



IRB ASSISTANT

Submission Processing

Version 11.02

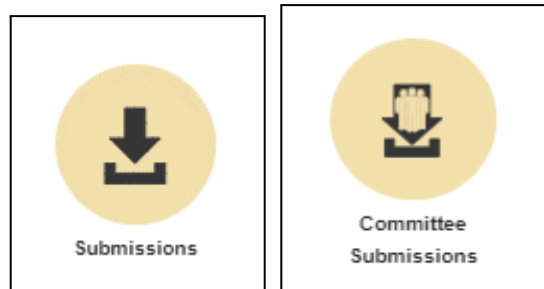
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IRB Submission Processing

Introduction

IRB Assistant will allow you to process new study applications and oversee existing studies. You can review the study, informed consents, and any other study related documents. Through the Submissions area of the Study Assistant, you can process new submissions, assign reviewers, conduct meetings, send out minutes, and letters based on the review outcome. 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 IRB Assistant within the Submissions menu item.

Your build of iRIS™ may display either **Submissions** or **Committee Submissions** in the IRB Assistant list, depending on how your system is setup (Review Board property “rb.use_submission_by committee”. See the IRB 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 six tabs: Not Assigned, Assigned, Completed, Agendas, Pending Action, and Outstanding Board Tasks. When you open the Submissions link, default tab is the Not Assigned tab.

My Workspaces ▾ IRB **Board Submissions** Back

Close Search

Submission Type: All ▾

Active Principal Investigator:

Date Board Received: -

IRB Number: All

Ref Number:

Assigned Analyst:

IRB Expiration Date: -

Reset Find Options

Find ...

Not Assigned **Assigned** Completed Agendas Pending Action Outstanding Board Tasks Print Friendly Display Submissions by: IRB Number ▾

6 result(s) found... 1 - 6

Open	Reference Number	Type	Date Board Received	IRB Expiration Date	Principal Investigator	Assigned Analyst	Codes
	Effectiveness of the Drug Blaxar on people with Diabetes IRB-19-171--1.0	Multi Site Data Request	06/27/2019 04:03:10 AM PDT		Investigator, John		
	Effectiveness of the Drug Blaxar on people with Diabetes IRB-19-171-0001--1.0	Site Progress Report	06/27/2019 05:42:33 AM PDT		Jefferson, Tom		
	Core Study for Multi Site IRB-19-172-0001--1.0	Site Progress Report	06/27/2019 06:20:53 AM PDT		Jefferson, Tom		
	Long-Term Prenatal Use of Acetaminophen Associated with ADHD Risk IRB-19-176-NEW-1.1	Initial Review Submission Form	07/09/2019 03:43:30 PM PDT		Investigator, John	Coordinator, Jane	

“Submission Type” filter, the search results shown in the queue will display the Corrections and Review Response forms along with the same type of forms that were not sent back to the study team.

My Workspaces ▼ IRB **Board Submissions**

Close Search

Submission Type	All ▼	Assigned Analyst:	<input type="text"/>	<input type="button" value="Reset Find Options"/>
Active	Principa Investigator Date Board Received IRB Number Ref Number:	IRB Expiration Date	<input type="text"/> - <input type="text"/>	
	All Initial Review Submission Form Multi Site Data Request Site Progress Report Study Amendment Form			

Not Assigned

Any new submission that is unprocessed will populate within this tab. The columns listed in the Not Assigned tab are as follows:

Not Assigned	Assigned	Completed	Agendas	Pending Approval Letter	<input type="button" value="Print Friendly"/>	Display Submissions by: <input type="text" value="IRB Number"/>					
903 result(s) found... 1 - 100 ▶											
Open		IRB Number	Ref Number	Type		Date Board Received		IRB Expiration Date	Principal Investigator	Assigned Analyst	Department

The column headings can be used to sort the submissions in ascending and descending order.



Display Submissions By – This will change the display of the list of submissions. Whatever number is selected (IRB, Proposal, 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).

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.

IRB, Proposal, or IBC Number – If your system is setup to automatically generate an IRB Number for each study submitted, the number will display here.

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.

Expiration Date – The IRB 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.

Study Classification – This column displays the study classification assigned to the study. The display of this column can be controlled through the Review Board Administration and may or may not be activated in your system (refer to the Review Board Administration Manual).

Risk Assigned – This column displays the risk assigned to the study. The display of this column is also controlled by the Review Board Administration in the Configure Board Properties and may or may not be activated in your system (refer to the Review Board Administration Manual).

Assigned

After assigning a 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.

Not Assigned Assigned Completed Agendas Pending Action Outstanding Board Tasks										Print Friendly	Display Submissions by: IRB Number
73 result(s) found...										1 - 73	
Open	Letters	Reference Number	Type	Review Process	Date Board Received	IRB Expiration Date	Principal Investigator	Assigned Analyst	Assigned Reviewers		
		Depression in older adults IRB-2018-11-???-1.0	Initial Review Submission Packet	Expedite	04/01/2018 01:44:55 PM PDT		Investigator, Principal	Coordinator, Jane	Primary Dean Primary Member Review Ph.D		
		Studying Drug interactions with patients on Presinex IRB-2018-12-???-1.0	Initial Review Submission Packet	Process Administratively	04/01/2018 11:20:20 PM PDT		Administrator		Primary IRB Coordinat		

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 **Review Process, Submission Type, Date Board Completed, Etc.** You can search by additional criteria below by indicating study information or personnel associated to a study. Click the **Reset Find Options** button to refresh the page will reset the search result.

My Workspaces v
IRB | Board Submissions
Back

Close Search
Print Friendly
Display Submissions by: IRB Number v

Submission Type: All

Review Process: All

Active Principal Investigator:

Date Board Received: -

IRB Number: All

Ref Number:

Assigned Analyst:

Assigned Reviewers:

Department: All +

IRB Expiration Date: -

Date Board Completed: 07/23/2019 - 08/06/2019

Reset Find Options

Find ...

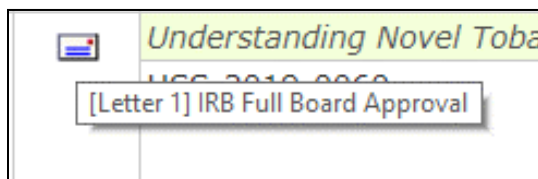
Not Assigned | **Assigned** | Completed | Agendas | Pending Approval Letter
Print Friendly
Display Submissions by: IRB Number v

7 result(s) found...

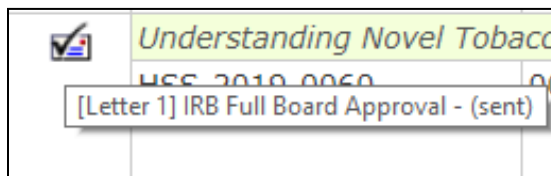
Open	Letters	IRB Number	Ref Number	Type	Review Process	Date Board Completed	IRB Expiration Date	Principal Investigator	Assigned Analyst
						Date Board Received			

Additional fields on this page are:

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



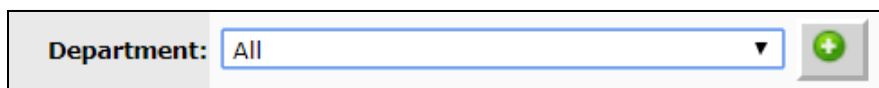
If the letter has already been sent, '(sent)' will appear after the letter type.



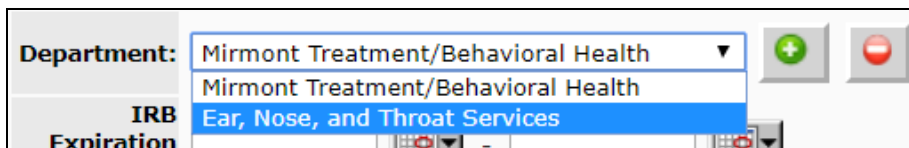
Study Number – This column displays the Study Number associated with the study.

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

Department - The Department filter has a dropdown list, and departments can be added by clicking the green plus button. This filter and column are only displayed if the property rb.use_department_displayed is set to “Yes”.



Clicking the green plus button prompts an ajax window to be prompted where departments can be searched, and many departments can be added at once. When departments are added, the filter allows the system to search for studies associated with all of the selected departments simultaneously. The results from the search are displayed in the queue, and the Department column displays the department name. Once departments have been added, a red minus button appears next to the green plus button. To delete a department, the selection needs to be chosen and the red minus button must be clicked.



Agendas

The Agendas tab will open to the next upcoming meeting for the review board. This page will list out 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 detail on Agenda submission processing see the IRB Meeting Agenda manual.

My Workspaces IRB **Board Submissions** Back

Not Assigned | Assigned | Completed | **Agendas** | Pending Action | Outstanding Board Tasks

Items to be Reviewed at Committee 1 Meeting : ◀ 07/10/2019 ▶ Agenda State: Finalized Reviewer Notifications: Enabled

Show the Finalized Agenda Submission Review validation Save the Agenda Order

Initial Reviews - 1 Submissions

Order	Click to open	Reference Number	COI	Letters	Outcome	Type	Principal Investigator	Reviewer(s)	Date Board Received
1		IRB-19-180-NEW-1.0			Approved	Initial Review Submission Form	Investigator, John	Primary Luke Reviewer, Ph.D	07/10/2019 8:54:05 AM UTC

Continuing Reviews - 1 Submissions

Order	Click to open	Reference Number	COI	Letters	Outcome	Type	Principal Investigator	Reviewer(s)	Date Board Received
1		IRB-19-178-NEW-1.0			Approved	Initial Review Submission Form	Investigator, John	Primary Luke Reviewer, Ph.D	07/09/2019 3:26:11 PM UTC

Expedited Items - 0 Submissions
0 Items for review in this category.

Amendments - 0 Submissions
0 Items for review in this category.

Administrative Action - 0 Submissions
0 Items for review in this category.

Others - 0 Submissions
0 Items for review in this category.

Pending Action

The Pending Action tab will open a list of submissions that require a response or a specific tasks to be completed by the study side before the submission can continue.

Not Assigned | Assigned | Completed | Agendas | **Pending Action** | Outstanding Board Tasks Print Friendly Display Submissions by: IRB Number

2 result(s) found... 1 - 2

Open	Letters	Reference Number	Type	Review Process	Review Outcome	Date Board Received	IRB Expiration Date	Principal Investigator	Assigned Analyst	Assi Rev
		A Prospective Multi-Center Study to Evaluate the Prevalence and Prognostic Significance of T-Wave Alternans in Patients with Left Ventricular Dysfunction	Initial Review Submission Packet	Expedite	Misc. pending Items	03/29/2018 03:18:54 AM PDT		Administrator	Administrator	
		Insomnia in older adults	Initial Review Submission Packet	Expedite	Misc. pending Items	04/01/2018 01:42:45 PM PDT		Investigator, Principal		

Outstanding Board Tasks

The Outstanding Board Tasks tab will open a list of submissions that require action from the review board side. Here, the tasks type and task assigned will show what task needs to be completed and who was assigned the task.

Not Assigned | Assigned | Completed | Agendas | Pending Action | **Outstanding Board Tasks**

27 result(s) found... 1 - 27

Click to open	Task Type	Received	Protocol Status	Protocol Title	Principal Investigator	Assigned Analyst	Assigned Reviewers	RB Number	Ref Number	RB Expiration
	Task Assigned			Study Number						
	Analyst Assignment	04/22/2019 09:34 AM PDT	Pending - Submitted for Initial Review	Use of stem cells on subjects currently being treated for Diabetes Type 2	Investigator, John	Coordinator, Jane		IRB-19-130	IRB-19-130-AMD-1.0	

Processing Submissions

When you open a submission from the Not Assigned tab, you will open the submission processing pages. These pages will present the RB with 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).

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.

Listed in the header:

IRB Number – This is where the IRB number for the study being submitted will display. If the IRB number has not been assigned, then the Study Number will display here.

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

Type of Submission – The type of submission (Initial Review, Adverse Event, 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 four tabs: Protocol Items, Miscellaneous, and 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.

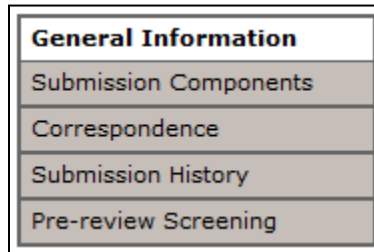
Project/IRB Number – Depending on your configuration of iRIS™, the project number or IRB number will display here in bolded red letters.

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 IRB. This status will change depending on what part of the review cycle it 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.

If a user has multiple board access and the submission has been sent to different review boards, users will be able to see an option to switch between the boards through a link located in the Submission Processing Queue. An open submission with association to multiple boards will create links to the boards that the user has a role in, in the **General Information** tab.

By clicking the different boards associated with the submission, it will open the submission under the board that was clicked on as long as user has access to the specific boards.

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.

Study Personnel Update personnel status to latest				
Role		Name	Account Status	COI Under Review?
Principal Investigator :		Admin Admin admin, B.S. Brig. Gen.	Active	
Study Contact:		Admin Admin admin, B.S. Brig. Gen.	Active	
Study Author:		Admin Admin admin, B.S. Brig. Gen.	Active	

Additional information can be viewed about Study Personnel by clicking on the icon next to the username. 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 IRB. Training is configured to be checked in the workflow, so by the time a submission reaches the IRB, 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 IRB begins the submission processing, you can get the most current information by clicking on the **Update personnel status to the latest** button.

iMedRIS has extended the functionality which enables review board members to **Unlock Submission for Editing** from different rounds accessible in the Miscellaneous lab.

Protocol Items		Miscellaneous	Submission Forms
		Study Summary Information	
Ref Number :	021146	Submission History	
Study Status:	Pending - S Initial Revi	Stipulation History	

Studies that were already completed will be edible except for the “Review Outcome” field within the Outcome tab. However, if the finalized meeting minutes are published for a certain round, then that submission round is locked. The only way board members can unlock that round is if the finalized meeting minutes are unpublished. This functionality will also allow review board members to unlock rounds of submissions that were sent back to the study team for correction and were already opened by the study team.

Submissions in Process		Completed Submissions	Submissions Returned with Changes							
Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
021141			Initial Review Submission Form Real							
			Submission Response for Initial Review Submission Form Real		IRB		Process Administratively		Approved	08/05/2019 04:26:11 PM PDT
			Submission Response for Initial Review Submission Form Real		IRB		Process Administratively		Pre-Review response required	08/05/2019 04:18:50 PM PDT
			Initial Review Submission Form Real		IRB		Process Administratively		Pre-Review response required	08/05/2019 04:07:51 PM PDT

There are many rounds within this submission, two of which have been “Returned for Corrections”. All of these rounds are now editable, the Review Board can unlock the rounds by clicking the **Unlock Submission for Editing** button within each form.

Unlock Submission for Editing

Archival Ref Number: 021141

Department **WW - willy wonka**

Study Personnel

Role	Name	Account Status	COI Under Review?	IRB Training:
Principal Investigator :	Admin Admin admin, B.S. Brig. Gen.	Active		Active training
Study Contact:	Admin Admin admin, B.S. Brig. Gen.	Active		Active training
Study Author:	Admin Admin admin, B.S. Brig. Gen.	Active		Active training

After clicking the **Unlock Submission for Editing** button, a new button which reads **Lock Submission from Editing** appears. Board members should click this button when they have made the desired changes to the round.

Lock Submission from Editing

Department **WW - willy wonka**

Study Personnel

Update personnel status to latest

Role	Name	Account Status	COI Under Review?	IRB Training:
Principal Investigator :	Admin Admin admin, B.S. Brig. Gen.	Active		Active training
Study Contact:	Admin Admin admin, B.S. Brig. Gen.	Active		Active training
Study Author:	Admin Admin admin, B.S. Brig. Gen.	Active		Active training

After unlocking a submission, board members can edit the submission, but cannot alter the **Review Outcome** field. When navigating to the Outcome tab, the Review Outcome field is visibly read-only, and cannot be altered. Board members can however edit everything else on the screen, including the Protocol Status.

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, any attached consents, and study documents. 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 IRB 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 most top-level form, working down to document attachments.

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Current Submission Components (All Rounds)	More Details
Submission Form(s)						
<input type="checkbox"/>					Initial Review Submission Form Real - (Version 1.0)	
Application						
<input type="checkbox"/>					IRB Application - (Version 1.0)	
Consent Form(s)						
Category : Study Consent Category I						
<input type="checkbox"/>					Consent Document (English) - (Version 1.0)	
Document(s)						
Category : Survey						
<input type="checkbox"/>					Study Document 1 - (Version 1.0)	

There are four 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.

Consent Form(s) – Any consent forms that were attached to the parent form will display in this group.

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, no new versions have been created at this time.

Current Submission Components (All Rounds)		More Details
		+
	Initial Review Submission Form Real - (Version 1.0)	⊞
	IRB Application - (Version 1.0)	⊞
	Consent Document (English) - (Version 1.0)	⊞
	Study Document 1 - (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 consents and 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 return this submission to the PI, requesting a modification to the consent form, 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)	More Details
		+
	Initial Review Submission Form Real - (Version 1.0)	⊞
📁	IRB Application - (Version 1.1)	⊞
	Consent Doc (English) - (Version 1.0)	⊞
	Study Document 1 - (Version 1.0)	⊞

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

Application					
<input type="checkbox"/>	<input type="checkbox"/>				IRB Application - (Version 1.1)
<input type="checkbox"/>	<input type="checkbox"/>				IRB Application - (Version 1.0)

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

Viewing Submission Items

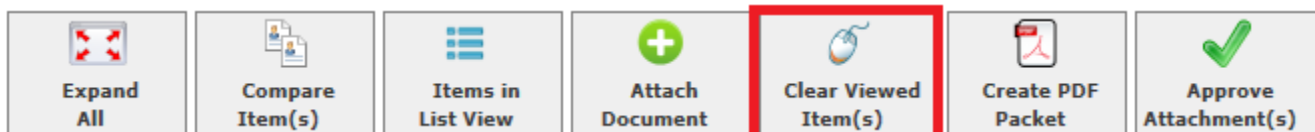
The name of the submission component and the item version number will display in the Current Submission Rounds column. You can click on the name of the item to open and view.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Form Real - (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	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Form Real - (Version 1.0) - You already viewed this item	
Application								
<input type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.1)	
<input type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.0)	
Consent Form(s)								
Category : Study Consent Category 1								
<input type="checkbox"/>	<input type="checkbox"/>						Consent Doc (English) - (Version 1.0)	
Document(s)								
Category : Survey								
<input type="checkbox"/>	<input type="checkbox"/>						Study Document 1 - (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.



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

My Workspaces | IRB Number: **IRB-19-5442** | IRB | Initial Review Submission Form Real - (Version 1.0) | Back

Print Friendly | Refresh Constant Fields

Section view of the Form | Entire view of the Form | Review Board Sections

7.0 Consent Forms

7.1 Attach all required consent forms!!!

Attach Study Consent Documents

Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
1.0		Consent Doc	Study Consent Category I	English				

Attach to Attachment/Sub Form - Meriter.Com Web Form

Text - Rich Text Editor (Embedded NO)

8.0 HIPAA Authorization

8.1 Attach HIPAA Authorization form(s)

If you open a consent form or other 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 two columns: **View the Unapproved Consent** and **View the Approved Consent** (which will be empty at this time, as there is no approved consent). You can click on the icon of the document in the **View the Unapproved Consent** column.

Create a new version | Save Changes

Consent Review | Consent CheckList

View the Unapproved Consent	View the Approved Consent

* Title: Consent Doc

Version Date: 08/07/2019

Category: Study Consent Category I

Version Number: 1.0

Sponsor Version:

Outcome: Approved

Language: English

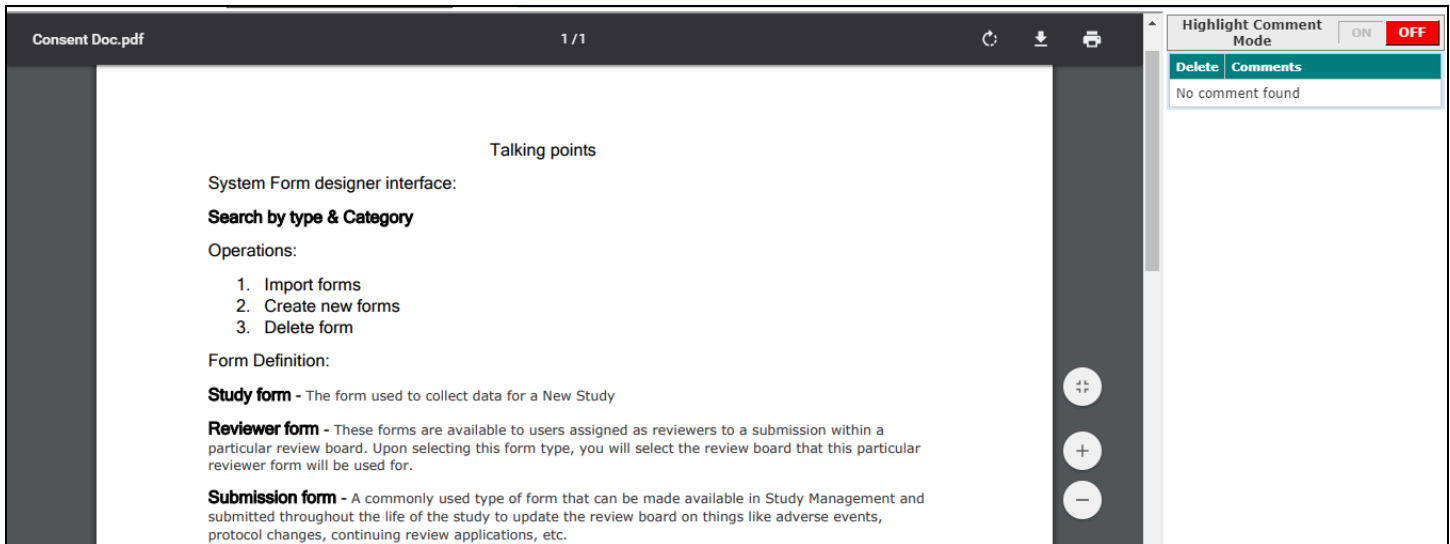
IRB Approval Date:

IRB Expiration Date:

Description:

Comments:


This will open the consent or other study document within the window if the file is a Microsoft Word file. Other attachment types are not supported.




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  icon to add a comment.

Attach Study Consent Documents

Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
1.0		Consent Doc	Study Consent Category I	English				

A Reviewer Comments Editor will open within the page, allowing you to type any comments. Click the **Save** icon when you are done or click the red **X** at the top of the editor if you do not want to add any comments.

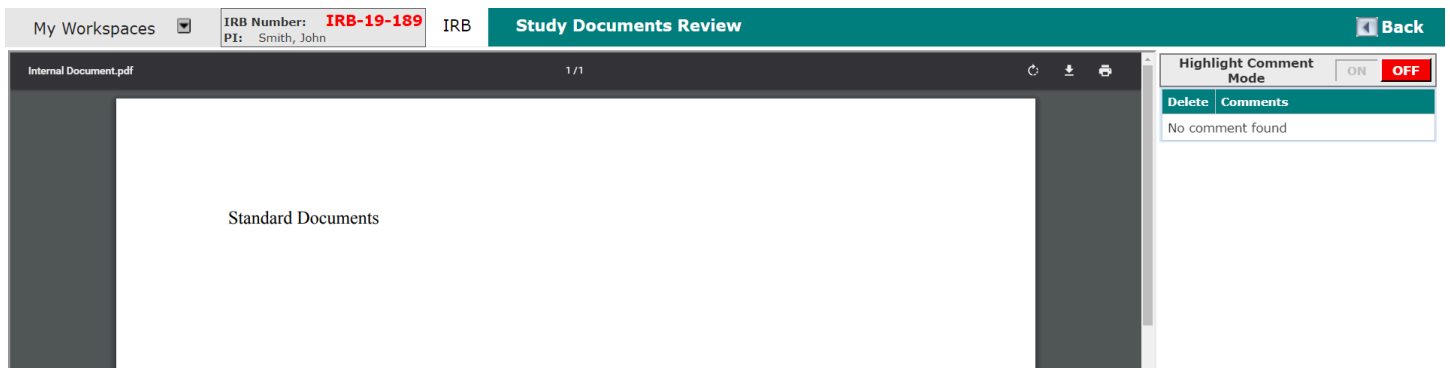


Questions in the form that have a comment added will display a changed icon. You can modify or remove your comments by clicking on the icon again.

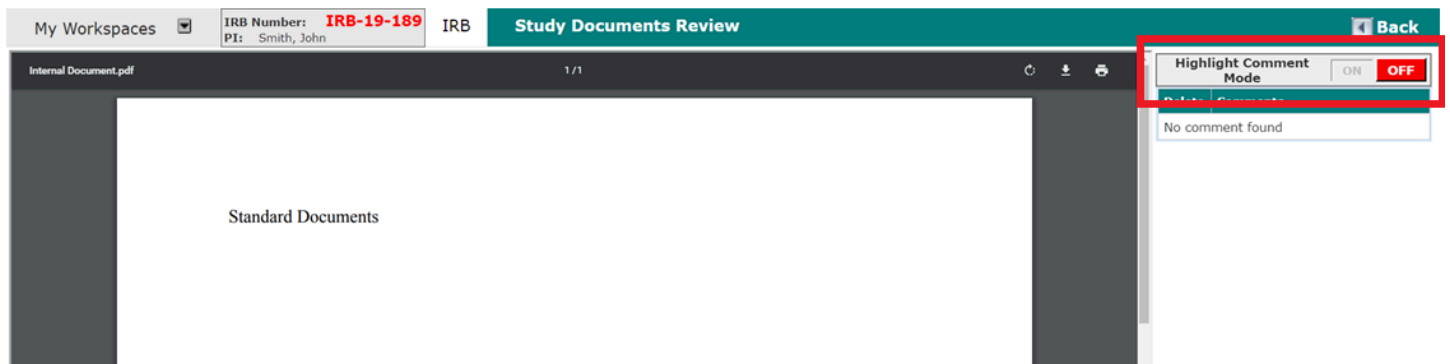
Attach Study Consent Documents

Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
1.0		Consent Doc	Study Consent Category I	English				

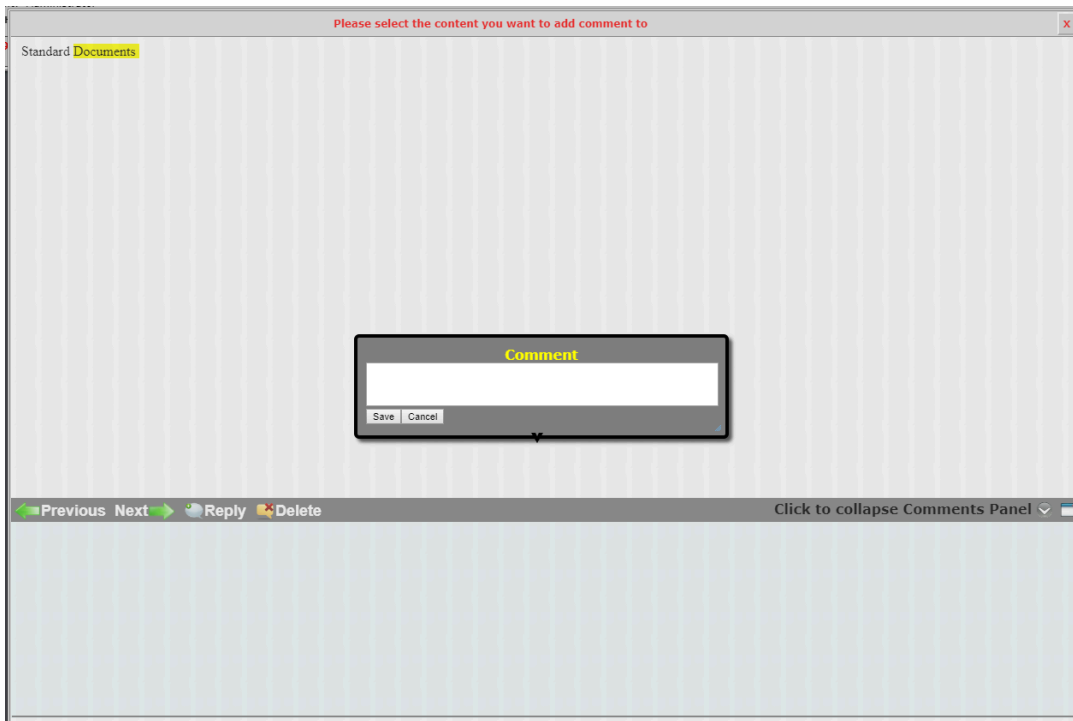
Comments for Consents and Other Study documents will be available when you are viewing the documents.



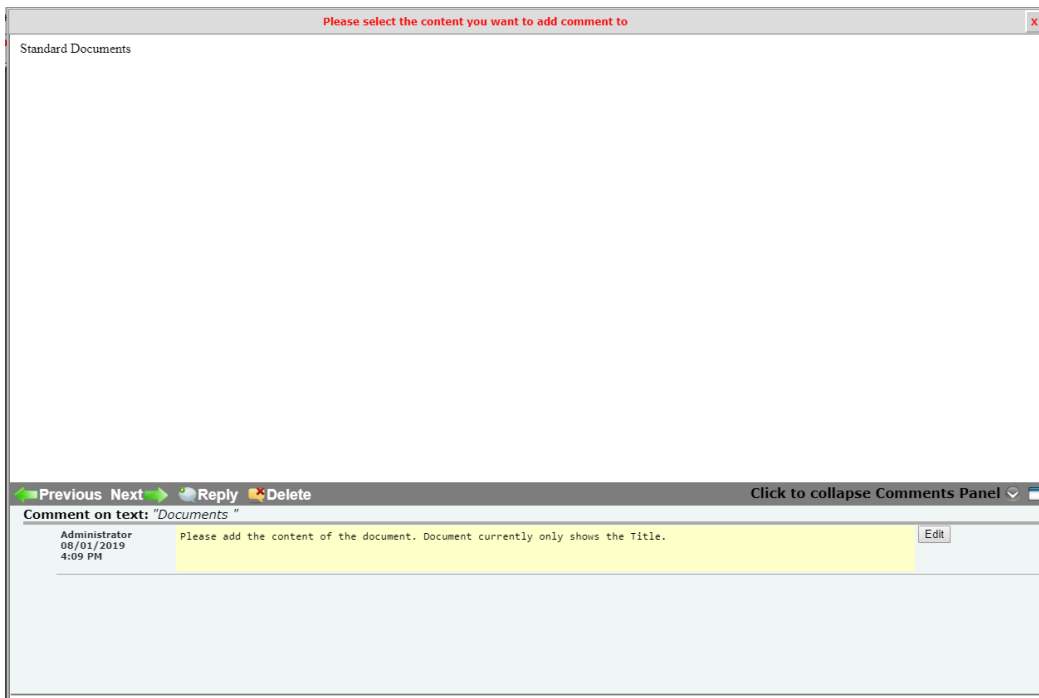
Users can then click on the **On** button in the “Highlight Comment Mode” to open another window where users can highlight and comment on specific areas of the document.



When the user highlights a word or phrase in the document, it will turn yellow and a small pop-up screen will appear where the user can input the comment. Click **Save** when the comment has been made to save the comment to the document.



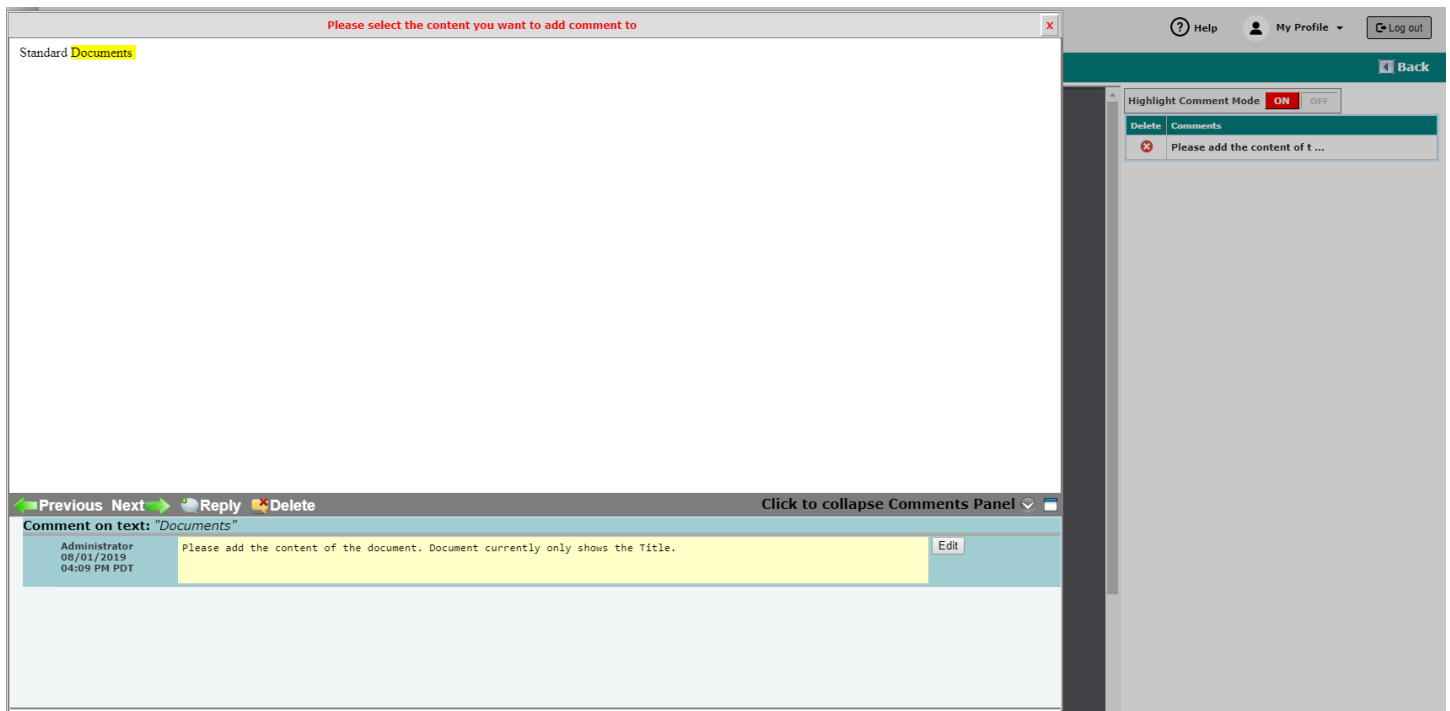
The comment will be added to the document and will appear at the bottom of the window. Users have the option to **Edit**, **Reply**, and **Delete** the comments as well.



The comment will also show up right under the **Highlight Comment Mode** button under the "Comments" column.



Here, the user can delete the comment, hover over the comment to show the comment, or click on it to enter the window again to see the highlighted section and the comment.



Special Note: This functionality only works with RTF or Microsoft Word files.

More Details


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

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Form Real - (Version 1.0)	
Application								
<input type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.1)	


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

Compare	Include in PDF Packet	Revise/ Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>			Initial Review Submission Packet - (Version 1.0)	
	Submitted to Workflow:		07/08/2019 11:33:18 AM GMT		

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. This is helpful for items that have been submitted several times. Newer items associated to the submission would have newer dates than components that have been associated longer.

Initial Submission Packet - (Version 1.0)	
 Submitted to Workflow:	07/24/2019 2:21:26 PM EDT
Stipulation 1 out of 1:	
Description:	Revise this
Stipulation Type:	(Stipulation must be addressed)
Acceptance:	Yes
Stipulation Response:	Revised

Once you begin to send items back to the study for corrections, the information in the details area will update. An example listed above shows stipulations that were associated to a Study Application that were returned with the latest round of the submission.

Consent Form(s)	
Category : Consent	
Consent Document (English) - (Version 1.0 Approved on 07/09/2019) - You already viewed this item	
 Submitted to Workflow:	07/09/2019 02:49:07 AM PDT
Outcome:	Approved
Approval Date:	07/09/2019
Expiration Date:	07/31/2019

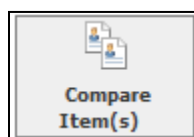
Consent forms and Other Study Documents will display when they were originally submitted as well as any approval information associated.

Expand All – Located above the submission components table is a button that will allow you to expand or collapse all the details at once. When you click this button, the additional details for all the submission items will expand to display full detail.



Compare Item(s)

Submission components that have multiple versions can be compared using the Compare Tool.



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 (cannot compare one version of an application to a consent form, etc.).

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 2px solid red; padding: 2px;"></div> <div></div> <div></div> <div></div> <div></div> </div>								
Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Form Real - (Version 1.0)	
Application								
<input checked="" type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.1)	
<input checked="" type="checkbox"/>	<input type="checkbox"/>						IRB Application - (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 out all of the submission components, regardless of which round they were submitted with. Any item that has more than one version will have the yellow folder in the **Revisions** column.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Form Real - (Version 1.0)	
Application								
<input type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.1)	
<input type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.0)	

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

List View

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

Items in Folder View | Add New Component | Create PDF Packet | Approve Attachment(s)

Include in PDF Packet	Revise/Attach	Submission Component Name - Version	More Details
Submission Form(s)			
<input type="checkbox"/>		IRB - IRB - Pre-Review Response Form - (Version 1.0)	+
<input type="checkbox"/>		Initial Review Submission Packet - (Version 1.0)	+
Application			
<input type="checkbox"/>		Simple Study Application - (Version 1.2)	+
Consent Form(s)			
Category : Consent			
<input type="checkbox"/>		Consent Document (English) - (Version 1.0 Approved on 07/09/2019)	+
Document(s)			

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 rounds document.

For a round selected, the only components that display only pertain to that round's documents. This would mean any unchanged form or document from the previous round (in the example above, the Initial Review Submission Form was unchanged from the previous round). Any new versions will display (the Study Application and Consent Form were both revised with this current round) and also brand-new attachments will display in this round (the Pre-Review Response Form was added in round 2).

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, IRB Application, a Study document and Consent Form).

Show submission component(s) in round: 1

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

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version	More Details
Submission Form(s)				
<input type="checkbox"/>	<input type="checkbox"/>		Initial Review Submission Form Real - (Version 1.0)	+
Application				
<input type="checkbox"/>	<input type="checkbox"/>		IRB Application - (Version 1.1)	+
<input type="checkbox"/>	<input type="checkbox"/>		IRB Application - (Version 1.0)	+
Consent Form(s)				
Category : Study Consent Category I				
<input type="checkbox"/>	<input type="checkbox"/>		Consent Doc (English) - (Version 1.0 Approved on 08/08/2019)	+
Document(s)				
Category : Survey				
<input type="checkbox"/>	<input type="checkbox"/>		Study Document 1 - (Version 1.0)	+

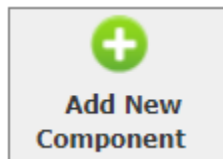
In addition to viewing components associated to a specific round, you can choose to combine all rounds for a summary. If you change the filter to All Rounds, the page will update and display all components ever associated to the submission. A label next to each component will detail which round the component was submitted with.

Show submission component(s) in round: All Rounds				Compare Item(s)	Items in Folder View	Add New Component	Create PDF Packet	Approve Attachment(s)
Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version	More Details			
Submission Form(s)								
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		IRB - IRB - Review Response Form - (Version 1.0)				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Initial Review Submission Form Real - (Version 1.0)				
Application								
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		IRB Application - (Version 1.1)				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		IRB Application - (Version 1.0)				
Consent Form(s)								
Category : Study Consent Category I								
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent Doc (English) - (Version 1.0 Approved on 08/08/2019)				
Document(s)								
Category : Survey								
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Study Document 1 - (Version 1.0)				

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

Attach New Component

You have the ability to add attachments to the submission. You can add Consent Forms or Other Study Documents.



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

A window will open within the browser allowing you to specify which type of document you would like to add to the submission.

Select an attachment type X

Select the type of attachment you would like to add to this submission:
(Click on the radio button and it will transition you to next page)

Informed Consent

Other Study Document

Attaching Consents

If you choose to attach a Consent form, you will be directed to the list of submitted Consent forms on the study. Any consent that has already been attached to the submission will be indicated by *Already Attached* in the first column.

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

Select an attachment type

Select the type of attachment you would like to add to this submission:
(Click on the radio button and it will transition you to next page)

Informed Consent

Study Contract

Other Study Document

If you choose to add a new consent form, you will be directed to a page that allows you to enter in the consent information. You can also upload a form from this page. Note that the Reference Number is already associated for you, because as you create the consent record, the system automatically associates it to the submission you are processing.

After entering the information, click the **Save Changes** button.

My Workspaces
IRB Number: **HSS-2019-0063** IRB
Consent Form History Back

Study Status: **Pending**
IRB Number : HSS-2019-0063
Study Title : Understanding Novel Tobacco Product Use among Low-Income Smokers

Save Changes

No document has been loaded.

*** Consent Title:**

Reference Number: 004620

*** Version Date:**

Category: --none--

*** Version Number:** .0

*** Language:** --none--

Description:

Comments:

*** Upload your document** (Microsoft Word, RTF or PDF file only)

Instructions

Complete the fields to the left side of the screen, then click the **Upload Your Consent Document...** button. When the file browsing window comes up, click on the **browse** button. This will bring up your file system's file browser. Select the file you want to upload and click the **Open** button. **NOTE: Informed consent documents must be in either Microsoft Word "doc" format, "rich text format (rtf)" or pdf to be loaded into iRIS.**

You will return to the list of consents on the study. The new record will display, indicating the consent is attached to the submission. Note, that there is an indicator that the revision was created by the IRB.

Already Attached		1.0 07/09/2019		NEW Consent *Added by the IRB.				Add Revision
				English				

You can choose to revise an existing consent form record. If you do this, you will be brought to a new page that indicates the new version of the consent form. You can modify the information on this page or check out the document. When you are finished with the revisions, click the **Save Changes** button.

My Workspaces IRB Number: **HSS-2019-0063** IRB **Consent Form History** [Back](#)

Study Status: **Pending** IRB Number: HSS-2019-0063 Study Title: Understanding Novel Tobacco Product Use among Low-Income Smokers

[Create a new version](#) [Save Changes](#)

Consent Review | **Consent CheckList**

View the Unapproved Consent | View the Approved Consent

*** Title:** Consent Document

Version Date: 07/09/2019

Category: Consent

Version Number: 1.1

Outcome: --none--

Language: English

Description:

Comments:

IRB Approval Date:

IRB Expiration Date:

Check-out the Unapproved Document to your machine for editing: [Check-out Unapproved Document...](#)

You will return to the list of consents on the study. The new version will display, indicating the consent version is attached to the submission. Also, note that there is an indicator that the revision was created by the IRB.

Attach Study Consent

Click the **Add Consent** button to add a new consent.
Click the **Add Revision** button to create a document revision.
Click the **Attach** button to attach the select Consent form(s)

[Add Consent](#) [Attach](#)

UnApproved Consent	Approved Consent	Language	Review Outcome	Approval Date	Expiration Date	Checkout By	Create a Revised Document
		Consent Doc					Add Revision
		Consent Document 2 *Added by the IRB.					Add Revision

After adding the consent form, click the X button to return to the Submission Components page.

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

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revisions	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			IRB - IRB - Review Response Form - (Version 1.0)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			Initial Review Submission Form Real - (Version 1.0)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			IRB Application - (Version 1.1)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent Document 2 (English) - (Version 1.1) *Revision modified by the IRB.	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>		Consent Doc (English) - (Version 1.0 Approved on 08/08/2019)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>		Study Document 1 - (Version 1.0)	<input type="checkbox"/>

Any document you add will display in the table, along with the note that the version was added by the IRB.

Attaching Other Study Documents

If you choose to attach Study Document, 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, or you may revise an existing consent or add a completely new consent record.

Attach Study Document(s) X

Instructions

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

Add Multiple Documents Add a New Document Attach

	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Attached			1.0 08/07/2019		Study Document 1 * This document was part of this submission. Survey	Chris Schroeder	08/07/2019 11:03:37 AM	Add Revision

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

My Workspaces

IRB Number: **IRB-19-5442**
 Alias: New Study
 PI: Chris, MSN

IRB
Study Documents
Back

Save Changes

***Document Title:**

Reference Number: 021153

***Version Number:** _0

Version Date:

Sponsor Version:

Category:

Comments:

Description:

Drag your file here or click in this area.

***Load the document into iRIS:**

Add in browser:

View the document
View the stamped document

The new document will display in the list, make sure it is selected then click on the **Attach** button

Attach Study Document(s) X

Instructions

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

Add Multiple Documents Add a New Document Attach

	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
Already Attached			1.0		Study Document 2 *Added by the IRB.	Chris	08/08/2019 03:38:53 PM	Add Revision

This will return you to the Submission Components page with the added document listed. Any documents added by the IRB will also display the note indicating such.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revisions	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)								
<input type="checkbox"/>	<input type="checkbox"/>						IRB - IRB - Review Response Form - (Version 1.0)	
<input type="checkbox"/>	<input type="checkbox"/>						Initial Review Submission Form Real - (Version 1.0)	
Application								
<input type="checkbox"/>	<input type="checkbox"/>						IRB Application - (Version 1.1)	
Consent Form(s)								
Category : Study Consent Category I								
<input type="checkbox"/>	<input type="checkbox"/>						Consent Document 2 (English) - (Version 1.1) *Revision modified by the IRB.	
<input type="checkbox"/>	<input type="checkbox"/>						Consent Doc (English) - (Version 1.0 Approved on 08/08/2019)	
Document(s)								
<input type="checkbox"/>	<input type="checkbox"/>						Study Document 2 - (Version 1.0) *Added by the IRB.	
Category : Survey								
<input type="checkbox"/>	<input type="checkbox"/>						Study Document 1 - (Version 1.0)	

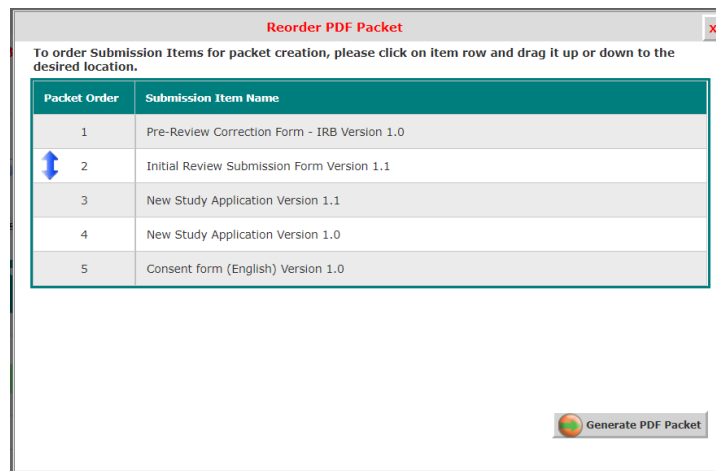
Create PDF Packet

You can select multiple components to be bundled and printed.

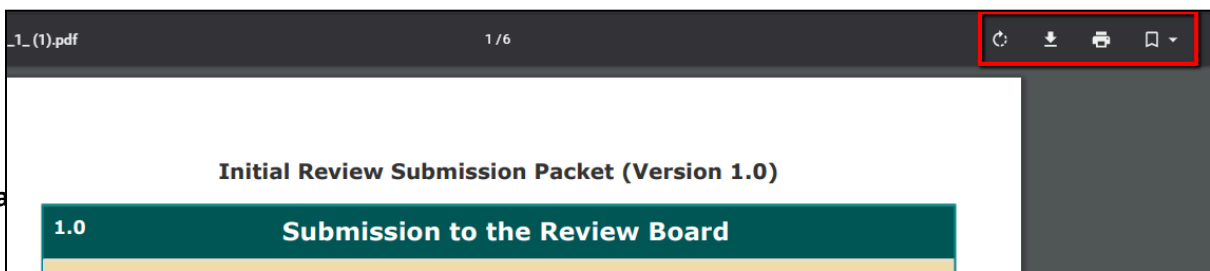


The first step: check off which items you would like to print in the **Include in PDF Packet** column. Then click the **Create PDF Packet** button.

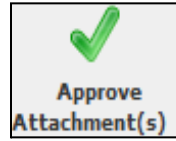
The second step: organize your selected items in the order you would like to print them. Do so by hovering over the item (a blue arrow will appear in the **Packet Order** column) and dragging it to the desired location. When you are done, click the **Generate PDF Packet** button on the bottom right of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

Please use the check box to select the consents and documents you want to approve. Approve

5 result(s) found...

	View History	Title	Version	Original	Stamped	Review Outcome Click here approve all	Approval Date	Expiration Date
Consent attachment(s).								
<input type="checkbox"/>		Consent Document 2 <i>*Revision modified by the IRB.</i>	1.1 08/08/2019			--none--		
<input type="checkbox"/>		Consent Doc	1.0 08/07/2019			Approved	08/08/2019	08/08/2020
Document attachment(s).								
<input type="checkbox"/>		Study Document 2 <i>*Added by the IRB.</i>	1.0			--none--		
<input type="checkbox"/>		Study Document 1	1.0 08/07/2019			--none--		

When you have clicked the **Approve Attachments** button, a new page will open, listing all the Consents and Study Documents. This page will list out 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.

Consent attachment(s).		
<input checked="" type="checkbox"/>		Consent Document <i>*Revision modified by the IRB.</i>
<input checked="" type="checkbox"/>		Consent Doc
Document attachment(s).		

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

	View History	Title	Version	Original	Stamped	Review Outcome Click here approve all	Approval Date	Expiration Date
Consent attachment(s).								
<input checked="" type="checkbox"/>		Consent Document 2 <i>*Revision modified by the IRB.</i>	1.1 08/08/2019			--none--		
<input checked="" type="checkbox"/>		Consent Doc	1.0 08/07/2019			Approved	08/08/2019	08/08/2020
Document attachment(s).								

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.

Please use the check box to select the consents and documents you want to approve. Approve

5 result(s) found...

<input type="checkbox"/>	View History	Title	Version	Original	Stamped	Review Outcome <input type="checkbox"/> Click here approve all	Approval Date	Expiration Date
Consent attachment(s).								
<input checked="" type="checkbox"/>		Consent Document 2 <i>*Revision modified by the IRB.</i>	1.1 08/08/2019			--none--		
<input checked="" type="checkbox"/>		Consent Doc	1.0 08/07/2019			Approved	08/08/2019	08/08/2020
Document attachment(s).								
<input type="checkbox"/>		Study Document 2 <i>*Added by the IRB.</i>	1.0			--none--		
<input type="checkbox"/>		Study Document 1	1.0 08/07/2019			--none--		

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.

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 institutions Consent and Study Document stamp. You can access the approved document in the **Stamped** column of this page.

Please use the check box to select the consents and documents you want to approve. Approve

5 result(s) found...

<input type="checkbox"/>	View History	Title	Version	Original	Stamped	Review Outcome <input type="checkbox"/> Click here approve all	Approval Date	Expiration Date
Consent attachment(s).								
<input checked="" type="checkbox"/>		Consent Document 2 <i>*Revision modified by the IRB.</i>	1.1 08/08/2019			Approved	08/08/2019	08/08/2020
<input checked="" type="checkbox"/>		Consent Doc	1.0 08/07/2019			Approved	08/08/2019	08/08/2020
Document attachment(s).								
<input type="checkbox"/>		Study Document 2 <i>*Added by the IRB.</i>	1.0			--none--		
<input type="checkbox"/>		Study Document 1	1.0 08/07/2019			--none--		

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

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)							
<input type="checkbox"/>	<input type="checkbox"/>					IRB - IRB - Review Response Form - (Version 1.0)	
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form Real - (Version 1.0)	
Application							
<input type="checkbox"/>	<input type="checkbox"/>					IRB Application - (Version 1.1)	
Consent Form(s)							
Category : Study Consent Category I							
<input type="checkbox"/>	<input type="checkbox"/>					Consent Document 2 (English) - (Version 1.1 Approved on 08/08/2019) *Revision modified by the IRB.	
<input type="checkbox"/>	<input type="checkbox"/>					Consent Doc (English) - (Version 1.0 Approved on 08/08/2019)	

Compare to Last Approved and View in Separate Window

Two new features have been added to the Submission Components tab in in the Submission Processing Queue. Two new functions and columns have been created to compare the last approved version of an application with the current version of the application attached to the submission, and to view the application in another window.

A new column, **View in Separate Window**, has been added which provides the user the ability to open the component of a submission in a new window while the user is still in the main screen.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)							
<input type="checkbox"/>	<input type="checkbox"/>					IRB - IRB - Review Response Form - (Version 1.0)	
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form Real - (Version 1.0)	
Application							
<input type="checkbox"/>	<input type="checkbox"/>					Sandboxing's - (Version 1.0)	

IRB Number: **12-006**
 Alias: dates
 PI: admin, Admin Admin, Ph.D. Brig. Gen.

IRB - Pre-Review Correction Form (Version 1.0) Print Friendly Close Window

VASDHS IRB Pre-Review Correction Form

Date Prepared:
04/25/2013

Revisions Required

The following list details the information necessary to resubmit your IRB Protocol for pre-screening. Please note that until your Protocol is resubmitted with these corrections, it has not been assigned to a meeting agenda and cannot be processed further.

Stipulation 1 out of 1:

Description:
Changes users

Stipulation Type: (Stipulation must be addressed)

Category: IRB - Board Stipulation Category I

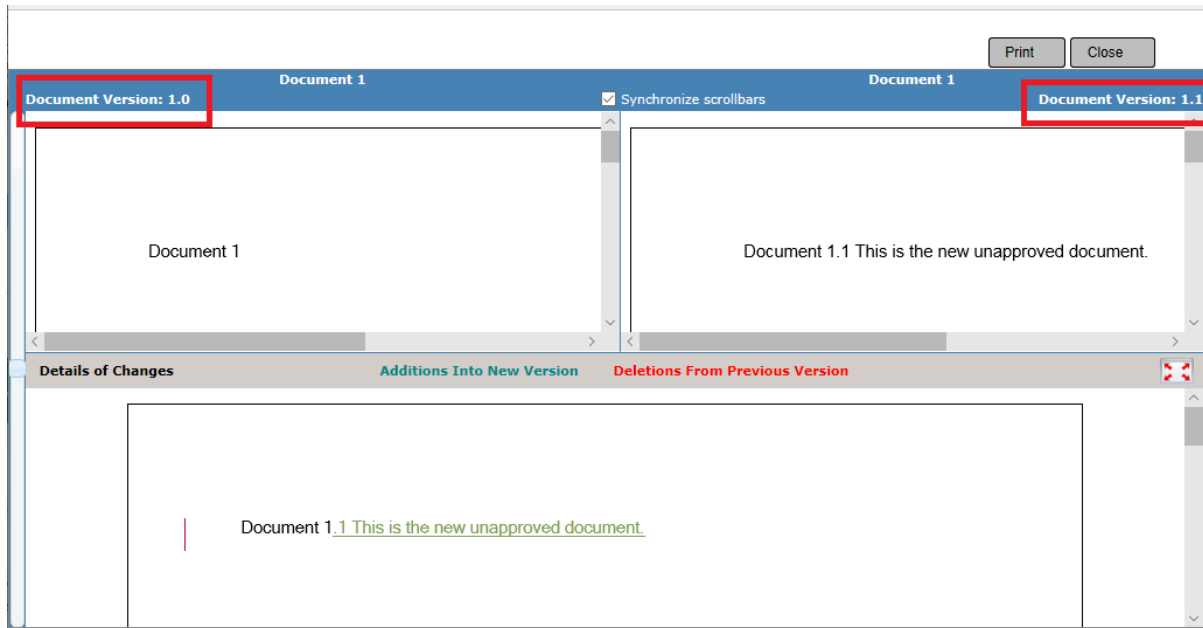
Do you accept this Stipulation? N/A Yes No

Provide an explanation on how you addressed this Stipulation:

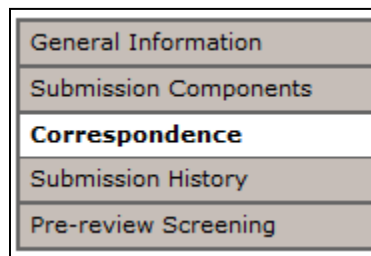
The column **Compare to Last Approved** gives the user the ability to compare forms and documents that have been approved to the latest version.

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)							
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form Real - (Version 1.0)	
Application							
<input type="checkbox"/>	<input type="checkbox"/>					MAIN IRB APP 6 - (Version 1.0)	
Document(s)							

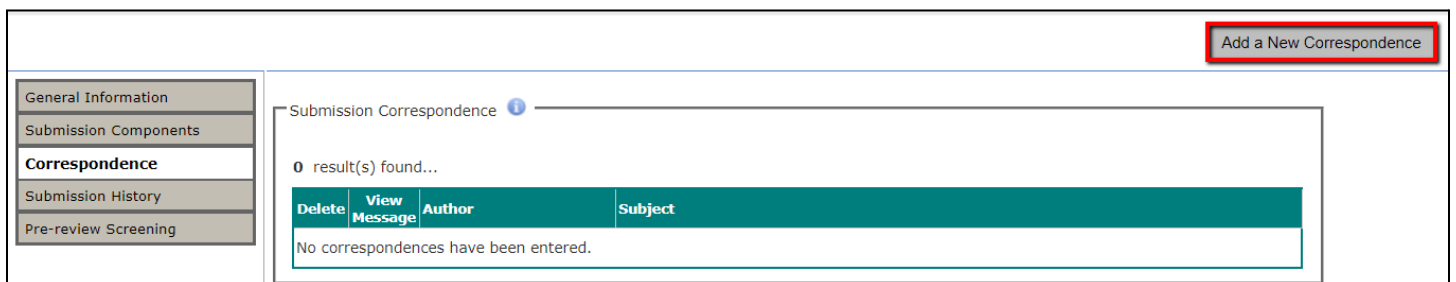
A new window will appear with the side by side comparison of both documents. Changes will be denoted in different colors: additions in green and deletions in red.



Correspondence



This tab allows users to communicate with other board members or study personnel. This section will also allow users to send the 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:



The page will list all correspondences associated with the submission. To add a correspondence, select the **Add a New Correspondence** button.

Send E-mail - This checkbox is checked by default, meaning that the correspondence will also be sent to the specified recipients via email (if available). The correspondence will send to the email provided in the user’s account. Whether or not this box is checked, this correspondence will be initially available on the recipient’s home screen under the Not Opened Correspondence tab.

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

My Workspaces ▾ IRB **Correspondence contact** Back

Save Changes

Contacts	Role	<input type="checkbox"/>	
Protocol Personnel			
	Site Investigator	<input type="checkbox"/>	Jefferson, Tom
	Site Contact	<input type="checkbox"/>	Jefferson, Tom
IRB Committee 1			
	Board Member	<input type="checkbox"/>	Analyst, John
		<input type="checkbox"/>	Chair, Department
		<input type="checkbox"/>	Reviewer, Luke, Ph.D
	Coordinator	<input type="checkbox"/>	Administrator
		<input type="checkbox"/>	Coordinator, Jane
		<input type="checkbox"/>	Member, IRB

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.

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

My Workspaces ▾ IRB **Correspondence Additional Contacts** Back

Add A New Contact Save And Return

<input 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.

My Workspaces ▾		IRB	Correspondence Additional Contacts	Back
		<input type="button" value="Add A New Contact"/> <input type="button" value="Remove Selected Contacts"/> <input type="button" value="Save And Return"/>		
	Name	E-mail Address		
<input type="checkbox"/>	John Adams	jadams@imedris.com		

Reply to List/ Additional Reply To - 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 outside email when another person replies to this correspondence thread outside of iRIS.

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

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

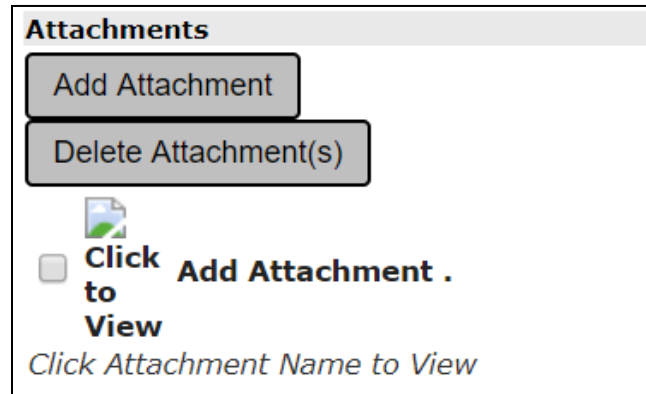
You will be required to enter the title of the attachment. The actual attachment can be uploaded by clicking the **Upload** button. You will then be prompted for the file's location.

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

Document Location: No file chosen

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

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 the 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** Icon 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.

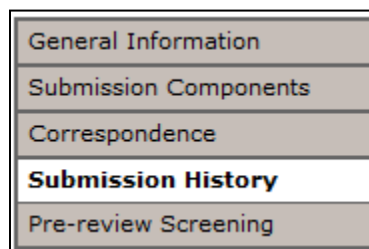
Submission Correspondence i

1 result(s) found...

Delete	View Message	Author	Subject
		Administrator	Posted: Delivery in Progress HSS-2019-0063 (Understanding Novel Tobacco Product Use among Low-Income Smokers) New Correspondence

If you do not see a user or a role to send the correspondence to, the user may be hidden. The Review Board Administrator can set up different roles to be able to receive and be seen on the correspondence contact list.

Submission History



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

My Workspaces IRB Number: IRB-19-171-0001 IRB Site Progress Report Back

Lead PI: Investigator, John
Site PI: Jefferson, Tom

Protocol Items Miscellaneous Submission Forms

Ref Number: IRB-19-171-0001--1.0 IRB Number: IRB-19-171-0001 Protocol Title: Effectiveness of the Drug Blaxar on people with Diabetes

Protocol Status: Approved

Add Additional Signoff

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

Status	View Details	Date Received / Date Completed	Event Description
		06/27/2019 05:42 AM PDT /	IRB received the submission
		06/27/2019 05:42 AM PDT / 06/27/2019 05:42 AM PDT	Tom Jefferson as Site Investigator review and apply signoff
		06/27/2019 05:37 AM PDT / 06/27/2019 05:42 AM PDT	Site Progress Report is waiting to be submitted

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 cancelled, the status will be cancelled, and the Cancel icon will be displayed.

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
			07/09/2019 11:12 AM PDT /	IRB received the submission

This will cause the item to appear as so:

	Status	View Details	Date Received / Date Completed	Event Description
			07/09/2019 11:12 AM PDT /	<p>IRB received the submission</p> <p>Study Title: Understanding Novel Tobacco Product Use among Low-Income Smokers</p> <p>Principal Investigator: Administrator</p> <p>Submission Type: Submission Correction for Initial Review Submission Packet</p> <p>Reference Number: 004620</p> <p>IRB Number: HSS-2019-0063</p>

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

If the submission needs to be routed for further signoff before review, the RB 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 using the **Delete Additional Signoff** button. 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).

A new property has been added to the new version that allows the name of the current user to be included in specific tasks completed. This new property is under System Administration. Please contact your system administrator for more information. When set to “Yes”, the name of the current user will be included in the task name when the task was created.

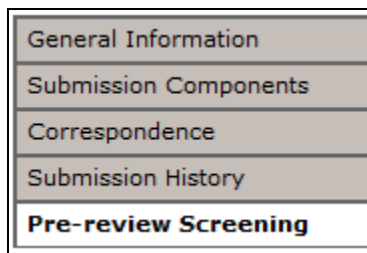
General Information	Submission History			
Submission Components	Status	View Details	Date Received / Date Completed	Event Description
Correspondence			07/25/2019 08:12 AM PDT /	Luke Reviewer, Ph.D has been assigned as the Primary for an Expedited Review on the Submission Correction for Initial Review Submission Form, assigned by Smith, Adam Ph.D
Submission History			07/24/2019 02:02 PM PDT /	Jane Coordinator has been assigned as the analyst
Pre-review Screening			07/25/2019 08:12 AM PDT	
Review Checklist and Comments			07/24/2019 02:02 PM PDT /	IRB received the submission
Review Summary			04/22/2019 04:11 PM PDT /	Jane Coordinator has been assigned as the analyst
Submission Discussion			07/24/2019 01:53 PM PDT	
Stipulation			04/22/2019 04:11 PM PDT /	IRB received the submission
Internal Submission Routing			07/24/2019 01:53 PM PDT	
Expedited by			04/22/2019 04:11 PM PDT /	Notice to complete conflict of interest protocol disclosure questionnaire assigned to John Investigator
Outcome			04/22/2019 04:11 PM PDT /	Notice to complete conflict of interest protocol disclosure questionnaire assigned to Jorge Alvarenga
Outcome Letter	✓		07/25/2019 08:12 AM PDT /	IRB assigned a Pre-review action of Expedite, assigned by Administrator
Submission Complete	✓		07/25/2019 08:12 AM PDT /	John Investigator as Principal Investigator review and apply signoff

When set to “No”, the name of the current user will not be included in the task name when the task was created.

Ref Number : 000566	IRB Number : IRB-19-85	Protocol Title : Use of stem cells on subjects currently being treated for Diabetes Type 2
Protocol Status : Pending - Submitted for Initial Review		
General Information	Submission History	
Submission Components	Status	View Details
Correspondence		Date Received / Date Completed
Submission History		Event Description
Pre-review Screening		07/25/2019 08:16 AM PDT /
Review Checklist and Comments		07/25/2019 08:12 AM PDT /
Review Summary		07/24/2019 02:02 PM PDT /
Submission Discussion		07/25/2019 08:16 AM PDT
Stipulation		07/24/2019 02:02 PM PDT /
Internal Submission Routing		07/24/2019 02:02 PM PDT /
Expedited by		07/24/2019 02:02 PM PDT /
Outcome		04/22/2019 04:11 PM PDT /

Note: This property *only* affects the Submission Histories while the property is on. If the property is turn on and a user is assigned a task, the assigner’s name will be shown. However, if the property is turned off and another task is assigned, that task will not have the assigner’s name associated with the task. For example, in the screens above, the property was turn on while Adam Smith was assigning the task. However, after he assigned the task, the property was turned off by the System Administrator. When he, or another user, went into the Submission Processing Queue and assigned another reviewer, the current user was not included in the task name when the task was created. The property being off however, did not change the previous task detail that included Adam Smith.

Pre-Review Screening



This screen is used to assign the analyst, process the submission (i.e. pre-review changes assigned to agenda), and assign reviewers.

The screenshot shows the 'Pre-review Screening' form with the following sections:


- Analyst Assignment:** A dropdown menu set to '--none--' and a 'View Analyst Workload' button.
- IRB Number:** A text field containing 'HSS-2019-0063' and a 'Generate Number' button.
- Review Fee:** A section with the question 'Apply Fee For Service?' and radio buttons for 'Yes' and 'No' (selected).
- Determine Review Process:** A list of radio buttons: 'Not Assigned' (selected), 'Full Committee Review', 'Expedited', 'Designated Reviewer', and 'Exempt'.

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.

This close-up shows the 'Analyst Assignment' section where the dropdown menu is set to 'Coordinator, IRB'. The 'View Analyst Workload' button is highlighted with a red rectangular box.

A new button, **View Analyst Workload**, has been added to the Analyst Assignment section of the Pre-review Screening tab. Users can now check the workload of analyst by selecting the **View Analyst Workload** button before assigning the analyst to a submission.

Show Reviews	Analyst Name	# Assigned/ Date Notified	Submission Type	IRB Number	PI Name	Review Process	Meeting Date
	Administrator	0					
	 Coordinator, Jane	16					
			Study Amendment Form	IRB-19-197	Administrator		
			Study Amendment Form	IRB-19-133	Administrator	Expedite	
			Submission Response for Initial Review Submission Form	IRB-19-132	Administrator	Expedite	
			Initial Review Submission Form	IRB-19-176	Investigator, John		
			Initial Review Submission Form	IRB-19-198	Investigator, John		
			Study Amendment Form	IRB-19-130	Investigator, John	Expedite	
			Initial Review Submission Form	IRB-19-139	Investigator, John	Expedite	

Users can select an Analyst from the Assign Analyst drop-down menu. When the **View Analyst Workload** button is selected, a new page will open a listing of analysts and the number of open assignments currently assigned to them.

Users can select 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 desired. Select the **Close** button to return to the Pre-Review Screening page.

IRB 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 click the “Generate Number” button. If you do not have this button next to the text field, it means that your IRB Numbers have already been automatically assigned.

Review Fee – This option is used for IRB invoicing and may not be available for your system. For more information on how this functionality is used, see the IRB Invoicing document.

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.

<input checked="" type="radio"/>	Not Assigned
<input type="radio"/>	Full Committee Review
<input type="radio"/>	Expedited
<input type="radio"/>	Facilitated Review
<input type="radio"/>	Emergency Use
<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

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.

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

<input checked="" type="radio"/>	Full Committee Review	Committee Name: --none--
		Upcoming Meeting Date: --none-- or click here to select past meetings
		Agenda Category: --none--

Expedited – 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 also be turned on/off in your Review Board Configurations.

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 ten new tabs will be available for that submission. This option can also be turned on/off in your Review Board Configurations.

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.

These are the most commonly used Review Processes. You can also hover your mouse over the icon to see descriptions of the different review processes.

General Information	Analyst Assignment																												
Submission Components																													
Correspondence																													
Submission History																													
Pre-review Screening																													
	Assign Analyst: --none-- <input type="button" value="View Analyst Workload"/>																												
	Determine Review Process																												
	<table border="1"> <tr> <th colspan="2">Submission Processing</th> </tr> <tr> <td><input checked="" type="radio"/></td> <td>Not Assigned</td> <td>Determine how the submission is to be processed. The options include: The initial submission state.</td> </tr> <tr> <td><input type="radio"/></td> <td>Full Committee</td> <td>Assign to Committee Agenda</td> </tr> <tr> <td><input type="radio"/></td> <td>Expedited</td> <td>Expedite</td> <td>Allows the selection of a sub-committee and meeting date. Allows the submission to bypass the meeting and go straight to the reviewers.</td> </tr> <tr> <td><input type="radio"/></td> <td>Exempt</td> <td>Exempt</td> <td>Indicates this submission is exempt from review.</td> </tr> <tr> <td><input type="radio"/></td> <td>Limited Review</td> <td>Forward to Another Board/Committee</td> <td>Send the submission to another board or committee, bypassing the workflow. Indicate if the submission should return to this board or committee when the other board/committee is finished reviewing.</td> </tr> <tr> <td><input type="radio"/></td> <td>Pre-Review changes requested</td> <td>Pre-Review changes requested</td> <td>Indicates that the submission is incomplete and will be sent back for corrections.</td> </tr> <tr> <td><input type="radio"/></td> <td>Process Administratively</td> <td>Process Administratively</td> <td>Indicates the internal review board staff will process the submission and assign the final outcome.</td> </tr> </table>	Submission Processing		<input checked="" type="radio"/>	Not Assigned	Determine how the submission is to be processed. The options include: The initial submission state.	<input type="radio"/>	Full Committee	Assign to Committee Agenda	<input type="radio"/>	Expedited	Expedite	Allows the selection of a sub-committee and meeting date. Allows the submission to bypass the meeting and go straight to the reviewers.	<input type="radio"/>	Exempt	Exempt	Indicates this submission is exempt from review.	<input type="radio"/>	Limited Review	Forward to Another Board/Committee	Send the submission to another board or committee, bypassing the workflow. Indicate if the submission should return to this board or committee when the other board/committee is finished reviewing.	<input type="radio"/>	Pre-Review changes requested	Pre-Review changes requested	Indicates that the submission is incomplete and will be sent back for corrections.	<input type="radio"/>	Process Administratively	Process Administratively	Indicates the internal review board staff will process the submission and assign the final outcome.
Submission Processing																													
<input checked="" type="radio"/>	Not Assigned	Determine how the submission is to be processed. The options include: The initial submission state.																											
<input type="radio"/>	Full Committee	Assign to Committee Agenda																											
<input type="radio"/>	Expedited	Expedite	Allows the selection of a sub-committee and meeting date. Allows the submission to bypass the meeting and go straight to the reviewers.																										
<input type="radio"/>	Exempt	Exempt	Indicates this submission is exempt from review.																										
<input type="radio"/>	Limited Review	Forward to Another Board/Committee	Send the submission to another board or committee, bypassing the workflow. Indicate if the submission should return to this board or committee when the other board/committee is finished reviewing.																										
<input type="radio"/>	Pre-Review changes requested	Pre-Review changes requested	Indicates that the submission is incomplete and will be sent back for corrections.																										
<input type="radio"/>	Process Administratively	Process Administratively	Indicates the internal review board staff will process the submission and assign the final outcome.																										

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.

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

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

The screen will refresh allowing users to select from a list of reviewer roles that are pre-defined in the Review Board Configurations (see the Review Board Configurations – List Maintenance Setup manual for more details).

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

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

	Reviewer Role	Reviewer	Completed ?	Has COI?	Date Notified	Date Completed
	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 ?	Has COI?	Date Notified	Date Completed
	Ad Hoc	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 ?	Has COI?	Date Notified	Date Completed
	Primary	Investigator, Principal	No	No	07/10/2019	

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

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

Comments to Reviewers

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

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	Alz, William, Medical	No	08/12/2019	
✘ Secondary	Ack, Abby, MSN Ph.D.	No	08/12/2019	

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 **Apply** button at the bottom right of the window to add the comments. If you do not want to save the comments, click the icon.

Add Comments for All Reviewers

Please take special note of Expedited Category selected.

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.

Assign Reviewers ⓘ

	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
	Primary	Alz, William, Medical	No	08/12/2019	
	Secondary	Ack, Abby, MSN Ph.D.	No	08/12/2019	

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

Section view of the Form | Entire view of the Form

1.0 Instructions

2.0 Primary Reviewer

1.0 Instructions

1.1 Comments or instructions related to this submission (if any):

Please take special note of Expedited Category selected.

Reviewers Workload

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

Assign Reviewers ⓘ

	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
	Primary	Alz, William, Medical	No	08/12/2019	
	Secondary	Ack, Abby, MSN Ph.D.	No	08/12/2019	

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

Show Reviews	Member Name	Specialty/ Submission Type	# Assigned/ Date Notified	IRB Number	PI Name	Reviewer Role	Review Process	Meeting Date
	Acheson, Dean T, R.N. COL	Emergency Medicine Family Medicine	2					
	Achis, Jamie Marie, B.S.	Administration Urology	0					
	Ack, Abby, MSN Ph.D.		2					
	Ack, Billy, R.N.		11					

When this button is clicked, a new page will open listing board members and the number of open assignments currently assigned. 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.

The screenshot shows the 'All Tasks' interface. At the top, there are tabs for 'All Tasks', 'Outstanding', and 'Completed'. Below this, there are sub-tabs for 'All Tasks' and 'Study Tasks'. A 'Task List' dropdown menu is set to 'All'. The main area displays '1 result(s) found...' and a table with the following data:

Click to open	Task Type	Received	Description
	Reviewer Assignment	07/10/2019 10:46 AM PDT	Principal Investigator has been assigned as the Primary for an Administrative Review on the Submission Correction for Initial Review Submission Packet

At the bottom of the table area, it says '1 result(s) found...' and '1 - 1'.

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

The reviewer checklist form is defined in the System Form Designer and can contain any number of questions for the reviewer to fill out. 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 shows the 'Reviewer Checklist Form' interface. At the top right, there are buttons for 'Print Friendly', 'Reviewer Panel', 'Save Section', and 'Save and Continue to Next Section'. Below these are tabs for 'Section view of the Form' and 'Entire view of the Form'. The main area displays the following content:

1.0 Reviewer Checklist Form

1.1 Please answer all of the following:

- * The convened Board (or designated reviewer) has adequate expertise to conduct review.
 - Yes No
- * The assigned reviewer has a Conflict of Interest.
 - Yes No

Please Look all teh review components submitted withign the submission.

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

At the bottom right, there are buttons for 'Items in Folder View', 'Clear Viewed Item(s)', and 'Create PDF Packet'. Below these is a table with columns for 'Include in PDF Packet', 'Submission Component Name - Version', and 'More Details'.

The screenshot below shows the data value for the Current Submission Components. The reviewer can click to open any of the documents to view them.

My Workspaces IRB Number: **IRB-19-179** IRB PI: Investigator, John **Review Checklist - (Version 1.0)** Back

Protocol Items Miscellaneous **Submission Forms**

Print Friendly Reviewer Panel Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 **Reviewer Checklist Form**
2.0 Indication of Completion

1.0 Reviewer Checklist Form

1.1 Please answer all of the following:

- * The convened Board (or designated reviewer) has adequate expertise to conduct review.
 Yes No
- * The assigned reviewer has a Conflict of Interest.
 Yes No

Please Look all teh review components submitted within the submission.

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

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

Include in PDF Packet	Submission Component Name - Version	More Details
<input type="checkbox"/>	IRB - Pre-Review Correction Form - IRB - (Version 1.0)	

As the reviewer progresses through the form, navigation will build on the left of the form, allowing the reviewer to jump back and forth between sections.

My Workspaces IRB Number: **IRB-19-179** IRB PI: Investigator, John **Review Checklist - (Version 1.0)** Back

Protocol Items Miscellaneous **Submission Forms**

Print Friendly Reviewer Panel Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 Reviewer Checklist Form
2.0 **Indication of Completion**

2.0 Indication of Completion

2.1 Is your review complete?
 Yes No

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

When all reviewers on the submission have completed their review, the analyst task will update to indicate all are complete and will also receive a separate Submission Reviewers Complete task, as shown in the image below.

All Tasks Outstanding Completed Settings

All Tasks Study Tasks **Task List:** Submission Reviewers Complete

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

Click to open	Task Type	Received	Description
	Submission Reviewers Complete	07/24/2019 11:50 AM PDT	All reviewers completed the review of the submission.

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

Review Checklist and Comments

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

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

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

General Information

Submission Components

Correspondence

Submission History

Pre-review Screening

Review Checklist and Comments

Review Summary

Submission Discussion

Recommendation

Stipulation

Internal Submission Routing

Expedited by

Reviewer Check List ?

View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards
No form was entered	Primary	Alz, William, Medical	No	08/12/2019		📖
No form was entered	Secondary	Ack, Abby, MSN Ph.D.	No	08/12/2019		📖

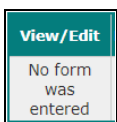
Member Check List ?

Delete	Members Name
No member checklists have been assigned to the submission	

Reviewer Check List

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

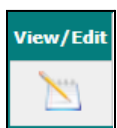
View/Edit – Depending on the status of the review, this column will change.



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 review 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.



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

- All
- COI
- IACUC
- R&D
- SRS (Safety)

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 then click the **Save 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 i

View/Edit	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	Share Review with other Boards
	Primary	Board, Review	No	07/10/2019		

Member Check List

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

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

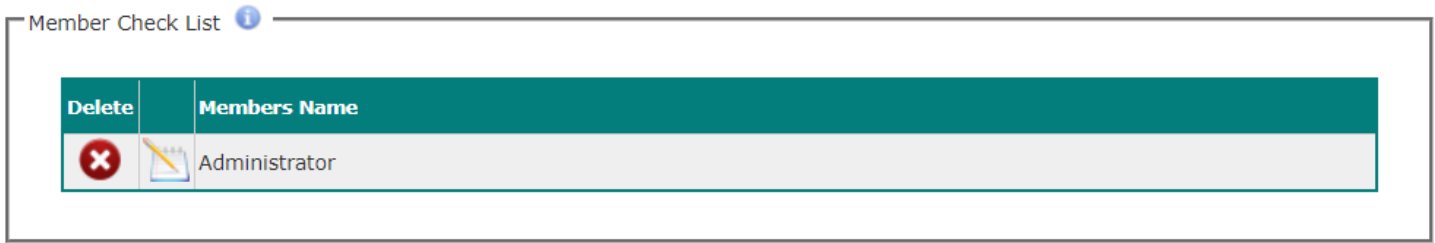
Print Friendly Reviewer Panel Refresh Constant Fields Save Section Save and Continue to Next Section Exit Form

Section view of the Form

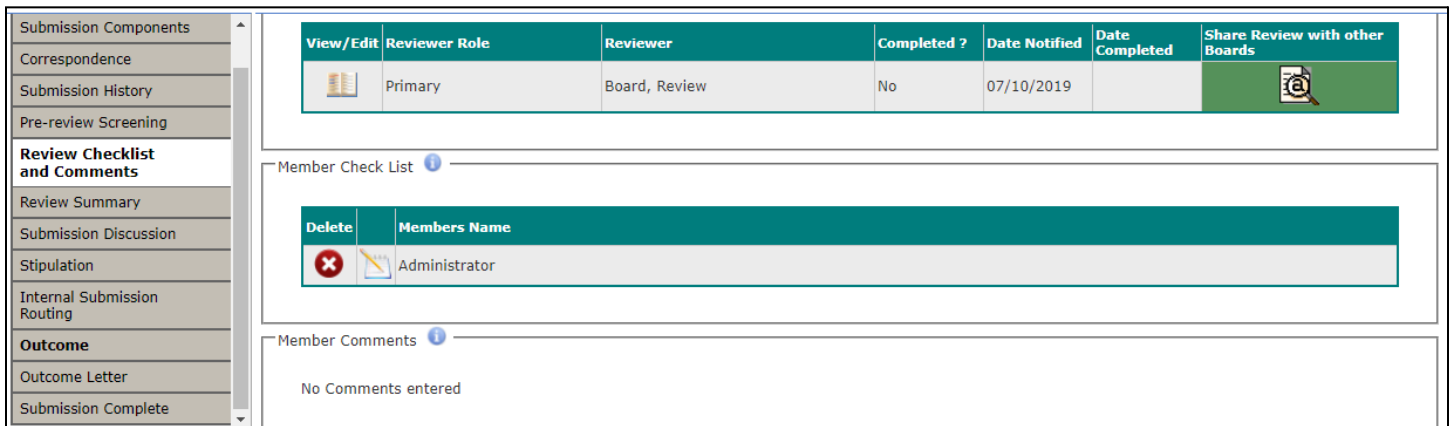
Entire view of the Form

1.0	Submission Package:	1.0 Submission Package:
2.0	Reviewer Comments:	
3.0	Indication of Completion	1.1 Submission Package and Status

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.




Member Comments


Any board member can add comments to the submission to be discussed at the meeting. This section can also be turned on/off in Review Board Configurations.

When adding a comment, 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 would 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 would 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.



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

Member Comments 

 Administrator Board Member Comments on Review Checklist and Comments page

Review Summary

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


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 Submission Discussion, into an Outcome Letter or into a Stipulation.




Protocol Items | Miscellaneous | Submission Forms | Additional Attached Forms

Ref Number: **IRB-2017-1746-INI-5.0** | IRB Number: **IRB-2017-1746** | Study Title: 15936 > submit to tech transfer


Study Status: Pending - Submitted for Initial Review


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


Review Summary for IRB-2017-1746 

			Name	Rank	Reference	Item Number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Admin Admin admin, Ph.D. Brig. Gen.	Major	Initial Review Submission Form Real Version 5.0	2.0
Please add more background information of the discovery of this new drug.						
IRB Reviewers Form						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Admin Admin admin, Ph.D. Brig. Gen.			

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. The columns for the comment’s 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 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, Continuing Review, etc.), the Study Application, the Consent Form 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.

Protocol Items
Miscellaneous
Submission Forms
Additional Attached Forms



Ref Number: **IRB-2017-1746-INI-5.0**
IRB Number: **IRB-2017-1746**
Study Title: 15936 > submit to tech transfer

Study Status: Pending - Submitted for Initial Review

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

Review Summary for IRB-2017-1746 ?

			Name	Rank	Reference	Item Number
<input type="checkbox"/>	<input type="checkbox"/>		Admin Admin admin, Ph.D. Brig. Gen.	Major	Initial Review Submission Form Real Version 5.0	2.0
Please add more background information of the discovery of this new drug.						
IRB Reviewers Form						
<input type="checkbox"/>	<input type="checkbox"/>		Admin Admin admin, Ph.D. Brig. Gen.			

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 comment 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.

Review Summary for IRB-2017-1746 ?

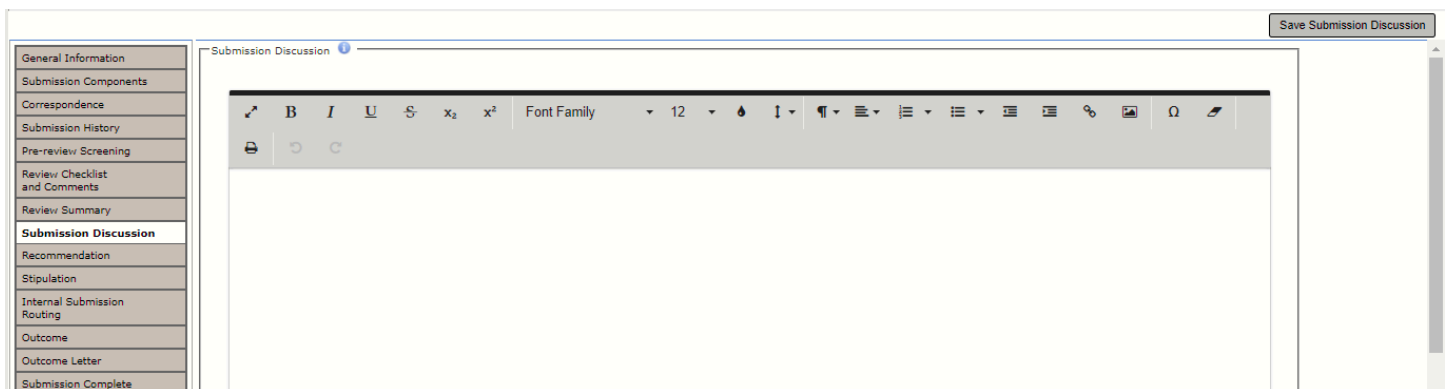
			Name	Rank	Reference	Item Number
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Admin Admin admin, Ph.D. Brig. Gen.	Major	Initial Review Submission Form Real Version 5.0	2.0
Please add more background information of the discovery of this new drug.						

Submission Discussion

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

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 take place during a meeting. Items from the Reviewer Checklist can also be merged into the Submission Discussion. Submission Discussion can then in turn 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 above. You can modify the discussion by entering that information into the text editor. Click the **Save Submission Discussion** when you are finished.



Stipulation

The stipulations tab allows you to manage stipulations for the submission. You can create new stipulations and manage stipulations that were merged from 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

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

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

<ul style="list-style-type: none"> General Information Submission Components Correspondence Submission History Pre-review Screening Review Checklist and Comments Review Summary Submission Discussion Recommendation Stipulation Internal Submission 	<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>Stipulations to be sent for Response ⓘ</p> <table border="1" style="width: 100%; border-collapse: collapse; background-color: #2e8b57; color: white;"> <thead> <tr> <th style="width: 5%;">Delete</th> <th style="width: 5%;">Edit</th> <th style="width: 10%;">Sorting Number</th> <th style="width: 20%;">Stipulation Type</th> <th style="width: 15%;">Stipulation Category</th> <th style="width: 10%;">Follow-up Due</th> <th style="width: 25%;">Stipulation</th> <th style="width: 10%;">Created By</th> <th style="width: 5%;">Link To Component</th> </tr> </thead> <tbody> <tr> <td colspan="9" style="text-align: center; color: #ccc;">No Stipulations entered</td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Stipulations with the responses from the previous submission ⓘ</p> <table border="1" style="width: 100%; border-collapse: collapse; background-color: #2e8b57; color: white;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">Review Action</th> <th style="width: 10%;"></th> <th style="width: 10%;"></th> <th style="width: 10%;"></th> <th style="width: 10%;"></th> <th style="width: 10%;">Follow-Up By</th> <th style="width: 10%;">Response</th> <th style="width: 5%;">View</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">=</td> <td colspan="7" style="background-color: #2e8b57; color: white; font-weight: bold;">IRB</td> <td></td> </tr> </tbody> </table> </div>	Delete	Edit	Sorting Number	Stipulation Type	Stipulation Category	Follow-up Due	Stipulation	Created By	Link To Component	No Stipulations entered										Review Action					Follow-Up By	Response	View	=	IRB							
Delete	Edit	Sorting Number	Stipulation Type	Stipulation Category	Follow-up Due	Stipulation	Created By	Link To Component																													
No Stipulations entered																																					
	Review Action					Follow-Up By	Response	View																													
=	IRB																																				

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.

Save the Stipulation

Stipulation Information:

***Stipulation Type:**
 Stipulation must be addressed ▾

***Stipulation Category:**
 --none-- ▾

Select the components to be modified with this stipulation:

+ **Attach Component(s) to the Stipulation**

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

*** Stipulation Content**

↶ B I U ~~ABC~~ x₂ x² Font Family 12 🔥 ↑ ▾

🖼️ Ω ✎ 🗑️ ↻

Stipulation must be addressed

***Stipulation Type:**

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 IRB. Choosing this type of stipulation indicates to the study, that this stipulation must be addressed before any further action can be taken on the submission.

Comments that must be addressed

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

***Stipulation Type:**

Comments that must be addressed ▾

***Follow-Up Due**

🗓️ ▾

Comments

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

***Stipulation Type:**

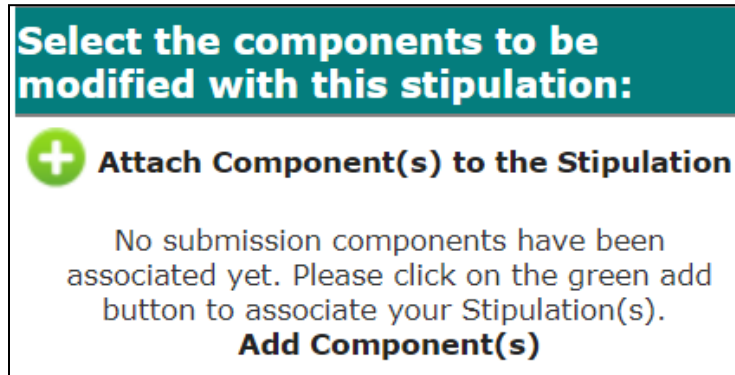
Comments ▾

Associating Components

After selecting a Stipulation Type, you may 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, consent form, or study document. Rather than search for their document or form to make changes, the stipulation will do the work for them. If the stipulation is a requirement for a new attachment of a consent form or study document, it would not be necessary to associate the stipulation to a previously submitted item.

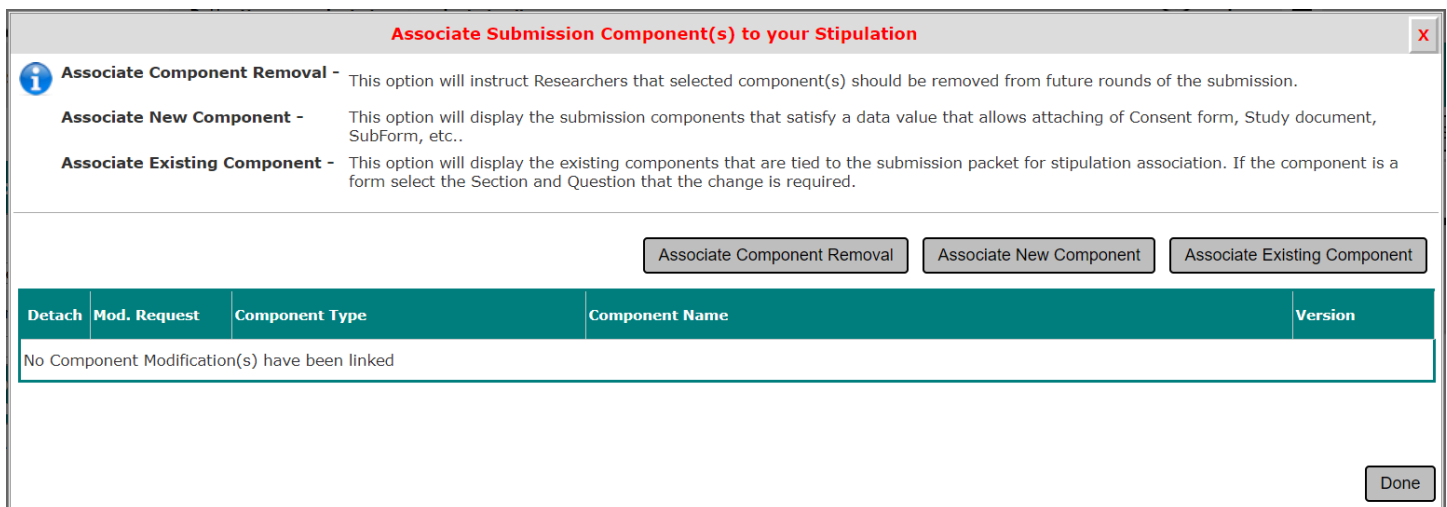
Begin by clicking on the green icon **Attach Components to Stipulation** or click **Add Component(s)**.



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



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				
<p>Removal - Associate the removal of an existing component from the submission components for future rounds.</p>				
				<input type="button" value="Return to List"/> <input type="button" value="Add Link to Selection"/>
	Type	Component Name	Version	
<input type="radio"/>	Consent (English)	Consent form	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. If you need to change the document requested to be removed, click the icon in the Edit 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				
<p>Associate Component Removal - This option will instruct Researchers that selected component(s) should be removed from future rounds of the submission.</p> <p>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..</p> <p>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.</p>				
				<input type="button" value="Associate Component Removal"/> <input type="button" value="Associate New Component"/> <input type="button" value="Associate Existing Component"/>
Detach	Mod. Request	Component Type	Component Name	Version
		Consent (English)	Consent form	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**, as shown in the screenshot below.

Associate Submission Component(s) to your Stipulation				
<p>New - Associate a New component that was not attached in the submission components.</p>				
				<input type="button" value="Return to List"/> <input type="button" value="Add Link to Selection"/>
Select	Component to Attach	Location to Attach (Form Name)		
<input type="radio"/>	Protocol Document	Initial Review Submission Form		
	Section:	Other Study Documents	Question:	If a document was already attached in the Study Application, DO NOT upload it again here. This will create duplicates of ...
<input type="radio"/>	Protocol Consent	Initial Review Submission Form		
	Section:	Consent Documents	Question:	In this section, you can create and attach a new consent/assent form, or revise an existing one and attach it to this s ...

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. If you need to change the document requested to be added, click the icon in the Edit 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 X

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

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

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

Associate Component Removal
Associate New Component
Associate Existing Component

Detach	Mod. Request	Component Type	Component Name	Version
		Consent (English)	Consent form	Version 1.0
		Study Document	Attach a Study Document to the Initial Review Submission Form	

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 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 X

Existing - Associate an existing component from the submission components for stipulation association. If the component is a form select the Section and Question that the change is required.

Return to List
Add Link to Selection

	Type	Component Name	Version
<input type="radio"/>	Submission Form	Initial Review Submission Form	Version 1.1
<input type="radio"/>	Application	New Study Application	Version 1.1
<input type="radio"/>	Consent (English)	Consent form	Version 1.0

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. If you need to change the modification requested, click the icon in the Edit column. Note: the image in the **Mod. Request** column indicates that the request linked to this stipulation is a Modify request.

Associate Submission Component(s) to your Stipulation X

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

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

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

Associate Component Removal
Associate New Component
Associate Existing Component

Detach	Mod. Request	Component Type	Component Name	Version
		Consent (English)	Consent form	Version 1.0
		Study Document	Attach a Study Document to the Initial Review Submission Form	
		Application	New Study Application	Version 1.1
Stipulation placed at	Section: Application Selection Question:			

After you are done creating your component associations close the window using the (X) located in the upper right-hand corner. You will be directed back into 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 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 submission corrections 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.

Stipulations to be sent for Response							
Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By	Link To Component
		1	Stipulation must be addressed	N/A	Remove Study Document and upload informed consent.	Administrator (07/15/2019) Administrator (07/15/2019)	



- You can delete a stipulation by clicking the checkbox in this column then click the **Delete Selected** button.

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.

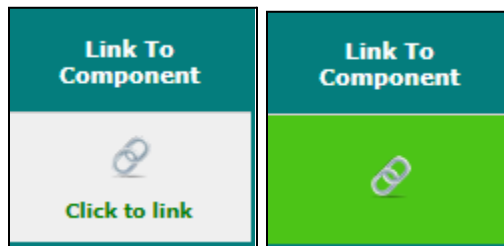
Stipulation Type – This column displays the Stipulation Type selected for the stipulation.

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.

Created By/Edited By - A Created By/ Edited By column has been added to the Stipulation Sent for Response table. This table keeps track of the name and date on when the stipulation created/edited.

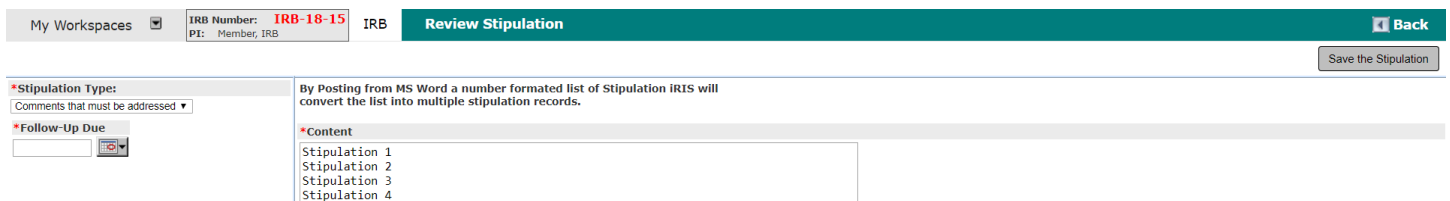
Link to Component – If you have linked components to the stipulation, this column will appear with a green background. You can select the image in this column to change the association. If the stipulation does not have components associated, the background will display without the green color. You can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



Each stipulation added will be listed as a separate record.

List of approved canned Stipulation

4 result(s) found...

<input checked="" type="checkbox"/>	Stipulation
<input type="checkbox"/>	Predefined Stipulation 1
<input type="checkbox"/>	Predefined Stipulation 2
<input type="checkbox"/>	Predefined Stipulation 3
<input type="checkbox"/>	Predefined Stipulation 4

Stipulations to be sent for Response

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By	Link To Component
						Edited By	
		1	Stipulation must be addressed	N/A	Stipulation 1	Administrator (07/15/2019) Administrator (07/15/2019)	 Click to link
		2	Stipulation must be addressed	N/A	Stipulation 2	Administrator (07/15/2019) Administrator (07/15/2019)	 Click to link
		3	Stipulation must be addressed	N/A	Stipulation 3	Administrator (07/15/2019) Administrator (07/15/2019)	 Click to link

Add Pre-Defined

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

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

My Workspaces IRB Number: IRB-18-15 PI: Member, IRB IRB Review Stipulation Back

List of approved canned Stipulation

1 result(s) found...

<input checked="" type="checkbox"/>	Stipulation
<input checked="" type="checkbox"/>	All Training certifications must be "active". Please ensure all study personnel's records are up to date and valid.

Save Selected Stipulations for Protocol

The pre-defined stipulations will be added to the submission, creating a separate stipulation record for each pre-defined stipulation you added. 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 i

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By	Link To Component
						Edited By	
		4	Stipulation must be addressed	N/A	Predefined Stipulation 1	Administrator (07/15/2019) Administrator (07/15/2019)	 Click to link
		5	Stipulation must be addressed	N/A	Predefined Stipulation 3	Administrator (07/15/2019) Administrator (07/15/2019)	 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.

			Name	Rank	Reference	Item Number
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	System		Request for Initial Review of Research Project Involving Human Subjects Version 1.0	
Revision Required Section: Main Line Hospitals Institutional Review Board Request for Initi ... Question: Table 1:						
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	System		Request for Initial Review of Research Project Involving Human Subjects Version 1.0	
Revision Required 2 Section: Table 2: Question: Provide an answer to each question:						

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.

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 i

Delete	Edit	Sorting Number	Stipulation Type	Follow-up Due	Stipulation	Created By	Link To Component
						Edited By	
		1	Stipulation must be addressed	N/A	Please reconcile these stipulations and resubmit for evaluation.	Administrator (08/12/2019) Administrator (08/12/2019)	

Stipulation Responses

The stipulations created will be added into the Review Response Form, when the submission is returned to the study for corrections. The Principal Investigator or designated personnel will need to address the stipulations within the Review Response Form and make the required changes, to the submission and its components and resubmit the form to the IRB.

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

This will allow you to review the responses and status the stipulation, indicating to the system whether or not to close a 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	Created By	Follow-up By Completed By	Response Ack	View Stipulation Component
The Submission was Received 04/17/2018 and completed 04/17/2018								
1		None --none--		Stipulation must be addressed	Jane Coordinator (04/17/2018)	N/A	Yes	
				Stipulation: Add Perinatal Research Review Committee.				
				Response: Research Review Committee added.				

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** date field. You would only supply a date if the stipulation is closed.

The drop-down list containing the Review Board Actions is a configurable list in Review Board Administration. Actions can be configured to tell the system whether or not a stipulation is considered closed or not. If the stipulation is given a type of non-closed, the system will copy the stipulation and the details of the stipulation, into a new stipulation record so it can be returned to the study.

Also displayed on this page is the Stipulation Type, the Follow-up Due, if any, the Stipulation Content and the response from the study in the Response Acknowledge and Response Statement fields.

You can also view the stipulations history, track stipulations, and add memos to stipulations from the menu bar located at the top of the screen. Hover over the **Miscellaneous Menu** and click to open the **Stipulation History** Link. You will be able to track all of the studies open and closed stipulation from this page.

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

My Workspaces IRB Number: **IRB-18-15** IRB Stipulations Tracking Back

Protocol Status: **Pending - Submitted for Initial Review** IRB Number: **IRB-18-15** Protocol Title: Safety and Effectiveness of S-adenosyl-l-methionine (SAME) for the Treatment of Major Depression

Reference Number: Follow-up Date: -

Stipulation Type: **--none--** Find... Print

Open Stipulations **Closed Stipulations**

2 result(s) found...

Open	Edit	Ref Num	Type	Principal Investigator	Stipulation Type	Follow-up Due	Response Acknowledge	Assigned Reviewers	Assigned Analyst	Review Board
		IRB-18-15-NEW-1.1	Initial Review Submission Form	Investigator, IRB, Ph.D.	Stipulation must be addressed		Yes		Coordinator, Jane	IRB
<p>Stipulation: Add Perinatal Research Review Committee.</p> <p>Response: Research Review Committee added.</p>										
		IRB-18-15-NEW-1.1	Submission Correction for Initial Review Submission Form	Investigator, IRB, Ph.D.	Stipulation must be addressed				Coordinator, Jane	IRB
<p>Stipulation: Please reconcile these stipulations and resubmit for evaluation.</p> <p>Response:</p>										

This 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** date field. You would only supply a date if the stipulation is closed.

My Workspaces IRB Number: **IRB-18-15** IRB Process Stipulation Back

Protocol Status: **Pending - Submitted for Initial Review** IRB Number: **IRB-18-15** Protocol Title: Safety and Effectiveness of S-adenosyl-l-methionine (SAME) for the Treatment of Major Depression

Add Memo Save Stipulation

Review Board Action: **--none--**

Review Board Date Closed:

Stipulation Type: Stipulation must be addressed

Follow-up Due:

Stipulation: Add Perinatal Research Review Committee.

Response Acknowledge: Yes

Response Statement: Research Review Committee added.

Edit	Name	Date Modified	Memo Details
No Memos have been added			

Add a memo to the stipulation by clicking the **Add Memo** button on the top right of the page.

This will open a new page containing an embedded editor. You can copy and paste or type in your memo and use the tools within the editor to format your memo. Click the **OK** button when you are done.

My Workspaces IRB Number: **IRB-18-15** IRB IRB - Stipulation Memo Back

Save

Stipulation Memo

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This will add a memo record to the Process Stipulation page. More memos can be added, and your memo can be modified or deleted.

My Workspaces IRB Number: **IRB-18-15** PI: Member, IRB **IRB** **Process Stipulation** Back

Protocol Status: Pending - Submitted for Initial Review IRB Number: IRB-18-15 Protocol Title: Safety and Effectiveness of S-adenosyl-L-methionine (SAME) for the Treatment of Major Depression

Add Memo Delete Memo Save Stipulation

Review Board Action:	--none--
Review Board Date Closed:	<input type="text"/>
Stipulation Type:	Stipulation must be addressed
Follow-up Due:	
Stipulation:	Add Perinatal Research Review Committee.
Response Acknowledge:	Yes
Response Statement:	Research Review Committee added.

Edit	Name	Date Modified	Memo Details
	Administrator	08/12/2019	Checked the application - the stipulation was not addressed properly

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 above shows a stipulation given the action of 'Not Addressed'. When the page is saved, a stipulation record is created.

Stipulations with the responses from the previous submission ⓘ

Order	Edit	Review Action	Date Closed	Stipulation Type	Created By	Follow-Up By Completed By	Response Ack	View Stipulation Component
The Submission was Received and completed 04/17/2018								
1		None Accepted Not Met --none--	<input type="text"/>	Stipulation must be addressed	Jane Coordinator (04/17/2018)	N/A	Yes	
				Stipulation: Add Perinatal Research Review Committee. Response: Research Review Committee added.				

You can set the Review Outcome for all stipulations at once. At the top of the table in the **Review Action** column is a drop-down 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 date 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 Addressed will close out in the system.

Stipulations with the responses from the previous submission ⓘ

Order	Edit	Review Action	Date Closed	Stipulation Type	Created By	Follow-Up By Completed By	Response Ack	View Stipulation Component
The Submission was Received 04/17/2018 and completed 04/17/2018								
1		Accepted	<input type="text"/>	Stipulation must be addressed	Jane Coordinator (04/17/2018)	N/A	Yes	
				Stipulation: Add Perinatal Research Review Committee. Response: Research Review Committee added.				

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 default to **NO**. After you select your routing personnel make sure you set the selection to **YES** and then click the **Save Routing List** button.

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

Internal Review Routing ⓘ

Protocol Title: Safety and Effectiveness of S-adenosyl-L-methionine (SAME) for the Treatment of Major Depression
 Reference Number: IRB-18-15-NEW-1.1
 Submission Type: Submission Correction for Initial Review Submission Form
 Assigned Analyst: Coordinator, Jane

Assignment notes:

Have you completed your selection of required routings?

Yes
 No

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

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

Internal Review Routing ⓘ

Protocol Title: Safety and Effectiveness of S-adenosyl-l-methionine (SAME) for the Treatment of Major Depression
Reference Number: IRB-18-15-NEW-1.1
Submission Type: Submission Correction for Initial Review Submission Form
Assigned Analyst: Coordinator, Jane

Assignment notes:

Have you completed your selection of required routings? Yes No

Order Number	Click to review	Assignment Comments		
		Assigned To	Date Notified	Date Completed
✘ 0		Assignment Comments:		
		Reviewer, Luke, Ph.D ▾		
User Comments:				

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

My Workspaces ▾ IRB Number: **IRB-18-15** IRB PI: Member, IRB **Search User Directory** Back

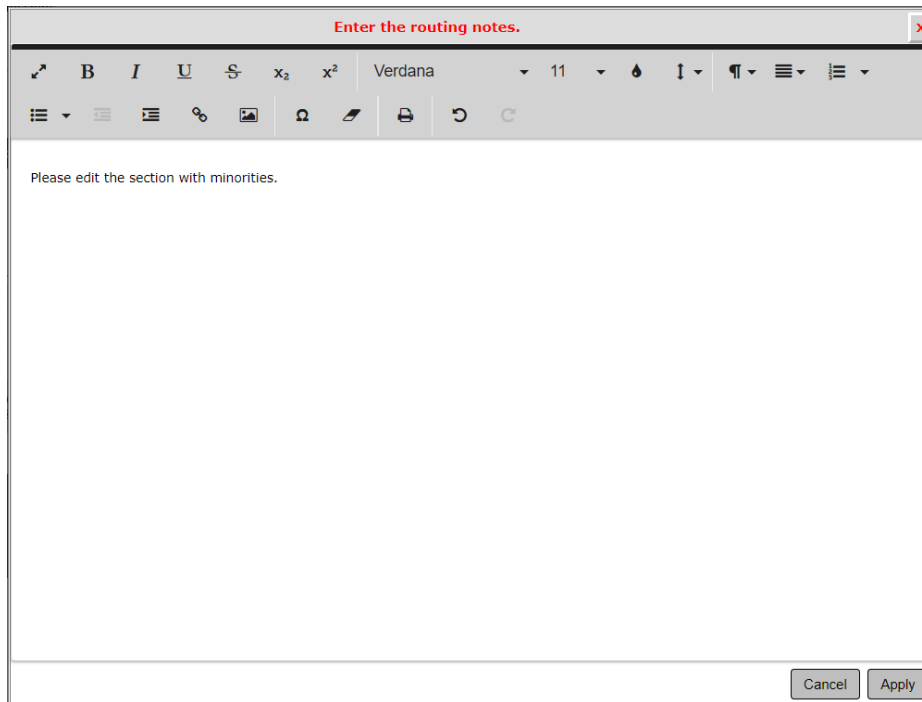
Directory Browse/Find:

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

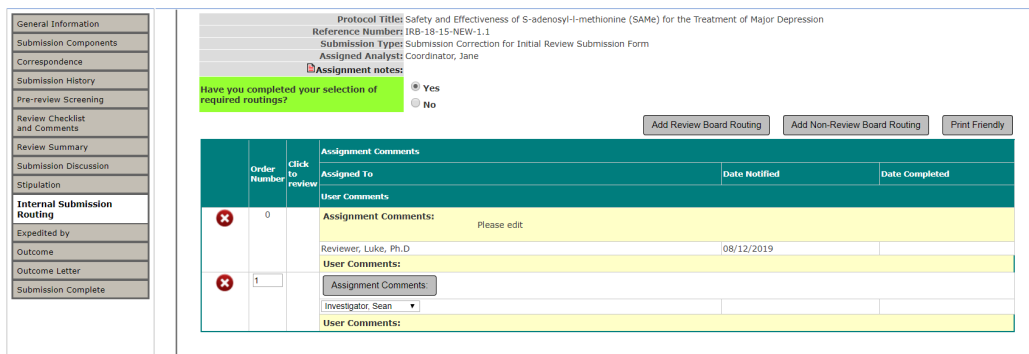
Any users added to the routing will be listed in order. You can assign reviewer specific assignment notes to each user. These comments would appear to the assigned user in addition to the Assignment notes and would be private to the assigned user only. Click the **Assignment Comments** link above the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

Order Number	Click to review	Assignment Comments		
		Assigned To	Date Notified	Date Completed
✘ 0		Assignment Comments:		
		Reviewer, Luke, Ph.D		
User Comments:				
✘ 1		Assignment Comments:		
		Investigator, Sean ▾		
User Comments:				

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



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.



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.

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

Internal Routing Task

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

All Tasks Outstanding Completed ⚙️

All Tasks Study Tasks Task List: Internal Submission Routing Signoff

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

Click to open	Task Type	Received	Description
	Internal Submission Routing Signoff	07/15/2019 09:35 AM PDT	Administrator has been assigned to Administratively review the submission.

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

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, Outcome Letters generated for the review and finally at the end of the page the Internal Submission Routing information.

The user would review each of these items then would scroll to the bottom of the page to finish the review.

My Workspaces ⌵ IRB Number: **E-19-5027** IRB **Submission validation** ⏪ Back

Protocol Items Miscellaneous Submission Forms

Ref Number: **000783** IRB Number: **E-19-5027** Study Title: Understanding Novel Tobacco Product use among Low-Income Smokers

Study Status: Pending - Submitted for Initial Review

Submission components: 📄 Items in List View Create PDF Packet

Include in PDF Packet	Current Submission Components (All Rounds)	More Details
<input checked="" type="checkbox"/>	Submission Form(s)	
<input type="checkbox"/>	Initial Submission Packet - (Version 1.0)	
<input type="checkbox"/>	Application	
<input type="checkbox"/>	Request for Initial Review of Research Project Involving Human Subjects - (Version 1.0)	

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 comments link that also contains their name.

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.

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

From the tasks 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.

Vote / Expedited By / Acknowledged By

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

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

Vote

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

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

My Workspaces

IRB Number: **IRB-18-15**
IRB
Submission Correction for Initial Review Submission Form
Back

Protocol Items

Miscellaneous

Submission Forms

Ref Number: **IRB-18-15-NEW-1.1**

IRB Number: **IRB-18-15**

Protocol Title: Safety and Effectiveness of S-adenosyl-L-methionine (SAME) for the Treatment of Major Depression

Protocol Status: Pending - Submitted for Initial Review

Add Motion
Save the Vote Summary

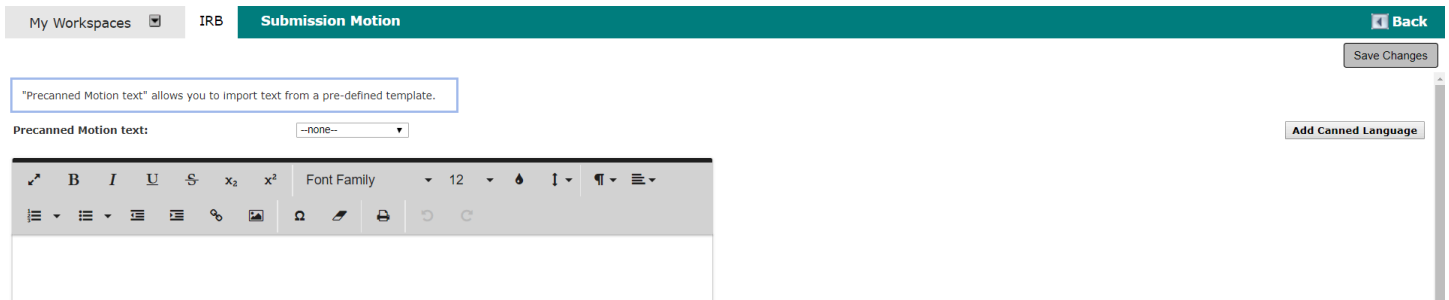
- General Information
- Submission Components
- Correspondence
- Submission History
- Pre-review Screening
- Review Checklist and Comments
- Review Summary
- Submission Discussion
- Stipulation
- Internal Submission Routing
- Vote**
- Outcome

Meeting Vote
0

No Motions have been added.

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

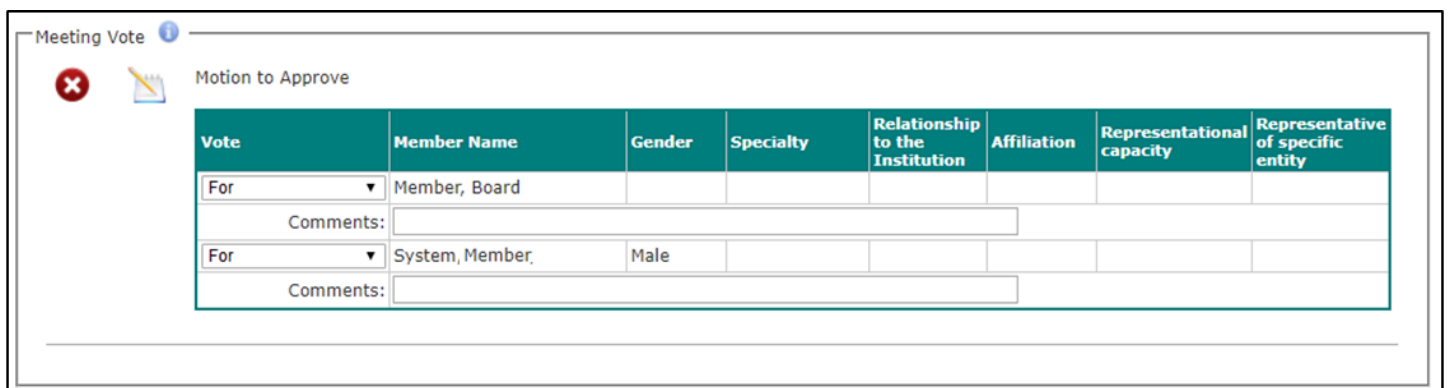
Once your motion is defined in the text editor, click on the **Save Changes** button.



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 **Specialty**, **Affiliation**, and **Alternate** 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 (see the Review Board Administration – System Setup manual).



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 Review Board Configurations manual.

If anonymous voting is setup, then the screen will appear similar to the screenshot above. Select the **Add** button to add a vote result, and a new row will appear.

Enter the number of members that voted for the selected vote type in the **Number** text field. To remove a vote, select the checkbox(es) next to the appropriate vote type and click on the **Remove** button. After you’ve finished entering your

motion, be sure to click the **Save** button.

Meeting Vote ?

✖ ✎ Motion to Approve

Number	Vote Type	Comments
<input type="text" value="0"/>	For	<input style="width: 95%;" type="text"/>
<input type="text" value="0"/>	Absent	<input style="width: 95%;" type="text"/>
<input type="text" value="0"/>	Against	<input style="width: 95%;" type="text"/>
<input type="text" value="0"/>	Abstain	<input style="width: 95%;" type="text"/>
<input type="text" value="0"/>	Conflict of Interest	<input style="width: 95%;" type="text"/>
<input type="text" value="0"/>	Not present for Vote	<input style="width: 95%;" type="text"/>

Expedited By

If the submission has been processed 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.

- 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

Expedited by ?

Expedited	Member Name	Gender	Specialty	Relationship to the Institution	Affiliation	Representational capacity	Representative of specific entity
<input type="checkbox"/>	Administrator, Investigator						
<input type="checkbox"/>	Bowden, Derek						
<input type="checkbox"/>	Cord, Administrator						
<input type="checkbox"/>	Dudley, Alia						
<input type="checkbox"/>	Keshgegian , Albert A						
<input type="checkbox"/>	Lock, Don	Male					
<input type="checkbox"/>	Member, Alternate						
<input type="checkbox"/>	Member, Board						
<input type="checkbox"/>	Ohl, Karen	Female	Cardiology	Affiliated		Non-Scientist	

Acknowledged By

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

This page will display review board members. Next to each member’s name there will be a checkbox in the **Acknowledged** column. By checking the 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.

Acknowledged by:								
Acknowledged	Member Name	Gender	Specialty	Relationship to the Institution	Affiliation	Representational capacity	Representative of specific entity	
<input type="checkbox"/>	Administrator, Investigator							
<input type="checkbox"/>	Bowden, Derek							
<input type="checkbox"/>	Cord, Administrator							
<input type="checkbox"/>	Dudley, Alia							
<input type="checkbox"/>	Keshgegian , Albert A							
<input type="checkbox"/>	Lock, Don	Male						
<input type="checkbox"/>	Member, Alternate							
<input type="checkbox"/>	Member, Board							

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

This section tab you can set the review outcome of the submission. Depending on the setting 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.

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.

The screenshot shows the 'IRB Review Outcome' form. On the left is a navigation menu with options: General Information, Submission Components, Correspondence, Submission History, Pre-review Screening, Review Checklist and Comments. The main form area has a 'Save the Submission Outcome' button at the top right. The form contains several sections: 'Review Outcome' with a dropdown menu currently set to '--none--'; 'Additional information required' set to 'No'; 'Submission Approval' with a date field and a calendar icon; 'Study Status' with a dropdown menu set to 'Pending - Submitted for Initial Review'; 'Assign the Submission to Agenda' section with 'Committee Name' (dropdown: '--none--'), 'Meeting Date' (dropdown: '--none--' or a link 'click here to select past meetings'), and 'Agenda Category' (dropdown: 'Initial Review - Active').

IRB Review Outcome

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

You would 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.

This is a close-up of the 'IRB Review Outcome' form. It shows the 'Review Outcome' dropdown set to '--none--', the 'Study Status' dropdown set to 'Pending - Submitted for Initial Review', 'Additional information required' set to 'No', and the 'Submission Approval' field with a date input and a calendar icon.

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 into the review board submission queue.

This is another close-up of the 'IRB Review Outcome' form. In this state, the 'Review Outcome' dropdown is set to 'Approved', the 'Study Status' dropdown is set to 'Open', 'Additional information required' is still 'No', and the 'Submission Approval' date field is populated with '07/23/2019'.

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 Correction 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:	Approved	Study Status:	Open
Additional information required:	No	Assign the Submission to Agenda:	Committee Name: --none-- Meeting Date: --none-- or click here to select past meetings Agenda Category: --none--
Submission Approval:	07/22/2019		

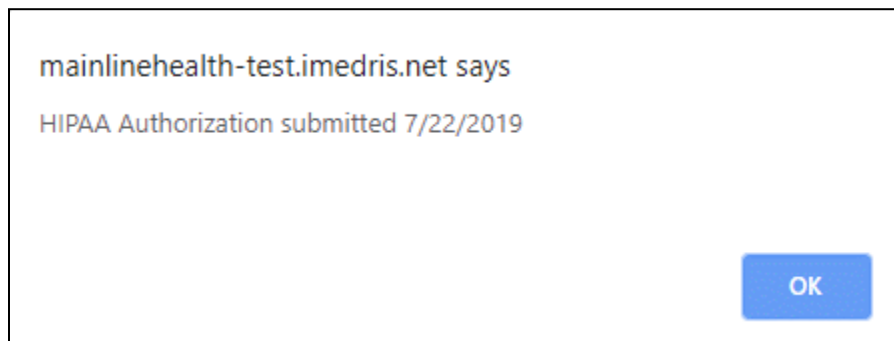
Comments

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

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

Internal Comments:	Internal Comments
Shared Comments:	Shared Comments
Take Note:	<u>HIPAA</u> Authorization submitted 7/22/2019

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 form is opened for that particular study. For example, a certain document that is normally included in the Continuing Review Process is submitted with the Initial Review. The Coordinator can create a Take Note reminder, so that in a year when the Continuing Review is submitted, the note will pop up when the Coordinator begins to process the submission.



Study Information

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

Later, when you are setting outcome information for other submission forms for the study (e.g. Continuing Review, Adverse Event 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:	08/01/2019
IRB of Record:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Use Review Notification to KSP:	<input type="radio"/> Yes <input checked="" type="radio"/> No
IRB Initial Approval:	<input type="text"/>
Review Cycle:	--none-- ▼
IRB Expiration Date:	<input type="text"/> Calculate Date
Continuing Review Due:	<input type="text"/>
Temporary Closed:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Risk Assigned:	--none-- ▼
Exempt:	<input type="checkbox"/>
Subject Approved:	0

The fields in this area are as follows.

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

IRB of Record – Use this option to specify whether the board processing the submission is the IRB of Record. Initial Reviews that are submitted to the IRB will default to “Yes”. If the IRB is not the IRB of Record, but only processes submissions on behalf of another review, you would set this to “No”. You would also set this to “No” if your system is using more than one IRB and the IRB that is processing this submission is not the board of record. Note that any study that comes through this IRB that has the IRB of Record flag set to “No”, the system will exclude those studies from Continuing Review reporting. That study will not receive continuing review tasks or notifications, and will not appear Continuing Review Monitor.

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

IRB Initial Approval:

IRB Initial Approval: 07/23/2019

Review Cycle – This is a configurable drop-down list of review cycles. Each cycle has a month-period associated that will update the **IRB Expiration** date based on the **Submission Approval** date.

Review Cycle:	12 month ▾
RB Expiration:	--none-- 3 month 6 month 12 month
Continuing Review	

IRB Expiration Date – You can manually set the expiration date, or, based on the **Submission Approval** date and the **Review Cycle**, you can calculate the date. A new property has been added which allows users with board administration access to modify the way the system calculates the study expiration date. When this property is set to "No" the system calculates the study expiration date based on the study date and the selected review cycle and sets the expiration date for a day **before** the study expires.

Submission Approval: 07/22/2019

Internal Comments: Internal Comments

Shared Comments: Shared Comments

Take Note: HIPAA Authorization submitted 7/22/2019

IRB of Record: Yes No

Use Review Notification to KSP: Yes No

IRB Initial Approval: 07/22/2019

Review Cycle: 12 Months ▾

IRB Expiration Date: 7/21/2020 **Calculate Date**

When this property is set to "Yes" the system will set the study expiration date to the exact date of the expiration of the study, and the study will expire right when the next date begins.

Note: This functionality will only take effect if the auto expiration function is activated within your system.

Submission Approval: 07/24/2019

Internal Comments:

Shared Comments:

Take Note:

IRB of Record: Yes No

Use Review Notification to KSP: Yes No

IRB Initial Approval:

Review Cycle: 12 Months

IRB Expiration Date: 7/24/2020 **Calculate Date**

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

If you are processing a submission that is not the Initial Review or the Continuing Review, the Review Cycle and the IRB Expiration date will be locked down. This information can be changed if necessary, through the Study Summary Profile.

IRB of Record: Yes No

IRB Initial Approval: 07/24/2019

Review Cycle: 12 Months

IRB Expiration Date: 07/24/2020 **Calculate Date**

Continuing Review Due: 07/24/2020

Temporary Closed: Yes No

Risk Assigned: --none--

Exempt:

Subject Approved: 0

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.

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 that the study 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 date here.

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

Exempt – Use this field to categorize this project as **Exempt** from further review by the current Review Board.

Subjects Approved – Use this field to set number of allowable subjects and/or controls in the **Subjects Approved**. If you are also using Subject Management, the number of approved subjects in this field will control the number of subjects the study can enroll.

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

Annual IRB/SRB review notification type sent based off of Study Status

With the implementation of the new common rule, “Common Rule – Effective January 2019”, different notifications can be configured to remind users about study expirations and renewals. The option to choose the new common rule is available in the Outcome tab in the Submission Processing Queue under “Select Categories for Study”.

A new property has been added to setup the new common rule and activates the function to send a type of continuing review notification based on study status.

Email with Home Screen Task and Continuing Review – This will send an email notification regarding the upcoming expiration status of the study to the user’s default email address for notifications and will receive a task on their home screen as well as a request for a Continuing Review Submission.

Email with Home Screen Task Notification – This will send an email notification regarding the upcoming expiration status of the study to the user’s default email address for notifications and will receive a task on their home screen.

Email Notification Only – This will send an email notification regarding the upcoming expiration status of the study.

No Notification – This will not send an email notification to the user.

When the property is set to “Yes” and the IRB or SRB members go to the Outcome tab, they will have the option to choose the new Common Rule, under “Select Categories for Study:” and can change the Type of Review Notification from the associated Study Status. If the user selects Common Rule – Effective 2019, then the option, “Please Select the Type of Review Notification that Must be Sent:” appears but will only be Read-Only.

The way to change the Type of Review Notification received is to change the Study Status. Below are two examples of different Study Statuses and different Type of Review Notification associations.

Study Status is “Open” and Type of Review Notification is “Email with Home Screen Task and Continuing Review”.

The screenshot shows the 'IRB Review Outcome' form. On the left is a sidebar with navigation tabs: General Information, Submission Components, Correspondence, Submission History, Pre-review Screening, Review Checklist and Comments, Review Summary, Submission Discussion, Recommendation, Stipulation, Internal Submission Routing, Outcome, Outcome Letter, and Submission Complete. The 'Outcome' tab is currently selected. The main form area contains several sections: 'Review Outcome' (dropdown set to '--none--'), 'Additional information required' (set to 'No'), 'Submission Approval' and 'Meeting Approval Date' (input fields with icons), 'Internal Comments' and 'Shared Comments' (text areas), 'Take Note' (text area), 'IRB of Record' (radio buttons for Yes/No), and 'Please Select the Type of Review Notification that Must be Sent' (dropdown set to 'No Notification'). On the right, there is a section for 'Assign the Submission to Agenda' with dropdowns for 'Study Status' (set to 'Closed to Accrual with follow-up'), 'Committee Names' (set to '--none--'), 'Meeting Date' (set to '--none--' with a link to select past meetings), and 'Agenda Category' (set to '--none--').

Study Status is “Closed to Accrual with follow-up” and Type of Review Notification is “No Notification”.

After entering in 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

A vertical list of navigation tabs for the IRB Assistant Manual. The tabs are: 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 (highlighted in white), and 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](#)

General Information	Outcome Letter ⓘ Notification Letter: --none-- <table border="1"> <thead> <tr> <th>Delete/Void</th> <th>Send</th> <th>Edit/View</th> <th>Title</th> <th>Signature Required</th> <th>Status</th> <th>Route Signoff</th> <th>Copy</th> </tr> </thead> <tbody> <tr> <td colspan="8">No Letters have been created for this submission.</td> </tr> </tbody> </table>	Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy	No Letters have been created for this submission.							
Delete/Void		Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy									
No Letters have been created for this submission.																	
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																	

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

Outcome Letter ⓘ	Notification Letter: --none-- <table border="1"> <thead> <tr> <th>Delete/Void</th> <th>Send</th> <th>Edit/View</th> <th>Title</th> <th>Signature Required</th> <th>Status</th> <th>Route Signoff</th> <th>Copy</th> </tr> </thead> <tbody> <tr> <td colspan="8">No Letters have been created for this submission.</td> </tr> </tbody> </table>							Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy	No Letters have been created for this submission.							
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy																
No Letters have been created for this submission.																							
	--none-- Exempt Letter Expedited Final Report Full Board - Modifications Required - New Study Full Board - New Study Full Board Amendment - Approval Full Board Approval - CR General Approval - Acknowledgement NHSR Letter																						

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 in 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, IRB Number, Study Number** and **Assigned Analyst**).

Reference Number: 000783
 Submission Type: Initial Submission Packet
 IRB Number: E-19-5027
 Study abbreviated title: Understanding Novel Tobacco Product use among Low-Income Smokers
 Assign Analyst: Administrator Cord
 Does this letter require signature signoffs?
 Yes No
 Share this letter with other Boards?
 Yes No

HTML Content

Dear Dr. Investigator Administrator, M.D.:

The above referenced study was reviewed and approved by the Institutional Review Board at their meeting on 08/01/2019 in accordance with 45 CFR 46.111 and 21 CFR 56.111 for a period of one year.

Approved:

Submission Components Approved		
Document Type	Version	Date Approved
Submission-Initial	Version 1.0	
Submission Packet		

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, our software will adjust to these issues by giving you the option of downloading and uploading the letter when necessary.

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 a user 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

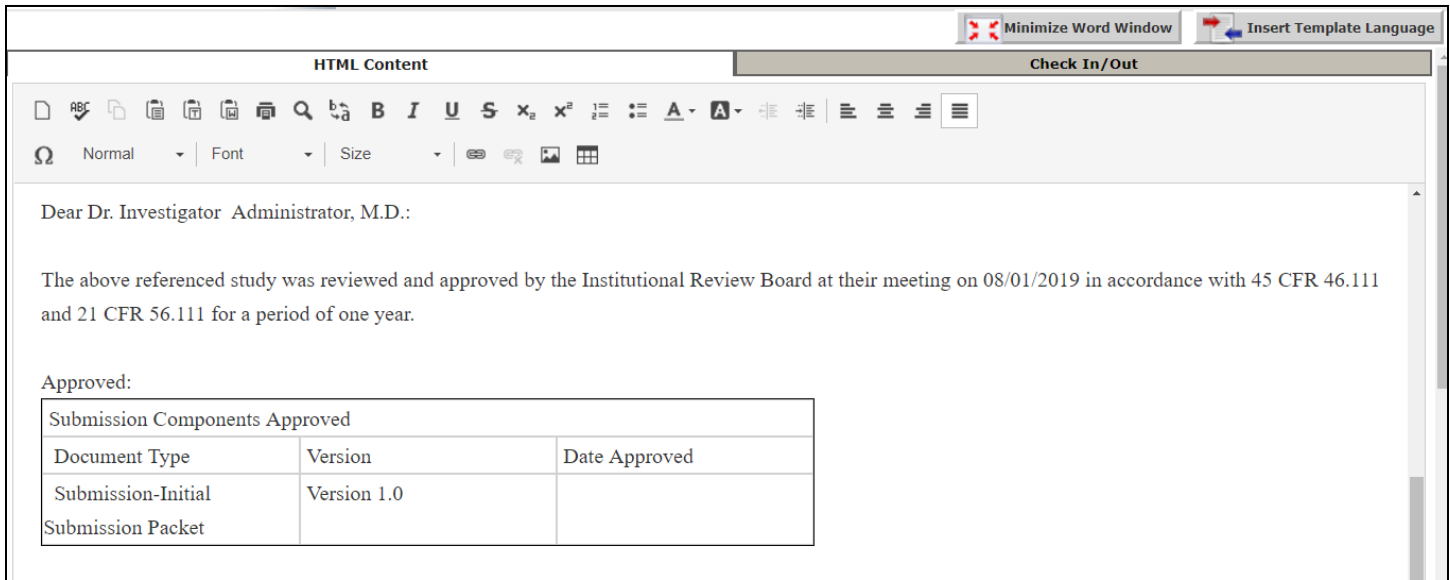
Share with Review Board:

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

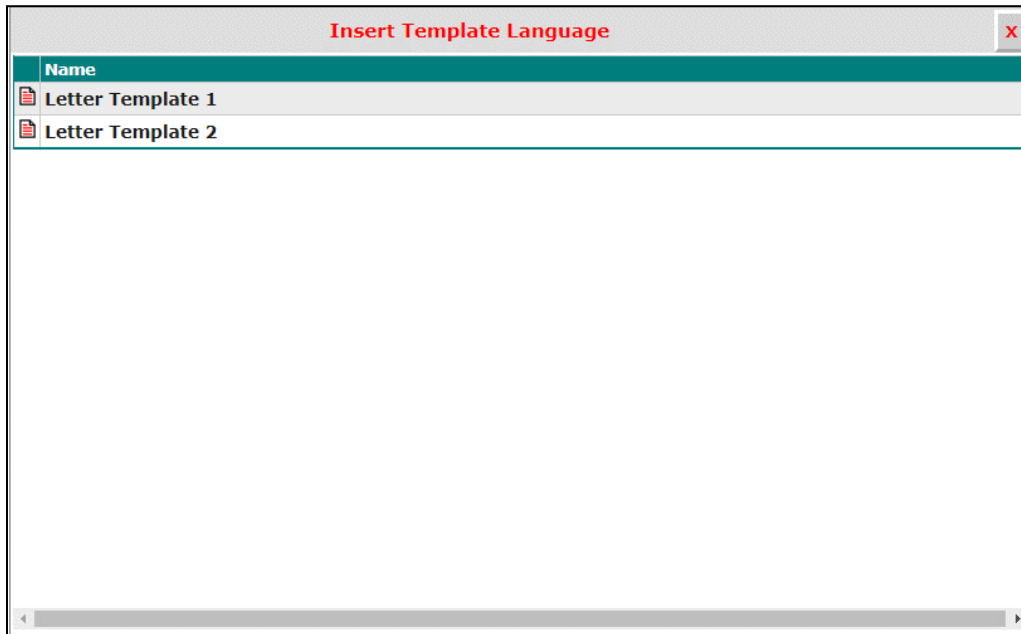
Make changes to the content of the letter as necessary.


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 templates by selecting the **Insert Template Language** button.



A list of template language will appear. This list is also pre-defined in Review Board Configurations – System Setup – Setup Template Language. To select the template, click on the  icon next to it. After all necessary revisions/additions are made select the **Save Letter Changes** button.

Outcome Letter i

Notification Letter:

Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study 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 made void.



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.

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’, which means that the letter can be sent;

‘Waiting to be Routed for Signoff’, 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’ 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 for the letter 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 first 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**.

Notification Letter: --none--							
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study Version 1	No	Letter sent --- Completed Sent: 07/22/2019 02:28 PM PDT		

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

Notification Letter: --none--							
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study Version 1	No	Letter sent --- Voided		

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

My Workspaces ▾
IRB
Letter ◀ Back

IRB Number:
E-19-5027

Study abbreviated title:
Understanding Novel Tobacco Product use among Low-Income Smokers

Assign Analyst:
Administrator Cord

Does this letter require signature signoffs?

Yes No

Share this letter with other Boards?

Yes No

After voiding the letter, you would want to Re-send it to the study personnel.

Notification Letter:

--none-- ▾

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study 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 grayed out 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.

My Workspaces ▾ IRB **Letter Recipients** Back

Submission Type:	Submission Correction for Initial Review Submission Form		
IRB Number:	IRB-18-15	Reference Number:	IRB-18-15-NEW-1.1
Protocol Title:	Safety and Effectiveness of S-adenosyl-l-methionine (SAME) for the Treatment of Major Depression		
Letter Title:	<input type="text" value="Outcome Letter Notification"/>		

Key Protocol Personnel

Contacts	Role	<input type="checkbox"/>	
Project Personnel			
	Principal Investigator	<input checked="" type="checkbox"/>	IRB Member
	Co-Investigator	<input checked="" type="checkbox"/>	Co Investigator
	Nurse	<input checked="" type="checkbox"/>	Research Staff
	Contact	<input checked="" type="checkbox"/>	IRB Member
IRB - Committee 1			
	Coordinator	<input checked="" type="checkbox"/>	Administrator
		<input checked="" type="checkbox"/>	Jane Coordinator
		<input checked="" type="checkbox"/>	IRB Member

Additional Recipients

Association	<input type="checkbox"/> Send if checked	Additional Recipients
No additional recipients have been selected		

At the top of the page, study and submission specific information is listed, Submission Type, IRB Number, Study Title, and Reference Number. Letter Title is an editable field, allowing you to type in the desired title for the letter.

My Workspaces ▾ IRB **Letter Recipients** Back

Submission Type:	Submission Correction for Initial Review Submission Form		
IRB Number:	IRB-18-15	Reference Number:	IRB-18-15-NEW-1.1
Protocol Title:	Safety and Effectiveness of S-adenosyl-l-methionine (SAME) for the Treatment of Major Depression		
Letter Title:	<input type="text" value="Outcome Letter Notification"/>		

Key Protocol Personnel

Contacts	Role	<input type="checkbox"/>	
Project Personnel			
	Principal Investigator	<input checked="" type="checkbox"/>	IRB Member
	Co-Investigator	<input checked="" type="checkbox"/>	Co Investigator
	Nurse	<input checked="" type="checkbox"/>	Research Staff
	Contact	<input checked="" type="checkbox"/>	IRB Member
IRB - Committee 1			
	Coordinator	<input checked="" type="checkbox"/>	Administrator
		<input checked="" type="checkbox"/>	Jane Coordinator
		<input checked="" type="checkbox"/>	IRB Member

Additional Recipients

Association	<input type="checkbox"/> Send if checked	Additional Recipients
No additional recipients have been selected		

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

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

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

My Workspaces ▾ IRB Number: **IRB-18-15** PI: Member, IRB IRB **Search User Directory** Back

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

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

Association	Send if checked	Additional Recipients
<input type="text"/>	<input checked="" type="checkbox"/>	George Jefferson

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

My Workspaces ▾ IRB Letter Additional recipients Back		
<input checked="" type="checkbox"/>	Name	E-mail Address
<input checked="" type="checkbox"/>	Jane Doe, MSN	jdoe@research.com

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

My Workspaces ▾ IRB Letter Additional recipients Back		
<input type="checkbox"/>	Name	E-mail Address
<input type="checkbox"/>	Jane Doe, MSN	jdoe@research.com
<input type="checkbox"/>	Adam Brown, Ph.D	abrown@research.com

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

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

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

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 Board - New Study Version 2	Yes	Routing Complete Waiting to be sent		

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.

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.

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

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

Order Number – Specifies who will receive the signoff task first.

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 current logged in user. An icon will populate in this column for each personnel. If you are looking at this page and are selected as the 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 sign off will be allowed to edit the letter.

Date Received – Date user receives the letter for signature.

Date Completed – Date the user applies electronic signature.

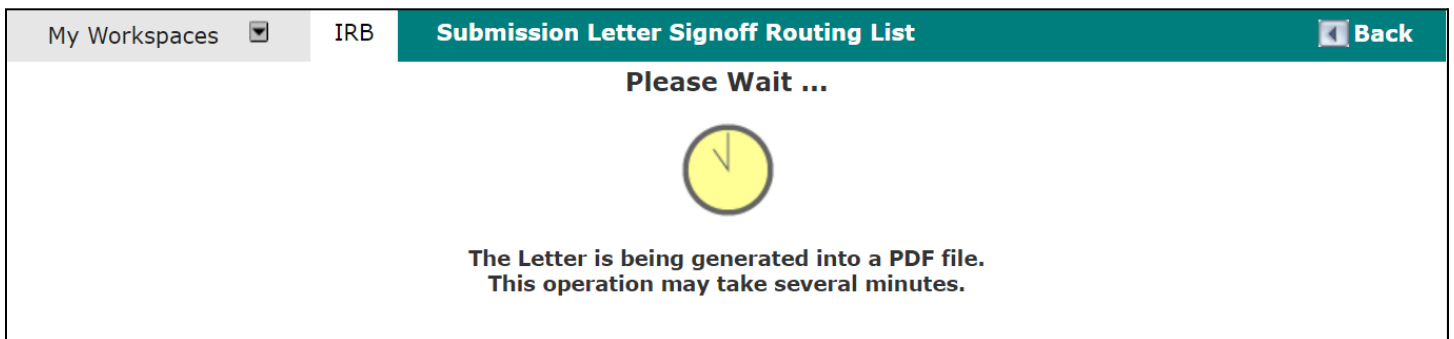
Comments – Any comments the user may have entered upon sign off.

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

Once all selections are made, click “Yes” in the field **Have you completed your selection of required signatures?** 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.



Click the **Back** button to navigate back to the Letter page. The Outcome Letter now appears in the window as an un-editable PDF document.

My Workspaces ▾	IRB	Letter	Back
Reference Number: 000783 Submission Type: Initial Submission Packet IRB Number: E-19-5027 Study abbreviated title: Understanding Novel Tobacco Product use among Low-Income Smokers Assign Analyst: Administrator Cord	Date: July 23, 2019 To: Dr. Administrator, Investigator , M.D. Lankenau – Oncology 1234 Main Street Redlands, CA 92374 Professor RE: E-19-5027 – Understanding Novel Tobacco Product use among Low-Income Smokers Sponsor: Performance Site : Oncology Action: Approved/Modifications Required/Additional Information Required Action Date: 07/23/2019 Study Expiration Date: 07/22/2020	Does this letter require signature signoffs? <input checked="" type="radio"/> Yes <input type="radio"/> No Is batch signoff applicable? <input type="radio"/> Yes <input checked="" type="radio"/> No	

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

All Tasks				Outstanding	Completed	
All Tasks	Study Tasks	Task List: Outcome Letter Signoff ▾				
1 result(s) found...				1 - 1		
Click to open	Task Type	Received	Description			
	Outcome Letter Signoff	05/16/2019 10:53 AM PDT	Dr. Investigator Administrator, M.D. has been assigned to review and signoff the IRB Full Board Approval outcome letter.			
1 result(s) found...				1 - 1		

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 above displays the PDF letter, meaning this user was not granted the ability to modify the letter before approving or denying the letter.

To the left of the letter, study and submission information is listed. There is a drop-down list that the user can use to select either Approve or Deny.

Comments can also be added to the letter on this page.

My Workspaces ▾ IRB **Letter Signoff** Back

Save Letter Review

Reference Number: 013484
 Submission Type: Initial Review Submission Form Real
 IRB Number: IRB-19-4129
 Alias: MAIN IRB
 admin, Admin Admin Mr, B.S. Brig. Gen.
 do you Approve or Deny this letter?
 --none-- ▾

Regulatory Determinations Pertaining to this Approval:

Today's Date: February 11, 2019


[Click here to add comments.](#)

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.

Dr. Administrator, Investigator , M.D.
do you Approve or Deny this letter?

Deny ▾

 [Click here to revise a copy of the letter with your suggestions.](#)

[Click here to add comments.](#)


No Comments have been posted.

When the button **Click here to revise a copy of the letter with your suggestions** is clicked, the page refreshes to display a copy of the letter in an embedded Word editor. After any changes are made, you would click the **Save Letter Changes** button.

My Workspaces ▾ Study Assistant **Submission Letter Revision** Back

Reference Number: 000783
 Submission Type: Initial Submission Packet
 IRB Number: E-19-5027
 Study abbreviated title: Understanding Novel Tobacco Product use among Low-Income Smokers
 Assign Analyst: Administrator Cord

HTML Content

Ω Format ▾ | Font ▾ | Size ▾ | 

Date: July 23, 2019

To: Dr. Administrator, Investigator , M.D.
 Lankenau - Oncology
 1234 Main Street
 Redlands, CA 92374
 Professor

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 Board - New Study Version 1	Yes	Denied in Routing		

Click the **Route Signoff** button.

My Workspaces ▾ IRB **Submission Letter Signoff Routing List** Back

Study Title: Understanding Novel Tobacco Product use among Low-Income Smokers

Reference Number: 000783

Submission Type: Initial Submission Packet

Letter Name: Full Board - New Study

Have you completed your selection of required signatures? Yes No

<input checked="" type="checkbox"/>	Order Number	Name	Signoff	Approved	Include Signature	Allow Change	Date Received	Date Completed	Comments
	0	Dr. Administrator, Investigator , M.D.		No	Yes	No	07/23/2019 12:39:49 PM EDT	07/23/2019 12:45:08 PM EDT	
	1	Member, Board		 Click here to view changes	Yes	No	07/23/2019 12:45:08 PM EDT		

Because the letter was denied, any other signoff tasks have been cancelled and the Submission Letter Signoff Routing List page is locked down. There will display a Word icon in the **Approved** column for the user that denied the letter. You can click on this to view any suggested changes.

A new page will open. The modified letter is displayed in the embedded Word editor. You can view the changes and make any other necessary modifications. Once necessary changes are made, click the **Copy Revised Letter**.

My Workspaces ▾ IRB **Submission Letter Revision** Back

Copy Revised Letter

Reference Number: 000783

Submission Type: Initial Submission Packet

IRB Number: E-19-5027

Study abbreviated title: Understanding Novel Tobacco Product use among Low-Income Smokers

Assign Analyst: Administrator Cord

HTML Content

Date: July 23, 2019

To: Dr. Administrator, Investigator , M.D.
Lankenau - Oncology
1234 Main Street
Redlands, CA 92374
Professor

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 bellow shows two Outcome Letter records, Version 1 and Version 2. Version 1 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 2 of the Outcome Letter is in an editable state and can be routed for signoff or it can be sent to the study personnel.

Notification Letter: --none--							
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study Version 2	No	Waiting to be sent		
			Full Board - New Study Version 1	Yes	Denied in Routing		

Approving the Outcome Letter

Dr. Administrator, Investigator , M.D.
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.](#)

No Comments have been posted.

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.

When the approval signoff is completed, the letter will generate a PDF. If the signoff task was flagged to Include Signature and the Electronic Signature merge code has been inserted into the Outcome Letter template, the signature information will populate in the Outcome Letter, similar to the screenshot above.

At this point, the Analyst assigned to the submission would receive a notification from the system regarding the completion of the Outcome Letter Signoffs.

Notification Letter: --none--							
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study Version 2	Yes	Routing in progress		
			Full Board - New Study Version 1	Yes	Denied in Routing		

Returning to the Outcome tab in the Submission Processing screens, the letter record will update indicating that signature routing is complete in the **Status** column.

At this point, the **Send** icon will be selectable, allowing you to send the letter to the study personnel.

You can click on the icon in the **Route Signoff** column to obtain any additional details about the signoffs collected for the Outcome letter.

My Workspaces ▾
IRB
Submission Letter Signoff Routing List
Back

Study Title: Understanding Novel Tobacco Product use among Low-Income Smokers

Reference Number: 000783

Submission Type: Initial Submission Packet

Letter Name: Full Board - New Study

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	Dr. Administrator, Investigator , M.D.		Yes	Yes	No	07/23/2019 12:54:07 PM EDT	07/23/2019 12:57:27 PM EDT	
1	Member, Board		Yes	Yes	No	07/23/2019 12:57:27 PM EDT	07/23/2019 01:15:38 PM EDT	

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. And 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 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 could copy the existing letter and make any changes, instead of re-creating the letter from scratch.

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

		Full Board - New Study Version 2	Yes	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 if for signoff.

Delete/ Void	Send	Edit/ View	Title	Signature Required	Status	Route Signoff	Copy
			Full Board - New Study Version 3	No	Waiting to be sent		
			Full Board - New Study Version 2	Yes	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 this last tab in the Submission Processing Screens is to indicate to the system, that you are finished processing the submission from the review board, whether that be for Pre-Review, Full Board, 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, it will not be completely Approved, even if the meeting date assigned to the submission has passed. You must indicate that the submission is complete on this page. Doing so will complete this round of the submission, moving the submission record from the Assigned tab to the Completed tab. If you indicated that Pre-Review Changes or Post-Review Changes are required, the system will generate a response form, attach the submission and components and return to the study.

My Workspaces
IRB Number: **IRB-18-15**
PI: Member, IRB
IRB
Submission Correction for Initial Review Submission Form
Back

Protocol Items
Miscellaneous
Submission Forms

Ref Number: **IRB-18-15-NEW-1.1**

Protocol Status: Pending - Submitted for Initial Review

IRB Number: **IRB-18-15**

Protocol Title: Safety and Effectiveness of S-adenosyl-L-methionine (SAME) for the Treatment of Major Depression

Save the 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

Review Complete

Review Outcome: No

Additional information required: No

Protocol Status: Pending - Submitted for Initial Review

Submission processing complete:

Review Outcome Letters

Edit/View	Title	Signature Required	Status
	Changes Requested Version 2	Yes	Waiting to be Routed for Signoff
	Changes Requested Version 1	No	Letter sent --- Voided

Display Submission components status

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)

The Submission Complete tab is broken up in to three sections: Review Complete, Review Outcome Letters, and Display Submission Components.

The screenshot shows the IRB Assistant interface for a submission. At the top, it displays the Ref Number (021144), IRB Number (IRB-19-5436), and Study Title (Department Drop Error). The Study Status is 'Pending - Submitted for Initial Review'. On the right, there are buttons for 'Send Bundle Email' and 'Save the Submission Complete'. A sidebar on the left lists navigation options: Submission History, Pre-review Screening, Review Checklist and Comments, Review Summary, Submission Discussion, Recommendation, Stipulation, Internal Submission Routing, Outcome, Outcome Letter, and Submission Complete. The main content area is divided into sections: 'Review Complete' with fields for Review Outcome (Pre-Review response required), Additional information required (Yes), and Study Status (Pending - Submitted for Initial Review); 'Review Outcome Letters' with a table header (Indicate items to bundle, Edit/View, Title, Signature Required, Status) and a message 'No Letters have been created for this review.'; and 'Display Submission components status'. A red box highlights the 'Restore context on response' checkbox, which is currently unchecked. Below it, a yellow box indicates 'Submission processing complete:' with an unchecked checkbox.

A field called “Restoring Context on Response” has been added to Submission Complete screen. If the submission will be sent back to the study team, the “Restore context on response” can be checked if the board member wishes to retain the assigned reviewers. Restoring the context of a response can be applied to each review process.

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.

A close-up of the 'Submission processing complete:' checkbox, which is currently checked (indicated by a blue checkmark in a small square).

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 1

Edit/View	Title	Signature Required	Status
	Full Board - New Study Version 3	No	Letter sent --- Completed Sent: 07/23/2019 10:36 AM PDT
	Full Board - New Study Version 2	Yes	Letter sent --- Voided
	Full Board - New Study Version 1	No	Letter sent --- Voided
	Full Board - New Study Version 1	No	Letter sent --- Voided

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 portion of this document. See that section for more details.

Display Submission Components 1

Show submission component(s) in round: 3 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	Revise/Attach	Submission Component Name - Version	More Details
Submission Form(s)				
<input type="checkbox"/>	<input type="checkbox"/>		IRB - IRB - Pre-Review Response Form - (Version 2.0)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		Initial Review Submission Packet - (Version 1.0)	<input type="checkbox"/>
Application				
<input type="checkbox"/>	<input type="checkbox"/>		Simple Study Application - (Version 1.2)	<input type="checkbox"/>
Consent Form(s)				
Category : Consent				
<input type="checkbox"/>	<input type="checkbox"/>		Consent Document (English) - (Version 1.1 Approved on 07/09/2019) <i>*Revision modified by the IRB.</i>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>		NEW Consent (English) - (Version 1.0 Approved on 07/09/2019) <i>*Added by the IRB.</i>	<input type="checkbox"/>
Document(s)				
Category : Other				
<input type="checkbox"/>	<input type="checkbox"/>		NEW Study Document - (Version 1.0) <i>*Added by the IRB.</i>	<input type="checkbox"/>
Category : Standard Operating Procedures				
<input type="checkbox"/>	<input type="checkbox"/>		Study document - (Version 1.0)	<input type="checkbox"/>