



IACUC ASSISTANT

Submission Processing

Version 11.02

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IACUC Submission Processing

Introduction

IACUC Assistant will allow you to process new study applications and oversee existing studies. You can review the study, species information, and any other study related documents. Through the Submissions area of the assistant, you can process new submissions, assign reviewers, and send out minutes and letters based on the review. This document will review the steps to process submissions and will detail how to assign reviewers and manage studies.

IACUC Assistant Workspace	IACUC Assistant Workspace
Select the Committee	Select the Committee
Add a new Study	Add a new Study
Find a Study	Find a Study
Submissions	Committee Submissions

Submissions

Once a new study is submitted, it will be received by the IACUC Assistant within the Submissions menu item.

Your instance of iRIS™ may display either **Submissions** or **Committee Submissions** in the IACUC Assistant list, depending on how your system is setup (Review Board property “rb.use_submission_by_committee.” See the IACUC Assistant - Properties manual for more information).

This feature allows you to view and process all submissions sent to the review board.

When you click on the Submissions or Committee Submissions link, a page will open displaying all submissions, divided into four tabs: **Not Assigned**, **Assigned**, **Completed**, **Agendas**, **Pending Approval Letter**, **Outstanding Board Tasks**. When you open the Submissions link, the default tab is the **Not Assigned** tab.

My Workspaces ▾
IACUC
Board Submissions
Back

Close Search

Submission Type: All ▾
Active Principal
Investigator:
Date Board Received: -
IACUC Number: All
Ref Number:

Assigned Analyst:
Department: All ▾
IACUC Expiration Date: -
Reset Find Options
Find ...

Not Assigned
Assigned
Completed
Agendas
Pending Approval Letter
Outstanding Board Tasks
Print Friendly
Display Submissions by: IACUC Number ▾

299 result(s) found... 1 - 100 ▶

Open	IACUC Number	Ref Number	Type	Date Board Received	IACUC Expiration Date	Principal Investigator	Assigned Analyst	Study Classification	Ri
	Evaluation of live <i>Shigella sonnei</i> vaccine candidates in a gnotobiotic piglet model								
	ANI-15-346	002674	Initial Review Submission Form	05/15/2015 11:16:27 AM PDT		Ruiz, Roman, M.D.			
	Bacteriological Investigation and Biochemical Characterisation of <i>Brucella</i> Strains Isolated from Animal Samples in the Country of Georgia								
	ANI-15-356	002826	Initial Review Submission Form	07/27/2015 04:35:49 PM PDT		Glaser, Trevor			
	Endothelin Type A Receptor Antagonist during Myocardial Ischemia and Reperfusion								

Not Assigned

Any new submission that is unprocessed will populate within this tab. The column headings can be used to sort the submissions in ascending and descending order.



The columns listed in the **Not Assigned** tab are as follows:

Display Submissions By – This will change the display of the list of submissions. Whatever number is selected (IACUC, Project, or IBC, depending on what other modules are turned on) will appear as the column heading.

 or  (**Display Response**) – If an icon appears in this column, then there is a submission response or correction available for viewing. A green icon indicates there is an attached submission correction that was made prior to the board meeting. A red icon indicates there is an attached submission response (for submissions already reviewed).

IACUC Number– If the submission belongs to a study with an IACUC Number assigned, that number will display here.

Ref Number – Whenever a form is created in iRIS, a unique Reference Number is created for that submission. This number will display in this column.

Type – This is useful to quickly recognize the type of form that was submitted to the review board.

Date Board Received – The date that the board initially received the submission will display here.

IACUC Expiration Date – The IACUC Expiration Date assigned to the study will display in this column. Brand new studies will not have an expiration date assigned yet, but any continuing studies that submit items to the board will have the date populated in this column.

Full Renewal Expiration - The IACUC Full Renewal Expiration Date assigned to the study will display in this column. Brand new studies will not have an expiration date assigned yet, but any continuing studies that submit items to the board will have the date populated in this column.

Principal Investigator – This column displays the name of the Principal Investigator designated on the study.

Assigned Analyst – If an analyst has been assigned to this submission, the name will display here.

Assigned

After assigning a review process to a new submission, the record will move from the **Not Assigned** tab to the **Assigned** tab and can be accessed from this tab until the submission is completed.

This page lists any processed submissions, and contains the same columns and information as the submissions described in the Not Assigned section of this document plus the following:

Review Process – This section will display the review process selected for this submission.

Assigned Reviewers – If reviewer(s) have been assigned to this submission, their name(s) will display here.

My Workspaces ▼ IACUC **Board Submissions** Back

Close Search

Submission Type: All ▼	Assigned Analyst:
Review Process: All ▼	Assigned Reviewers:
Active ☐ Principal Investigator:	IACUC Expiration Date: -
Date Board Received: -	Reset Find Options
IACUC Number: All	Find ...
Ref Number:	

Not Assigned **Assigned** Completed Agendas Pending Action Print Friendly Display Submissions by: IACUC Number ▼

16 result(s) found... 1 - 16

Open	Letters	Reference Number	Type	Review Process	Date Board Received	IACUC Expiration Date	Principal Investigator	Assigned Analyst
		<i>Evaluation of live Shigella sonnei vaccine candidates in a gnotobiotic piglet model</i>	Initial Review Submission Packet	Process Administratively 12/21/2018	02/21/2018 02:59:00 AM PDT		Investigator, Principal	Boardmember
		<i>Bacteriological Investigation and Biochemical Characterisation of Brucella Strains Isolated from Animal Samples in the Country of Georgia</i>	Initial Review Submission Packet	Process Administratively	03/28/2018 07:15:22 PM PDT		Administrator	

Completed

The Completed tab will contain a link to previously processed and completed submission forms. When you open this tab it will display a search tool and any previously completed submissions. You can use the search tool to narrow down the list of results to find the completed submission you are looking for.

The search tool contains a list of filters available to search by. You can indicate a time frame of when the submission was completed by entering dates in the **Date Board Completed** and **to** date fields. Click the **Refresh** button to refresh the page with any resulting submissions. You can then open the item.

My Workspaces ▼ IACUC **Board Submissions** Back

Close Search

Submission Type: All ▼	Assigned Analyst:
Review Process: All ▼	Assigned Reviewers:
Active ☐ Principal Investigator:	IACUC Expiration Date: -
Date Board Received: -	Date Board Completed: -
IACUC Number: All	Reset Find Options
Ref Number:	Find ...

Not Assigned Assigned **Completed** Agendas Pending Action Print Friendly Display Submissions by: IACUC Number ▼

1 result(s) found... 1 - 1

Open	Letters	Reference Number	Type	Review Process	Date Board Completed	IACUC Expiration Date	Principal Investigator	Assigned Analyst
		<i>Copy of TSRL App - Differences in Social Behavior of Syrian Hamsters</i> IACUC-2019-075-NEW-1.0	Submission Correction for Initial Review Submission Form	Full Committee Review 05/15/2019	08/20/2019 08:29:18 PM PDT 05/14/2019 08:19:06 PM PDT		Investigator, John	Coordinator, IACUC

Additional fields on this page are:

Letters – An icon will appear in this column when outcome letters have been created for a submission. Hover your mouse over the icon and the name of the letter created will be displayed.

Letters	Reference Number
	Copy of TSRL Demo App - Difference: IACUC-2019-075-NEW-1.0 [Letter 1] Approval Letter

If the letter has already been sent, “(sent)” will appear after the letter type.

Letters	Reference Number	T
	Copy of TSRL Demo App - Difference: IACUC-2019-075-NEW-1.0	Sut
	[Letter 1] Approval Letter - (sent)	

Department / Study Number – This column displays the Department and Study Number associated with the study.

Date Completed – This displays the date that the submission was completed.

Agendas

The Agendas tab will open to the next upcoming meeting for the review board. This page will list any submissions assigned to this meeting date. Submissions will populate in categories, based on the type of submission.

You can flip between meeting dates by clicking the green arrows next to the meeting date.

If you are looking for a particular submission on the meeting, you can locate it and then open it by clicking on the icon in the **Open** column.

For more details on Agenda submission processing, see the IACUC Assistant - Meetings manual.

My Workspaces
IACUC
Board Submissions
Back

Not Assigned
Assigned
Completed
Agendas
Pending Action

Items to be Reviewed at IACUC Meeting :
05/15/2019
Agenda State: Finalized
Reviewer Notifications: Enabled
Show the Finalized Agenda
Submission Review validation
Save the Agenda Order

Initial Reviews - 1 Submissions

Order	Click to open	Reference Number	COI	Letters	Outcome	Type	Principal Investigator	Reviewer(s)	Date Board Received
1		Sex Differences in Social Behavior of Syrian Hamsters							
		IACUC-2019-071-NEW-1.0			Approved	Submission Correction for Initial Review Submission Form	Investigator, John		05/14/2019 10:02:23 PM UTC

Continuing Review - 0 Submissions

Pending Approval Letter

The Pending Approval Letter tab will contain a link to submissions that have been approved but does not contain an approval letter. When you open this tab, it will display a search tool and any previously approved submission pending the attached approval letter. You can use the search tool to narrow down the list of results to find the approved submission you are looking for.

This tab will only display “Hold Approval Letter” field is set to “Yes” in the Setup Board Review Outcome page found under IACUC >Review Board Administration > List Maintenance Setup > Review Outcome/ Outcome Configuration List. if the field is set to “No”, then the tab will not be displayed.

My Workspaces
IACUC
Board Submissions
Back

Close Search

Submission Type: All
Review Process: All
Active
Principal Investigator:
Date Board Received:
IACUC Number: All
Ref Number:

Assigned Analyst:
Assigned Reviewers:
Department: All
IACUC Expiration Date:

Reset Find Options
Find ...

Not Assigned
Assigned
Completed
Agendas
Pending Approval Letter
Outstanding Board Tasks
Print Friendly
Display Submissions by: IACUC Number

1 result(s) found...
1 - 1

Open	Letters	IACUC Number	Ref Number	Type	Review Process	Review Outcome	Date Board Received	IACUC Expiration Date	Principal Investigator
		Mouse Study IACUC-2017-1128	006785	Initial Review Submission Form	Full Committee Review	Pending Letter	12/20/2017 09:03:39 AM PST		John Smith

Additional fields on this page are:

Letters – An icon will not appear in this column since the approval letter has not been created. Once the approval letter has been created and attached to the approved submissions, the submission will immediately transfer to the completed tab.

Outstanding Board Tasks

The Outstanding Board Tasks tab will contain a link to pending tasks that have not been addressed by the board. When you open this tab, it will display a search tool and any tasks that are related to the submission. You can use the search tool to narrow down the list of results to find the tasks you are looking for.

This tab is controlled through a property, if the property `rb.use_submission_outstanding_board_tasks` is set to “Yes” then the tab will display in the submissions page. If set to “No”, then the tab will not display. Please see the IACUC- properties manual for more detail on this property and its functionality.

Not Assigned Assigned Completed Agendas Pending Approval Letter Outstanding Board Tasks										
20 result(s) found...										◀ 1 - 10 ▶
Click to open	Task Type Task Assigned	Received	Study Status	Study Title Alias	Principal Investigator	Assigned Analyst	Assigned Reviewers	RB Number	Ref Number	RB Expiration
	Member Review Assignment	05/26/2016 03:03 PM PDT	Pending- Submitted for Initial Review	10262 Mouse Application						
	admin, Admin, Admin, Ph.D. Brig. Gen.			10262	admin, Admin Admin, Ph.D. Brig. Gen.	admin, Admin Admin		PRO-14-1191	002115	null <Not Assigned>

Processing Submissions

When you open a submission from the **Not Assigned** tab, you will open the submission processing pages. These pages will present information and tools to process a submission form. Depending on the way the form is processed, you may or may not see certain tabs (on the left side menu).

My Workspaces

IACUC Number: **IACUC-2019-059**
PI: Investigator, John

IACUC

Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

This Submission has association to Multiple Boards. Please click on the link below to see the submission in the respective board

IBC Board

General Information ⓘ

Study Number: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Internal Comments:
Enrollments: 0
Accrual Target: 0
Archival Ref Number: 000587

Department ⓘ
GHW - 7543 - General Hospital

Protocol Personnel ⓘ

Update personnel status to latest

Role	Name	Account Status	COI Under Review?	General Training Course Training:
Principal Investigator:	John Investigator	Active		Active training
Contact:	John Investigator	Active		Active training
Additional Principal Investigator:	Jorge Alvarenga	Active		Training not posted
Study Author:	John Investigator	Active		Active training

As you step through the processing screens, the area in the middle of the page will update with information related to the tab you selected. At the top of the page is a study header that will remain on the page while you complete your processing.

My Workspaces	IACUC Number: IACUC-2019-059 PI: Investigator, John	IACUC	Submission Correction for Initial Review Submission Form	Back
Protocol Items	Miscellaneous	IACUC Items	Submission Forms	
Ref Number: IACUC-2019-059-NEW-1.0	IACUC Number: IACUC-2019-059	Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice		
Protocol Status: Pending - Submitted for Initial Review				

Listed in the header:

Study Number – This is where the Study Number for the study being submitted will display.

PI – The (Primary) Principal Investigator will be displayed here.

Type of Submission – The type of submission form (Initial Review, Animal Incident Report, etc.) appears bolded at the top of the screen, next to the PI.

Study Menu Bar – Mouse over the menu bar to open a drop-down menu. The menu bar allows users to quickly access any component of Study Management. There are five tabs: **Protocol Items**, **Miscellaneous**, **IACUC Items**, **Submission Forms**, and **Additional Attached Forms** (the items are divided into sections corresponding with sections found on the Study Management page for the study).

Reference Number – The submission reference number displays here in bolded red letters.

Project/IACUC Number – Depending on your configuration of iRIS, the project number or IACUC number will display here in bolded red letters.

Study Title – The full title of the study appears here. If the title is longer than the space provided, you may use the scroll bars to view the entire title.

Study Status – The status of the study should display Pending – Submitted for Initial Review when the Initial Review form is first received by the IACUC. This status will change depending on what part of the review cycle the study is in. The status is also color coded for easier identification.

Expiration Date – If the study has been given an expiration date, it will display here.

General Information

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

The first tab in the submission processing screens lists brief details about the study being viewed. You can view General Information related to the current submission you are processing, as well as study-specific information. The summary detail on this page is the same information listed in the Not Assigned, Assigned, and Completed tabs. From this page, you

can view basic details about the study and see the listed study personnel, their COI status (if applicable), and their training status.

The General Information tab allows you to gain a brief summary of the study and submission to begin your pre-review.

My Workspaces
IACUC Number: **IACUC-2019-059**
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

This Submission has association to Multiple Boards. Please click on the link below to see the submission in the respective board

IBC Board

General Information

Study Number: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Edit the Master Lay Summary
A summary of the study could be provided here.

Internal Comments:

Enrollments: 0

Accrual Target: 0

Archival Ref Number: 000587

Department

GHW - 7543 - General Hospital

Protocol Personnel

Update personnel status to latest

Role	Name	Account Status	COI Under Review?	General Training Course Training:
Principal Investigator:	John Investigator	Active	COI	Active training
Contact:	John Investigator	Active	COI	Active training
Additional Principal Investigator:	Jorge Alvarenga	Active	COI	Training not posted
Study Author:	John Investigator	Active	COI	Active training

General Information displays the Study Number and also pulls in the Master Lay Summary from the submitted study application.

The master lay summary can be edited by clicking on the link, **Edit the Master Lay Summary**.

A pop-up editor will open, allowing you to make any necessary changes. When you are finished, click the **OK** button.

Below the Master Lay Summary is the Submission Summary. This is a field where you can add a summary for the submission you are processing.

Also displayed are any previously entered Internal Comments. These are entered in a later part of the process and are used more for additional rounds of the submission, so when you first open a new application, this field will not have information to display.

Listed below the General Information, you will also be able to view the associated Departments and the Study Personnel.

Protocol Personnel

[Update personnel status to latest](#)

Role		Name	Account Status	COI Under Review?	General Training Course Training:
Principal Investigator:		John Investigator	Active		Active training
Contact:		John Investigator	Active		Active training
Additional Principal Investigator:		Jorge Alvarenga	Active		Training not posted
Study Author:		John Investigator	Active		Active training

Additional information can be viewed about Study Personnel by clicking on the icon next to the user's name. This will open Contact Information related to the user.

If your system is also using the Conflict of Interest Module, a column displaying the study personnel's COI standing will be displayed. If your mouse is hovered over the COI icon, you can gain additional information about the user's COI.

You can also track the study personnel's training status with the IACUC. Training is configured to be checked in the workflow, so by the time a submission reaches the IACUC, the current status of training is displayed. If there have been any training updates for study personnel between the time of submission and when the IACUC begins the submission processing, you can get the most current information by clicking on the **Update personnel status to the latest** button.

Submission Components

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

Submission Components will display the submission form(s) and any items associated to it. From this page, you can pre-review any of the submitted items including the study application and any attached study documents. You can make revisions of the submission components. You will also be able to add comments to the attached items to later use as Stipulations, if the submission needs to be returned to the PI for pre-review changes.

This page will also be used when a submission is returned to the IACUC with corrections. Any revisions created can be viewed and compared against previous versions. As the submission is modified, this area will contain a list of originally submitted items as well as any new versions and attachments.

A table on the page will list out the details of the submitted items, starting with the top-level form, working down to document attachments.

My Workspaces
IACUC Number: **IACUC-2019-059**
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

[Print Friendly](#)

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Submission Received Notification Letter

Display Submission Components

Compare Item(s)

Items in List View

Add New Component

Clear Viewed Item(s)

Create PDF Packet

Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐						Initial Review Submission Form - (Version 1.0)	
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)								
Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1)	

There are three groups of items that may or may not display as part of the submission package, depending on what the study included with their submission form.

Submission Form(s) - In the example shown above, the Initial Review is the top-level form, or parent form for the submission. Enclosed within the Submission Form are all of the items listed below as attachments.

Application – This is the main application form that was completed for this submission. This form will only display if it was attached to the parent submission form.

Document(s) – Any additional study documents that were attached to the parent form will display in this group. The study documents are often categorized when they are uploaded to the study, so there will be additional categories below this group.

Document Versions

When a new submission is processed, the attached items will all be in their original state as no new versions have been created at this time.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Protocol Status: Pending - Submitted for Initial Review

Print Friendly

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

Display Submission Components

Compare Item(s)
Items in List View
Add New Component
Clear Viewed Item(s)
Create PDF Packet
Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐						Initial Review Submission Form - (Version 1.0)	
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)								
Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1)	
☐	☐						ACORP Diagram - (Version 1.0)	

The documents are all versioned “X.0”, indicating they are in their original state. “X” denotes the starting version number, which can be any number for study documents, based on what version they started out at when they were uploaded to iRIS. “.0” denotes the iRIS version of the document. When a revision of a document or submission form is created in iRIS, this number will increment by 1. If you were to create a revision of an item or return this submission to the PI, requesting a modification to the study document, iRIS would assign version “X.1” to the new version, allowing you to see that there is more than one iRIS version associated to that particular document.

Revise/ Attach	Revisions	Current Submission Components (All Rounds)
		IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)
		Initial Review Submission Form - (Version 1.0)
		IACUC APPLICATION (ANIMALS) - (Version 1.1)
		ACORP Diagram - (Version 1.1)
		ACORP Diagram - (Version 1.0)

When a form or a document has been revised, the number will change, as shown above. The Revisions column will populate with a folder icon that you can click to display any previous versions of that form or document.

	ACORP Diagram - (Version 1.1)
	ACORP Diagram - (Version 1.0)

You may view the previous document by clicking on the

The review board may create revisions of the submission components once per round by clicking the icon in the Revise/Attach Column. Click the icon next to the desired component and a pop-up will appear asking you to confirm the revision. Click **OK** to proceed and you will have the opportunity to make revisions to the form or document. When you are done revising, the icon will no longer appear in the Revise/Attach column because you have already made your one revision per round.

Display Submission Components ⓘ

Show submission component(s) in round: 2 Current Round ▼

Compare Item(s)
 Items in Folder View
 Add New Component
 Clear Viewed Item(s)
 Create PDF Packet
 Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Submission Component Name - Version	More Details
Submission Form(s)							
☐	☐					IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐					Initial Review Submission Form - (Version 1.0)	
Application							
☐	☐					IACUC APPLICATION (ANIMALS) - (Version 1.1) - You already viewed this item	
Document(s)							

If the study team has made a revision of a submission component that has not yet been submitted to the board, an



icon will appear in the Revise/Attach column.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐						Initial Review Submission Form - (Version 1.0)	
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1) - You already viewed this item	

The board now can attach the latest, study-created version of the item to this round of the submission. Clicking the paperclip will open a window that allows you to select the version of the item you would like to attach to the submission.

Attaching Protocol Application
X

Select the application that you would like to attach to the submission.

Select	Edit/View	Form Name	Approved
		IACUC APPLICATION (ANIMALS) (Version 1.2)	No
Already Submitted		IACUC APPLICATION (ANIMALS) (Version 1.1)	No
Already Submitted		IACUC APPLICATION (ANIMALS) (Version 1.0)	No

Click the icon in the Select column to choose your desired version and attach it to the submission components. You will not be able to revise this component in this submission round.

Viewing Submission Items

The name of the submission component and the item version number will display in the Current Submission Rounds column. You can click on the name of the item to open and view in the same window.

Display Submission Components ⓘ

Compare Item(s)
 Items in List View
 Add New Component
 Clear Viewed Item(s)
 Create PDF Packet
 Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	⊕
☐	☐						Initial Review Submission Form - (Version 1.0)	⊕
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	⊕
Document(s)								
Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1)	⊕
☐	☐						ACORP Diagram - (Version 1.0)	⊕

Or to open the submission in a separate window, click on the **View in Sperate Window** icon.

Compare Item(s)
 Items in List View
 Add New Component
 Clear Viewed Item(s)
 Create PDF Packet
 Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	⊕
☐	☐						Initial Review Submission Form - (Version 1.0)	⊕
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	⊕
Document(s)								
Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1)	⊕

Viewed submission components will change color. Any form, application or document you open to view or add comments to will then highlight green. Submission components that you have not opened will remain un-highlighted.

Compare Item(s)
 Items in List View
 Add New Component
 Clear Viewed Item(s)
 Create PDF Packet
 Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	⊕
☐	☐						Initial Review Submission Form - (Version 1.0)	⊕
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1) - You already viewed this item	⊕

You can reset the viewed forms and documents by clicking the **Clear Viewed Item(s)** button in the ribbon above the Submission Components table.

							Compare Item(s)	Items in List View	Add New Component	Clear Viewed Item(s)	Create PDF Packet	Approve Attachment(s)
Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)				More Details	
Submission Form(s)												
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)					
☐	☐						Initial Review Submission Form - (Version 1.0)					
Application												
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1) - You already viewed this item					

If you open a submission form or the application, the form will open allowing you to scroll through the form and see the content of the form.

My Workspaces
IACUC Number: **IACUC-2019-059**
IACUC
Initial Review Submission Form - (Version 1.0)
Back

Print Friendly
Refresh Constant Fields

Section view of the Form
Entire view of the Form

1.0 Transitioning to Initial Review Submission

1.1 Please select the type of **Research**:

☐ Human Research
☒ IACUC Research
☐ Biochemical Review

2.0 IACUC - Initial Review Submission Packet

Note:

- This is the submission packet. The Study Application should be attached below under "Study Application Form". To access the attached "Study Application", click on the "Edit/View" icon next to it.
- To create and attach your consent form(s), go to section "Consent Documents" below.
- To upload and attach any study related document(s) that were not already attached in the Study Application, go to section "Other Study Documents" below.

2.1 Study Title:

Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

2.2 IACUC Number:

IACUC-2019-059

2.3 Principal Investigator:

John Investigator

If you open a study document, the page will be displaying review board details about that document. At the time of pre-review, you will not be changing any of the details on this page. This will be discussed later.

At the top right of the page is a table containing a column: **View the document**. You can click on the icon of the document in this column.

My Workspaces	IACUC Number: IACUC-2019-059 PI: Investigator, John	IACUC	Study Documents	Back
			Create a new version	Save Changes
*Document Title:	ACORP Diagram			
Category:	Flyer			
Comments:				
Description:				
Version Date:				
*Version Number:	1.1			
Sponsor Version:				
Outcome:	--none--			
Approval Date:				
Expiration Date:				
Check-out the Unapproved Document to your machine for editing:	Check-out Unapproved Document...			
Edit in browser:	Edit in browser			

View the document

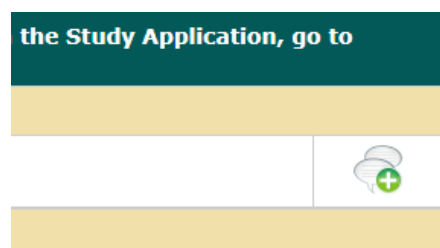
This will open the study document within the window.

Commenting

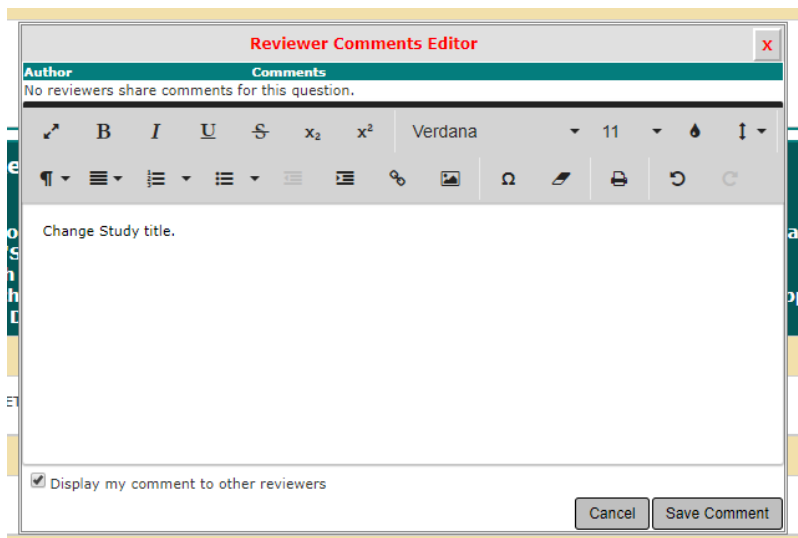
You can add comments to any of the questions in the submission form, and to any of the application questions after the study shell (the first three sections of the application).

Questions in the form that have the commenting feature will display the **Comment** icon to the right of the question.

Click on the icon to add a comment.



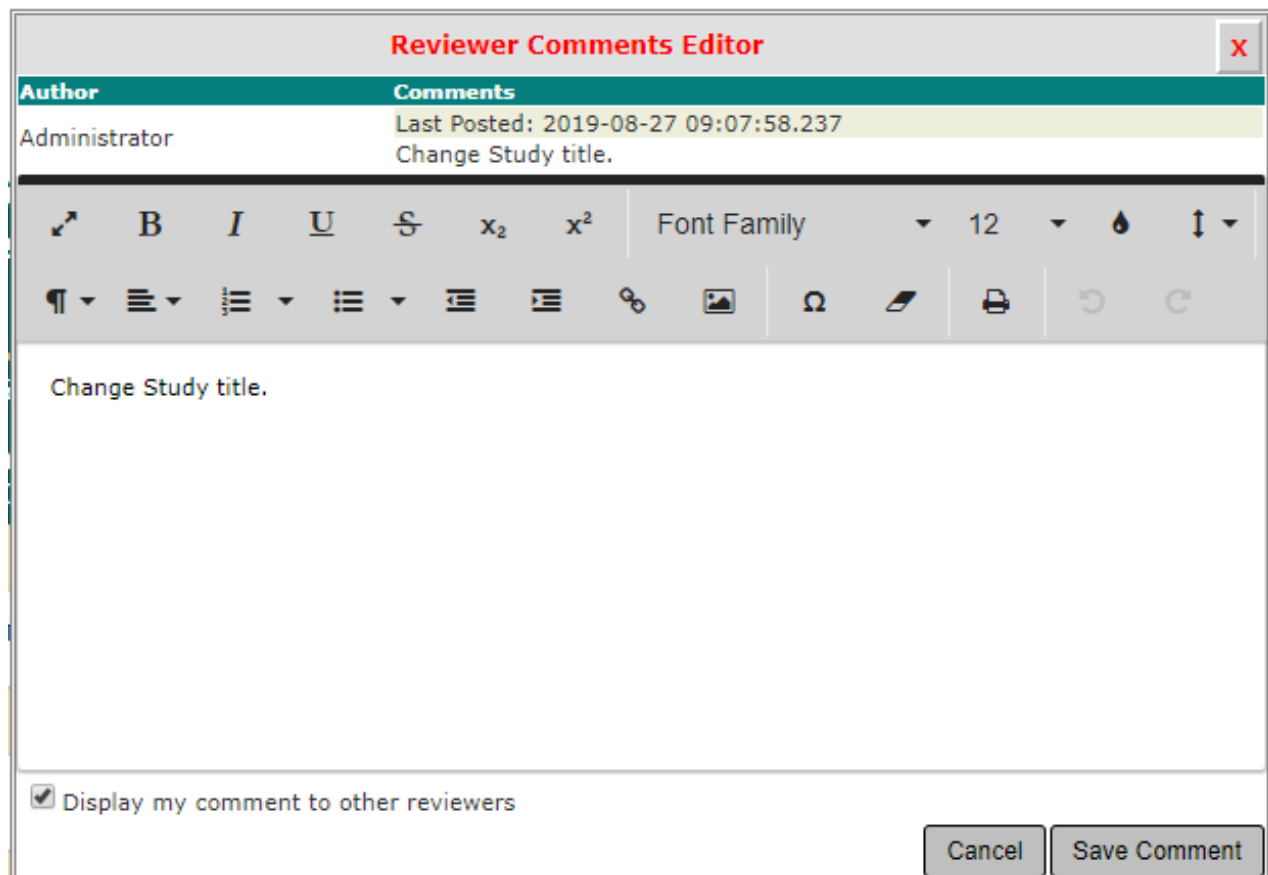
A Reviewer Comments Editor will open within the page, allowing you to type any comments. Click **Save Comment** when you are done or click **Cancel** if you do not want to add any comments.



The image shows a 'Reviewer Comments Editor' window. At the top, there is a header bar with the title 'Reviewer Comments Editor' and a close button (X). Below the header, there is a table with two columns: 'Author' and 'Comments'. The 'Author' column is empty, and the 'Comments' column contains the text 'No reviewers share comments for this question.' Below the table, there is a rich text editor with a toolbar containing various formatting options (bold, italic, underline, strikethrough, subscript, superscript, font family, font size, color, background color, bulleted list, numbered list, link, unlink, image, link icon, print, undo, redo). The text area of the editor contains the text 'Change Study title.' At the bottom of the window, there is a checkbox labeled 'Display my comment to other reviewers' which is checked. To the right of the checkbox are two buttons: 'Cancel' and 'Save Comment'.

Questions in the form that have a comment added will display a changed icon. You can modify or remove your comments by clicking on the icon again. The Reviewers Comments Editor will display the Author's name next to the comment.

Under the comments section the comment entered, the time and date of the comment will display as shown in the image below.



The image shows a 'Reviewer Comments Editor' window. At the top, there is a header bar with the title 'Reviewer Comments Editor' and a close button (X). Below the header, there is a table with two columns: 'Author' and 'Comments'. The 'Author' column contains the text 'Administrator', and the 'Comments' column contains the text 'Last Posted: 2019-08-27 09:07:58.237' and 'Change Study title.' Below the table, there is a rich text editor with a toolbar containing various formatting options (bold, italic, underline, strikethrough, subscript, superscript, font family, font size, color, background color, bulleted list, numbered list, link, unlink, image, link icon, print, undo, redo). The text area of the editor contains the text 'Change Study title.' At the bottom of the window, there is a checkbox labeled 'Display my comment to other reviewers' which is checked. To the right of the checkbox are two buttons: 'Cancel' and 'Save Comment'.

You may choose to display your comments to other reviewers by selecting the **Display my comments to other reviewers** check box.

2.0 IACUC - Initial Review Submission Packet

Note:

- This is the submission packet. The Study Application should be attached below under "Study Application Form". To access the attached "Study Application", click on the "Edit/View" icon next to it.
- To create and attach your consent form(s), go to section "Consent Documents" below.
- To upload and attach any study related document(s) that were not already attached in the Study Application, go to section "Other Study Documents" below.

2.1 Study Title:

Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

2.2 IACUC Number:

Comments for Other Study Documents will be available when you are viewing the documents.

Turn on **Highlight Comment Mode** button that appears at the top right of the page.

My Workspaces IACUC Number: **IACUC-2019-059** IACUC **Protocol Documents Review**

Highlight Comment Mode ☐ ON ☒ OFF

Delete Comments

No comment found

Worksheet to Assist in Addressing the Required Points 3 and 4 of the
Vertebrate Animal Section (VAS) for NIH
Applications and Proposals
Members of NIH Scientific review groups are instructed to evaluate the 5 point

A comment window will open in the page. You can highlight the section you would like to comment on then type in your comment associated to that section, then click the **Save** button or click **Cancel** if you do not want to add a comment.

My Workspaces IACUC Number: **IACUC-2019-059** IACUC **Protocol Documents Review**

Please select the content you want to add comment to

Worksheet to Assist in Addressing the Required Points 3 and 4 of the Vertebrate Animal Section (VAS) for NIH
Applications and Proposals

Previous Next Reply Delete Click to collapse Comments Panel

Comment

Save Cancel

Any comment that you add to the document will display to the right of the document. You can edit these comments by clicking on the comment text or you can delete the comments by clicking the red “x” next to the comment.

Comments that you add to the forms and documents can later be merged into a stipulation.

Highlight Comment Mode	
ON	OFF
Delete	Comments
	Study Information needs to ...
	List alternative methods fo ...

More Details

Each submission component will have additional information, such as submission dates, stipulations, and review outcomes, depending on what processes have been applied to the components.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						Initial Review Submission Form - (Version 1.0)	

The icon to the right of the submission item is where you can click to see these additional details.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						Initial Review Submission Form - (Version 1.0)	
Submitted to Workflow: 04/25/2019 2:51:46 PM UTC								

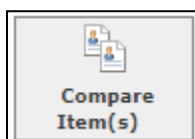
When you click this icon, an area below the submission item will populate with the details. This is helpful for items you have received into the submission queue multiple times. You will be able to see when an item was originally submitted, as shown above. Newer items associated to the submission would have newer dates than components that have been associated longer.

Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1 approved on 08/27/2019) - You already viewed this item	
Added to the Submission: 08/26/2019 2:31:59 PM UTC								
Outcome: approved		Approval Date: 08/27/2019		Expiration Date: 08/27/2019				

Other Study Documents will display associated approval information.

Compare Item(s)

Submission components that have multiple versions can be compared using the Compare Tool. This option will only be available when there are items in Submission Components that can be compared.



When there are multiple versions of a submission or document, the first column in the Submission Components table allows you to select which items to view. Before you can view an item, you would need to open the yellow folder icon to access previous versions. Also, note that you cannot compare items that are not the same item (you cannot compare one version of an application to a study document, etc.).

Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1 approved on 08/27/2019)	
☐	☐						ACORP Diagram - (Version 1.0)	

Items in List View/Folder View

You can change the view of the components to List View or Folder View. Folder View is the default view. When you click **Items in List View**, the button will change to read **Items in Folder View**.



Folder View

Folder View will list all of the submission components, regardless of which round they were submitted with. Any item that has more than one version will have the yellow folder in the **Revisions** column.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐						Initial Review Submission Form - (Version 1.0)	
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)								
Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1 approved on 08/27/2019)	
☐	☐						ACORP Diagram - (Version 1.0)	

You can click on the folder to view the previous version. You can also use the Compare Tool to compare the different versions. To see when components were initially submitted you can click on the **More Details** icon.

List View

List View allows you to view components as they relate to a certain round for the submission. A round is tallied each time a submission is returned to the study for corrections. Any submission can be sent back multiple times with no limit for pre-review changes or post-review corrections, so a submission can have an unlimited number of rounds. For each round, the study and board may revise forms and documents and add new study documents. This creates new information each round – revised submission forms, revised study documents, and new study documents.

With List View, you can filter by Round Number to see what is related to a specific round.

Show submission component(s) in round: 2 Current Round ▼

Compare Item(s)

Items in Folder View

Add New Component

Clear Viewed Item(s)

Create PDF Packet

Approve Attachment(s)

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Submission Component Name - Version	More Details
Submission Form(s)							
☐	☐					IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐					Initial Review Submission Form - (Version 1.0)	
Application							
☐	☐					IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)							
Category : Flyer							
☐	☐					ACORP Diagram - (Version 1.1 approved on 08/27/2019)	
☐	☐					ACORP Diagram - (Version 1.0)	

When you first click **Items in List View**, you default to the most current round. A new field populates on the page allowing you to select a round from the drop down list. The Compare column is not applicable in this view, because you are only looking at the current round's documents.

For a round selected, the components that display only pertain to that round's documents, meaning any unchanged form or document from the previous round. Any new versions will display, and also brand new attachments will display in this round.

You can switch the round numbers. In the screenshot below, the round was changed to Round 1. The view of the submission components has changed to the items associated to Round 1 (Initial Review Submission Form, Study Application and Study Document).

Display Submission Components ⓘ

Show submission component(s) in round:

Items in Folder View
 Add New Component
 Clear Viewed Item(s)
 Create PDF Packet
 Approve Attachment(s)

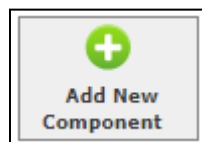
Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version	More Details
Submission Form(s)				
☐			Initial Review Submission Form - (Version 1.0)	
Application				
☐			IACUC APPLICATION (ANIMALS) - (Version 1.0)	

In addition to viewing components associated to a specific round, you can choose to combine all rounds for a summary. If you change the filter to All Rounds, the page will update and display all components associated to the submission.

The List View display is more applicable for submissions that have been returned for changes.

Attach Document

You have the ability to add new components to the submission. You can add Other Study Documents.



Start by clicking on the **Add New Component** button.

You will be directed to the list of Study Documents associated to the study. Any document that has already been attached to the submission will be indicated by *Already Attached* in the first column.

You may choose a document from the library, revise an existing document, or add a completely new document.

Attach Protocol Document(s)

Instructions

- Select the document(s) that you would like to attach
- Click the **Add a New** button to add a new document.
- Click the **Add Multiple** button to add multiple new documents.
- Click the **Attach** to attach checked documents.
- Click the **Add Revision** button to create a revised document.

Add Multiple Documents
 Add a New Document

	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Attached			1.0		Study Timeline *Added by the IACUC.	Administrator	08/27/2019 11:26:27 AM	
Already Attached			1.1		ACORP Diagram Flyer	Administrator	08/27/2019 10:51:24 AM	
Already Attached			1.0		ACORP Diagram Flyer		08/27/2019	

If you choose to add a new Study Document, you will be directed to a page that allows you to enter in the document information. You can also upload a document from this page. After entering the information, click the **Save Changes** button.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Protocol Documents
Back
Save Changes

*Document Title:
Reference Number: 000587
*Version Number: .0
Version Date:
Sponsor Version:
Category:
Comments:
Description:
*Load the document into iRIS:
Add in browser:
Add in browser

View the document
View the stamped document

The new document will display in the list and will automatically apply to the submission. Also, note that next to the title of the document, information stating the item was added by the IACUC will be displayed.

Attach Protocol Document(s)
X

Instructions

- Select the document(s) that you would like to attach
- Click the **Add a New** button to add a new document.
- Click the **Add Multiple** button to add multiple new documents.
- Click the **Attach** to attach checked documents.
- Click the **Add Revision** button to create a revised document.

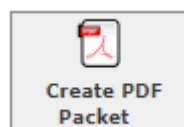
Add Multiple Documents
Add a New Document

	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Attached			1.0	RTF	Study Timeline *Added by the IACUC.	Administrator	08/27/2019 11:26:27 AM	Add Revision
Already Attached			1.1	RTF	ACORP Diagram Flyer	Administrator	08/27/2019 10:51:24 AM	Add Revision
Already Attached			1.0	RTF	ACORP Diagram Flyer		08/27/2019	

You can click the **X** icon on the top right of the page or continue on to add another document. If you return to the submission, you will see the newly added document in the list of Other Study Documents.

Create PDF Packet

You can send multiple components to be bundled and printed.



The first step: check off which items you would like to print in the **Include in PDF Packet** column. Then click the **Create PDF Packet** button.

The second step: organize your selected items in the order you would like to print them. Do so by mousing over the item (a blue arrow will appear in the **Packet Order** column) and dragging it to the desired location. When you are done, click the **Generate PDF Packet** button on the bottom right of the window.

Reorder PDF Packet X

To order Submission Items for packet creation, please click on item row and drag it up or down to the desired location.

Packet Order	Submission Item Name
1	IACUC APPLICATION (ANIMALS) Version 1.1
2	IACUC - Pre-Review Correction Form Version 1.0
3	Study Timeline Version 1.0

Generate PDF Packet

Completing step two will send any documents you selected to a PDF view. This will open in a new window. From here you can save the document for viewing and printing later, or you can print now.

Close
Save

System_Download_Servlet
1 / 26

↻ ↓ 🖨 🔖

IACUC APPLICATION (ANIMALS) (Version 1.1)

1.0 ■ General Information

***Please enter the full title of your study:**

Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

***Please enter the Study Number you would like to use to reference the study:**

Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Please identify the Research Type?

--none--

Please identify the Study Classification?

--none--

Please identify the Study Phase:

Approve Attachment(s)



Documents can be approved from the Submission Components page. You can individually approve documents by clicking on the document or you can use the **Approve Attachment(s)** button to approve multiple documents at once.

My Workspaces ☒ IACUC Number: **IACUC-2019-059** IACUC **Submission Attachment(s) Approval** [Back](#)

PI: Investigator, John

Please use the check box to select the consents and documents you want to approve. [Approve](#)

3 result(s) found...

☒	View History	Title	Version	Original	Stamped	Review Outcome ☒ Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
☐		ACORP Diagram	1.1			approved ▼	08/27/2019	Use of the Expiration Date has been disabled
☐		Study Timeline <i>*Added by the IACUC.</i>	1.0			--none-- ▼		Use of the Expiration Date has been disabled

When you have clicked the Approve Attachments button, a new page will open listing all the Study Documents associated to the submission. This page will list the document Title, the Version Number and Date, and the Original file. You can click on the icon in this column to view the document.

☒	View History	Title
Document attachment(s).		
☒		ACORP Diagram
☐		Study Timeline <i>*Added by the IACUC.</i>

To approve documents, you need to select which ones you will be approving. Do this by clicking the check box next to the document.

☒	View History	Title	Version	Original	Stamped	Review Outcome ☒ Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
☒		ACORP Diagram	1.1			approved ▼	08/27/2019	Use of the Expiration Date has been disabled
☒		Study Timeline <i>*Added by the IACUC.</i>	1.0			--none-- ▼		Use of the Expiration Date has been disabled

After checking the approve check box, you must select a Review Outcome for the document in the Review Outcome column. If you are approving all documents, you can use the Select All button and the Approve All button, to select all documents and set all outcomes to Approved.

	View History	Title	Version	Original	Stamped	Review Outcome  Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
☒		ACORP Diagram	1.1			approved ▼	08/27/2019	Use of the Expiration Date has been disabled
☒		Study Timeline <i>*Added by the IACUC.</i>	1.0			approved ▼	08/27/2019	Use of the Expiration Date has been disabled

After approving, enter in the Approval and Expiration Dates, if any. If you are approving documents after a meeting and setting Outcome information, these dates may pre-populate with the same approval and expiration information provided to the submission. Depending on your system settings, the Expiration Date may or may not be applicable. The property `rb.use_no_expiration_for_document_approval` is available in Review Board Administration > Board Configurations > Document Processing. See the IACUC Assistant – Review Board Properties manual for more information.

When the dates have been entered, the last step in approving documents is to click the **Approve** button and the system will approve the selected attachments. When you approve a document, the system will convert it to a PDF and stamp the document with your IACUC Study Document approval stamp. You can access the approved document in the **Stamped** column of this page.

	View History	Title	Version	Original	Stamped	Review Outcome  Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
☒		ACORP Diagram	1.1			approved ▼	08/27/2019	Use of the Expiration Date has been disabled
☒		Study Timeline <i>*Added by the IACUC.</i>	1.0			approved ▼	08/27/2019	Use of the Expiration Date has been disabled

When you return to the Submission Components page, any document you approved will update with a note that the document is approved if an approval date was given.

Compare	Include in PDF Packet 	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Revisions 	Current Submission Components (All Rounds)	More Details 
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐						Initial Review Submission Form - (Version 1.0)	
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)								
☐	☐						Study Timeline - (Version 1.0 approved on 08/27/2019) <i>*Added by the IACUC.</i>	
Category : Flyer								
☐	☐						ACORP Diagram - (Version 1.1 approved on 08/27/2019)	

Correspondence

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

This tab allows users to communicate with other board members or study personnel. This section will also allow users to send correspondence to an email address outside of iRIS. When you choose to access the area to add a correspondence, the screen will look like this:

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

Add a New Correspondence

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

Submission Correspondence ⓘ
0 result(s) found...

Delete	View Message	Author	Subject
No correspondences have been entered.			

The page will list all correspondence associated with the submission.

To add correspondence, select the **Add a New Correspondence** button.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Submission Correspondence
Back

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

Save & Send Correspondence

*Send Email ☒
*Subject
* Recipient(s):
Additional Recipient(s):
Reply To(s):
Additional Reply To(s):
Attachments
Add Attachment
No Attachments have been added to this message

Template: --none-- Import template
*Content

B I U S x₂ x² Font Family 12

Send E-mail: This checkbox is checked by default, meaning that the correspondence will also be sent to the specified recipients via email. The correspondence will send to the email provided in the user's account. Whether or not this box is checked, this correspondence will be available under My Assistant.

Subject: This field determines what will show up in the subject field of the correspondence.

Recipient(s): Choose from a list of key personnel and members on the Review Board. To select the individual(s), check the box(es) next to the name(s). To select all of the listed Personnel, select the icon above the checkboxes. Select the **Save Changes** button when finished.

My Workspaces ▾ IACUC		Correspondence contact		Back
Save Changes				
Contacts	Role			
<u>Protocol Personnel</u>				
☒	Principal Investigator	☒	Investigator, John	
☐	Additional Principal Investigator	☐	Alvarenga, Jorge	
☐	Study Author	☐	Investigator, John	
☐	Contact	☐	Investigator, John	
<u>IACUC IACUC</u>				
☒	Board Member	☒	Chair, Department	
☐		☐	Reviewer, Luke, Ph.D	
☐		☐	Sandbox, Beaumont	

Additional Recipient(s): Used to add persons to the list of recipients that are not users in iRIS. Select the **Add A New Contact** button.

My Workspaces ▾ IACUC		Correspondence Additional Contacts		Back
Add A New Contact Save And Return				
	Name	E-mail Address		
No Additional Recipients have been added.				

Enter the **Name** and a valid **E-mail Address** for the recipient. You can add as many additional recipients as needed. If you need to remove a contact, click the checkbox next to the contact, then click the **Remove Selected Contacts** button. Click the **Save and Return** button to return to the correspondence page.

My Workspaces ▾ IACUC		Correspondence Additional Contacts		Back
Add A New Contact Remove Selected Contacts Save And Return				
	Name	E-mail Address		
☐	John Smith	jsmith@hotmail.com		

Reply To(s)/ Additional Reply To(s): Add users here if you would like them included in any replies to the correspondence outside of iRIS. Any user added here will receive an email to their email address when another person replies to this correspondence thread outside of iRIS.

Attachments: If there is a document you would like to add to the correspondence, click the **Add Attachment** button.

My Workspaces
IACUC
Add Attachment
Back

Save And Return

*Title:

Load the document into iRIS:
Upload ...

You will be required to enter the title of the attachment. The actual attachment can be uploaded by clicking the **Upload** button. You will then be prompted for the file's location.

Select the **Browse** button to use your window browser to browse through your system files. After the file is located, select the **Save selected file** button to upload the file or the **Cancel** button to cancel the process. After the document is uploaded, an icon will display next to the **Title**. To replace this document with another one, select the **Upload** button again. Select the **Save And Return** button.

Document Location:
Choose File
No file chosen

Instruction: Uploading a document into iRIS™ requires locating the document on the computer. Once you have located the document click on the 'Save selected file' button. The buttons will become disabled. If the document is a large document the window will stay in place until the upload operation has completed.

Save selected file
Cancel

The attachment will appear in your notification. You will be able to delete the attachment(s) or add more attachment(s) as necessary.

Attachments

Add Attachment
Delete Attachment(s)

☐

Study Contract Document(s).rtf

Click Attachment Name to View

Import Template: Within Review Board Administration, correspondence templates can be set up. These templates can then be imported into the correspondence by selecting the desired template from the drop-down list and clicking the **Import Template** button.

Content: Use the text editor provided here to enter the content of your correspondence.

After you have entered the necessary information for the correspondence, select the **Save & Send Correspondence** button. Once the correspondence has been saved and sent, the information regarding the correspondence will display in a table (see the screen shot below). You may add a reply to the correspondence by clicking the **Post a Reply to this Topic** link, or click the **Forward this Topic** link to forward the message to a recipient. This would also be sent in the same manner as explained above. You may also view the content of the correspondence by clicking on the **View Message** Icon.

1 result(s) found...

Delete	View Message	Author	Subject
	Post a Reply to this Topic / Forward this Topic		
	Administrator	Posted: Delivery in Progress (Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice) Correspondence	

Submission History

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening

This tab will display the current workflow step for the submission and any previous steps the form has taken.

My Workspaces

IACUC Number: **IACUC-2019-059**
PI: Investigator, John

IACUC

Submission Correction for Initial Review Submission Form
[Back](#)

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

Add Additional Signoff

General Information	Submission History			
Submission Components				
Correspondence				
Submission History				
Pre-review Screening				

	Status	View Details	Date Received / Date Completed	Event Description
			04/25/2019 07:56 AM PDT / 04/26/2019 09:29 AM PDT	IACUC received the submission
			04/25/2019 07:49 AM PDT / 04/25/2019 07:52 AM PDT	IBC Coordinator has been assigned as the analyst
			04/25/2019 07:49 AM PDT /	IBC Board received the submission
			04/25/2019 07:49 AM PDT /	Notice to complete conflict of interest protocol disclosure questionnaire assigned to John Investigator
			04/26/2019 09:27 AM PDT / 04/26/2019 09:27 AM PDT	IACUC assigned a Pre-review action of Process Administratively
			04/25/2019 07:56 AM PDT / 04/25/2019 07:56 AM PDT	John Investigator as Principal Investigator review and apply signoff

Any steps that are still in process will be displayed at the top of the list with the status of **In Process**. The steps that are completed will be displayed with the status of **Completed**. Once a step has moved from In Process to Completed the step will order by the date/time stamp. If any step was canceled, the status will be canceled and the Cancel icon will be displayed (see example below).

			04/25/2019 07:56 AM PDT / 04/25/2019 07:56 AM PDT	John Investigator as Principal Investigator review and apply signoff
--	--	--	---	--

The date the process was received is displayed in the **Date Received/Date Completed** column. The **Event Description** will display the description of the process. Each item in this table can be expanded to show more details in the Event Description. This can be done by clicking the expand button:

	+	Status	View Details	Date Received / Date Completed	Event Description
	+			04/25/2019 07:56 AM PDT / 04/26/2019 09:29 AM PDT	IACUC received the submission

This will cause the item to appear as so:

	+	Status	View Details	Date Received / Date Completed	Event Description
	⊞			04/25/2019 07:56 AM PDT / 04/26/2019 09:29 AM PDT	IACUC received the submission Study Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice Principal Investigator: Investigator, John Submission Type: Submission Correction for Initial Review Submission Form Reference Number: 000587 IACUC Number: IACUC-2019-059

To minimize this view, click on the small collapse  button.

If the submission needs to be routed for further signoff before review, the Board Coordinator can use the **Add Additional Signoff** button at the top of the Submission History page. This will allow them to route the submission for signoff (similar to the process of the submission undergoing signoff by the PI). These additional signoff routings can be removed by clicking the **Delete** icon. Either way, an entry will be created in the workflow and any associated user chosen for signoff will be notified via a task on their home page and an email notification (if one has been configured).

Pre-Review Screening

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

This screen is used to assign the analyst, process the submission (for example, send back for pre-review changes or assign for full board review), and assign reviewers.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: **Pending - Submitted for Initial Review**

Save the Pre-Review Screening

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

Analyst Assignment

Assign Analyst:
Coordinator, IACUC
View Analyst Workload

IACUC Number:

IACUC Number:
IACUC-2019-059

Determine Review Process

☒	Not Assigned	
☐	Assign to Review Committee Agenda	
☐	Expedited	
☐	Pre-Review Forward to another Board/Committee	
☐	Pre-Review changes requested	
☐	Process Administratively	

Note: Remember to click the **Save the Pre-Review Screening** button if you make any modifications to this page.

Assign Analyst – Select the user who will provide and/or coordinate comprehensive technical and compliance pre-review of study submissions. The user assigned as the Analyst will receive a homepage task related to the submission until the submission form is closed by processing. The Analyst will also receive submission related notifications – Reviewer Complete Notifications, Outcome Letter Signoff Complete Notifications, and Review Response Complete Notifications.

IACUC Number – Depending upon your system settings, the Review Board number may have been automatically generated in your workflow or it will be required for you to manually enter in or generate by clicking the “Generate Number” button. If you do not have this button next to the text field, it means that your IACUC Numbers have already been automatically assigned.

Determine Review Process – Use the selections presented here to process the submission form. Once you select a review process and save the screen, you will be able to assign reviewers and more processing tabs will populate on the screen.

Review Processes available are as follows:

Not Assigned - The submission will default to this status when it is first submitted to the submissions queue. This indicates that a Review Process has not yet been assigned and causes the form to populate in the **Not Assigned** tab.

Assign to Review Committee Agenda – This option allows you to process the submission as a full board review. After this option is selected, the committee and meeting selections will be displayed.

☒	Assign to Review Committee Agenda	Committee Name: --none-- ▼ Upcoming Meeting Date: --none-- ▼ or click here to select past meetings Agenda Category: --none-- ▼
----------------------------------	--	---

This option can be turned on or off depending on your system settings. The property `rb.use_review_process_agenda` is available in Review Board Administration > Board Configurations > Submission Prereview. See the IACUC Assistant – Review Board Properties manual for more information.

After selecting this option, nine different tab options (depending on your system configurations) will be displayed: **Review Checklist and Comments**, **Review Summary**, **Submission Discussion**, **Stipulation**, **Internal Submission Routing**, **Vote**, **Outcome**, **Outcome Letter**, and **Submission Complete**.

[Save the Pre-Review Screening](#)

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Submission Received Notification Letter

Review Checklist and Comments

Review Summary

Submission Discussion

Recommendation

Stipulation

Internal Submission Routing

Vote

Outcome

Outcome Letter

Submission Complete

Analyst Assignment ⓘ

Assign Analyst:

Coordinator, IACUC ▼

View Analyst Workload

IACUC Number: ⓘ

IACUC Number:

IACUC-2019-059

Determine Review Process ⓘ

☐	Not Assigned	
☒	Assign to Review Committee Agenda	Committee Name: IACUC ▼ Upcoming Meeting Date: 05/15/2019 ▼ or click here to select past meetings Agenda Category: Continuing Review ▼
☐	Expedited	
☐	Pre-Review Forward to another Board/Committee	
☐	Pre-Review changes requested	
☐	Process Administratively	

Expedite – If this option is selected, the screen will refresh with the option of selecting a reviewer(s). Once you have finished with your selections on this page, click the **Save the Pre-Review Screening** button. Again, the new tabs will be available for that submission. This option can be turned on or off depending on your system settings.

The property `rb.use_review_process_expedited` is available in Review Board Administration > Board Configurations > Submission Prereview. See the IACUC Assistant – Review Board Properties manual for more information.

Designated Reviewer – This option allows you to initiate a Designated Review. When you select this process, you will be able to assign the submission to a meeting date and also assign the Designated Reviewer and Designated Member. This option can be turned on or off depending on your system settings.

The property `rb.use_designated_reviewer` is available in Review Board Administration > Board Configurations > Reviewers. See the IACUC Assistant - Review Board Properties manual for more information.

Exempt - If this option is selected, the screen will refresh with the option of selecting a reviewer(s). Once you have finished with your selections on this page, click the Save the Pre-Review Screening button. Again, the nine new tabs will be available for that submission. This option can be turned on or off depending on your system settings.

The property `rb.use_review_process_exempt` is available in Review Board Administration -> Board Configurations -> Submission Prereview. See the IACUC Assistant - Review Board Properties manual for more information.

Pre-Review changes requested – Use this option to send the submission back to the Study for pre-review corrections. When you choose this option, you will not have the ability to assign reviewers, but you will get the same nine tabs as the

other review processes. This will allow you to define any necessary Stipulations before returning the submission to the Study.

Process Administratively – This process is a useful action for submissions that need to be processed through the review board but not reviewed. Selecting this review process will also allow you to select reviewers for the submission, if the reviewer option is turned on. The same tab options will also appear after this option is selected and saved.

Assign Reviewers

This option will be available on Submissions that have been assigned a review process. This area can be turned completely off in Review Board Configuration – System Setup. This section allows you to assign a user within the review board to review a submission.

Assign Reviewers 

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed
	Secondary ▼	Anson, Brianna ▼	No			

To add a reviewer, select the **Add Reviewer** button.

The screen will refresh, allowing you to select from a list of reviewer roles that are pre-defined in the Review Board Configurations (see the IACUC Assistant – RB Administration manual for more details).

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed
	--none-- ▼		No			

After the role (a non-Ad Hoc role) is selected, the screen will refresh to allow you to select from a list of reviewers.

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed
	Secondary ▼	--none-- ▼	No			

If an Ad Hoc reviewer is selected, the screen will refresh, allowing you to manually enter the reviewer's name or select it from a list of users.

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed
	Ad Hoc ▼	Known System identified User: --none-- ▼ OR First Name: Last Name: 	No			

After selecting and/or entering the correct data, select the **Save Pre-Review Screening** button. The screen will refresh with the reviewer's information.

You may add as many reviewers as needed. A reviewer can also be deleted from the list simply by clicking the icon in the first column. A confirmation will be displayed to confirm the removal. Select the **OK** button to proceed or the **Cancel** button to cancel the process.

[Add Comments for All Reviewers](#)
[Add Reviewer](#)
[View Reviewers Workload](#)

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed
	Secondary	Anson, Brianna	No	No	08/27/2019	

After the reviewers are selected, they will receive a notification advising them that a submission is waiting for their review. This notification can be set up in Review Board Configurations. The Review Assignment will also appear as a task on their home screen.

If the Review Process is assigned to Review Committee Agenda, the reviewer will not receive a notification until the coordinator enables the reviewer notifications for that particular meeting date.

Comments to Reviewers

When you assign reviewers to a submission, you can add comments to the reviewers.

[Add Previous Reviewers](#)
[Add Reviewer](#)
[View Reviewers Workload](#)

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed	Request for Full Committee Review
No Reviewers have been assigned to this submission.							

As soon as you create a reviewer assignment record, a new button will populate at the top of the reviewer table called **Add Comments for All Reviewers**.

[Add Comments for All Reviewers](#)
[Add Reviewer](#)
[View Reviewers Workload](#)

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed	Request for Full Committee Review
	Secondary	Bray, Mari	No				No

Clicking this button will open a popup within the browser where you can add any information you would like to communicate to the reviewers assigned to the submission. Click the **OK** button at the top right of the window to add the comments. If you do not want to save the comments, click **Cancel**.

When comments have been added for the reviewer, the button will change to **View Comments for All Reviewers**. You can click this button to view or modify the comments.

Any comments added can be displayed within the Reviewer Checklist using the "Submission Comments for All Reviewers" data value in the System Forms Designer.

Reviewers Workload

© iMedRIS Data Corporation

View Comments for All Reviewers

Add Reviewer

View Reviewers Workload

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed	Request for Full Committee Review
	Secondary ▼	Bray, Mari ▼	No	No			No

Above the reviewer table is a button called **View Reviewers Workload**.

Print

Close

Show Reviews	Member Name	Specialty/ Submission Type	# Assigned/ Date Notified	IACUC Number	PI Name	Reviewer Role	Review Process	Meeting Date
	13, Agent, NOC 2LT	Physical Therapy General Practitioner Administration	0					
	Ack, Abby, MSN Ph.D.		0					
	Ack, Billy, R.N.		0					
	admin, Admin Admin, Ph.D. Brig. Gen.	Medical Oncology Anesthesiology Endocrinology Emergency Medicine Microbiology Medical Oncology	6					
	Afshar, Maryam, Dr.		1					

When this button is clicked, a new page will open listing board members and the number of open assignments currently assigned to them. You can click on the yellow folder icon to expand a view of all assignments for a particular member and view the study details for those assignments. This page can be printed if needed. Click the **Close** button to return to the Pre-Review Screening page.

Reviewer Assignments

When you assign a reviewer to a submission, the reviewer will get a notification from iRIS to let them know of the task under the **All Task** tab. When the reviewer logs in to iRIS, there will be a task in the **Outstanding IACUC tasks** group under Reviewer Assignment.

The reviewer will click the Open icon to start a reviewer checklist form.

All Tasks

Outstanding

Completed

All Tasks

Study Tasks

Project Tasks

Task List: Reviewer Assignment

91 result(s) found...1 - 5

Click to open	Task Type	Received	Description
	Reviewer Assignment	08/14/2019 11:16 AM PDT	Admin Admin admin, Ph.D. Brig. Gen. has been assigned as the Primary for an Administrative Review on the Submission Response for Initial Review Submission Form Real, assigned by John Investigator, B.S.

The reviewer checklist form is defined in the System Form Designer and can contain any number of questions for the reviewer to fill out.

Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
Secondary	admin, Admin Admin, Ph.D. Brig. Gen.	No	08/28/2019	

Also available to the reviewer are buttons for different actions.

Print Friendly – Allows the reviewer to print the form.

Reviewer Panel – Will open the submission components in a separate window, allowing the Reviewer to flip between the Reviewer Checklist and the submitted items. This will only be available if the reviewer panel property is enabled. See the IACUC Review Board Properties manual for more information.

Refresh Constant Fields – This button is used to obtain more current information related to the study and submission.

Save Section – The button is used to save work while completing a section.

Save and Continue to Next Section – Allows the reviewer to navigate through each section in the form.

One data value used in the reviewer checklist form is a value that will link to the submission components for the reviewer to view. The screenshot above shows the data value for the Current Submission Components. The reviewer can click to open any of the documents to view them.

As the reviewer progresses through the form, navigation will build on the left of the form, allowing the reviewer to navigate between sections.

My Workspaces ☒ Alias: Study Application PI: Blevins, Deborah IACUC

Reviewers Checklist- IACUC - (Version 7.0) [Back](#)

Print Friendly Reviewer Panel Refresh Constant Fields Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Protocol Information

2.0 **Reviewer's Recommendations**

2.0 Reviewer's Recommendations

2.1 Recommended Committee Finding:

- ☐ Pre-Review Responses Needed
- ☐ Approve
- ☐ Modifications Required to Secure Approval followed by Designated Member Review and completion of modifications of items listed
- ☐ Modifications Required to Secure Approval followed by Full Committee Review and completion of modifications of items listed
- ☐ Refer to Full Committee for Review (DMR reviews only)
- ☐ Withhold Approval (Not available for DMR Outcome)

2.2 Review Comments: Here is the list of comments and questions compiled for this review - this is your last chance on this round to submit questions/comments. The next screen will complete this review process

At the end of the reviewer checklist, the reviewer will indicate that they have completed the review and click the **Save and Continue** button. Selecting “Yes” in this section will flag the review as complete.

1.4 Have you completed your review?

☒ Yes ☐ No

The incomplete reviewer task will move from the home screen and the analyst assigned to this submission will receive a notification and home screen task indicating the reviewer is finished with the review.

Submission Received Notification Letter

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Submission Received Notification Letter

This screen is used to send out a submission received notification letter. A letter is created and sent as an acknowledgement of the submission to individuals on the study.

This tab will only display in your submission, depending on how your system is setup (Review Board property “rb.use_submission_letters.” See the IACUC Assistant - Properties manual for more information)

My Workspaces ☒ IACUC Number: **IACUC-2019-059** IACUC **Submission Correction for Initial Review Submission Form** [Back](#)

Protocol Items Miscellaneous IACUC Items Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0** IACUC Number: **IACUC-2019-059** Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

[Create Letter](#)

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter

Submission Received Notification Letter ⓘ
Submission Received Letter: --none--

Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
No Letters have been created for this submission.							

Select the Submission Received Letter type from the drop-down list. The letters are created from the submission group in Outcome Letter Templates. Please see the IACUC Assistant – Review Board Administration manual for more details.

Submission Received Letter: --none--

Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
No Letters have been created for this submission.							

Letter Generation

To create a letter, begin by selecting a template from the **Submission Received Letter** drop-down list. After the template is selected, click the **Create Letter** button.

The letter templates are created under Review Board Administration > System Setup > Setup Outcome Letter Templates. You can have any number of templates defined as needed.

After clicking the create button, a screen will be displayed with an embedded text editor. The text editor will contain the modifiable version of your letter. To the left of the screen is the submission information (**Reference Number**, **Submission Type**, **Study Number**, and **Assigned Analyst**).

My Workspaces ☒ IACUC **Letter** [Back](#)

[Expand Word Window](#) [Insert Template Language](#) [Save Letter Changes](#)

Reference Number:
IACUC-2019-059-NEW-1.0
Submission Type:
Submission Correction for Initial Review Submission Form
IACUC Number:
IACUC-2019-059
Study Number:
Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Assign Analyst:
IACUC Coordinator
Does this letter require signature signoffs?
☐ Yes ☒ No
Share this letter with other Boards?
☐ Yes ☒ No

HTML Content

B I U S x₂ x² Times New Roman 14

Check In/Out

Submission Received Letter
Animal Research Committee

Today's Date: August 27, 2019

Title of the study: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

To require signature signoffs for this letter, select “Yes” under **Does this letter require signature signoffs?** When this is done, another field will populate as shown below.

Batch signoff allows the user assigned for letter signoff to sign more than one letter at a time. If this is applicable, select “Yes.”

Does this letter require signature signoffs?

☒ Yes ☐ No

Is batch signoff applicable?

☐ Yes ☒ No

You may also choose to share the Submission Received Letter with other boards that will be reviewing this submission. Select “Yes” to the **Share this letter with other Boards** option. This will expand to a list of available review boards in your system. You can choose any number of boards or select to share with “All”. When this submission is sent to another board, the letter will be accessible when processing the submission.

Share this letter with other Boards?

☒ Yes ☐ No

Share with Review Board:

- ☐ All
- ☐ Conflict of Interest Assistant
- ☐ Contracts Review Board
- ☐ Export Control
- ☐ IBC Board
- ☐ IRB

While you are working on the letter, you may expand the embedded editor by clicking on the Expand Word Window button.

This will expand the editor, allowing you more room while working on the letter. Click the Minimize Word Window button to return to the normal view.

HTML Content

Check In/Out

Minimize Word Window

Insert Template Language

Submission Received Letter

Animal Research Committee

Today's Date: August 27, 2019

You may also insert template languages by selecting the **Insert Template Language** button.

Insert Template Language

Name
 Language 1

A list of template language will appear. This list is pre-defined under Review Board Administration > System Setup > Setup Template Language. To select the template language, click on the  icon next to it.

After all necessary revisions/additions are made to the letter, select the **Save Letter Changes** button

Submission Received Notification Letter 

Submission Received Letter: --none-- ▾

Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 1	No	Waiting to be sent		

After creating the letter, a record will populate on the Submission Received Letter page. At this point, the letter can be deleted, sent to the study, or edited. Some of the columns in the Submission Received Letter table will change depending on the status of the letter.

Delete – You can delete a letter as long as it has not been sent. Once a letter is sent, it can be voided.

Send – The Submission Received Letter can only be sent if there are no tasks pending for the letter. When a letter is available to be sent, the button appears selectable. Once a letter is sent, you have the option to Resend the letter. The button will change from a selectable Send to a selectable Resend. If the letter is pending signoffs, the button will gray out. You will not be able to send the letter until the signatures are collected.

Edit/View – The icon in this column will remain the same, however, depending on whether or not the letter has generated into a PDF document, you may or may not be able to edit the letter when you open it.

Title – The title of the outcome letter will populate in this column, along with the version number of this particular outcome letter.

Signature Required – This column will display either “Yes” or “No” to indicate whether or not this letter requires signatures before it can be sent.

Status – The status of the letter will display in this column. Available statuses:

‘Waiting to be sent’: This means that the letter can be sent;

‘Waiting to be Routed for Signoff’: This means that you cannot send the letter until signatures have been collected. If the letter status is this, an icon will populate in the Route Signoff column;

‘Routing in progress’: This means that the letter has been routed for signoff and cannot be sent until the signatures have been collected;

‘Denied in Routing’: This means that the person assigned to sign the letter denied the letter. You still cannot send the letter; you must reroute the letter for signatures;

‘Routing Complete Waiting to be sent’: means that the signature was collected, and you can send the letter.

Route Signoff – This column will populate with an icon if you indicated that a signature is required on the letter before it can be sent. Clicking this icon will display a new page, allowing you to either select the person or persons needed to sign the letter; or, if you have already done this, clicking the icon will display who you have routed the letter to and what their signature status is.

Copy – You can copy a letter if you need to resend a letter or make changes to an existing letter. Often this is used if the signature was denied on a letter and you need to make changes and reroute the letter. Clicking this icon will copy the

letter contents and a new letter record will be created on the page. After the letter is copied, you can edit the new letter and route that letter for signatures.

Delete Letters

You can delete a Submission Received Letter, but only if it has not been sent. After a letter is sent, you cannot delete the letter. To delete the letter, click the checkbox in this column then click the **Delete Letter(s)** button

Submission Received Notification Letter

Submission Received Letter: --none-- ▼

Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
☒			Letter Version 1	No	Waiting to be sent		

After deleting the letter, you may want to **Resend** it to the study personnel.

Sending a Letter

The send column will populate with a button allowing you to send the letter. If the letter is being routed for signatures, the button will appear gray and you will not be able to send the letter until the signatures have been completed.

When you click the **Send** button, a new page will open. This page allows you to enter a Letter Title, select the Outcome Letter recipients, and add additional recipients if they are not listed on the page.

At the top of the page, study and submission specific information is listed: Submission Type, Study Number, Study Title, and Reference Number. Letter Title is an editable field, and will pull in the given letter name from Review Board Administration > Review Board Notification Setup > Outcome Letter > List of RB Outcome Letter Notifications. You can override the given Letter Title by typing in this field.

My Workspaces ☒
IACUC
Letter Recipients
Back

Add recipient from directory
Add recipient manually
Send to selected recipients

Submission Type: Submission Correction for Initial Review Submission Form
IACUC Number: IACUC-2019-059
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Reference Number: IACUC-2019-059-NEW-1.0
Letter Title:

Key Protocol Personnel

Contacts	Role	☒	
<u>Project Personnel</u>			
	Principal Investigator	☒	John Investigator
	Contact	☒	John Investigator
<u>IACUC - IACUC</u>			
	Coordinator	☒	Administrator
		☒	Boardmember
		☒	IACUC Coordinator
		☒	Jane Coordinator
<u>IBC Board - IBC Board</u>			
	Coordinator	☒	IBC Coordinator

Additional Recipients

Association	Send if checked	Additional Recipients
No additional recipients have been selected		

Below this information are tables containing lists of users in iRIS. These users are broken into different groups. Listed are the Study Personnel, Sponsor Contacts, and members of different review board committees. Depending on property settings, the users listed in these groups may or may not be pre-selected. Any user with a checkbox next to their name indicates they will be a Submission Received Letter recipient when you send the letter.

You can add additional recipients to receive the Submission Received Letter by choosing to add a recipient from iRIS or you can choose to enter an email address.

Click **Add recipient from directory** to add an iRIS user to the letter.

This will open the **Search User Directory** page, allowing you to search for the desired iRIS user. When you find the user to add, click the **Select User** icon.

My Workspaces
IACUC
Search User Directory
Back

Save Selected User(s)

Directory Browse/Find:

Last Name: Admin (You may enter a partial name to search)
First Name:
by Department: All Departments

Find

Check for Multiple	Select User	Training	User Name	Department	Email
☐			Admin, ORA	Grants Office (primary)	
☐			Administrator	General Hospital (primary) [+]	admin.administrator@imedris.net

The user will populate in the Additional Recipients table with the checkbox pre-selected. You can add an Association to the user by entering that information into the **Association** column.

My Workspaces
IACUC
Letter Additional recipients
Back

Add A Recipient
Remove Selected Recipients
Save And Return

	Name	E-mail Address
☐		

A new page will open, allowing you to click the **Add a Recipient** button to add a non-iRIS recipient.

Clicking the **Add a Recipient** button will add a row to the page. You can type in the Name and E-mail address. You can add as many non-iRIS recipients as needed by continuing to click **Add a Recipient**. When you are finished, click the **Save and Return** button.

My Workspaces
IACUC
Letter Additional recipients
Back

Add A Recipient
Remove Selected Recipients
Save And Return

	Name	E-mail Address
☐	John Smith	jsmith@hotmail.com
☐	Emily Scott	escott@hotmail.com

The non-iRIS recipients will be listed in Additional Recipients. The **Association** field is a required field; you will not be able to send the letter without information in this field.

If you do not need to send the letter to any Additional Recipients, you cannot delete the recipient. You will need to uncheck the checkbox in the **Send if Checked** column before you save this page.

Additional Recipients

Association	Send if checked	Additional Recipients
Research Admin.	☒	John Smith
Research Admin.	☒	Emily Scott

When you are ready to send the letter to the selected recipients, click the **Send to selected recipients'** button on the top right of the page.

Once the letter is sent, the system will generate a PDF from the Word document and attach that PDF to the Submission Received Letter notification as defined in Review Board Administration. You will be returned to the Submission Received Letter tab.

Routing for Signatures

After saving the letter, if you indicate signatures are required on the letter, you will be directed to the **Submission Letter Signoff Routing List** page.

My Workspaces ▾
IACUC

Submission Letter Signoff Routing List
Back

Add Review Board Signoff
Add Non-Review Board Signoff
Delete Selected Signoff(s)
Save Signoff List

Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Reference Number: IACUC-2019-059-NEW-1.0
Submission Type: Submission Correction for Initial Review Submission Form
Letter Name: Letter

Have you completed your selection of required signatures?
☐ Yes
☒ No

	Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
No Personnel have been designed to signoff									

There are two ways to add a user to approve and signoff on the letter:

Add Review Board Signoff – This allows you to choose from any board member.

	Order Number	Name
☐	0	--none-- --none-- Administrator Boardmember Chair, Department Coordinator, Jane Coordinator, IACUC Reviewer, Luke Reviewer, IACUC Sandbox, Beaumont

Add Non-Review Board Signoff – This allows you to choose any user in the iRIS database, regardless of their access to the Review Board.

My Workspaces
IACUC
Search User Directory
Back

Save Selected User(s)

Directory Browse/Find:

Last Name: (You may enter a partial name to search)
First Name:
by Department: All Departments

Find

Check for Multiple	Select User	Training	User Name	Department	Email
☐	☒		Coordinator, Jane	Study Team (primary) [+]	test@imedris.com

After selecting the users required to sign off, their records will appear as shown in the screen shot below

	Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
☐	0	Coordinator, Jane			Yes	No			
☐	1	Administrator			Yes	No			

Order Number – Specifies who will receive the signoff task first. Users with the same number in this column will receive tasks at the same time.

Name – This is the name of the user (selected from the drop-down menu) who must sign the outcome letter.

Signoff – This column is only useful for the currently logged in user. An icon will populate in this column for each personnel. If you are looking at this page and have been selected as signoff personnel, the icon next to your name will darken and you will be able to signoff the letter by selecting this icon.

Approved – This area will display the status of the letter after the user has approved or denied it.

Include Signature – If this field is set to “Yes,” the user’s electronic signature will be included in the letter.

Allow Change – If this is set to “Yes,” the user designated for signoff will be allowed to edit the letter.

Date Received – Date user receives the letter for signature.

Date Completed – Date the user applies their electronic signature.

Comments – Any comments the user may have entered upon signoff.

Delete Selected Signoff(s) – Delete users selected for signoff by checking the box next to their name and clicking this button.

Once all selections are made, click “Yes” in the **Have you completed your selection of required signatures?** field. This will send the Outcome Letter Signoff tasks to the selected users when you save the signoff list.

Click the **Save Signoff List** button.

At this point, the system will send the signoff tasks and the Submission Received letter will convert from a Word document to a PDF.

My Workspaces
IACUC
Letter
Back

Reference Number:
IACUC-2019-059-NEW-1.0
Submission Type:
Submission Correction for
Initial Review Submission
Form
IACUC Number:
IACUC-2019-059
Study Number:
Enzyme-treated asparagus
extract (ETAS) restores
dysbiosis in APP-
overexpressed mice
Assign Analyst:

Approval Letter
Animal Research Committee

Today's Date: August 28, 2019

Any user assigned to sign off on a Submission Received Letter will receive a homepage task. Opening the Signoff task will open the letter in a new page. If the user signing the letter had been given rights to edit the letter, the letter on this page would display as an editable document within an embedded browser.

Once opened the user may deny or approve the letter by simply choosing to the Deny or Approve options from the drop-down list.

Copy a Letter

Letters can be copied to create a new Submission Received Letter based on a previously generated letter. This is generally done in the case that a letter was routed for signoffs and was denied in that process, or if a letter had been generated and sent but was later voided for an error. You can copy the existing letter and make any changes instead of re-creating the letter from scratch.

To copy the letter, click the **Copy** button.

Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:28 AM PDT		

A new version of the letter will be created and will display in the Submission Received Letter table. You will be able to Send the letter, edit the letter, and route it for signoff.

Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 2	No	Waiting to be sent		
			Letter Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:28 AM PDT		

Review Checklist and Comments

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Review Checklist and Comments
Review Summary

This area of the processing screens will contain information about any reviewer assignments for this submission. If reviewers have been assigned in the **Pre-review Screening** tab, a record will populate on this page displaying the review status for this assigned reviewer. Members can also access this portion of the submission to add any comments desired.

[Print Friendly](#)
[Add Member Checklist](#)
[Add Member Comments](#)
[Save the Review Status](#)

General Information Submission Components Correspondence Submission History Pre-review Screening Submission Received Notification Letter Review Checklist and Comments	Reviewer Check List i <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #0070c0; color: white;"> <th>View/Edit</th> <th>Reviewer Role</th> <th>Reviewer</th> <th>Completed ?</th> <th>Date Notified</th> <th>Date Completed</th> <th>Share Review with other Boards</th> </tr> </thead> <tbody> <tr> <td style="background-color: #f2f2f2;"></td> <td style="background-color: #f2f2f2;">Primary</td> <td style="background-color: #f2f2f2;">Reviewer, IACUC</td> <td style="background-color: #f2f2f2;">Yes</td> <td style="background-color: #f2f2f2;">08/28/2019</td> <td style="background-color: #f2f2f2;">08/28/2019</td> <td style="background-color: #f2f2f2;"></td> </tr> </tbody> </table> Member Check List i	View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards		Primary	Reviewer, IACUC	Yes	08/28/2019	08/28/2019	
View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards									
	Primary	Reviewer, IACUC	Yes	08/28/2019	08/28/2019										

Reviewer Check List

Any reviewer that was assigned on the Pre-Review Summary tab will display in this table. As the review board coordinator, you will be able to see the reviewer's status.

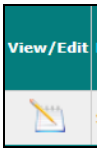


View/Edit – Depending on the status of the review, this column will change.



When you are viewing this page and the reviewer has not yet started their review, the column will display text indicating the form has not been started yet.

Once the reviewer begins the review, the column will update to display an open book icon. You can click on this icon to view a Read Only version of the reviewer checklist.



If you access this page as the reviewer, the icon in this column will appear as a notepad with a pen, meaning you can open your reviewer checklist from this page and fill it out.

Reviewer Role – Displays the role assigned to the reviewer.

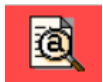
Reviewer – Displays the name of the reviewer.

Completed? – Indicates whether or not the reviewer is complete with the review. This column will either display “Yes” or “No.”

Date Notified – Displays the date the reviewer was notified of the review assignment.

Date Completed – If the “Completed?” status is “Yes,” the date the reviewer completed the review will populate in this column.

Share Review with Other Review Boards – You can choose to share this review with other involved review boards. Click



on the icon in this column to display a list of available review boards.

My Workspaces
IACUC
Setup the sharing of the Reviewer Form with other Boards

Select what Review Board(s) to share IACUC Reviewer reviewers form

- ☐ All
- ☐ Conflict of Interest Assistant
- ☐ Contracts Review Board
- ☐ Export Control
- ☐ IBC Board
- ☐ IRB

If another review board will be receiving this submission, you may share the review with that review board. Select the review board(s) from the list, and then click the **Save the Selections** button.

If you have selected to share the review with other boards, the column will update with a green background to indicate this particular review has been shared.

Reviewer Check List

View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards
	Primary	Reviewer, IACUC	Yes	08/28/2019	08/28/2019	

Member Check List

This section functions similar to the Reviewer Check List table. Any member of the Review Board can optionally fill out the same form the assigned reviewer fills out. This section can be turned on/off in Review Board Configuration > System

Setup under Board Configuration Options in the Submission Review Properties group using the `rb.use_member_checklist` property. See the IACUC Assistant – Review Board Properties manual for more information.

Any member wishing to complete a checklist can click on the **Add Member Checklist** button. This will open the Reviewer Checklist form, as defined in the System Form Designer.

The screenshot displays the IACUC Review Checklist form (Version 2.0). At the top, there is a header bar with 'My Workspaces' and a dropdown menu, 'IACUC Number: IACUC-2019-059', 'IACUC', and a 'Back' button. Below this is a navigation bar with tabs for 'Protocol Items', 'Miscellaneous', 'IACUC Items', and 'Submission Forms'. A row of buttons includes 'Print Friendly', 'Reviewer Panel', 'Save Section', and 'Save and Continue to Next Section'. The main content area is titled 'Section view of the Form' and 'Entire view of the Form'. The 'Reviewer Checklist Form' section is active, showing a form with two questions: 'The convened IACUC (or designated member reviewer) has adequate expertise to conduct review.' and 'The assigned reviewer has a Conflict of Interest.' Each question has 'Yes' and 'No' radio button options. Below the questions is a text prompt: 'Please Look all teh review components submitted withign the submission.' (Note: 'teh' and 'withign' are typos in the original image). At the bottom, there are four buttons: 'Compare Item(s)', 'Items in List View', 'Clear Viewed Item(s)', and 'Create PDF Packet'. A table at the very bottom contains links: 'Compare', 'Include in PDF Packet', 'Compare to Last Approved', 'View in Separate Window', 'Revisions', 'Current Submission Components (All Rounds)', and 'More Details'.

The board member can answer the same questions but will not have to indicate completion, as this is not a reviewer task but simply a form they are filling out.

When the form is finished, and the board member returns to the Review Checklist and Comments page, the Member Check List table populates with an entry. The member can access their checklist by clicking on the **Edit** icon.

Reviewer Check List 

View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards
	Primary	Reviewer, IACUC	Yes	08/28/2019	08/28/2019	

Member Check List 

Delete	Members Name
	Administrator

Member Comments 

No Comments entered

Member Comments

Any board member can add comments to the submission to be discussed at the meeting. This section can be turned on/off in Review Board Configuration – System Setup under Board Configuration Options in the Submission Review Properties group using the `rb.use_member_comments` property. See the IACUC Assistant – Properties manual for more information.

After clicking **Add Member Comments**, a text editor will appear with two options, allowing the user to decide how they would like the comments to be displayed. If the member wishes to keep the comments hidden from other board members, the **Display my comments on the review** checkbox should be deselected. If the board member wishes to post their comments for other board members, but wants to keep the comments anonymous, the **Display my name with the comments** checkbox should be deselected. Once comments are entered, click the **Save the comments** button to save the comments and return to the Reviewer Checklist and Comments page.

My Workspaces  IACUC Number: **IACUC-2019-059** IACUC **Member Comments**  Back

Save the comments

Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice - Comments for Administrator

☒ Display my comments on the review

☒ Display my name with the comments








Font Family
12















If the comments had been flagged as anonymous or hidden, only the user who added the comments would see their name and/or the comments displayed on this page.

Member Comments 


Administrator

Review Summary

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion

The Review Summary page will contain a summary of any comments added to any of the submission components and a summarized view of any reviewer checklists that have been completed. From this screen, you can choose to merge comments from the components or from the reviewer checklist into the Submission Discussion, into an Outcome Letter, or into a Stipulation.

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion

Review Summary - Agenda Number : 1 

Reviewer Checklist Form			
			Please answer all of the following:
☐	☐	☐	IACUC Reviewer * The convened IACUC (or designated member reviewer) has adequate expertise to conduct review. Yes * The assigned reviewer has a Conflict of Interest. Yes Please Look all teh review components submitted withn the submission.
☐	☐	☐	Administrator

When a reviewer has completed a Reviewer Checklist, the answers supplied in the form will be summarized here with three checkboxes next to each question. Also, any comments added to a submission component will be listed above any checklist summaries. Shown in the screenshot above are the summarized comments the reviewer had added to the Study Application and Other Study Document. The columns for the comments summary are as follows.

 - This column is used to flag comments to be merged into the Submission Discussion, the next tab in the Submission Processing Screens. Typically, any item that should be flagged for review at the meeting would be merged to the Submission Discussion.

 - This column is used to flag comments to be merged into an Outcome Letter when it is generated at a later time. Any item that should be communicated to the study in the formal letter would be merged.

 - This column is used to flag comments to be merged into a Stipulation. Any comment that originated from a submission item that is then merged into Stipulations will link the Stipulation to that item in the submission components. This is discussed in more detail in the Stipulation section below.

Below the components comment summary is listed the reviewer checklist summary. These are the questions and answers coming from the Reviewer Checklist. If more than one member has completed the checklist, they will be listed together in this view. The same three columns used to merge the comments are available here. Also listed is the name of the Reviewer and the Question and Answer from the Reviewer Checklist.

If you chose to merge any of the comments into the Submission Discussion, Outcome Letter, or Stipulation, click the check box next to the comment in the appropriate column, then click either the **Merge Comments into Stipulations** button, the **Merge Comments into Submission Discussion** button, or the **Save the Checklist Status** button. To merge comments into an outcome letter, the appropriate merge code needs to be used in the template.

Print Friendly
Merge Comments into Stipulations
Merge Comments into Submission Discussion
Save the CheckList Status

Review Summary - Agenda Number : 1 ?

Protocol Information

			Principal Investigator:
☐	☐	☐	Admin Admin admin, Ph.D. Brig. Gen.
☐	☐	☐	Randy Minarik, M.S. Brig. Gen.

Submission Discussion

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Review Checklist and Comments
Review Summary
Submission Discussion
Stipulation

Submission Discussion can be used to capture information related to the submission. These can be notes from the analyst or any discussion about the submission that takes place during a meeting. Items from the Reviewer Checklist can also be merged into the Submission Discussion. The Submission Discussion can then be merged into letters and meeting minutes.

My Workspaces


IACUC Number: **IACUC-2019-059**
PI: Investigator, John

IACUC

Submission Correction for Initial Review
Submission Form

 Back

Protocol Items

Miscellaneous

IACUC Items

Submission Forms

Ref Number:

IACUC-2019-059-NEW-1.0

IACUC Number :

IACUC-2019-059

Protocol Title :

Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status:

Pending - Submitted for Initial Review

Recommendation

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation

55

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
IACUC - Review Recommendation
Back
Save

Recommendation Editor

B
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x₂
x²
Verdana
11

Submission Editor

Stipulation

The Stipulations tab allows you to manage stipulations for the submission. You can create new stipulations and manage stipulations that were merged from the Review Checklist and Comments. Later, when you are processing a submission response or submission correction, you will be able to status a stipulation as closed or unmet.

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Review Checklist and Comments
Review Summary
Submission Discussion
Stipulation
Internal Submission

When you initially open this page, no stipulations will be added, unless they had been merged from Review Checklist and Comments.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

Print Friendly
Add Multiple
Add New
Add Pre-defined
Save and Update Stipulation

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments

Stipulations to be sent for Response ⓘ

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By	Link To Component
						Edited By	
No Stipulations entered							

Add a New Stipulation

You can add a new stipulation by clicking on the **Add New** button at the top right of the screen.

A new page will open allowing you to enter details for the stipulation. There are three parts of the stipulation: the Stipulation Type, associating components to the stipulation, and the Stipulation Content. The Stipulation Type and Stipulation Content are both required fields. You may choose to associate a submission component to the stipulation, if the stipulation is related to a submitted item.

Enter in the Stipulation Content. You can copy and paste from another source, or you can type in the stipulation, using the tools in the editor to format your stipulation text.

Choose a Stipulation Type from the dropdown list. There are three types available.

Stipulation must be addressed

This Stipulation Type is the most commonly used for a stipulation. A stipulation that must be addressed is a required change requested by the review board. Choosing this type of stipulation indicates to the study that this stipulation must be addressed before any further action can be taken on the submission.

Comments that must be addressed

Comments that must be addressed are stipulations that require a separate follow up due date. Any stipulation or recommendation from the board that can be addressed separately from the submission approval criteria would be given this type. When you select “Comments that must be addressed” from the drop down list, a date field will populate, allowing you to specify what the stipulation follow-up due date is.

Comments

*Stipulation Type:

Comments ▼

The Comments Stipulation Type is general recommendations set by the board. This type of stipulation requires no action from the study team.

Associating Components

After selecting a Stipulation Type, you may optionally choose to associate the stipulation to a submission component. Associating a component to a stipulation will attach the stipulation to that item, so when the study accesses the stipulations, iRIS will direct them to that submission component. This is helpful for stipulations that require the study to make changes to any attached submission form, application, or study document. Rather than search for their document or form to make changes, the stipulation will do the work for them.

Begin by clicking on the green icon **Attach Components to Stipulation** or click **Add Component(s)**.

Select the components to be modified with this stipulation:



Attach Component(s) to the Stipulation

No submission components have been associated yet. Please click on the green add button to associate your Stipulation(s).

Add Component(s)

A new window will open where you are able to specify the component association to the stipulation.

Select one of the three options to initiate the component link:

1. Associate Component Removal
2. Associate New Component
3. Associate Existing Component

Associate Submission Component(s) to your Stipulation



- Associate Component Removal** - This option will instruct Researchers that selected component(s) should be removed from future rounds of the submission.
- Associate New Component** - This option will display the submission components that satisfy a data value that allows attaching of Consent form, Study document, SubForm, etc..
- Associate Existing Component** - This option will display the existing components that are tied to the submission packet for stipulation association. If the component is a form select the Section and Question that the change is required.

Associate Component Removal

Associate New Component

Associate Existing Component

Detach	Mod. Request	Component Type	Component Name	Version
No Component Modification(s) have been linked				

Component Removal

To indicate that a specific document needs to be removed from the Submission, click the **Associate Component Removal** button. Clicking this button will direct you to a page that will list the existing documents attached to the submission. Select the component you would like to request to be removed from the submission and then click the **Add Link to Selection**, as shown in the screenshot below.

Associate Submission Component(s) to your Stipulation x

i **Removal -** Associate the removal of an existing component from the submission components for future rounds.

Return to List
Add Link to Selection

	Type	Component Name	Version
☐	Document -	Study Timeline	Version 1.0
☐	Document -Flyer	ACORP Diagram	Version 1.1

Once an item is associated for removal, you will be returned to the previous page with detail related to the Remove Attachment request. If you made an error associating the Remove Attachment request, you can delete it from the stipulation by clicking the icon in the Detach column. Note: the image in the **Mod. Request** column indicates that the request linked to this stipulation is a Remove Attachment request.

Associate Submission Component(s) to your Stipulation x

i **Associate Component Removal -** This option will instruct Researchers that selected component(s) should be removed from future rounds of the submission.

Associate New Component - This option will display the submission components that satisfy a data value that allows attaching of Consent form, Study document, SubForm, etc..

Associate Existing Component - This option will display the existing components that are tied to the submission packet for stipulation association. If the component is a form select the Section and Question that the change is required.

Associate Component Removal
Associate New Component
Associate Existing Component

Detach	Mod. Request	Component Type	Component Name	Version
	 Remove Attachment	Document -Flyer	ACORP Diagram	Version 1.1

New Component

To indicate that a specific Study Document needs to be added to the Submission, click the **Associate New Component** button. Clicking this button will direct you to a page that will list areas within the submission that contain document attachment data values. Select the component you would like to request to be added to the submission and then click the **Add Link to Selection** button, as shown in the screenshot below.

Associate Submission Component(s) to your Stipulation



New - Associate a New component that was not attached in the submission components.

Return to List

Add Link to Selection

Select	Component to Attach	Location to Attach (Form Name)
☐	Protocol Document	IACUC APPLICATION (ANIMALS)
	Section: Project Identification	Question: IACUC Funding Questions
☐	Protocol Document	IACUC APPLICATION (ANIMALS)
	Section: Animal Procurement and Maintenance Information	Question: Completed Experiment
☐	Protocol Document	Initial Review Submission Form

Once an item is associated to the stipulation, you will be returned to the previous page, with detail related to the Add Attachment request. If you made an error associating the Add Attachment request, you can delete it from the stipulation by clicking the icon in the Detach column. Note: the image in the **Mod. Request** column indicates that the request linked to this stipulation is an Add Attachment request.

Associate Submission Component(s) to your Stipulation



Associate Component Removal - This option will instruct Researchers that selected component(s) should be removed from future rounds of the submission.

Associate New Component - This option will display the submission components that satisfy a data value that allows attaching of Consent form, Study document, SubForm, etc..

Associate Existing Component - This option will display the existing components that are tied to the submission packet for stipulation association. If the component is a form select the Section and Question that the change is required.

Associate Component Removal

Associate New Component

Associate Existing Component

Detach	Mod. Request	Component Type	Component Name	Version
	 Add New Attachment	Study Document	Attach a Study Document to the IACUC APPLICATION (ANIMALS)	

Associate New Component- Components Not included in the Submission Form

To indicate that a specific Study Document needs to be added to the Submission, click the **Associate New Component** button. At the bottom of the window, you can select a list of components that were not included in the submission form. Select the component you would like to request to be added to the submission and then click the **Add Link to Selection** button, as shown in the screenshot below.

Associate Submission Component(s) to your Stipulation

**New** - Associate a New component that was not attached in the submission components.[Return to List](#)[Add Link to Selection](#)

Select	Component to Attach	Location to Attach (Form Name)
☐	Protocol Document	Study Amendment Form
	Section: Revised Materials	Question: * Revised material includes:
☐	Protocol Consent	Study Amendment Form
	Section: Revised Materials	Question: * Revised material includes:

The following components(s) are not included in the submission form:

Select	Component(s) Not included in the Submission Form:
☐	Protocol Application

Once an item is associated to the stipulation, you will be returned to the previous page, with detail related to the Add Attachment request. If you made an error associating the Add Attachment request, you can delete it from the stipulation by clicking the icon in the Detach column. Note: the image in the **Mod. Request** column indicates that the request linked to this stipulation is an Add Attachment request.

Modify Existing

To indicate that a specific Submission Form, Study Application, or Study Document currently attached to the submission needs to be modified, click the **Associate Existing Component** button. Clicking this button will direct you to a page that will list all items currently attached to the submission (including the submission form itself). Select the component you would like to request to be changed and then click the **Add Link to Selection**, as shown in the screenshot below.

If you select a form to include, additional Section and Question information will populate on the page, allowing you to specify exactly what question needs to be modified.

Associate Submission Component(s) to your Stipulation

**Existing** - Associate an existing component from the submission components for stipulation association. If the component is a form select the Section and Question that the change is required.[Return to List](#)[Add Link to Selection](#)

	Type	Component Name	Version
☐	Submission Form	Initial Review Submission Form	Version 1.0
☐	Application	IACUC APPLICATION (ANIMALS)	Version 1.1
☐	Document -	Study Timeline	Version 1.0
☐	Document -Flyer	ACORP Diagram	Version 1.1

Once an item is associated to the stipulation, you will be returned to the previous page with detail related to the Modify request. If you made an error associating the Modify request, you can delete it from the stipulation by clicking the icon in the Detach column. Note: the image in the **Mod. Request** column indicates that the request linked to this stipulation is a Modify request.

Associate Submission Component(s) to your Stipulation X

Associate Component Removal - This option will instruct Researchers that selected component(s) should be removed from future rounds of the submission.

Associate New Component - This option will display the submission components that satisfy a data value that allows attaching of Consent form, Study document, SubForm, etc..

Associate Existing Component - This option will display the existing components that are tied to the submission packet for stipulation association. If the component is a form select the Section and Question that the change is required.

Associate Component Removal
Associate New Component
Associate Existing Component

Detach	Mod. Request	Component Type	Component Name	Version
	 Modify Existing Attachment	Application	IACUC APPLICATION (ANIMALS)	Version 1.1
Stipulation placed at Section: General Information Question:				

After you are done creating your component associations, click **Done**. You will be directed back to the stipulation content page where you can make any changes to the stipulation content, attach additional components, and verify already-attached components. Once you are done with this page, click the **Save the Stipulation** button located in the upper right-hand corner of the screen.

Note: In the example below, multiple request types have been associated to one stipulation. You have the ability to add as many request types as needed to each stipulation, or you can create one stipulation for each request type.

My Workspaces

IACUC Number: **IACUC-2019-059**
 PI: Investigator, John

IACUC

Review Stipulation

Back

Save the Stipulation

Stipulation Information:

***Stipulation Type:**
 Stipulation must be addressed ▼

Select the components to be modified with this stipulation:

Attach Component(s) to the Stipulation

Request to Remove Attachment
 ACORP Diagram Version 1.1
 Document -Flyer

Request to Add New Attachment
 Attach a Study Document to the IACUC APPLICATION (ANIMALS)
Section: Project Identification
Question: IACUC Funding Questions

*** Stipulation Content**

B *I* U ~~S~~ x_2 x^2 Verdana 11

Remove VAS attachment

After saving this page, you will be returned to the Stipulation tab of the submission processing screens. Any stipulations that have been created will be listed on the stipulations tab. The green color in the **Link to Component** column indicates that the stipulation has been linked to a component in the submission.

Note: The Study Side will respond to stipulations using either the Return Response Form or the Pre-Review Correction Form (depending on how the stipulations were returned to the study from the Review Board). There are specific Data Values that must be entered into the Return Response forms that will allow this feature to function correctly. The setup of these data values can be reviewed by reviewing the System Administration – System Forms Designer manual.

After saving the Stipulation, you will return to the Stipulations tab and the stipulation will display in the table. The following fields display for stipulations added to the submission.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC

Submission Correction for Initial Review
Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

Print Friendly
Add Multiple
Add New
Add Pre-defined
Save Stipulation

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments

Stipulations to be sent for Response

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By Edited By	Link To Component
		1	Stipulation must be addressed	N/A	Remove VAS attachment	Administrator (08/28/2019) Administrator (08/28/2019)	

Delete - You can delete a stipulation by clicking icon in this column.

Edit – Click this icon to open the stipulation for editing. You will be able to change the Stipulation Type, Associated Components, and Stipulation Content.

Sorting Number – Stipulations can be reordered based on the numbering here.

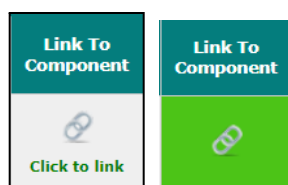
Stipulation Type – This column displays the Stipulation Type selected for the stipulation.

Follow-up Due – If the Stipulation Type is “Comments that must be addressed”, the Follow up Due Date provided will display here. For the other two Stipulation Types, “Stipulation must be addressed” and “Comments”, N/A will display.

Stipulation – The Stipulation Content will display here.

Requested By – The information in this column indicates the creator of the stipulation as well as the last user to edit the stipulation.

Link to Component – If you have linked components to the stipulation, this column will appear with a green background. You can select the image in this column to change the association. If the stipulation does not have components associated, the background will display without the green color. You can click on the icon to associate components.



Add Multiple Stipulations

If you have more than one stipulation to add, you can choose to add them all at once by clicking on the **Add Multiple** button.

This is a tool used generally when you have a list of stipulations in a Word document. You can copy and paste the stipulations into the editor provided, add the Stipulation Type and then save the page to add all stipulations at once.

My Workspaces ▼

IACUC Number: **IACUC-2019-059**
PI: Investigator, John

IACUC

Review Stipulation

***Stipulation Type:**
Stipulation must be addressed ▼

By Posting from MS Word a number formatted list of Stipulation iRIS will convert the list into multiple stipulation records.
***Content**
Stipulation 1
Stipulation 2
Stipulation 3

Each stipulation added will be listed as a separate record.

Stipulations to be sent for Response ⓘ

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By Edited By	Link To Component
		2	Stipulation must be addressed	N/A	Stipulation 1	Administrator (08/28/2019) Administrator (08/28/2019)	 Click to link
		3	Stipulation must be addressed	N/A	Stipulation 2	Administrator (08/28/2019) Administrator (08/28/2019)	 Click to link
		4	Stipulation must be addressed	N/A	Stipulation 3	Administrator (08/28/2019) Administrator (08/28/2019)	 Click to link

Add Pre-Defined

If you have a list of commonly used stipulations, you can define a list in Review Board Administration > List Maintenance Setup > Predefined Stipulations.

When you click on the **Add Pre-defined** button, a new page will open listing the available pre-defined stipulations. Check off which stipulations you would like to add and click the **Save Selected Stipulations for Study** button.

My Workspaces
IACUC Number: **IACUC-2019-059**
IACUC
Review Stipulation
Back

Save Selected Stipulations for Protocol

List of approved canned Stipulation

1 result(s) found...

Stipulation
☐ Please correct the your species in the applictation

The pre-defined stipulations will be added to the submission, creating a separate stipulation record for each pre-defined stipulation you add. You can modify the stipulation by clicking on the **Edit** button. You may also link the stipulations to components using the **Link To Component** column.

Merge From Review Summary

In the **Review Summary** tab, you are able to flag comments that can merge into the Stipulations tab.

Stipulations to be sent for Response							
Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By Edited By	Link To Component
		1	Stipulation must be addressed	N/A	Please correct the your species in the applictation	Administrator (08/28/2019) Administrator (08/28/2019)	 Click to link

If a comment was made within a submission component, it will be listed in the **Reference** column. The example above shows several comments that were made in the Study Application form. When these comments are merged into stipulations, the link to the Study Application will pull over as well, so when the study responds to the stipulation, they will be directed to that component.

In the Review Summary tab the column is used to flag comments to be merged into a Stipulation. Click the checkbox next to any comment that you would like to merge into stipulations then click the **Merge Comments into Stipulations** button.

Print Friendly
Merge Comments into Stipulations
Merge Comments into Submission Discussion
Save the CheckList Status

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation

Review Summary - Agenda Number : 1

Reviewer Checklist Form
Please answer all of the following:
☐ ☐ ☒ IACUC Reviewer
* The convened IACUC (or designated member reviewer) has adequate expertise to conduct review.
Yes
* The assigned reviewer has a Conflict of Interest.
Yes
Please Look all teh review components submitted withign the submission.
☐ ☐ ☒ Administrator
* The convened IACUC (or designated member reviewer) has adequate expertise to conduct

A stipulation record will be created for each comment merged into stipulations. If the comment originated from a submission component, the **Link to Component** column will reflect the association. You can modify the stipulation by clicking on the **Edit** button and change the components association by clicking the icon in the **Link to Component** button.

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By	Link To Component
						Edited By	
		1	Stipulation must be addressed	N/A	Please correct the your species in the applictation	Administrator (08/28/2019) Administrator (08/28/2019)	

Stipulation Responses

The stipulations created will be added into the Review Response Form, when the submission is returned to the study for corrections. The Principal Investigator or designated personnel will need to address the stipulations within the Review Response Form. Once the study team has made the required changes, they will need to resubmit the form to the IACUC.

When the study responds to stipulations and returns the submission to the review board, the responses to the stipulations will populate in the Stipulation tab.

When stipulations are returned, you will be able to review the stipulation responses and then either close/accept the stipulation. You can also indicate if a stipulation is not adequately addressed and copy it to a new stipulation to return back to the study again.

Click the icon in the **Edit** column to open details about the Stipulation Response.

By clicking the icon in the Edit column, it will open a Process Stipulation page. From this area you can choose a **Review Action** and provide a date that the stipulation was closed in the **Date Closed** field. You would only supply a date if the stipulation is closed.

My Workspaces
IACUC Number: **IACUC-2019-059**
IACUC
Process Stipulation
Back

Protocol Status: Pending - Submitted
IACUC Number : IACUC-2019-059
Protocol Title : Enzyme-treated asparagus extract (ETAS) restores dvsbiosis in APP-overexpressed mice

Add Memo
Save Stipulation

Review Board Action:	--none--
Review Board Date Closed:	04/26/2019
Stipulation Type:	Stipulation must be addressed
Follow-up Due:	
Stipulation:	Modify Existing Application
Response Acknowledge:	Yes
Response Statement:	cahnged

Edit	Name	Date Modified	Memo Details
No Memos have been added			

You can also add memos to the stipulation. Click the **Add Memo** button. A new page will open, allowing you to enter the text for the memo. Click the **OK** button when you are done.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
IACUC - Stipulation Memo
Back
Save

Stipulation Memo

B I U S x₂ x² Verdana 11
Memo text.

The memo will add to the stipulation record. Memos allow you to keep a log of comments from different review board users with information specific to the stipulation. When you are finished setting information on this page, click the **Save Stipulation** button to return to the submission processing screens.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Process Stipulation
Back

Protocol Status: Pending - Submitted
IACUC Number : IACUC-2019-059
Protocol Title : Enzyme-treated asparagus extract (ETAS) restores

Add Memo
Delete Memo
Save Stipulation

Review Board Action:	--none--
Review Board Date Closed:	04/26/2019
Stipulation Type:	Stipulation must be addressed
Follow-up Due:	
Stipulation:	Modify Existing Application
Response Acknowledge:	Yes
Response Statement:	cahnged

Edit	Name	Date Modified	Memo Details
	Administrator	04/26/2019	Closed by submission

Returning to the Stipulation tab, you can also set the Review Action and the Date Closed for each stipulation. If you set the action to a stipulation that indicates the stipulation is not accepted and then save the page, the system will copy that stipulation record into a new stipulation to be returned to the study. The example below shows a stipulation given the action of "Not Met." When the page is saved, a stipulation record is created in the list of current stipulations to be sent to the study.

Stipulations to be sent for Response ⓘ

Delete	Edit	Sorting Number	Stipulation Type	Stipulation Category	Follow-up Due	Stipulation	Created By	Link To Component
							Edited By	
		1	Stipulation must be addressed		N/A	Please correct the your species in the application	Administrator (08/28/2019) Administrator (08/28/2019)	

Stipulations with the responses from the previous submission ⓘ

IACUC									
Order	Edit	Review Action	Date Closed	Stipulation Type	Stipulation Category	Created By	Follow-Up By	Response Ack	View Stipulation Component
		None ▼					Completed By		
The Submission was Received 04/25/2019 and completed 04/25/2019									
1		--none-- ▼	07/11/2019	Stipulation must be addressed		Administrator (04/25/2019)	N/A Investigator, John 04/25/2019 02:56:08 PM UTC	Yes	
Stipulation: Modify Existing Application									

You can set the Review Outcome for all stipulations at once. At the top of the table in the **Review Action** column is a dropdown list that, when an option is selected, will apply to the rest of the stipulations on the page.

After selecting the Review Action at the top of the table, the action will be applied to all stipulations.

You can then add the Date Closed for the stipulations. If you do not enter a date, when you save the Stipulations page, the system will insert today's date. The stipulations you mark as "Accepted" will close out in the system.

Stipulations with the responses from the previous submission ⓘ

IACUC									
Order	Edit	Review Action	Date Closed	Stipulation Type	Stipulation Category	Created By	Follow-Up By	Response Ack	View Stipulation Component
		None ▼					Completed By		
The Submission was Received 04/25/2019 and completed 04/25/2019									
1		Approved	04/26/2019	Stipulation must be addressed		Administrator (04/25/2019)	N/A Investigator, John 04/25/2019 02:56:08 PM UTC	Yes	
Stipulation: Modify Existing Application									
Response:									

You can view the change made the stipulation by clicking on the **View Stipulation Component** icon. Once selected, a window will open displaying the component with the changes made. The window will immediately open to the specific section that was associated to the stipulation.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
IACUC APPLICATION (ANIMALS) (Version 1.1)
Back
Print Friendly

Section view of Application
Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 **Form Information**
5.0 Project Identification
6.0 Personnel Identification and Qualifications
7.0 Use of Privately Owned Animals
8.0 Project Description and Procedures
9.0 Drug/Agent Administration

4.0

NOTE: The IACUC recommends investigators contact the Attending Veterinarian during the planning of the project if animal procedures have the potential to cause more than momentary pain or distress.

If you encounter problems with completing the form, please contact the Animal Welfare Office (IACUC office):
Email: animalcompliance@imedris.com
Phone: 979-845-1828

4.1 Current AUP (automatic number may not initially populate):

IACUC-2019-059

Internal Routing

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Vote

The Internal Submission Routing tab within a submission is a very useful tool for review board Analysts, who can use this tab to route the submission internally, any number of times, all at once. Internal Routing can be used to show a Chairperson a specific submission or to have a specialty reviewer review the submission.

The Internal Routing tab contains a table that first lets you define any notes to pass on to anyone you select for routing. Click the **Assignment notes** link to add these notes.

Underneath the assignment notes is a “Yes/No” selection. This is defaulted to “No”. After you select your routing personnel, make sure you set the selection to “Yes,” and then click the **Save Routing List** button.

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Submission Received Notification Letter

Review Checklist and Comments

Review Summary

Submission Discussion

Recommendation

Stipulation

Internal Submission Routing

Vote

Internal Review Routing ⓘ

Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Reference Number: IACUC-2019-059-NEW-1.0

Submission Type: Submission Correction for Initial Review Submission Form

Assigned Analyst: Coordinator, IACUC

Assignment notes:

Have you completed your selection of required routings?

☐ Yes
☒ No

Order Number	Click to review	Assignment Comments	Date Notified	Date Completed
		Assigned To		
		User Comments		
No Submission Routing entered				

You can compile a list of users needed to complete an internal signoff on the submission. Review Board Members can be added by clicking the **Add Review Board Routing** button. This will create a row that allows you to choose from a drop down list of members on the Review Board.

Order Number	Click to review	Assignment Comments	Date Notified	Date Completed
		Assigned To		
		User Comments		
✖	0	Assignment Comments: --none-- --none-- Administrator Boardmember Chair, Department Coordinator, Jane Coordinator, IACUC Reviewer, Luke, Ph.D		

Non-Review Board members can be added by clicking the **Add Non-Review Board Routing** button. A new page will open, allowing you to use the Search User Directory screen where a user can be searched and added to the routing.

My Workspaces ▾ IACUC
Search User Directory
⏪ Back

Directory Browse/Find:

Last Name: (You may enter a partial name to search)

First Name:

by Department:

Check for Multiple	Select User	Training	User Name	Department	Email
☐	✔		Administrator	General Hospital (primary) [+]	admin.administrator@imedris.net

Any users added to the routing will be listed in order. You can assign reviewer-specific assignment notes to each user. These comments would appear to the assigned user in addition to the assignment notes and would be private to the assigned user only. Click the **Assignment Comments** link above the user’s name.

Add Review Board Routing

Add Non-Review Board Routing

Print Friendly

	Order Number	Click to review	Assignment Comments		
			Assigned To	Date Notified	Date Completed
			User Comments		
	0		Assignment Comments: Chair, Department User Comments:		
	1		Assignment Comments: Administrator User Comments:		

A text editor will open allowing you to type in or copy and paste your comments. Click the **OK** button after adding your comments.

Enter the user comments.

Font Family 12

Cancel

Apply

Your comments will populate to the right of the **Assignment Comments** link. These comments are specific to the user and will populate in the assignment when the user opens their task.

	Order Number	Click to review	Assignment Comments		
			Assigned To	Date Notified	Date Completed
			User Comments		
	0		Assignment Comments: Chair, Department User Comments:		
	1		Assignment Comments: Administrator User Comments: The outcome letter needs your review.		

Once you have selected the appropriate users and added your comments, select “Yes”, to the **Have you completed your selection of required routings?** field and click the **Save Routing List** button. This will cause an email notification to be sent (if this notification is configured in the Review Board Administration) to the user with the *smallest order number* in the list. If the list is not marked as Complete in the Internal Submission Routing tab and Saved, the email notification will not be sent. When the user with the lowest order number completes the assigned routing, the next user in the order on the list will be notified for signoff. This process will continue until the list is completed. Users with the same order number will be notified at the same time.

Additionally, if you delete a user that has already been notified, the user with the next order number will be notified. This allows you to keep the submission moving, in the event a user does not signoff in a timely manner.

Internal Routing Task

When a user is notified of an Internal Routing Signoff assignment and they log in to iRIS, there will be a home screen task under the **All Task**.

All Tasks			
Outstanding		Completed	
All Tasks		Study Tasks	
Project Tasks		Task List: Internal Submission Routing Signoff	
1 result(s) found... 1 - 1			
Click to open	Task Type	Received	Description
	Internal Submission Routing Signoff	08/16/2019 09:20 AM PDT	Admin Admin admin, Ph.D. Brig. Gen. has been assigned to Administratively review the submission, assigned by Admin Admin admin, Ph.D. Brig. Gen.

This will open a Submission Validation page. The page will list the Submission and its elements defined in the Submission Processing Screens including the Submission Components, Assigned Reviewers and the ability to view their checklists, Submission Discussion, Stipulations, Outcome information, Species and other IACUC details related to the study, Outcome Letters generated for the review, and finally, at the end of the page, the Internal Submission Routing information.

After the user reviews each of these items, they can scroll to the bottom of the page to finish the review.

My Workspaces
IACUC Number: **IACUC-2019-059**
IACUC
Submission validation
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

Protocol Status: Pending - Submitted for Initial Review

Submission components:

Compare Item(s)
Items in List View
Clear Viewed Item(s)
Create PDF Packet

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)						
☐	☐				IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐				Initial Review Submission Form - (Version 1.0)	
Application						
☐	☐				IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)						
☐	☐				Study Timeline - (Version 1.0 approved on 08/27/2019) *Added by the IACUC.	
Category : Flyer						
☐	☐				ACORP Diagram - (Version 1.1 approved on 08/27/2019) *Revision created by the IACUC.	

From the Submission Routing area, the user can indicate whether or not they are finished with the review. They can also add additional routing if needed or remove another routing task if needed.

If the user needs to comment back to the Analyst, they can click on the **User Comments** button.

Before the task can be moved from the user's home page, the user must indicate "Yes" in the **Completed** column and click on the **Save Routing** button.

Internal Submission Routing:

Add Routing
Remove Routing
Save Routing

Submission Routing.

Assigned Analyst : Coordinator, IACUC

Assignment notes :

Assignment comments

Assigned To	Assigned From	Date Notified	Completed ?	Date Completed
User comments				
Assignment Comments:				
Administrator	Administrator	08/28/2019	Complete: ☐ Yes ☒ No	
User Comments:				

When all the users assigned to the Internal Routing have completed their routing assignments, the analyst of the submission receives a notification from the system as well as a home screen task. When the task is opened, the analyst will be returned to the Internal Routing tab.

After clicking the task on the home page, you can see when the users completed their assignments and if they had left any comments. You will also be able to add additional users to the routing, if needed.

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Vote
Outcome

Internal Review Routing

Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Reference Number: IACUC-2019-059-NEW-1.0
Submission Type: Submission Correction for Initial Review Submission Form
Assigned Analyst: Coordinator, IACUC

Assignment notes:
Have you completed your selection of required routings?
☒ Yes
☐ No

Add Review Board Routing
Add Non-Review Board Routing
Print Friendly

Order Number	Click to review	Assignment Comments		
		Assigned To	Date Notified	Date Completed
0		Assignment Comments:		
		Administrator	08/28/2019	08/28/2019
		User Comments: comments.		

Vote / Expedited By / Acknowledged By

General Information	General Information	General Information
Submission Components	Submission Components	Submission Components
Correspondence	Correspondence	Correspondence
Submission History	Submission History	Submission History
Pre-review Screening	Pre-review Screening	Pre-review Screening
Review Checklist and Comments	Review Checklist and Comments	Review Checklist and Comments
Review Summary	Review Summary	Review Summary
Submission Discussion	Submission Discussion	Submission Discussion
Stipulation	Stipulation	Stipulation
Internal Submission Routing	Internal Submission Routing	Internal Submission Routing
Vote	Expedited by	Acknowledged By
Outcome	Outcome	Outcome
Outcome Letter	Outcome Letter	Outcome Letter
Submission Complete	Submission Complete	Submission Complete

Depending on the review process set on the Pre-review Screening tab for this submission, one of the above tabs may display. If you have assigned the submission for a full board review, the **Vote** tab will appear. Expedited submissions will have the **Expedited By** tab and any Exempt submissions will display the **Acknowledged By** tab.

Vote

The Vote tab allows you to capture the meeting vote for a full board review submission.

You can capture the vote at the time of the meeting, or any time afterwards but before you complete the submission processing. Start by clicking the **Add Motion** button.

My Workspaces	IACUC Number: IACUC-2019-059 PI: Investigator, John	IACUC	Submission Correction for Initial Review Submission Form	Back
Protocol Items	Miscellaneous	IACUC Items	Submission Forms	
Ref Number: IACUC-2019-059-NEW-1.0	IACUC Number: IACUC-2019-059	Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice		
Protocol Status: Pending - Submitted for Initial Review				

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Vote

Meeting Vote ⓘ
No Motions have been added.

A new page will open with a text editor where you can type in or copy and paste a motion. You can also use pre-canned motions by selecting a template from the **Pre-canned Motion text** dropdown list; then click the **Add Canned Language** button. The Pre-canned language for the motions can be set up in Review Board Administration > System Setup > Setup Canned Motion.

Once your motion is defined in the text editor, click on the **Save Changes** button.

My Workspaces	IACUC	Submission Motion	Back
		Save Changes	

"Precanned Motion text" allows you to import text from a pre-defined template.

Precanned Motion text: --none--

B I U S x₂ x² Font Family 12

List, Indent, Decrease Indent, Increase Indent, Link, Image, Unlink, Print, Undo, Redo

Meeting Attendance will need to be set before voting can take place. If attendance has not been set, voting board members will not display on this page. Once the attendance on the meeting has taken place, any voting member marked as present at the meeting will be listed here.

The vote type can be selected in the **Vote** column next to each **Members Name**. Each member's **Gender, Specialty, Relationship to the Institution, Affiliation, Representational Capacity, and Representative of Specific Entity** information can also be found under the corresponding columns.

After the votes for the motions have been set, select the **Save the Members Vote** button. The vote will be saved and can be used to merge into the outcome letters and meeting minutes templates (see the Review Board Administration manual).

Meeting Vote 




Vote	Member Name	Gender	Specialty	Relationship to the Institution	Affiliation	Representational capacity	Representative of specific entity
For ▼	Chair, Department						
Comments:							
For ▼	Reviewer, IACUC						
Comments:							
For ▼	Reviewer, Luke, Ph.D			Affiliated			
Comments:							

Anonymous Voting

Depending on your Review Board Configurations, the motion you added may or may not be set for anonymous voting. For more details on setting this configuration, please refer to the IACUC - Review Board Properties manual. The property `rb.use_submission_vote_summary` can be found within Review Board Assistant – Board Configuration Options – Submission Review Properties.

If anonymous voting is setup, then the screen will appear similar to the screenshot below.

Enter the number of members who voted according to each Vote Type in the corresponding Number text field. Add any comments, if desired. After you have finished entering votes, click **Save the Vote Summary**.

Add Motion

Save the Vote Summary

Meeting Vote 




Main Full Board Vote:

A motion was made and seconded to renew approval of this study for one year with the current stamp/approved Documents. A vote was taken and the motion was approved.

Number	Vote Type	Comments
0	For	
0	Absent	
0	Against	
0	Abstain	
0	Conflict of Interest	
0	Not present for Vote	

Expedited By

If the submission has been processed as an Expedited Review, this tab will display as **Expedited By**. In addition to assigning an Expedited Reviewer in the Pre-review Screening tab, you can also indicate here who the submission will be expedited by.

This page will display review board members. Next to each member's name there will be a checkbox in the **Expedited** column. By checking the checkbox next to the appropriate member(s), you will indicate the board member's approval or acknowledgement, on the process of the submission.

If you make any changes to this page, click the **Save the Acknowledgement** button on the top right corner.

Save the Acknowledgement

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Submission Received Notification Letter

Review Checklist and Comments

Review Summary

Submission Discussion

Recommendation

Stipulation

Internal Submission Routing

Expedited by

Outcome

Outcome Letter

Submission Complete

Expedited by i

Expedited	Member Name	Gender	Specialty	Relationship to the Institution	Affiliation	Representational capacity	Representative of specific entity
☐	Administrator		Anesthesiology	Affiliated	iMedRIS Affiliation 2C		
☐	Boardmember						
☐	Chair, Department						
☐	Coordinator, ARC	Male					
☐	Coordinator, IACUC						
☐	Coordinator, Jane			Affiliated			
☐	Investigator, IACUC	Female		Affiliated		Scientist	
☐	Mossman, Nathan						
☐	Reviewer, IACUC						
☐	Reviewer, Luke			Affiliated			
☐	Sandbox, Beaumont						
☐	Transfer, ARC	Female		Affiliated		Scientist	
☐	Veterinarian, ARC	Male		Affiliated		Scientist	

Acknowledged By

If the submission has been set to **Exempt** the tab will read as **Acknowledged By**.

This page will display review board members. Next to each member's name there will be a checkbox in the **Acknowledged** column. By checking the box next to the appropriate member(s), you will indicate the board member's approval or acknowledgement, on the process of the submission.

If you make any changes to this page, click the **Save the Acknowledgement** button on the top right corner.

General Information	Acknowledged by:							
Submission Components	Acknowledged	Member Name	Gender	Specialty	Relationship to the Institution	Affiliation	Representational capacity	Representative of specific entity
Correspondence	☐	Administrator		Anesthesiology	Affiliated	iMedRIS Affiliation 2C		
Submission History	☐	Boardmember						
Pre-review Screening	☐	Chair, Department						
Submission Received Notification Letter	☐	Coordinator, ARC	Male					
Review Checklist and Comments	☐	Coordinator, IACUC						
Review Summary	☐	Coordinator, Jane			Affiliated			
Submission Discussion	☐	Investigator, IACUC	Female		Affiliated		Scientist	
Recommendation	☐	Mossman, Nathan						
Stipulation	☐	Reviewer, IACUC						
Internal Submission Routing	☐	Reviewer, Luke			Affiliated			
Acknowledged By	☐	Sandbox, Beaumont						
Outcome	☐	Transfer, ARC	Female		Affiliated		Scientist	
	☐	Veterinarian, ARC	Male		Affiliated		Scientist	

Outcome

Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Vote
Outcome
Outcome Letter
Submission Complete

On the Outcome tab, you can set the review outcome of the submission. Depending on the settings of your software and the review process, the features on this tab may vary.

When you are processing an item that has been given the Review Process of “Pre-review changes requested”, the Outcome tab will simply contain the ability to modify the overall status of the study. Often, before returning an Initial Review submission to a study for corrections, the review board will change the study status to something that will indicate the study is currently undergoing revisions.

If you modify the study status, click the **Save the Submission Outcome** button before proceeding.

[Save the Submission Outcome](#)

General Information Submission Components Correspondence Submission History Pre-review Screening	IACUC Review Outcome ? Protocol Status: Pending - Submitted for Initial Review
--	--

When you are processing an item that has been placed on a full board meeting, you would come to the Outcome tab when you are ready to enter the outcome information based on the review. If the process was Expedited, Exempt, or Process Administratively, you would come to this page when you are ready to set the outcome information.

The Outcome tab allows you to set the outcome information for the submission. You will also be able to manage certain aspects of the study record from this screen.

[Save the Submission Outcome](#)

General Information Submission Components Correspondence Submission History Pre-review Screening Submission Received Notification Letter Review Checklist and Comments Review Summary Submission Discussion Recommendation Stipulation Internal Submission Routine	IACUC Review Outcome ? Review Outcome: --none-- Additional information required: Yes Follow-up Due: Internal Comments: Shared Comments: Take Note: Protocol Status: Pending - Submitted for Initial Review Assign the Submission to Agenda: Committee Name: --none-- or Meeting Date: --none-- click here to select past meetings Agenda Category: --none--
--	--

IACUC Review Outcome

The first portion of the **Outcome** tab contains submission approval information.

You select the **Review Outcome** from the drop down list. This is a configurable list defined in Review Board Administration. Depending on what outcome you select, you can control whether or not the submission is approved, not approved, or needs to be returned to the study for a review response.

IACUC Review Outcome ?

Review Outcome:

--none--

Additional information required: Yes

Follow-up Due:

Protocol Status:

Pending - Submitted for Initial Review

Assign the Submission to Agenda:

Committee Name:

--none--

or

Meeting Date:

--none--

[click here to select past meetings](#)

Agenda Category:

--none--

Approval Outcomes

To approve a submission, select the appropriate approval outcome from the **Review Outcome** drop down list.

Additional Information required will display “No”. Enter the **Submission Approval** date. This is the date the submission is approved. You would also want to change the **Study Status** to the appropriate status. When the review board sets the

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Study Status, the system will grant certain allowances to the study personnel. This is dependent on the settings for the Study Status configuration, as defined in Review Board Administration.

If you select an Outcome that will return the submission to the study, the column for **Additional information required** will flip from “No” to “Yes.” “No” indicates that when you complete this submission, it will complete out in the workflow. “Yes” will indicate the submission will return to the study for any requested stipulations by the review board.

If you are approving the submission, enter in the **Submission Approval** date. If you have selected an outcome that requires additional information, this field will change to read **Follow-up Due**. You can enter the date the response is due back in to the review board submission queue.

IACUC Review Outcome ⓘ

Review Outcome:	Approved ▼	Protocol Status:	Open ▼
Additional information required:	Yes		
Follow-up Due:	08/22/2019 		

Denial Outcomes

If the submission is denied, you can set denial information in the Outcome tab.

Choose the appropriate **Review Outcome**. Leave the **Submission Approval** field empty and change the **Study Status** to a denied type of status.

Review Outcome:	Denied ▼	Protocol Status:	Declined - Acceptance ▼
Additional information required:	Yes		
Follow-up Due:			

Additional Information Required

When a submission needs to be returned to the study after a meeting, you would set the process in the **Outcome** tab, rather than go to the **Pre-review Screening** tab to set the Review Process to Pre-review Changes Requested. If you change the Review Process once a submission has been processed on an agenda for full board review, you may lose reviewer assignments and the information regarding the submission on the meeting.

Set the **Review Outcome** to indicate changes requested. When you select an outcome marking the return to the study, **Additional information required** will change to “Yes”. This means when you complete the submission, a Submission Response form will generate and send to the study, containing Stipulations and the Submission Components.

If the review board has set a follow up due date, enter that date in the **Follow-up Due** field. You can change the **Study Status** if that is a requirement of your board.

Review Outcome:	Approved - Pending Changes ▼	Protocol Status:	Pending - Submitted for Initial Review ▼
Additional information required:	Yes		
Follow-up Due:			

For Expedited, Exempt, or Administratively Processed submissions, when you are entering the Outcome information, you will be able to assign the submission to an agenda.

Review Outcome:	--none-- ▼	Protocol Status:	Pending - Submitted for Initial Review ▼
Additional information required:	Yes		
Follow-up Due:			
Assign the Submission to Agenda:		Committee Name: --none-- ▼ Meeting Date: --none-- ▼ or click here to select past meetings Agenda Category: --none-- ▼	

Comments

Below the submission outcome information is a comments area for the submission. There are three types of comments, Internal Comments, Shared Comments, and Take Note.

To enter comments that will be viewable for the current review board only, select the **Internal Comments** link. A text editor will be displayed, allowing you to edit or add any comments. To enter comments that will be viewable for all Review Boards that have access to this study, select the **Shared Comments** link. A text editor will be displayed, allowing you to edit or add any comments.

 Internal Comments:	
 Shared Comments:	
Take Note:	

There is also a feature allowing you to enter a **Take Note** item. A pop-up with the Take Note text will open every time a submission is opened for that particular study. For example, if a certain document that is normally included in the Full Renewal Form is submitted with the Initial Review, the Coordinator can create a Take Note reminder, so that when the Full Renewal is submitted, the note will pop-up when the Coordinator begins to process the submission.

Study Information

After you add the submission approval information and any necessary comments, you can then go on to set study-specific information. Listed below are the standard options available. When you are approving an Initial Review, you would enter information related to Initial Approval, the Expiration Date, Full Renewal Expiration, the Review Cycle, the Continuing Review Due Date, and Species Approval.

Later, when you are setting outcome information for other submission forms for the study (e.g. Continuing Review, Full Renewal, Animal Incident Report, and Modification), information in this area would pre-populate from the study record. You would change only what needs to be changed based on the outcome of the review.

Review Cycle:	--none-- ▼	IACUC Initial Approval:		
Teaching:	☐ Yes ☒ No	IACUC Expiration Date:		
Type Assigned:	--none-- ▼	Full Review Expiration:		
Temporary Closed:	☐ Yes ☒ No	USDA Class:	--none-- ▼	
Temporary Closure Start:		Last Continuing Review Approved:		
Temporary Closure End:		Continuing Review Due:		
		Study Closure:		
		Termination:		

The fields in this area are as follows.

*Note: Your system may or may not contain the same fields as described below, depending on your specific system settings.

Meeting Date – If the submission was placed on a full board meeting, this field will populate with the meeting date.

IACUC Initial Approval – If you are processing an Initial Review, you can enter in the IACUC Initial Approval Date here. Otherwise, this date field will be locked down and will display the Initial Review Approval Date.

IACUC Initial Approval:	08/29/2019	
--------------------------------	------------	--

IACUC Initial Approval	05/15/2019
-------------------------------	------------

Review Cycle – This is a configurable dropdown list of review cycles. Each cycle has an associated period of months that will update the **IACUC Expiration** date based on the **Submission Approval** date.

Review Cycle:	--none-- ▼
Teaching:	--none-- Yearly 18 months

IACUC Expiration – You can manually set the expiration date or based on the **Submission Approval** date and the **Review Cycle**, you can calculate the date.

Review Outcome:	--none-- ▼	Protocol Status:	Declined - Acceptance ▼
Additional information required:	Yes	Assign the Submission to Agenda:	Committee Name: --none-- ▼ Meeting Date: 05/15/2019 ▼ or click here to select past meetings Agenda Category: 3 Year Renewal ▼
Follow-up Due:	08/29/2019		

Internal Comments:	
Shared Comments:	
Take Note:	Take note

Review Cycle:	18 months ▼	IACUC Initial Approval:	
Teaching:	--none-- Yearly 18 months	IACUC Expiration Date:	

Clicking the **Calculate Expiration Date** button when there is a **Submission Approval** date and an option selected in the **Review Cycle** drop down list will calculate the IACUC Expiration date. This date bases itself off the Review Cycle, minus one day.

Teaching – Specify “Yes” or “No” to indicate whether or not this study is a Teaching Study.

Full Review Expiration - You can enter the Full Renewal Due date here. The system will automatically assign a date if you use the Expiration Calculation feature described above. The date that populates here will be 3 years minus 1 day based on the Submission Approval Date. The system will track Full Review information for open/active studies and will send Full Renewal Notifications based on this date.

USDA Class – You can associate a USDA Classification to the study using the drop down list. This information is a configurable list found in Review Board Administration > List Maintenance Setup > USDA Class Configuration List.

Last Continuing Review Approved – This field will be empty for a study that has not gone through a continuing review. For Initial Reviews, this field will be empty. Once a study has had one continuing review approval, this date will populate for future submissions with the last date the continuing review was approved for the study. ***Feature not used with IACUC**

Continuing Review Due –You can enter the Continuing Review Due date here. The system is setup to track Continuing Review Reporting information on open/active studies. Depending on your system settings, the system will send Continuing Review Notifications to the study based on the IRB Expiration Date, or the Continuing Review Due date.

The remaining fields are available to set when that information is relevant to the study.

Study Closure – If you are processing a submission that warrants the study to be closed, enter the Study Closure date here.

Temporary Closed – If you need to temporarily close the study, set the flag to “Yes.”

Temporary Closure Start –You can enter the Temporary Closure Start date here.

Temporary Closure End – Enter the Temporary Closure End date here.

Termination – If the Board terminates the study, the date of termination is entered here.

Below this information will list any species-specific information entered into the IACUC Application that was submitted with the Initial Review. Study Species are added through the IACUC Species Data Value used in the application form (added through the System Form Designer). Some forms use all or some of the data values, so your system may or may not contain the same information.

The details listed here are also viewable through the IACUC Application, but they are also presented here to provide a basic summary of what is being approved. You will also be able to indicate to the study the actual number of approved Species within the Study Species table. Type in the number of approved Species in the **Total Number Approved** column. This information will be viewable by the study when you finish the Outcome of the submission.

Study Species - Currently Pending

Species Name				Scientific Name		Common Name		
Sex	Age	Weight	Highest Pain Category	Total Number Requested	Total Number Approved		Wildlife	Laboratory
Mouse				Mus		Mouse		
Male & Female	1 month old	8 oz	A ▼	300	0		No	No

Listed below the Study Species information, you may or may not see additional information, depending on your system settings. The screenshot below displays additional species/study-related information as it was added in the Study Application. When you are approving the Initial Review Submission for a new study, you are also approving the information listed in these additional tables. If this information is incorrect, before you approve the submission, you would return it to the study with Stipulations requesting the appropriate changes.

Study Species - Currently Pending

Species Name				Scientific Name		Common Name		
Sex	Age	Weight	Highest Pain Category	Total Number Requested	Total Number Approved		Wildlife	Laboratory
Mouse				Mus		Mouse		
Male & Female	1 month old	8 oz	A ▼	300	0		No	No

Study Strain - Currently Pending

View Details	Species	Strain	Stock # / Order Code	Special Care	Special Conditions
⊕	Mouse	C57BL/6	2		

Pain Classification - Currently Pending

Species	Strain	B	C	D	E	Total
Mouse	C57BL/6	300	0	0	0	300

After entering the appropriate Outcome information, click the **Save the Submission Outcome** button. Any changes you make to the study will reflect immediately; however, the submission will not complete or return to the study until you indicate in the Submission Complete tab that you are finished with the submission.

Outcome Letter

and Comments
Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Expedited by
Outcome
Outcome Letter
Submission Complete

This tab will allow you to create an Outcome Letter to send to the Principal Investigator and study team.

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Review Checklist and Comments
Review Summary
Submission Discussion
Stipulation
Internal Submission Routing
Vote
Outcome
Outcome Letter

Print Friendly

Create Letter

Outcome Letter ⓘ

Notification Letter: --none--

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
No Letters have been created for this submission.							

Select the Notification Letter type from the drop down list. The outcome letters associated to this list are configured within Review Board Administration. Please see the IACUC Assistant – Review Board Administration manual for more details.

Outcome Letter ⓘ

Notification Letter: --none--

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
No Letters have been created for this submission.							

Letter Generation

To create a letter, begin by selecting a template from the **Notification Letter** drop down list. After the template is selected, click the **Create Letter** button.

The letter templates are created under Review Board Administration > System Setup > Setup Outcome Letter Templates. You can have any number of templates defined as needed.

After clicking the create button, a screen will be displayed with an embedded text editor. The text editor will contain the modifiable version of your letter. To the left of the screen is the submission information (**Reference Number**, **Submission Type**, **Study Number**, and **Assigned Analyst**).

The screenshot displays the 'Letter' creation interface. On the left sidebar, the following information is shown:

- Reference Number:** IACUC-2019-064-NEW-1.0
- Submission Type:** Submission Response for Initial Review Submission Form
- IACUC Number:** IACUC-2019-064
- Study Number:** Evaluating the impact of aerosolized nano-enabled consumer products on respiratory health
- Assign Analyst:** IACUC Coordinator
- Does this letter require signature signoffs?** (Radio buttons: Yes, ☒ No)
- Share this letter with other Boards?** (Radio buttons: Yes, ☒ No)

The main editor area has a teal header with 'Letter' and a 'Back' button. Below the header are buttons for 'Expand Word Window', 'Insert Template Language', and 'Save Letter Changes'. The editor itself has a toolbar with various formatting options (bold, italic, underline, strikethrough, subscript, superscript, font color, background color, bulleted list, numbered list, link, unlink, indent, outdent, decrease indent, increase indent, undo, redo) and a 'Check In/Out' tab. The text in the editor reads:

IACUC

Title of the study: Evaluating the impact of aerosolized nano-enabled consumer products on respiratory health

IACUC Number: IACUC-2019-064

Review Type: Expedited

Action: Change Requested

Today's Date: August 29, 2019

Dear Investigator, John

*Note: If you are using a browser other than IE, you may need to use the download and upload button that will be available when you Edit/View the letter or signoff on it. The reason for this is that the plug-in implemented in the browser is not available in Firefox and Safari and other browsers. Thus, the software will adjust to these issues by giving you the option of downloading and uploading the letter when necessary. Using a browser other than IE, you may download the Outcome Letter to your computer and make any necessary edits using Microsoft Word. When you finish your edits, return to this page and upload the Outcome Letter.

To require signature signoffs for this letter, select "Yes" under **Does this letter require signature signoffs?** When this is done, another field will populate as shown below.

Batch signoff allows the user assigned for letter signoff to sign more than one letter at a time. If this is applicable, select "Yes."

This block shows a close-up of the two signoff questions:

- Does this letter require signature signoffs?** (Radio buttons: Yes, ☒ No)
- Share this letter with other Boards?** (Radio buttons: Yes, ☒ No)

You may also choose to share the Outcome Letter with other boards that will be reviewing this submission. Select “Yes” to the **Share this letter with other Boards** option. This will expand to a list of available review boards in your system. You can choose any number of boards, or select to share with “All”. When this submission is sent to another board, the letter will be accessible when processing the submission.

Does this letter require signature signoffs?

☐ Yes ☒ No

Share this letter with other Boards?

☒ Yes ☐ No

Share with Review Board:

- ☐ All
- ☐ Conflict of Interest Assistant
- ☐ Contracts Review Board
- ☐ Export Control
- ☐ IBC Board
- ☐ IRB

Make changes to the content of the letter as necessary.

Note: The following functionality is only available when using the embedded Word editor within Internet Explorer. If using a different browser, you will not be able to Expand/Minimize the document or insert Template Language.

While you are working on the letter, you may expand the embedded editor by clicking on the **Expand Word Window** button.

This will expand the editor, allowing you more room while working on the letter. Click the **Minimize Word Window** button to return to the normal view.

The screenshot displays the IACUC Assistant submission processing interface. At the top, there are two buttons: "Minimize Word Window" and "Insert Template Language". Below these is a tabbed interface with "HTML Content" and "Check In/Out". The "HTML Content" tab is active, showing a Word document editor. The document content includes:

IACUC

Title of the study: Evaluating the impact of aerosolized nano-enabled consumer products on respiratory health

IACUC Number: IACUC-2019-064

Review Type: Expedited

Action: Change Requested

Today's Date: August 29, 2019

You may also insert template languages by selecting the **Insert Template Language** button.

Insert Template Language	
Name	Language 1

A list of template language will appear. This list is pre-defined under Review Board Administration > System Setup > Setup Template Language. To select the template language, click on the  icon next to it.

After all necessary revisions/additions are made to the letter, select the **Save Letter Changes** button.

Outcome Letter 

Notification Letter:

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Changes Requested Version 1	No	Waiting to be sent		

After creating the letter, a record will populate on the Outcome Letter page. At this point, the letter can be deleted, sent to the study, or edited. Some of the columns in the Outcome Letter table will change depending on the status of the letter.

Delete/Void – You can delete a letter as long as it has not been sent. Once a letter is sent, it can be voided.



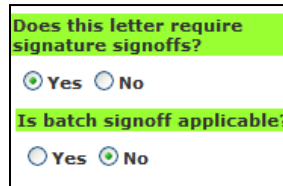
Send – The Outcome Letter can only be sent if there are no tasks pending for the letter. When a letter is available to be sent, the button appears selectable. Once a letter is sent, you have the option to Resend the letter. The button will change from a selectable Send to a selectable Resend. If the letter is pending signoffs, the button will gray out. You will not be able to send the letter until the signatures are collected.



Edit/View – The icon in this column will remain the same, however, depending on whether or not the letter has generated into a PDF document, you may or may not be able to edit the letter when you open it.

Title – The title of the outcome letter will populate in this column, along with the version number of this particular outcome letter.

Signature Required – This column will display either “Yes” or “No” to indicate whether or not this letter requires signatures before it can be sent.



Status – The status of the letter will display in this column. Available statuses:

‘Waiting to be sent’: This means that the letter can be sent;

‘Waiting to be Routed for Signoff’: This means that you cannot send the letter until signatures have been collected. If the letter status is this, an icon will populate in the Route Signoff column;

‘Routing in progress’: This means that the letter has been routed for signoff and cannot be sent until the signatures have been collected;

‘Denied in Routing’: This means that the person assigned to sign the letter denied the letter. You still cannot send the letter, you must reroute the letter for signatures;

‘Routing Complete Waiting to be sent’: means that the signature was collected and you can send the letter.

Route Signoff – This column will populate with an icon if you indicated that a signature is required on the letter before it can be sent. Clicking this icon will display a new page, allowing you to either select the person or persons needed to sign the letter; or, if you have already done this, clicking the icon will display who you have routed the letter to and what their signature status is.

Copy – You can copy a letter if you need to resend a letter or make changes to an existing letter. Often this is used if the signature was denied on a letter and you need to make changes and reroute the letter. Clicking this icon will copy the letter contents and a new letter record will be created on the page. After the letter is copied, you can edit the new letter and route that letter for signatures.

Delete/Void Letters

You can delete an Outcome Letter, but only if it has not been sent. After a letter is sent, you can void the letter. To delete the letter, click the checkbox in this column then click the **Delete Letter(s)** button. A confirmation popup will open within the browser window asking if you are sure you would like to delete the letter. Click **OK** to confirm.

To void a letter, it must have been sent. The checkbox in this column will change to a **Void** button. When you click this button, the system will ask if you are sure you want to void the letter. Click **OK**.

Outcome Letter 

Notification Letter: --none--

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Changes Requested Version 1	No	Letter sent --- Completed Sent: 08/29/2019 05:11 AM PDT		

The letter will be voided. The **Status** column will update to read that the letter has been voided.

Outcome Letter 

Notification Letter: --none--

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Changes Requested Version 1	No	Letter sent --- Voided		

If you open the letter to view, the PDF document will be stamped with VOID on all pages.

My Workspaces 
IACUC

Letter 

Reference Number:
IACUC-2019-064-NEW-1.0

Submission Type:
Submission Response for Initial Review Submission Form

IACUC Number:
IACUC-2019-064

Study Number:
Evaluating the impact of aerosolized nano-enabled consumer products on respiratory health

Assign Analyst:
IACUC Coordinator

Does this letter require signature signoffs?
☐ Yes ☒ No

Share this letter with other Boards?
☒ Yes ☐ No

Share with Review Board:

- ☐ All
- ☐ Conflict of Interest Assistant
- ☐ Contracts Review Board
- ☐ Export Control
- ☐ IBC Board
- ☐ IRB
- ☐ Post Award Board

IACUC

Title of the study: Evaluating the impact of aerosolized nano-enabled consumer products on respiratory health

IACUC Number: IACUC-2019-064

Review Type: Expedited

Action: Change Requested

Today's Date: August 29, 2019

Dear Investigator, John

After voiding the letter, you may want to **Resend** it to the study personnel.

Outcome Letter 

Notification Letter:

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Changes Requested Version 1	No	Letter sent --- Voided		

Sending a Letter

The send column will populate with a button allowing you to send the letter. If the letter is being routed for signatures, the button will appear gray and you will not be able to send the letter until the signatures have been completed.

When you click the **Send** button, a new page will open. This page allows you to enter a Letter Title, select the Outcome Letter recipients, and add additional recipients if they are not listed on the page.

At the top of the page, study and submission specific information is listed: Submission Type, Study Number, Study Title, and Reference Number. Letter Title is an editable field, and will pull in the given letter name from Review Board Administration > Review Board Notification Setup > Outcome Letter Notification > List of RB Outcome Letter Notifications. You can override the given Letter Title by typing in this field.

My Workspaces  IACUC **Letter Recipients**  Back

Submission Type: Submission Response for Initial Review Submission Form

IACUC Number: IACUC-2019-064 **Reference Number:** IACUC-2019-064-NEW-1.0

Protocol Title: Evaluating the impact of aerosolized nano-enabled consumer products on respiratory health

Letter Title:

Key Protocol Personnel

Contacts	Role		
<u>Project Personnel</u>			
	Principal Investigator		John Investigator
	Contact		John Investigator

Below this information are tables containing lists of users in iRIS. These users are broken into different groups. Listed are the Study Personnel, Sponsor Contacts, and members of different review board committees. Depending on property settings, the users listed in these groups may or may not be pre-selected. Any user with a checkbox next to their name indicates they will be an Outcome Letter recipient when you send the letter.

You can add additional recipients to receive the Outcome Letter by choosing to add a recipient from iRIS or you can choose to enter an email address.

Click **Add recipient from directory** to add an iRIS user to the letter.

This will open the **Search User Directory** page, allowing you to search for the desired iRIS user. When you find the user to add, click the **Select User** icon.

My Workspaces ▾ IACUC **Search User Directory** [Back](#)

[Save Selected User\(s\)](#)


Directory Browse/Find:

Last Name: (You may enter a partial name to search)
 First Name:
 by Department:

Find

Check for Multiple	Select User	Training	User Name	Department	Email
☐	☒		Administrator	General Hospital (primary) [+]	admin.administrator@imedris.net

The user will populate in the Additional Recipients table with the checkbox pre-selected. You can add an Association to the user by entering that information in to the **Association** column.

My Workspaces ▾ IACUC **Letter Additional recipients** [Back](#)

[Add A Recipient](#)
[Remove Selected Recipients](#)
[Save And Return](#)

	Name	E-mail Address
☐	John Smith	jsmith@hotmail.com

Click the **Add recipient manually** button to enter in an email address for a person who does not have an account in iRIS.

My Workspaces ▾ IACUC **Letter Additional recipients** [Back](#)

[Add A Recipient](#)
[Save And Return](#)

	Name	E-mail Address
No Additional Non-iRIS Recipients have been added.		

A new page will open, allowing you to click the **Add a Recipient** button to add a non-iRIS recipient.

Clicking the **Add a Recipient** button will add a row to the page. You can type in the Name and E-mail address. You can add as many non-iRIS recipients as needed by continuing to click **Add a Recipient**. When you are finished, click the **Save and Return** button.

My Workspaces ▾ IACUC **Letter Additional recipients** [Back](#)

[Add A Recipient](#)
[Remove Selected Recipients](#)
[Save And Return](#)

	Name	E-mail Address
☐	John Adams	jadams@gmail.com
☐	Scott West	Swest@gmail.com

The non-iRIS recipients will be listed in Additional Recipients. The **Association** field is a required field; you will not be able to send the letter without information in this field.

If you do not need to send the letter to any Additional Recipients, you cannot delete the recipient. You will need to uncheck the checkbox in the **Send if Checked** column before you save this page.

Additional Recipients

Association	Send if checked	Additional Recipients
	☒	Administrator
	☒	John Adams
	☒	Scott West

When you are ready to send the letter to the selected recipients, click the **Send to selected recipients** button on the top right of the page.

My Workspaces
IACUC
Letter Recipients

Add recipient from directory
Add recipient manually
Send to selected recipients

Once the letter is sent, the system will generate a PDF from the Word document and attach that PDF to the Outcome Letter notification as defined in Review Board Administration. You will be returned to the Outcome Letter tab.

Outcome Letter

Notification Letter:
--none--

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Change Request Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:15 AM PDT		

Routing for Signatures

After saving the letter, if you indicate signatures are required on the letter, you will be directed to the **Submission Letter Signoff Routing List** page.

My Workspaces
IACUC
Submission Letter Signoff Routing List

Add Review Board Signoff
Add Non-Review Board Signoff
Delete Selected Signoff(s)
Save Signoff List

Protocol Title: Copy of Cardioprotective Effects of an Endothelin Type A Receptor Antagonist during Myocardial Ischemia and Reperfusion in a Ovine Model
Reference Number: IACUC-2018-006-NEW-1.0
Submission Type: Initial Review Submission Form
Letter Name: Changes Requested

Have you completed your selection of required signatures?
☒ Yes
☐ No

	Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
No Personnel have been designed to signoff									

There are two ways to add a user to approve and signoff on the letter:

Add Review Board Signoff – This allows you to choose from any board member.

	Order Number	Name	Signoff	Approved	Include Signature	Allow Change
☐	0	--none-- --none-- Administrator Boardmember Chair, Department Coordinator, Jane Coordinator, IACUC Reviewer, Luke Reviewer, IACUC Sandbox, Beaumont			Yes ▼	No ▼

Add Non-Review Board Signoff – This allows you to choose any user in the iRIS database, regardless of their access to the Review Board.

My Workspaces
IACUC

Search User Directory
Back

Save Selected User(s)

Directory Browse/Find:

Last Name: Admin (You may enter a partial name to search)
First Name:
by Department: All Departments

Find

Check for Multiple	Select User	Training	User Name	Department	Email
☐			Administrator	General Hospital (primary) [+]	admin.administrator@imedris.net

After selecting the users required to sign off, their records will appear as shown in the screen shot below.

	Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
☐	0	Boardmember			Yes ▼	No ▼			
☐	1	Administrator			Yes ▼	No ▼			

Order Number – Specifies who will receive the signoff task first. Users with the same number in this column will receive tasks at the same time.

Name – This is the name of the user (selected from the drop down menu) who must sign the outcome letter.

Signoff – This column is only useful for the currently logged in user. An icon will populate in this column for each personnel. If you are looking at this page and have been selected as signoff personnel, the icon next to your name will darken and you will be able to signoff the letter by selecting this icon.

Approved – This area will display the status of the letter after the user has approved or denied it.

Include Signature – If this field is set to “Yes,” the user’s electronic signature will be included in the letter.

Allow Change – If this is set to “Yes,” the user designated for signoff will be allowed to edit the letter.

Date Received – Date user receives the letter for signature.

Date Completed – Date the user applies their electronic signature.

Comments – Any comments the user may have entered upon signoff.

Delete Selected Signoff(s) – Delete users selected for signoff by checking the box next to their name and clicking this button.

Once all selections are made, click “Yes” in the **Have you completed your selection of required signatures?** field. This will send the Outcome Letter Signoff tasks to the selected users when you save the signoff list.

Click the **Save Signoff List** button.

At this point, the system will send the signoff tasks and the outcome letter will convert from a Word document to a PDF.

If you view the letter again, the Outcome Letter now appears in the window as an un-editable PDF document.

My Workspaces ▾ IACUC **Letter** [Back](#)

[Expand Word Window](#) [Insert Template Language](#) [Save Letter Changes](#)

Reference Number:
IACUC-2018-006-NEW-1.0

Submission Type:
Initial Review Submission Form

IACUC Number:
IACUC-2018-006

Study Number:
ERA sheep

Does this letter require signature signoffs?
☒ Yes ☐ No

Is batch signoff applicable?
☒ Yes ☐ No

HTML Content **Check In/Out**

IACUC

Title of the study: Copy of Cardioprotective Effects of an Endothelin Type A Receptor Antagonist during Myocardial Ischemia and Reperfusion in a Ovine Model

IACUC Number: IACUC-2018-006

Any user assigned to sign off on an Outcome Letter will receive a homepage task.

All Tasks **Outstanding** **Completed** [Settings](#)

All Tasks **Protocol Tasks** **Project Tasks** Task List: All ▾

18 result(s) found... 1 - 18

	Click to open	Task Type	Received	Description
☐		Outcome Letter Signoff	08/29/2019 05:47 AM PDT	Administrator has been assigned to review and signoff the Changes Requested outcome letter

Opening the Signoff task will open the letter in a new page. If the user signing the letter had been given rights to edit the letter, the letter on this page would display as an editable document within an embedded browser. The example below displays the PDF letter, meaning this user was not granted the ability to modify the letter before approving or denying the letter.

My Workspaces ▾ IACUC **Letter Signoff** [Back](#)

[Save Letter Review](#)

Reference Number:
000133

Submission Type:
Initial Review Submission Form

IACUC Number:
IACUC-2018-006

Study Number:
ERA sheep

Administrator do you Approve or Deny this letter?
--none-- ▾

[Click here to add comments.](#)
No Comments have been posted.

IACUC

Title of the study: Copy of Cardioprotective Effects of an Endothelin Type A Receptor Antagonist during Myocardial Ischemia and Reperfusion in a Ovine Model

IACUC Number: IACUC-2018-006

To the left of the letter, study and submission information is listed. Comments can also be added to the letter on this page by clicking the **Click here to add comments** link.

There is a dropdown list that the user can use to select either Approve or Deny. After making a selection, the user will be prompted to enter their UIN and password to complete the signoff. Click **Save Letter Review** after signing off on the letter.

Denying the Outcome Letter

To deny the letter, the user simply chooses the Deny option from the drop down list. When this option is chosen, a button will populate below the dropdown list allowing the user to edit the letter with any suggested changes.

Administrator do you Approve or Deny this letter?

Deny ▾

[Click here to revise a copy of the letter with your suggestions.](#)

[Click here to add comments.](#)
No Comments have been posted.

When the button **Click here to revise a copy of the letter with your suggestions** is clicked, the page refreshes to display a copy of the letter in an embedded Word editor. After any changes are made, the user would click the **Save Letter Changes** button.

My Workspaces
IACUC
Submission Letter Revision
Back

Insert Template Language
Save Letter Changes

Reference Number:
000133
Submission Type:
Initial Review Submission Form
IACUC Number:
IACUC-2018-006
Study Number:
ERA sheep

HTML Content

B I U S x₂ x² Font Family 12

IACUC
Title of the study: Copy of Cardioprotective Effects of an Endothelin Type A Receptor Antagonist during Myocardial Ischemia and Reperfusion in a Ovine Model

IACUC Number: IACUC-2018-006

At the point where the user denies and saves the letter, the system will update the letter record in the Outcome tab, in the Submission Processing screens. The Status updates to reflect the signature was denied and the letter cannot be sent.

My Workspaces
IACUC
Submission Letter Signoff Routing List
Back

Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Reference Number: IACUC-2019-059-NEW-1.0
Submission Type: Submission Correction for Initial Review Submission Form
Letter Name: Changes Requested

Have you completed your selection of required signatures?
☒ Yes
☐ No

Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
0	Administrator		No Click here to view changes	Yes	No	08/30/2019 09:58:17 AM UTC	08/30/2019 09:59:53 AM UTC	
1	Coordinator, Jane			Yes	No	08/30/2019 09:59:53 AM UTC		

Click the **Route Signoff** button.

Because the letter was denied, any other signoff tasks have been cancelled and the Submission Letter Signoff Routing List page is locked down. A Word icon in the **Approved** column will display for the user that denied the letter. You can click on this to view any suggested changes.

A new page will open. The modified letter is displayed in the embedded Word editor. You can view the changes and make any other necessary modifications. Once necessary changes are made, click the **Copy Revised Letter**.

My Workspaces
IACUC
Submission Letter Revision
Back
Copy Revised Letter

Reference Number:
000587
Submission Type:
Submission Correction for Initial Review Submission Form
IACUC Number:
IACUC-2019-059
Study Number:
Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice
Assign Analyst:
IACUC Coordinator

HTML Content

B I U S x₂ x² Font Family 12

IACUC

Title of the study: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice

IACUC Number: IACUC-2019-059

Review Type: Expedited

Action: Change Requested

Today's Date: August 30, 2019

A copy of the letter will need to be made, because the original letter has been denied and locked down for version control. Creating a copy will create a new Outcome Letter record that you can also route for signature and send to the study. The screenshot below shows three Outcome Letter records, Version 1, Version 2, and Version 3. Version 1 was voided. Version 2 has been denied approval and is thus locked down. It cannot be sent and it cannot be modified. You can, however, delete the Outcome Letter. Version 3 of the Outcome Letter is in an editable state and can be routed for signoff or it can be sent to the study personnel.

Outcome Letter

Notification Letter: --none--

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 1	Yes	Routing in progress		
			Letter Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:28 AM PDT		
			Letter Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:18 AM PDT		

Approving the Outcome Letter

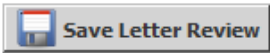
Coordinator, Jan
do you Approve or Deny this letter?

Approve ▾

To approve this letter,
Please enter User ID &
Password:

User ID:

Password:

 Save Letter Review

[Click here to add comments.](#)

Letter Signoff Comments.

To approve an Outcome Letter, select the **Approve** option from the dropdown list. When you select this option, a User ID and Password field will populate on the page. Before you can save the Approval, you must supply your User ID and password and then click the **Save Letter Review** button.

approve your study. Please submit a Continuing Review no later than 11/22/2014

The following items have been approved:

Thank you,

Signature applied by Board Coordinator on 12/23/2013 09:20:52 AM PST

When the approval signoff is completed, the letter will generate a PDF. If the signoff task was flagged to Include Signature and the Electronic Signature merge code has been inserted into the Outcome Letter template, the signature information will populate in the Outcome Letter, similar to the screenshot above.

At this point, the analyst assigned to the submission would receive a notification from the system regarding the completion of the Outcome Letter Signoffs.

Notification Letter:

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 1	Yes	Routing in progress		

Returning to the Outcome tab in the submission processing screens, the letter record will update indicating that signature routing is complete in the **Status** column.

At this point, the **Send** icon will be selectable, allowing you to send the letter to the study personnel.

You can click on the icon in the **Route Signoff** column to obtain any additional details about the signoffs collected for the Outcome letter.

My Workspaces		IACUC	Submission Letter Signoff Routing List							
Protocol Title:		Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressed mice								
Reference Number:		IACUC-2019-059-NEW-1.0								
Submission Type:		Submission Correction for Initial Review Submission Form								
Letter Name:		Letter								
Have you completed your selection of required signatures?		☒ Yes ☐ No								
	Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments	
	0	Coordinator, Jane			Yes	No	08/28/2019 08:41:34 AM UTC			

The Submission Letter Signoff Routing List page will be opened. Since the letter signoffs have been completed, this page will be locked down from editing. Comments added by any of the assigned users can be viewed in the **Comments** column.

Copy a Letter

Letters can be copied to create a new Outcome Letter based on a previously generated letter. This is generally done in the case that a letter was routed for signoffs and was denied in that process, or if a letter had been generated and sent but was later voided for an error. You can copy the existing letter and make any changes instead of re-creating the letter from scratch.

To copy the letter, click the **Copy** button.

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:15 AM PDT		

A new version of the letter will be created and will display in the Outcome Letter table. You will be able to Send the letter, edit the letter, and route it for signoff.

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Letter Version 2	No	Waiting to be sent		
			Letter Version 1	No	Letter sent --- Completed Sent: 08/27/2019 08:15 AM PDT		

Submission Complete

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Outcome
Outcome Letter
Submission Complete

The purpose of the last tab in the submission processing screens is to indicate to the system that you are finished processing the submission within the review board, whether that be for Pre-Review, Full Board Review, Designated Member Review, Expedited, Exempt or Process Administratively. Until you come to this tab and check off that the submission is complete, the submission record will remain in the **Assigned** tab in the Submissions queue. It will not return to the study for any corrections required by the review board and it will not be completely Approved, even if the meeting date assigned to the submission has passed. You must indicate that the submission is complete on this page. Doing so will complete this round of the submission, moving the submission record from the **Assigned** tab to the **Completed** tab. If you indicated that Pre-Review Changes or Post-Review Changes are required, the system will generate a response form, attach the submission and components, and return to the study.

My Workspaces
IACUC Number: **IACUC-2019-059**
PI: Investigator, John
IACUC
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
IACUC Items
Submission Forms

Ref Number: **IACUC-2019-059-NEW-1.0**
IACUC Number: **IACUC-2019-059**
Protocol Title: Enzyme-treated asparagus extract (ETAS) restores dysbiosis in APP-overexpressing mice
Protocol Status: **Declined - Acceptance**

Save the Submission Complete

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening
Submission Received Notification Letter
Review Checklist and Comments
Review Summary
Submission Discussion
Recommendation
Stipulation
Internal Submission Routing
Outcome
Outcome Letter
Submission Complete

Review Complete

Review Outcome:
Additional information required: Yes
Protocol Status: Declined - Acceptance
Submission processing complete: ☐

Review Outcome Letters

Edit/View	Title	Signature Required	Status
	Letter Version 1	Yes	Routing in progress

Display Submission components status

Compare Item(s)
Items in List View
Add New Component
Clear Viewed Item(s)
Create PDF Packet

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details

Submission Form(s)

The Submission Complete tab is broken up in to three sections: Review Complete, Review Outcome Letters, and Display Submission Components Status.

Review Complete

Listed in this table is the submission outcome information: Review Outcome, Additional Information Required, and Study Status. You will not be able to complete a submission if the Review Outcome has not been set, unless the Review Process in the Pre-Review Screening tab is set to Pre-review Changes Requested.

Also listed in this table is the **Submission processing complete** checkbox. This is the indicator that the review board is finished with processing the submission and this is the flag that will move the submission from the **Assigned** tab to the **Completed** tab.

Submission processing complete: ☐

Do not set this indicator until you are ready to complete the submission. Once you click this checkbox and save the page, the system will take action on the submission based on the Review Process and the Outcome. If this submission has been marked to return to the study for changes, the system will generate a response form to return to the study. The submission will lock down for editing when the submission is complete, meaning you can no longer change the Outcome information, generate letters, assign reviewers, or create stipulations. *Completing the submission is the last step in the Review Process and should not be completed until all elements of the submission are gathered and entered into the submission screens.*

If you do mark the submission as complete before it was necessary, you may reset the completion in the General Information tab.

If, however, the submission has been returned to the study for corrections, you will not be able to undo the completion due to the study having the submission. In this case, you would need to request the study submit the new round to the review board for processing and at that time you could enter any additional details. However, that information would be associated to the new round of the submission.

Review Outcome Letters

Also listed in this tab is a summary of any Outcome Letters that have been generated.

You can edit a letter that has not yet been sent or view any letter that has been locked down from this area. The Outcome Letter table serves as a reminder to generate and send any necessary letters before completing the submission.

Review Outcome Letters 

Edit/View	Title	Signature Required	Status
	Letter Version 1	Yes	Routing in progress

Display Submission Components Status

The components of the submission are listed on this page as well. This will allow you the opportunity to approve documents before completing the submission, if the documents have not yet been approved in the Submission Components tab prior to completing the submission.

The functionality of the Submission Components table is the same as described in the Submission Components section of this document.

Display Submission components status 

 Compare Item(s)  Items in List View  Add New Component  Clear Viewed Item(s)  Create PDF Packet								
Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
☐	☐						IACUC - IACUC - Pre-Review Correction Form - (Version 1.0)	
☐	☐						Initial Review Submission Form - (Version 1.0)	
Application								
☐	☐						IACUC APPLICATION (ANIMALS) - (Version 1.1)	
Document(s)								
☐	☐						Study Timeline - (Version 1.0 approved on 08/27/2019) *Added by the IACUC.	
Category : Flyer								
							ACORP Diagram - (Version 1.1)	