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HAZARD SAFETY TRAINING GUIDE

Overview

This guide is designed to walk the implementation team and administrators through the training and testing of the Hazard Safety application. Please note that the screenshots in this guide may differ from your institution's site.

Supported Browsers

Chrome, Safari, and Firefox

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Hazard Safety Roles

Access to the Hazard Safety application is controlled by roles. Key roles for the application are defined below. User accounts and roles can be managed by users with the RS Admin Administrator role. Please see the section 'Manage Users' at the end of this guide for instructions on how to create accounts and manage roles. It is important for the IBC office to understand how to access and manage roles. Users who rotate on and off the IBC committee will need to have roles updated accordingly. In addition, new IBC coordinators or administrative staff may need the IBC Office role.

The Hazard Safety Office role is the main administrative role in the application. This role will allow the user to:

- view all of the submissions in the IBC program
- create, edit, and submit protocols, amendments, continuing reviews, and De Novo renewal protocols on behalf of the PI
- route submissions through the review process
- access set up menus to manage the committee roster, meeting dates, agents, and options available for selection in the protocol form
- manage the committee agenda process
- access all Searches and Reports

The Hazard Safety Member role is the role for committee members and any other users that will need to be assigned reviews in the system or access the committee meeting agenda. Users with this role will only be able to see review assignments and the agenda. This role may be modified to allow members access to certain reports or searches.

The Animal Oversight & Hazard Safety Research Staff Member role is assigned to all researchers in the system including PIs and research staff. This role filters the view in the applications to only allow access to protocols applicable to the researcher.

Role	Application(s)	Permissions
Cayuse Product User	All	Default role. Can access the Cayuse landing page. Every active user should have this role.
RS Admin Administrator	Platform Admin	Maintains system settings within the Admin module on the Cayuse Platform.
RS Admin Viewer	Platform Admin	Can access a read-only view of the Admin module on the Cayuse Platform.
HR Connect Administrator	Platform Admin	Manages the HR connect updates
Animal Oversight & Hazard Safety Research Staff Member	Animal Oversight, Hazard Safety, Animal Procurement, Animal Inventory, Vet Care, Billing, & Services	Protocol Creation; Ordering, Census, Vet Care, and Invoicing workflow (PI can submit/PI member cannot)
Animal Oversight & Hazard Safety Training Coordinator	Training Management	Responsible for setting up training events and managing personnel training records



Biosafety Officer	Hazard Safety	This role is typically not used. Participate in IBC protocol reviews; assist PIs with protocols
Cayuse IBC Link Viewer	Hazard Safety	Allows access to see Hazard Safety module
Cayuse Training Management Link Viewer	Training Records in Animal Oversight & Hazard Safety	Allows access to see Training module
Hazard Safety Member	Hazard Safety	Participates in protocol reviews and committee meetings
Hazard Safety Occupational Health	Hazard Safety	View protocols in draft and in review
Hazard Safety Office	Hazard Safety	Manages protocol workflow; builds set up dictionaries; manages committee meetings etc.

Hazard Safety Set Up and Management

• Applicable Role: IBC Office

The IBC Office role is the main administrative role in the application. Users with this role can access and manage the set-up options for Hazard Safety. Throughout the IBC protocol form, many pages such as the Surgery page or Non-Surgical Procedure page provide lists of options for selection by the PI. Controlled lists provide the IBC office the ability to create clean reports, provide best practice recommendations to researchers, and maintain consistency of nomenclature.

Best Practices

Notice that many setup lists have the **Delete** button at the bottom of the grid. Once you have started using the specific item in your protocols, we recommend that you hide the item rather than delete it to avoid issues with data integrity.

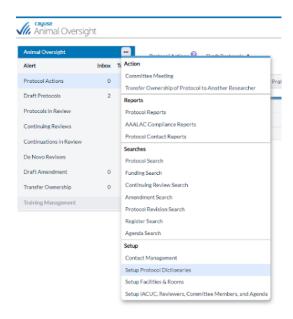
Shared Setup Lists with Animal Oversight

Some set up lists are shared with the Animal Oversight applications and are only accessible from the Animal Oversight application action menu.

To access these Setup Lists, the IACUC or IBC Office role clicks the action menu in Animal Oversight.

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The shared lists are:

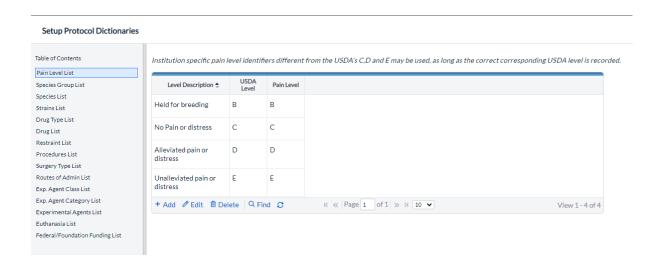
- Contact Management: All users are displayed in this list
- <u>Protocol Lists (Dictionaries):</u> These lists populate the protocol form with drugs, procedures, and other information
 - o the Federal/Funding list is shared with Hazard Safety
- <u>Facilities & Rooms</u>: All animal use and housing locations are entered in this menu for both Animal Oversight and Hazard Safety
- <u>IACUC, Reviewers, Committee Members and Agenda</u>: IACUC Meeting dates, members, and preferences are set in this menu
 - Protocol preferences such as approval periods for Animal Oversight and Hazard Safety are managed in this list

Animal Oversight: Protocol Dictionary Lists

Role: IACUC Office

Support Site Resource: Setting up Dictionaries





Protocol Dictionary List

Federal/Foundation Funding List

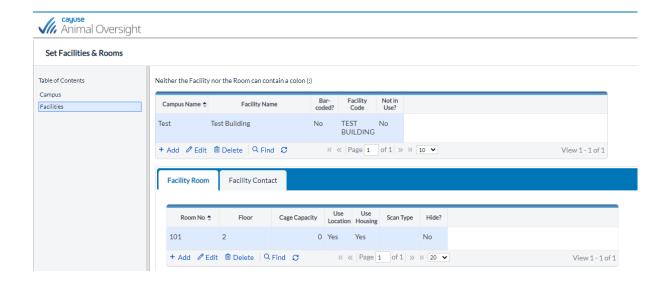
This list provides options on the funding page. The details on the Funding page in the IBC protocol display on the Funding Search results.

NOTE - this list is shared with Hazard Safety (IBC) if applicable.

Animal Oversight: Facilities and Rooms

Roles: IBC Office and Animal Buyer

Support Site Resource: Setting up Facilities and Rooms



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Protocol Dictionary List

Campus

One or more campuses should be listed. Buildings will be associated with each campus.

Facilities

The first grid lists the facilities/buildings in your institution.

Rooms

The second grid defines the rooms and the facility contacts. To add rooms to a facility, highlight the facility first. All rooms flagged as Use Location are available for selection on protocols, regardless of setup selections.

- Room number: only unique room numbers/letters are allowed.
- Floor: optional
- Cage Capacity: optional
- Use Location: room will display in the IACUC or IBC protocol form
- Use Housing: (Vivarium applications) room will display on animal order in Vivarium Operations applications to house the animals only if 'Use Housing' is selected.
- Scan Type: (Vivarium applications) Online/Offline if Wi-Fi is available in the room indicate Online. Otherwise, select Offline.

TIPs - Rooms must have the 'Use Location' Checkbox checked to see the option in the protocol form for Animal Oversight and Hazard Safety

Rooms must have the 'Use Housing' Checkbox checked to see the option in the Procurement and Inventory applications

Facility Contact (Not applicable for Hazard Safety)

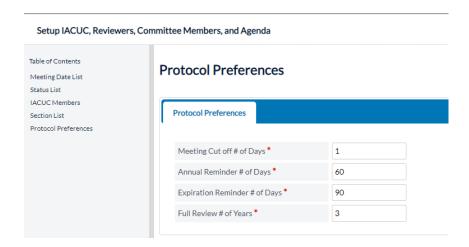
Animal Facility Supervisors, Receiving Technicians, Veterinarians and Animal Health Technicians should all be listed as Facility Contact personnel.

Animal Oversight: Setup IACUC, Reviewers, Committee Members, and Agenda

Role: IACUC Office

Support Site Resource: Setting up Meetings, Members and Agenda





IACUC, Reviewers, Committee Members, and Agenda Lists

Protocol Preferences

Navigate to view the settings (Please don't make any changes unless you intend to permanently change the site)

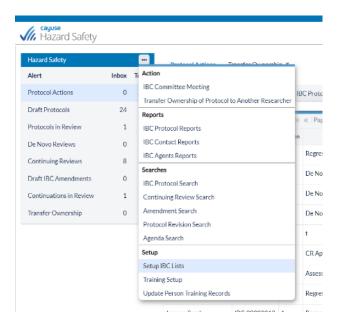
These preferences define the following.

- Meeting cut off: Minimum # of days prior to a meeting that protocols can be placed on the agenda
- Annual Reminder: # of days prior to a protocol review date triggers the protocol to display in the Tab/Alert Continuing Reviews.
- Expiration Reminder: # of days prior to a protocol expiration date triggers the protocol to display in the Tab/Alert De Novo Reviews
- Full Review: Number of years in the cycle to trigger a De Novo review

Hazard Safety Setup Lists

To access the Setup/Dictionary Lists, the IBC Office role clicks the action menu and selects Setup Protocol Dictionaries.

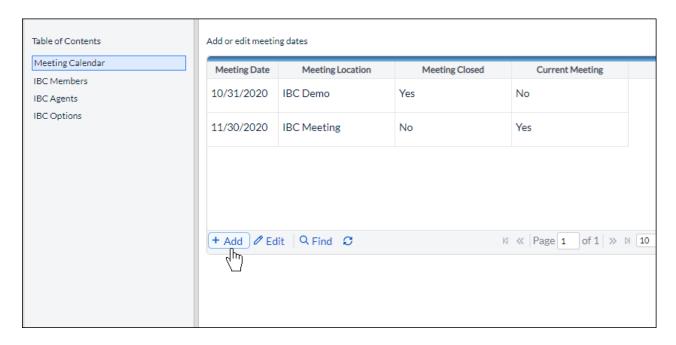




Meeting Calendar

Setting up Meetings

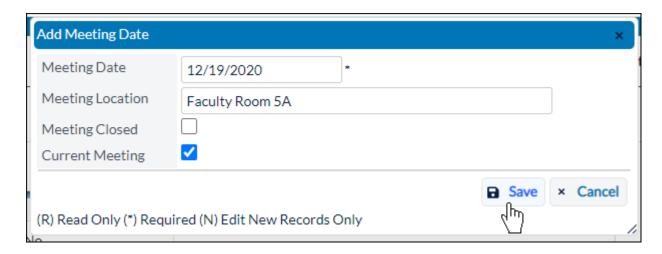
The Table of Contents will automatically open the Meeting Calendar. Click on Add to create a new meeting.





In the new dialog, select the meeting date and fill in the meeting location. Check Current only if the meeting is the next upcoming meeting. When a meeting is closed, the meeting will be updated as closed here, and the next meeting will become the new current meeting. There always needs to be a future meeting date before the last meeting is closed.

Click Save.



Meeting Calendar

This is where the calendar of meeting dates is maintained. When protocols are placed on the meeting agenda, they automatically go to the upcoming current meeting. As protocols are approved, they are listed in the approved protocols tab in the meeting agenda. It is important to always have a current meeting setup. We recommend you set up several meetings in advance.

For the initial setup:

- Setup one meeting date in the past, and check 'closed', do not check 'current'.
- Setup one meeting date in the near future, and check 'current'.
- Setup several meeting dates in the future, and do not check 'closed' or 'current'. After the initial setup, meetings are closed from the Committee Meeting process. Meetings should **never** be closed manually from this setup section. If future meeting dates change you may edit the dates here

To handle canceled meetings, please consider going to this list, change the next month's meeting to a month in the future. Then take the current meeting and update the date to the correct date (next month's date) This will keep the Agenda history accurate.

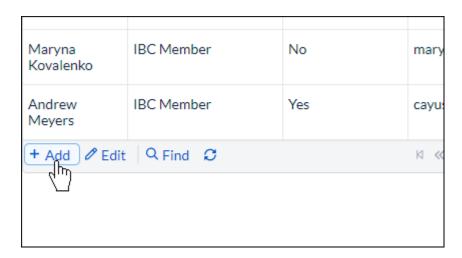


IBC Members

Adding IBC Members

Adding new members

1. Click Add.



2. In the new dialog, begin typing the name of the individual until they display in the drop-down menu, and then click on their name.



3. Select their role by using the drop-down menu, check Active, and click Save.





Note: The active flag must be checked for them to display in the list of members on the submit to members workflow page. If a member is no longer on the committee, edit their record and uncheck the active flag.



Setup IBC Lists Table of Contents Meeting Calendar IBC Members IBC Agents IBC Options

Add/edit information about IBC committee members.

Member 🕏	Role	Active	Email Id
1, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
11, member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
10, member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
9, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
2, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
3, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
4, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
5, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
6, Member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
7, member	Animal Buyer Staff	Yes	sarah.josway@cayuse.co
+ Add Ø Edit	Q Find S		⋈ ≪ Page 1 of 2 >>

IBC Members

Any person that will need to conduct an official review of submissions (for example hazard specialists, etc.) must be added to this list and granted the committee member role in Platform Admin.

As committee members rotate off the committee, the IBC office role will need to update their profile in this list to uncheck the Active flag. This will hide their name from the Reviewer workflow process. In addition, the administrator will need to remove the Committee role from the person's account.

IBC Agents

Adding IBC Agents

Throughout your institution's IBC protocol form, there are drop-down options managed with the IBC Agents list

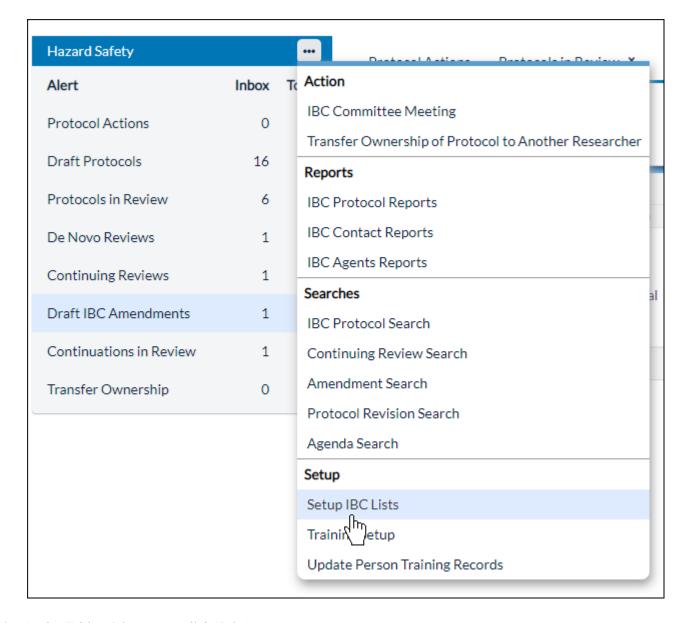


in setup. For example, on the R/sNA > Synthetic Experiments page, there is a drop-down for Backbone Source. The IBC Office role will manage these lists.

It is important to note that if options are no longer applicable to your IBC program, the IBC office role can hide those options using the Hide function. The Delete function is not to be used for any option, as the deletion can impact data integrity for protocols with that option select.

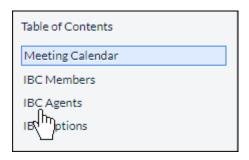
Adding an Agent

1. Click on the menu next to Hazard Safety and click on Setup IBC Lists.



2. In the Table of Contents, click IBC Agents.

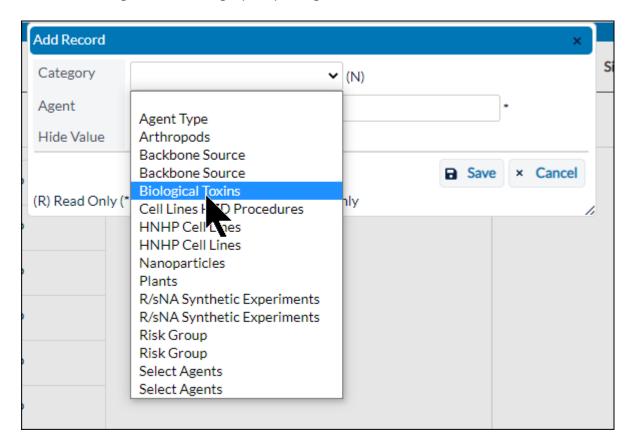




3. Click Add.

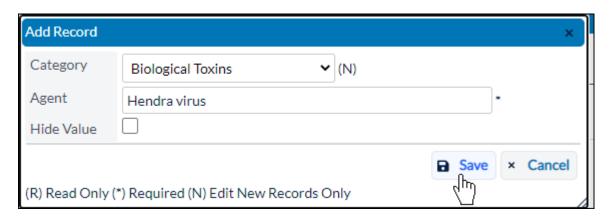


4. In the new dialog, choose a category for your agent. Note: These are not customizable.





- 5. Fill in the name of your agent. You can choose to hide the value if you don't want the agent displaying in the IBC protocol form options.
- 6. Click Save.



You can also edit an agent by clicking on the line item, and then click Edit.



IBC Agents

This list provides options for selection in the form. The IBC office role may need to manage these lists to add or edit options available to researchers.



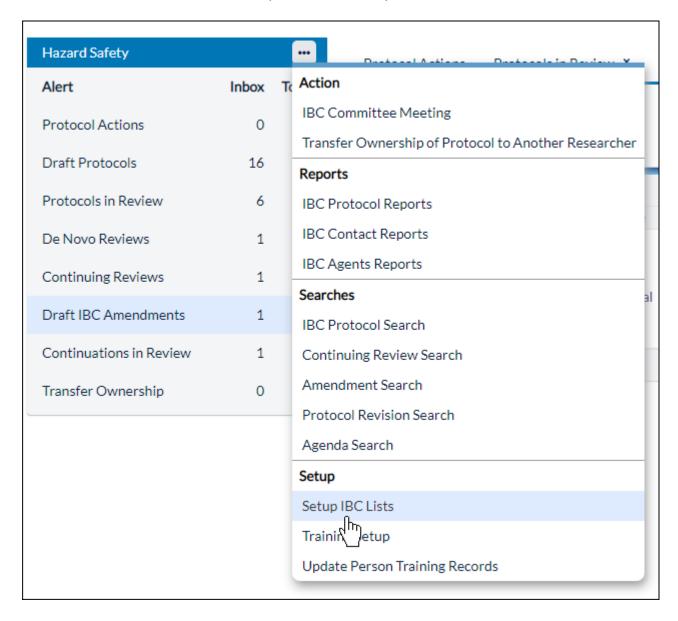
IBC Options

Adding IBC Options

IBC Options are selectable checkboxes throughout your institution's IBC protocol form and can be added through setup. Unlike the drop lists, a checkbox list allows more than one option to be selected. For example, on the R/sNA > Synthetic Experiments page, there is a check box list for Nature of DNA Sequences.

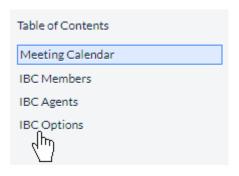
Adding an Option

1. Click on the menu next to Hazard Safety and click on Setup IBC Lists.



2. In the Table of Contents, click IBC Options.

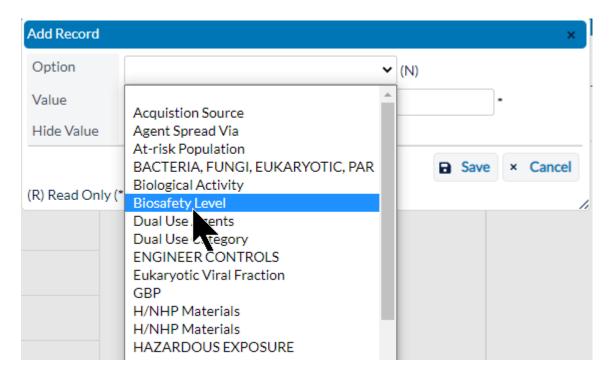




3. Click Add.



4. In the new dialog, choose a category for your option. Note: These are not customizable.



- 5. Fill in the name of your agent. You can choose to hide the value if you don't want the agent displaying in the IBC protocol form options.
- 6. Click Save.





You can also edit an option by clicking on the line item, and then click Edit.



IBC Options

This list provides options for selection in the form. The IBC office role may need to manage these lists to add or edit options available to researchers.

Other IBC Actions

Protocol Actions Alert



The IBC Office role has the ability to perform additional tasks in the system. From the Protocol Actions alert, there are buttons to perform various actions. These are described in detail below.



Start a New Protocol Application

Creates a new protocol draft. If the IBC office initiates a new protocol, the office role must define the PI name.

Copy Protocol to a New Document

Support Site Resource: Copying an Approved Protocol

Copies all of the details in the protocol into a new protocol draft. The new protocol will be accessible in Draft Protocols for editing and submission.

Start an Amendment

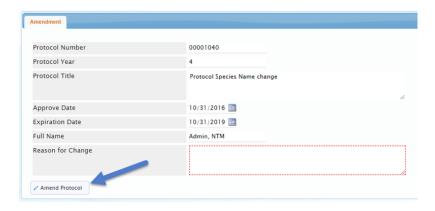
Creates an amendment. The amendment process starts by prompting the user to describe the changes to be made. Then the system will create a new version of the approved protocol which the user can edit and submit for review.



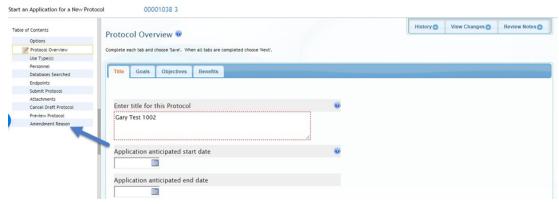
The IBC office can perform an amendment on behalf of the PI. To start an amendment, select the protocol from the Protocol Actions alert and click on the Start an Amendment button.

When an amendment is started, the general information about the protocol is displayed and the user is asked to enter the reason for the amendment. When the Amend Protocol button is clicked, the entire protocol is displayed allowing the user to make the necessary changes to the protocol.





Notice that the reason for amendment becomes a part of the protocol TOC and is also included in the revision. When a change is made to a page, the tablet with a pencil icon is displayed on the TOC.



Protocol Versions Preview

Support Site Resource: Comparing Protocol Versions

Allows the user to view all versions of the protocol. The application will create new version numbers of a protocol for each amendment and De Novo renewal.



In the example above, protocol 00001001 has two versions. The source column indicates the reason for each version. Version 1 is the New Document submission and approval. Version 2 was due to an Amendment. Each version can be viewed by clicking on the hyperlink found on the protocol number.



Transfer Protocol Ownership

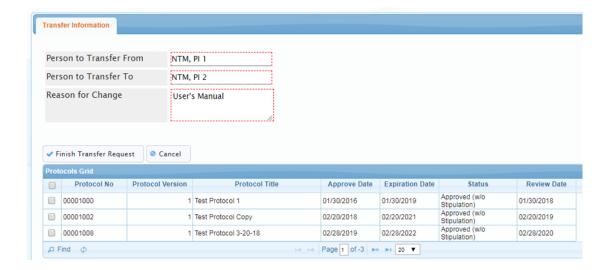
An investigator, or the IBC Office role, may initiate a protocol ownership transfer. This feature is available in the IBC Management Actions menu.

Enter all of the required fields and click on the Show Protocols to Transfer.





All approved protocols display. Select the protocol needed to transfer and click on the Finish Transfer Request. An email is submitted to the IBC office indicating a Transfer Request has been submitted.

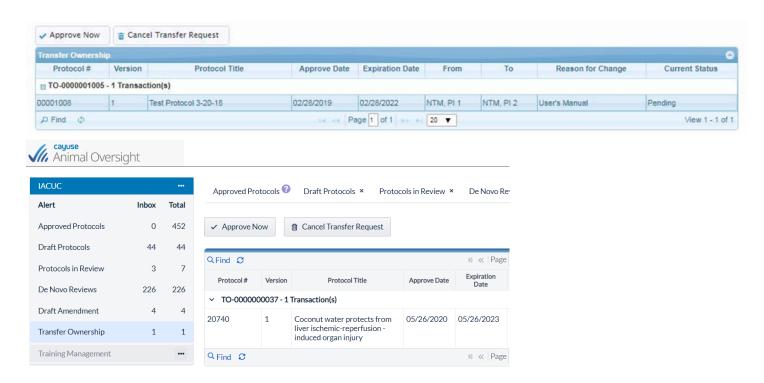


IBC Office Processes a Protocol Transfer Request

Support Site Resource: <u>Using the Transfer Ownership Tool</u>

When a protocol transfer request is submitted, the request lands in the Transfer Ownership alert. The IBC office can either Approve the request or Cancel it. Highlight the protocol and click either of the buttons.

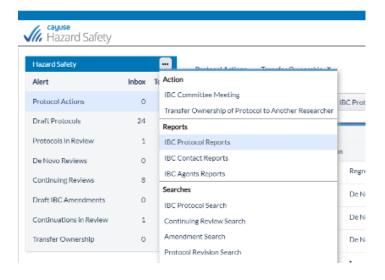




Hazard Safety Reports

The Cayuse Hazard Safety application offers many in-application reports. These reports can be easily generated by administrators to display important information about the institutional IBC compliance program. Each report has built-in filters to create detailed, targeted results. Sets of filters can be saved to allow users quick access to create, save, and export routine reports. All reports can be exported to CSV files for manipulation in other applications.

The Hazard Safety application has three main types of reports: IBC Protocol Reports, IBC Contact Reports, and IBC Agents Reports. Here is a brief overview of the reports.



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Tips for Using Filters

- All filters are case sensitive. When searching for a PI last name, capitalize the first letter.
- If using the Equals option, the keywords searched must match exactly.
- Use the Status or Current filters to generate a list.
- Save Filters allows you to save a filter to rerun the search another time with the same parameters.
- Export generates a CSV file with the results of the search.

IBC Protocol Reports

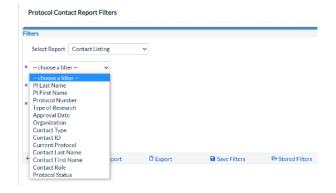
This set of reports can be used to generate lists of protocols that meet certain filter criteria or counts of protocols by various parameters. Our customers commonly use these reports to monitor protocol approval activity on a quarterly basis.



Protocol Contacts Reports

These reports provide lists of protocol staff, which can be used by the Hazard Safety program to develop email lists for new policies, training courses, or program updates.

- Contact Listing
- Contact Listing by Protocol



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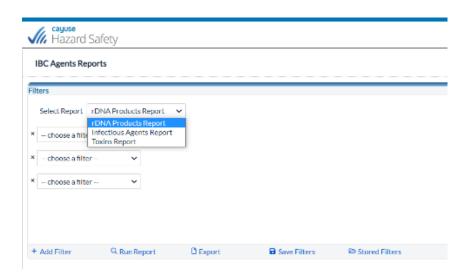
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IBC Agents Reports

These reports will display agent details from protocols based on the search parameters selected. This is a great tool for IBC programs to pull specific information about hazard types.

There are three report types:

- rDNA Products Report
- Infectious Agents Report
- Toxins Report



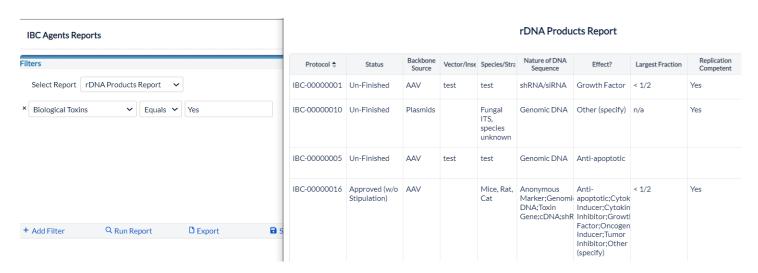
Tip:

The Filter options below provide the ability for users to combine or exclude agent types. The user will indicate if the system should include (Equals Yes) or exclude (Equals No) protocols with the agent type under Select Report and the filter option.

For example, in the screenshot below, the system will display data from the toxins page. If the Whole Animals/Animal Material filter equals 'Yes', the system will display protocols that have toxins and whole animals. If the Whole Animals/Animal Material filter equals 'No', the system will display results excluding protocols that have Whole Animal work.

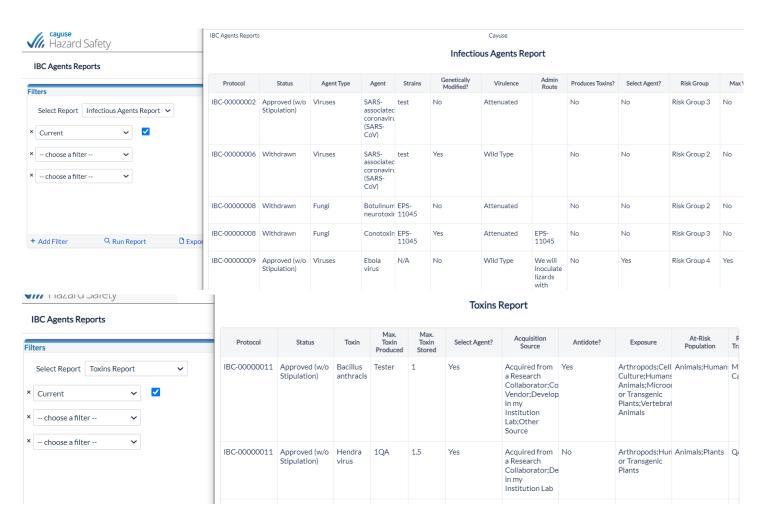


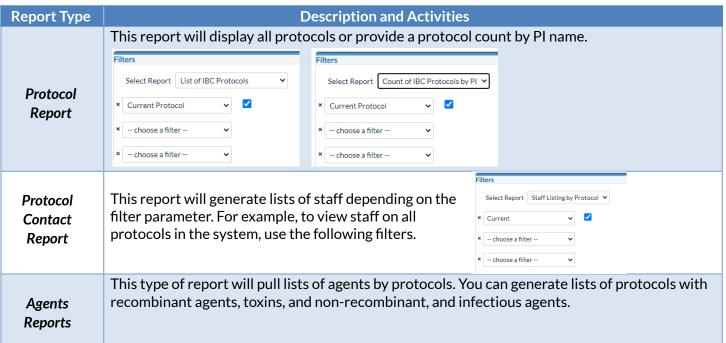
The results below show details from the rDNA page of protocols that also have Biological Toxins.



Here are screenshots of the different report types with the filter Current checked. This displays all data in the system.









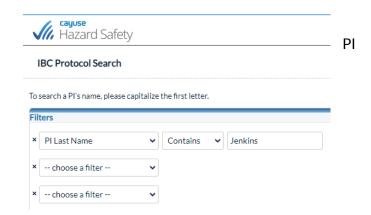
Hazard Safety Searches

Running a Search

Access the Search options by clicking on the IBC Action menu. Click on the type of search you want to perform.

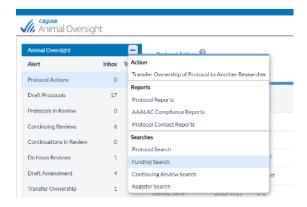
Tips for Using Filters

- All filters are case sensitive. When searching for a last name, capitalize the first letter.
- If using the *Equals* option, the keywords searched must match exactly.
- Use the Status or Current filters to generate a list.
- Save Filters allows you to save a filter to rerun the search another time with the same parameters.
- Export generates a CSV file with the results of the search.



Animal Oversight: Funding Search

To perform searches on Funding information, the IBC office role will need to access the Funding Search under the Animal Oversight application action menu.

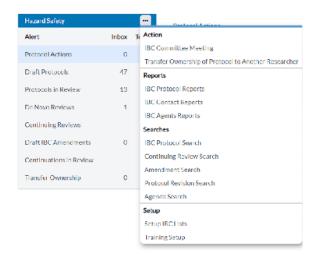


The following is a sample result of a Funding Search:



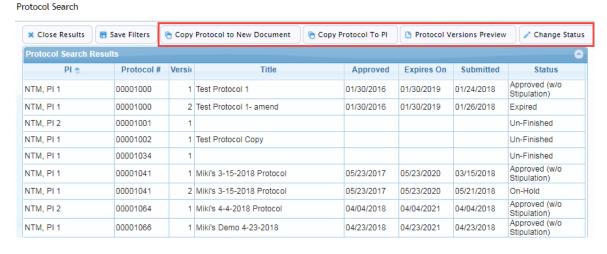


Hazard Safety Searches



IBC Protocol Search

The Protocol Search displays the list of protocols per the search filters used. Additionally, there are four buttons at the top of the page which allows you to Copy Protocol to a New Document, Copy Protocol to PI, Preview Protocol Versions and also Change the Status of a protocol.



- Copy Protocol to New Document: refer to the section above
- Protocol Versions Preview: refer to the section above
- Copy Protocol to PI: refer to the section above

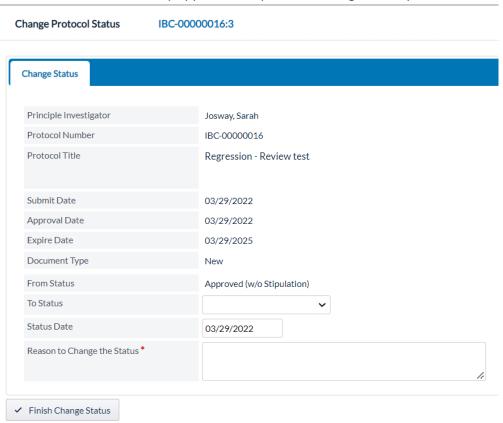




Change the Status of an Approved IBC Protocol (Closing or suspending a protocol)

Allows the IBC Office role to change the status of a protocol. For example, if there is a compliance issue, the IBC Office role may change the protocol status to 'On Hold'. After the issue is addressed the status may be reverted back to 'Approved'. NOTE that protocols with Un-Finished status cannot be changed to approved from here. They can only be approved via the Review process.

Protocols that are currently approved may also be changed to Expired.

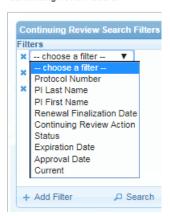


Continuing Review Search

This feature searches for Continuing Reviews using these filters:



Continuing Review Search



The search result returns the following information:



Click on the hyperlink to view the details of the Continuing Review. The following screenshot is a sample of what a Continuing Review looks like.



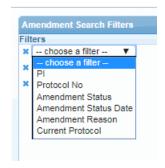




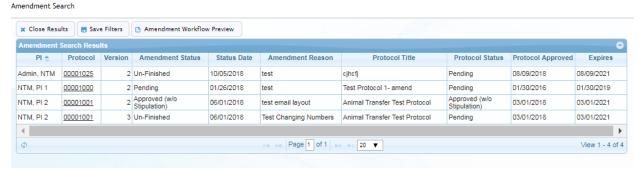
Amendment Search

To search for amendments, use the following filters from the Amendment Search:

Amendment Search



The image below is a sample search:



Click on the protocol number hyperlink to preview the protocol.

Highlight a row and click on the Amendment Workflow preview to view the details of the workflow. The snapshot below is a sample preview:





Protocol Revision Search

This feature allows you to locate and view comments and responses from the IBC and IMBRs' review of protocols.

The example below is the result of a Revision Search:

Protocol Revision Search

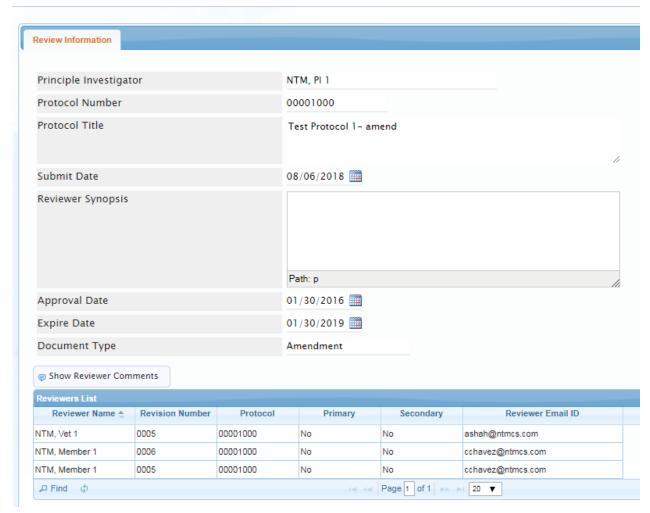


SHOW ALL REVIEWERS

This feature displays the list of reviewers who reviewed this protocol. It allows you to drill down to see individual comments on the protocol's sections.



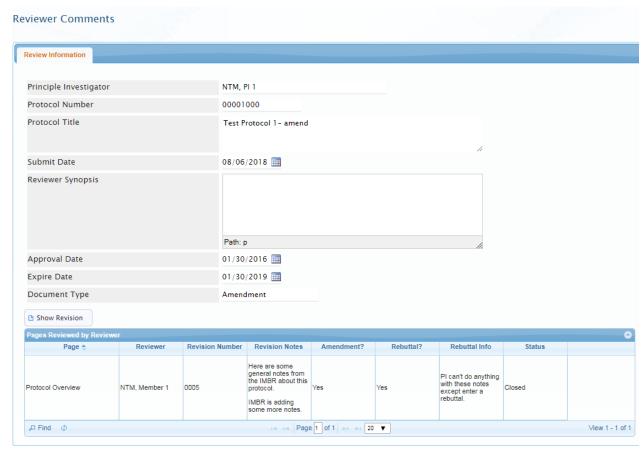
Protocol Revision Search



In the example above, Vet 1 and Member 1 made comments on Revision #005 and only Member 1 made comments on Revision #6.

To view the comments, highlight the row and click Shor Reviewer Comments. In the example below, we can see Member 1's comments.





To drill down even more, highlight the row and click on Show Revision. A new browser tab displays with three sections.

The Previous section displays the information on the page prior to PI's modifications:



Previous	
Protocol Overview	
Complete each tab and choose 'Save'. When all tabs are completed choose 'Next'.	
Enter title for this Protocol	
Test Protocol 1- amend	
Application anticipated start date	
Application anticipated end date	
IACUC Notes	
How would you explain to a non-scientist the long term or overall scientific goals of the proposed work?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitior conque massa. Fus amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
How would you explain to a non-scientist the scientific objectives of the proposed work?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitor congue massa. Fus amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
How would you explain <u>to a non-scientist</u> the way the proposed animal use might <u>benefit</u> human or animal health, the <u>advancement</u> of knowledge, or the <u>good</u> of society?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitior congue massa. Fus amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	

The Review Notes Made which has the Reviewer notes at the bottom of the section:



Review Notes Made	
Protocol Overview	
Complete each tab and choose 'Save'. When all tabs are completed choose 'Next'.	
Enter title for this Protocol	
Test Protocol 1 <u>- amend</u>	
Application anticipated start date	
Application anticipated end date	
IACUC Notes	
How would you explain to a non-scientist the long term or overall scientific goals of the proposed work?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitor congue massa. Fu amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellu ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
How would you explain <u>to a non-scientist</u> the <u>scientific objectives</u> of the proposed work?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitior congue massa. Fu amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellu ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
How would you explain <u>to a non-scientist</u> the way the proposed animal use might <u>benefit</u> human or animal health, the <u>advancement</u> of knowledge, or the <u>good</u> of society?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitior congue massa. Fu amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellu ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
Reviewer Notes	
Here are some general notes from the IMBR about this protocol. IMBR is adding some more notes.	

And finally, the Changes Made section. Had the PI made changes here, they would display with green for added text or red crossed out text for text that was removed. In the sample below, the PI responded with a Rebuttal:

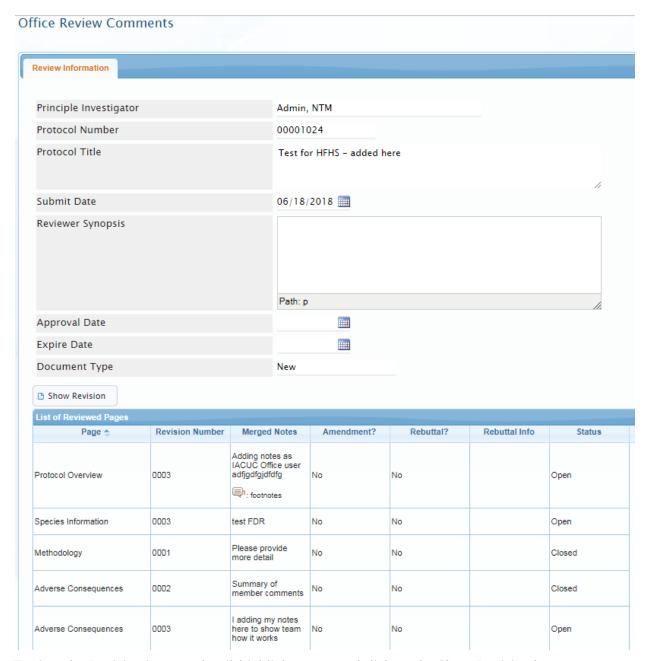


Changes made	
Protocol Overview	
Complete each tab and choose 'Save', When all tabs are completed choose 'Next'.	
Enter title for this Protocol	
Test Protocol 1- amend	
Application anticipated start date	
Application anticipated end date	
IACUC Notes	
How would you explain to a non-scientist the long term or overall scientific goals of the proposed work?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitior congue massa. F amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tell ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
How would you explain to a non-scientist the scientific objectives of the proposed work?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa. F amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tell ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
How would you explain to a non-scientist the way the proposed animal use might	
<u>benefit</u> human or animal health, the <u>advancement</u> of knowledge, or the <u>good</u> of society?	
Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas portitior congue massa. F amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tell ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.	
Pi Rebuttal	
Plican't do anything with these notes except enter a rebuttal	

SHOW OFFICE COMMENTS

Displays all merged Office comments for each page reviewed in the protocol.



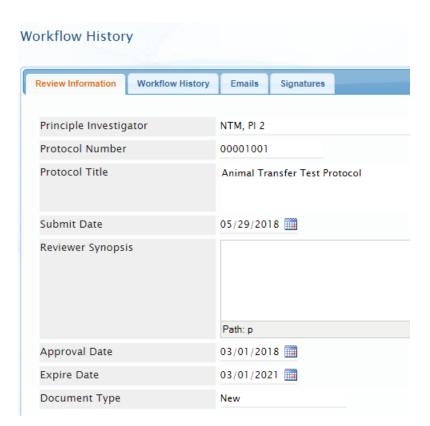


To view the Revision in more detail, highlight a row and click on the Show Revision button.

WORKFLOW HISTORY

The Workflow History feature provided information about the workflow

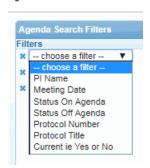




Agenda Search

This feature allows the IBC Office role to locate and view previous meeting agendas. The filters available for this search are:

Agenda Search



The search returns the list of protocols grouped by the specific date of the meeting:





The IBC Office role can edit the meeting minutes by selecting a row and clicking on the edit button. To preview the meeting minutes, select a row and click on the Preview Minutes button. The minutes display as follows:

Meeting Minutes

Meeting Date	03/15/2018
Meeting Location	Conference Room
General Notes	

Attendees



Additional Attendees

Additional Attendees

Approved Protocols

Protocol #	PI	Title	Date Approved	Next Review Date	Expiration Date
00001000	NTM, PI 1	Test Protocol 1	01/30/2016	01/30/2018	01/30/2019
00001001	NTM, PI 2	Animal Transfer Test Protocol	03/01/2018	03/01/2019	03/01/2021



Search Type	Description and Activities		
	Searches all protocols (ex. PI name, protocol number, etc.)		
	Protocol Search		
	X Close Results Save Filters Copy Protocol to New Document Copy Protocol To PI Protocol Versions Preview Change Status		
IBC Protocol	? Change Status: change the status of a protocol that is Approved, Expired or On-Hold		
Search	? Protocol Versions Preview: view older versions of the protocol and compare versions		
	Copy Protocol to New Document: copy the protocol to a new document. Keeps the PI but creates a copy of the protocol that can be edited and submitted.		
	? Copy Protocol to PI: copies the protocol and allows a new PI to be selected. The copy remains in the draft state where it can be edited and then submitted by the new PI.		
Continuing Review Search	Provides a full document view of the Continuing Review		
	View amendments, protocol versions and amendment workflows		
Amendment Search	② Amendment Workflow Preview: Full Document View of Amendment Workflow including reviewers, history, signatures and email notifications.		
	View workflow, protocol versions, reviewer comments and PI responses from past		
Protocol	reviews		
Revision	Protocol Revision Search		
Search	X Close Results Save Filters Show All Reviewers Show Office Comments Morkflow History Protocol Versions Preview		
	Show All Reviewers: see all review comments associated with each reviewer. View the comment, PI response and revised protocol text associated with each comment.		
	Show Office Comments: shows IACUC Office Comments, protocol revisions per comment and Rebuttal (if provided in response to the question)		
	Workflow History: view workflow including emails, signature and workflow history		
	? Protocol Versions Preview: view older versions of the protocol and compare versions		
Agenda	View protocols assigned to committee meetings and to review past meeting minutes		
Search	? Preview Minutes: view the meeting minutes (full document view)		



Hazard Safety Alerts

Support Site Resource: <u>Understanding Alerts</u>

In Cayuse Hazard Safety, the left-hand menu contains different sections for alerts. Each alert displays submissions that apply to that alert. From this view, the IBC office role can see the activity and status of all approved or pending submissions.

Hazard Safety		
Alert	Inbox	Total
Protocol Actions	0	2
Draft Protocols	0	0
Protocols in Review	0	3
De Novo Reviews	0	0
Continuing Reviews		
Draft IBC Amendments	0	0
Continuations in Review		

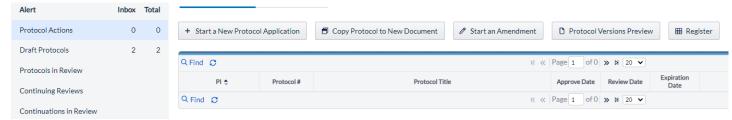
Alert	Description
Protocol Actions	Displays all approved protocols.
Draft Protocols	Displays all protocols which have been started but not yet submitted to the IBC office.
Protocols in Review	Displays the list of protocols which have been submitted to the IBC office for review. All protocols will be grouped by new protocols, amendments and De Novos. Clicking on the hyperlink displays the IBC Workflow page.
Continuing Reviews	Displays the list of protocols up for continuing review
Continuations in Review	Displays the list of protocols which have been submitted for the continuation review. Clicking on the hyperlink displays the IBC Workflow page.
De Novo Reviews	Display the list of protocols due for De Novo review.



Draft Amendment	Displays the amendments which have been started but not yet submitted to the IBC office.
Transfer Ownership	Displays the list of protocols being requested for transfer from one PI to another.

Protocol Actions

This alert displays all approved protocols and actions available to the researcher and the IBC office. For more details about the action buttons available in this alert, please see the Protocol Actions Alert section above.



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 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 are due for continuing review on the first or second year anniversary of the protocol approval.

Continuations in Review

This alert shows continuing reviews that have been submitted for review by the IBC committee.

De Novo Reviews

This alert will show protocols due for the 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.

IBC Review Workflow

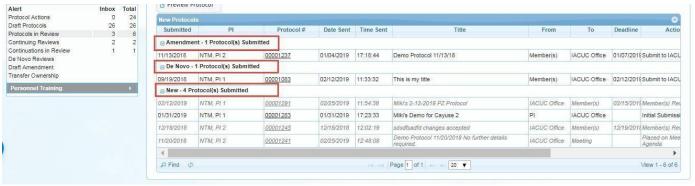
The IBC may review different submission documents including New Protocols, Amendments, De Novos or Continuing Reviews. Each institution has a unique protocol review workflow process. Some IBC programs send submissions to all members to poll the committee to determine if items should be called to a full committee meeting. The Cayuse Hazard Safety application relies on the IBC office role to route the submission through the applicable review workflow.

As documents move throughout the review process, the Hazard Safety application sends email notifications to users.

Understanding the Review Alerts

There are two separate alerts to manage these submissions; Protocols in Review alert and Continuations in Review alert. Both alerts behave in the same way such that they provide information to the coordinator about where the protocols are in the IBC Workflow.

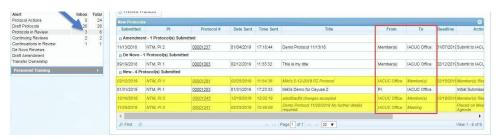
The screenshot below displays the **Protocols in Review alert**. When a New Protocol, an Amendment or a De Novo is submitted to the IBC office by a Principal Investigator, it displays in the Protocols in Review alert. This alert is grouped by the different types of submissions: New, Amendment or De Novo.



Protocols remain in these alerts throughout the entire review process. Once the protocol is approved, it no longer displays in these alerts. It will be displayed in the Protocol Actions alert as an approved protocol.

The 'inbox' number in the example below, indicates that 3 of the 6 protocols in the IBC workflow are waiting on action from the IBC office. These would be the three that are displayed in black. All protocols in gray italics reflect protocols the IBC office has submitted for review or to the meeting. The columns From and To, indicate where the protocol came from and where it is currently. In the example below, protocols 00001291 and 00001245 were submitted by the IBC Office to Members for review. Protocol 00001241 was submitted to the meeting.





Each submission is date and time stamped and is visible in the Date Sent and Time Sent columns.

The Continuations in Review alert behaves in the same way.

IBC Review Workflow

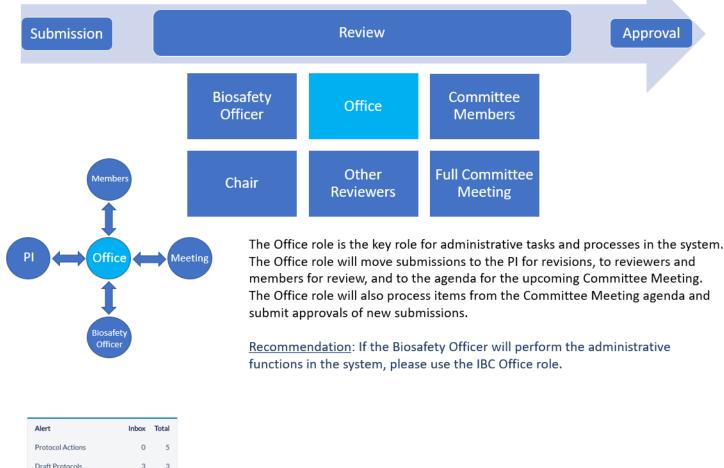
The Office role is the key role for administrative tasks and processes in the system. The Office role will move submissions to the PI for revisions, to reviewers and members for review, and to the agenda for the upcoming Committee Meeting. The Office role will also process items from the Committee Meeting agenda and submit approvals of new submissions.

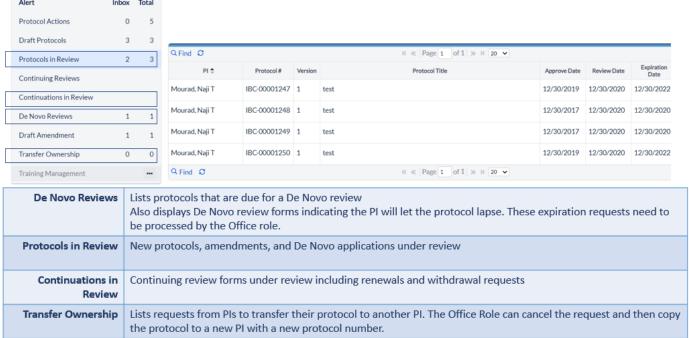
The IBC Office role has complete control over the protocol workflow. Cayuse's flexibility allows you to perform any of the following actions without any pre-set order:

- return the protocol to unfinished status (only applies to New and De Novo protocols)
- conduct an IBC 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 IBC 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

Cayuse sends an email each time a protocol is submitted.

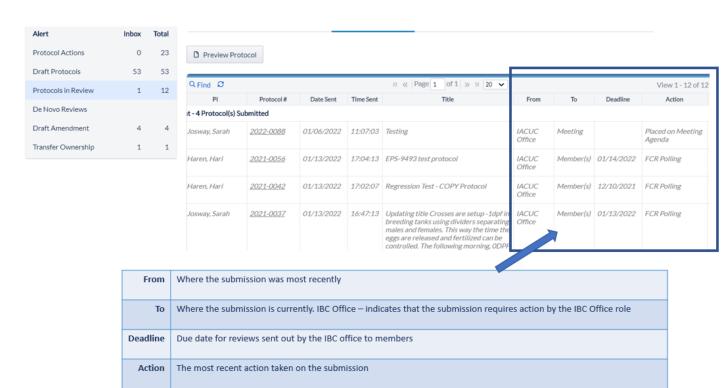


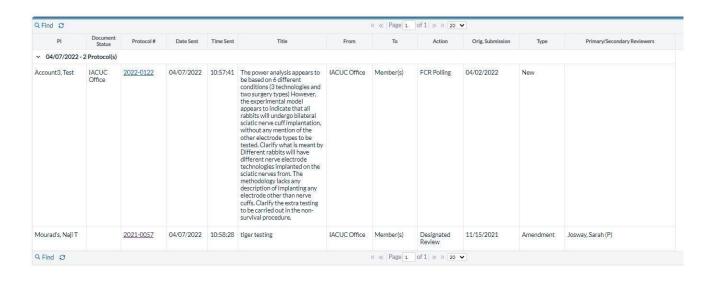




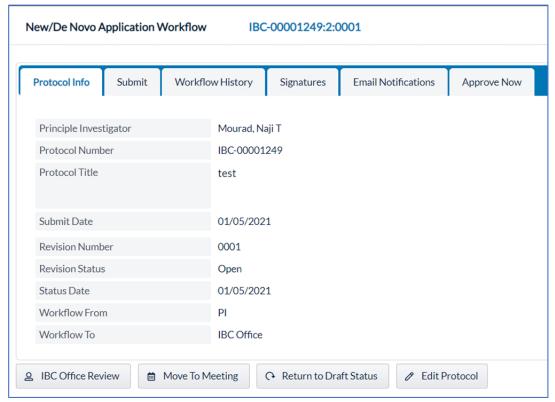
To open the IBC workflow, click on the hyperlink found on the protocol number in either the Protocols in Review or Continuations in Review alert. This will open the Review tools.











The tabs, at the top of the workflow page, are used as follows:

Workflow Tabs	Description
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 IBC office.
	The Workflow From/To indicates who submitted the protocol and where it is in the IBC workflow
Submit	IBC submits the protocol to PI, Member(s), Chairperson(s) or Vet(s) for review. Only available when the protocol is in the IBC office
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
	Refer to the Workflow History section for more details.
Signatures	Stores the date/time stamp each time the PI, IBC Office role, Vet or Reviewers enter their password to submit the protocol.
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 sends an email notification.

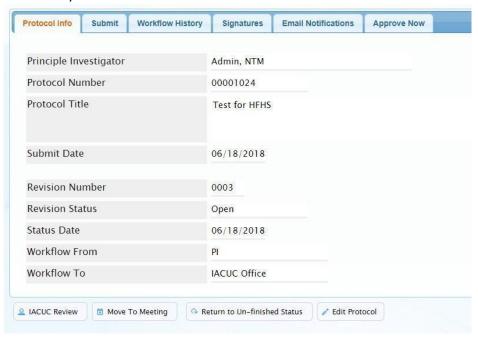


Approve Now The IBC Office role approves the protocol from here

The review workflow displays the Protocol Number: Version #: Revision #

Review Workflow Protocol #: Version: Revision IBC-00001249:2:0001 New/De Novo Application Workflow IBC-00001249:2:0001 Protocol #: Assigned when the PI creates a new protocol. Consistent for the life of the protocol even Protocol Info Submit Workflow History **Email Notifications** Approve Now through De Novo renewals. Principle Investigator IBC-00001249:2:0001 Protocol Number IBC-00001249 Version #: Protocol Title test Increases with each action in the system such as amendment, De Novo renewal, or transfer Submit Date 01/05/2021 Revision Number 0001 IBC-00001249:2:0001 Revision Status Open Revision #: 01/05/2021 Status Date Increases each time the PI submits to the office. Workflow From For example, after the PI addresses comments Workflow To IBC Office from a reviewer and resubmits a protocol, the revision number will increase △ IBC Office Review Move To Meeting Return to Draft Status Edit Protocol

The buttons available at the bottom of the IBC workflow page vary depending on where the protocol is in the review cycle.

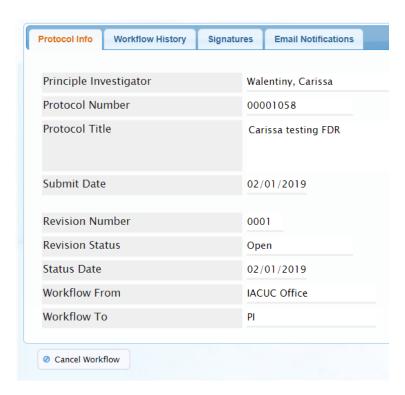




Workflow Buttons	Description	Available
IBC Review	Coordinator reviews protocol and provides comments	When protocol is IN IBC Office role workflow
Move to Meeting	Puts protocol on the upcoming meeting agenda	When protocol is IN IBC Office role workflow
Return to Un- finished Status	Coordinator may send protocol back to PI without committee review or recommendations	When protocol is IN IBC Office role workflow and no recommendations have been made.
Edit Protocol	Opens protocol for editing by coordinator.	When protocol is IN IBC Office role workflow. Not available on Amendments or Continuing Reviews
Cancel Workflow	Coordinator may pull the protocol back from reviewers if necessary. Reviewer comments will NOT be lost.	When protocol is OUT of IBC Office role workflow and is out to Members or Vet for review. Not available when protocol is in the meeting agenda.



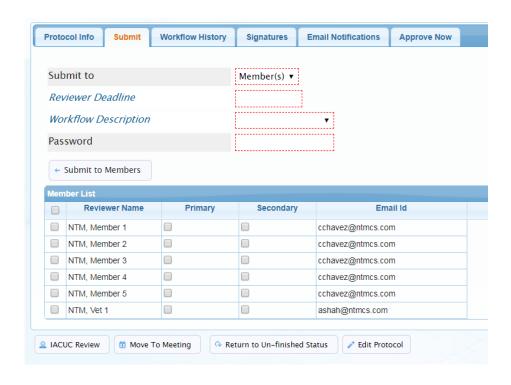
When a protocol has been submitted for review or is in the meeting agenda, the IBC Workflow page displays like this:



Only the Protocol Info, Workflow History, Signatures and Email Notifications tabs are available when the protocol is out of the IBC Office role workflow i.e. out to the PI, to members or in the meeting agenda.

In this example, the IBC office has submitted the protocol back to the PI.

SUBMIT TAB - IBC Office role SUBMITS THE PROTOCOL



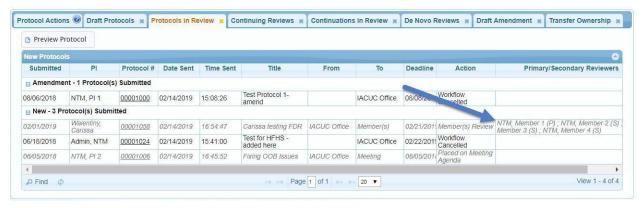


When submitting to the Members, the list of members will display in the Member List grid.

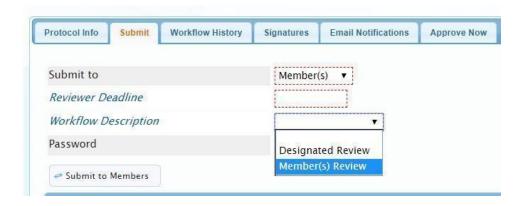
The list of members displayed are those defined in the IBC Members list from the IBC setup list.

These members must have the IMBR role to access Cayuse.

The Primary and Secondary selections are optional. If Primary and Secondary members are selected, their names will display in the Review alerts:



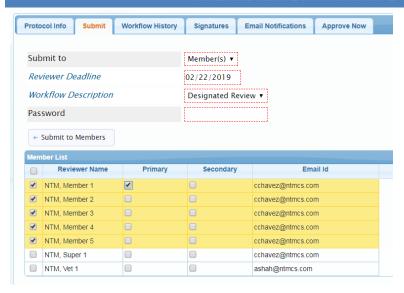
Additionally, the Primary reviewer has the ability of writing a Synopsis when reviewing the protocol.



The Workflow Description options are Designated Review and Member(s) Review. These may be updated during implementation.

When a Designated Review Workflow is selected and a Primary Reviewer is also selected, the protocol is automatically returned to the IBC office when the primary reviewer has reviewed and the due date has arrived, regardless if any other reviewers have submitted their revi



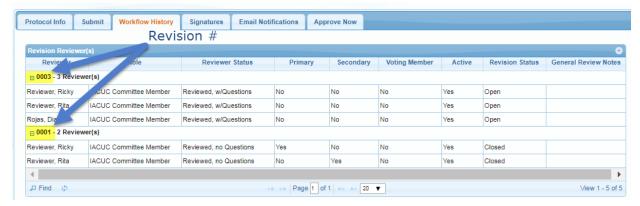


In this example, when the date 2/22/19 arrives, if member NTM, Member 1 has completed the review, the protocol will automatically be returned to the IBC office. This will happen even if none of the other members have reviewed.

In the event that this was not a Designated Review, but a Members Review, the protocol will remain out to reviewers even past the deadline date until all reviewers complete the review or the IBC office cancels the workflow.

WORKFLOW HISTORY TAB

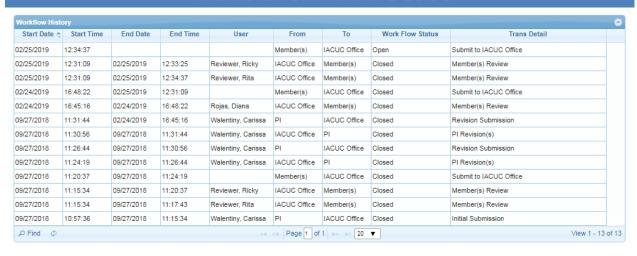
This page provides historical information about each submission. There are two tabs. The Revision Reviewers tab and the Workflow History tab. The Revision Reviewer(s) tab displays the reviewers the document has been sent to for each review.



In this example, the protocol has been sent out to reviewers in Revision #1 and Revision #3. The Reviewer Status column indicates each of the reviewer's submission status.

The Workflow History tab displays the date and timestamp of each submission. The Trans Detail column provides information on the type of submission.





SIGNATURES TAB

Stores the date/time stamp each time the PI, Office, or Reviewers submits the protocol or review

EMAIL NOTIFICATIONS TAB

Stores the date/time stamp of each email notification that was sent out during the review process. Every time a protocol is submitted, Cayuse sends an email notification.

APPROVE NOW TAB

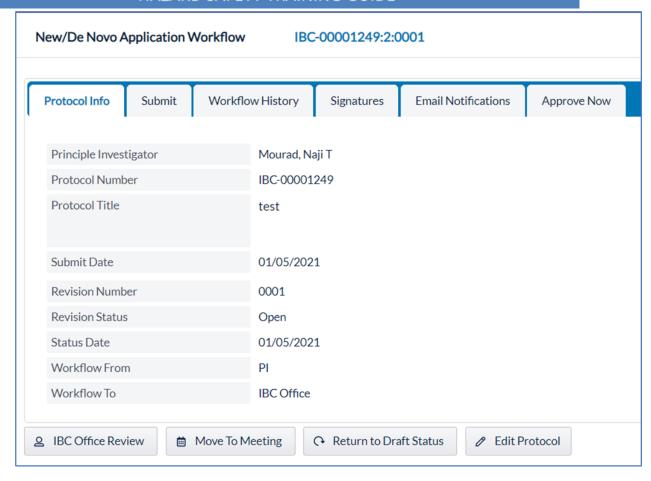
The Approve Now tab is used to approve the protocol. The date field is flexible such that it allows the IBC office to set the approval date either in the past, today or any time in the future. Once the protocol is approved, the date cannot be changed.



IBC Office role Pre-Review

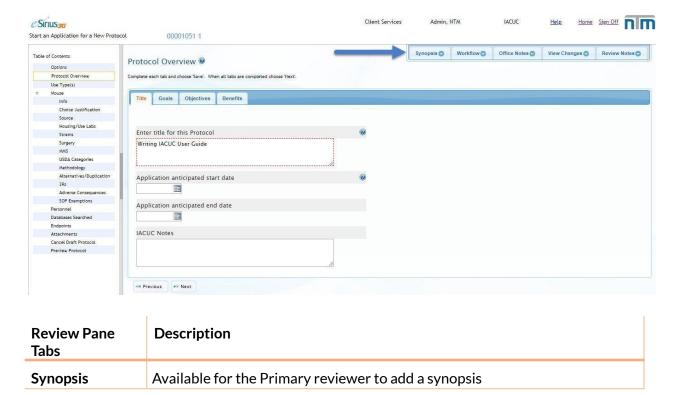
The IBC Office role may choose to review the protocol prior to submitting it to out to review or after.





To review a protocol, go to the IBC workflow page and click on the IBC Review button.

The Review pane displays on each page of the Protocol form at the top right corner of the page.



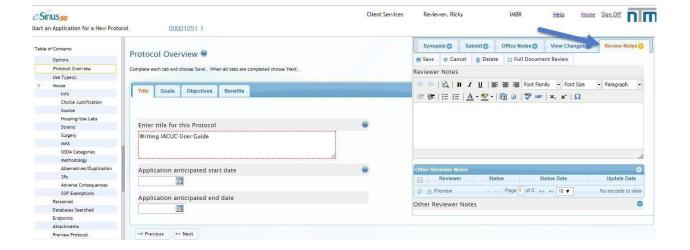
_.



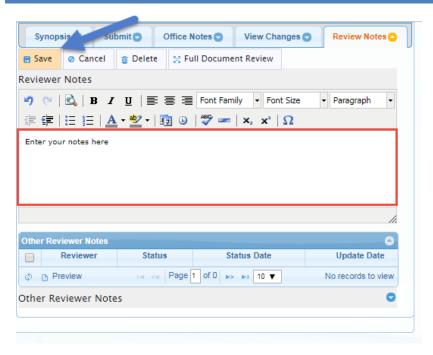
	HAZARD SAFETY TRAINING GUIDE
Workflow	Return to the IBC Workflow page
Office Notes	Displays Designated reviewer's comments as well as IBC Office role merged comments. All previous revision comments are available for viewing here.
View Changes	Displays the changes made by the PI. It has two tabs: <u>Previous</u> , displays the previous contents of the field. <u>Changes</u> , displays the current changes made by the PI.
Review Notes	All reviewer notes. All comments made by all reviewers can be seen here. IBC Office role can also add comments here. This is where the IBC Office role merges comments. Only merged comments and Designated Reviewer comments are viewable to the PI.

Adding Review Comments

Activate the Reviewer's Notes section by clicking on the Review Notes tab to enter comments. You may also click on a Text or Word editor field to enable the review pane.





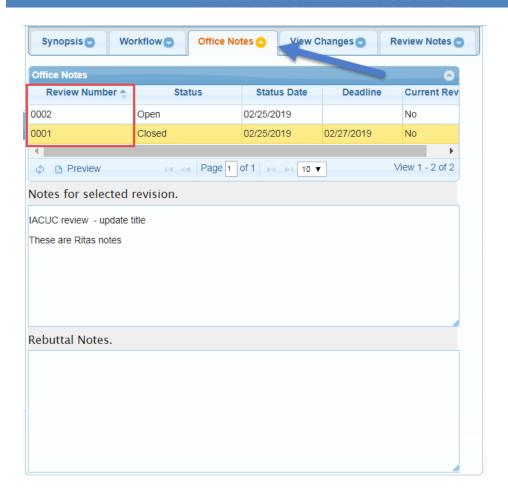


Enter your notes in the Reviewer Notes section and click Save. Each page has its own Reviewer Notes section.

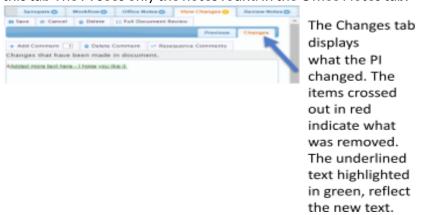
If you are reviewing *after* committee members have made comments – you will see their comments and can merge them to be sent to the PI. All IBC review notes are automatically displayed in the Office Notes tab. Each revision is identified by its Review Number. When IBC merges all of the reviewer's comments, 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 IBC office.





All IBC review notes are automatically displayed in the Office Notes tab. Each revision is identified by its Review Number. When IBC 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 IBC office. In the sample above, this protocol is currently in its second round of revision. Notice how revision 0001 is closed,

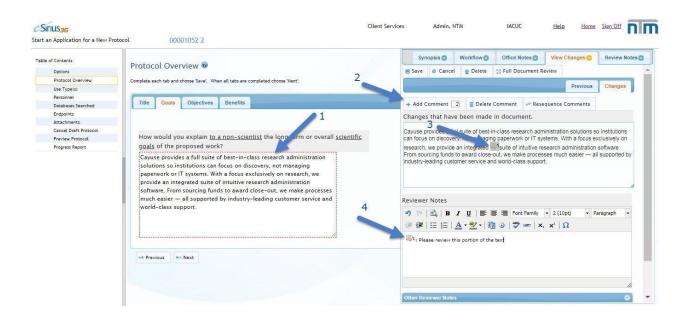


however, when you click on it you can see which notes were sent back to the PI for this page.

Adding Footnotes in Large Text Responses

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 the location in the text exactly, to make their comments clearer to the PI.

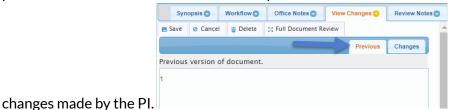
- 1. Click within the text response in the protocol form to enable the Changes tab in the Review pane. This is useful when reviewers need to reference an exact location in the text.
- 2. Click the Add Comment button, then click in the location of the text needed to reference
- 3. Click by the comment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



In the example above, when the field is clicked (#1) on the protocol form, the View Changes tab from the reviewer's pane displays the entire text in the Changes section. To add a footnote comment, click the Add Comment button (#2), then click in the location of the text needed to reference (#3) and add your comments in the Reviewers Notes section (#4).

View Changes Tab - Review Pane

The view changes tab, in the Review Pane, displays a Previous tab and a Changes tab. When the protocol comes back from the PI after they address the recommendations, these tabs reflect the

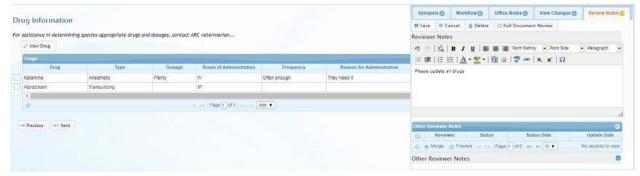


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Reviewing Pages with Grids

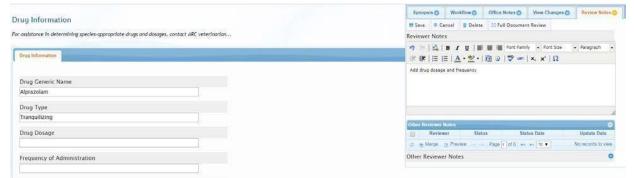
Pages with grids are reviewed differently from pages without grids. Recommendations may be entered specific to the entire page or they may reference a specific line item. To enter a recommendation to the entire page, click on the Review Notes tab and enter your comments:



To enter a recommendation specific to one of the line items, select the line item and click on the Edit button. In this sample below, we are adding a note to the drug Alprazolam by highlighting the line and clicking on the View button.



Activate the Review Notes tab and enter comments:



Click Save to return to the page level review and notice the icon which appears next to the line item just reviewed:

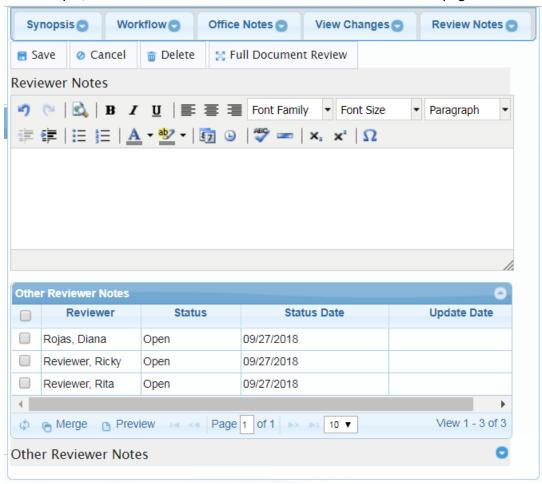




This icon indicates the line item has been revised by you.

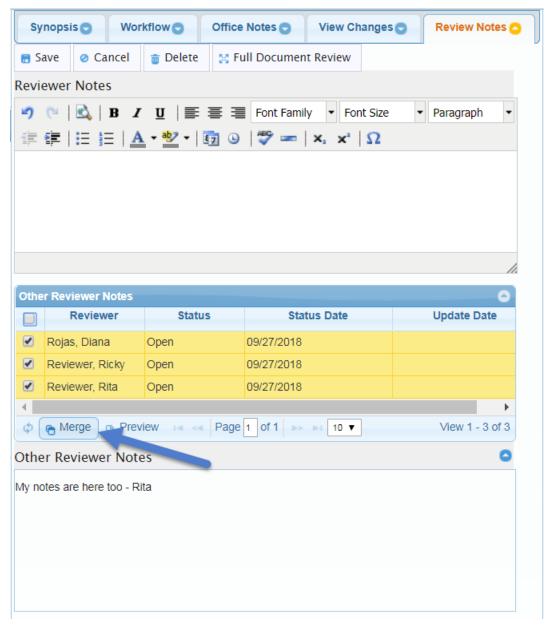
Merging Comments from other Reviewers for PI Revision

When all reviewers' comments are returned to the IBC office – the IBC Office role can choose which comments to merge prior to submitting the protocol to the investigator for a response. In this example, three reviewers have submitted comments on the same page:



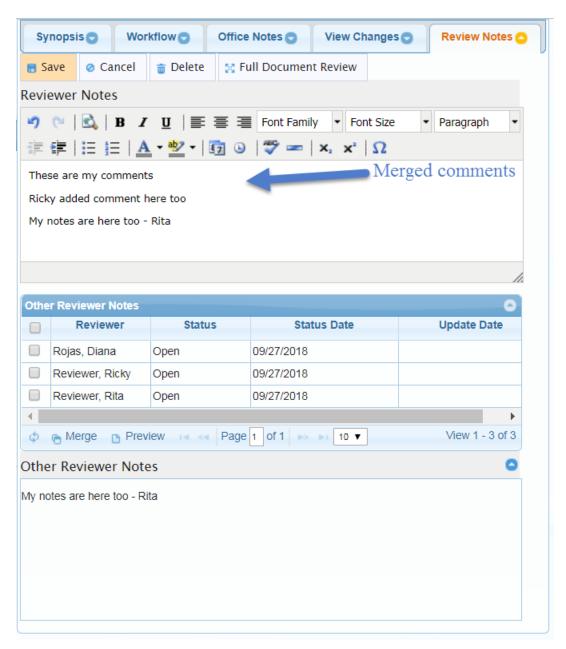
Click on the Reviewer, from the Other Reviewer Notes grid, to view their comments. To merge all comments or a selection of comments, click on the reviewer and then Merge them:





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

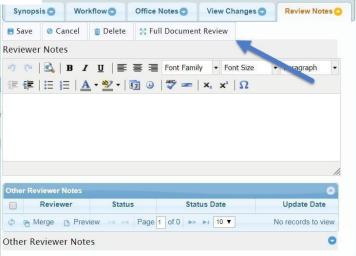




Full Document Review (FDR)

The Cayuse system offers another way for reviewers to add comments. The Full Document Review (FDR) allows the reviewer to view the entire protocol in one view.





While in review mode, click on the Full Document Review button found in the Review Pane.

A new web page opens with the protocol document in review mode. Important facts about the FDR process:

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

The FDR document opens to the protocol TOC







PI:	Walentiny, Carissa	% **
Protocol #	00001037	
Status :	Pending	
Approved:	1.1	
Expires :	11	
Title:	Carissa Second FDR Protocol	

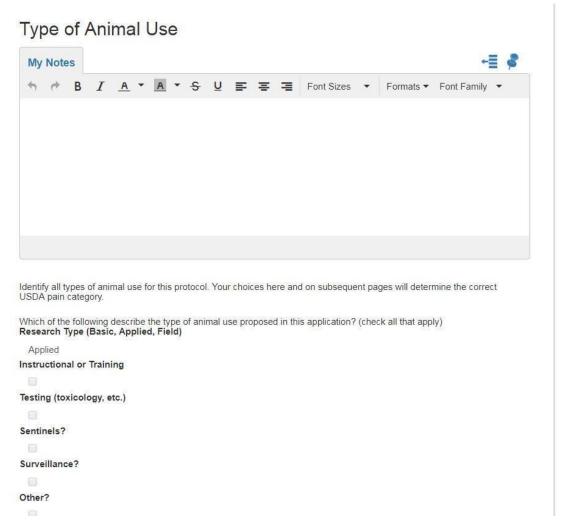
Table of Contents

Protocol Introduction
Protocol Overview
Protocol Agency Funding List
Protocol Fellowship Funding
Offsite Work Location
Outside Institution Collaboration
Antibodies Source
Animal Tissues Info
Type of Animal Use
Housing Outside Central Facility
Human Clinical Info
Transportation of Animals
Hazardous Use Info
Field Study
Mouse

Species Information

In this example, the Protocol Agency Funding List page has been reviewed by other reviewers. The other pages with the single head icon have been reviewed by me. Each page in FDR review displays the review pane on top of the protocol page.





Enter review notes in the My Notes section. Reviewer notes are automatically saved. The icons at the top right portion of the My Notes section are used to pin the notes section. The

symbol is used to hold the section to the left of the web page. The pin, is used to pin it 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.

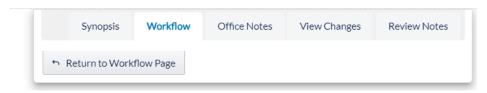
As different reviewers enter their review notes, the notes display in the Reviewer's Notes tab:



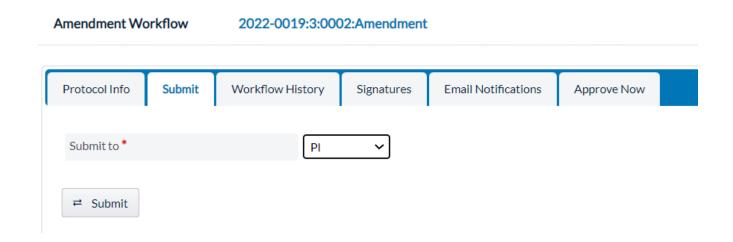


Sending a Submission back to the PI for Revision

After the Office role has completed a pre-review or merged comments from members, the office role can click the Workflow tab and click Return to Workflow Page to return to the Workflow Review tools.



Then the Office role can click the Submit tab and send the submission back to the PI for revision to address the comments.



Reviewing PI Revisions and Rebuttals

When the investigator submits a protocol back to the IBC 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 IBC 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.

This table describes how each field modified by the PI is displayed when the protocol returns to the IBC office.

How PI Revisions are Displayed

Field Type	Description
Text/Numeric	Years covered by search
Text Area or Word Editor	Will you be using animal tissues? Yes No no ientist the search Type (Basic, Applied, Field) Applied Research
Yes/No Radio	Not Funded? Was 'No', PI changed it to 'Yes'. ☑ <mark>no</mark>
Dropdown list	'Research' was replaced with 'Applied'
Checkbox	es the previous value was No and has now been d to Yes.
New Record	NTM University 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/Numbers page	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.



Review Icons

Multiple reviewers can review a protocol simultaneously. As comments are being saved by the different committee members, different icons display on the TOC indicating each action. If the protocol has been sent to the PI and is now back in for review, the icons indicate what actions the PI has made. This simplifies the review process by knowing what has changed.

Committee Icons	Description
One head	The page has only been reviewed by me
Two heads	The page has been reviewed by other committee members
Three heads	Reviewer's comments have been merged by IBC Office role into one comment
Pencil on notepad	PI has revised a page which was not marked for review
Green 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

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Continuing Reviews

A protocol with 60 days or less to its upcoming review date will display in the Continuing Reviews alert – and remain there until the PI or IBC Office role takes action. The number of days to display in this alert can be changed in the protocol preferences in the setup section.

Cayuse sends the PI email reminders, every 30 days, indicating the due date of the Continuing Review. The PI should open it, complete the form and submit it to the IBC Office for review.



When the protocol reaches its due date, the line item turns red indicating it is past due.

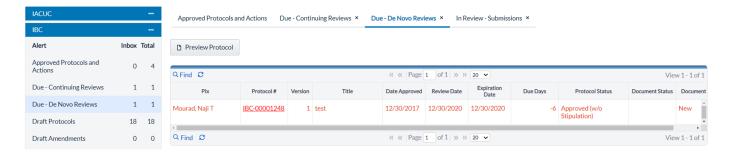
Continuations in Review

When a Continuing Review is submitted to the IBC office, the protocol lands in the Continuation in Review alert. The Continuing Review process is handled in the same way reviews are done for New Protocols, Amendments, and De Novos. For more details on this, review the IBC Protocol Review Workflow section in this user's manual.

De Novo Reviews

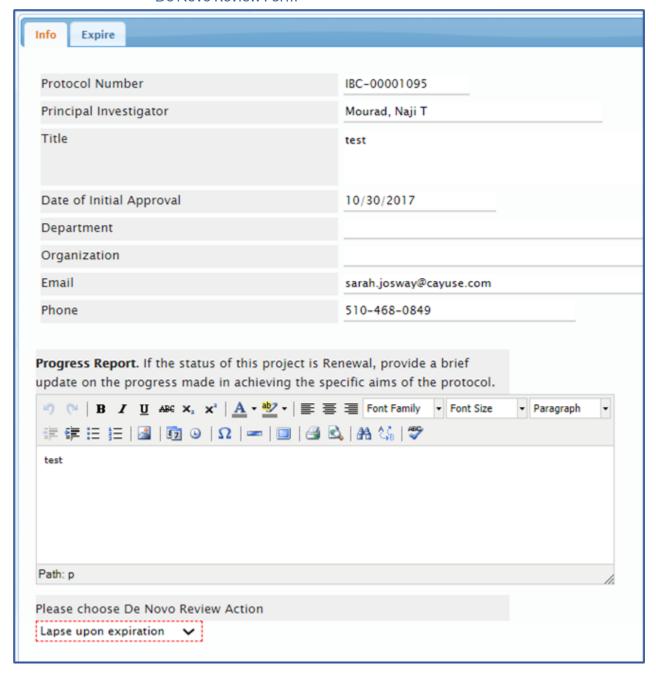
A protocol with an expiration date less than 90 days out will display in the De Novo Reviews alert. The number of days to display in this alert can be changed in the protocol preferences in the setup section.

The protocol remains in this alert until the PI takes action and submits it for approval or withdraws it. Email reminders are sent to the PI every 30 days until he submits the protocol. When a PI indicates that the protocol should Lapse upon Expiration, the Document Type is set to Withdrawn and will no longer display in the PI's De Novo Reviews alert. This flags the IBC to expire the protocol.





De Novo Review Form



Expiring a Protocol During De Novo Review

When a PI indicates that the protocol should Lapse upon Expiration, the Document Type is set to Withdrawn and will no longer display in the PI's De Novo Reviews alert. This flags the Office to expire the protocol.

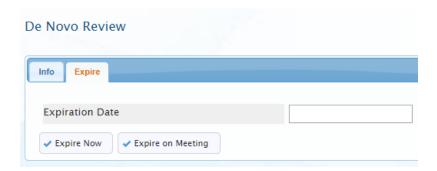


Office role may expire a protocol by opening the protocol from the De Novo Reviews alert. You have the option of Expiring the protocol Now or to Expire on Meeting*.

The Expiration Date is used to override the initial expiration date.

The Expire Now button expires the protocol now and uses the Expiration Date information to set the expiration date in the database. The Expire on Meeting option sends the protocol to the meeting agenda with the status of Expired. If Expiration Date was provided, that is the date in which the expiration will be recorded. The protocol is still an approved protocol until the protocol is reconciled in the meeting.

*Recommendation: Process "Lapse upon Expiration" De Novo reviews from the De Novo Reviews Due alert instead of sending them to a committee meeting. This will generate an expiration notice for the PI indicating that the protocol has been closed.



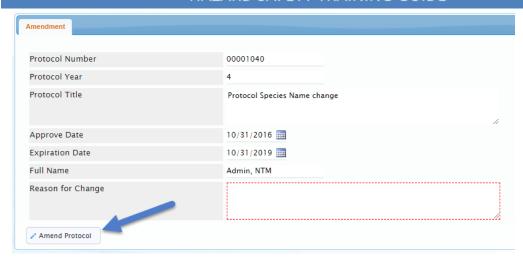
Amendments

Submitted amendments will display in the Protocols in Review alert. The IBC 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.



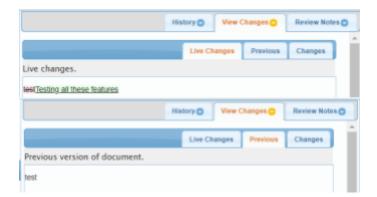
When an amendment is started, the general information about the protocol is displayed and the user is asked to enter the reason for the amendment.





When the Amend Protocol button is clicked, the entire protocol is displayed allowing the user to make the necessary changes to the protocol.

Notice that the reason for amendment becomes a part of the protocol TOC and is also included in the revision. When a change is made to a page, the tablet with a pencil icon is displayed on the TOC. The tabs at the right of the screen provide information about any previous reviews the protocol has gone through via the History tab.



The View Changes tab includes three additional tabs.
The Live Changes reflects what was added or deleted from the field.

The Previous tab reflects what was in the field previously.





The Changes tab reflects the final changes on the field.

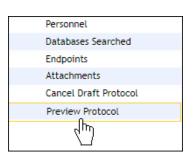
When the amendment is submitted to the IBC office, the revision is the same as that for a New or De Novo protocol submission. The amendments display in the Protocols in Review alert and are grouped in the Amendment section of the alert. See the IBC Office role Review section for details on how to review an Amendment.

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.

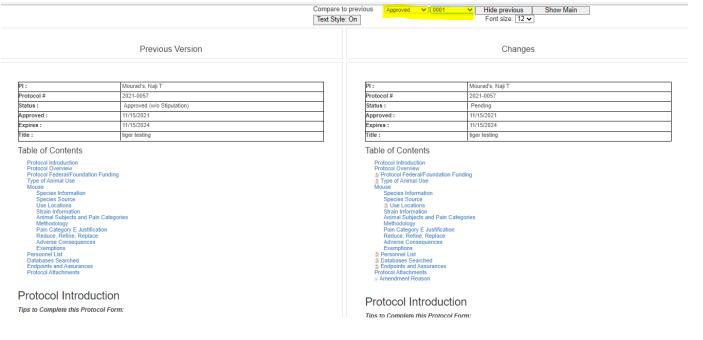




3. A new window will pop up containing the protocol. At the top of the protocol, use the **Compare to previous** drop-down menu to choose the two versions to compare. To compare the current version of the amendment with the last approved version of the protocol, select 'Approved' and then select the highest version available. The highest approved version is the latest approved version of the protocol.





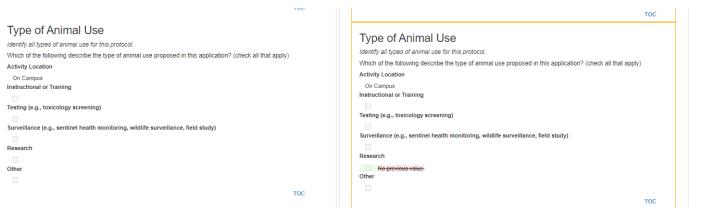


A side-by-side view of the previous version and changes will populate. Sections that have been changed will be bordered by orange, and specific changes will be highlighted red and green.

Review the entire comparison to understand the changes made in all of the revisions of the Amendment. It is important that committee members and other reviewers understand how to use this functionality as well.

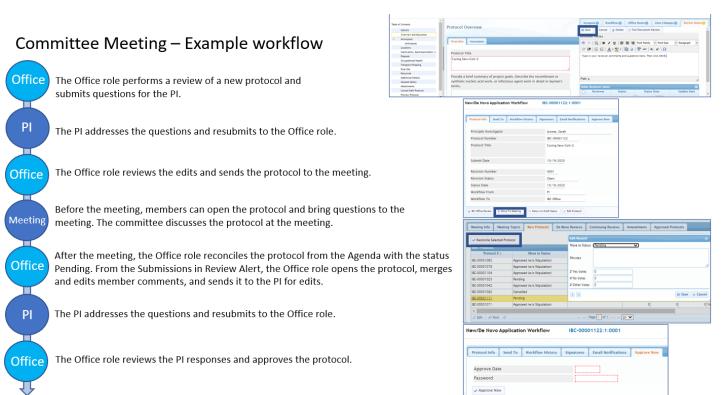
Review notes cannot be entered from the Protocol Preview comparison. Reviewer notes must be entered on the applicable pages back in the review site or from the FDR tool.

When you're finished reviewing the comparison, close the pop-up window. Return to the main submission review screen to add reviewer comments and complete the review.



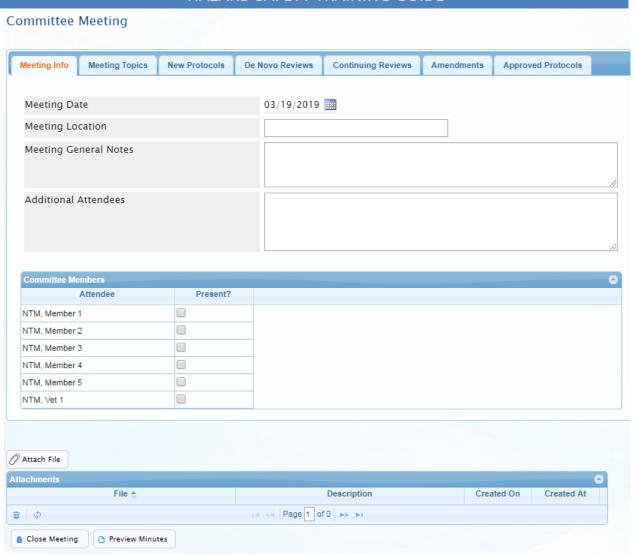


Committee Meeting Management

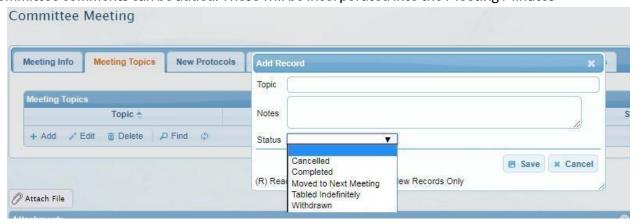


Access the meeting by clicking on the Actions menu of the IBC Management application. The committee meeting opens up to the Meeting Info tab. The Meeting Date and the Meeting Location fields are populated from the Agenda setup and can only be modified from the setup. See Meeting Date List section for more details. The list of Committee Members is populated by the list of Committee Members defined in the IBC Members setup. These members must have the IMBR role.





In the Meeting Topics tab, add the topics that will be discussed in the meeting. During or after the meeting, Committee comments can be added. These will be incorporated into the Meeting Minutes



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As protocols are sent to the meeting, they will be viewable in their corresponding tab in the Meeting. Note: Committee members are not alerted when items are added to an agenda. If you want to let the committee know that an agenda is ready for an upcoming meeting, it is recommended that you send an email to prompt them to log into the system and review the agenda.

Tip: If you want specific reviewers to present a submission at the meeting, it is recommended to send the submission to the reviewers initially via Members Review in the review workflow and notify them of their Full Committee Review assignment via email. After they submit comments, then move the submission to the meeting.

The Approved Protocols tab is read only. All protocols that have been approved between the current meeting and the previous meeting will be displayed here for information purposes only.

Reviewing Submissions at the Meeting

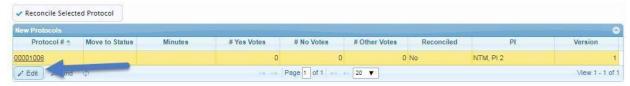
All protocols sent to the meeting can be reviewed in the meeting by clicking on the protocol number hyperlink. In the example below, a new protocol 00001006 has been sent to the meeting.



The review of the protocol works in the same way as a review outside of the meeting. For more information on reviewing a protocol refer to the IBC review section.

Processing Submission Statuses Post-Meeting

All protocols must be reconciled prior to closing a meeting. To reconcile a protocol, you must first edit its status. To edit the status of a protocol in the meeting, highlight the protocol and click on the edit button:



The Status options are:

• Approved (w/o Stipulation): approves the protocol.



- Deferred: the protocol is deferred to the next meeting.
- Pending: Protocol is sent back to the IBC workflow
- Expired: Expires the protocol, this only applies to De Novos
- Withdrawn: Withdraws the protocol, this only applies to Continuing Reviews.



As you edit the status of a protocol, you can also enter meeting minutes and number of votes specific to each protocol. These minutes will be accessible in the Agenda Search. Please note that the notes on the Topics section of the Agenda are not editable after the meeting is close.

To reconcile the protocols, highlight the protocol and click on the Reconcile Selected Protocol button.

Closing a Meeting

To close a meeting, all protocols in the meeting must be reconciled. When the Close Meeting button is clicked, the meeting closes and the next scheduled meeting will become the active meeting. You must have the next meeting setup in the dictionary. For details on how to set up meeting dates refer to the MEETING DATE LIST section.

Manage Users

Overview

This guide is for administrators managing users in the system for the following applications: Hazard Safety, Hazard Safety, Training Records, Animal Procurement, Animal Inventory, Vet Care, Billing, Services, and Schedules. Administrators must be assigned the RS Administrator role in the platform to manage accounts. Section I details how to add a new user to the platform admin. Section II details how to assign or update user roles. Section III outlines how to manage PI groups in the Site Management tool.



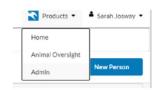
Sites Required - Reach out to your admin or Cayuse team if you need assistance with URLs

Cayuse Platform site (Example: https://customer.app.cayuse.com/)

Cayuse Site Management tool site (Example: https://customer.app.cayuse.com/esAdminPage.wc?1)

Section I. Creating new users in Cayuse platform

1. Only users with the RS Administrator role will be able to create new accounts and manage existing accounts on Cayuse platform. Log into the Cayuse platform site. Select Admin from the Product dropdown menu.



2. Click on Users. From this screen, you can use the search filters to locate an existing account or click 'New Person' to add a new account manually. Accounts can also be added or updated via the HR Connect tool. To add a new person, fill out the first and last name. If HR connect will be used by your institution, you must also include the person's Employee ID. This field is used to compare accounts during the HR Connect process. Toggle the Active switch to Yes and click Save.



- 3. Complete the relevant sections (outlined below) of the person profile. New accounts will need the email address to be filled in on the Contact Info Section. Internal Associations will feed into the Hazard Safety, Hazard Safety, and Vivarium Operations applications.
- **Profile:** Edit the person's name, academic degrees, and whether or not that person is active in your system.
- Contact Info: Edit the person's email, phone and fax numbers, and physical address.
- Internal Associations: Edit or add the person's unit(s) (generally an institutional department) and the title they have within the unit(s).
- **External Associations:** Edit or add the person's external associations and the title they have within the external association(s).
- User Account & Roles: Edit or add the user account of the person. The user account is how the individual will log in. You can also assign the user roles on this screen, which will grant them additional permissions within the Cayuse products.
- Trainings & Certifications: Edit or add trainings and certifications to the person's profile.
- 4. Under User Account & Roles, click + New Account. Update the email and username as needed. If this Cayuse platform site has Single Sign On enabled, please use the SSO account username for this user. If SSO is not enabled, you will need to send an activation email to the user. This will send them a temporary password for account creation.





Section II. Adding or updating user roles in the Cayuse Platform site

- 1. Users will automatically be assigned the role of Cayuse Product User by default. You can assign the user additional roles, which will grant them extra permissions within their Cayuse product. Roles are defined at the end of this section.
- 2. To update the roles of an existing user, first search for the account under Users in Cayuse Platform admin. Then open the Account & User Roles section in the person profile. Add or manage the existing roles. Unit-based roles allow admins to assign users a role for a certain unit or units.
 - Note: For the Cayuse Product User and Cayuse Application Link Viewer roles, the units default to All
 Units. Other roles will need to have the Unit defined. It is important to assign the correct unit to access
 the applications. Please refer to your admin or Cayuse team if you need assistance with this selection.
- 3. After roles have been managed in a person's account, the user may need to log out and log back into the system to see the role updates.

Cayuse Roles

Role	Application(s)	Permissions
Cayuse Product User	All	Default role. Can access the Cayuse landing page. Every active user should have this role.
RS Admin Administrator	Platform Admin	Maintains system settings within the Admin module on the Cayuse Platform.
RS Admin Viewer	Platform Admin	Can access a read-only view of the Admin module on the Cayuse Platform.
HR Connect Administrator	Platform Admin	Manages the HR connect updates
Animal Buyer Staff	Animal Procurement	Manage ordering and Receiving Workflow for entire facility
Animal Care Staff	Vet Care	Manage Animal Care activities
Animal Census Coordinator	Animal Inventory	Manages animal inventory activities
Animal Facility Billing Contact	Billing	Financial and Invoicing workflow for accounts they are listed as Billing Contact on

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cayuse -		Manage
Facility Business Office Staff	Billing/Services	financial aspects
Animal Facility Diagnostic Lab	Vet Care	Perform Vet Care Activities
Animal Facility Global Access	Vet Care	Global view only access to all applications - Can perform reports and searches
Animal Facility IT Staff	Animal Oversight , Hazard Safety, Animal Procurement, Animal Inventory, Vet Care, Billing, & Services	Allows users to access the Site Administration to manage role permissions - currently not working. (anyone with the URL can access the Administration site)
Animal Facility Staff Veterinarian	Vet Care	Manages all aspects of Vet Care
Animal Facility Supervisor	Animal Procurement, Animal Inventory, Vet Care, and Schedules	Manage Housing requirements as well as define the schedule in the Schedules application
Animal Health Technician	Vet Care	Manage workflow for animal health related activities
Animal Husbandry Staff	Vet Care	Manage Husbandry activities for respective housing facilities
Animal Oversight Committee Member	Animal Oversight	Participates in protocol reviews and committee meetings
Animal Oversight Office	Animal Oversight	Manages protocol workflow; builds set up dictionaries; manages committee meetings etc.
Animal Receiving Technician	Animal Procurement	Manage animal receipt workflow
Animal Research Grants & Admin Staff	Animal Oversight and Hazard Safety	View only access to protocol funding
Cayuse Animal Inventory Link Viewer	Animal Inventory	Allows access to see Inventory module
Cayuse Animal Procurement Link Viewer	Animal Procurement	Allows access to see Procurement module
Cayuse Animal IACUC Link Viewer	Hazard Safety	Allows access to see Animal Oversight module
Cayuse Resource Scheduling Link Viewer	Schedules	Allows access to see Scheduling module
Cayuse Veterinary Care Link Viewer	Vet Care	Allows access to see Veterinary Care module
Animal Oversight & Hazard Safety Researcher Accounting Staff	Animal Procurement	Manage the researcher's accounts
Animal Oversight & Hazard Safety Research Staff Member	Animal Oversight, Hazard Safety, Animal Procurement, Animal Inventory, Vet Care, Billing, & Services	Protocol Creation; Ordering, Census, Vet Care, and Invoicing workflow (PI can submit/PI member cannot)

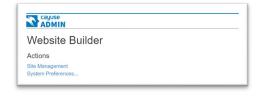
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Safety & Hazard Safety Training Coordinator	Animal Oversight & Hazard Safety	Responsible for setting up training events and managing personnel training records	
Biosafety Officer	Hazard Safety	Participate in IBC protocol reviews; assist PIs with protocols	
Cayuse IBC Link Viewer	Hazard Safety	Allows access to see Hazard Safety module	
Cayuse Training Management Link Viewer	Training Records in Animal Oversight & Hazard Safety	Allows access to see Training module	
Hazard Safety Member	Hazard Safety	Participates in protocol reviews and committee meetings	
Hazard Safety Occupational Health	Hazard Safety	View protocols in draft and in review	
Hazard Safety Office	Hazard Safety	Manages protocol workflow; builds set up dictionaries; manages committee meetings etc.	

Section III. Setting up PI user groups in Site Management

(Note: this is a different URL in this format https://customer.app.cayuse.com/esAdminPage.wc?1 Reach out to your admin or Cayuse team for assistance.)

Members assigned to a PI group will be able to create drafts for the PI to review and submit. When the PI group member clicks Submit from a protocol or amendment draft, the PI will receive an email notifying them a submission is ready for review.

1. Navigate to the Cayuse Admin site and click on **Site Management**.

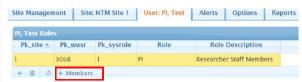


2. Select your site in the grid to highlight it in yellow. Click on the new tab with the site name. A list of users will be displayed. Use the magnifying glass tool to search for the user.



3. Select the name of the PI and click the new tab that opens to the right. Click **+Members** from the actions.





4. Click the + next to the name of the user(s) you wish to add to the group. The namove from the right-hand column to the left-hand column. Use the – to delete from the PI group. Click **Save**.



5. When the PI group member logs into the applications, they will be able to select the PI's name from a dropdown menu to access their submission



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FAQs

General

Question	Response
Can Cayuse host guest accounts?	Yes. Guest accounts can be manually created by a user with the RS Administrator role. 1. Navigate to the People 2. Click New Person 3. Complete the information 4. On the Account/Roles tab, toggle YES for Guest Account 5. After you save, the person will receive an email from Cayuse prompting them to create a password for the new account. Note: Guest accounts will be able to bypass Single Sign On.
How do you manage users?	Please see the Guide Sheet at the end of this document 'Guide for Administrators - How to Manage Users'
Log in Error Messages Users may encounter error messages if there is an issue with their account. The message may say "Forbidden" "Authentication Error User ID invalid"	If a user receives an error message when logging in, please verify the following: Is the Username correct for SSO (if applicable)? Is the Email correct for SSO (if applicable)? Is the Employee ID correct (if applicable)? Is the Profile set to Active? Is the User Account set to Active? Does the user have the correct link viewers and roles? Are the unit-assignable roles connected to the correct unit? Is the User accessing Cayuse through Internet Explorer or Microsoft Edge? If so, please ask them to try the preferred browsers, Chrome, Safari, and Firefox. Is the User connecting with the correct SSO password? Are they connecting to the correct UAT or LIVE link? If your institution uses Okta or another universal application management service, please ensure the IT team has provided the user access to the link(s). If a user is encountering an error while trying to access the mobile site or Site Managements, please ensure the user is following these exact steps:



 □ The user will first need to log into the LIVE platform environment. □ The user will need to navigate to Animal Oversight, Hazard Safety, Procurement, Inventory, Billing or Services. □ In a new tab in the same window browser, the user should then click the link for Site Manager. If your institution accesses applications from an applications management system, please enter Site Manager from there. It is important to do these steps in order to allow the system to recognize credentials. □ Ensure the user is using a Cayuse-compatible browser like Chrome or Firefox. 	
	 environment. The user will need to navigate to Animal Oversight, Hazard Safety, Procurement, Inventory, Billing or Services. In a new tab in the same window browser, the user should then click the link for Site Manager. If your institution accesses applications from an applications management system, please enter Site Manager from there. It is important to do these steps in order to allow the system to recognize credentials. Ensure the user is using a Cayuse-compatible browser like



Cayuse Access Issues

This tool was specifically developed for institutions using the following applications: Animal Oversight, Hazard Safety, Animal Procurement, Animal Inventory, Billing, Services, Vet Care, Schedules

If users are experiencing access issues, the information on this form will help your Cayuse team quickly diagnose the problem. Please complete the form for users and include any screenshots displaying errors encountered by the user.

	Customer Response
User Name	
User Email	
Does your institution use SSO?	
If Yes to the question above:	
Please ensure the login credentials match the SSO specific credent	ials.
· Is the Name correct for SSO?	
· Is the Username correct for SSO?	
· Is the Email correct for SSO?	
· Is the Employee ID correct (if applicable)?	
Provide all links the user is using to access Cayuse.	



What browser is the user using? Note: Ensure the user is using a Cayuse-compatible browser like Chrome, Safari or Firefox. Microsoft Edge is not compatible with Cayuse.	
Does your institution use an applications management system (e.g., Okta)?	
If Yes to the question above: Please ensure the user has been granted the correct permissions at your institutional IT group.	nd access to the URLs by
 Has your institutional IT group confirmed that the user has access to the relevant URLs? 	
Is the Profile set to Active?	
Is the User Account set to Active?	
Does the user have the correct link viewers and roles? Please list the roles and link viewers that the user should have.	
Are the unit-assignable roles connected to the correct unit?	
Please describe the issues experienced by the user including if the error occurred when the user accesses a specific part of the system.	
Providing screenshots of error messages will help the Cayuse team troubleshoot the issue quickly.	



• Can the u	user access the platform home page?	
	user access the applicable products from the n home page dropdown?	
• Can the u	user access the mobile site (if applicable)?	
• Can the t	user access the Site Management (if applicable)?	
mobile site or Sit following these	·	
environn 2. The user	r will need to navigate to Animal Oversight, Safety, Procurement, Inventory, Billing or	
3. In a new then clicl accesses system, p importar	tab in the same window browser, the user should that the link for Site Manager. If your institution is applications from an applications management please enter Site Manager from there. It is not to take these steps to allow the system to ze credentials.	
	the user is using a Cayuse-compatible browser ome or Firefox.	



Additional Notes:

If your institution has configured roles in Site Management, certain configurations may lead to access issues. Cayuse recommends testing any role-based configurations done in Site Management thoroughly in the UAT environment before applying those configurations to the LIVE site.

Here is an example:

An institution wanted to limit the actions researchers could take in Animal Inventory.

In Site Management, the institution removed all alerts from the Inventory for the Researcher Staff Member role. The Researcher Staff Member role only had access to Reports and Searches in Animal Inventory. When users with the Researcher Staff Members role logged in to the LIVE platform site and clicked Animal Inventory from the products drop down, the system presented an error. They were unable to navigate directly to that application from the login screen. They were able to access other applications from the drop down menu (ex. Billing) that had alerts available to the Researcher Staff Members role.

Hazard Safety

Question	Response
What is the PI role? How do you add someone as a PI delegate?	 All researchers and PIs should have the Animal Oversight and Hazard Safety Researcher Staff Members role.
	 To update PI groups, please see the Guide Sheet at the end of this document 'Guide for Administrators - How to Manage Users'
Does Cayuse track and maintain records of submission to approval timing for review?	Yes, Cayuse tracks metrics throughout the review process. However, the system doesn't have an easy way to report on these metrics. To view the metrics, open the Protocol Revision Search from the IACUC action menu. Click on an approved version of a protocol (versions can include the initial submission, amendments, renewal, etc.) and then click Workflow history. The Workflow



	history tab will show you the steps of the review process including timestamps.
Does Cayuse maintain tracking of the submission workflow (i.e. submissions to reviewers, when/who, are they primary/secondary, comments by reviewer and PI edits?	Yes. This is all documented in the Protocol Revisions Search. You can look up a submission and click 'Show Reviewers' or 'Show Office Comments.' The 'Show Reviewers' tool will display all of the reviewers that a submission was routed to. By selecting the name of the reviewer and clicking 'Show Reviewer Comments', you can view the comments made by a specific reviewer and any PI revisions associated with that comment. The 'Show Office Comments' tool will display all comments that the Office Role created or merged to send back to the PI for edits. If you click on one of the comments, you can click the button 'Show Revision' to see how the PI responded, either via revision or rebuttal.
How do you suspend a protocol or close a protocol outside of the renewal process?	To do this, use the Protocol Search. Search for the protocol, select it, and click 'Change Status.' You can move the protocol to on-hold (for suspensions) or Expire it to close the protocol. It is important to note that the Change Status function does not have any notifications associated with it. Therefore, the office should notify the PI of the change in status outside of the Cayuse system. NOTE that protocols with Un-Finished status cannot be changed to approved from here. They can only be approved via the Review process.
How can you copy protocols from one PI to another without requiring approval and protocol transfer?	Search for the protocol in Protocol Search. Then click 'Copy Protocol to PI.' You will be prompted to type in the name of the new PI. The system will create a copy of the approved protocol as a new draft protocol with the new PI's name. It will show up in the PI's draft protocols alert.
Personnel page - what do these checkboxes do? • Primary Contact Flag • Copy on all Emails • Requestor Flag	 Primary Contact Flag This person may be contacted by the office for information about the protocol. Copy on all Emails For a researcher on the protocol to receive emails about the protocol, both this and the Primary Contact Flag checkboxes must be checked Requestor Flag the system will automatically check this for the person that created the protocol. This field is not editable by the researcher.
How are expiration dates calculated for protocols?	The Cayuse system is automatically set for 3-year approval periods. Expiration notifications are sent by the system at 12:00am on the Expiration Date. The expiration date displayed by the system is the first date that the protocol is Expired. Therefore,



cayuse HAZARD SAFETY TRAINING GUIDE

	protocols are in the approved status for exactly 3 years.	
FAQ for Researchers	Answer	
What is Cayuse Hazard Safety?	Cayuse Hazard Safety is a web-based application used to draft, review, approve, and manage Institutional Biosafety Committee (IBC) protocols. All submissions can be accessed via the website on any device linked to the internet. Users will receive emails from the Cayuse system when action is required on a protocol, such as at the annual renewal or De Novo (3-year) renewal.	
Who has access to Cayuse Hazard Safety?	Users will need to be granted access by the IBC administrators. If you need to access the application, please reach out to your IBC team for assistance.	
Who can submit protocols in Cayuse Hazard Safety?	Users with the Researcher Staff Members role that have PI eligibility may submit protocols.	
How do I receive updates regarding my Cayuse IBC submissions?	The application will send users emails when action is required on submissions. For example, the Cayuse Hazard Safety application will send users notifications when a protocol has questions from the IBC that need to be addressed or when a protocol is due for renewal.	
Can I initiate multiple submissions (e.g., Amendment and Renewal) for the same study at the same time?	The system does not allow multiple amendments on a single protocol at one time.	
Where can I get help with Cayuse Hazard Safety?	Cayuse Hazard Safety offers an in-application resource center. Please click the question mark in the bottom right of your screen when you are in the Animal Oversight application. For additional resources, reach out to your IBC team.	
How will Hazard Safety help researchers?	The application offers many benefits to researchers. Transparency: view protocol status at all times Improved Compliance: renewal reminders are automated and submissions requiring action will display in your inbox Web-Based: submissions can be accessed on	



 any device with an internet connection Reduced Administrative Burden: the smart-form technology will simplify the protocol drafting process by only displaying the questions
that apply to your project