



IACUC ASSISTANT

Submission Processing

Version 10.03.02

Contents

Introduction.....	2
Submissions.....	2
Not Assigned.....	3
Assigned.....	3
Completed.....	4
Agendas.....	5
Processing Submissions.....	5
General Information.....	7
Submission Components.....	9
Correspondence.....	23
Submission History.....	26
Pre-Review Screening.....	27
Reviewer Assignments.....	33
Review Checklist and Comments.....	36
Review Summary.....	39
Submission Discussion.....	41
Stipulation.....	42
Internal Routing.....	53
Vote / Expedited By / Acknowledged By.....	58
Outcome.....	62
Outcome Letter.....	69
Submission Complete.....	84

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.



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).

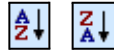
This feature allows you to view and process all submissions sent to the review board.

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**, and **Agendas**. When you open the Submissions link, the default tab is the **Not Assigned** tab.

IACUC - Submission Back									
Not Assigned		Assigned	Completed	Agendas	Print Friendly	Display Submissions by: IACUC Number			
Open	*	IACUC Number	Ref Number	Type	Date Board Received	IACUC Expiration Date	Full Renewal Expiration	Principal Investigator	Assigned Analyst
4 result(s) found... 1 - 4									
		<i>Mouse Study</i>							
			000215	Initial Review Submission Form	07/02/2014 03:24:51 PM PDT			Investigator, Susan M., Ph.D.	
		<i>Swine Management and Production</i>							
		GH-14001-1	000219	IACUC Animal Incident Report	07/08/2014 02:18:12 PM PDT	07/15/2014		Investigator, Susan M., Ph.D.	Coordinator, Jan
		<i>Reproductive Biology and Fertility</i>							
		GH-14002	000223	IACUC Animal Incident Report	07/08/2014 02:32:11 PM PDT			Investigator, Susan M., Ph.D.	



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.

IACUC - Submission Back											
Not Assigned		Assigned		Completed		Agendas		Print Friendly		Display Submissions by: IACUC Number	
3 result(s) found...											1 - 3
Open	*	IACUC Number	Ref Number	Type	Review Process	Date Board Received	IACUC Expiration Date	Full Renewal Expiration	Principal Investigator	Assigned Reviewers	Assigned Analyst
<i>Reproductive Biology and Fertility</i>											
		GH-14002	000221	Initial Review Submission Form	On Agenda 07/25/2014	07/08/2014 02:30:14 PM PDT			Investigator, Susan M., Ph.D.	Primary Joe Member	
<i>Swine Management and Production</i>											
		GH-14001-1	000222	IACUC Annual Review of Animal Use	On Agenda 07/19/2014	07/08/2014 02:31:36 PM PDT	07/15/2014		Investigator, Susan M., Ph.D.		

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 processes available to search by. **Expedited, Facilitated, Processed Administratively, Returned for Correction, and Designated Reviewer** are the available processes for submission forms. You can search by a process, and then indicate a time frame of when the submission was completed by entering dates in the **Submission Completed from** and **to** date fields. Click the **Refresh** button to refresh the page with any resulting submissions. You can then open the item.

IACUC - Submission Back											
Not Assigned		Assigned		Completed		Agendas		Print Friendly		Display Submissions by: IACUC Number	
<input type="radio"/> Expedited <input type="radio"/> Facilitated <input checked="" type="radio"/> Processed Administratively <input type="radio"/> Returned for Correction <input type="radio"/> Designated Reviewer											
						Submissions Completed from 10/28/2016 to 11/11/2016 Refresh					
1 result(s) found...											1 - 1
Open	Letters	IACUC Number	Ref Num	Type	Principal Investigator	Department Study Nickname	Date Completed	Assigned Analyst			
		ANI-16-493	005011	iMedRIS Initial Review Submission Form	Investigator, Susan	Healthcare System - Sample Site Application for Animal Research	11/09/2016	Analyst, Ann			

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	IACUC Number	Ref Num
	GH-1223	000226
[Letter 1] Full Approval Letter		

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

Letters	IACUC Number	Ref Num	T
<input checked="" type="checkbox"/>	GH-1223	000226	Ini Su
[Letter 1] Full 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.

IACUC - Submission ◀ Back

Not Assigned | Assigned | Completed | Agendas

Items to be Reviewed at Committee 01 Meeting : ◀ 07/25/2014 ▶ Agenda State: Draft
Reviewer Notifications: Disabled

✔ Submission Review validation
📄 Save the Agenda Order

New Protocols - 1 Submissions

Order	Click to open	*	Ref Num	COI	Letters	Outcome	IACUC Number	Type	Principal Investigator	Reviewer(s)	Date Board Received
<i>Reproductive Biology and Fertility</i>											
1			000221				GH-14002	Initial Review Submission Form	Investigator, Susan M., Ph.D.	Primary Joe Member	07/08/2014 2:30:14 PM PDT

Full Renewals - 0 Submissions

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).

Study Number: MII
 PI: Investigator, Susan M., Ph.D. **IACUC - Initial Review Submission Form** Back

Protocol Items | Miscellaneous | IACUC Items | Submission Forms

Ref Number: **000262** | IACUC Number: **GH-14-016** | Study Title: Mouse Study II

Study Status: Pending - Submitted for Initial Review

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

General Information ⓘ

Study Number: MII

[Edit the Master Lay Summary](#) To construct the recombinant Lactococcus lactis as oral delivery vaccination against malaria.

[Click Here to edit the submission summary](#) Oral vaccination of mice against rodent malaria.

Internal Comments:

Department ⓘ

GH - 12345 - Department

Study Personnel ⓘ [Update personnel status to latest](#)

Role	Name	COI Under Review?	IACUC Training:
Principal Investigator:	Susan M. Investigator, Ph.D.		Active training
Study Contact:	Susan M. Investigator, Ph.D.		Active training
Veterinarian:	Nancy Veterinarian		Active training
Co-Investigator:	Patrick Investigator, Ph.D		Active training
Study Coordinator:	Mary Jane Coordinator, R.N.		Training not posted
Study Author:	Susan M. Investigator, Ph.D.		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.

Study Nickname: Application for Research
 PI: Investigator, Susan **IACUC - iMedRIS Initial Review Submission Form** Back

Protocol Items | Miscellaneous | IACUC Items | Submission Forms | Additional Attached Forms

Ref Number: **004939** | IACUC Number: **ANI-16-490** | Study Title: Application for Research

Study 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.

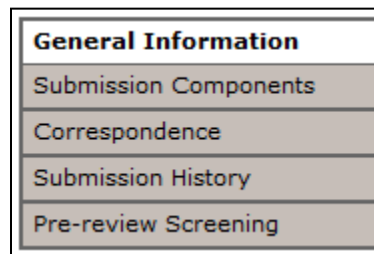
Project/IACUC Number – Depending on your configuration of iRIS, the project number or IACUC number will display here in bolded red letters.

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



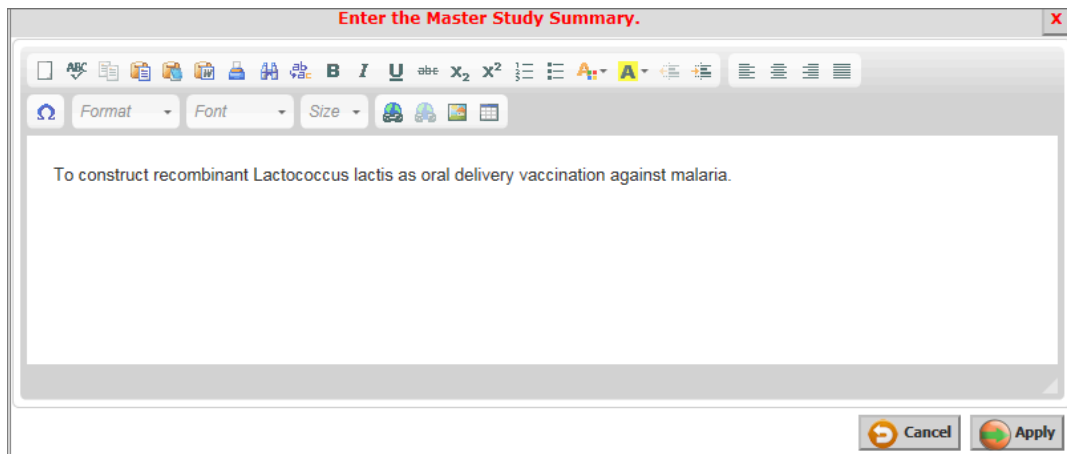
The first tab in the submission processing screens lists brief details about the study being viewed. You can view General Information related to the current submission you are processing, as well as study-specific information. The summary detail on this page is the same information listed in the Not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

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.

Department ⓘ
GH - 12345 - Department

Study Personnel ⓘ Update personnel status to latest

Role		Name	COI Under Review?	IACUC Training:
Principal Investigator:		Susan M. Investigator, Ph.D.		Active training
Study Contact:		Susan M. Investigator, Ph.D.		Active training
Veterinarian:		Nancy Veterinarian		Active training
Co-Investigator:		Patrick Investigator, Ph.D		Active training
Study Coordinator:		Mary Jane Coordinator, R.N.		Training not posted
Study Author:		Susan M. Investigator, Ph.D.		Active training

Additional information can be viewed about Study Personnel by clicking on the icon next to the user 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 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.

The screenshot shows the 'Display Submission Components' interface. On the left is a sidebar with navigation options: General Information, Submission Components (highlighted), Correspondence, Submission History, Pre-review Screening, and Submission Received Notification Letter. The main area has a 'Print Friendly' button in the top right. Below the title are five action buttons: Compare Item(s), Items in List View, Add New Component, Create PDF Packet, and Approve Attachment(s). The main content is a table with columns: Compare, Include in PDF Packet, Unattach, Revise/Attach, Current Submission Components (All Rounds), and More Details. The table lists three items: a Submission Form (iMedRIS Initial Review Submission Form - Version 1.0), an Application (IACUC Application Form - Version 1.0), and a Document (ACORP Diagram - Version 1.0). Each row has checkboxes for 'Compare' and 'Include in PDF Packet', and a 'More Details' icon.

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.

Compare	Include in PDF Packet	Unattach	Revise/Attach	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input checked="" type="checkbox"/>				
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>			I MedRIS Initial Review Submission Form - (Version 1.0)	
Application					
<input type="checkbox"/>	<input type="checkbox"/>			IACUC Application Form - (Version 1.0)	
Document(s)					
Category : ACORP Diagram					
<input type="checkbox"/>	<input type="checkbox"/>			ACORP Diagram - (Version 1.0)	
Category : ACORP Study Timeline					
<input type="checkbox"/>	<input type="checkbox"/>			ACORP Study Timeline - (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.

Revisions	Current Submission Components (All Rounds)
	Pre-Review Correction Form - IACUC - (Version 1.0)
	Initial Review Submission Form - (Version 1.0)
	IACUC Application - (Version 1.1)

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.

	IACUC Application - (Version 1.1)
	IACUC Application - (Version 1.0)

You may view the previous document by clicking on that item.

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 ⓘ

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

Compare	Include in PDF Packet	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC - IACUC - Review Response Form - (Version 1.0)	⊕
<input type="checkbox"/>	<input type="checkbox"/>	✖			iMedRIS Initial Review Submission Form - (Version 1.2) <small>*Revision modified by the IACUC.</small>	⊕
Application						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC Application Form - (Version 1.0)	⊕

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.

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	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC - IACUC - Review Response Form - (Version 1.0)	⊕
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.0)	⊕
Application						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC Application Form - (Version 1.2)	⊕

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 Study Application ✕

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

Select	Edit/View	Form Name	Approved
		IACUC Application Form (Version 1.1)	No
		IACUC Application Form (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.

Compare	Include in PDF Packet	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.0)	

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	Include in PDF Packet	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.0) - You already viewed this item	
Application						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC Application Form - (Version 1.0)	

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

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	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.0) - 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.

Study Number: M4
PI: Investigator, Susan M., Ph.D. **Initial Review Submission Form** Back

Print Friendly
 Refresh Constant Fields

Section view of the Form
Entire view of the Form

1.0 Submission Packet to the Review Board

1.1 Review Board Reference Number	000240	
1.2 Study Title:	Mouse Study IV	
1.3 Principal Investigator:	Susan M. Investigator, Ph.D.	
1.4 * Lay Summary:	To construct the recombinant Lactococcus lactis as oral delivery vaccination against malaria.	

If you open a study document, a new page will open 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.

Study Number: M4
PI: Investigator, Susan M., Ph.D.

Study Documents Back

Create a new version Save Changes

*Document Title: VAS View the document

* Category: Other

Comments:

Description:

*Version Date: 07/16/2014

Version Number: 1.0

Outcome: --none--

Approval Date:

Expiration Date:

This will open the study document within the window.

Study Number: M4
PI: Investigator, Susan M., Ph.D.

Study Documents Review Back

Add Comment

Delete Comments

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

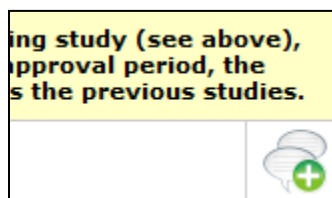
Members of NIH scientific review groups are instructed to evaluate the 5 point VAS to determine if it is complete and if plans for the use of vertebrate animals are appropriate relative to the scientific work proposed. Points 1, 2, and 5 are relatively straightforward and the detail

Commenting

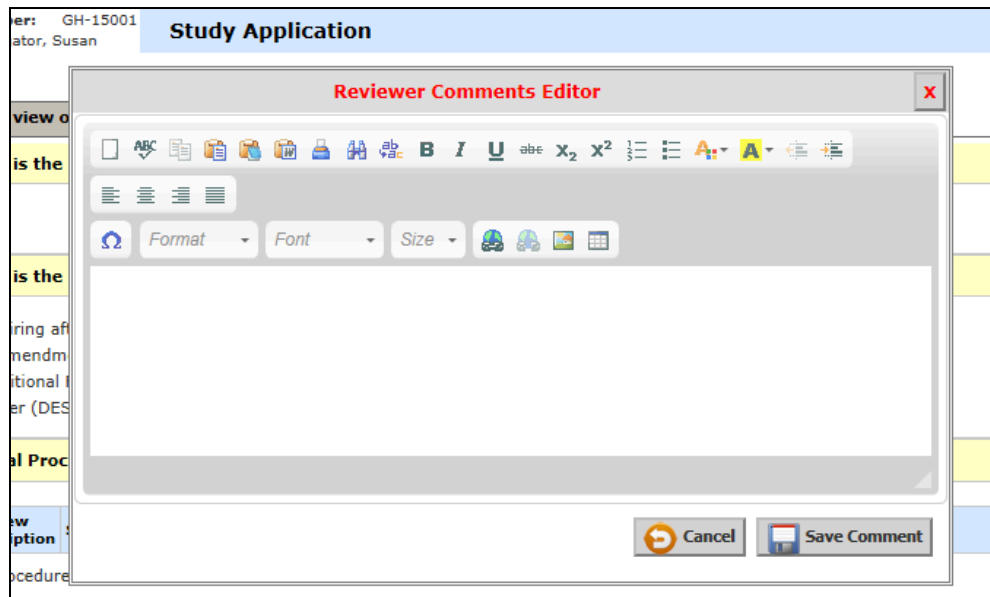
You can add comments to any of the questions in the submission form, and to any of the application questions after the study shell (the first three sections of the application).

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.

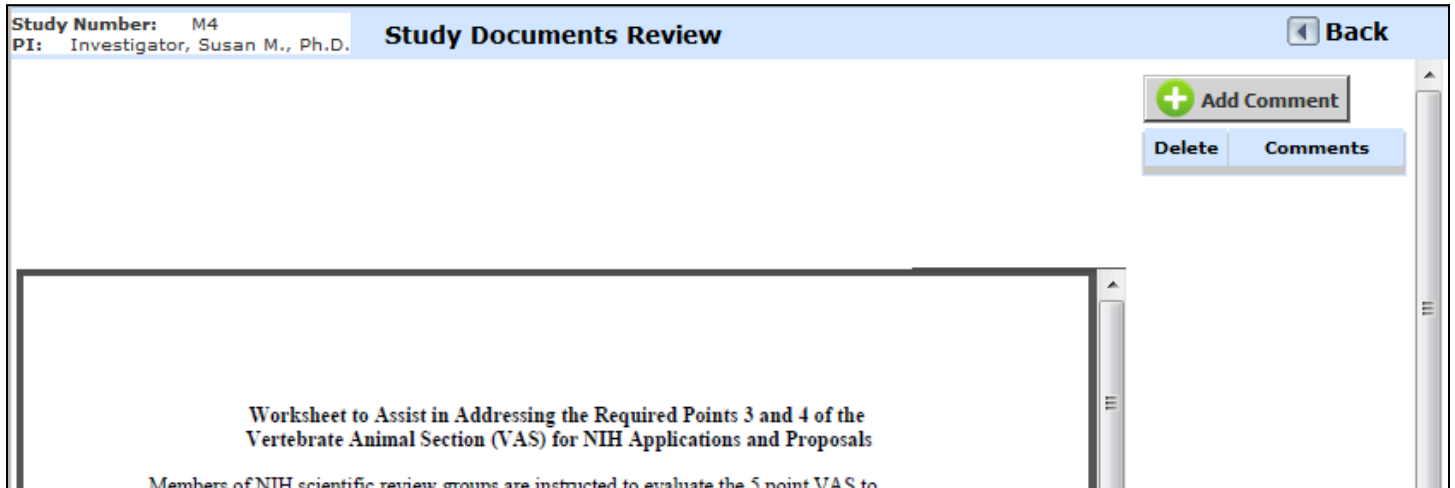


Questions in the form that have a comment added will display a changed icon. You can modify or remove your comments by clicking on the icon again.

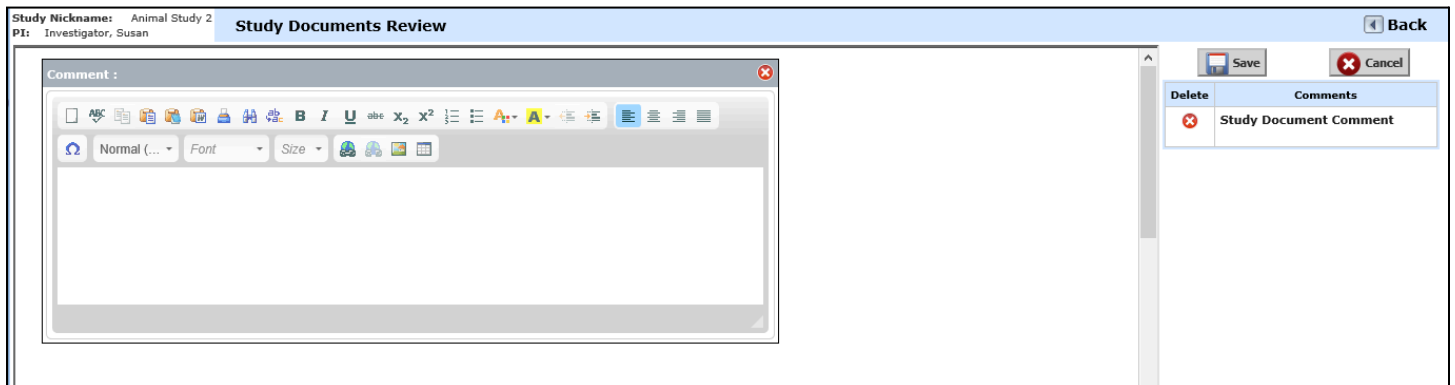
A screenshot of a web application form titled "Study Application". The header shows "Study Number: M4" and "PI: Investigator, Susan M., Ph.D.". There are "Back" and "Print Friendly" buttons in the top right. Below the header are two tabs: "Section view of Application" (selected) and "Entire view of the Application". The main content area is titled "Purpose:" and contains a list of radio button options: "Research (experimentation, testing, procedures)", "Teaching or training", "Breeding and production colony management only (includes genotyping, and individual marking) no experimental studies.", "Core Facility Standard Operating Protocol", "Contract Antibody Production with a commercial company only", and "Other". A green vertical bar with a white speech bubble icon is on the right side of the form.

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

Click the **Add Comment** button that appears at the top right of the page.

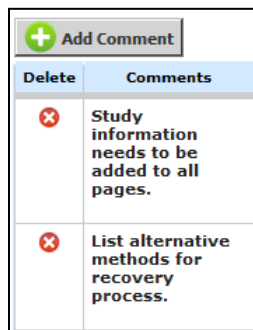


A comment window will open in the page. You can type in your comment, then click the **Save** button or click **Cancel** if you do not want to add a comment.



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.



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	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input checked="" type="checkbox"/>				iMedRIS 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	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details			
<input type="checkbox"/>	<input checked="" type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.0)				
<table border="1"> <tr> <td></td> <td>Submitted to Workflow:</td> <td>11/10/2016 01:18:20 PM PST</td> </tr> </table>								Submitted to Workflow:	11/10/2016 01:18:20 PM PST
	Submitted to Workflow:	11/10/2016 01:18:20 PM PST							

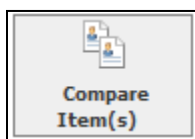
When you click this icon, an area below the submission item will populate with the details. This is helpful for items you have received into the submission queue multiple times. You will be able to see when an item was originally submitted, as shown above. Newer items associated to the submission would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

Category : ACORP Study Timeline						
<input type="checkbox"/>	<input checked="" type="checkbox"/>				ACORP Study Timeline - (Version 1.0 Approved on 11/10/2016) - You already viewed this item	
	Added to the Submission:		11/10/2016 1:55:50 PM PST			
	Outcome:	Approved	Approval Date:	11/10/2016	Expiration Date:	11/09/2018

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.).

<input checked="" type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.1)	
<input checked="" type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (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	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC - IACUC - Review Response Form - (Version 1.0)	+
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.1)	+
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.0)	+
Application						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC Application Form - (Version 1.0)	+
Document(s)						
Category : ACORP Diagram						
<input type="checkbox"/>	<input type="checkbox"/>				ACORP Diagram - (Version 1.1) <i>*Revision created by the IACUC.</i>	+

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.

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	Unattach	Revise/ Attach	Submission Component Name - Version	More Details
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>			IACUC - IACUC - Review Response Form - (Version 1.0)	+
<input type="checkbox"/>	<input type="checkbox"/>			iMedRIS Initial Review Submission Form - (Version 1.1)	+
<input type="checkbox"/>	<input type="checkbox"/>			iMedRIS Initial Review Submission Form - (Version 1.0)	+
Application					
<input type="checkbox"/>	<input type="checkbox"/>			IACUC Application Form - (Version 1.0)	+


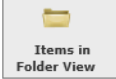




When you first click **Items in List View**, you default to the most current round. A new field populates on the page allowing you to select a round from the drop down list. The Compare column is not applicable in this view, because you are only looking at the current round's documents.

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: 1 ▼

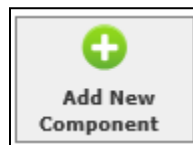
Compare	Include in PDF Packet	Submission Component Name - Version	More Details
Submission Form(s)			
<input type="checkbox"/>	<input type="checkbox"/>	iMedRIS Initial Review Submission Form - (Version 1.0)	⊕
Application			
<input type="checkbox"/>	<input type="checkbox"/>	IACUC Application Form - (Version 1.0)	⊕
Document(s)			
Category : ACORP Diagram			
<input type="checkbox"/>	<input type="checkbox"/>	ACORP Diagram - (Version 1.1)	⊕

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 Study 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
 Attach

<input type="checkbox"/>	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Attached			1.1 11/10/2016		ACORP Diagram *Revision modified by the IACUC.	Susan Investigator	11/10/2016 01:19:00 PM	
Already Attached			1.0 11/10/2016		ACORP Study Timeline * This document was part of this submission.	Susan Investigator	11/10/2016 02:08:39 PM	
<input type="checkbox"/>			1.0		Study Timeline	Susan Investigator	11/10/2016 04:35:48 PM	

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.

Study Number: MII
PI: Investigator, Susan M., Ph.D. **Study Documents**

***Document Title:**

Reference Number: 000233

***Version Number:** .0

***Version Date:**

***Category:** --none--

Comments:

Description:

***Load the document into iRIS:**

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 Study 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

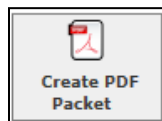
<input checked="" type="checkbox"/>	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Attached			1.1 11/10/2016		ACORP Diagram *Revision modified by the IACUC.	Susan Investigator	11/10/2016 01:19:00 PM	
Already Attached			1.0 11/10/2016		ACORP Study Timeline * This document was part of this submission.	Susan Investigator	11/10/2016 02:08:39 PM	
Already Attached			1.0		New Study Document *Revision modified by the IACUC.	Susan Investigator	11/10/2016 04:38:28 PM	
<input type="checkbox"/>			1.0		Study Timeline	Susan Investigator	11/10/2016 04:35:48 PM	

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.

Document(s)					
Category : ACORP Diagram					
<input type="checkbox"/>	<input type="checkbox"/>			ACORP Diagram - (Version 1.1) *Revision created by the IACUC.	
Category : ACORP Study Timeline					
<input type="checkbox"/>	<input type="checkbox"/>			ACORP Study Timeline - (Version 1.0 Approved on 11/10/2016) - You already viewed this item	
Category : Other					
<input type="checkbox"/>	<input type="checkbox"/>			New Study Document - (Version 1.0) *Added by the IACUC.	

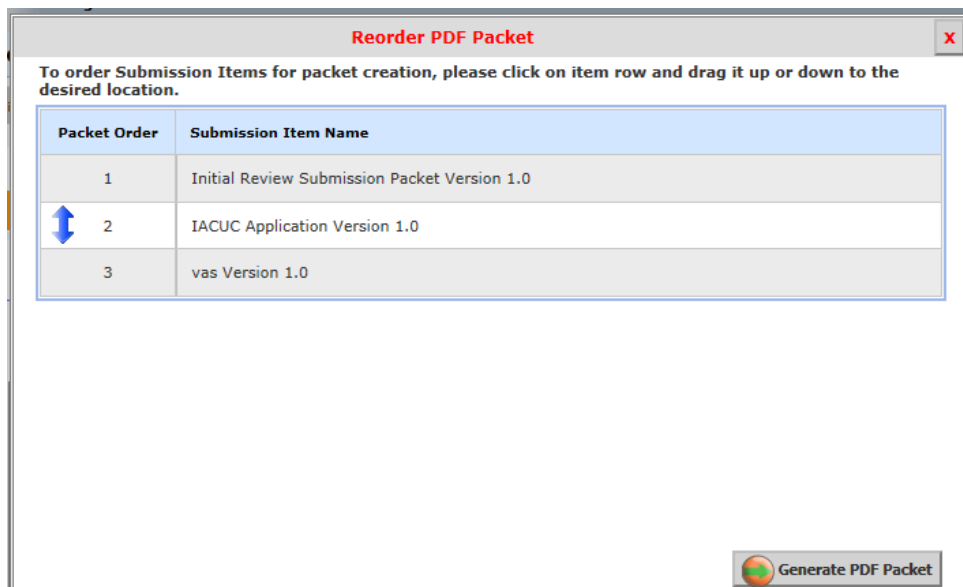
Create PDF Packet

You can send multiple components to be bundled and printed.

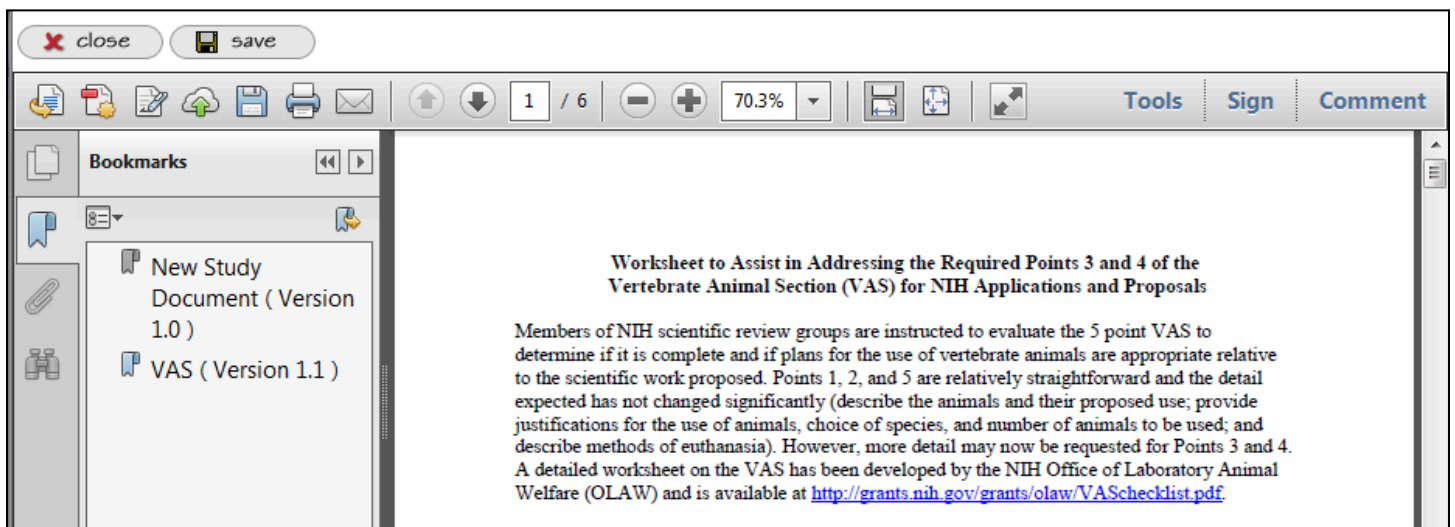


The first step: check off which items you would like to print in the **Include in PDF Packet** column. Then click the **Create PDF Packet** button.

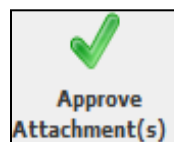
The second step: organize your selected items in the order you would like to print them. Do so by mousing over the item (a blue arrow will appear in the **Packet Order** column) and dragging it to the desired location. When you are done, click the **Generate PDF Packet** button on the bottom right of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



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.



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.

Study Number: MII PI: Investigator, Susan M., Ph.D.		Submission Attachment(s) Approval					Back	
Please use the check box to select the consents and documents you want to approve.								Approve
2 result(s) found...								
<input type="checkbox"/>		Title	Version	Original	Stamped	Review Outcome <input type="checkbox"/> Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
<input type="checkbox"/>		VAS	1.1 07/16/2014			--none--		Use of the Expiration Date has been disabled
<input type="checkbox"/>		New Study Document <i>*Revision modified by the IACUC.</i>	1.0 07/17/2014			--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.

Document attachment(s).		
<input checked="" type="checkbox"/>		VAS
<input type="checkbox"/>		New Study Document <i>*Revision modified 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.

<input checked="" type="checkbox"/>		Title	Version	Original	Stamped	Review Outcome <input checked="" type="checkbox"/> Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
<input checked="" type="checkbox"/>		VAS	1.1 07/16/2014			--none--		Use of the Expiration Date has been disabled
<input checked="" type="checkbox"/>		New Study Document <i>*Revision modified by the IACUC.</i>	1.0 07/17/2014			--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.

<input checked="" type="checkbox"/>		Title	Version	Original	Stamped	Review Outcome <input checked="" type="checkbox"/> Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
<input checked="" type="checkbox"/>		VAS	1.1 07/16/2014			Approved	07/17/2014	Use of the Expiration Date has been disabled
<input checked="" type="checkbox"/>		New Study Document <i>*Revision modified by the IACUC.</i>	1.0 07/17/2014			Approved	07/17/2014	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.

<input checked="" type="checkbox"/>		Title	Version	Original	Stamped	Review Outcome <input checked="" type="checkbox"/> Click here approve all	Approval Date	Expiration Date
Document attachment(s).								
<input checked="" type="checkbox"/>		VAS	1.1 07/16/2014			Approved	07/17/2014	Use of the Expiration Date has been disabled
<input checked="" type="checkbox"/>		New Study Document <i>*Revision modified by the IACUC.</i>	1.0 07/17/2014			Approved	07/17/2014	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 <input checked="" type="checkbox"/>	Unattach	Revise/ Attach	Revisions 	Current Submission Components (All Rounds)	More Details +
Submission Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC - IACUC - Review Response Form - (Version 1.0)	+
<input type="checkbox"/>	<input type="checkbox"/>				iMedRIS Initial Review Submission Form - (Version 1.1)	+
Application						
<input type="checkbox"/>	<input type="checkbox"/>				IACUC Application Form - (Version 1.0)	+
Document(s)						
Category : ACORP Diagram						
<input type="checkbox"/>	<input type="checkbox"/>				ACORP Diagram - (Version 1.1) <i>*Revision created by the IACUC.</i>	+
Category : ACORP Study Timeline						
<input type="checkbox"/>	<input type="checkbox"/>				ACORP Study Timeline - (Version 1.0) Approved on 11/10/2016	+

Correspondence

General Information
Submission Components
Correspondence
Submission History
Pre-review Screening

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:

Study Nickname: Animal Study
PI: Investigator, Susan

IACUC - Submission Response for iMedRIS Initial Review Submission Form Back

Protocol Items | Miscellaneous | IACUC Items | Submission Forms | Additional Attached Forms

Ref Number : **005012** | IACUC Number : **ANI-16-494** | Study Title : Animal Study

Study 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.

Study Nickname: Animal Study
PI: Investigator, Susan

Submission Correspondence Back

Ref Number : **005012** | IACUC Number : **ANI-16-494** | Study Title : Animal Study

Study 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

Rich text editor toolbar with icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert table, and other formatting options.

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.

Correspondence contact			Back
			Save Changes
Contacts	Role	<input checked="" type="checkbox"/>	
Study Personnel			
	Principal Investigator	<input type="checkbox"/>	Investigator, Susan M., Ph.D.
	Co-Investigator	<input type="checkbox"/>	Investigator, Patrick, Ph.D
	Study Coordinator	<input type="checkbox"/>	Coordinator, Mary Jane, R.N.
	Study Author	<input type="checkbox"/>	Administrator
	Study Contact	<input type="checkbox"/>	Investigator, Susan M., Ph.D.
IACUC Committee 01			
	Board Member	<input type="checkbox"/>	Administrator
		<input type="checkbox"/>	Member, Joe

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.

Correspondence Additional Contacts			Back
			Add A New Contact Save And Return
<input checked="" type="checkbox"/>	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.

Correspondence Additional Contacts			Back
			Add A New Contact Remove Selected Contacts Save And Return
<input checked="" type="checkbox"/>	Name	E-mail Address	
<input type="checkbox"/>	John Test	jtest@imedris.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.

Add Attachment		Back
		Save And Return
*Title:	<input type="text"/>	
Load the document into iRIS:	<input type="button" value="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.

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



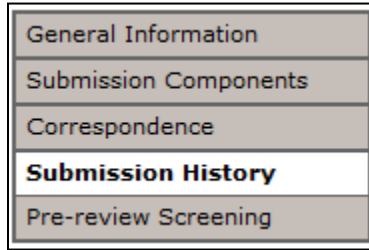
Import Template: Within Review Board Administration, correspondence templates can be set up. These templates can then be imported into the correspondence by selecting the desired template from the drop down list and clicking the **Import Template** button.

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.

Submission Correspondence 1			
1 result(s) found...			
Delete	View Message	Author	Subject
		Susan Investigator	Posted: Delivery in Progress (Animal Study) Submission Correspondence
Post a Reply to this Topic / Forward this Topic			

Submission History



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

+ Add Additional Signoff
 ✖ Delete Additional Signoff(s)

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Submission History ⓘ

	Status	View Details	Date Received / Date Completed	Event Description
⊕			07/16/2014 03:29 PM PDT /	IACUC received the submission
⊕			07/16/2014 03:29 PM PDT / 07/16/2014 03:29 PM PDT	IACUC assigned with the IACUC Number of GH-14-012
⊕			07/16/2014 03:29 PM PDT / 07/16/2014 03:29 PM PDT	All study personnel have been verified with up to date IACUC training records.
⊕			07/16/2014 03:29 PM PDT / 07/16/2014 03:29 PM PDT	Changed Study Status to Pending - Submitted for Initial Review
⊕			07/16/2014 03:29 PM PDT / 07/16/2014 03:29 PM PDT	Dr. Susan M. Investigator, Ph.D. 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).


		07/18/2014 10:58 AM PDT 07/18/2014 10:58 AM PDT	⊕	Patrick Investigator, Ph.D as Co-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
⊕			07/16/2014 03:29 PM PDT /	IACUC received the submission

This will cause the item to appear as so:

	+	Status	View Details	Date Received / Date Completed	Event Description
	-			07/16/2014 03:29 PM PDT /	IACUC received the submission Study Title: Mouse Study IV Principal Investigator: Dr. Susan M. Investigator, Ph.D. Submission Type: Initial Review Submission Form Reference Number: 000240 Study Number: M4


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

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.

 Save the Pre-Review Screening

<div style="border: 1px solid gray; padding: 2px;"> General Information Submission Components Correspondence Submission History Pre-review Screening </div>	<div style="border: 1px solid gray; padding: 5px; margin-bottom: 10px;"> Analyst Assignment i <div style="border: 1px solid gray; padding: 5px; margin-top: 5px;"> Assign Analyst: --none-- </div> </div> <div style="border: 1px solid gray; padding: 5px; margin-bottom: 10px;"> IACUC Number: i <div style="border: 1px solid gray; padding: 5px; margin-top: 5px;"> IACUC Number: GH-15001 </div> </div> <div style="border: 1px solid gray; padding: 5px;"> Determine Review Process i <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td><input checked="" type="radio"/> Not Assigned</td><td></td></tr> <tr><td><input type="radio"/> Assign to Review Committee Agenda</td><td></td></tr> <tr><td><input type="radio"/> Expedited</td><td></td></tr> <tr><td><input type="radio"/> Designated Reviewer</td><td></td></tr> <tr><td><input type="radio"/> Exempt</td><td></td></tr> <tr><td><input type="radio"/> Pre-Review Forward to another Board/Committee</td><td></td></tr> <tr><td><input type="radio"/> Pre-Review changes requested</td><td></td></tr> <tr><td><input type="radio"/> Process Administratively</td><td></td></tr> </table> </div>	<input checked="" type="radio"/> Not Assigned		<input type="radio"/> Assign to Review Committee Agenda		<input type="radio"/> Expedited		<input type="radio"/> Designated Reviewer		<input type="radio"/> Exempt		<input type="radio"/> Pre-Review Forward to another Board/Committee		<input type="radio"/> Pre-Review changes requested		<input type="radio"/> Process Administratively	
<input checked="" type="radio"/> Not Assigned																	
<input type="radio"/> Assign to Review Committee Agenda																	
<input type="radio"/> Expedited																	
<input type="radio"/> Designated Reviewer																	
<input type="radio"/> Exempt																	
<input type="radio"/> Pre-Review Forward to another Board/Committee																	
<input type="radio"/> Pre-Review changes requested																	
<input type="radio"/> 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.

<input checked="" type="radio"/>	Assign to Review Committee Agenda	Committee Name: Committee One ▼
		Upcoming Meeting Date: 12/02/2016 ▼
		Agenda Category: Continuing Reviews ▼

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.**

General Information	Analyst Assignment ⓘ <input type="button" value="Assign Analyst"/> --none-- ▼							
Submission Components								
Correspondence								
Submission History								
Pre-review Screening	IACUC Number: ⓘ <input type="button" value="IACUC Number"/> GH-15001							
Review Checklist and Comments								
Review Summary	Determine Review Process ⓘ <table border="1"> <tr> <td><input type="radio"/> Not Assigned</td> <td rowspan="2"> Committee Name: Committee 1 ▼ Upcoming Meeting Date: 08/17/2015 ▼ </td> </tr> <tr> <td><input checked="" type="radio"/> Assign to Review Committee Agenda</td> </tr> <tr> <td><input type="radio"/> Expedited</td> <td></td> </tr> <tr> <td><input type="radio"/> Designated Reviewer</td> <td></td> </tr> </table>	<input type="radio"/> Not Assigned	Committee Name: Committee 1 ▼ Upcoming Meeting Date: 08/17/2015 ▼	<input checked="" type="radio"/> Assign to Review Committee Agenda	<input type="radio"/> Expedited		<input type="radio"/> Designated Reviewer	
<input type="radio"/> Not Assigned		Committee Name: Committee 1 ▼ Upcoming Meeting Date: 08/17/2015 ▼						
<input checked="" type="radio"/> Assign to Review Committee Agenda								
<input type="radio"/> Expedited								
<input type="radio"/> Designated Reviewer								
Submission Discussion								
Stipulation								
Internal Submission Routing								
Vote								
Outcome								
Outcome Letter								
Submission Complete								

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 1


	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
	Primary	Member, Frank	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 ?	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 ?	Date Notified	Date Completed
	Primary	--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 ?	Date Notified	Date Completed
	Ad Hoc/ Tertiary	Known System identified User: --none-- OR First Name: <input type="text"/> Last Name: <input type="text"/>	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.


	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
	Primary	Member, Joe	No	07/18/2014	

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.

Assign Reviewers 

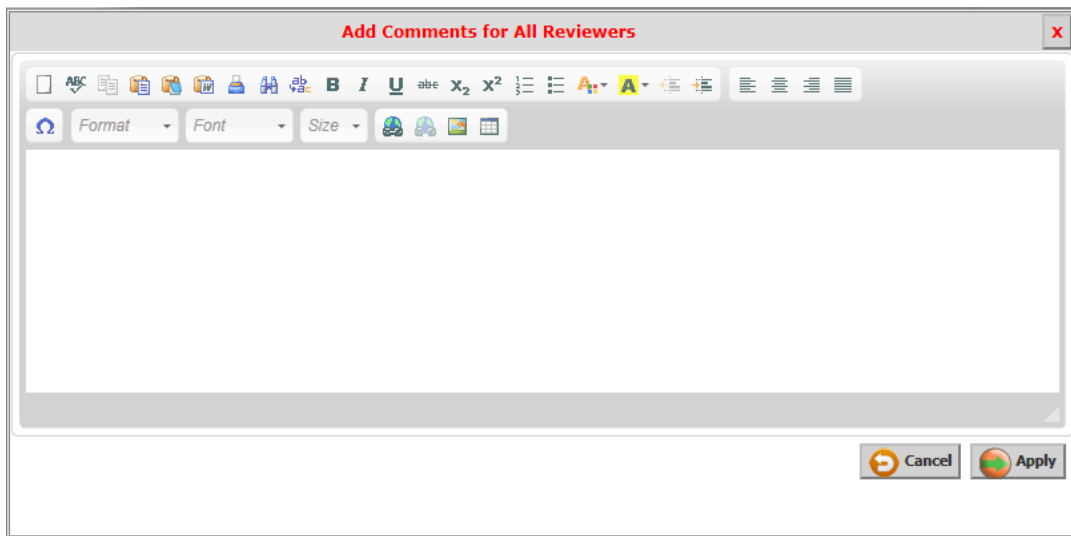
Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
No Reviewers have been assigned to this submission.				

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**.

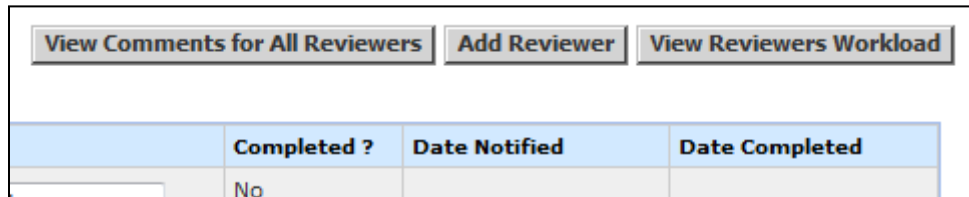
Assign Reviewers 

Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
 Primary	Member, Joe	No		

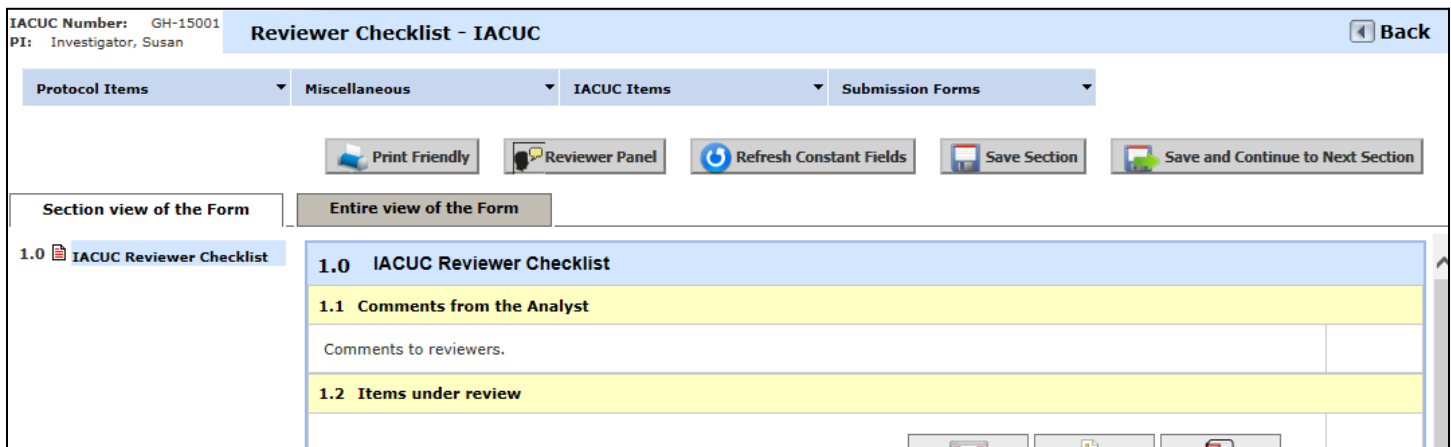
Clicking this button will open a popup within the browser where you can add any information you would like to communicate to the reviewers assigned to the submission. Click the **OK** button at the top right of the window to add the comments. If you do not want to save the comments, click **Cancel**.



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

You can check the workload before adding a board member to review a submission.

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

	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
	Primary	Member, Joe	No	07/18/2014	

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

close
 print

Show Reviews	Member Name	Specialty/ Submission Type	# Assigned/ Date Notified	IACUC Number	PI Name	Reviewer Role	Review Process	Meeting Date
	Administrator	Orthopedist	2					
	Chairperson, Gregory		0					
	Coordinator, Dan	Medical Oncology	0					
	Coordinator, Jan		0					
	Member, Frank		0					
	Member, George	Orthopaedic Surgery	0					
	Member, Joe		3					
		IACUC Animal Incident Report	07/11/2014	GH-14002	Investigator, Susan M..	Primary		
		Initial Review Submission Form	07/18/2014	GH-14-012	Investigator, Susan M..	Primary	Expedite	
		Initial Review Submission Form	07/16/2014	GH-14002	Investigator, Susan M..	Primary	On Agenda	07/25/2014
	Member, Nancy		0					
	Member, Robert		0					
	Member, Sue		0					

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.

Account: Ron User
Department: ADMIN. - RED - Redlands

[Home](#) [Logout](#) [Help](#)

Welcome Ron User

There are new system announcements since the last time you logged in!
[Click this link to view the announcements.](#)

Below are your incomplete IACUC tasks:

Reviewer Assignment

[Open Dashboard](#) **1**

When the reviewer logs in to iRIS, there will be a task in the **incomplete IACUC tasks** group.

When the group is expanded, a reviewer task with details about the submission will populate. The reviewer will click the Open icon to start a reviewer checklist form.

Below are your incomplete IACUC tasks:

Reviewer Assignment 1

Open Dashboard

1 task(s) found... 1 - 1

Open	Principal Investigator	IACUC Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IACUC Initial Approval	Expiration	Received
	Mouse Study IV									
	Dr. Susan M. Investigator, Ph.D.	GH-14-012	M4	Pending - Submitted for Initial Review	Initial Review Submission Form	07/16/2014	Expedited			07/18/2014

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

Study Nickname: Animal Study
PI: Investigator, Susan

IACUC - Submission Review Form 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

1.0 Protocol Information

1.1 Principal Investigator:

Susan Investigator

1.2 Protocol Information

IACUC Number
ANI-16-494
ACORP Title
Animal Study
ACORP Species (select from drop down)
Mouse

1.3 Reviewer:

Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
Primary	User, Ron	No	11/12/2016	

1.4 Comments for All Reviewers

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.

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.

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 Reviewers Complete										1
1 task(s) found...										1 - 1
Open	Principal Investigator	IACUC Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IACUC Initial Approval	Expiration	Received
	Mouse Study IV Dr. Susan M. Investigator, Ph.D.	GH-14-012	M4	Pending - Submitted for Initial Review	Initial Review Submission Form	07/16/2014	Expedited			07/18/2014

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.

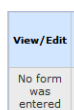
Print Friendly
 Add Member Checklist
 Add Member Comments
 Save the Review Status

<ul style="list-style-type: none"> General Information Submission Components Correspondence Submission History Pre-review Screening Review Checklist and Comments Review Summary Submission Discussion Stipulation Internal Submission Routing Expedited by Outcome Outcome Letter Submission Complete 	<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <p>Reviewer Check List ?</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #e6f2ff;"> <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></td> <td>Primary</td> <td>Member, Joe</td> <td>Yes</td> <td>07/18/2014</td> <td>07/18/2014</td> <td></td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <p>Member Check List ?</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #e6f2ff;"> <th>Delete</th> <th>Members Name</th> </tr> </thead> <tbody> <tr> <td colspan="2">No Member Comments have been assigned to this submission.</td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Member Comments ?</p> <p style="text-align: center;">No Comments entered</p> </div>	View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards		Primary	Member, Joe	Yes	07/18/2014	07/18/2014		Delete	Members Name	No Member Comments have been assigned to this submission.	
View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards													
	Primary	Member, Joe	Yes	07/18/2014	07/18/2014														
Delete	Members Name																		
No Member Comments have been assigned to this submission.																			

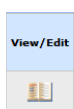
Reviewer Check List

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.

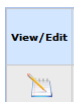
View/Edit – Depending on the status of the review, this column will change.



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.

IACUC - Define Sharing of Reviewer Form with other Boards

Select what Review Board(s) to share Joe Member reviewers form

All

COI



IBC

IRB

Radiation Safety Committee (RSC)

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	Member, Joe	Yes	07/18/2014	07/18/2014	

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.

IACUC Number: GH-15001
 PI: Investigator, Susan

Reviewer Checklist - IACUC

Protocol Items | Miscellaneous | IACUC Items | Submission Forms

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 IACUC Reviewer Checklist

1.0 IACUC Reviewer Checklist

1.1 Comments from the Analyst

Comments to reviewers.

1.2 Items under review

Expand All | Compare Item(s) | Create PDF Packet

Compare | Include in PDF Packet | Current Submission Components (All Rounds) | 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	Member, Joe	Yes	07/18/2014	07/18/2014	

Member Check List

Delete	Members Name
	Member, Robert

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.

The screenshot shows the 'Member Comments' form for Study Number M4, PI: Investigator, Susan M., Ph.D. The form includes a 'Save the comments' button, two checked checkboxes: 'Display my comments on the review' and 'Display my name with the comments', and a rich text editor with various formatting options like bold, italic, underline, and font color.

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.

The screenshot shows the 'Member Comments' form with a red 'X' icon and the member's name 'Member, Robert' displayed next to the text input field. The text in the input field reads: 'Board Member comments on Review Checklist and Comments page.'

Review Summary

The screenshot shows a vertical list of navigation options for the Review Summary page. The options are: General Information, Submission Components, Correspondence, Submission History, Pre-review Screening, Review Checklist and Comments, and Review Summary (which is highlighted in a darker shade).

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.

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
Review Checklist and Comments
Review Summary
Submission Discussion
Stipulation
Internal Submission Routing

Review Summary ⓘ

			Name	Rank	Reference	Item Number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Administrator		IACUC Application Version 1.1	
Please indicate a research purpose.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Administrator		VAS Version 1.0	
Study information needs to be added to all pages.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Administrator		VAS Version 1.0	
List alternative methods for recovery process.						
IACUC Reviewer Checklist						

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.

Name – The name of the user who created the comment displays here.

Rank – Some comments can be ranked. Comments are added to the Review Checklist through the Reviewer Submission Comments data value in the Reviewer Checklist. This will display either Major, Minor, or will be empty.

Reference – The Reference column indicates where the comment originated from. This can display the Submission Form (Initial Review, Full Renewal Form, etc.), the Study Application, or Study Document. This column will also display the version number for the form that the comment was made to.

Item Number – Comments added through the Reviewer Submission Comments data value can also be given an Item Number.

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

IACUC Reviewer Checklist			
Reviewer Findings			
			Item 1
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Joe Member
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Robert Member
			Item 1 text
			Item 2
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Joe Member
			<input type="radio"/> Option 1 <input type="radio"/> Option 2 <input type="radio"/> Option 3
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Robert Member
			<input checked="" type="radio"/> Option 1 <input type="radio"/> Option 2 <input type="radio"/> Option 3

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 ?

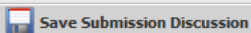
			Name	Rank	Reference	Item Number
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Administrator		IACUC Application Version 1.1	
			Please indicate a research purpose.			

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.

If any comments were merged from the Review Summary tab, that information would display in the discussion similar to the example below. You can modify the discussion by entering that information in to the text editor. Click the **Save Submission Discussion** button when you are finished.

Protocol Items		Miscellaneous		IACUC Items		Submission Forms	
Ref Number :	000240	IACUC Number :	GH-14-012	Study Title :	Mouse Study IV		
Study Status:	Pending - Submitted for Initial Review						
							

<ul style="list-style-type: none"> General Information Submission Components Correspondence Submission History Pre-review Screening Review Checklist and Comments Review Summary Submission Discussion Stipulation Internal Submission Routing Expedited by 	<p>Submission Discussion ⓘ</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Ranking:</p> <p>References: IACUC Application Version 1.1</p> <p>Item Number:</p> <p>Comment: Please indicate a research purpose.</p> <p>Recommendation: Full Approval</p> </div>
---	--

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.

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

The screenshot shows a form with two sections. The first section is titled '*Stipulation Type:' and contains a dropdown menu with the selected option 'Comments that must be addressed'. The second section is titled '*Follow-Up Due' and contains a date input field with a calendar icon to its right.

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

The screenshot shows a form with one section titled '*Stipulation Type:' containing a dropdown menu with the selected option '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)**.

The screenshot shows a dialog box titled 'Associate to components:'. It features a green plus icon next to the text 'Attach Component to Stipulation'. Below this, it states: 'No submission components have been associated yet. Please click on the green add button to associate your Stipulation(s)'. At the bottom, there is a button labeled '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.

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

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

	Type	Component Name	Version
<input type="radio"/>	Document -Other	VAS	Version 1.0

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

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.

Detach	Mod. Request	Component Type	Component Name	Version
<input checked="" type="radio"/>		Document -Other	New Study Document	Version 1.0

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)
<input type="radio"/>	Study Document	Initial Review Submission Form

Section: Study Document

Question: Attach any study documents to include with the initial review submission: Examples would include Drug Brochures, Sponso ...

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 Initial Review Submission Packet	

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.

	Type	Component Name	Version
<input type="radio"/>	Submission Form	Initial Review Submission Form	Version 1.0
<input checked="" type="radio"/>	Application	IACUC Application	Version 1.0

(Optional) Section: ANIMAL SUBJECT DESCRIPTION

(Optional) Question: Species and Animal Characteristics.

<input type="radio"/>	Document -Other	VAS	Version 1.0
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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

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..

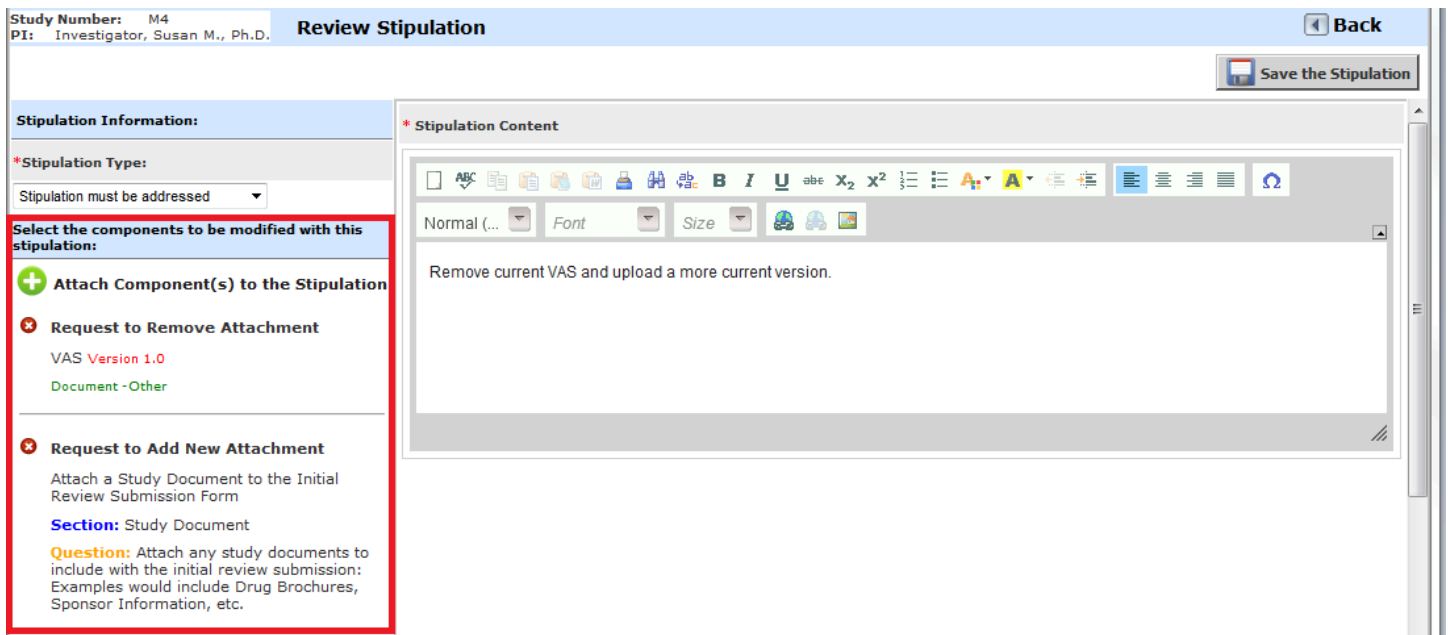
Associate Existing Component - This option will display the existing components that are tied to the submission packet for stipulation association. If the component is a form select the Section and Question that the change is required.

Detach	Mod. Request	Component Type	Component Name	Version
		Application	IACUC Application	Version 1.0

Section: ANIMAL HUSBANDRY AND CARE **Question:** Animal Housing Location Requested.

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.

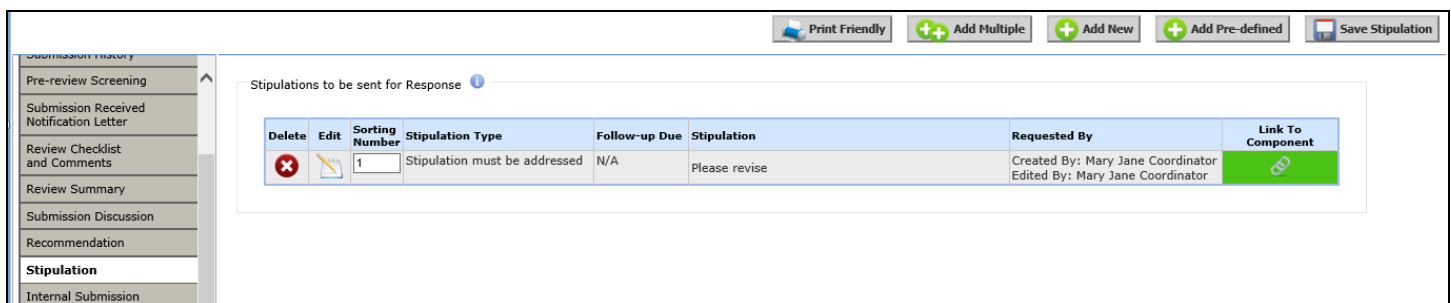
Note: In the example below, multiple request types have been associated to one stipulation. You have the ability to add as many request types as needed to each stipulation, or you can create one stipulation for each request type.



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.



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.

Study Number: M4 PI: Investigator, Susan M., Ph.D. Review Stipulation Back

Save the 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	Requested By	Link To Component
		1	Stipulation must be addressed	N/A	1. Stipulation 1	Created By: Mary Jane Coordinator Edited By: Mary Jane Coordinator	 Click to link
		2	Stipulation must be addressed	N/A	2. Stipulation 2	Created By: Mary Jane Coordinator Edited By: Mary Jane Coordinator	 Click to link
		3	Stipulation must be addressed	N/A	3. Stipulation 3	Created By: Mary Jane Coordinator Edited By: Mary Jane Coordinator	 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.

Study Number: M4 **Review Stipulation** [Back](#)

PI: Investigator, Susan M., Ph.D.

List of approved canned Stipulation

2 result(s) found...

		Stipulation
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Predefined Stipulation Text 1
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Predefined Stipulation Text 2

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.

Stipulations to be sent for Response ?							
Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Requested By	Link To Component
		1	Stipulation must be addressed	N/A	Section H: Animals are not assigned to the proper pain category(ies)	Created By: Mary Jane Coordinator Edited By: Mary Jane Coordinator	 Click to link
		2	Stipulation must be addressed	N/A	Section K: Animal numbers are not adequately justified	Created By: Mary Jane Coordinator Edited By: Mary Jane Coordinator	 Click to link

Merge From Review Summary

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

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.

- Submission History
- Pre-review Screening
- Submission Received Notification Letter
- Review Checklist and Comments
- Review Summary**
- Submission Discussion
- Recommendation

Review Summary ?

			Name	Rank	Reference	Item Number
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Jan Board Member, Ph.D. Please indicate a research purpose		IACUC Application Form Version 1.0	
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Jan Board Member, Ph.D. Please be more specific about dates		ACORP Study Timeline Version 1.0	

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.

Stipulations to be sent for Response ?							
Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Requested By	Link To Component
		7	Stipulation must be addressed	N/A	Please indicate a research purpose	Created By: Jan Board Member Edited By: Jan Board Member	
		8	Stipulation must be addressed	N/A	Please be more specific about dates	Created By: Jan Board Member Edited By: Jan Board Member	

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.

Stipulations with the responses from the previous submission ?						
Order	Edit	Review Action	Date Closed	Stipulation Type	Follow-Up By	Response Ack
The Submission was Received 07/16/2014 and completed 07/17/2014						
1		Accepted	<input type="text"/>	Stipulation must be addressed	N/A	Yes
				Stipulation: Revise app		
				Response:		
2		Accepted	<input type="text"/>	Stipulation must be addressed	N/A	Yes
				Stipulation: Revise this		
				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.

Study Number: MII
 PI: Investigator, Susan M., Ph.D. **Process Stipulation** Back

Study Status: Pending - Submitted for IACUC Number: **GH-14-006** Study Title: Mouse Study II

+ Add Memo Save Stipulation

Review Board Action:	Accepted
Review Board Date Closed:	07/16/2014
Stipulation Type:	Stipulation must be addressed
Follow-up Due:	
Stipulation:	Revise app
Response Acknowledge:	Yes
Response Statement:	

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.

Study Number: MII
 PI: Investigator, Susan M., Ph.D. **IACUC - Stipulation Memo** Back

OK

Stipulation Memo

Normal (...) Font Size

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.

+ Add Memo X Delete Memo Save Stipulation

Review Board Action:	Accepted
Review Board Date Closed:	07/16/2014
Stipulation Type:	Stipulation must be addressed
Follow-up Due:	
Stipulation:	Revise app
Response Acknowledge:	Yes
Response Statement:	

Edit	Name	Date Modified	Memo Details
	Administrator	07/23/2014	Memo text.

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	Follow-up Due	Stipulation	Requested By	Link To Component
		1	Stipulation must be addressed	N/A	Please indicate a research purpose	Created By: Mary Jane Coordinator Edited By: Mary Jane Coordinator	

Stipulations with the responses from the previous submission ?

Order	Edit	Review Action	Date Closed	Stipulation Type	Follow-Up By	Response Ack
The Submission was Received 11/14/2016 and completed 11/14/2016						
7		Response not accepted	11/14/2016	Stipulation must be addressed Stipulation: Please indicate a research purpose	N/A	Yes

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 ?

Order	Edit	Review Action	Date Closed	Stipulation Type
The Submission was Received 07/17/2014 and completed 07/17/2014				
1		Accepted	07/23/2014	Stipulation must be address Stipulation: Revise app Response:
2		Accepted	07/23/2014	Stipulation must be address Stipulation: Revise this Response:

Internal Routing

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

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.

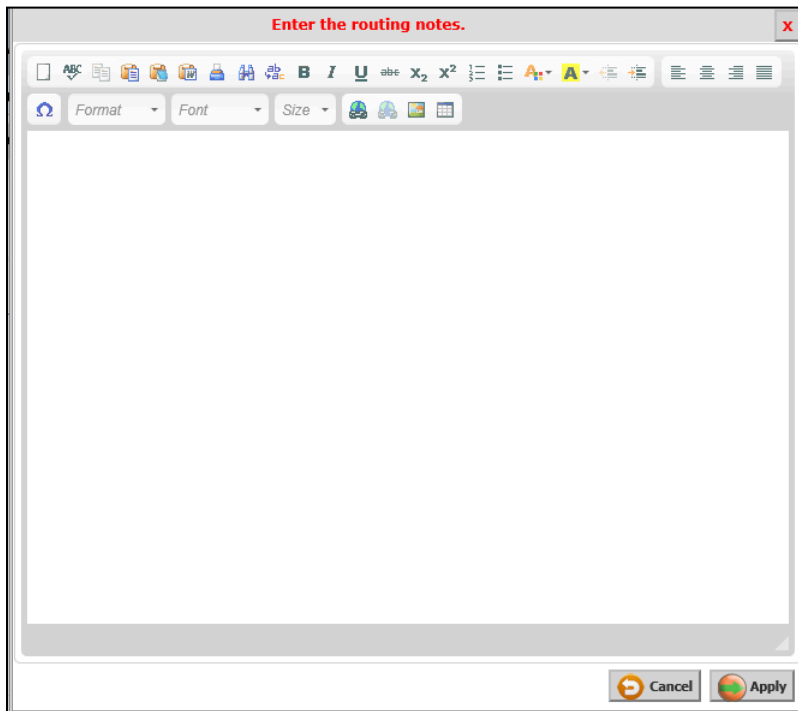
You can compile a list of users needed to complete an internal signoff on the submission. Review Board Members can be added by clicking the **Add Review Board Routing** button. This will create a row that allows you to choose from a drop down list of members on the Review Board.

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.

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.

	Order Number	Click to review	Assignment Comments
			Assigned To
			User Comments
	0		Assignment Comments: Board Member, Jan, Ph.D.
	1		Assignment Comments: Administrator

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



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
	0		Assignment Comments: Please pay special attention to the first document. Board Member, Jan, Ph.D.		
	1		Assignment Comments: The Outcome Letter needs your review. Administrator		

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 Study Routing Signoff assignment and they log in to iRIS, there will be a home screen task under the **Internal Board Routing Signoff** groups. Expand the group, and click the icon in the **Open** column.

<ul style="list-style-type: none"> My Assistant Project Assistant Study Assistant IRB Assistant Change your review board 	Welcome Jan Board Member, Ph.D. Below are your incomplete IACUC tasks: Internal Submission Routing Signoff 1 1 task(s) found... 1 - 1 <table border="1"> <thead> <tr> <th>Open</th> <th>Principal Investigator</th> <th>IACUC Number</th> <th>Study Alias</th> <th>Study Status</th> <th>Submission Form Name</th> <th>Submission Date</th> <th>Review Process</th> <th>IACUC Initial Approval</th> <th>Expiration</th> <th>Received</th> </tr> </thead> <tbody> <tr> <td></td> <td>Susan Investigator</td> <td>ANI-16-496</td> <td>Animal Study</td> <td style="background-color: orange;">Pending - Submitted for Initial Review</td> <td>Submission Response for iMedRIS Initial Review Submission Form</td> <td>11/14/2016</td> <td>Administrative</td> <td></td> <td></td> <td>11/14/2016</td> </tr> </tbody> </table>	Open	Principal Investigator	IACUC Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IACUC Initial Approval	Expiration	Received		Susan Investigator	ANI-16-496	Animal Study	Pending - Submitted for Initial Review	Submission Response for iMedRIS Initial Review Submission Form	11/14/2016	Administrative			11/14/2016
Open	Principal Investigator	IACUC Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IACUC Initial Approval	Expiration	Received													
	Susan Investigator	ANI-16-496	Animal Study	Pending - Submitted for Initial Review	Submission Response for iMedRIS Initial Review Submission Form	11/14/2016	Administrative			11/14/2016													

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.

Study Nickname: Animal Study
 PI: Investigator, Susan

IACUC - Submission validation Back

Protocol Items | Miscellaneous | IACUC Items | Submission Forms | Additional Attached Forms

Ref Number : **005017** IACUC Number : **ANI-16-496** Study Title : Animal Study

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

Submission components:

Compare	Include in PDF Packet	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)				
<input type="checkbox"/>	<input type="checkbox"/>		IACUC - Review Response Form - (Version 1.0) (Parent of the submission package)	⊕
<input type="checkbox"/>	<input type="checkbox"/>		iMedRIS Initial Review Submission Form - (Version 1.0)	⊕
Application				
<input type="checkbox"/>	<input type="checkbox"/>		IACUC Application Form - (Version 1.1)	⊕
Document(s)				
Category : ACORP Diagram				

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 :
 Assignment notes :

Assigned To	Assigned From	Date Notified	Completed ?	Date Completed
Assignment comments				
User comments				
Assignment Comments: Please pay special attention to the first document.				
Board Member, Jan, Ph.D.	Coordinator, Mary Jane, R.N.	11/14/2016	Complete: <input type="radio"/> Yes <input checked="" type="radio"/> No	
<input type="button" value="User Comments"/>				
Assignment Comments: The Outcome Letter needs your review.				
Administrator	Coordinator, Mary Jane, R.N.	11/14/2016	No	

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.

Welcome Ann Analyst

Below are your incomplete IACUC tasks:

- Analyst Assignment Open Dashboard 2
- Internal Submission Routing Complete 1

1 task(s) found... 1 - 1

Open	Principal Investigator	IACUC Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IACUC Initial Approval	Expiration	Received
	Animal Study Susan Investigator	ANI-16-496	Animal Study	Pending - Submitted for Initial Review	Submission Response for iMedRIS Initial Review Submission Form	11/14/2016	Administrative			11/14/2016

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.

Save Routing List

<ul style="list-style-type: none"> 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 	<p style="text-align: right;">Study Title: Mouse Study Reference Number: 000032 Submission Type: Initial Review Submission Packet Assigned Analyst:</p> <p>Assignment notes:</p> <p style="background-color: #90EE90; padding: 5px; text-align: center;">Have you completed your selection of required routings?</p> <p style="text-align: right;"> <input checked="" type="radio"/> Yes <input type="radio"/> No </p> <p style="text-align: center;"> <input type="button" value="+ Add Review Board Routing"/> <input type="button" value="+ Add Non-Review Board Routing"/> <input type="button" value="Print Friendly"/> </p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 10%;">Order Number</th> <th style="width: 10%;">Click to review</th> <th colspan="3">Assignment Comments</th> </tr> <tr> <th></th> <th></th> <th></th> <th>Assigned To</th> <th>Date Notified</th> <th>Date Completed</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;">0</td> <td></td> <td colspan="3">User Comments</td> </tr> <tr> <td></td> <td></td> <td></td> <td colspan="3">Assignment Comments: <i>Pay special attention to xyz.</i></td> </tr> <tr> <td></td> <td></td> <td></td> <td style="text-align: center;">Member, Frank</td> <td style="text-align: center;">08/06/2015</td> <td style="text-align: center;">08/06/2015</td> </tr> <tr> <td></td> <td></td> <td></td> <td colspan="3">Frank Member's Comments: <i>Reviewed required material.</i></td> </tr> <tr> <td></td> <td style="text-align: center;">1</td> <td></td> <td colspan="3">Assignment Comments: <i>The Outcome Letter needs your review.</i></td> </tr> <tr> <td></td> <td></td> <td></td> <td style="text-align: center;">Administrator</td> <td style="text-align: center;">08/06/2015</td> <td style="text-align: center;">08/06/2015</td> </tr> <tr> <td></td> <td></td> <td></td> <td colspan="3">Administrator's Comments:</td> </tr> </tbody> </table>		Order Number	Click to review	Assignment Comments						Assigned To	Date Notified	Date Completed	<input checked="" type="checkbox"/>	0		User Comments						Assignment Comments: <i>Pay special attention to xyz.</i>						Member, Frank	08/06/2015	08/06/2015				Frank Member's Comments: <i>Reviewed required material.</i>				1		Assignment Comments: <i>The Outcome Letter needs your review.</i>						Administrator	08/06/2015	08/06/2015				Administrator's Comments:		
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Vote / Expedited By / Acknowledged By

<ul style="list-style-type: none"> 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 Submission Complete 	<ul style="list-style-type: none"> General Information Submission Components Correspondence Submission History Pre-review Screening Review Checklist and Comments Review Summary Submission Discussion Stipulation Internal Submission Routing Expedited by Outcome Outcome Letter Submission Complete 	<ul style="list-style-type: none"> General Information Submission Components Correspondence Submission History Pre-review Screening Review Checklist and Comments Review Summary Submission Discussion Stipulation Internal Submission Routing Acknowledged By Outcome Outcome Letter Submission Complete
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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.

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.

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 i

✖ 📝 Approved

Vote	Member Name	Gender	Specialty	Relationship to the Institution	Affiliation	Representational capacity	Representative of specific entity
For	Analyst, Ann						
Comments: <input type="text"/>							
For	Board Member, Jan, Ph.D.	Female	Medical Oncology	Affiliated		Scientist	Radiation Safety
Comments: <input type="text"/>							
For	Coordinator, Mary Jane, R.N.	Female					
Comments: <input type="text"/>							
For	User, Ron						
Comments: <input type="text"/>							

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 i

✖ 📝 Approved

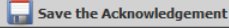
Number	Vote Type	Comments
<input type="text" value="0"/>	For	<input type="text"/>
<input type="text" value="0"/>	Absent	<input type="text"/>
<input type="text" value="0"/>	Against	<input type="text"/>
<input type="text" value="0"/>	Abstain	<input type="text"/>
<input type="text" value="0"/>	Conflict of Interest	<input type="text"/>
<input type="text" value="0"/>	Not present for Vote	<input type="text"/>

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.



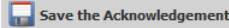
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If the submission has been set to **Exempt** the tab will read as **Acknowledged By**.

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.

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Outcome

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
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.

The screenshot shows the 'IACUC Review Outcome' tab selected in a sidebar menu. The main content area displays 'IACUC Review Outcome' with an information icon. Below this, there is a 'Study Status' dropdown menu currently set to 'Pending - Submitted for Initial Review'. In the top right corner of the main area, there is a 'Save the Submission Outcome' button with a floppy disk icon.

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.

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.

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 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.

Tabled Outcomes

There are times when a submission item cannot be reviewed at a particular meeting date. If this happens, you can set the outcome information to a Tabled status and send the submission to a different meeting for review.

You would select the **Review Outcome** from the drop down list and leave the **Submission Approval** and **Study Status** as is.

Review Outcome:	Tabled	Study Status:	Pending - Submitted for Initial Review
Additional information required:	No		
Submission Approval:	<input type="text"/>		

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	Study Status:	Disapproved
Additional information required:	No		
Submission Approval:	<input type="text"/>		

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	Study Status:	Pending - Submitted for Initial Review
Additional information required:	Yes		
Follow-up Due:	<input type="text"/>		

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--	Study Status:	Pending - Submitted for Initial Review
Additional information required:	No	Assign the Submission to Agenda:	Committee Name: --none--
Submission Approval:	<input type="text"/>		Meeting Date: --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.

The screenshot shows a sidebar with three options: **Internal Comments:** Internal comments to the review board; **Shared Comments:** Shared comments will be seen by other review boards associated to the study; and **Take Note:**. Below these options is a text editor containing the text: "IACUC take note of special circumstances on the study".

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.

The screenshot shows the IACUC Assistant interface with a sidebar on the left containing a navigation menu: **General Information**, Submission Components, Correspondence, Submission History, Pre-review Screening, Review Checklist and Comments, Review Summary, and Submission Discussion. The main content area shows the "General Information" tab with fields for "Study Number: M4", "Edit the Master Lay Summary", "Click Here to edit the submission summary", and "Internal Comments: Internal comments to the review board". A "Message from webpage" pop-up window is overlaid on the interface, displaying a warning icon and the text: "IACUC take note of special circumstances on the study". An "OK" button is visible at the bottom of the pop-up.

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.

Meeting Date:	08/25/2014	IACUC Initial Approval:	08/25/2014
Review Cycle:	12 Months	IACUC Expiration:	8/24/2015
Teaching:	<input type="radio"/> Yes <input checked="" type="radio"/> No	Calculate Expiration Date	
Type Assigned:	Survival Surgery	Full Review Expiration:	8/24/2017
Temporary Closed:	<input type="radio"/> Yes <input checked="" type="radio"/> No	USDA Class:	B
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:	08/25/2014
--------------------------------	------------

IACUC Initial Approval:	07/16/2014
--------------------------------	------------

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:	12 Months
Teaching:	--none--
Type Assigned:	3 Months
Temporary Closed:	6 Months
	12 Months
	18 Months
	<input type="radio"/> Yes <input checked="" type="radio"/> No

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.

IACUC Review Outcome ⓘ

Review Outcome: Approved

Study Status: Pending - Submitted for Initial Review

Additional information required: No

Submission Approval: 08/25/2014

Internal Comments:

Shared Comments:

Take Note:

Meeting Date: 08/25/2014

Review Cycle: 12 Months

Teaching: Yes No

IACUC Initial Approval: 08/25/2014

IACUC Expiration: 08/24/2015 **Calculate 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	Category Type	Total Number Requested	Total Number Approved	Strain Stock	
Mouse		Mus musculus		Laboratory mouse	
Male/Female	B	500	0		

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 Strain					
View Details	Species	Strain	Stock # / Order Code	Special Care	Special Conditions
+	Mouse	Isogenicity	123234234234		

Study Analgesia							
Species	Analgesia	Route	Dose	Frequency	Monitoring	Volume	Duration
Mouse	Chloroform	Oral	1	4 times		1 ml	1 week

Study Anesthetic							
Species	Anesthetic	Route	Dose	Monitoring	Volume	Frequency	Duration
Mouse	Propofol	Injection	1	4	2x day	2x day	1 week

Study Euthanasia							
------------------	--	--	--	--	--	--	--

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

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
Submission Complete

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

Print Friendly Create Letter

<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>General Information</td></tr> <tr><td>Submission Components</td></tr> <tr><td>Correspondence</td></tr> <tr><td>Submission History</td></tr> <tr><td>Pre-review Screening</td></tr> <tr><td>Review Checklist and Comments</td></tr> <tr><td>Review Summary</td></tr> <tr><td>Submission Discussion</td></tr> <tr><td>Stipulation</td></tr> <tr><td>Internal Submission Routing</td></tr> <tr><td>Vote</td></tr> <tr><td>Outcome</td></tr> <tr><td>Outcome Letter</td></tr> </table>	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	<div style="border: 1px solid #ccc; padding: 10px;"> <p>Outcome Letter ⓘ</p> <p>Notification Letter: --none--</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 10%;">Delete/Void</th> <th style="width: 10%;">Send</th> <th style="width: 10%;">Edit/View</th> <th style="width: 40%;">Title</th> <th style="width: 10%;">Signature Required</th> <th style="width: 10%;">Status</th> <th style="width: 10%;">Route Signoff</th> <th style="width: 10%;">Copy</th> </tr> </thead> <tbody> <tr> <td colspan="8" style="text-align: center;">No Letters have been created for this submission.</td> </tr> </tbody> </table> </div>	Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy	No Letters have been created for this submission.							
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																														
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--

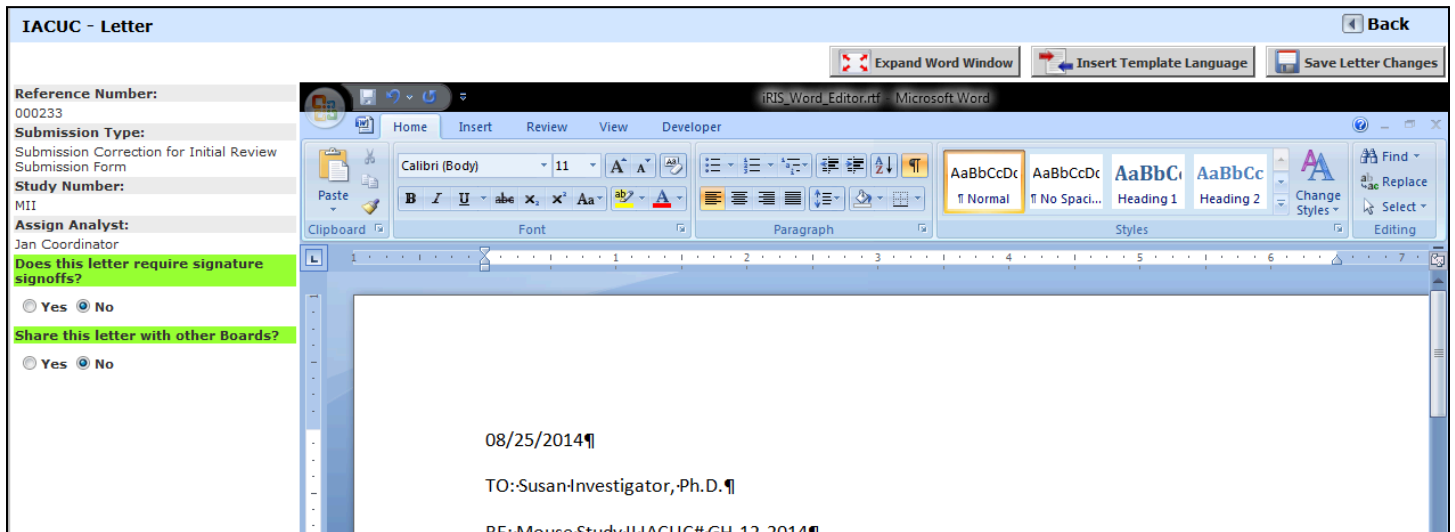
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
No Letters have been created for this submission.							
			Approved Pending Changes				
			Expedited Approval				
			Full Approval Letter				
			IACUC Initial Approval				

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**).



*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.”

Does this letter require signature signoffs?

Yes No

Is batch signoff applicable?

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.

Share this letter with other Boards?

Yes No

Share with Review Board:

All

COI

Contracts

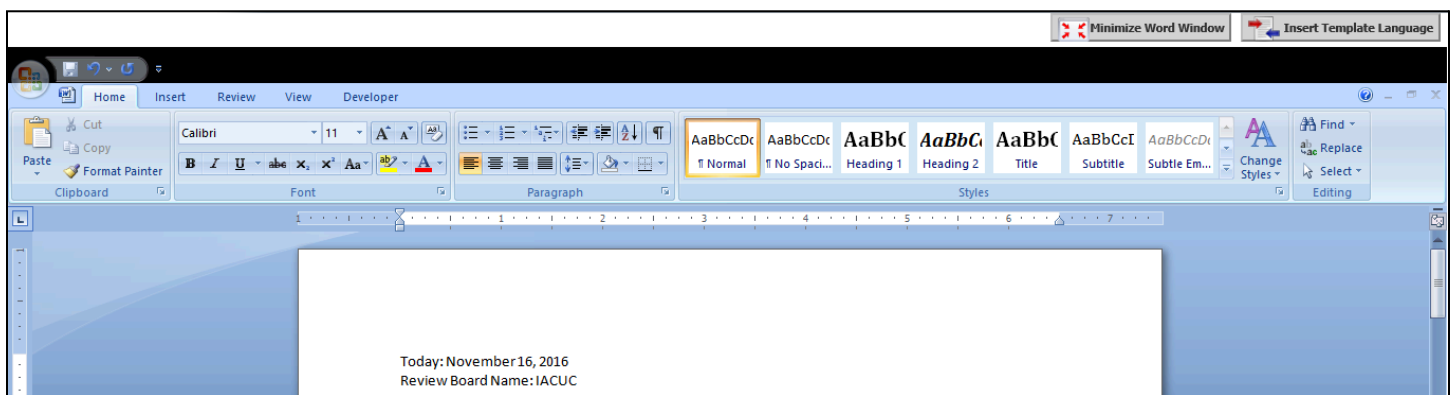
Finance

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.



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

Insert Template Language

Name
 Language 1
 Language 2

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: --none--

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			IACUC - Approval Letter 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.

Does this letter require signature signoffs?

Yes No

Is batch signoff applicable?

Yes No

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**.

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Full Approval Letter Version 1	No	Letter sent --- Completed Sent: 08/05/2014 02:42 PM PDT		

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


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

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

IACUC - Letter Back

<p>Reference Number: 000233</p> <p>Submission Type: Submission Correction for Initial Review Submission Form</p> <p>Study Number: MII</p> <p>Assign Analyst: Jan Coordinator</p> <p>Does this letter require signature signoffs? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Share this letter with other Boards? <input type="radio"/> Yes <input checked="" type="radio"/> No</p>	<p>08/25/2014</p> <p>TO: Susan Investigator, Ph.D.</p> <p>RE: Mouse Study II IACUC# GH-12-2014</p> <p>Dear Dr. Investigator,</p> <p>The IACUC met and reviewed the above mentioned protocol on August 25, 2014 at the Full Board Meeting. The board has motioned to approve your study. Please submit all updates in a timely manner.</p> <p>Thank you,</p> <p>IACUC Chair</p>
--	--

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

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Full Approval Letter 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.

Letter Recipients Back

Submission Type: Submission Correction for Initial Review Submission Form
Study Number: MII **Reference Number:** 000233
Study Title: Mouse Study II
Letter Title: IACUC Outcome Letter (attachment)

Key Study Personnel

Contacts	Role	<input type="checkbox"/>	
Project Personnel			
	Principal Investigator	<input checked="" type="checkbox"/>	Susan M. Investigator, Ph.D.
	Co-Investigator	<input checked="" type="checkbox"/>	Patrick Investigator, Ph.D.
	Study Coordinator	<input checked="" type="checkbox"/>	Mary Jane Coordinator, R.N.
	Veterinarian	<input checked="" type="checkbox"/>	Nancy Veterinarian

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.

Search User Directory Back

Directory Browse/Find:
Last Name: admin (You may enter a partial name to search)
First Name:
by Department: All Departments

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Administrator	Department (primary)	

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.

Additional Recipients

Association	Send if checked	Additional Recipients
iRIS	<input checked="" type="checkbox"/>	Administrator

Click the **Add recipient manually** button to enter in an email address for a person who does not have an account in iRIS.

Letter Additional recipients ◀ Back

+ Add A Recipient
Save And Return

<input checked="" type="checkbox"/>	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.

Letter Additional recipients ◀ Back

+ Add A Recipient
✖ Remove Selected Recipients
Save And Return

<input checked="" type="checkbox"/>	Name	E-mail Address
<input type="checkbox"/>	John Adams	jadams@imedris.com
<input type="checkbox"/>	Scott West	swest@imedris.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.


Association	Send if checked	Additional Recipients
iRIS	<input checked="" type="checkbox"/>	Administrator
	<input checked="" type="checkbox"/>	John Adams
	<input checked="" type="checkbox"/>	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.

Letter Recipients ◀ Back

+ 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.

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Full Approval Letter Version 1	No	Letter sent --- Completed Sent: 08/05/2014 02:42 PM 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.

IACUC - Submission Letter Signoff Routing List Back

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

Study Title: Mouse Study II
Reference Number: 000233
Submission Type: Submission Correction for Initial Review Submission Form
Letter Name: Full Approval 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	Signoff	Approved	Include Signature	Allow Change
0	Coordinator, Board			Yes	No
	--none--				
	Administrator				
	Coordinator, Jan				
	Coordinator, Board				
	Investigator, Anne				
	Investigator, Principal				
	Investigator				
	Member, Harold				
	Member, Bob				
	Member, Frank				

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

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
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Test, Joe	Department (primary)	jtest@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, Jan			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.

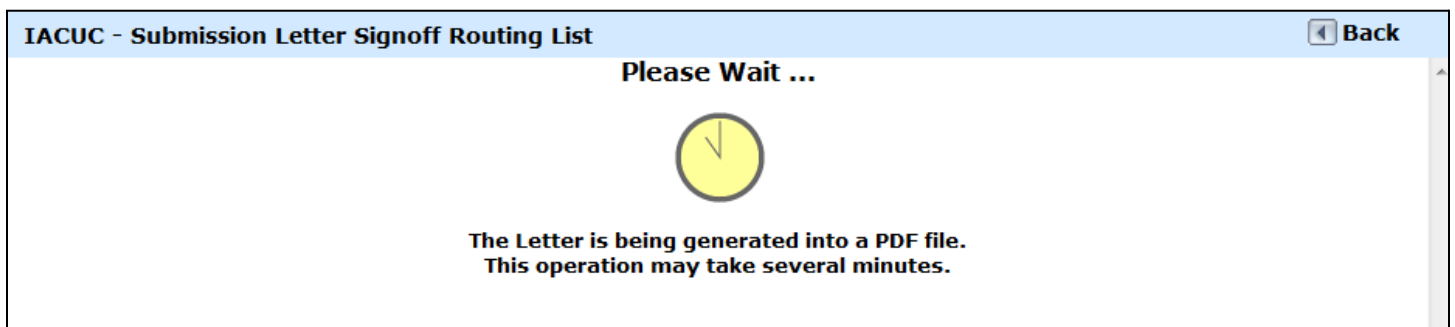
Comments – Any comments the user may have entered upon signoff.

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.

IACUC - Letter ◀ Back

Reference Number:	000233
Submission Type:	Submission Correction for Initial Review Submission Form
Study Number:	MII
Assign Analyst:	TO: Susan Investigator, Ph.D.
Does this letter require signature signoffs?	RE: Mouse Study II IACUC# GH-12-2014
<input checked="" type="radio"/> Yes <input type="radio"/> No	Dear Dr. Investigator,
Is batch signoff applicable?	The IACUC met and reviewed the above mentioned protocol on August 25, 2014 at the Full Board Meeting. The board has motioned to approve your study. Please submit all updates in a timely manner.

Any user assigned to sign off on an Outcome Letter will receive a homepage task.

◀ Welcome Jan Board Member, Ph.D.

Below are your incomplete IACUC tasks:

Outcome Letter Signoff 1

1 task(s) found... 1 - 1

Open	Principal Investigator	IACUC Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IACUC Initial Approval	Expiration	Received
	Animal Study									
	Susan Investigator	ANI-16-497	Animal Study 3	Pending - Submitted for Initial Review	iMedRIS Initial Review Submission Form	11/15/2016	Administrative			11/15/2016

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.

Letter Signoff ◀ Back

Save Letter Review

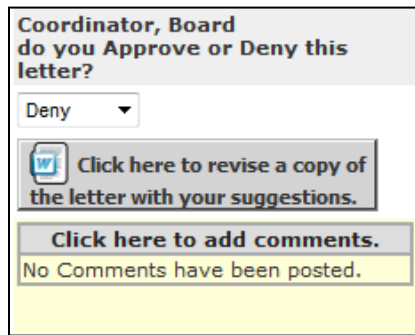
Reference Number:	000233
Submission Type:	Submission Correction for Initial Review Submission Form
Study Number:	MII
Coordinator, Jan do you Approve or Deny this letter?	TO: Susan Investigator, Ph.D.
--none--	RE: Mouse Study II IACUC# GH-12-2014
Click here to add comments.	Dear Dr. Investigator,
No Comments have been posted.	The IACUC met and reviewed the above mentioned protocol on August 25, 2014 at the Full Board Meeting. The board has motioned to approve your study. Please submit all updates in a timely manner.

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.

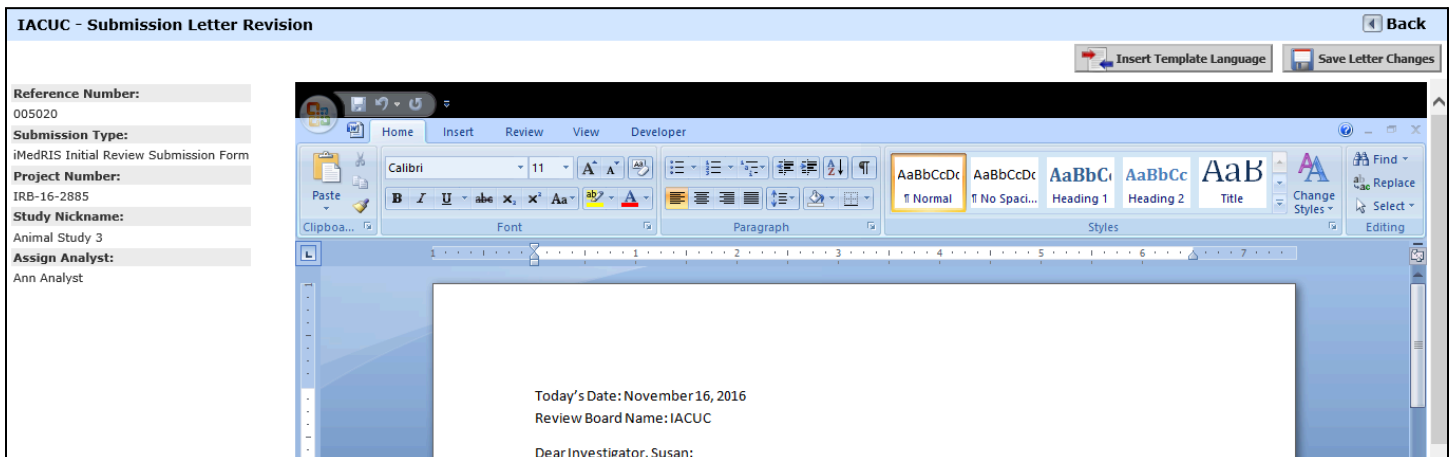
There is a dropdown list that the user can use to select either Approve or Deny. After making a selection, the user will be prompted to enter their UIN and password to complete the signoff. Click **Save Letter Review** after signing off on the letter.

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.



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.



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.

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Full Approval Letter Version 2	Yes	Denied in Routing		




Click the **Route Signoff** button.

IACUC - Submission Letter Signoff Routing List Back

Study Title:	Mouse Study II
Reference Number:	000233
Submission Type:	Submission Correction for Initial Review Submission Form
Letter Name:	Full Approval Letter

Have you completed your selection of required signatures?

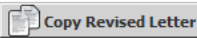
Yes
 No

Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
0	Coordinator, Jan		No  Click here to view changes	Yes	No	08/05/2014 03:08:37 PM PDT	08/05/2014 03:13:52 PM PDT	
1	Administrator			Yes	No			

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**.

IACUC - Submission Letter Revision Back













Reference Number: 000233 Submission Type: Submission Correction for Initial Review Submission Form Study Number: MII	<div style="background-color: #333; color: #fff; padding: 2px; font-size: 0.8em;">iRIS_Word_Editor.rtf - Microsoft Word</div> <div style="background-color: #4f81bd; color: #fff; padding: 2px; font-size: 0.8em;"> Home Insert Review View Developer </div> <div style="background-color: #e6f2ff; padding: 5px; font-size: 0.8em;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;"> Calibri (Body) 11 A A⁺ A⁻ </td> <td style="width: 30%;"> AaBbCcDc AaBbCcDc AaBbCc A </td> <td style="width: 40%;"> ¶ Normal ¶ No Spaci... Heading 1 Change Styles </td> </tr> </table> </div> <div style="border: 1px solid #ccc; height: 150px; margin-top: 5px; display: flex; align-items: center; justify-content: center; font-size: 1.2em;"> 08/25/2014 </div>	Calibri (Body) 11 A A ⁺ A ⁻	AaBbCcDc AaBbCcDc AaBbCc A	¶ Normal ¶ No Spaci... Heading 1 Change Styles
Calibri (Body) 11 A A ⁺ A ⁻	AaBbCcDc AaBbCcDc AaBbCc A	¶ Normal ¶ No Spaci... Heading 1 Change Styles		

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:

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			IACUC - Approval Letter Version 3	No	Waiting to be sent		
			IACUC - Approval Letter Version 2	Yes	Denied in Routing		
			IACUC - Approval Letter Version 1	No	Letter sent --- Voided		

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.

Outcome Letter i

Notification Letter: --none--

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			IACUC - Approval Letter Version 3	Yes	Routing Complete Waiting to be sent		

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.

Account: Susan Investigator
Navigation: Home > submissions > submission item

Home Logout Help

IACUC - Submission Letter Signoff Routing List Back

Study Title: Animal Study
Reference Number: 005020
Submission Type: iMedRIS Initial Review Submission Form
Letter Name: IACUC - Approval 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	Board Member, Jan, Ph.D.		Yes	Yes	No	11/15/2016 04:06:41 PM PST	11/15/2016 04:07:33 PM PST	

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
			Full Approval Letter Version 1	No	Letter sent --- Voided		

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
			Full Approval Letter Version 2	No	Waiting to be sent		
			Full Approval Letter Version 1	No	Letter sent --- Voided		

Submission Complete

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
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.

Study Nickname: Animal Study 4
PI: Investigator, Susan

IACUC - iMedRIS Initial Review Submission Form Back

Protocol Items | Miscellaneous | IACUC Items | Submission Forms | Additional Attached Forms

Ref Number : **005022** | IACUC Number : **ANI-16-498** | Study Title : Animal Study

Study Status: **Active**

Save the Submission Complete

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: Approved
Additional information required: No
Study Status: Active

Submission processing complete:

Review Outcome Letters

Edit/View	Title	Signature Required	Status
	IACUC - Approval Letter Version 1	No	Letter sent --- Completed Sent: 11/15/2016 04:32 PM PST

Display Submission components status

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
	IACUC - Approval Letter Version 1	No	Letter sent --- Completed Sent: 11/15/2016 04:32 PM PST

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
 Create PDF Packet
 Approve Attachment(s)

Compare	Include in PDF Packet	Unattach	Revise/Attach	Current Submission Components (All Rounds)	More Details
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>			iMedRIS Initial Review Submission Form - (Version 1.0)	
Application					
<input type="checkbox"/>	<input type="checkbox"/>			IACUC Application Form - (Version 1.0)	
Document(s)					
Category : ACORP Diagram					
<input type="checkbox"/>	<input type="checkbox"/>			ACORP Diagram - (Version 1.0)	