, select the protocol from the Protocol Actions alert and click on the Start an Amendment button.



Enter the reason for the amendment and click **Amend Protocol**.



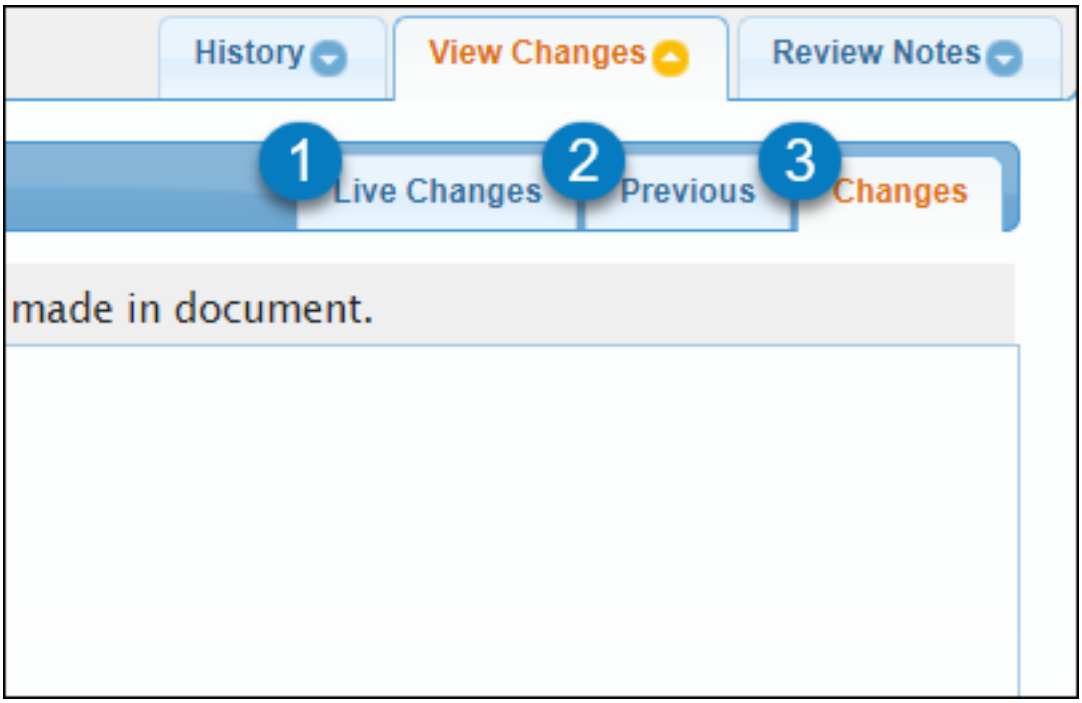
The entire protocol will display. The reason for amendment becomes a part of the protocol Table of Contents is included in the revision.



When a change is made to a page, a pencil icon will appear.

The tabs at the right of the screen provide information about previous reviews.

The View Changes tab includes three additional tabs:



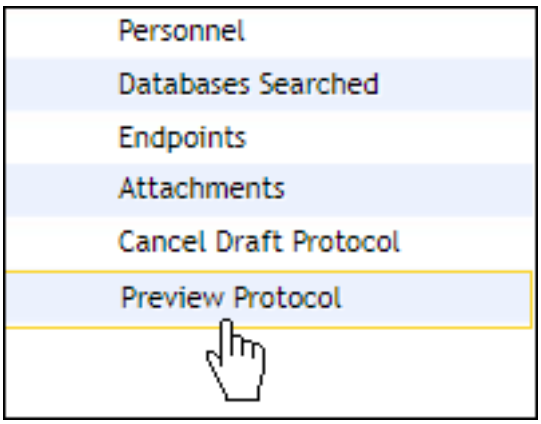
1. **Live Changes:** reflects what was added or deleted from the field.
2. **Previous:** reflects what was in the field previously.
3. **Changes:** reflects the final changes on the field.

When the amendment is submitted to the IACUC office, the revision is the same as that for a New or De Novo protocol submission. The amendments display in the Protocols in Review alert and are grouped in the Amendment section of the alert.

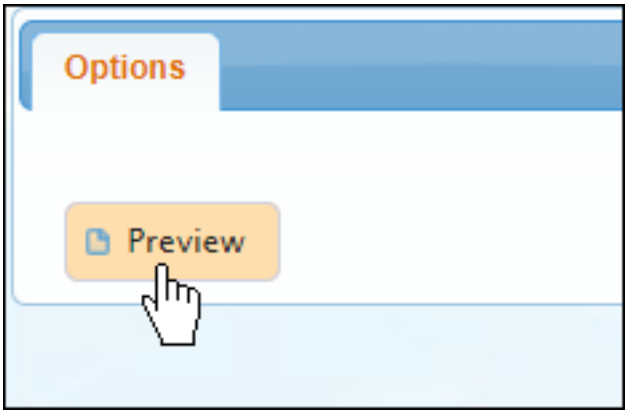
Comparing Protocol Versions

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** drop-down menu to choose the two versions to compare.

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

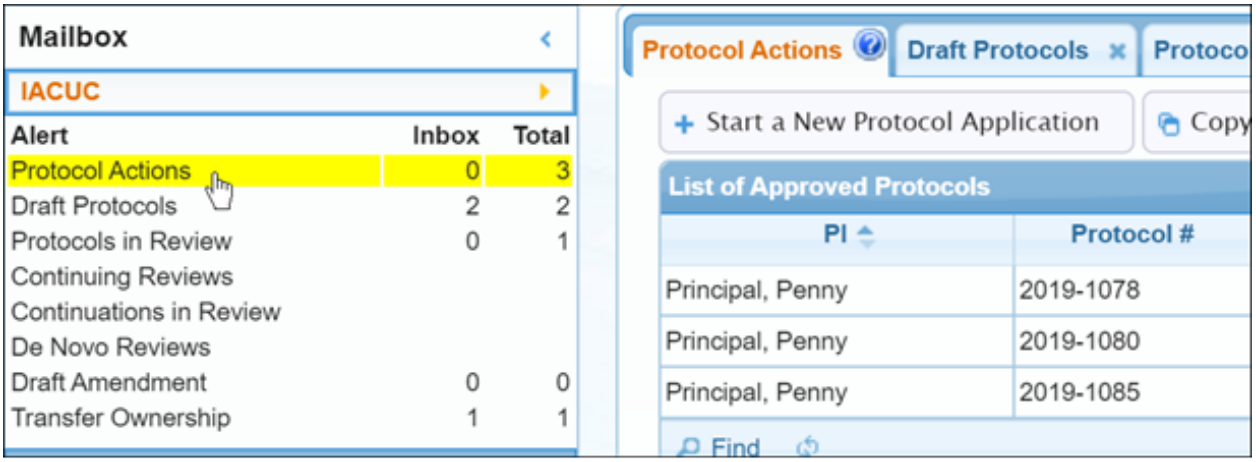
2019-07-3010:25:09Methodology
For each species, describe in narrative form all experimental or ~~instructional procedures~~ instructioocedures to be performed on the animals (e.g. blood collection, surgery, behavioral training, administration of substances or test compounds, breeding, tumor induction, 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~~ c on the procedures page should be described ~~below. Include~~ below. addedInclude 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

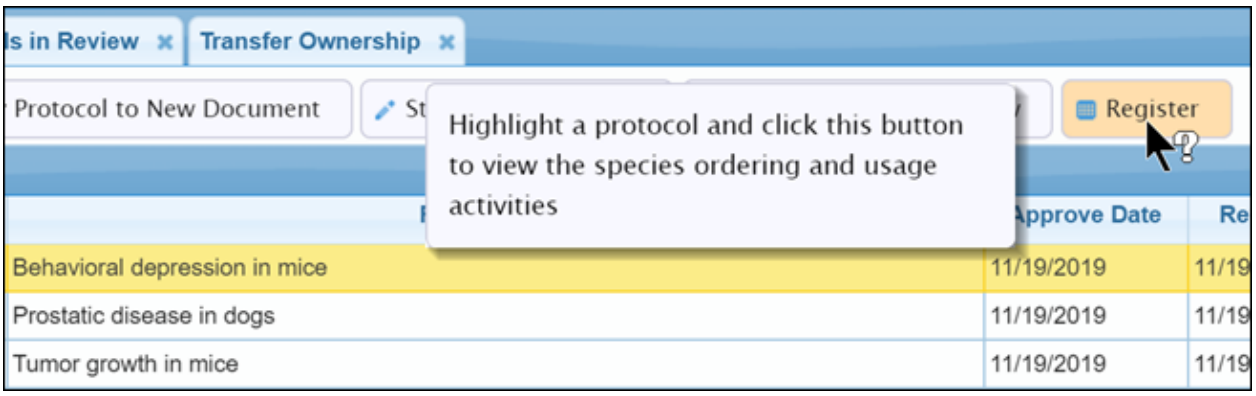
Managing Protocol Registers

Viewing and adjusting the register for a protocol allows you to view species ordering and usage activities. You can access this from Protocol Actions.

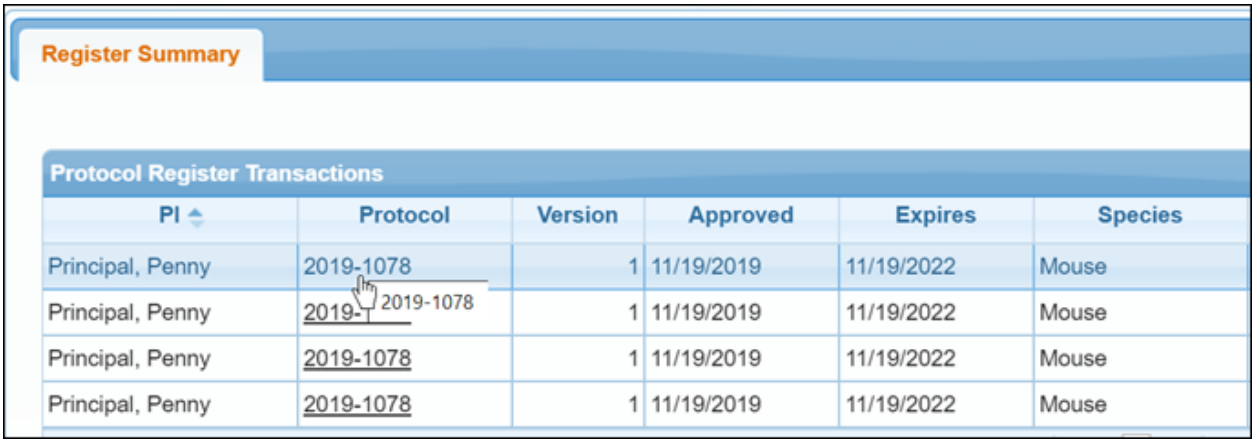
1. In the left-hand menu, click on **Protocol Actions**.



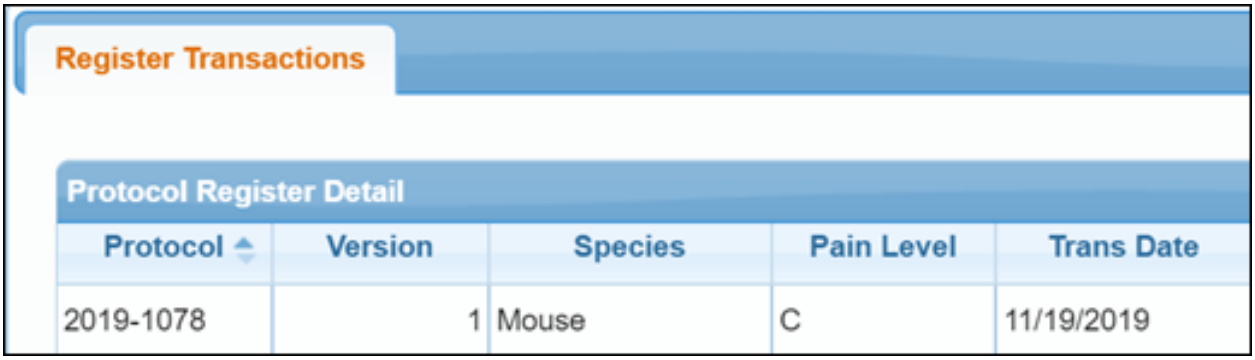
2. Click on the protocol for which you wish to view the registry, and click **Registry**.



3. Beneath Register Transactions, click on the protocol number to view additional information.



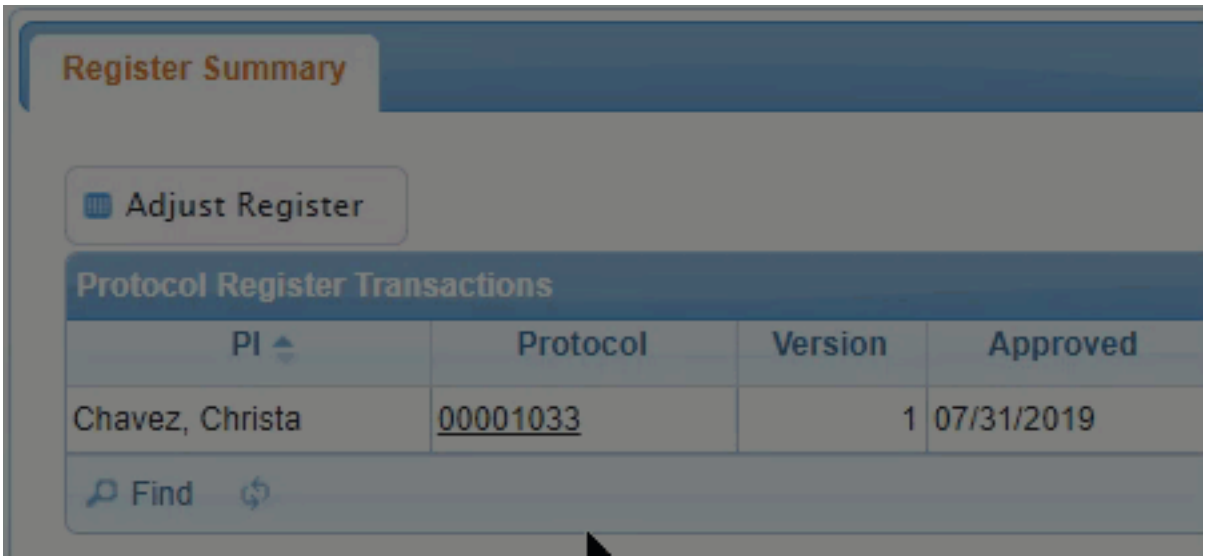
Additional information about the transaction will be displayed within a grid.



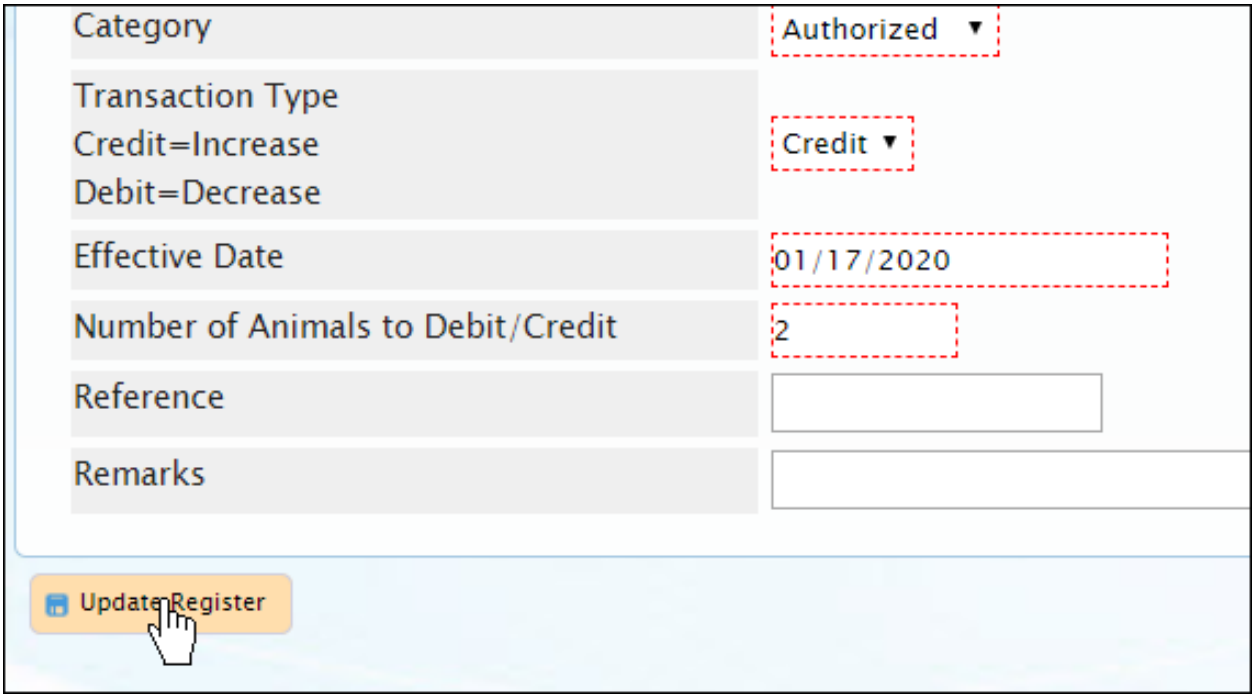
Adjusting the Register

An IACUC coordinator can make manual entries in the register if needed. On the Register Summary tab, highlight a line item and click on the Adjust Register button.

1. Click on a line item and click **Adjust Register**.

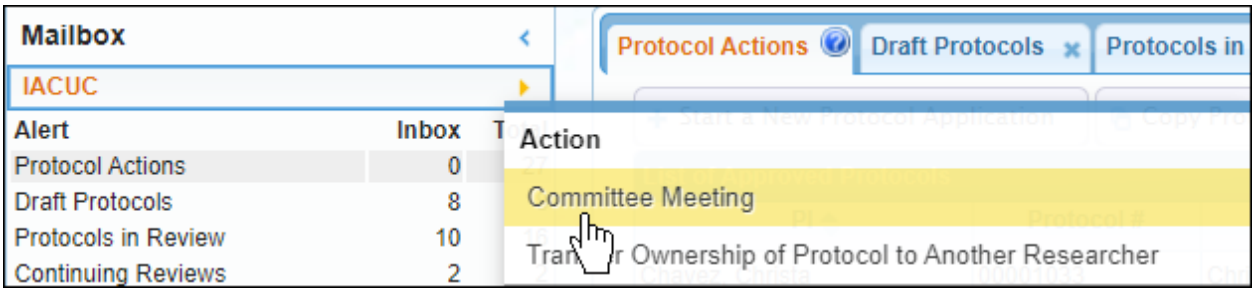


2. Enter the required fields in the Adjust Protocol Register window and click Update Register.



Managing Meetings

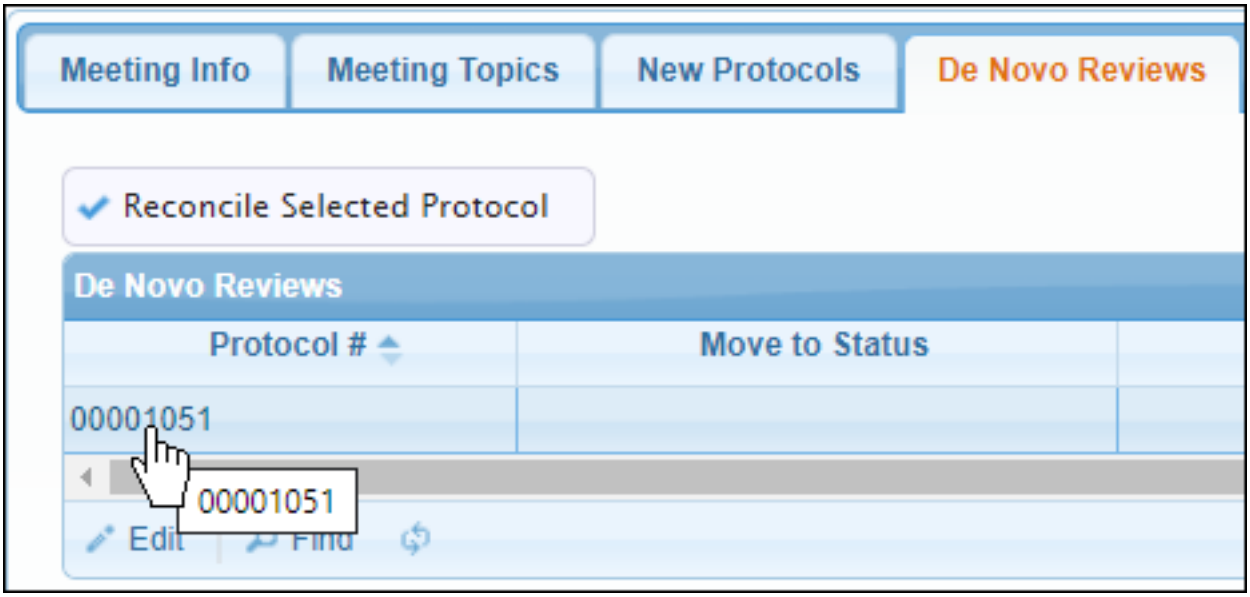
Committee Review Meetings are documented in Cayuse IACUC and can be accessed by clicking on the arrow next to IACUC, and clicking **Committee Meeting**.



Please note: The Meeting Date and the Meeting Location fields are populated from the Agenda setup and can only be modified from the setup.. The list of Committee Members is populated by the list of Committee Members in setup, and these members must have the IMBR role. Learn more here.

Reviewing Protocols

All protocols sent to the meeting can be reviewed in the meeting by clicking on a protocol tab and clicking on the protocol number within the list.

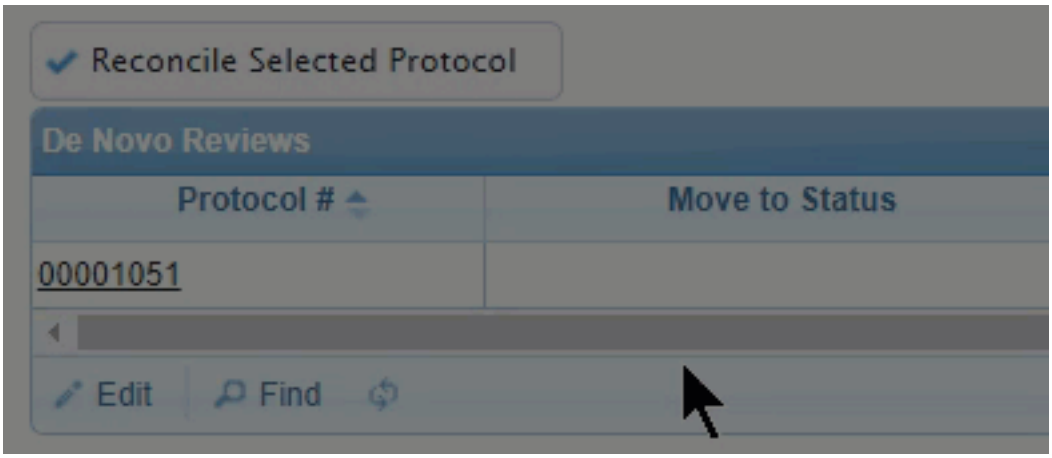


The review of the protocol works in the same way as a review outside of the meeting. Learn more about reviewing here.

Reconciling Protocols

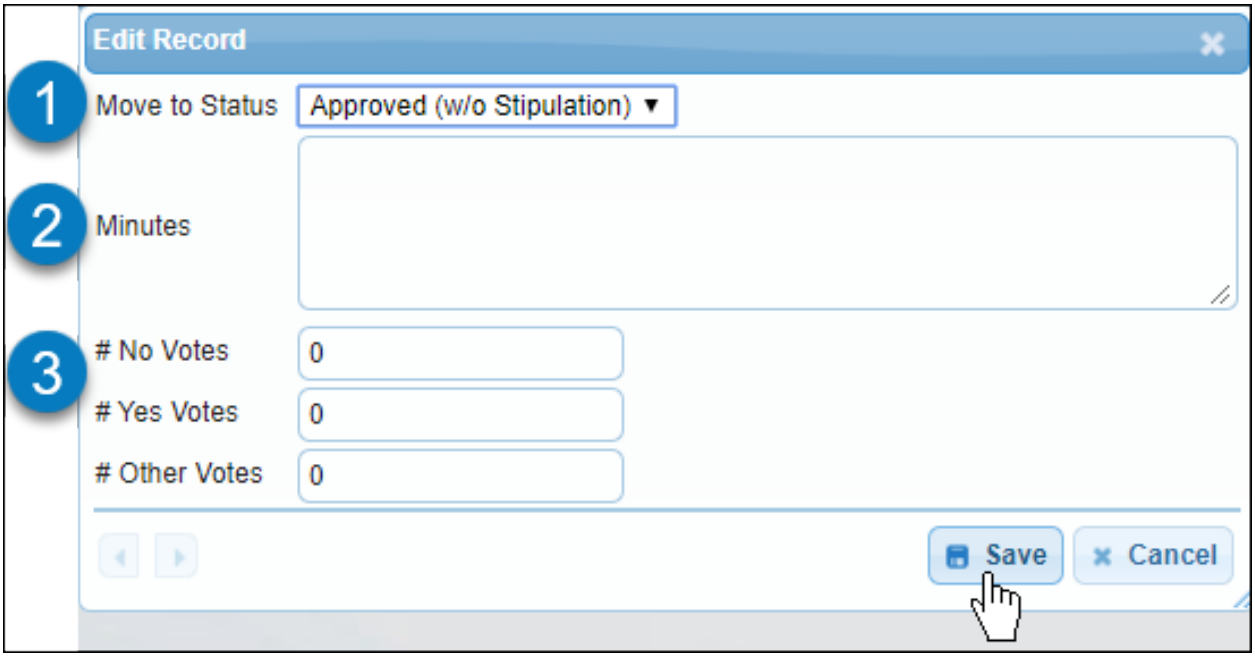
All protocols must be reconciled prior to closing a meeting. To reconcile a protocol:

1. Click on the protocol within the list to highlight it.
2. Click **Edit**.



3. Edit the record, and click **Save**.

Edit Record



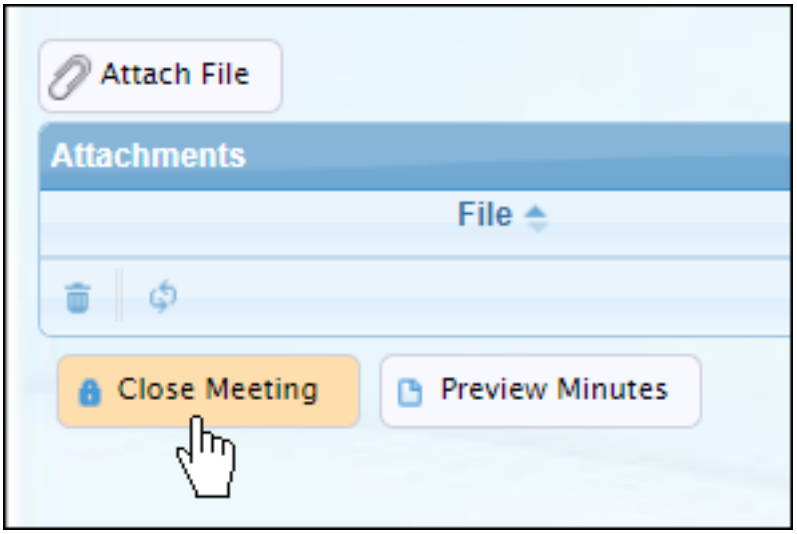
1. **Status:**
   - **Approved:** approves the protocol.
   - **Deferred:** defers to the next meeting.
   - **Pending:** protocol is sent back to the IACUC workflow.

- **Expired:** expires protocol (only applies to De Novos).
- **Withdrawn:** withdraws protocol (only applies to Continuing Reviews).

2. **Minutes:** enter the meeting records here.
3. **Votes:** records the number of meeting member votes for Yes, No, and Other.

Closing the Meeting

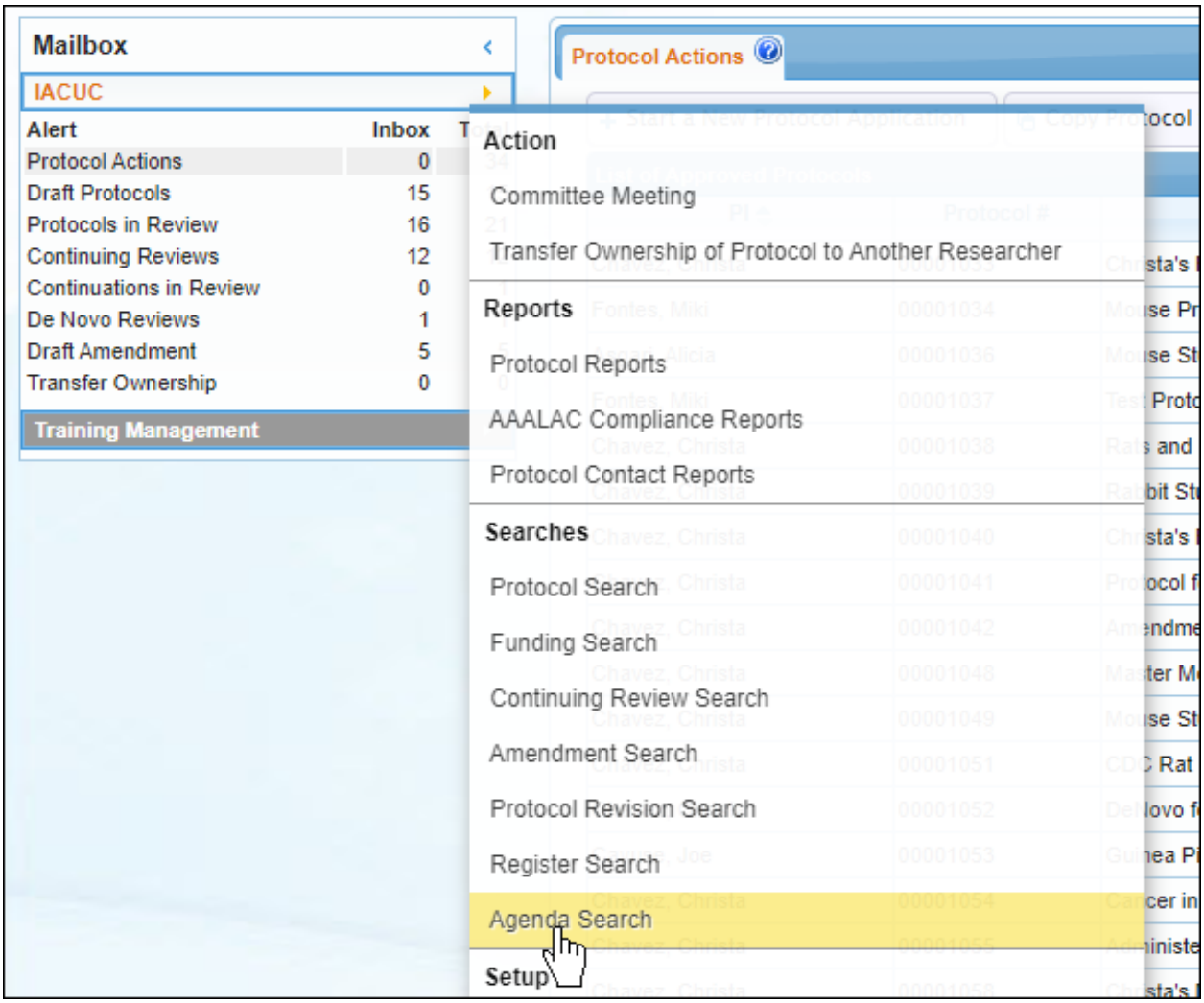
Click **Close Meeting** at the bottom of any tab.



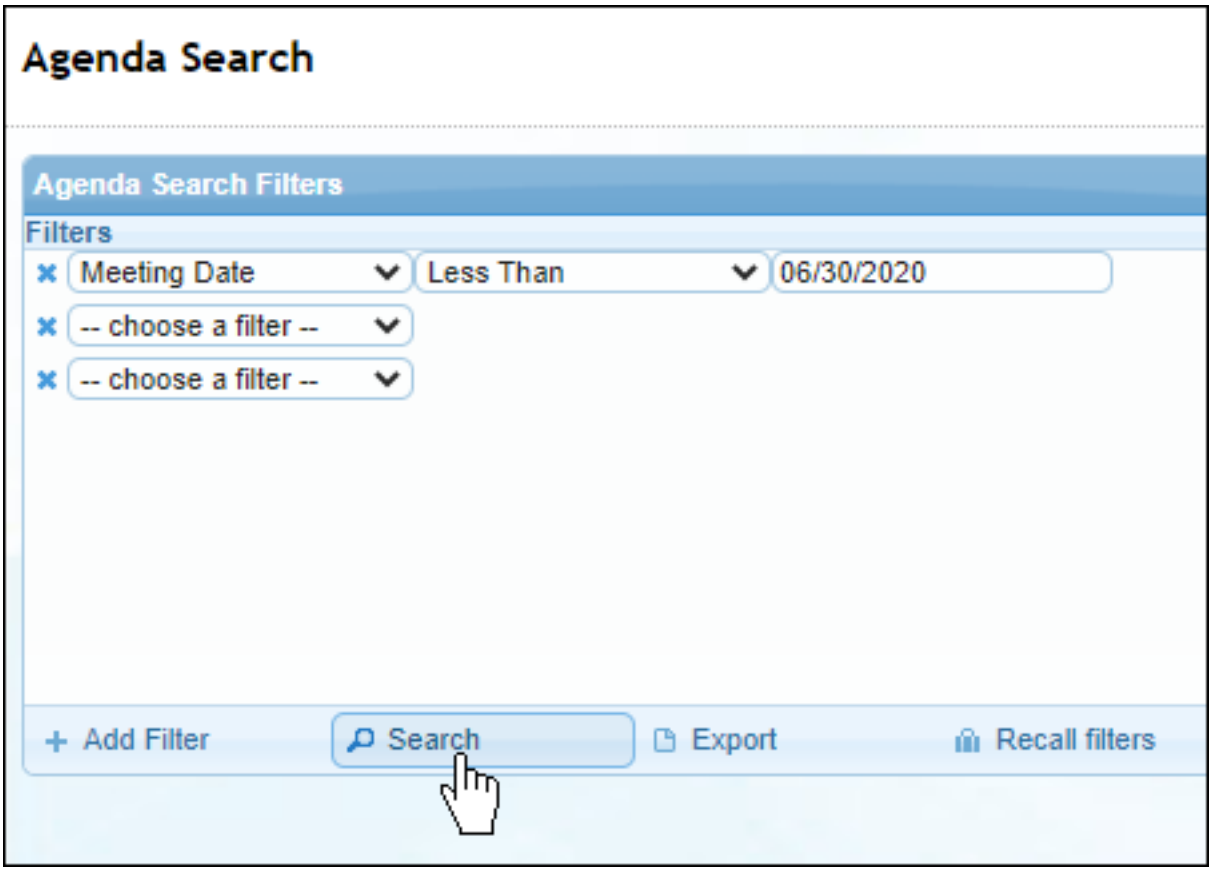
If agenda records are reconciled, the meeting will close and the next scheduled meeting will become the active meeting.

Editing Past Meeting Minutes

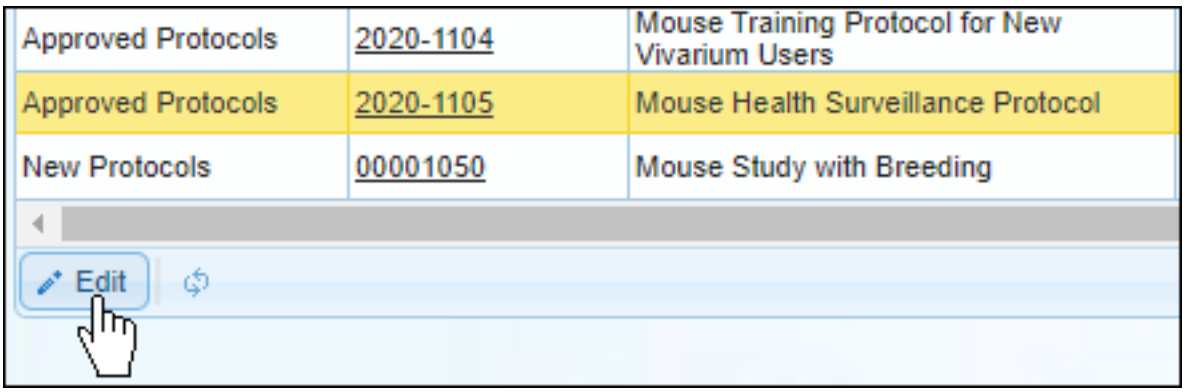
Committee Review Meetings are documented in Cayuse IACUC. You can edit past meeting minutes by clicking the arrow next to IACUC, and clicking **Agenda Search** beneath Searches.



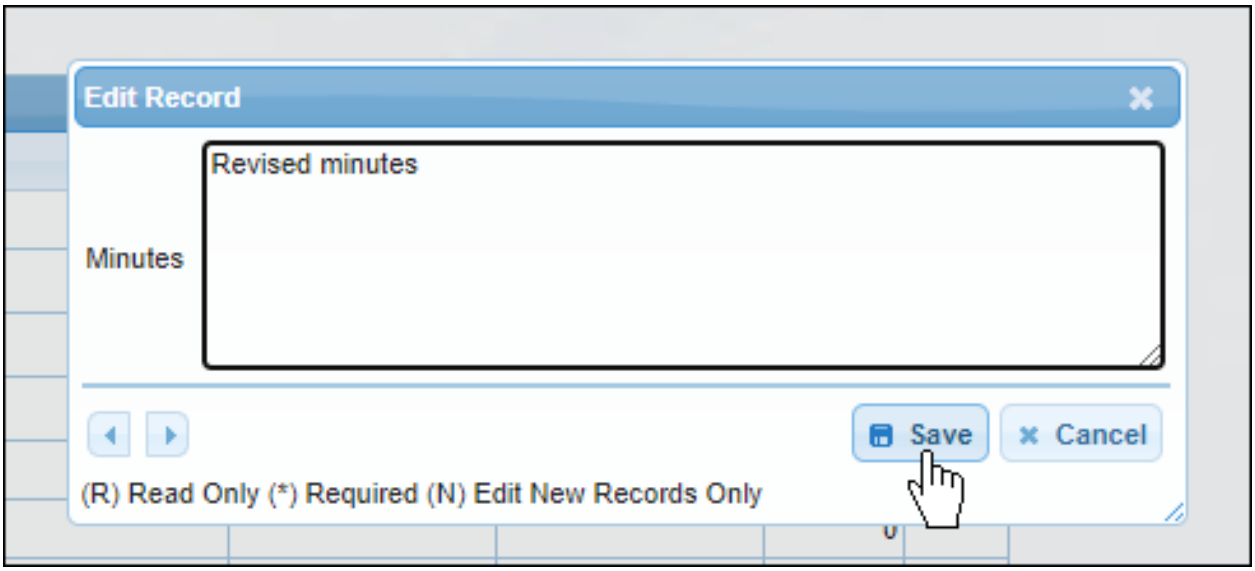
Use the filters to find the protocol requiring the edit, and click **Search**.



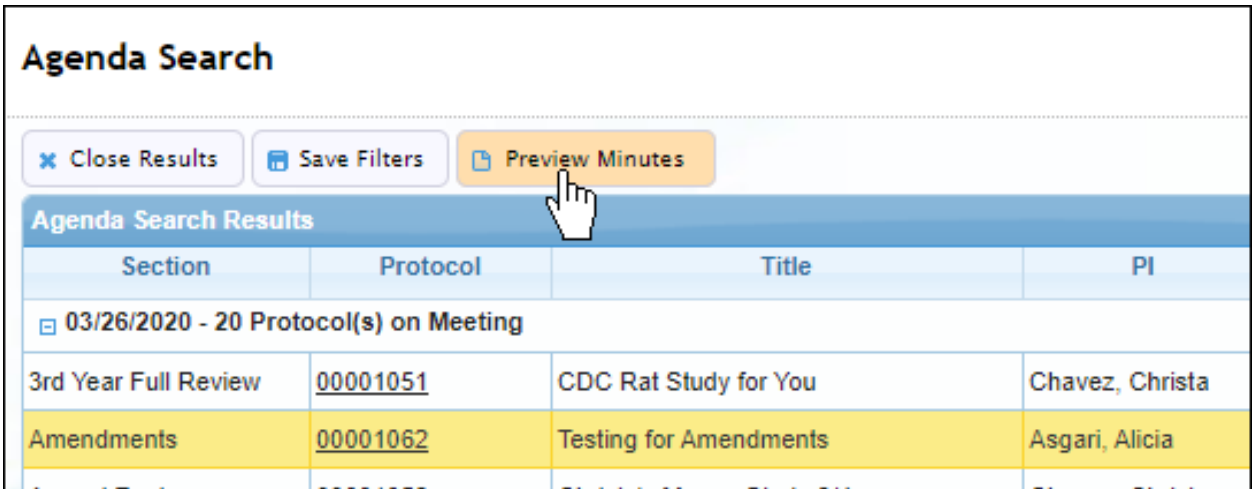
Click on the protocol, and then click **Edit**.



Edit the minutes in the provided field, and click **Save**.

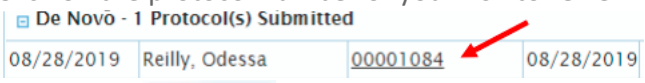


To preview the revised minutes, click on the protocol and then click **Preview Minutes**.

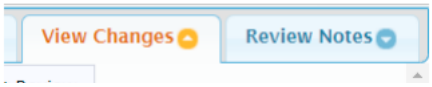


Adding Reviewer Footnotes

1. Click on the protocol number of you wish to review.

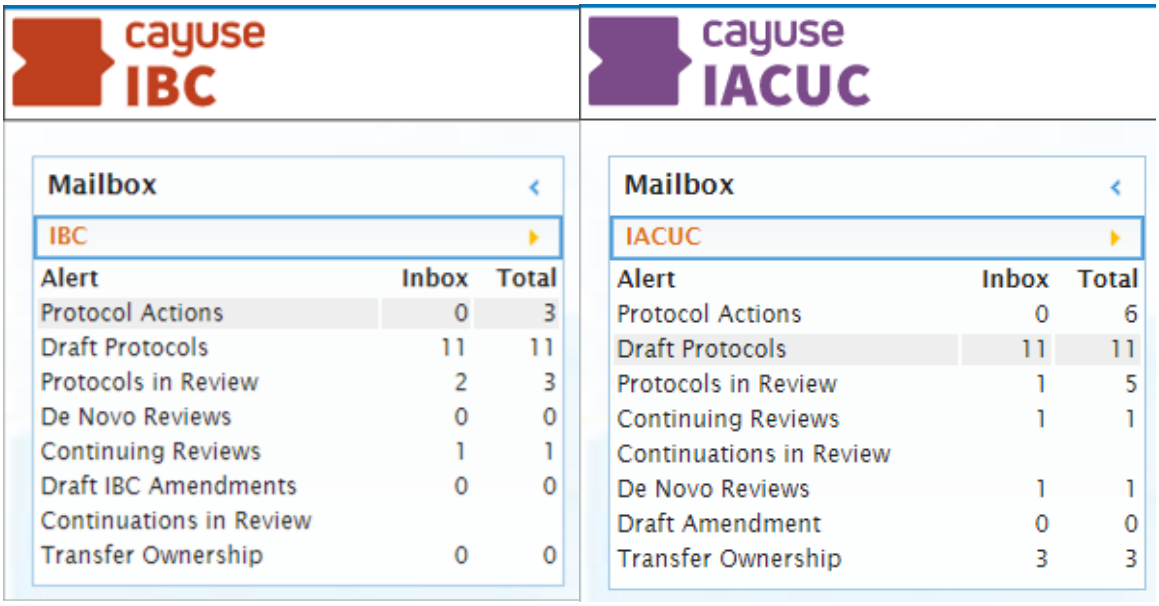


2. Click on the button at the bottom of the page.
3. Open your View Change tab in the upper right-hand corner.



4. In a text field where a change is required, click on the text box.
5. Notice that the identical text is shown in the first box under *Changes that have been made in document.*
6. Click on and notice that the button now has a black frame around it.
7. Highlight the section of protocol text that you would like the researcher to change.
    a. Notice that a new comment bubble appears in front of the highlighted text.
    b. Notice that a new comment bubble is added to the Reviewer Notes section.
8. Add your change request to space next to the bubble in the under the Reviewer

Mailbox Alerts



Mailbox

IBC

Alert	Inbox	Total
Protocol Actions	0	3
Draft Protocols	11	11
Protocols in Review	2	3
De Novo Reviews	0	0
Continuing Reviews	1	1
Draft IBC Amendments	0	0
Continuations in Review		
Transfer Ownership	0	0

Mailbox

IACUC

Alert	Inbox	Total
Protocol Actions	0	6
Draft Protocols	11	11
Protocols in Review	1	5
Continuing Reviews	1	1
Continuations in Review		
De Novo Reviews	1	1
Draft Amendment	0	0
Transfer Ownership	3	3

Summary of Alerts

1. ***Protocol Actions:*** approved protocols
    a. Actions
        i. *Start a New Protocol Application:* allows the user to create a new protocol.
        ii. *Copy Protocol to a New Document:* Creates a copy of the protocol and gives it a new protocol number. The new protocol is in Draft state and can be edited and submitted for committee review.
        iii. *Start an Amendment:* Creates an amendment by creating a new version of the approved protocol which the user can edit and submit for review.
        iv. *Protocol Versions Preview:* Allows the user to view all versions of the protocol.
        v. *Register:* Allows the user to see credits or debits to the animal numbers register.
2. ***Draft Protocols:*** protocols that have been started but not yet submitted for review.
3. ***Protocols in Review:*** protocols that have been submitted for review but are not yet approved.
4. ***De Novo Reviews:*** De Novo reviews due to the IACUC but not yet submitted.
5. ***Continuing Reviews:*** Continuing Reviews due to the IACUC but not yet submitted.
6. ***Draft Amendments:*** Amendments that have been started but not yet submitted for committee review.
7. ***Continuations in Review:*** Continuing Reviews that have been submitted for committee review but are not yet approved.
8. ***Transfer Ownership:*** Transfer of ownership requests submitted for review but not yet approved.