IRB ASSISTANT

Review Board Administration

Version 11.02

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11.02

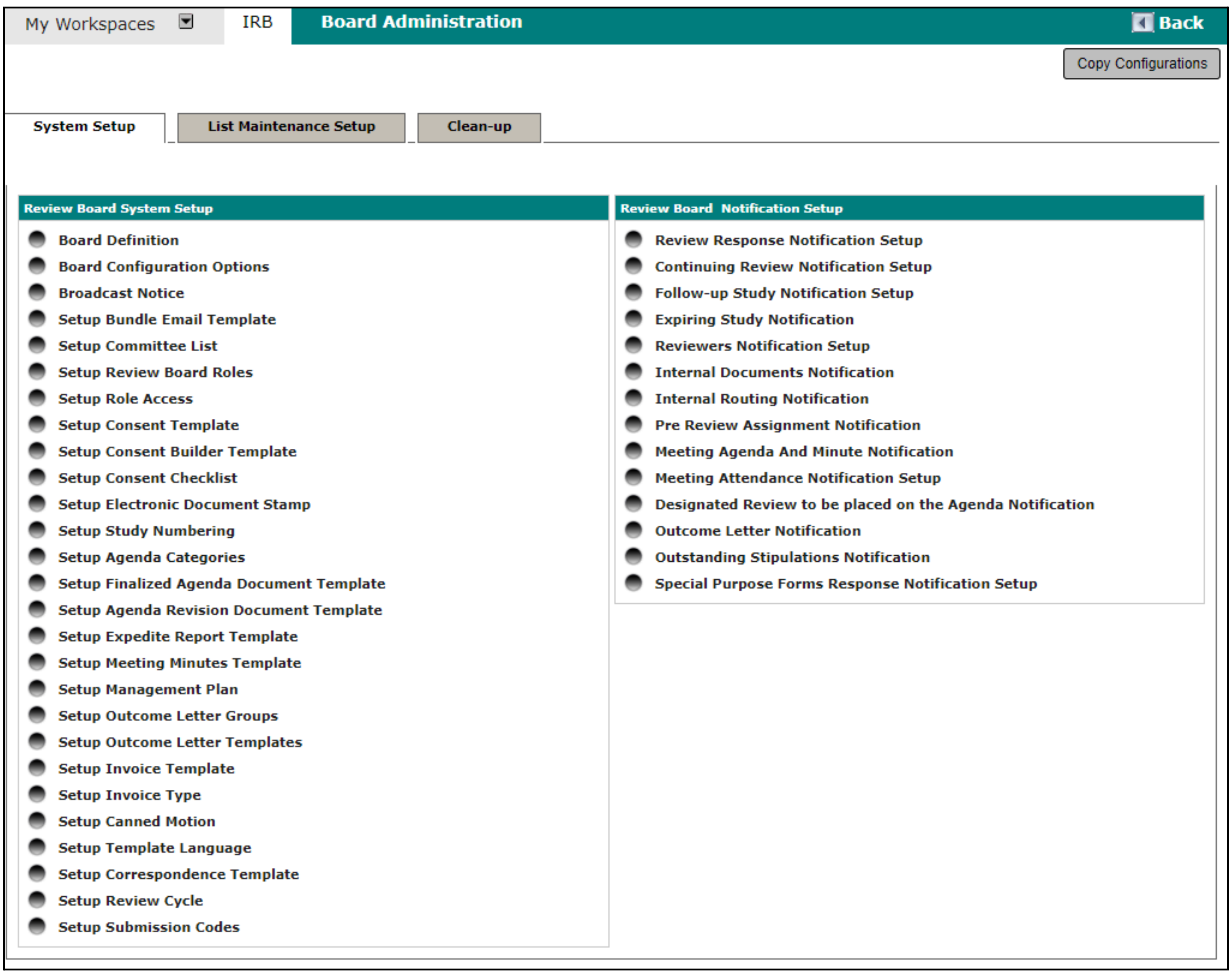
IRB Assistant - Review Board Administration

Introduction

Within IRB Review Board Administration, you can setup configuration lists, define Outcome Letters, define Meeting Agenda and Minutes templates, and setup automatic review board-related notifications. Review Board Administration is typically reserved for Review Board Administrators.

System Setup

The first section of Review Board Administration is System Setup. This area allows you to manage the general setup of the review board. You can define review board details, set up review board roles, and define their access in iRIS. You can also create the templates for Outcome Letters, Minutes and Agendas, Consents, Invoices, and Correspondence. You will also set up your institution's Review Board Notifications.

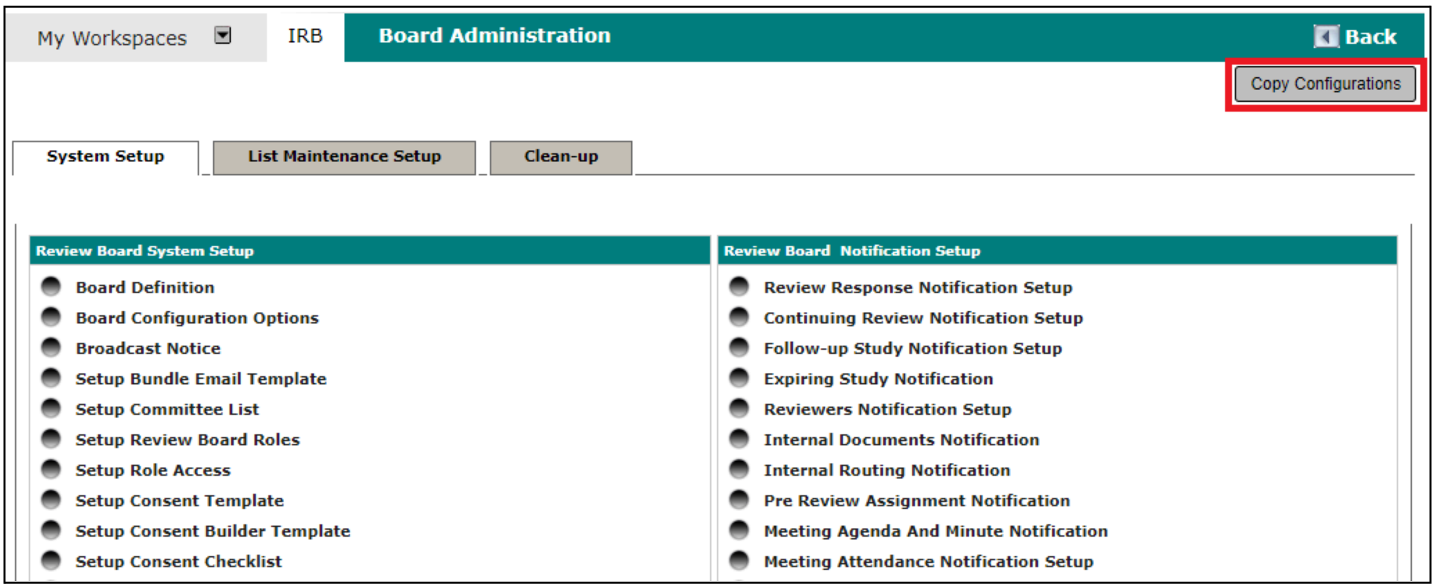


Copy Configurations

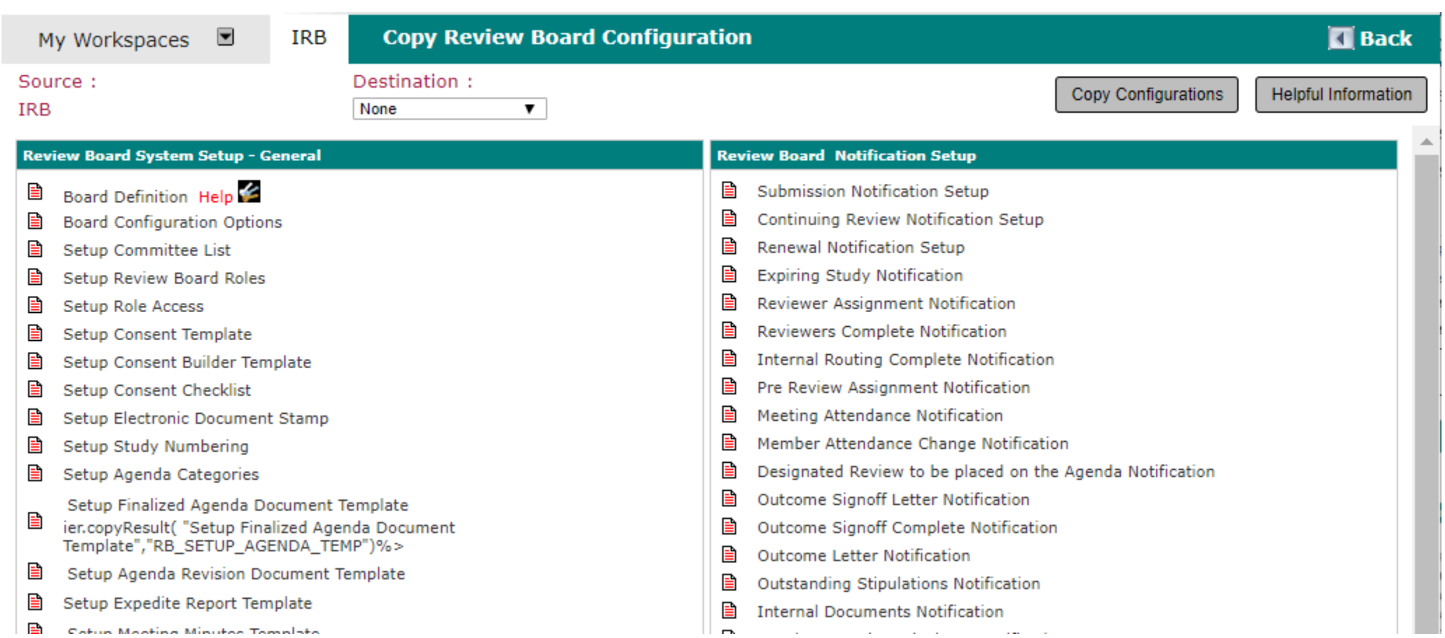
Note: This is a tool designed to help with the initial setup of iRIS. It is not recommended that this be used once your review boards are set up or once your system is live. This also must be used in conjunction with other IRB review board modules. Configurations cannot be copied from review boards that are different types (IRB to IBC, IRB to IACUC), but can only be copied to review boards that are the same type (IRB to IRB, IBC to IBC, IACUC to IACUC).

If you have two review boards of the same type, you can copy configurations that are set in one review board to another review board of the same type.

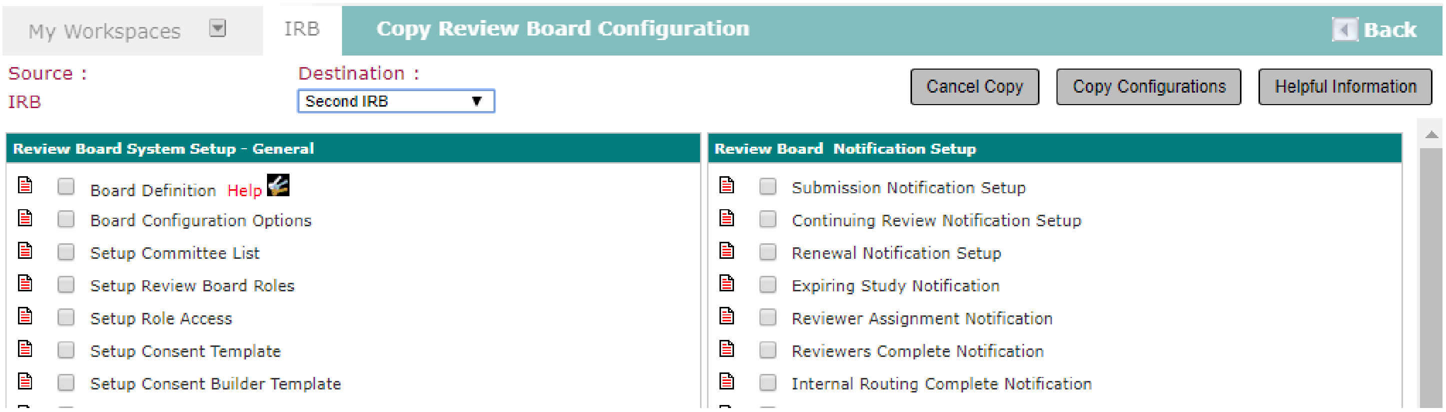
Click on the **Copy Configurations** button to get started.



A new screen will open, displaying the available configurations that can be copied to the other review board.



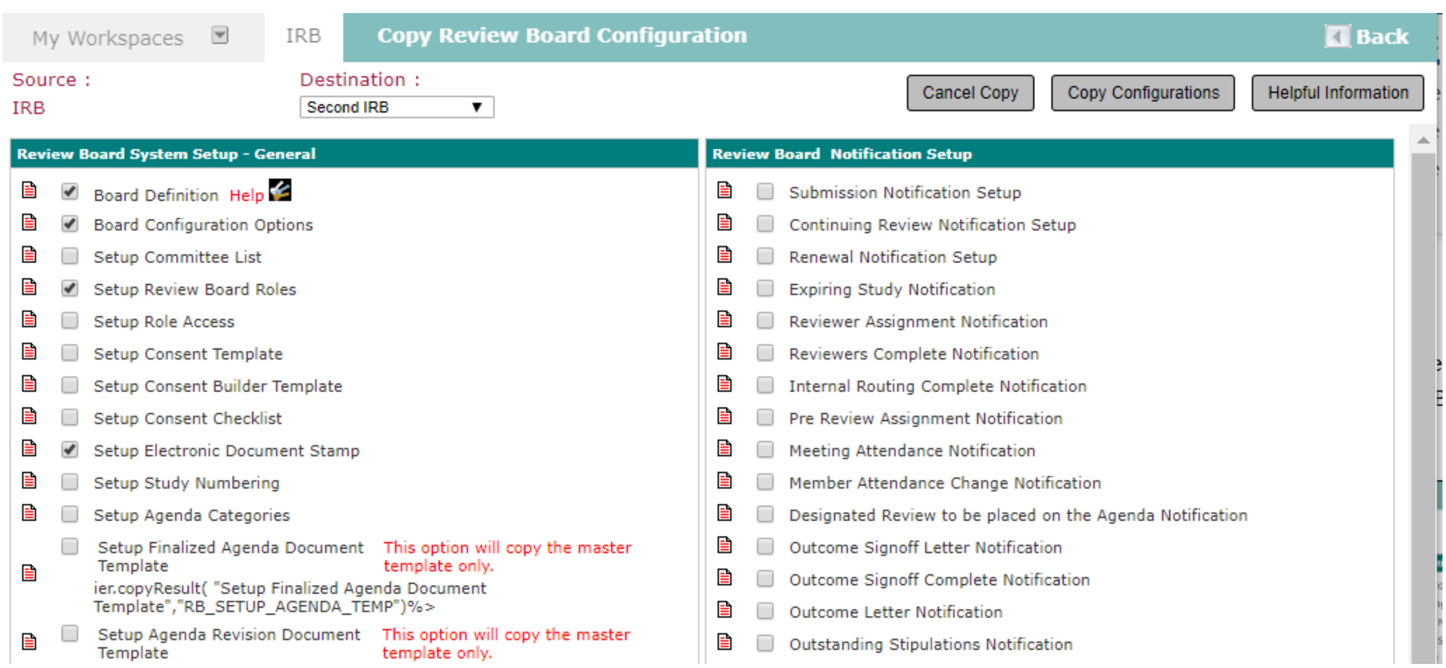
At the top of the page, the source is listed. This is the review board you are currently in. You will need to select a Destination review board. Only review boards of the same type will populate in the Destination drop-down list. When a destination is selected, checkboxes will populate next to each configuration option.



Note: certain configurations of the IRB cannot be copied:

- Setup Review Board Roles
- Setup Electronic Document Stamp
- Setup Correspondence Template
- Study Status Configuration List

Select the checkbox next to the configuration items that you would like to copy to the other review board. If you do not wish to proceed, click the **Cancel Copy** button to return to the Review Board Administration list. To proceed with the copy, click the **Copy Configurations** button.



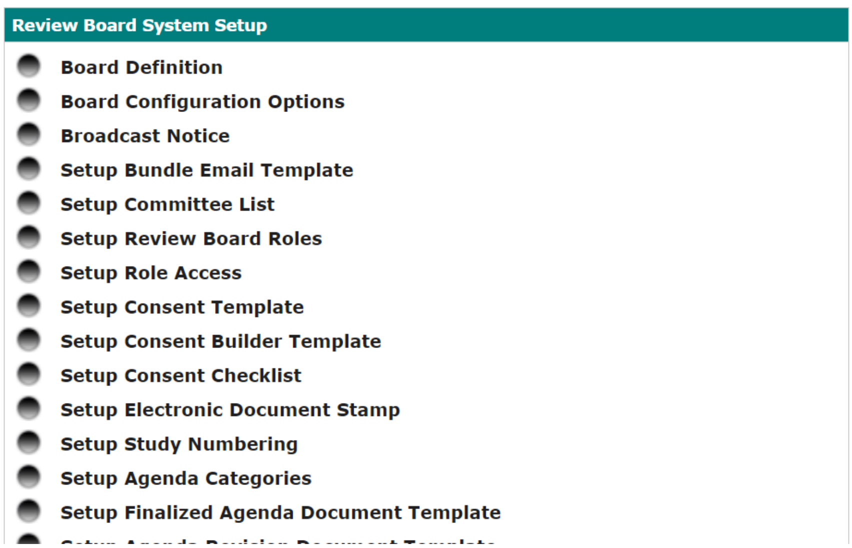
The screen will refresh and update. Any item successfully copied will turn green, and items that did not copy successfully will turn red. An item may not copy over if there is no data from the source review board or if that field is not turned on in the destination review board.

Note: When performing a copy from one board to another, if any field is populated in the destination board, it will be overwritten.

Good practice for successful copying is to have each item in the source review board completely configured and ready to copy so you only need to copy one time. iMedRIS recommends only performing the copy one time to the destination review board.

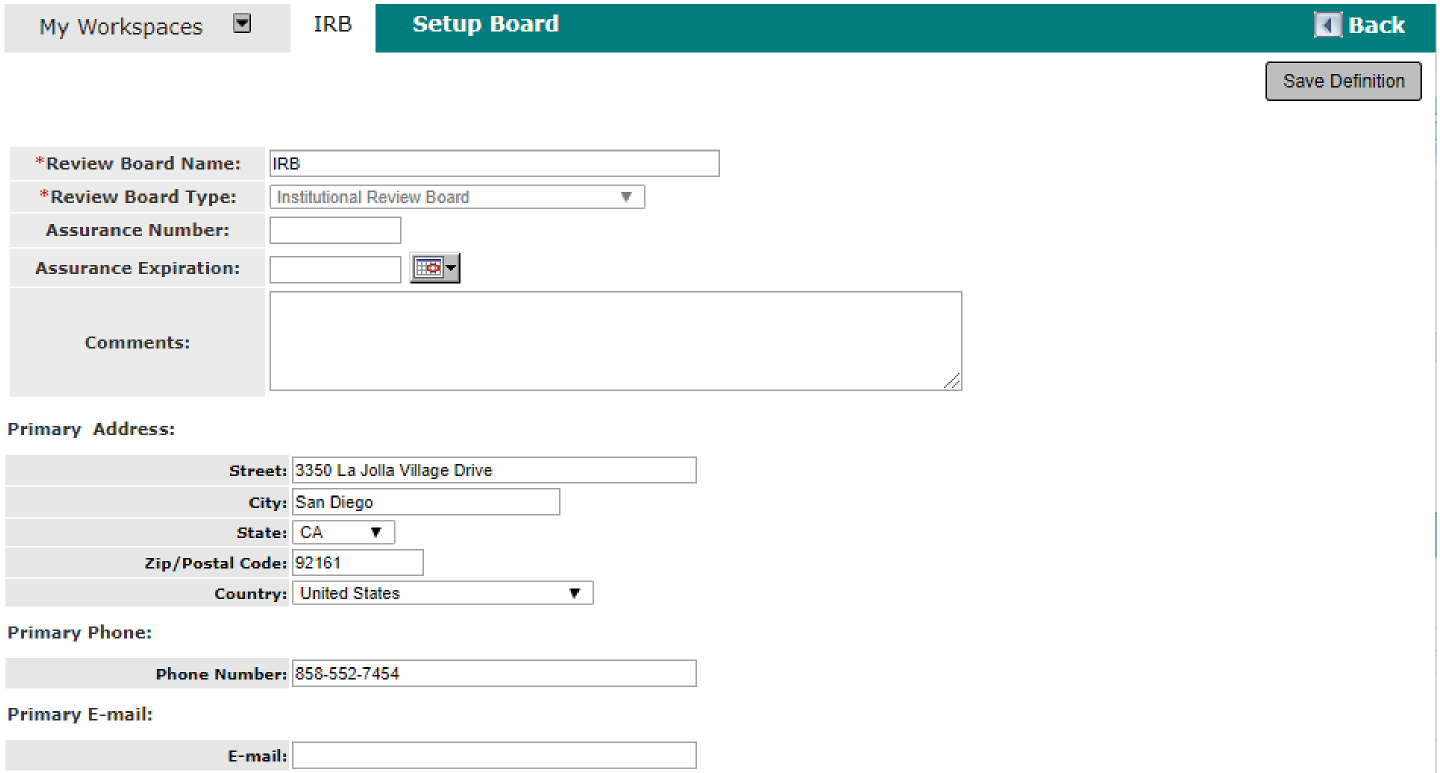
Board Definition

The first item in the Review Board System Setup list is the Board Definition.



This page allows you to specify details regarding the review board. There are two required information fields: Review Board Name and Review Board Type. The Review Board Type is a list of predefined board types as specified in your contract with iMedRIS Data Corporation. For more information on the different types of available review boards, please contact your iMedRIS project manager. This list will be grayed out on this page, as the review board type has already been defined.

You may update or add information regarding the board's Assurance Number and Assurance Expiration, Primary Address, Phone Number, and E-mail, and add any comments. Click the **Save Definition** button on the top right of the page to retain your changes.

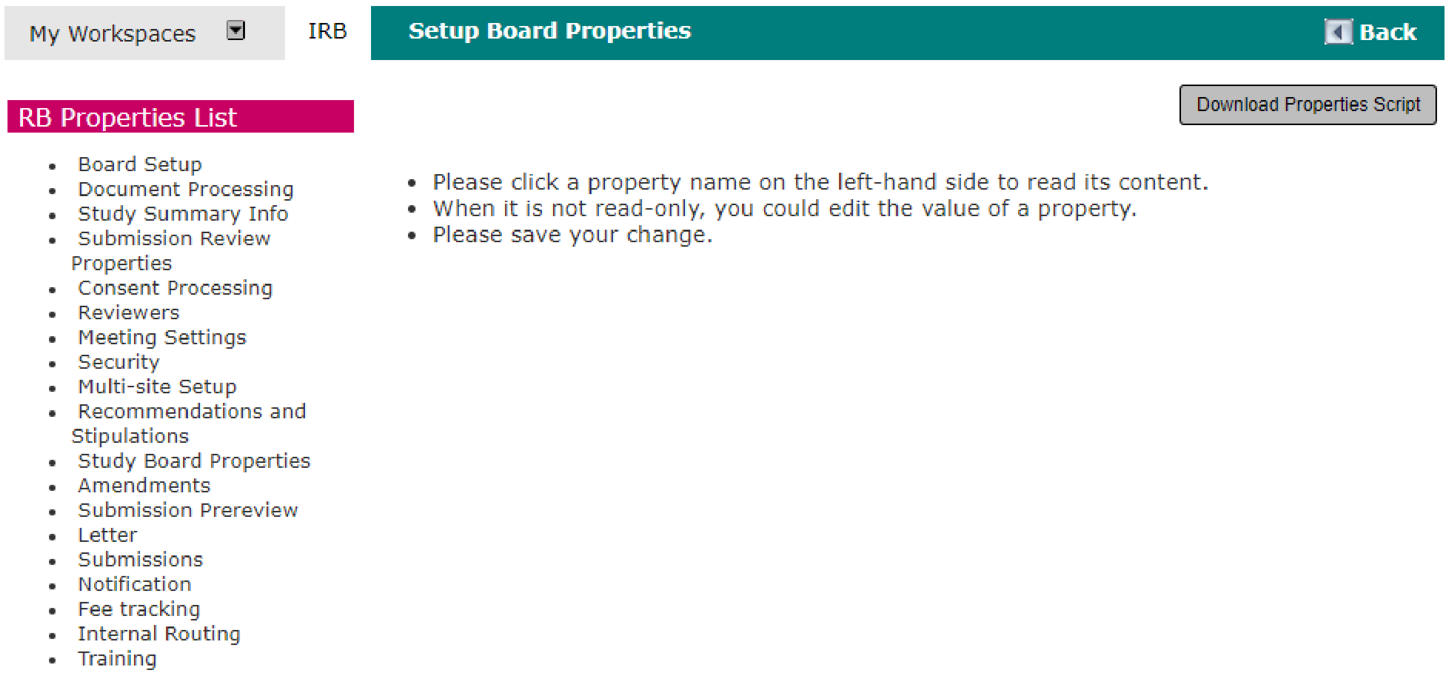


Board Configuration Options

This page lists the properties that you can configure within the review board. Before changing these properties, it is a good idea to have a working knowledge of your system and of any potential changes. It is also a good to verify changes with iMedRIS personnel before applying them to a live system.

The properties are divided into categories and these categories are displayed on the left panel of the screen. To view the properties in a category, click the category in the left panel, and all the properties related to that category will display. The “Yes” and “No” radio buttons indicate that the properties are on/off. Any other value indicates that the property is a variable.

Please see the IRB Assistant - Properties manual for specific information related to each property.



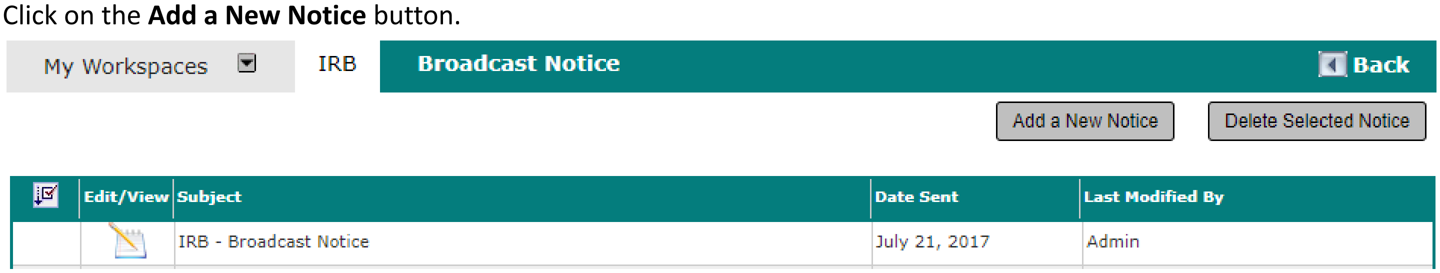
You can use the **Download Properties Script** button to download a .sql script containing the configurations for the review board properties, which can be used to import the configurations into another iRIS system.

Broadcast Notice

Broadcast Notice is a tool that will allow you to send an email to review board members and users associated to the review board (users on studies that are associated to the review board). Use this tool from within the review board to send out alerts and messages that pertain to this group of users. There is another Broadcast Notice that can be setup and sent from System Administration; however, this will send to all users in iRIS.

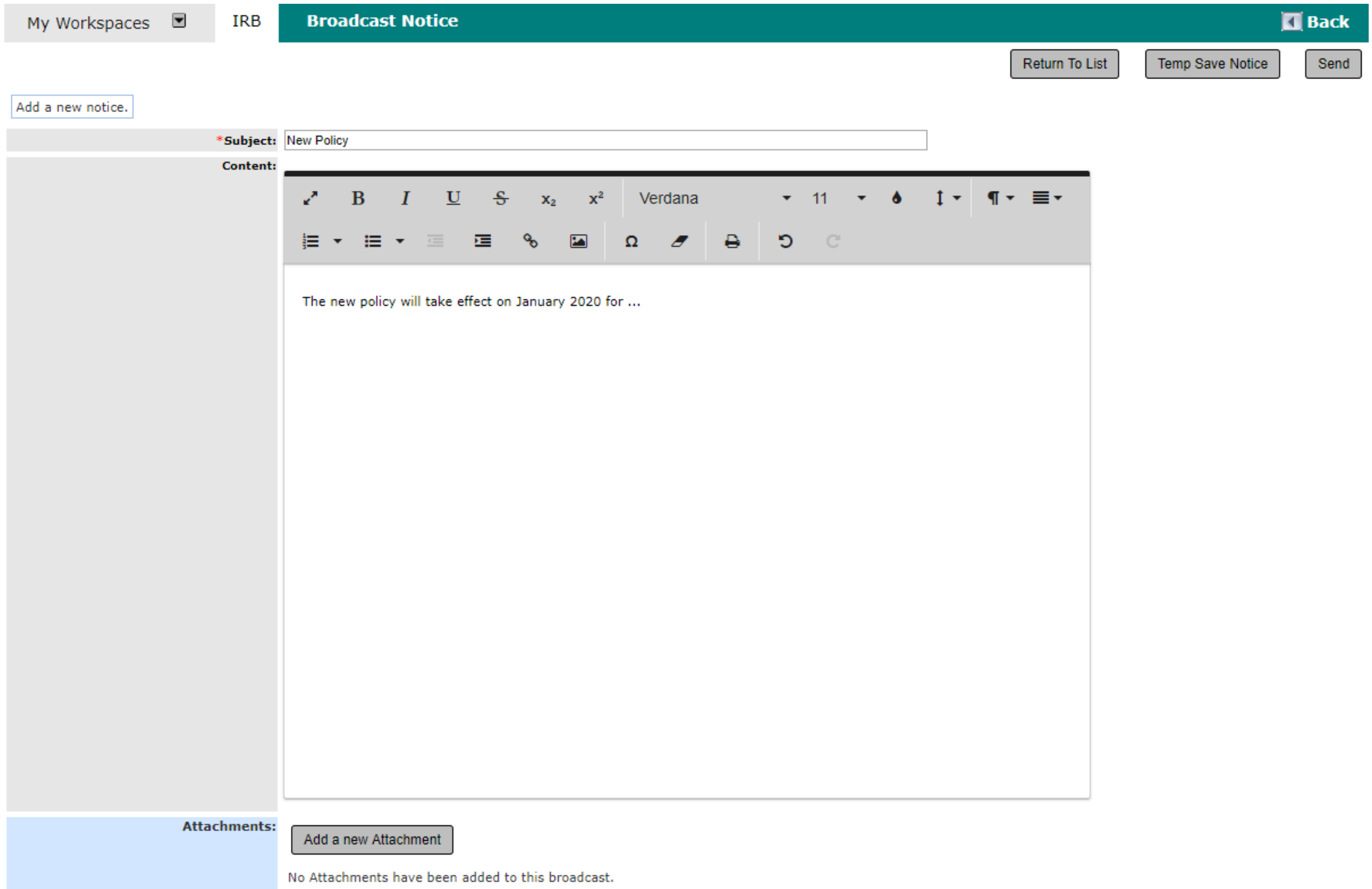
When you open the Broadcast Notice page, the system will display any broadcasts previously set up/sent out. The first time you open this page, the page will be empty.

Click on the **Add a New Notice** button.



A new page will open, allowing you to provide a Subject for the notice, enter the Content, and attach any documents, if necessary.

Click on the **Return to List** button to cancel and return to the list of broadcast notices.



If you have started the broadcast notice but are not ready to send it yet, you can save the notice without sending by clicking the **Temp Save Notice** button. Doing this will save the notice and return you to the list of broadcast notices. You can return to the notice by locating it in the list of notices and clicking on the  icon.

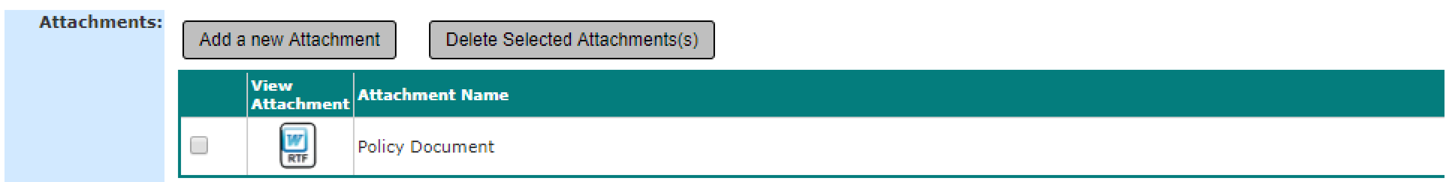
When creating your notice, only the Subject field is required. This allows you to temporarily save your notice without providing any detail in the Content section. You can type in the Content field or copy and paste.

If you need to attach a document to the notice, click on the **Add a new Attachment** button.

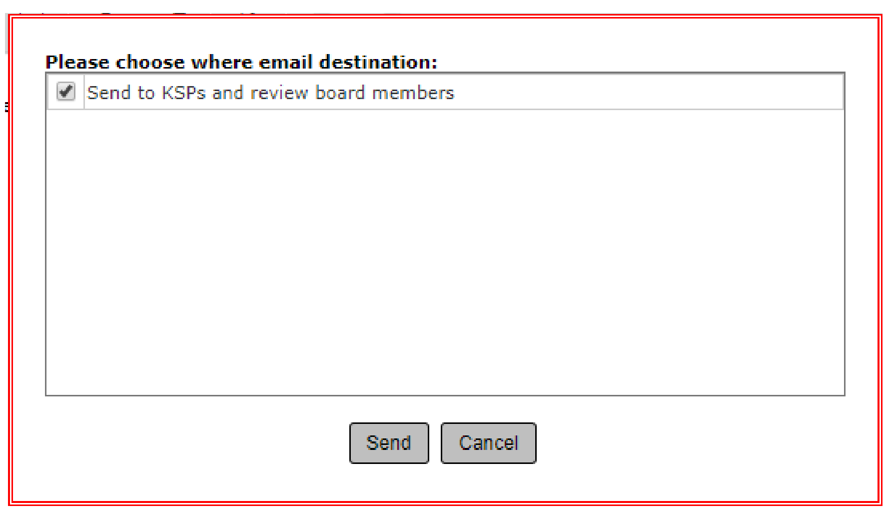
A new page will open. Enter the Title of the document and click the **Upload** button to search your computer for the document you wish to upload.

Once you upload a document, the page will refresh and display an icon to the left of the Title. Click the **Save and Return** button to associate the document to the notice.

The associated document will display in a table in the Attachments area. You can add multiple attachments to the broadcast; however, your email server may have a restriction on the max file size for documents attached to outgoing emails. You may want to check with your email administrator on any limitations before sending large documents through the broadcast. You can remove an associated document by selecting the checkbox next to the document and then click the **Delete Selected Attachment(s)** button.

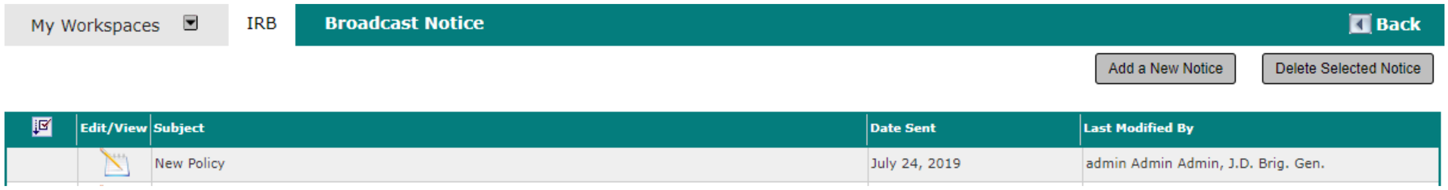


Once you have defined the Subject, entered Content, associated any necessary documents, and are ready to send the broadcast notice, click on the **Send** button. A small popup window will open, allowing you to choose the recipients of the broadcast notice. It will default to "Send to KSPs and review board members;" un-checking the box will give the option to send to all KSPs or review board members.



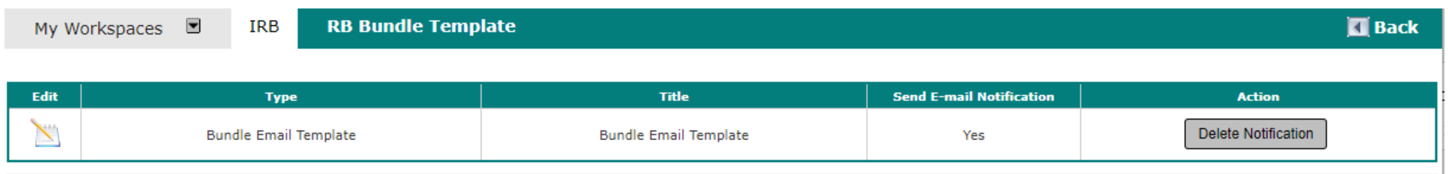
Make your selection and click **Send** or **Cancel** to close the window and return to editing the notice.

You will then be returned to the list of broadcast notices. Your broadcast notice will populate in the list. The Date Sent column will update with the date you sent the notice. You can view the notice to see the content, but you will not be able to edit or delete sent notices. You are only able to edit/delete notices that haven't been sent out.



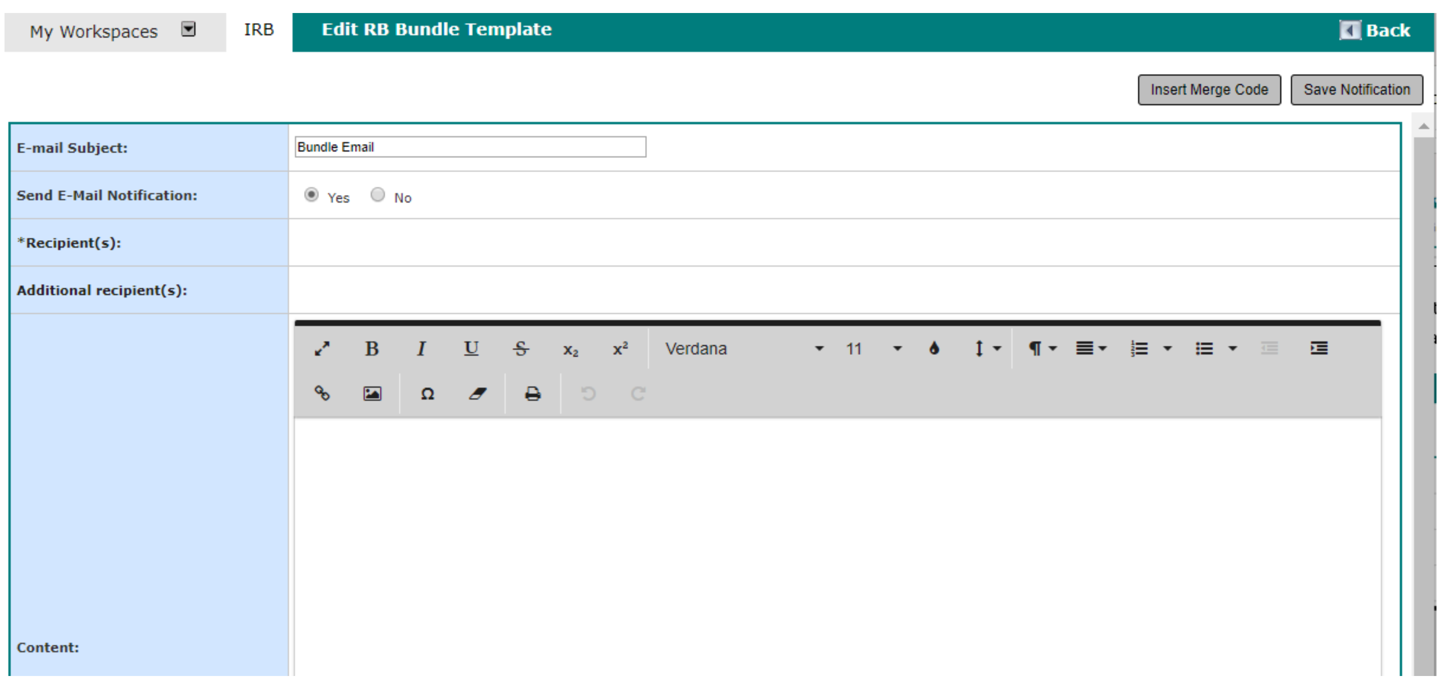
Setup Bundle Email Template

This option allows you to create an email template to be included with bundle emails sent from the Submission Complete tab of the submission processing screens. Clicking this link will open the RB Bundle Template screen, where you can click the icon to open and edit the template. You can click **Delete Notification** to delete the existing template.



If no template has been added, click **Add Notification**.

When editing the bundle email template, first, enter a subject in the E-mail Subject field. You can use the Send E-Mail Notification flag to determine whether an email will be sent along with the notification.



Click the **Recipient(s)** link to open a screen where you can search for users in your iRIS system to whom you can send the email or click **Additional recipient(s)** to add non-iRIS users and their email addresses. To delete a recipient, check the box next to their name and click **Delete**.

Enter email content in the Content field, and enter merge codes, if desired, by clicking the **Insert Merge Code** button.

Click **Save Notification** to save your changes.

Setup Committee List

Committee Setup lists the current committees for the review board. From the Committee Setup list page, you can add new committees and edit/delete existing committees.

Opening the Committee Setup page will display a list of the current committees in your review board. This is a list of the committees only; access to committees is defined in a user's account. Once a committee is set up, then you will be able to associate users to the committee through user access in the system.

If your review board is set up for Committee Submissions (property rb.use_submission_by_committee is set to Yes), the system will be setup to route submissions to individual committees and not the review board as a whole. The committees in this list are the committees that will be routed the submissions. When your review board is set up for Committee Submissions, members of one committee will not be able to access submissions that were not sent to their committee.

Most systems are not setup for Committee Submissions; rather, all submissions arrive in the review board's Submissions queue and, when processing a submission, it will be placed on the appropriate committee's meeting date. Each committee set up will have its own set of meeting dates.

Committees can be added, removed, and renamed from this area.

To add a new committee, click the **Add a Committee** button, enter the desired Order Number (order in which the committees are listed), committee name in the Description, and then click the **Save Committee** button.

To delete a committee, select the checkbox next to the committee name, and then click on the **Delete Selected Committee(s)** button.

To rename a committee, click on the icon next to the committee name.

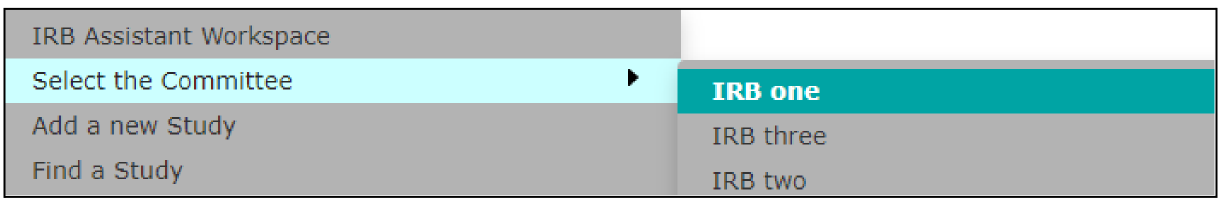
A new page will open. You can modify the name by changing the Description. Click the **Save Committee** button to save your changes.

The changes will display in the list of committees.

If your account has been assigned to more than one committee within the review board, you will be able to flip between the committees by selecting the appropriate committee from the Review Board Assistant menu.

Each committee will have its own unique information. Switching committees will show you details for that committee when you click on certain screens in the review board assistant menu – Meeting Agenda, Meeting Minutes, and Meeting Manager will all display information only for the committee you are currently in.

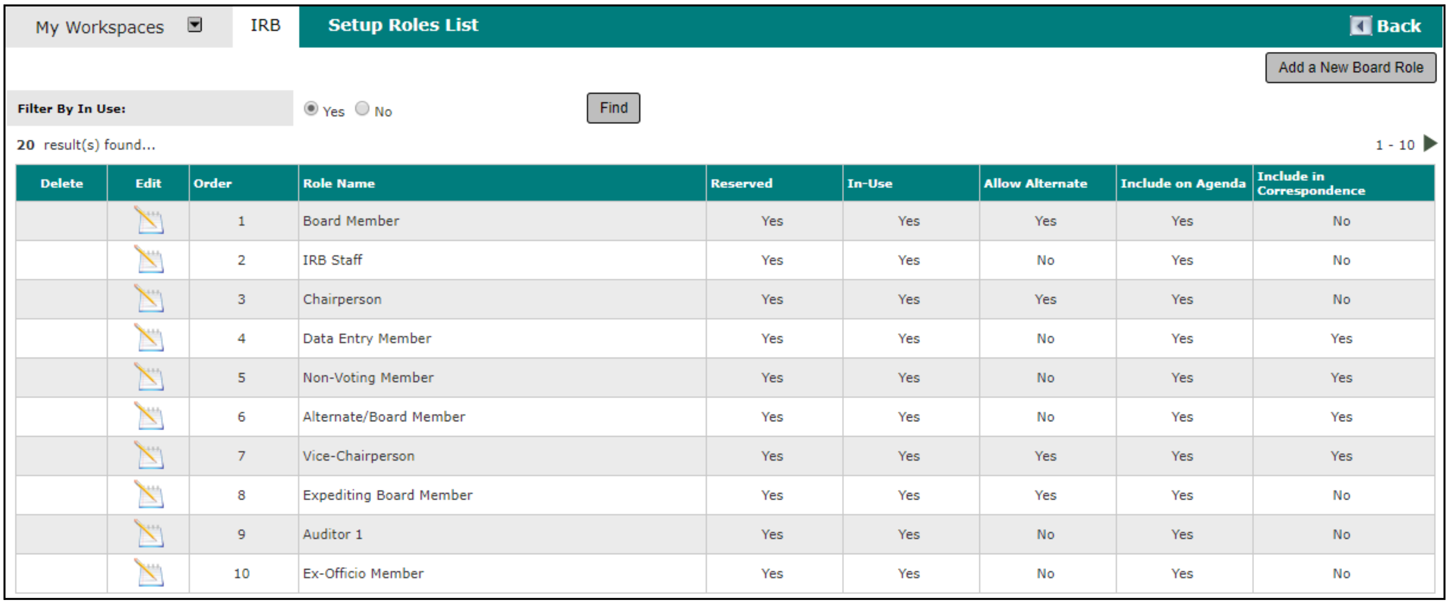
If your system is setup into Committee Submissions, the submissions queue will only contain forms sent to the committee you are currently in.



Setup Review Board Roles

Your review board will be preset with review board roles that you can associate to users within your review board. These roles are listed in Setup Review Board Roles. From here, you can rename certain roles or add new roles as needed. Each role you define in this list can then be setup in the Setup Role Access area to have access to only certain screens within the review board. This is covered in Setup Role Access in the following section.

Opening the page will list out all the current roles for your review board. These are iRIS predefined review board roles and you can rename these as needed (if you want to call a role something else) but you cannot delete the role. These predefined iRIS roles will say Yes in the Reserved column, and you will not see a icon next to the role name.



Delete	Edit	Order	Role Name	Reserved	In-Use	Allow Alternate	Include on Agenda	Include in Correspondence
		1	Board Member	Yes	Yes	Yes	Yes	No
		2	IRB Staff	Yes	Yes	No	Yes	No
		3	Chairperson	Yes	Yes	Yes	Yes	No
		4	Data Entry Member	Yes	Yes	No	Yes	Yes
		5	Non-Voting Member	Yes	Yes	No	Yes	Yes
		6	Alternate/Board Member	Yes	Yes	No	Yes	Yes
		7	Vice-Chairperson	Yes	Yes	Yes	Yes	Yes
		8	Expediting Board Member	Yes	Yes	Yes	Yes	No
		9	Auditor 1	Yes	Yes	No	Yes	No
		10	Ex-Officio Member	Yes	Yes	No	Yes	No

To change an existing role name or change the order in which it is displayed, click the icon.

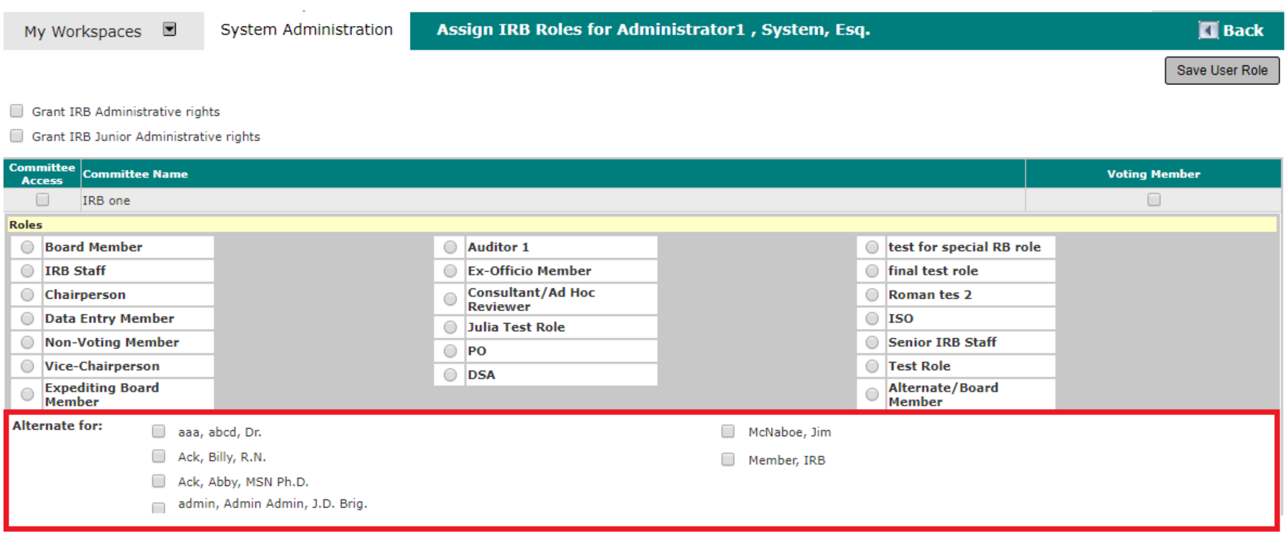
A new page will open. From here, you can change the Order Number and Role Name. You can also change the In Use and Allow Alternate for Meetings flags. When you are finished making changes, click the **Save** button. To return to the list of roles without making changes, click on the **Back to List** button.

To add a new role, click on the **Add a New Board Role** button.

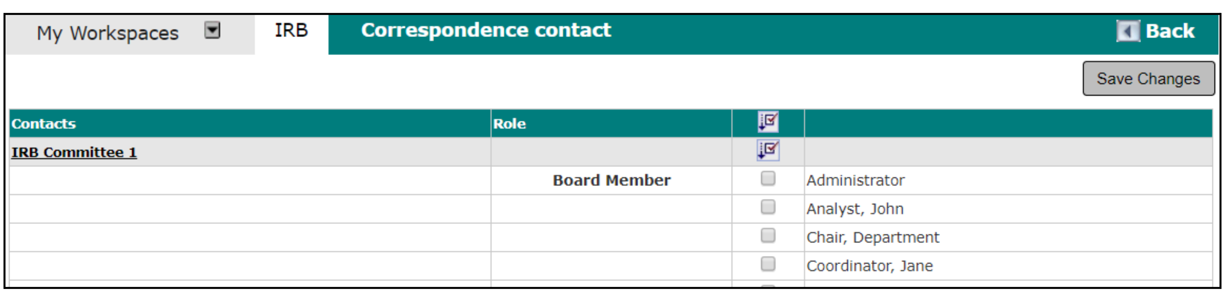
Enter the Order Number and Role Name.

In Use – You can specify whether a review board role is in use, telling the system whether to activate the role or not. If In Use is set to Yes, then you will be able to assign a user this role. If In Use is set to No, then you won't be able to assign a user this role. The reason for this functionality is to discourage deleting a role that has been used and is assigned to users. Rather than deleting the role, you can set In Use to No, which will preserve the history of this role and will remove the role from future use. If a role that has been used in the past is deleted, links and historical records associated to the role may not display properly.

Allow Alternate for Meetings – Set this flag to Yes to allow members assigned this role to be assigned an alternate at a meeting. Any user given the Alternate Member role or a role with this flag set to Yes will be included in the Alternate For list within Grant User Access & Define Roles as shown in the screenshot below.

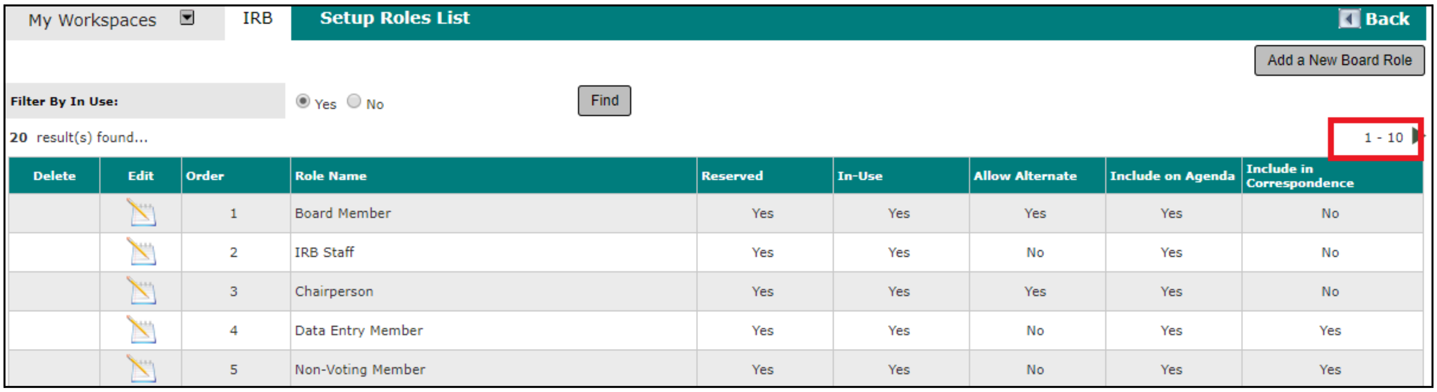


Include in Correspondence – Set this flag to yes will allow members to be included in the Correspondence Contact list. Users assigned to roles flagged to include in correspondence will appear in the Correspondence list when sending a study correspondence. If the role is flagged no, users associated to the role will not appear in the Correspondence List.



When you are finished adding the details for the new role, click on the **Save** button.

If there are more than ten roles in the list, you will need to use the page navigation to see the role you added. At the top right of the table is an arrow that you can click to view the next page.



My Workspaces | IRB | Setup Roles List | Back

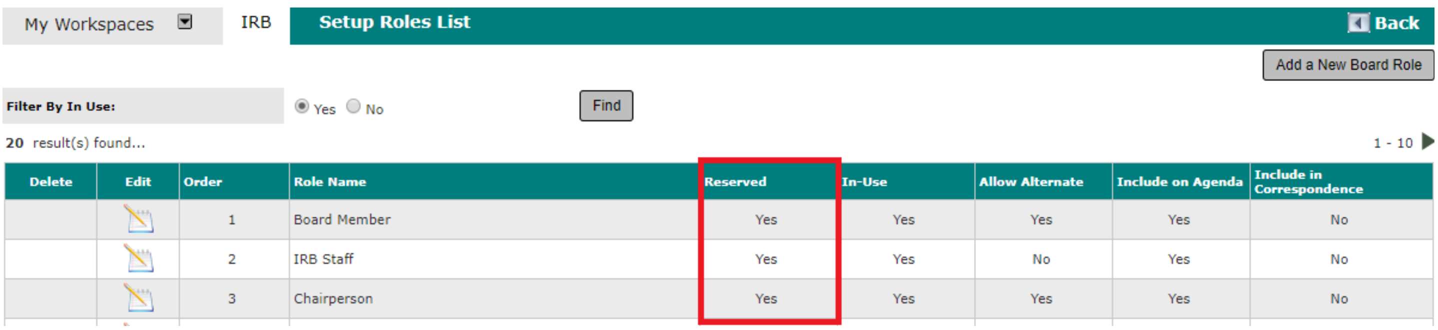
Add a New Board Role

Filter By In Use: Yes No Find

20 result(s) found... 1 - 10

Delete	Edit	Order	Role Name	Reserved	In-Use	Allow Alternate	Include on Agenda	Include in Correspondence
		1	Board Member	Yes	Yes	Yes	Yes	No
		2	IRB Staff	Yes	Yes	No	Yes	No
		3	Chairperson	Yes	Yes	Yes	Yes	No
		4	Data Entry Member	Yes	Yes	No	Yes	Yes
		5	Non-Voting Member	Yes	Yes	No	Yes	Yes

Any role added outside of the pre-existing roles will read “No” in the Reserved column.



My Workspaces | IRB | Setup Roles List | Back

Add a New Board Role

Filter By In Use: Yes No Find

20 result(s) found... 1 - 10

Delete	Edit	Order	Role Name	Reserved	In-Use	Allow Alternate	Include on Agenda	Include in Correspondence
		1	Board Member	Yes	Yes	Yes	Yes	No
		2	IRB Staff	Yes	Yes	No	Yes	No
		3	Chairperson	Yes	Yes	Yes	Yes	No

Setup Role Access

This feature gives you the ability to allow user(s), by role on the review board, read/write privileges within certain screens and forms. The Role Access matrix gives access to various screens within your review board assistant, study management, and forms that have been given IRB access in form designer.

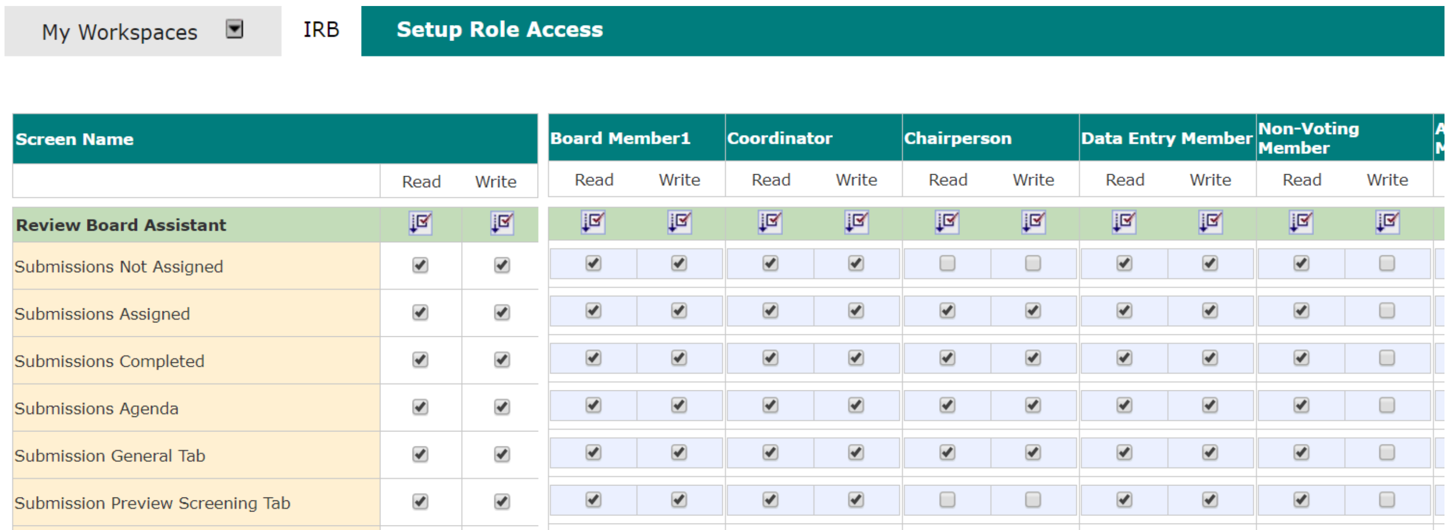
This page will list out available screens on the left side of the matrix. The top of the page displays a list of current review board roles. Within each role are checkboxes for Read and Write. Each of these cells represents access for that user to the screen name on the left.

If the Read and Write checkboxes are both selected, that means the user has been granted full access to that page in the system – to view the page and update records on the page.

If Read is selected, but Write is not selected, that means the user has been granted read-only access to that page in the system – to view the page but not modify records on the page.

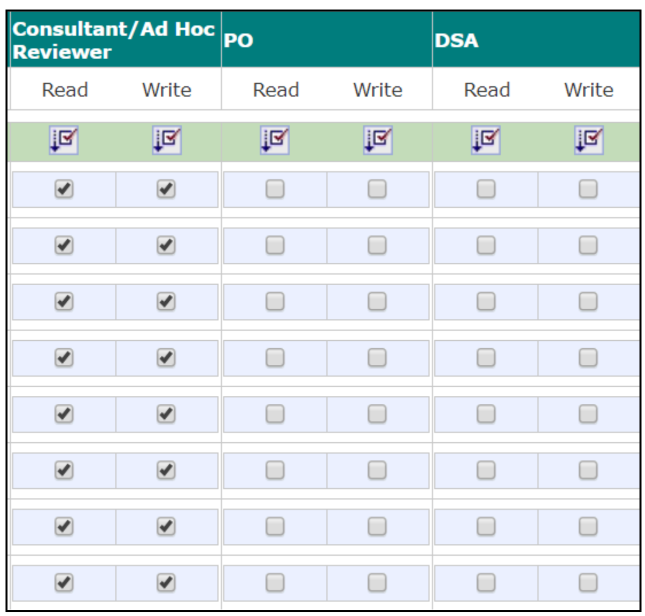
You cannot give a user Write access to a page without first giving them Read access.

The first set of Read and Write columns are to turn on/off a screen in general. If you remove Read and Write access at the top level, none of the roles on the review board will have access to that screen. This is recommended for use if you do not want to see a particular screen within your review board.



There are vertical and horizontal scroll bars at the bottom and right of the screen so you can navigate to the other roles and screens available on the page.

If you have set up a new role under Setup Review Board Roles, you will need to set up that role's access in the Role Matrix. Any new role added to Review Board Roles will populate in a column in the Role Matrix (at the end of the list of roles). iRIS will default all Read and Write cells to be unchecked for the new role.



After making any changes to this screen, be sure to click the **Save Changes** button to save your work.

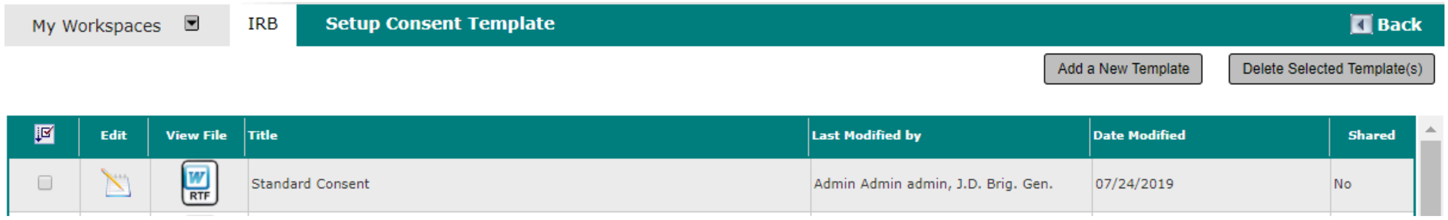
Setup Consent Template

Review Board Consent Templates give you the ability to upload consent templates or edit existing templates that researchers can download when building their informed consent document(s).

In the screenshot below, the existing templates are shown with an RTF icon, meaning that they are currently in rich text format and can be viewed in a word processor such as Microsoft Word.

11.02

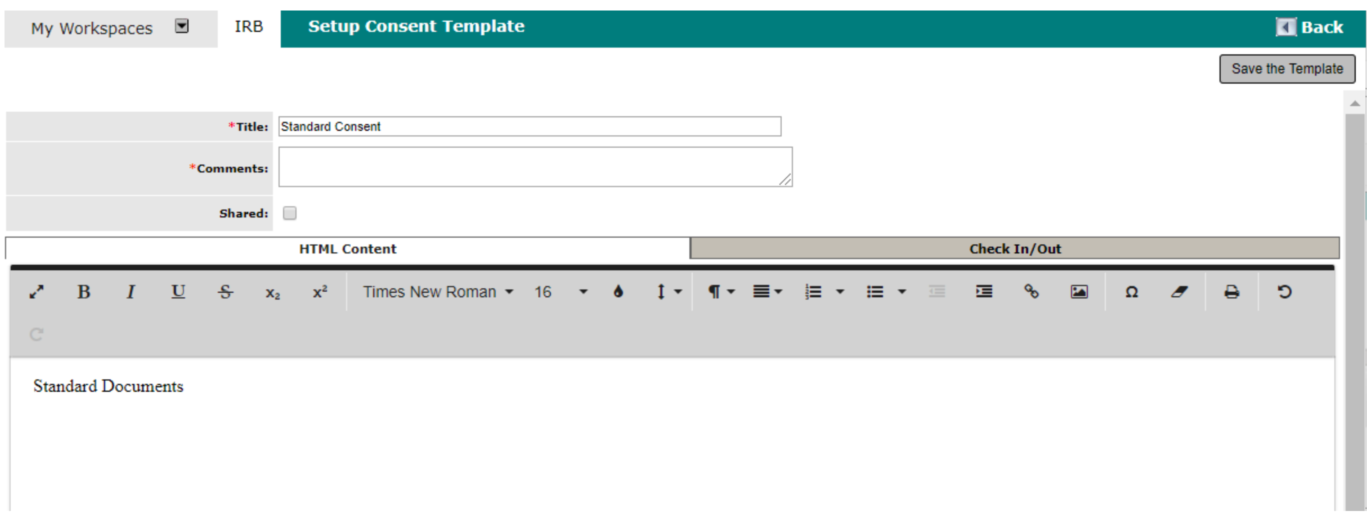
The list of documents shown in the screen shot below will be available when you add an Informed Consent to a study.



Click the **Add a New Template** button to add a new template. The text editor will appear again, but this time it is blank because a new template is being created.

Title – Enter the title of the consent template in the text box.

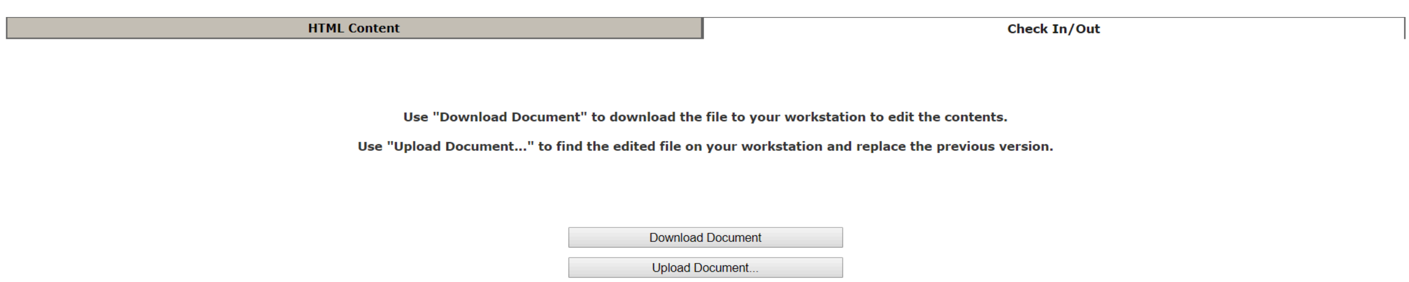
Comments – Enter any comments if necessary.



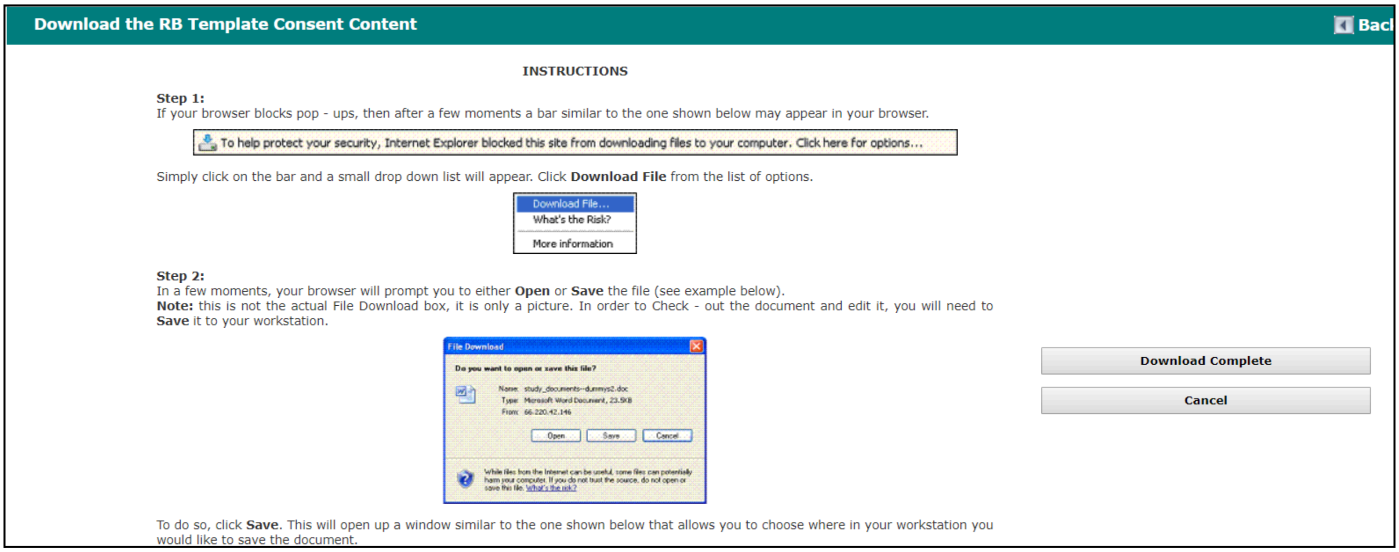
Shared – Check this box to share the consent template with other review boards that use consent documents.

Text Editor – Allows user to input content.

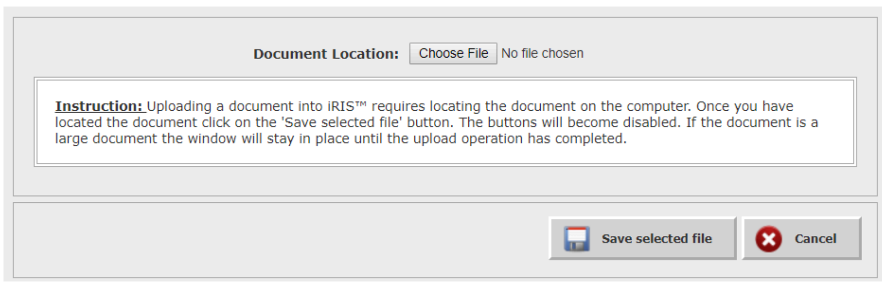
Check In/Out – Allows users to download the document to edit it off of the iRIS system and the re-upload it to the system.



After clicking **Download Document**, another screen will show with instructions to download the file, as seen below. Instructions are on the page, but users can choose to open only, save to their computer, or cancel the download.



To re-upload the document, click **Upload Document**, and then attach your file and then click **Save selected file.**



When you are finished creating the template, click the **Save the Template** button. To return to the list of consent templates without saving changes, click the **Back** button.

The new template appears in the list if you clicked the **Save the Template** button.

To delete one or more templates, check the box next to the appropriate consent template(s). There is an option to select or deselect all by clicking the icon. Then, click the **Delete Selected Template(s)** button. A dialog box opens confirming the delete. Click the **OK** button to continue and delete the selected consent template(s). Click the **Cancel** button to keep the consent templates. If you click the **OK** button, the selected consent template(s) will be deleted from the system and will no longer appear in the list of consent templates.

View File – Allows user to view the file.

Title – Displays the title of the consent.

Last Modified By – Displays the user who last changed the consent template.

Date Modified – Displays the date when the consent template was edited or created.

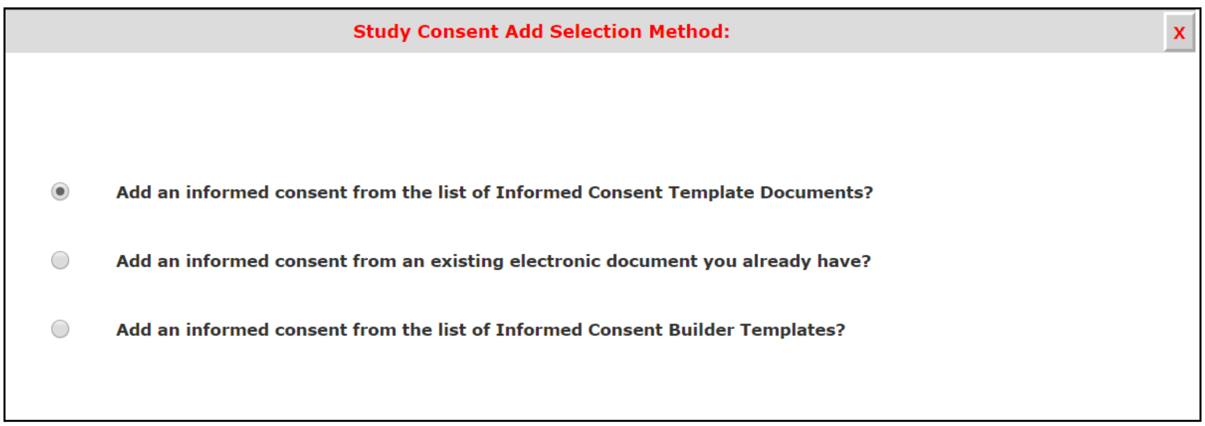
Shared – Displays whether the consent form has been shared (option is available when editing forms)

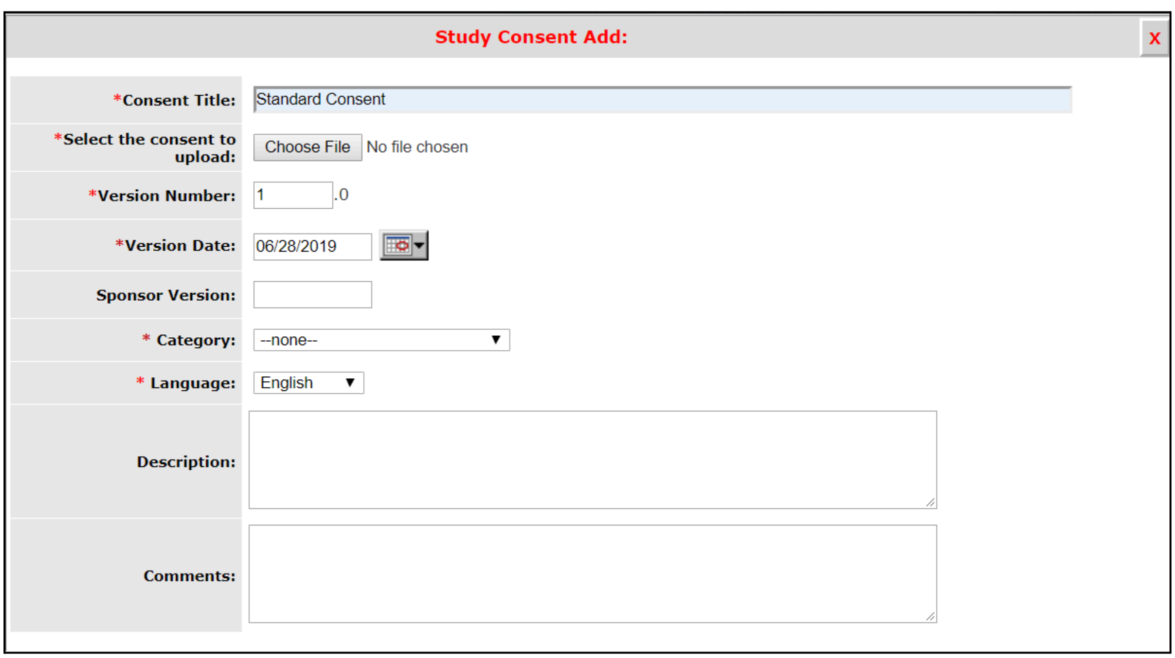
To edit a consent template in the list, click the icon.

When you open a template for editing, a rich text editor will open containing the text for the consent. Edit any of the text using the features provided in the text editor. You may also edit the title of the consent or the comments.

Text between brackets can be used to mark places in the template where the user needs to fill in required information. Other types of formatting can be used to denote the areas that require user attention on the consent form, such as bolding, underlining, or even changing the colors of the text they must replace. After making the necessary changes to the template, click the **Save the Template** button. To exit the editor without saving, click the **Back** button.

The screenshot below shows where the informed consent templates can be chosen. This screen is accessible when a new consent form is added, and user chooses to add from the list of Informed Consent Templates. Note that the consent template added in the example above is shown in the list of available templates.



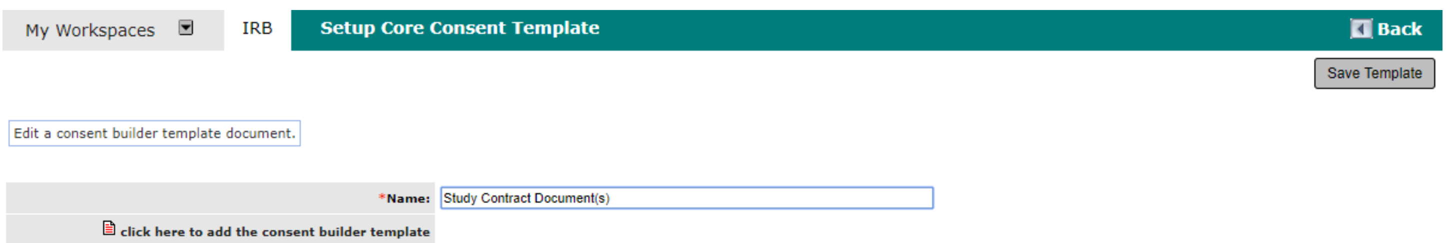


11.02
Setup Consent Builder Template

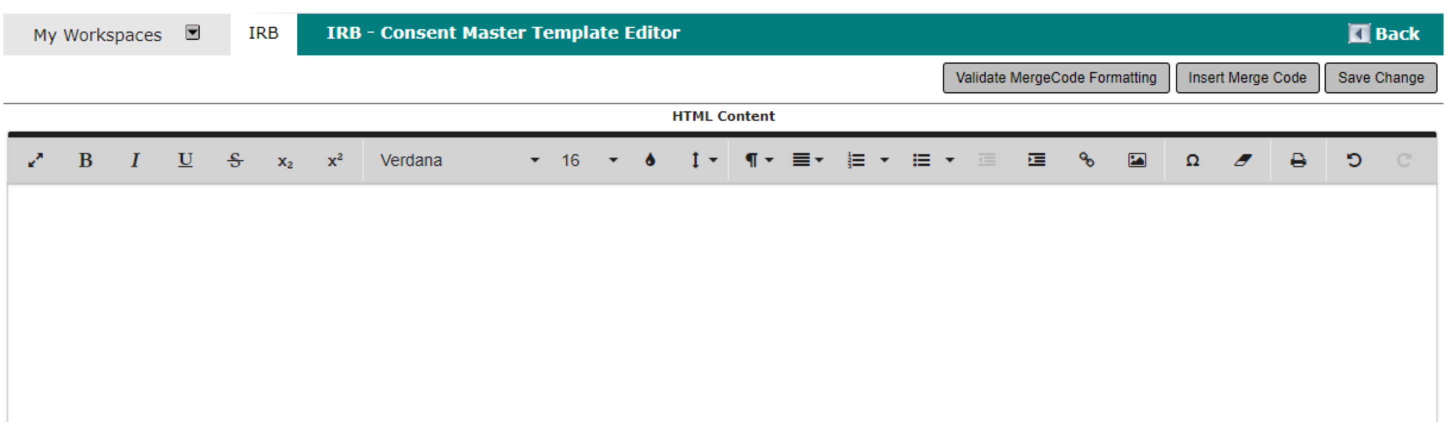
A Consent Builder Template is a document that has been specifically designed to step you through the process of customizing your consent form. When you click the Setup Consent Builder Template link, you will be brought to the list of master consent builder templates.

Click the icon to edit an existing template or click **Add a New Template Master** to create a new template.

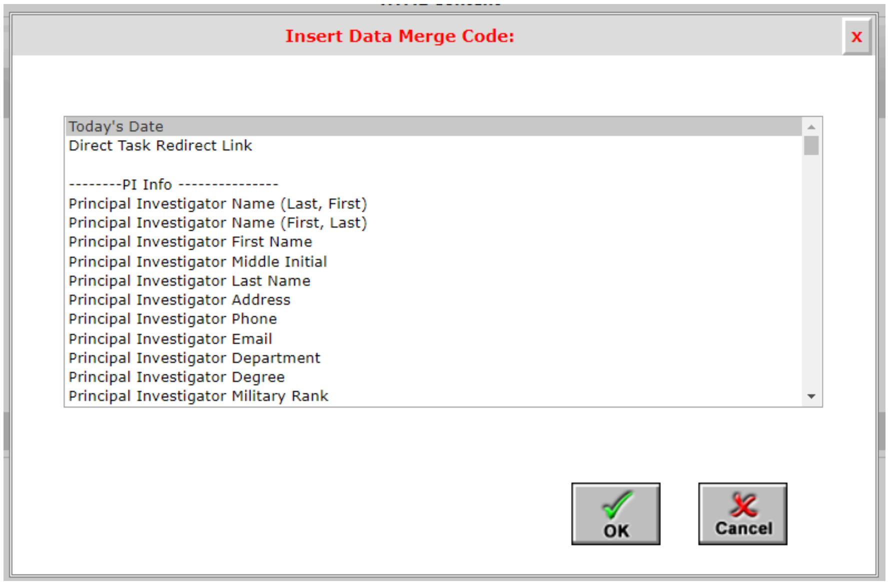
When creating a new template, enter a Name, and click the **Click here to add the consent builder template** link to proceed.



This will bring you to the Consent Master Template Editor screen, a rich text editor that you can use to design your template.



You can use merge codes in your template to bring in study-specific information to your document. A merge code is a programmed label that will pull information into the document when the document is generated. Click **Insert Merge Code** to view the list of available codes.

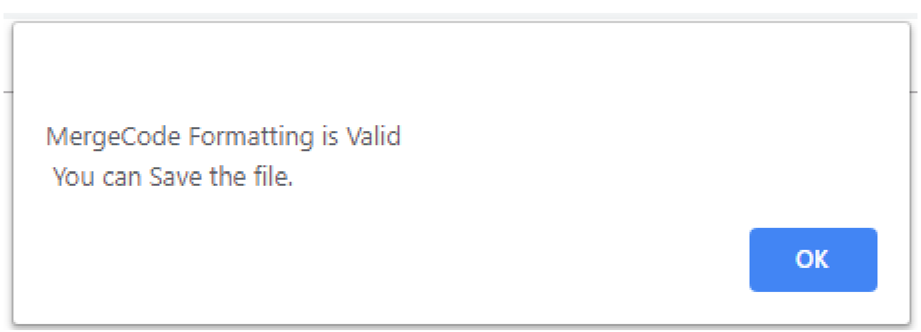


To insert a merge code, highlight it in the list and click **OK**. If, for example, you selected the merge code “Study Title,” it will appear in your current document as “[%study_title%].” However, when the actual document is generated, the real study title will appear.

Validate MergeCode Formatting

Validate MergeCode Formatting is a functionality that allows you to test whether the merge codes in your template contain invalid RTF content that will prevent them from populating correctly in your documents. For example, if the text in part of a merge code, but not the entire merge code, is bolded, this is the type of error that Validate Merge Code Formatting will correct.

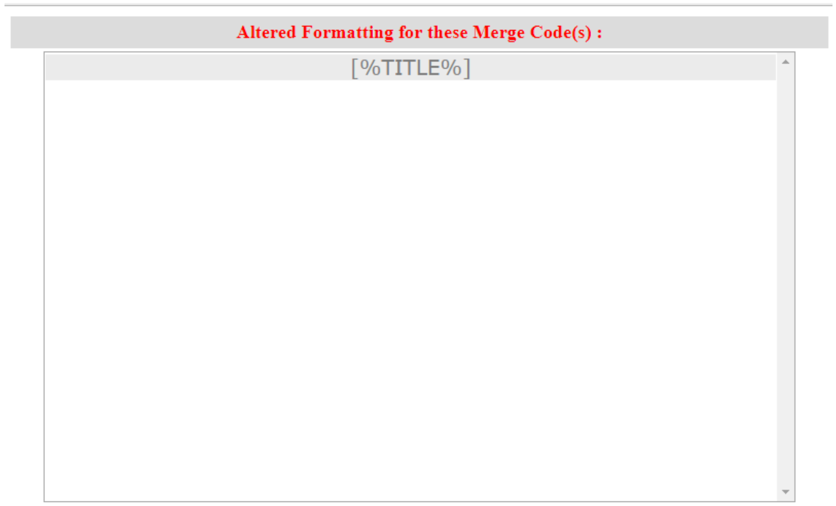
When you click Validate MergeCode Formatting, one of three things will occur. If all of the merge code formatting in your template is valid, you will see the following message:



If any of your merge codes contain invalid content, as seen below, you will get a popup message displaying the merge codes that the system was able to correct for you.

Study Title : [%**TITLE**%]

In the example given, you can see that part of one merge code is bolded. When you click Validate MergeCode Formatting, you will see the following popup:



When you look at the document again, the merge codes are corrected. If you need to, you can click the **Undo Changes** button to revert to the previous version of the merge codes.

If there is an incorrect merge code that cannot be validated, the system will return an error message. For example, if ”[%” or “%]” is entered in the template with no other associated merge code content, you will receive the following error:

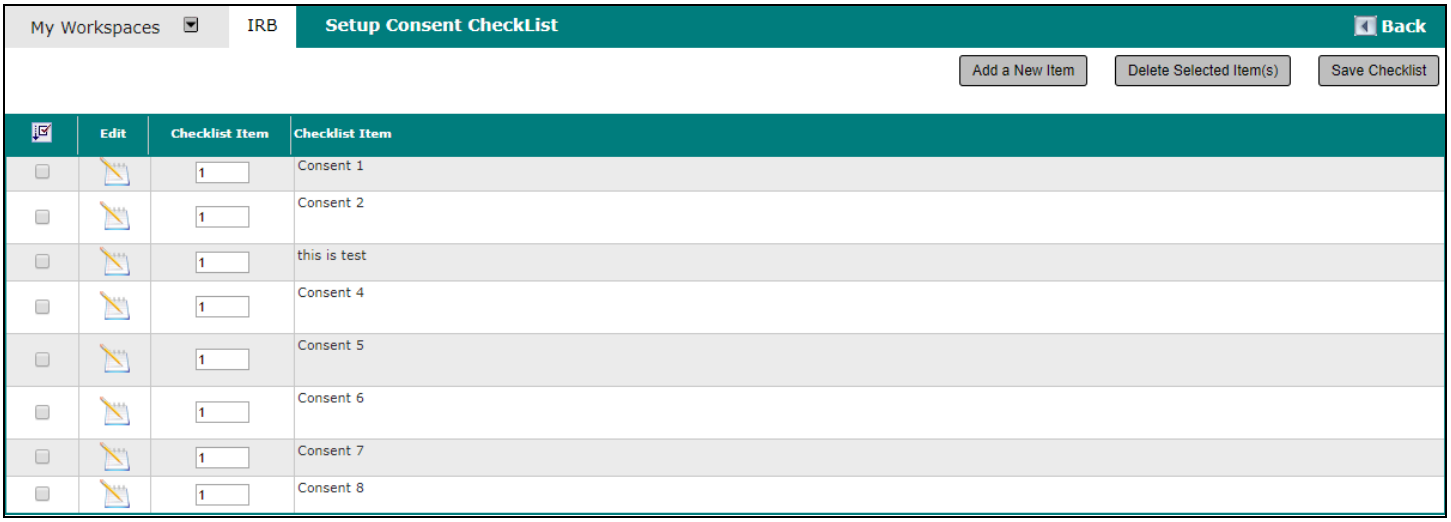
There was error while clearing merge code formatting. Please manually clear formatting of each merge code. 1. Select a merge code. 2. Go to 'Home' > 'Styles' > Click 'More' > Click 'Clear Formatting'.

You can go in and remove any incorrect merge code data as described above or follow the instructions in the error message to manually clear merge code formatting.

When you have finished editing the template, click **Save Change**, or click **Back** to return to the main setup screen without changes. On the Consent Template Master Setup screen, click **Save Template** to finish completing your template and return to the main list of templates.

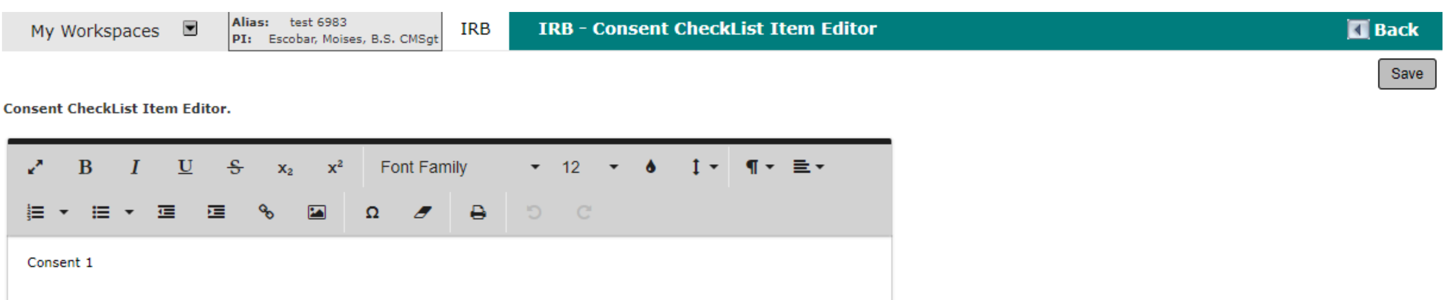
Setup Consent Checklist

The consent checklist configuration setup allows you to create a consent checklist that the review board can use when evaluating consent forms. In addition to being able to create new consent checklist items, you can order, edit, and delete existing checklist items.

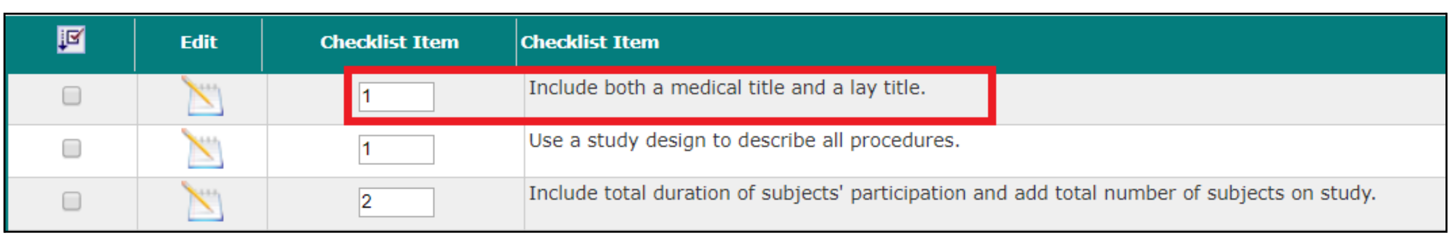


To add a new checklist item, click the **Add a New Item** button.

After a text editor appears, type in content, and then click the **OK** button.

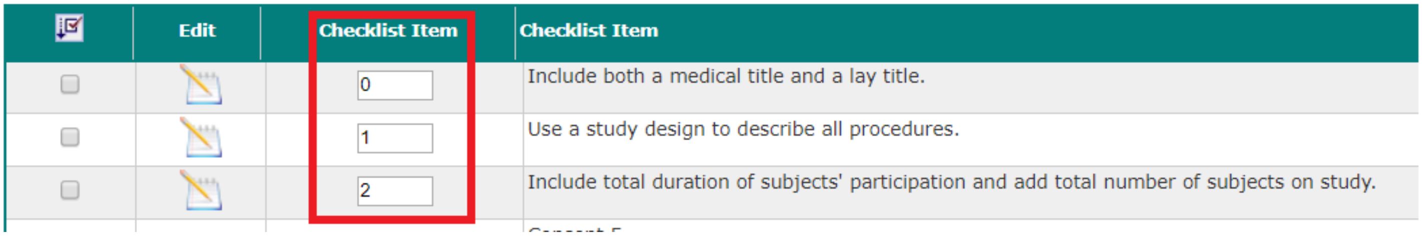


The new item is displayed in the list of checklist items. It will be given a default Checklist Item number of 1, so it will appear at the top of the document. (If an item is already at number 1, the new item will appear under the old item, still with the same item number). You can reorder the checklist items as needed.



To delete an item, check the box to the left of the item to be deleted. There is an option to select or deselect all by clicking the icon. Click the **Delete Selected Item(s)** button. When a Confirm dialog box appears, click the **OK** button to complete the deletion. The item will be removed from the list. To edit an item, click the icon next to the item to be edited. A text editor containing the text of the checklist item will appear. Make the necessary changes to the item, and then click the **OK** button. The item will be saved with the changes made on the main page.

To change the checklist item order, change the current number appearing in the Checklist Item text box. Type in the desired number, click the **Save Checklist** button, and the item will move to the order specified.

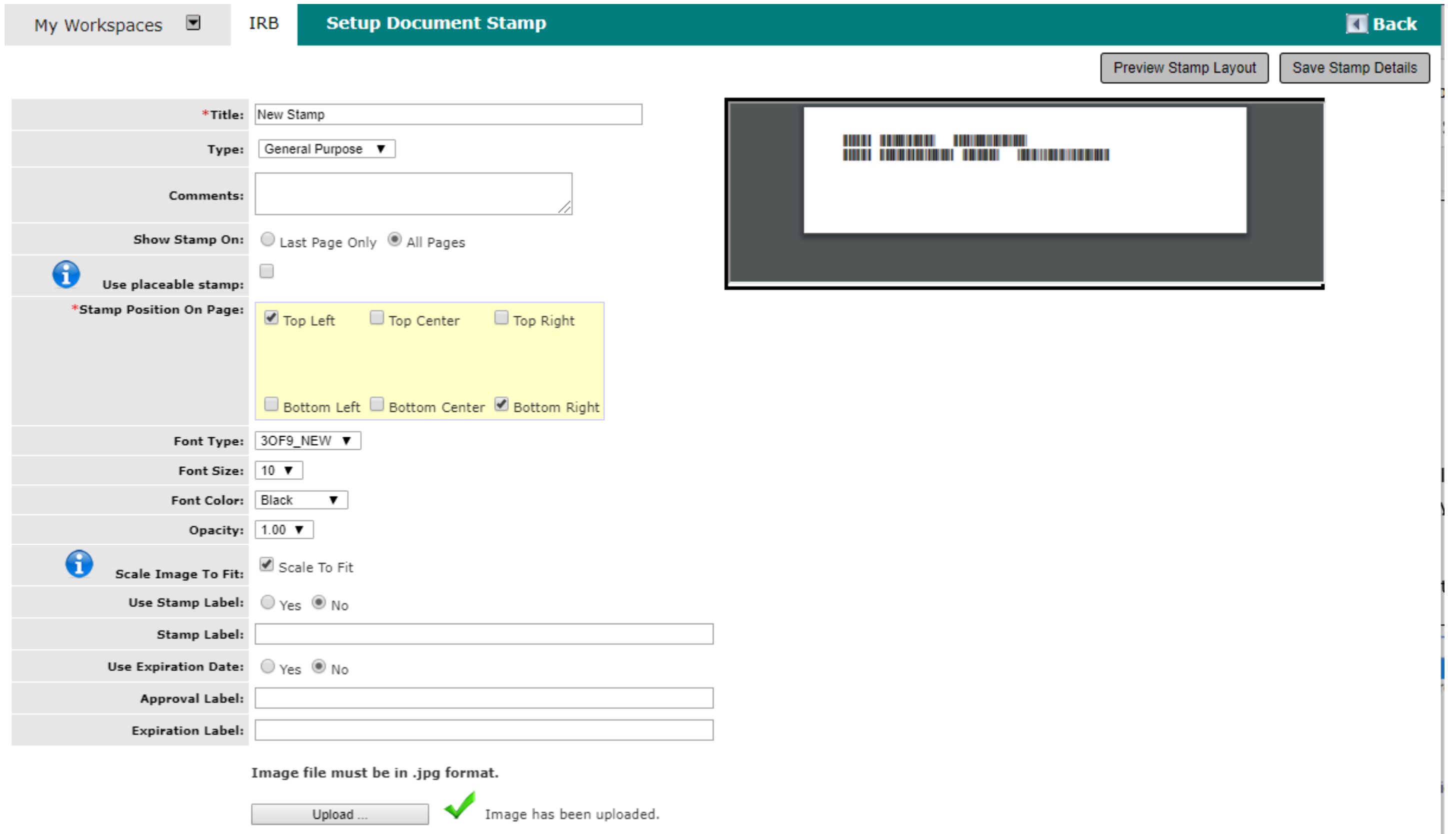


Setup Electronic Document Stamp

The Document Stamp Setup page is used to set up document stamp details. The document stamp is used on Study Documents and Consent Forms that require approval from the IRB.

To add a new stamp, click the **Add a New Stamp** button.

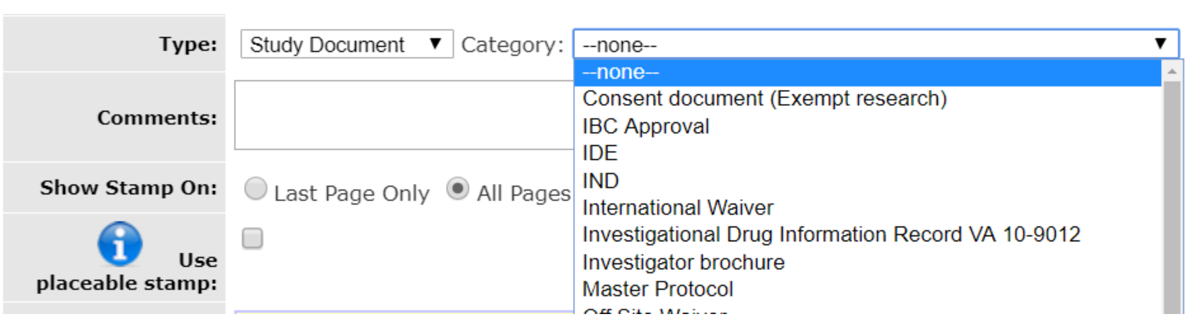
The following screen will display:



Title – Indicate the Title of the stamp by filling out this text box.

Type – Choose the type of stamp. Types available are General Purpose (used for all documents, consents and other study documents alike), Informed Consent (used only on consent forms), and Study Document (used only for other study documents).

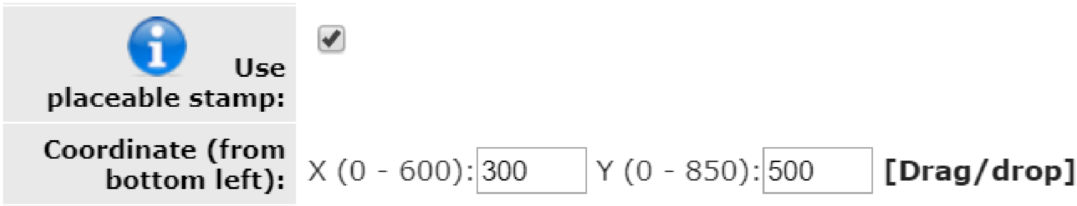
Category – When the Study Document Type is selected, the user will need to select a category.



Comments – Add any necessary comments in the Comments text area.

Show Stamp On – You can specify if the stamp should appear on all pages or the last page only.

Use Placeable Stamp – Checking this box will allow you to place the stamp on the document using exact coordinates.



Stamp Position On Page – If you do not wish to enter coordinates, you can select from Top Left, Top Center, Top Right, Bottom Left, Bottom Center, or Bottom Right.

Font Type – You can change the font type of the words appearing in the stamp. The preview at the top right will adjust to the selected font.

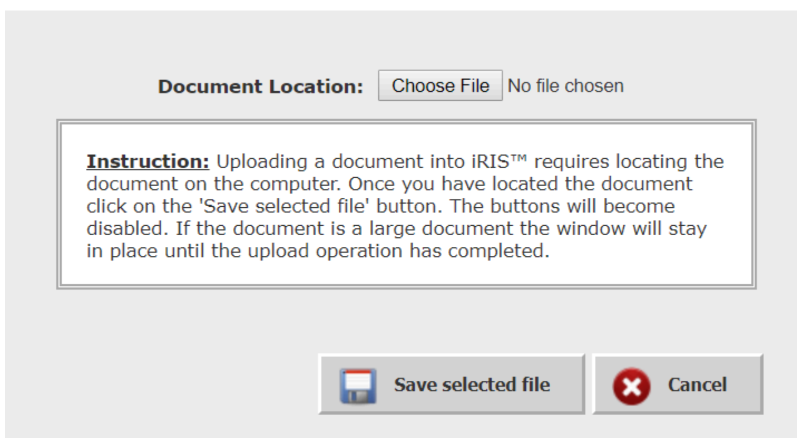
Font Size – You can change the font size of the words appearing in the stamp. The preview at the top right will adjust to the selected font size.

Font Color – You can change the font color of the words appearing in the stamp. The preview at the top right will adjust to the selected font color.

Opacity – You can change the opacity of the stamp. The preview at the top right will adjust to the selected opacity.

Scale Image to Fit – Checking this box is highly recommended when an image is included in the stamp. This checkbox will scale any uploaded images to fit the small size of the stamp.

Upload – Click the **Upload** button to browse your computer for the .jpg image that will be used with the stamp.



After clicking the **Upload** button, a dialog box displays. If the location of the image is known, type it into the **Document** Location text box. Or, click the **Browse** button to search for the image. When finished locating the image, click the **OK** button to upload the image, or click the **Cancel** button to cancel out of uploading an image.

When you are finished entering the details of the document stamp and uploading an image, click the **Save Stamp Details** button to save all changes made.

Preview Stamp Layout – After entering your desired options, you can click this button to open a new window containing a preview of how the stamp will look in a document. It is highly recommended that you do this, because some fonts might be too big and cut off part of the text.

After saving your stamp and returning to the main list of stamps, you can edit or delete existing stamps. To delete existing stamps, check the boxes next to the desired stamps. There is an option to select or deselect all by clicking the icon. Click the **Delete Stamp(s)** button.

	Edit	Title	Type	Document Category
☐		Declined - further information needed	Study Document	Safety SOP
☐		Approved	General Purpose	N/A

To edit an existing stamp, click the icon next to the stamp.

Setup Study Numbering

This feature is used to set up automated IRB numbers. This is where you will configure the auto-generated IRB number sequencing.

My Workspaces | IRB | **Setup Board Auto Generated Numbering** | Back

Save Numbering

Use Sequence for IRB Number: (•) Yes ( ) No

Use in Number	Description of Number Part	Number Part Information	Separator
☑	Constant Prefix	IRB	-
☐	School Code		-
☑	Calendar Year	( ) All 4 digits (•) Last 2 digits	-
☑	System Generated Number	5472 ☑ Zero Pad the Sequence Number Number of Digits 3	
☑	Multi-Site suffix Generated Number	☑ Zero Pad the Sequence Number Number of Digits 1	

To use this feature, select Yes to **Use Sequence for IRB Number.**

To set up variables in automated IRB numbers, check the box in the Use in Number column to indicate use in the IRB number. In this case, Constant Prefix, School Code, Calendar Year, and System Generated Number are being used to create the IRB number. These are listed in the second column, Description of Number Part. The next column, Number Part Information, is where data values are given to the auto-generated number. The last column, Separator, specifies which separator to use between the chosen number parts. Note: Multi-Site suffix Generated Number variable will only affect multi-site studies and will add a suffix to the end.

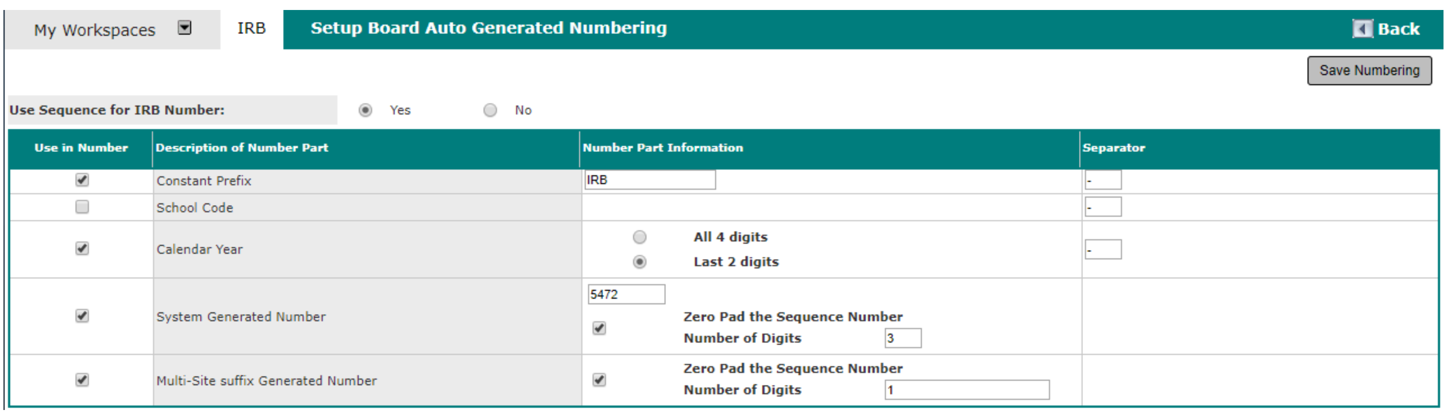
The Constant Prefix will begin all IRB numbers with the prefix specified under Number Part Information. It will be followed by a separator (-), as indicated in the Separator column. A School Code can also be used. This code is added when setting up the department list under System Administration. The school code will be pulled from the primary department listed on the study. The Calendar Year will use the year, displaying either all four digits, or only the last two, depending on which is selected. The last row indicates that a System Generated Number will be used. The first text box is used to specify where the number should begin. The selected number will increase each time a new IRB number is created. The Number of Digits specified indicates how many digits will be used. In this case, the auto generated number will start at GH-2016-019 and increase one digit each time it is assigned to a study, e.g. GH-2016-020, GH-2016-021, GH-2016-022, and so on.

Setup Agenda Categories

You can create agenda categories to use in the Finalized Agenda and Agenda Revision templates. These categories will be created using unique merge codes that identify each category. You will be able to associate submission types to each category. This allows you to create agendas for each type in either the Finalized Agenda Document Template section or the Agenda Revision Document Template section (see screenshot below).

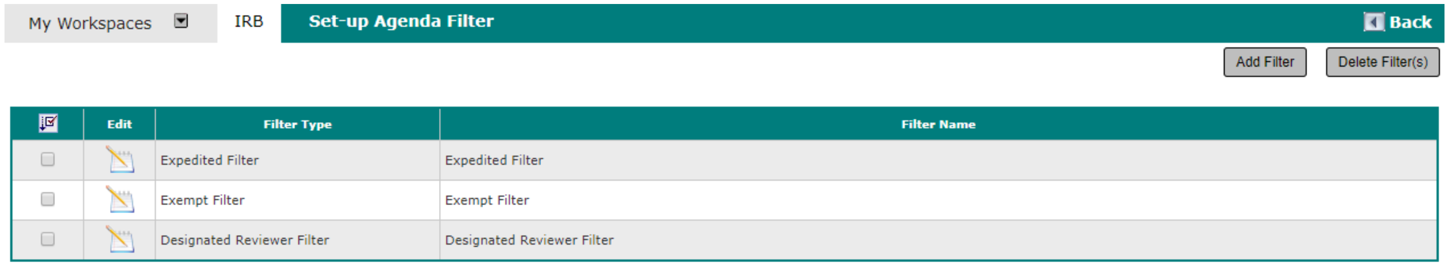
This is where you define the categories that will be included in the agendas (finalized and revision) and in the meeting minutes templates. The categories are for the different types of submissions that will be made to the review board and come up on a meeting's agenda. After you create a category, you can go into **Setup Finalized Agenda Document Template**, **Setup Agenda Revision Document Template** or **Setup Meeting Minutes Template** to create the template for this category. For more information on creating these templates, refer to further sections of the manual.

This section is only available if rb.use_meetings is set to Yes (See the Board Configuration Options section of this document).



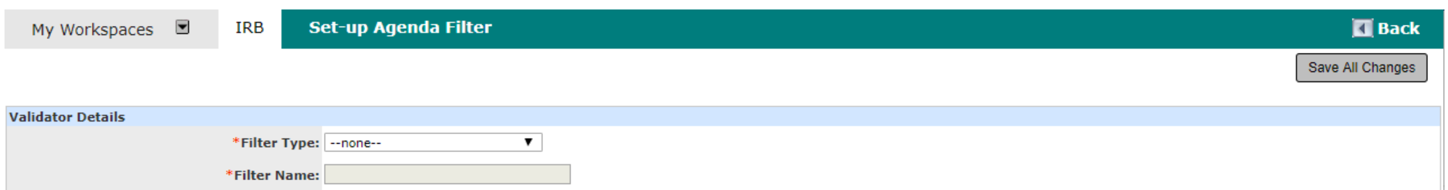
The name of the group will be displayed under Group Name. The code that will be used to reference this group will be displayed under Merge Code. The order in which the sections will appear in the **Setup Finalized Agenda Document Template**, **Setup Agenda Revision Document Template** and **Setup Meeting Minutes Template** sections will be displayed under Group Display Order. Two groups may have the same group number – the most recently added will be listed after the older group.

Before creating a new group, you must add the appropriate filters to the agenda. The filters are used to determine which agenda group a given submission will fall into. To do so, select the **Add Agenda Filter** button.

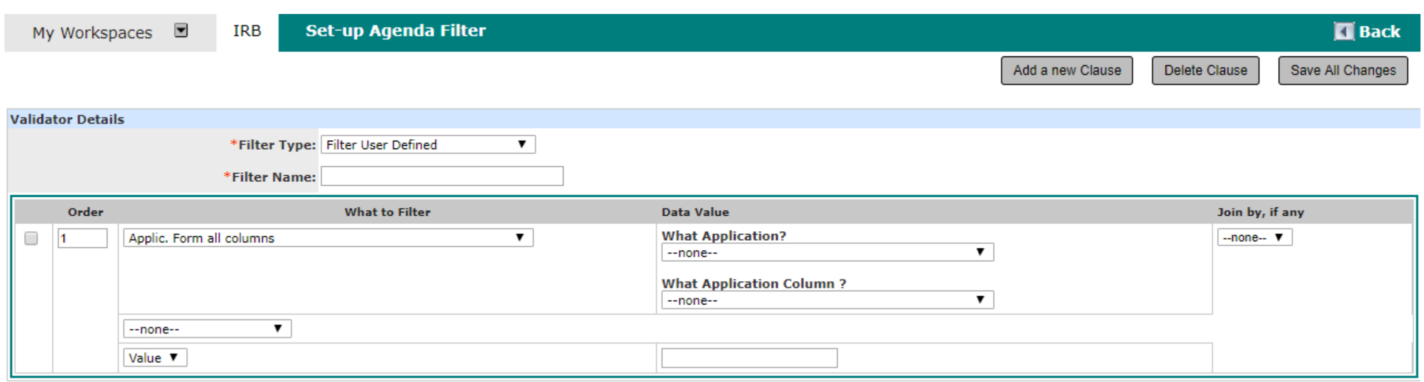


A new page will be displayed with a list of filter types (if any have already been defined). To delete one or more filters, select the checkbox(es) next to the filter(s) to be deleted. Click the **Delete Filter(s)** button. A confirmation dialog will appear; select the **OK** button to complete the deletion or select the **Cancel** button to cancel the deletion. To edit a filter, click the icon next to the appropriate filter. Make the necessary changes. When you are finished editing the filter, click the **Save All Changes** button.

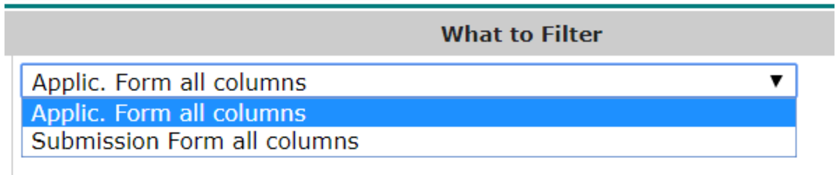
The Filter Type column displays the type of filter, while the name of the filter appears in the Filter Name column. To add a new filter, select the **Add Filter** button.



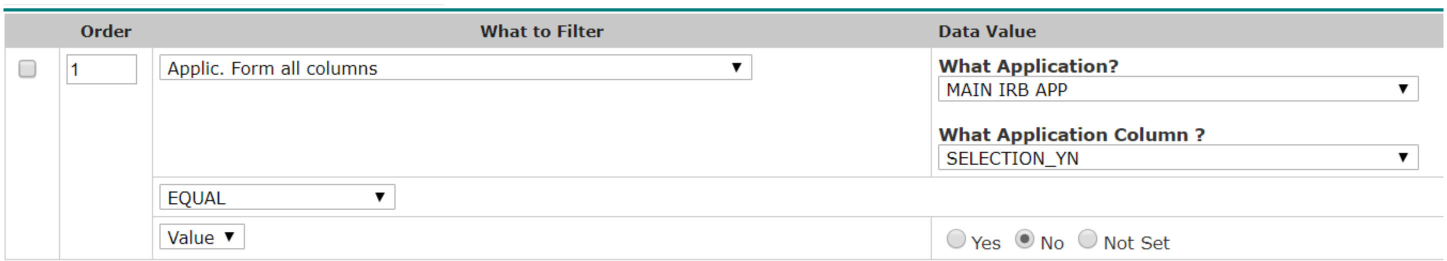
A new page will be displayed, prompting you to enter the Filter Type and Filter Name (both are required fields). The Filter Types that can be added are Designated Reviewer, Expedited, Facilitated Review, Exempt, Processed Administratively, Previously Reviewed, Conflict of Interest, Board Chair COI filter, and User Defined. The Filter Name field will be auto populated when a type is selected, unless the User Defined filter is selected. In that case, the name will have to be entered manually and rules for this filter will have to be defined (see below).



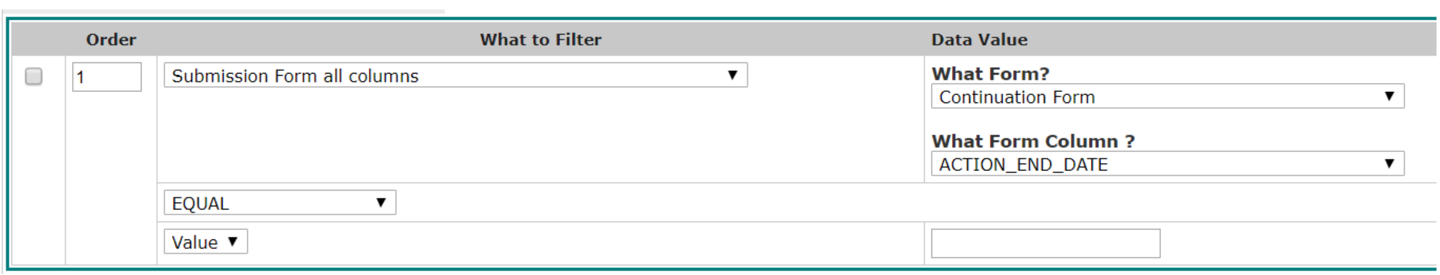
The checkbox can be used to delete a clause. If there is more than one clause to a filter, you can use the Order text box to specify in which order the clauses will run. The first drop-down menu in the What to Filter column consists of the items that may be selected for the system to check.



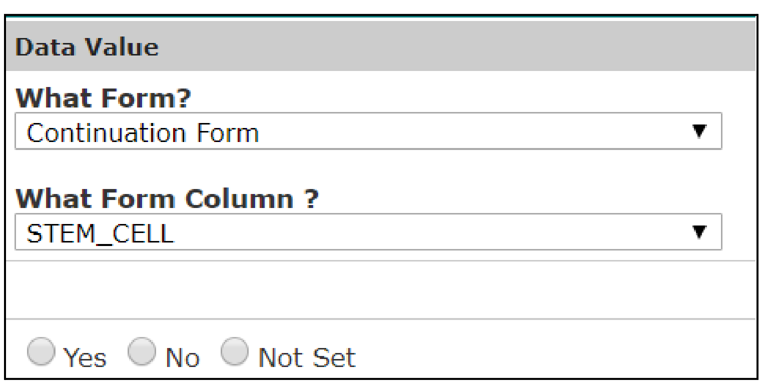
1. **Applic. Form all columns** – This will allow you to select from the list of study applications in your system and their respective data values.



2. **Submission Form all columns** – This will allow you to select from the list of submission forms in your system and their respective data values.



The Data Value column will populate depending on whether you select application form or submission form from the drop-down list in the What to Filter column. The What Form? Drop-down menu allows you to select the specific form that you would like to base your filter off of. The What Form Column? menu allows you to select the data value from the form, identified by its database column name. Once you have selected a form and a column, a space will appear to enter your needed value to create the filter. In the example below, the data value is a Yes/No selection. In other cases, you will have a text box in which you can type your needed value (see the above screenshot for an example).



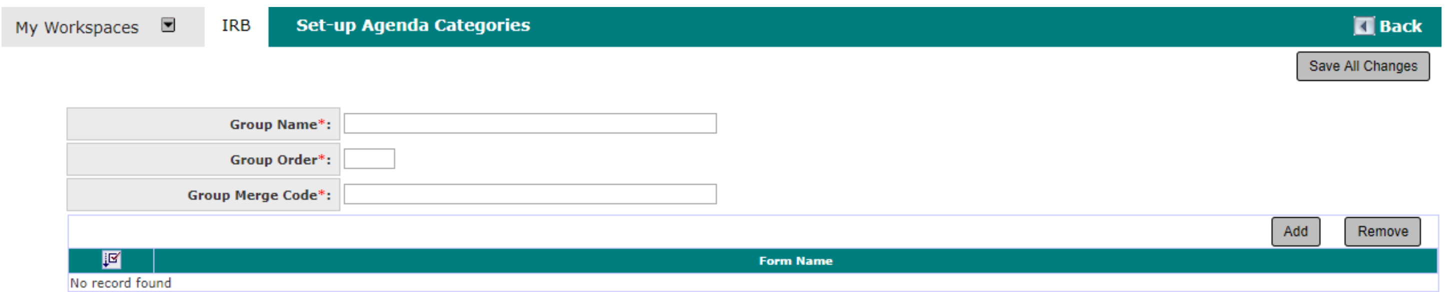
The second row in the What to Filter column is the comparator for the filtering item selected. You can select **EQUAL** to indicate that the response in the form for the chosen data value should equal the value you select, or **NOT EQUAL** to indicate that the answer given in the form should not equal the value you select.

The **"**Join by, if any" drop-down menu is used when you wish to define more than one clause. The AND value signifies that all clauses have to be true for the filter to be true. The OR value signifies that only one clause has to be true for the filter to be true. Select –none- when there is only one clause in the filter.

A new clause can be created by selecting **Add a new Clause** button. To delete a clause, select the box(es) next to the appropriate clause(s) and select the **Delete Clause(s)** button.

After all values for the filter have been defined, click the **Save All Changes** button. This will return you to the filter list screen with the new filter listed. Add new filters as needed or select the **Back** button to go back to the agenda group list.

To create a new group, click the **Add Group** button.

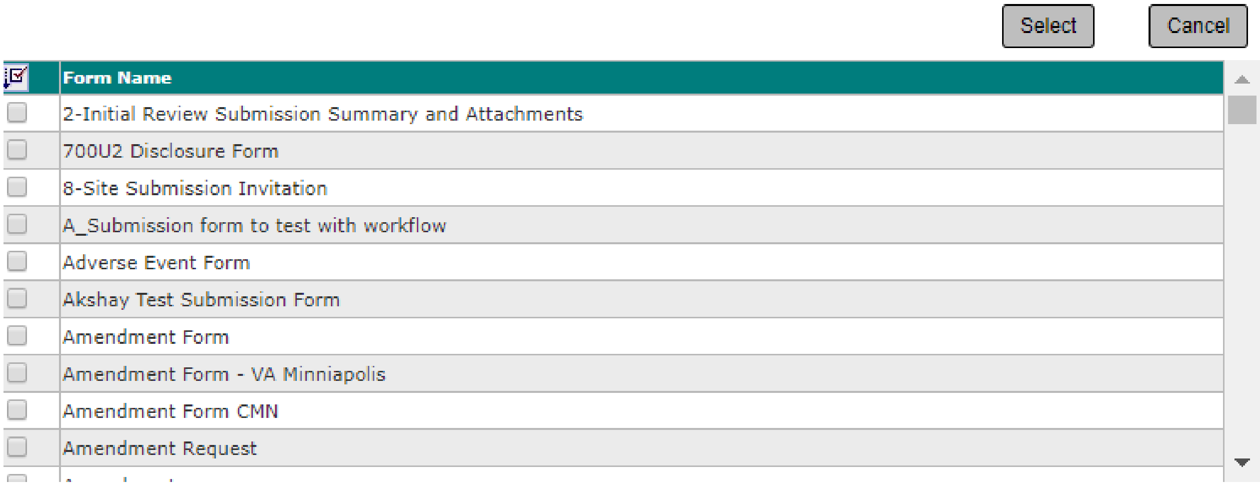


The 3 required fields are:

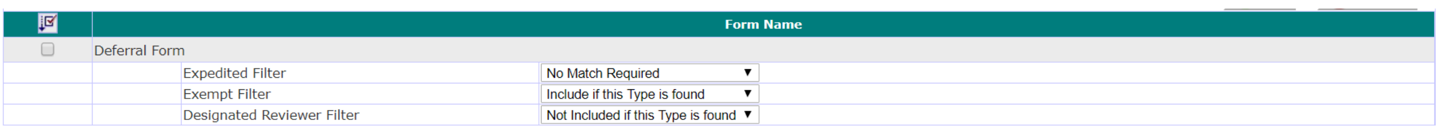
1. **Group Name** –This is what will be displayed in the **Setup Finalized Agenda Document Template**, **Setup Agenda Revision Document Template** and **Setup Meeting Minutes Template** sections, and within the **Agenda** page.
2. **Group Order** - This determines in which place in the list of groups this will appear. It must be a positive integer.
3. **Group Merge Code** - This is the code that the system will use to refer to this group when inserting it into the master template for the **Setup Finalized Agenda Document Template**, **Setup Agenda Revision Document Template,** and **Setup Meeting Minutes Template** sections.

There is a table underneath these fields. This is used to add submission types to this group. This means that any type of submission that is categorized with this group will pull into the section that uses the Merge Code created for this group. This will not display the entire form that is submitted, but only the information (e.g., PI, Study Title) that is specified in the **Setup Finalized Agenda Document Template**, **Setup Agenda Revision Document Template,** and **Setup Meeting Minutes Template** sections.

To add a submission type, click the **Add** button found above the right side of the table. A pop-up will open. This lists all of the available submission forms defined in your system. You may add one or more by checking the box(es) next to the form(s) that you would like to select. Click the **Select** button to add these forms to the group. Click the **Cancel** button to close the pop up without adding any forms.



The added form(s) will appear in the table with the filters created previously listed under it. Each filter will have a drop-down menu with three selectable options: “No Match Required,” “Include if this Type is found,” and “Not Included if this Type is found.”



No Match Required – Select this option to indicate that you want this submission status filter to be included in this group.

Not Included if this Type is found – Select this option to indicate you do not want any submissions with this status filter to be included with this group.

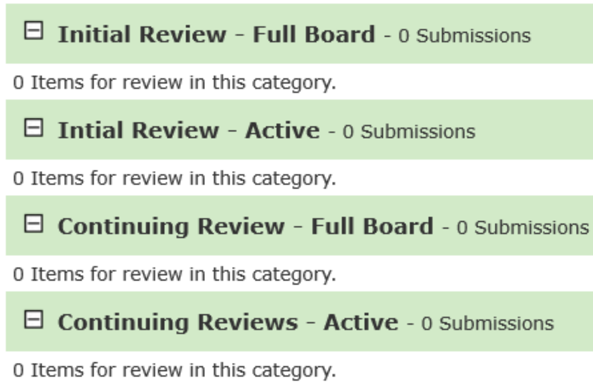
Include if this Type is found – Select this option to indicate that you want submission types with this status to be included in the group, and also exclude all undefined status filters from the group. It will also exclude the status filters that are defined as No Match Required.

When you are finished adding the form definitions for the group, click the **Save All Changes** button to add this group to the agenda categories list. To remove a form from the group, check the box next to the form to be deleted and click **Remove**.

After returning to the main Agenda Category screen, if you wish to delete one or more groups, check the boxes next to the group(s) to be deleted. There is an option to select or deselect all by clicking the icon. Click the **Delete Group(s)** button. A confirmation dialog box appears; click the **OK** button to complete the deletion. To cancel, click the **Cancel** button.

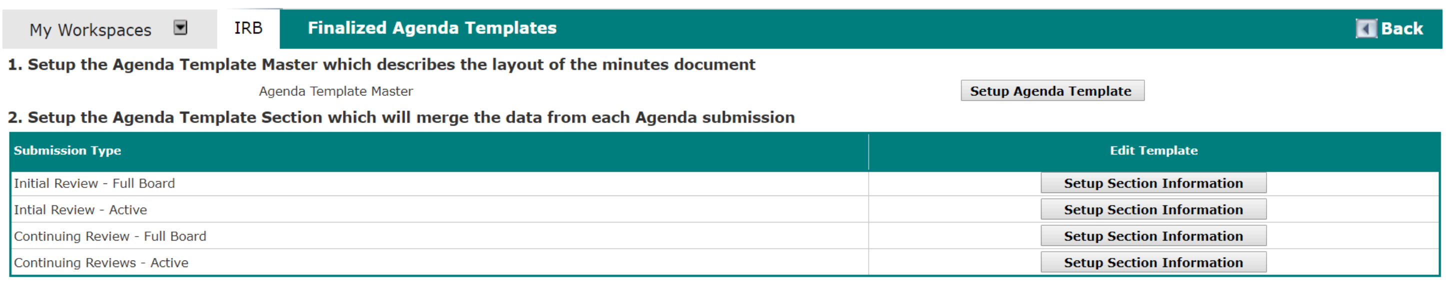
To edit a group, click the icon next to the appropriate group. Make the necessary changes. When you are finished editing the group, click the **Save All Changes** button.

This list will be viewable on the Meeting Agenda screen.



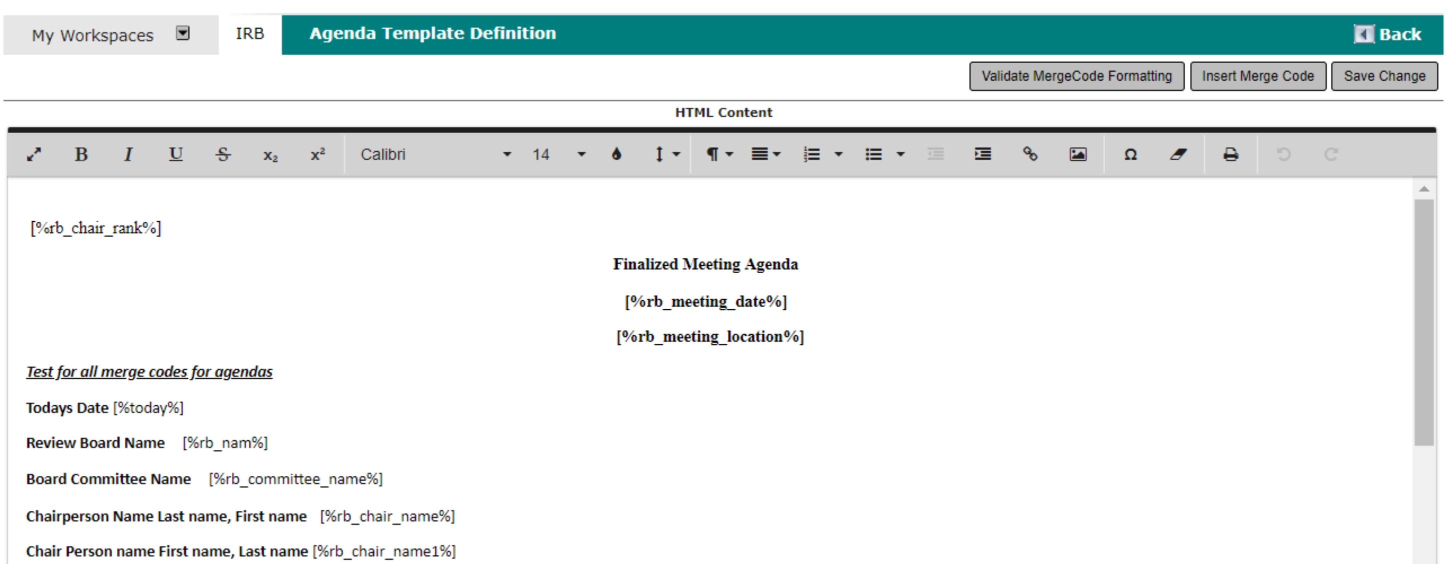
Setup Finalized Agenda Document Template

You can create a master template for your Meeting Agenda document to store your meeting agenda outline. You can use merge codes to pull submission information as well as other key study information into the agenda. (See the IRB Assistant - Meetings manual for instructions on how to generate the agenda for a specific meeting).



The Finalized Agenda Templates page gives you the option to view the Agenda Master Template, which displays the general layout of the agenda document, as well as the different sections that can be added to the master template (set up as agenda categories). You can set up the template for these sections individually, which will merge data from each submission into the Master Agenda Template.

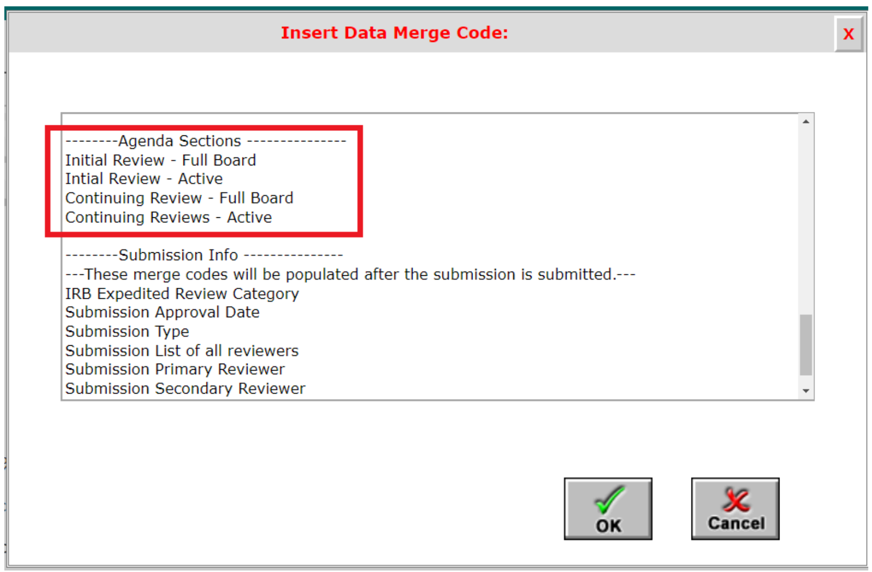
You will first define the content of the Master Agenda Template. To do so, click on the **Setup Agenda Template** button.



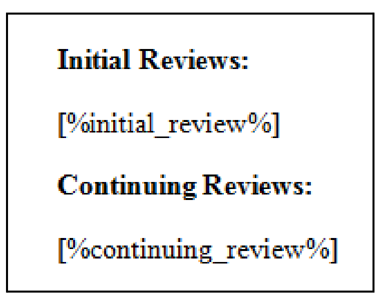
A new page will open, containing an embedded Word editor. If the master template has already been created, you will already see content in the window. You can edit the existing content or add new content by using the features of the text editor and inserting merge codes. To insert a merge code, click the **Insert Merge Code** button. A window will pop up listing the available merge codes. Select the merge code to insert, and then click the **OK** button.

A merge code is a programmed label that will pull information into the document when the document is generated from the template. In the example above, when the Agenda is generated for a specific meeting date, the merge code for the meeting date will populate with the date of the meeting.

You can now use merge codes to pull agenda sections into the master template. If you do not insert the sections, they will not display on your agenda.

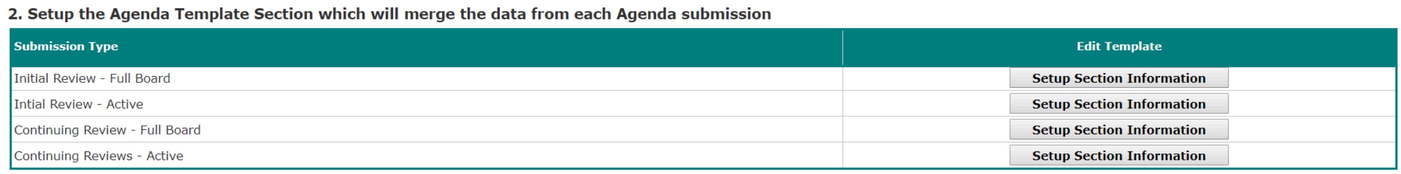


In the screenshot below, you can see how you can use the merge codes for the sections. Headers have been entered for the specific sections, with the section merge codes below. These merge codes will eventually be populated with the information you add to the templates for the individual sections.



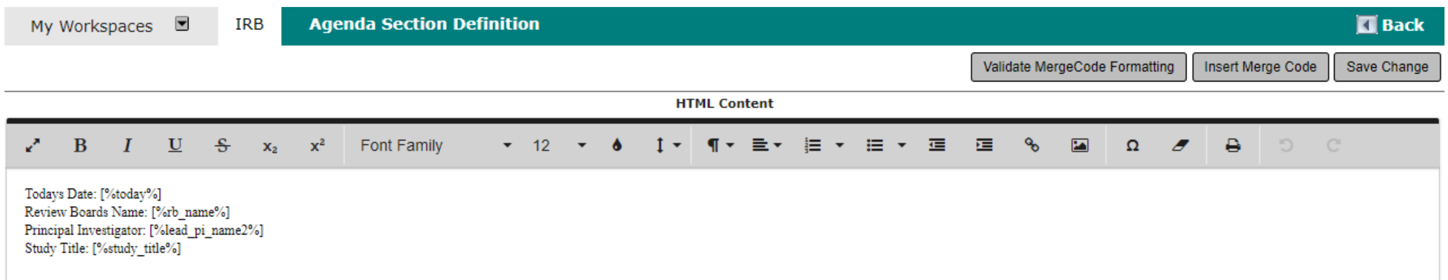
When finished creating or editing the master template, you can click the **Save Change** button to return to the main Finalized Agenda Templates screen.

At this point, you can edit the information that you wish to appear in the individual agenda sections. To edit a submission type template, click on the **Setup Section Information** button.


2. Setup the Agenda Template Section which will merge the data from each Agenda submission

Submission Type	Edit Template
Initial Review - Full Board	Setup Section Information
Intial Review - Active	Setup Section Information
Continuing Review - Full Board	Setup Section Information
Continuing Reviews - Active	Setup Section Information

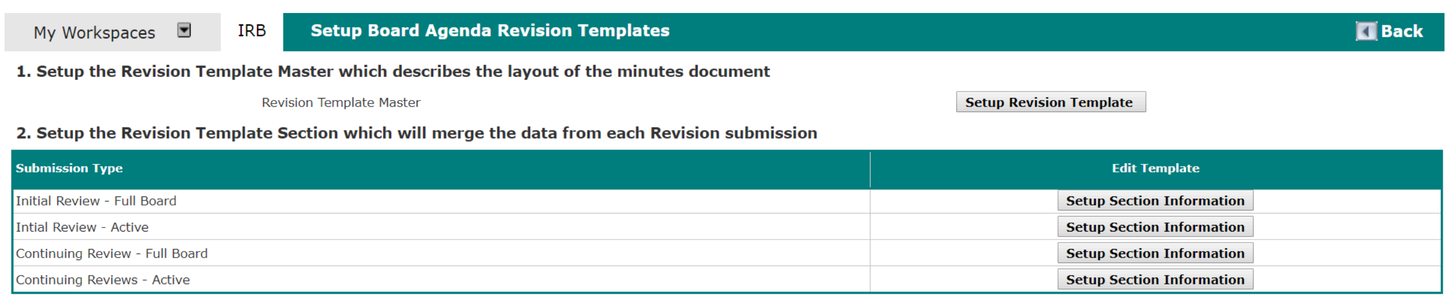
You can create and edit the section templates in the same way as the master template. Note: What is entered here is what will appear where you placed the section merge codes in the master template.



When you generate a Meeting Agenda on a specific meeting date, the system will generate one document combining the Agenda Template Master and the submission subsections and populate the merge codes with meeting and submission-specific information.

Setup Agenda Revision Document Template

Agenda Revision Documents are used when a new submission is placed on the agenda after the main agenda document for a meeting date has already been published. The Agenda Revision Template is designed in the same way as the Finalized Agenda Template, with a master template and individual subsections.


My Workspaces | IRB | Setup Board Agenda Revision Templates | Back

1. Setup the Revision Template Master which describes the layout of the minutes document

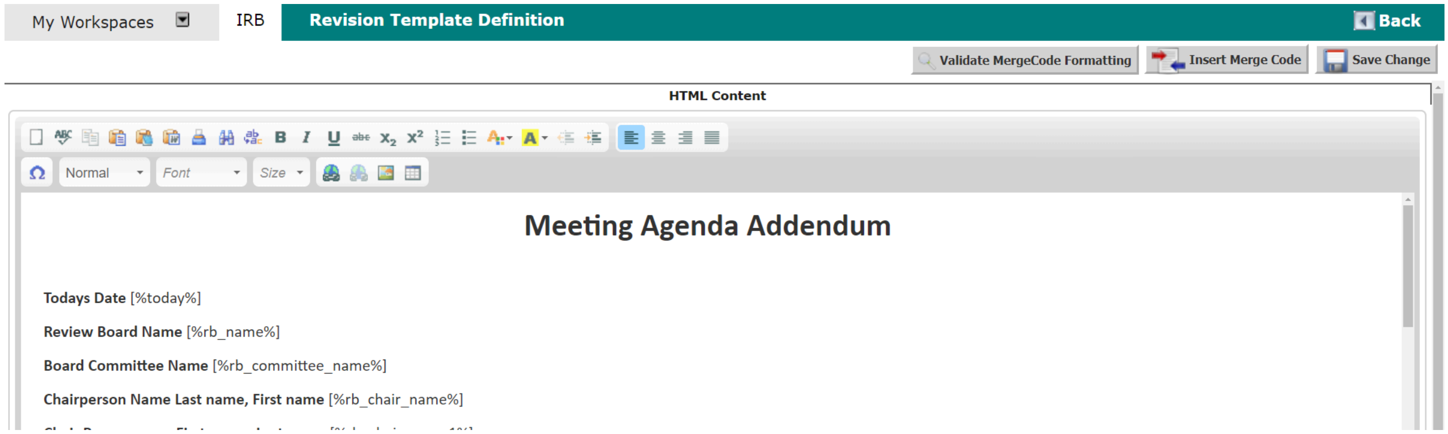
Revision Template Master — Setup Revision Template

2. Setup the Revision Template Section which will merge the data from each Revision submission

Submission Type	Edit Template
Initial Review - Full Board	Setup Section Information
Intial Review - Active	Setup Section Information
Continuing Review - Full Board	Setup Section Information
Continuing Reviews - Active	Setup Section Information

The Agenda Revision Templates page gives you the option to view the Revision Template Master, which displays the general layout of the agenda document, as well as the different sections that can be added to the master template (set up as agenda categories). You can set up the template for these sections individually, which will merge data from each submission into the Master Revision Template.

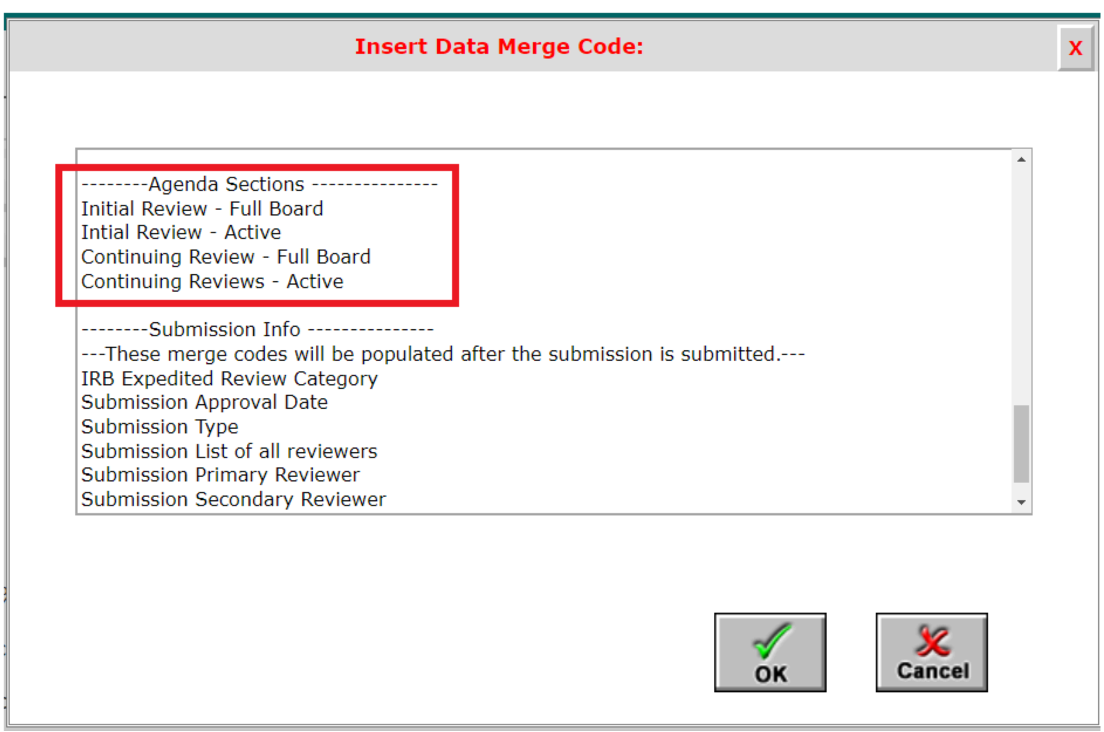
You will first define the content of the Master Revision Template. To do so, click on the **Setup Revision Template** button.



A new page will open, containing an embedded Word editor. If the master template has already been created, you will already see content in the window. You can edit the existing content or add new content by using the features of the text editor and inserting merge codes. To insert a merge code, click the **Insert Merge Code** button. A window will pop up listing the available merge codes. Select the merge code to insert, and then click the **OK** button.

A merge code is a programmed label that will pull information into the document when the document is generated from the template. In the example above, when the Agenda is generated for a specific meeting date, the merge code for the meeting date will populate with the date of the meeting.

You can now use merge codes to pull agenda sections into the master template. If you do not insert the sections, they will not display on your agenda.



In the screenshot below, you can see how you can use the merge codes for the sections. Headers have been entered for the specific sections, with the section merge codes below. These merge codes will eventually be populated with the information you add to the templates for the individual sections.

Initial Reviews:

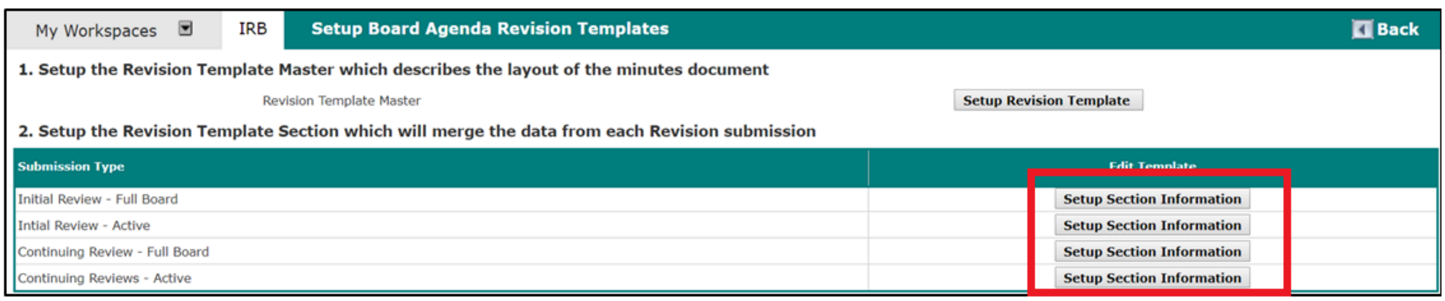
[%initial_review%]

Continuing Reviews:

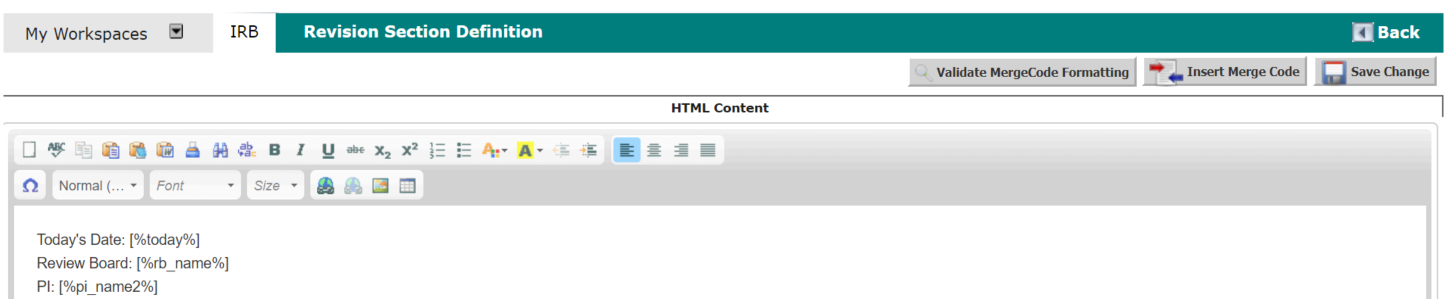
[%continuing_review%]

When finished creating or editing the master template, you can click the **Save Change** button to return to the main Agenda Revision Templates screen.

At this point, you can edit the information that you wish to appear in the individual agenda sections. To edit a submission type template, click on the **Setup Section Information** button.



You can create and edit the section templates in the same way as the master template. Note: What is entered here is what will appear where you placed the section merge codes in the master template.

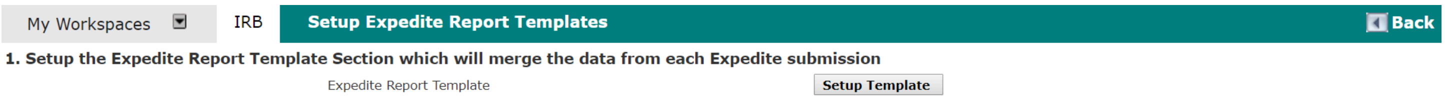


When you generate a Meeting Agenda on a specific meeting date, the system will generate one document combining the Revision Template Master and the submission subsections and populate the merge codes with meeting and submission-specific information.

Setup Expedite Report Template

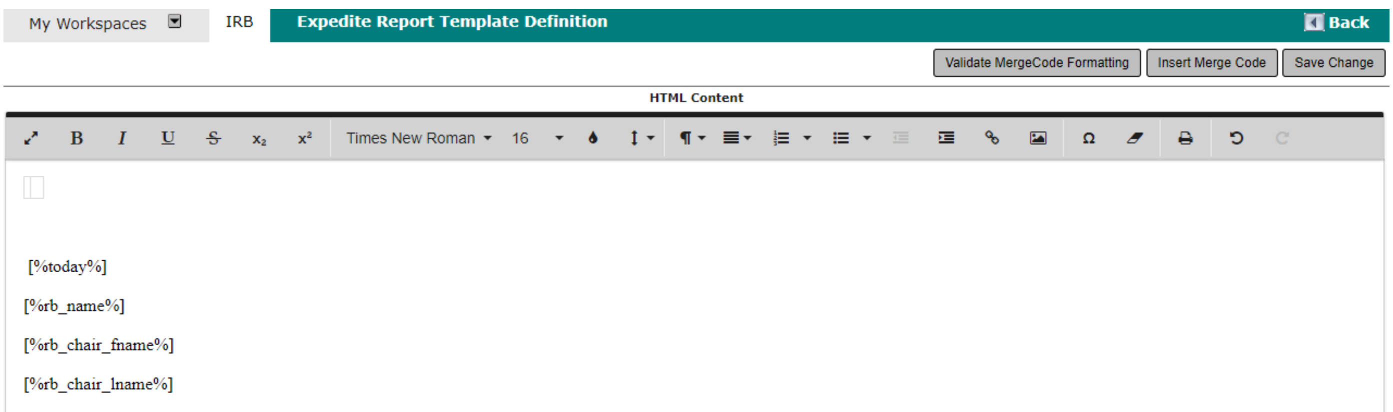
You can use this area of the system to create a template for a specialized type of meeting report that summarizes expedited submissions. This feature is only available if the review board property rb.use_expedited_report is set to Yes within the Meeting Settings group.

The Expedite Report Template functions similarly to the Meeting Agenda and Minutes templates, as it is created within an embedded word editor with available merge codes. However, there is just one section of the template to set up. Click the **Setup Template** button.

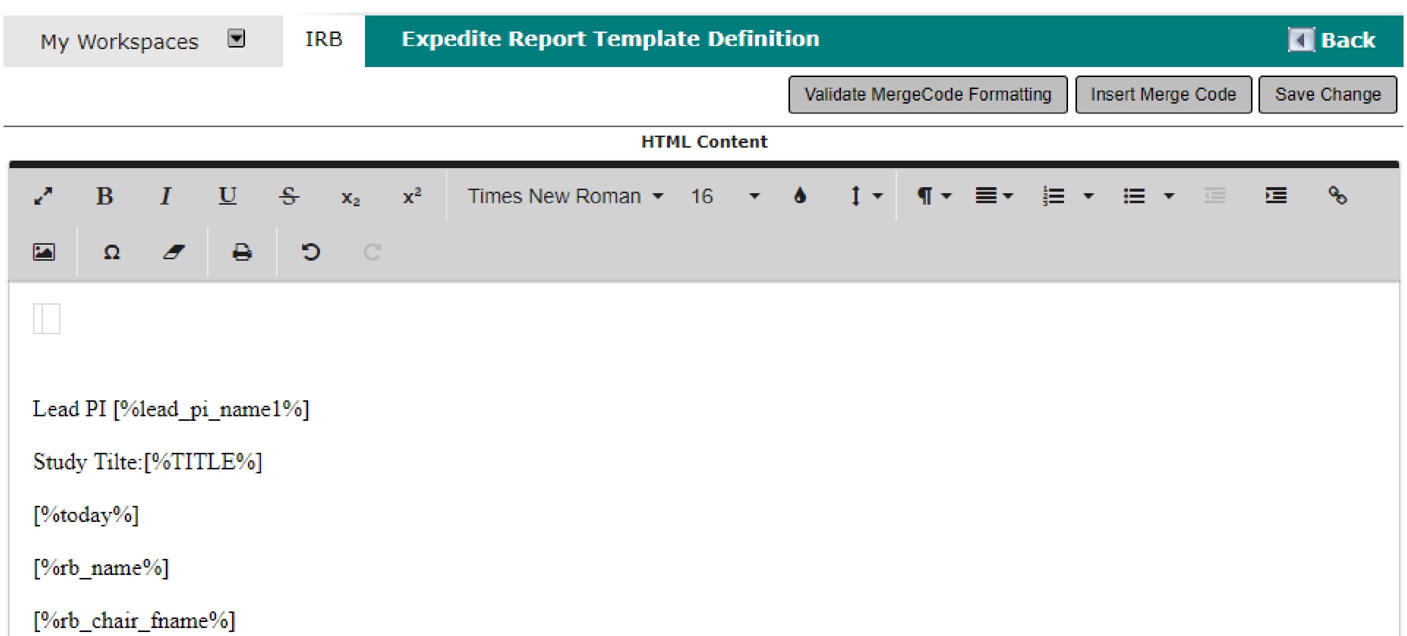


This will open the embedded Word editor. Click on **Insert Merge Codes** to pull in information about the meeting's expedited submissions. Using the merge codes, you created for the submission sections when you were setting up the agenda categories will pull in the associated content and populate it for each expedited submission on the agenda.

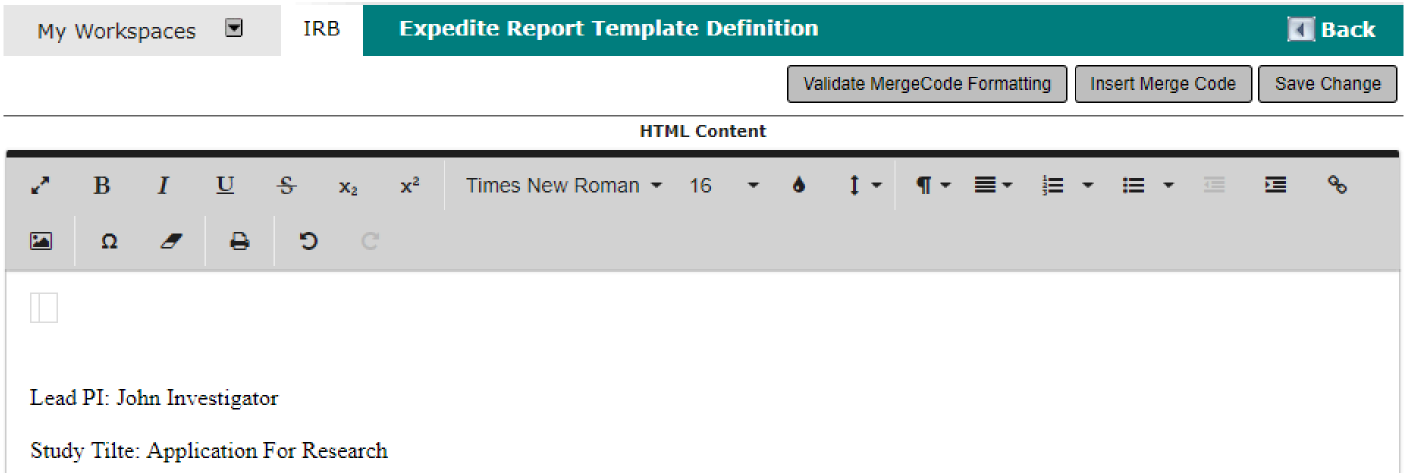
For example, in the screenshot below, the merge code for the expedited initial review section has been put into the Expedite Report Template.



When the Expedited Initial Reviews section was created for the Finalized Agenda Template, the section was set up to contain information about the name of the PI and the Study Title:

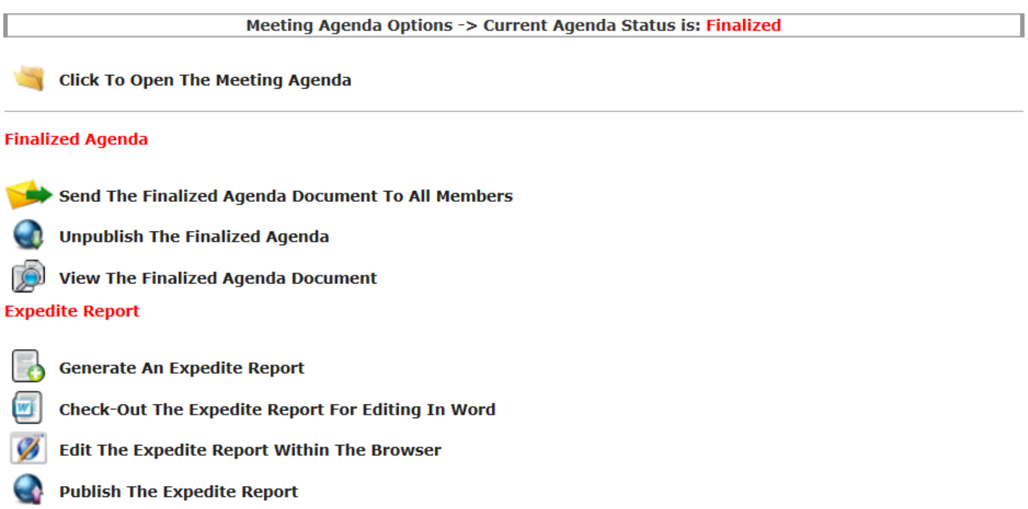


When the Expedited Report is generated, it will pull in the information as defined above for each expedited submission:



When you are done editing the Expedite Report Template, click **Save Change** to retain your changes and return to the previous screen.

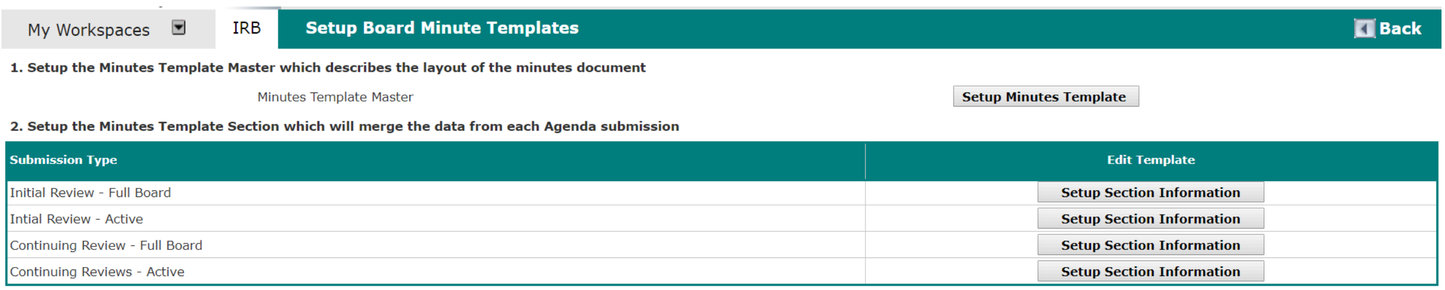
To generate an Expedite Report, you must go to a finalized meeting agenda within Review Board Assistant > Meeting Manager. Start by clicking **Generate an Expedite Report** under the Expedite Report group. The system will generate a document based on any expedited submission placed on this particular meeting date. You can edit this before publishing by checking out the document to your desktop (**Check-Out the Expedite Report For Editing In Word**), or you can make your changes within the browser (**Edit the Expedite Report Within The Browser**). When you are finished, click **Publish the Expedite Report** to convert the Word document to a PDF document.



Once you publish the Expedite Report, a PDF file will populate on the Meeting Agenda in the **Expedite Reports** section. This table will also contain the number of expedited submissions included in the report.

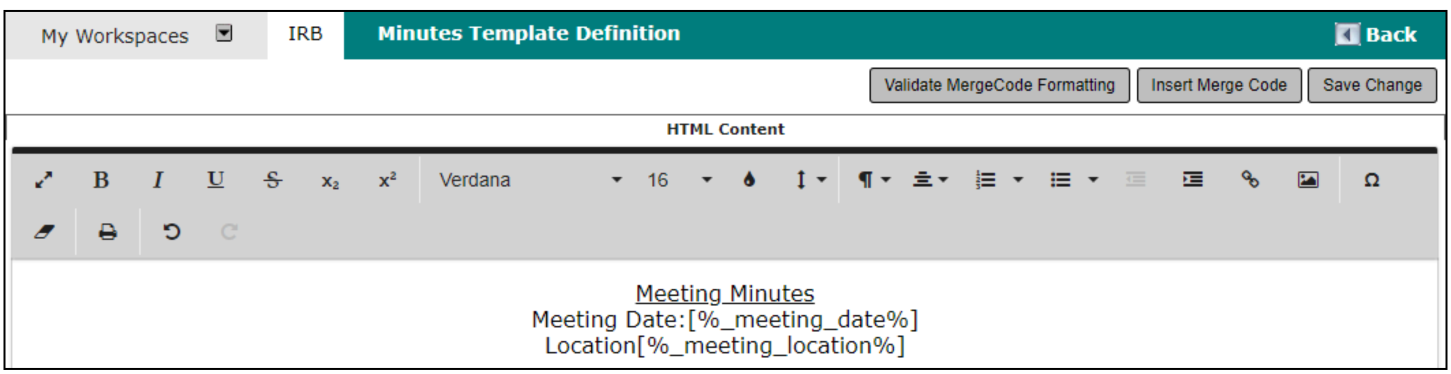
Setup Meeting Minutes Template

This area of the system allows you to create a master template for your Meeting Minutes document. This template will store your meeting minutes outline, and with the use of merge codes, will pull in specific information regarding the meeting when you generate the minutes.



The Minutes Templates page lists the Minutes Template Master and the different sections that can be added to the master template. You can set up the template for each section, representing different types of submissions, which you can then use to merge data from each submission into the master minutes template.

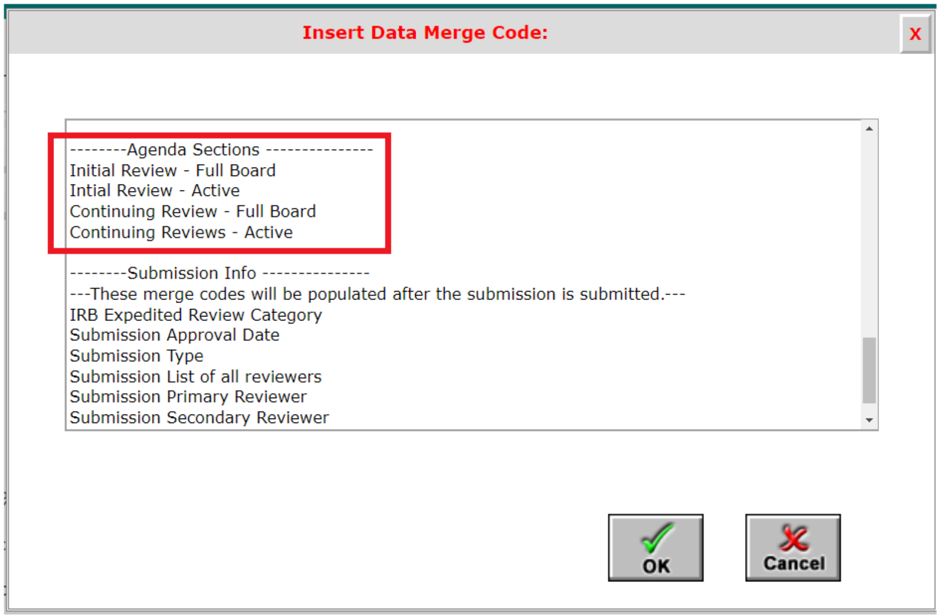
You will first define the content of the Minutes Template Master. Click on the **Setup Minutes Template** button.



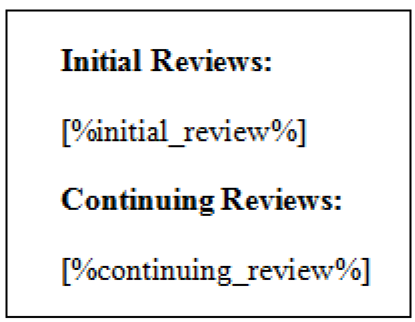
A new page will open, containing an embedded Word editor. If the master template has already been created, you will already see content in the window. You can edit the existing content or add new content by using the features of the text editor and inserting merge codes. To insert a merge code, click the **Insert Merge Code** button. A window will pop up listing the available merge codes. Select the merge code to insert, and then click the **OK** button.

A merge code is a programmed label that will pull information into the document when the document is generated from the template. In the example above, when the minutes document is generated for a specific meeting date, the merge code for the meeting date will populate with the date of the meeting.

You can now use merge codes to pull sections representing different submission types into the master template. If you do not insert the sections, they will not display in your minutes document.



In the screenshot below, you can see how you can use the merge codes for the sections. Headers have been entered for the specific sections, with the section merge codes below. These merge codes will eventually be populated with the information you add to the templates for the individual sections.



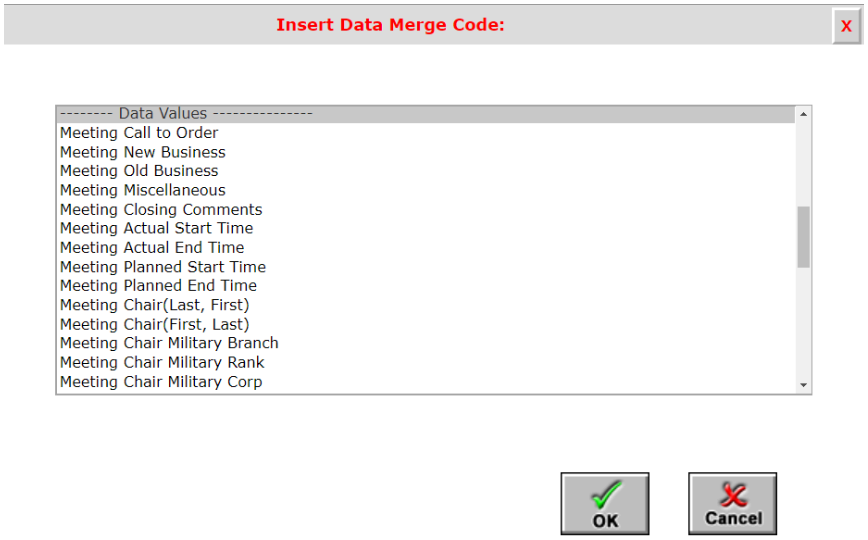
Initial Reviews:

[%initial_review%]

Continuing Reviews:

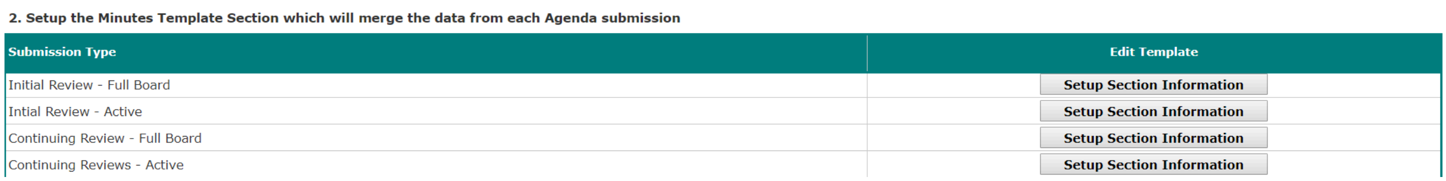
[%continuing_review%]

Note that there are also meeting-specific merge codes that you can use in the master template to pull in information about the meeting itself.



When finished creating or editing the master template, you can click the **Save Change** button to return to the main Minutes Templates screen.

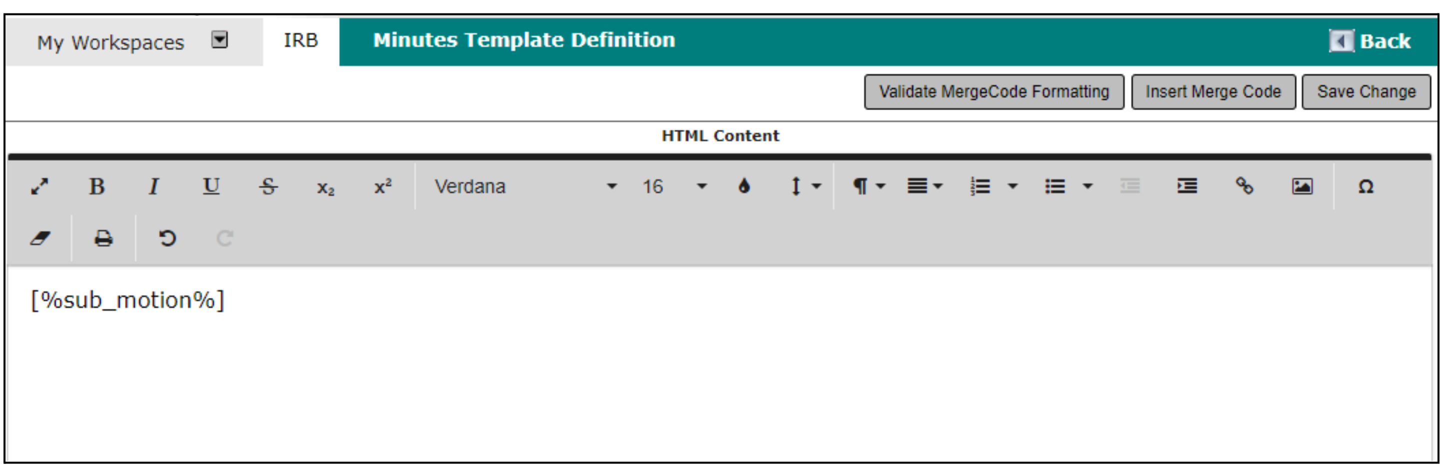
At this point, you can edit the information that you wish to appear in the individual minutes sections. To edit a submission type template, click on the **Setup Section Information** button.



2. Setup the Minutes Template Section which will merge the data from each Agenda submission

Submission Type	Edit Template
Initial Review - Full Board	Setup Section Information
Intial Review - Active	Setup Section Information
Continuing Review - Full Board	Setup Section Information
Continuing Reviews - Active	Setup Section Information

You can create and edit the section templates in the same way as the master template. Note: What is entered here is what will appear where you placed the section merge codes in the master template.



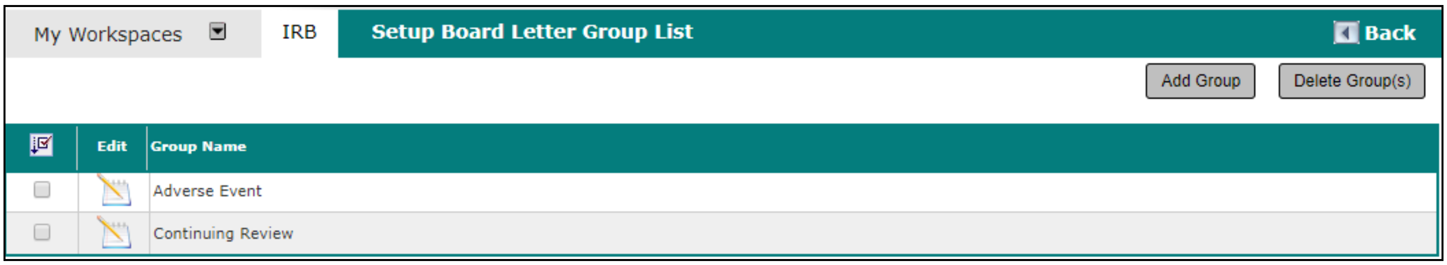
When you generate a meeting minutes document for a specific meeting date, the system will generate one document using the Minutes Template Master and Minutes Template subsections.

11.02

Setup Outcome Letter Groups

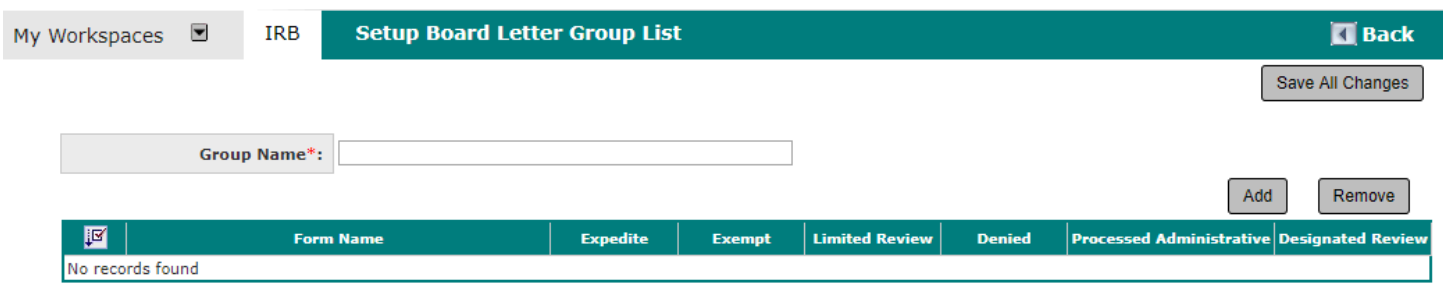
From this screen, you can define and list groups that can be used to categorize your outcome letters. When you are setting up your outcome letter templates, the groups that you have created will be available in the Letter Type drop-down list.

The list of Outcome Letter Groups will be similar to this screen:

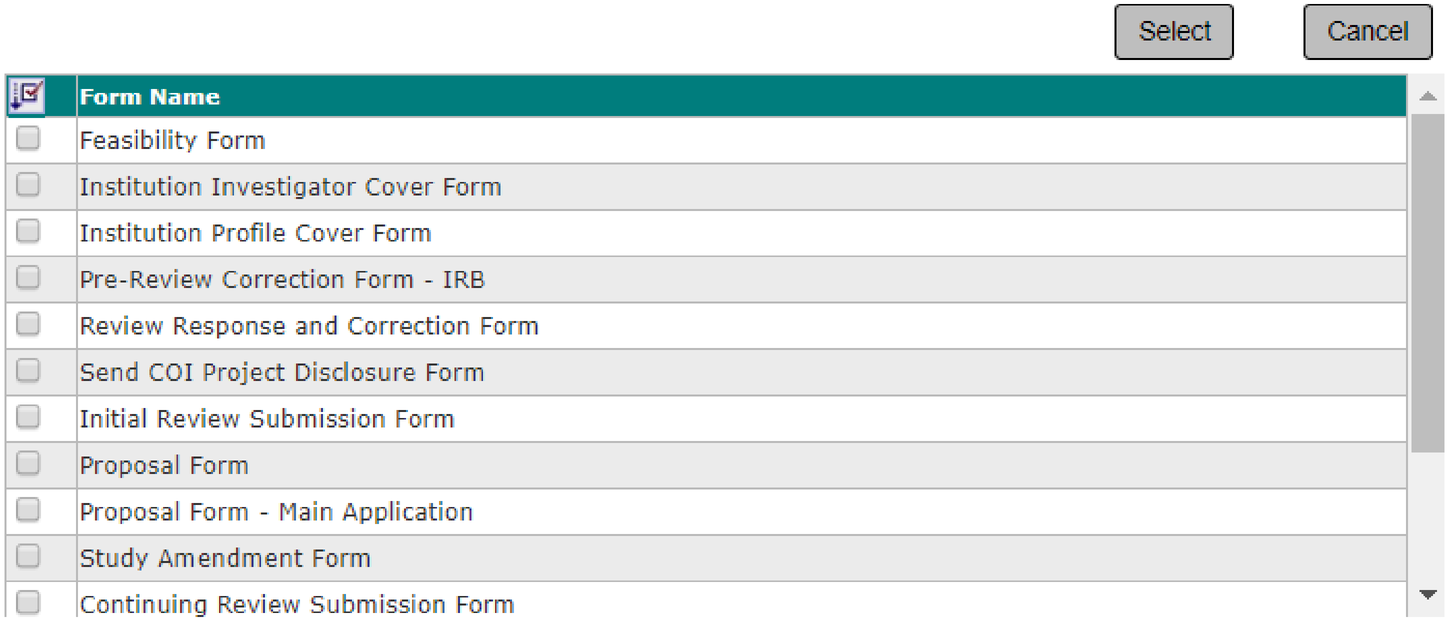


To delete existing groups, check the boxes next to the desired group(s) and click the **Delete Group** button. It is possible to select or deselect all checkboxes by clicking on the icon at the top of the column of checkboxes. To edit a group, click the icon.

To add a new group, click the **Add Group** button.



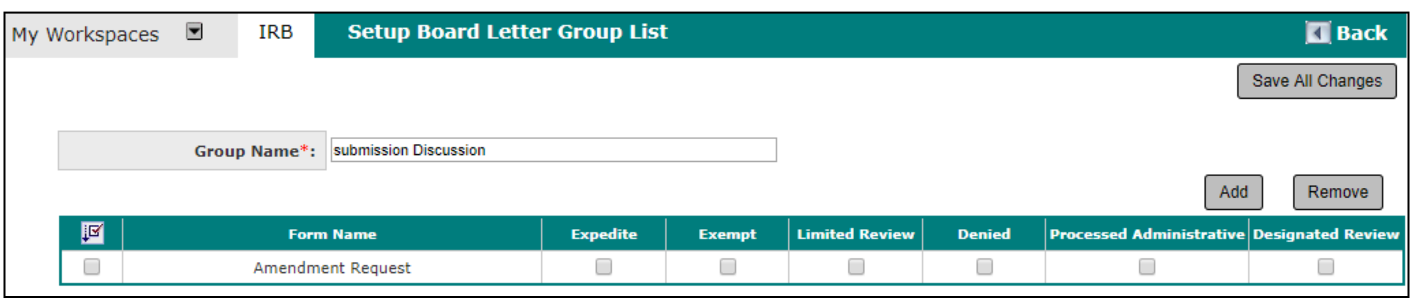
Type in the Group Name, as this is a required field. To associate this particular outcome letter type to a specific submission form, click the **Add** button. The following screen will display:



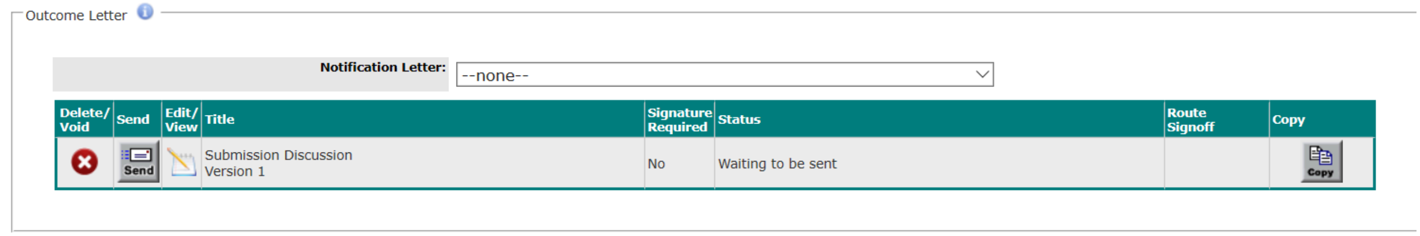
Check the box next to the desired submission form(s) to include in this category, and then click the **Select** button.

The selected form(s) will be added to the Outcome Letter Group. Listed in columns next to the submission form name will be several columns listing different review processes, depending on your system settings. This allows you to specify which review process any letter associated to this group should display for. If a letter group applies to a Full Board review, no selection is needed, as listing the form in the group will cause the letter to display. Select the checkbox in the columns that are applicable in addition to the Full Board Review, and then click the **Save All Changes** button.

To delete unwanted forms, check the box next to the desired form in the table and click the **Remove** button.

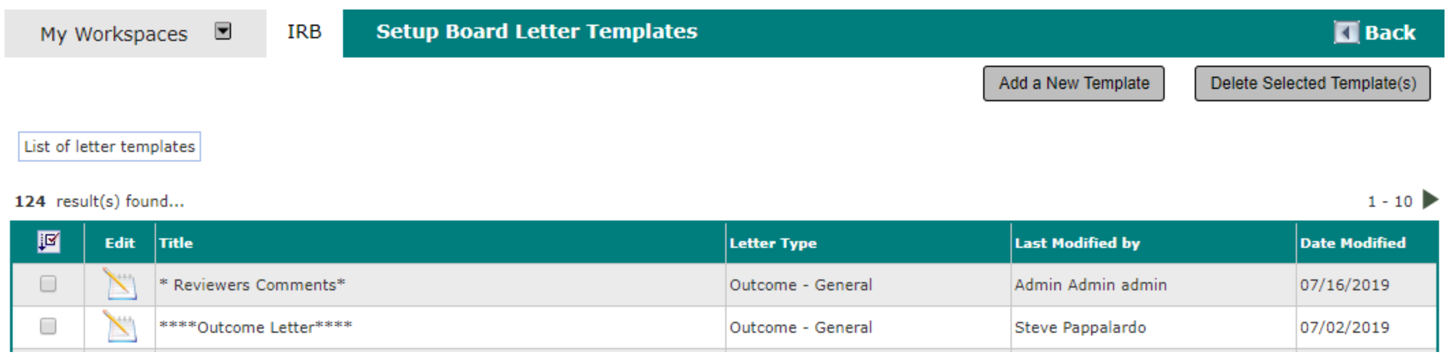


In the above screenshot, the Group Name is called “Submission Discussion.” In the Setup Outcome Letter Templates screen, outcome letter templates can be created and associated to this letter type by selecting the Outcome-Amendment type from the drop-down list. Any template that is saved in the Outcome Letter Templates list that is of the type “Amendment” will then appear in the Notification Letter drop-down list in the Outcome Letters tab of an Amendment Submission that has been assigned to a Full Board review.



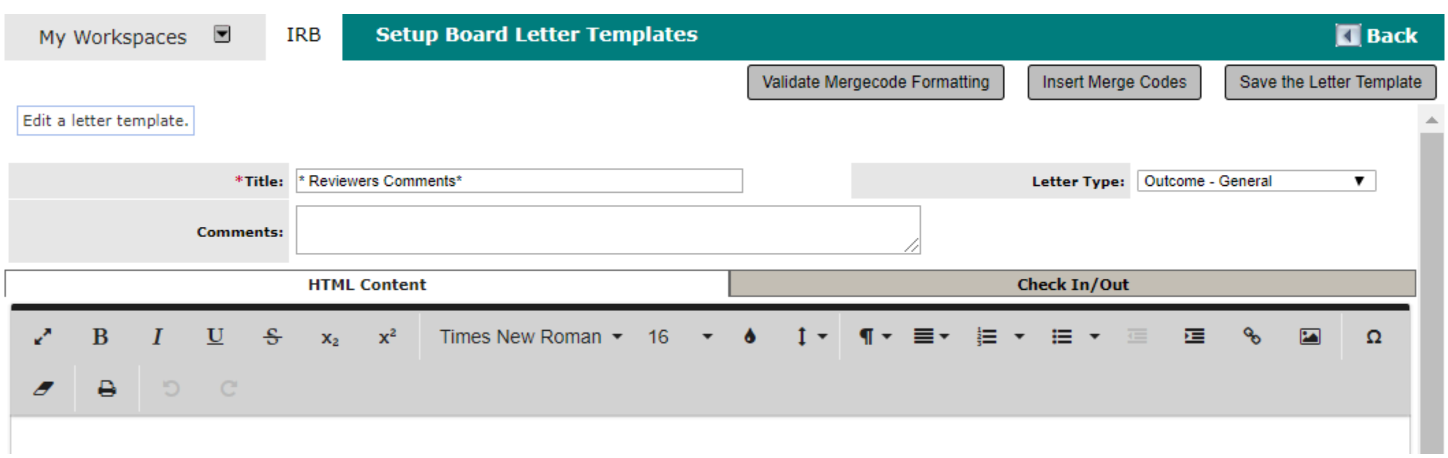
Setup Outcome Letter Templates

From this screen, you can set up templates for your review board's outcome letters. Letter templates are edited using a Word editor and can be created using merge codes that will pull information specific to the submission when the letter is generated.



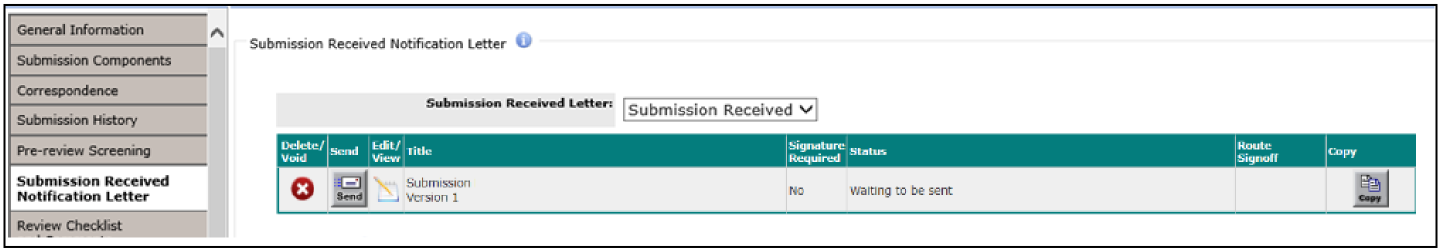
When you open the screen, any letter already defined for the review board will list on the page, displaying information regarding the Title, Letter Type, Last Modified By, and Date Modified information. You can edit an existing letter by clicking on the icon, or you can add a new letter by clicking on the **Add a New Template** button.

If the number of letter templates exceeds ten results, a small arrow will display on the top right of the letter templates table. Click this arrow to move to the next page of letter templates.



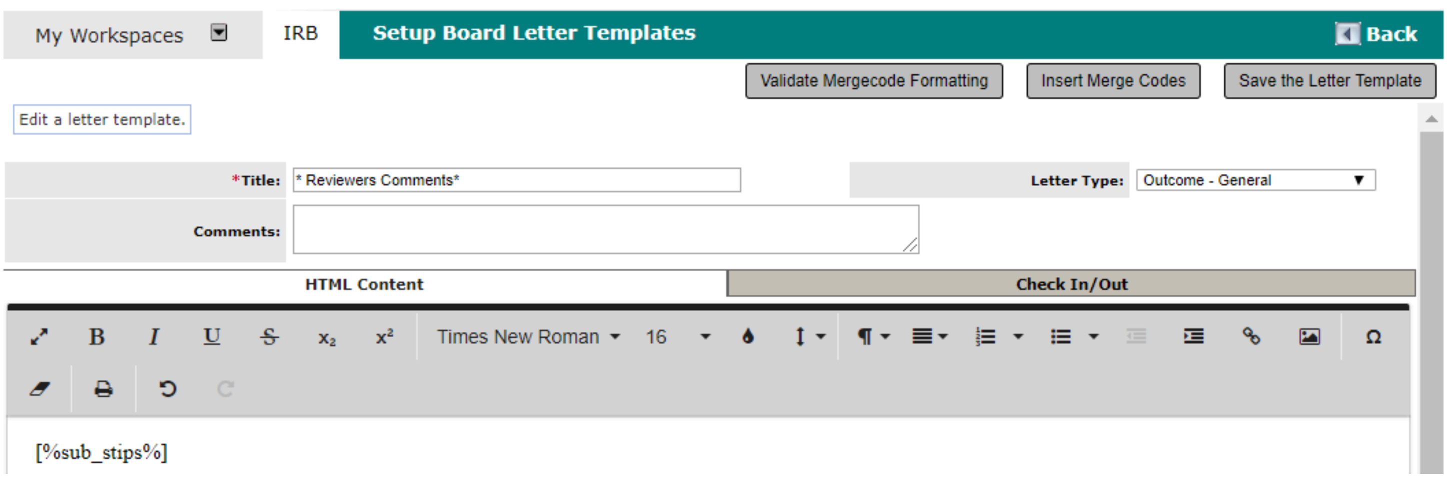
When you add a new letter template, a page will open containing a blank embedded Word editor. If you had chosen an existing template, the Word editor would contain the contents of the letter template. Enter the Title of the template and select a Letter Type from the drop-down list. The types of letter listed in the drop-down list will include Submission, Outcome – General, and any custom types defined when setting up outcome letter groups as described above.

Submission-type letter templates appear as options on the Submission Received Notification Letter tab of the submission processing screens.



Selecting the Outcome-General type from the drop-down list will cause the letter template to be listed among the templates available on the Outcome Letter tab in the submission processing screens. Templates that fall into a user-defined group will appear on the Outcome Letter tab as defined when the group was created.

Add content to the template by inserting merge codes (click the **Insert Merge Codes** button) and using the features of the embedded Word editor. The merge codes you insert into your letter will populate when the actual letter is generated.

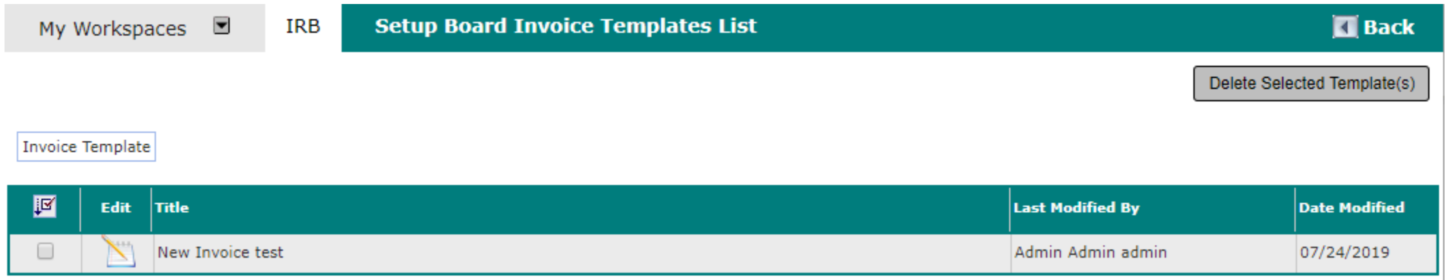


When finished creating the template, click the **Save the Letter Template** button to retain your changes.

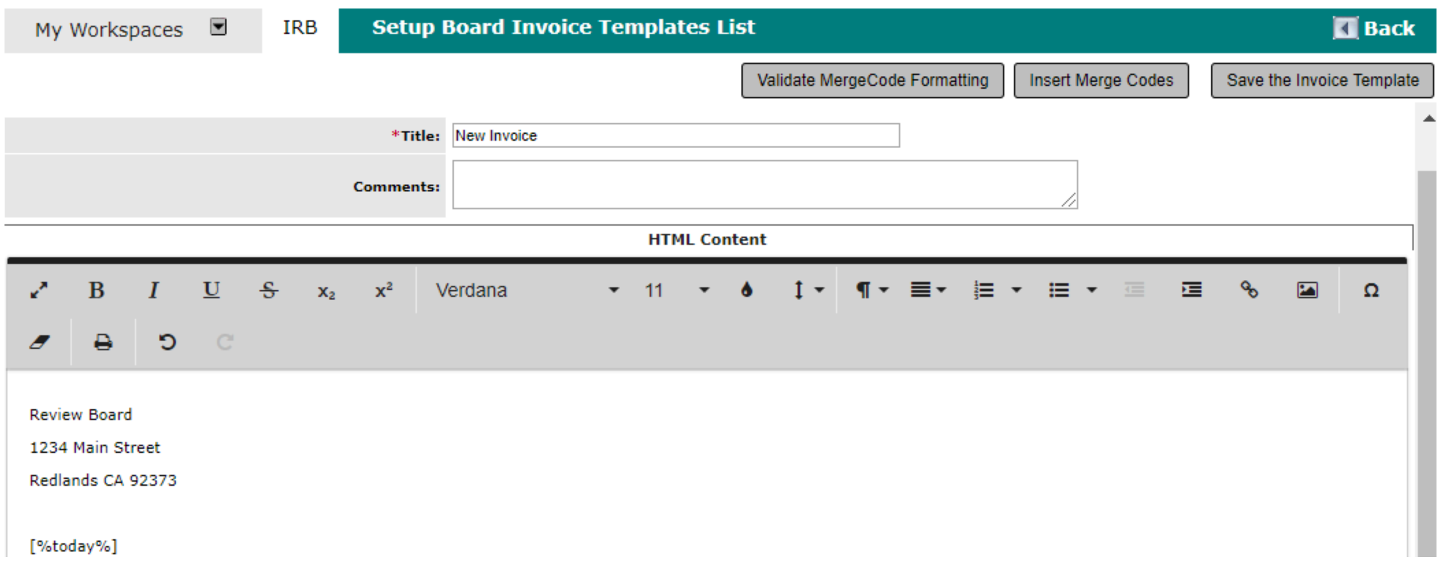
Setup Invoice Template

If you are using IRB Fee Tracking, you can define the templates that will be used to generate invoices to studies for collecting IRB-related fees. This feature is only available if rb.use_rb_invoicing in the Fee Tracking group of review board properties is set to Yes.

When you initially view the Review Board Invoice Template page, no record will be created. You may only have one invoice template created for the review board. Click the **Add a New Template** button to create the template.



When you add a new template, a page will open containing an embedded Word editor. If you chose an existing template, the Word editor would contain the contents of the existing letter template. Enter the Title of the template and enter any comments in the Comments field.



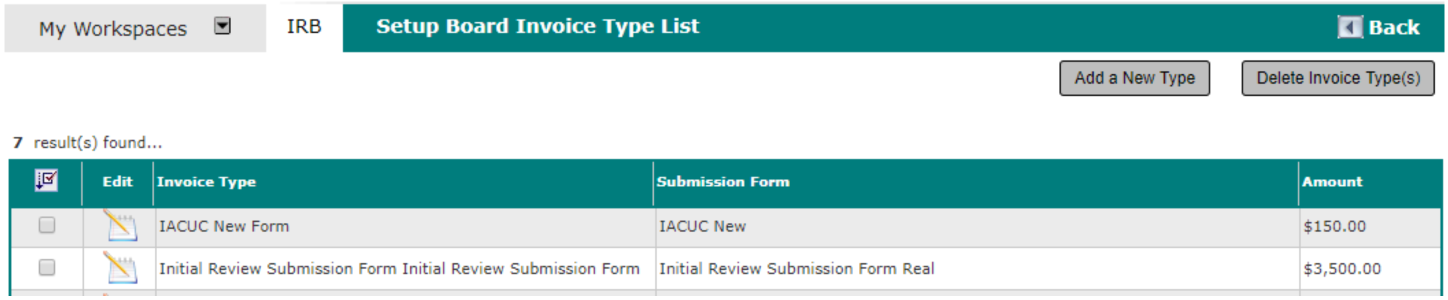
Add content to the template by inserting merge codes (click the **Insert Merge Code** button) and using the features available in the embedded Word editor.

When you are finished creating the template, click the **Save the Invoice Template** button to save.

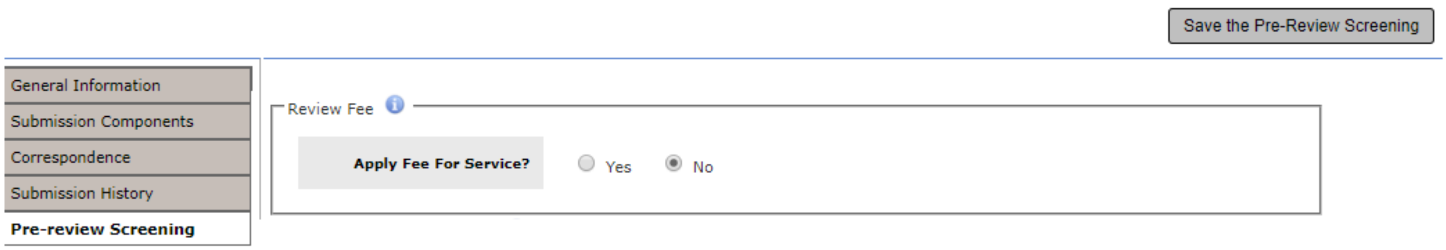
For more information on the IRB Invoicing feature, see the IRB Assistant - Invoicing manual.

Setup Invoice Type

In order for an item to appear on the Not Invoiced tab of the Invoice History list, there first must be an invoice type set up in Review Board Administration. Invoice types specify a fee and its associated submission form. Shown below is an example of a fee of $2,500.00 set up for Initial Review Submission forms.

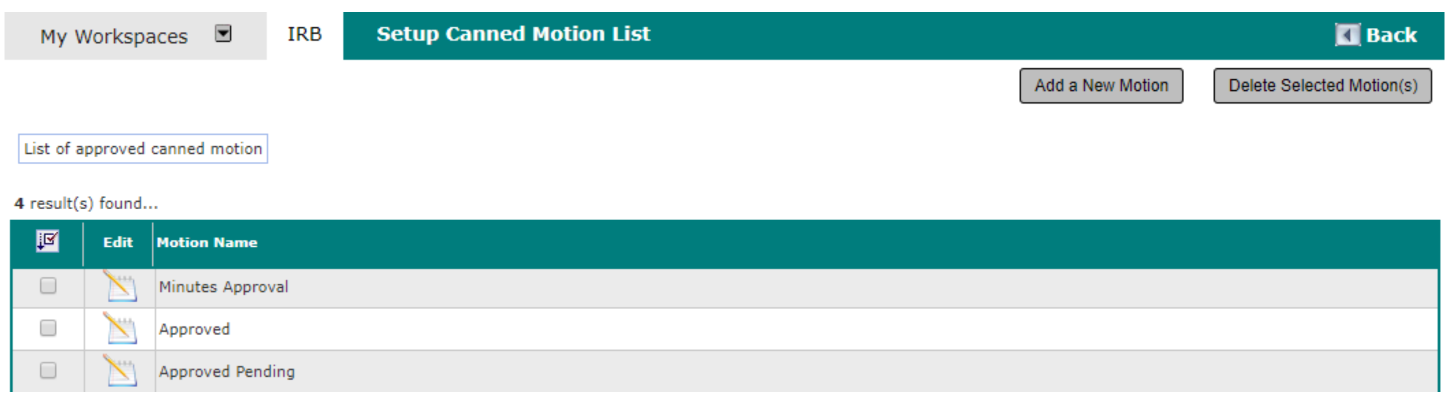


When a submission associated to an Invoice Type is processed by the IRB, the Coordinator will be able to indicate if the submission will receive a review service fee. If the review board indicates Yes to “Apply Fee For Service?” an Invoice item will be placed in Invoice History.

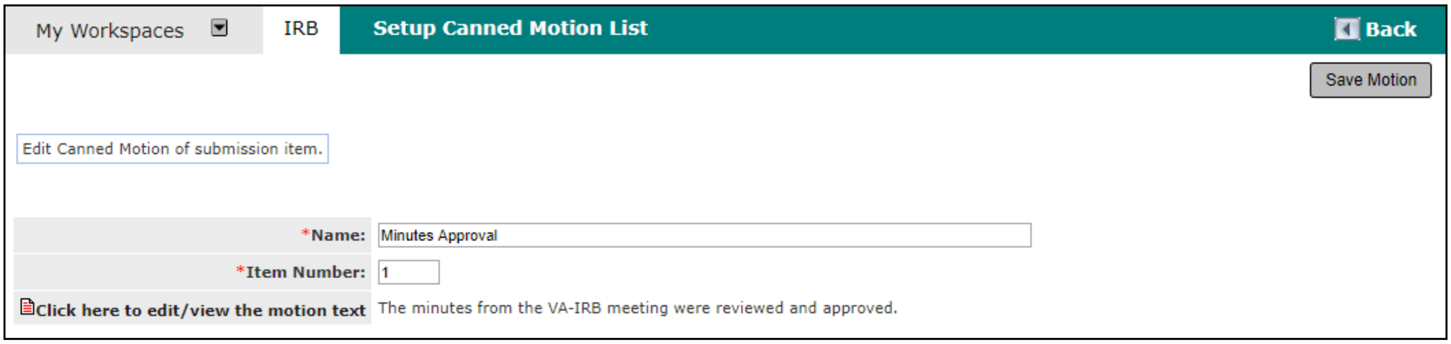


Setup Canned Motion

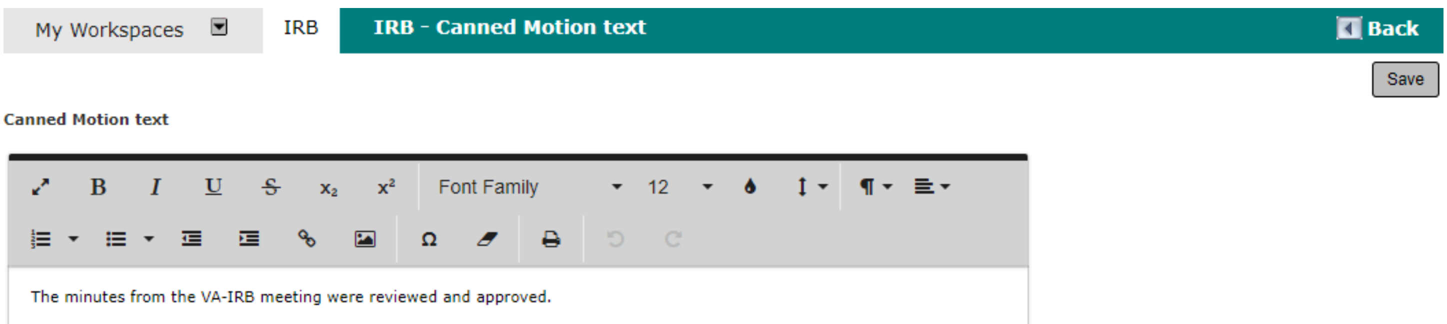
You can set up canned motion text that you can use to pull into a motion for a submission. You can have any number of canned motions in this list.



When you open the page, a list of any canned motions will display. If canned motions have not yet been added, this page will not list any records. You can click the **Add a New Motion** button to add a new canned motion to the list.

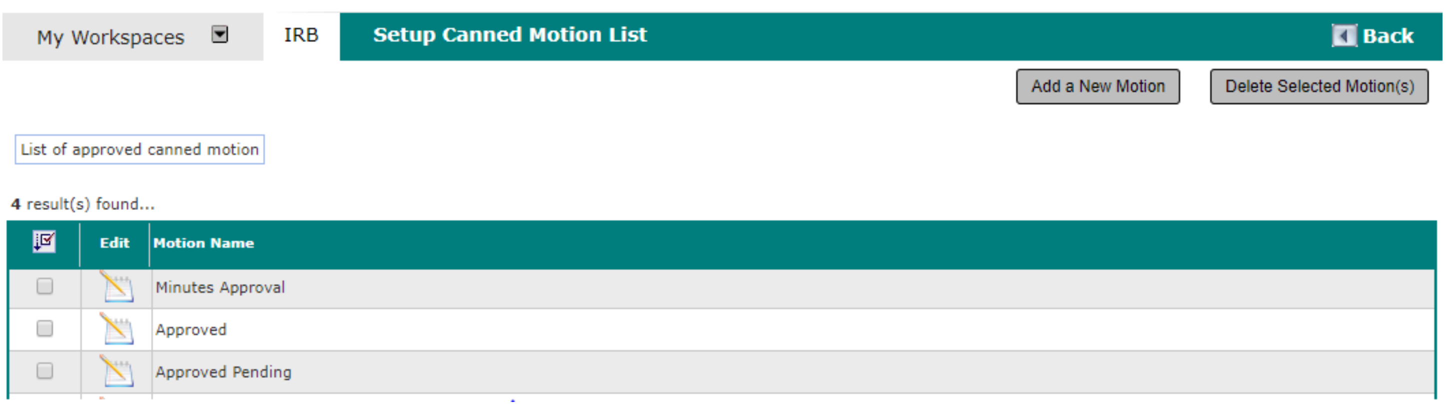


When you add a new canned motion, you will need to provide the Name of the motion and the Item Number (the order in which the canned motion is displayed). To add the content of the canned motion, click on **Click here to edit/view the motion text**.



This will open a new page containing an embedded rich text editor. You can copy and paste or type in your canned motion text. Click the **OK** button when you are ready to add the text to your motion.

After adding the Name, Item Number, and text for the canned motion, click the **Save Motion** button and the record will be added to the list of canned motions.



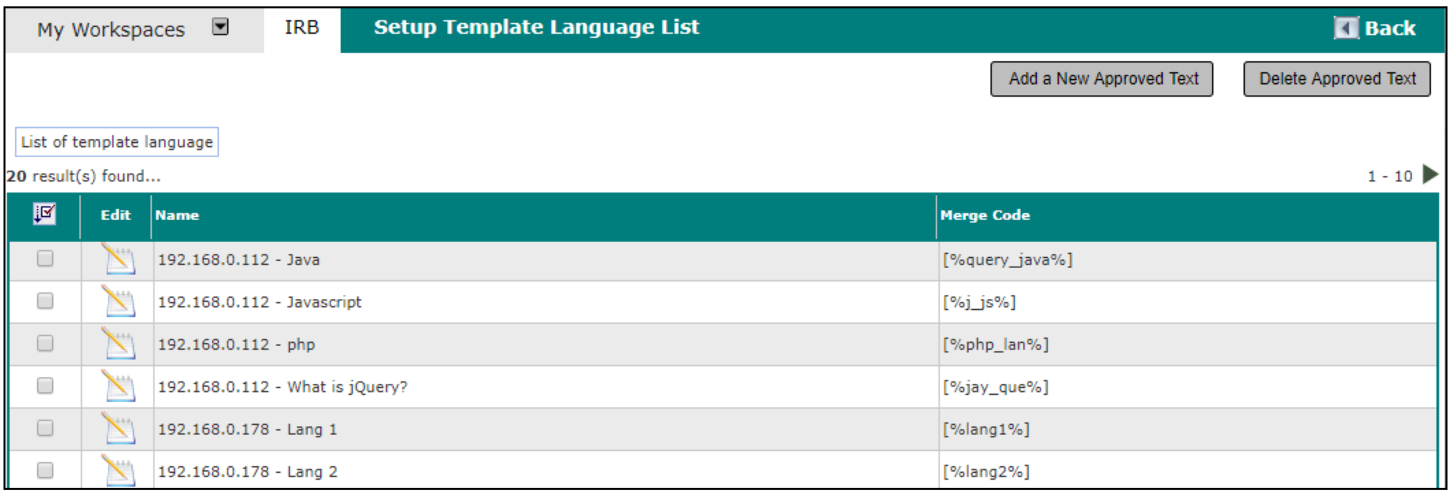
You can edit canned motions by clicking on the icon next to the name of the motion. This will open a new page allowing you to modify the Name, Item Number, and text for the canned motion.

You can delete a canned motion by selecting the checkbox next to the appropriate canned motion and clicking on the **Delete Selected Motion(s)** button. To select all of the motions listed, click the icon at the top of the column.

Any canned motion added will display in the Precanned Motion text drop-down list when you are adding a motion to a submission on the Vote tab of the submission processing screens.

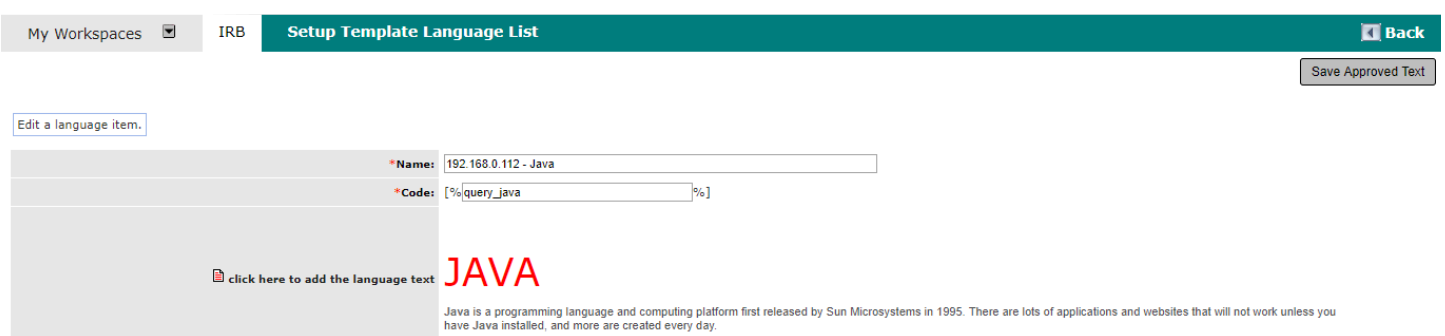
Setup Template Language

When you generate Minutes, Agendas, and Outcome Letters you have the ability to merge in template language. Template language can be used when there is specific language you need to repeatedly pull into documents. You can set up a list of different types of template language under Setup Template Language that you can pull as needed into your Minutes, Agenda, or Outcome Letter.

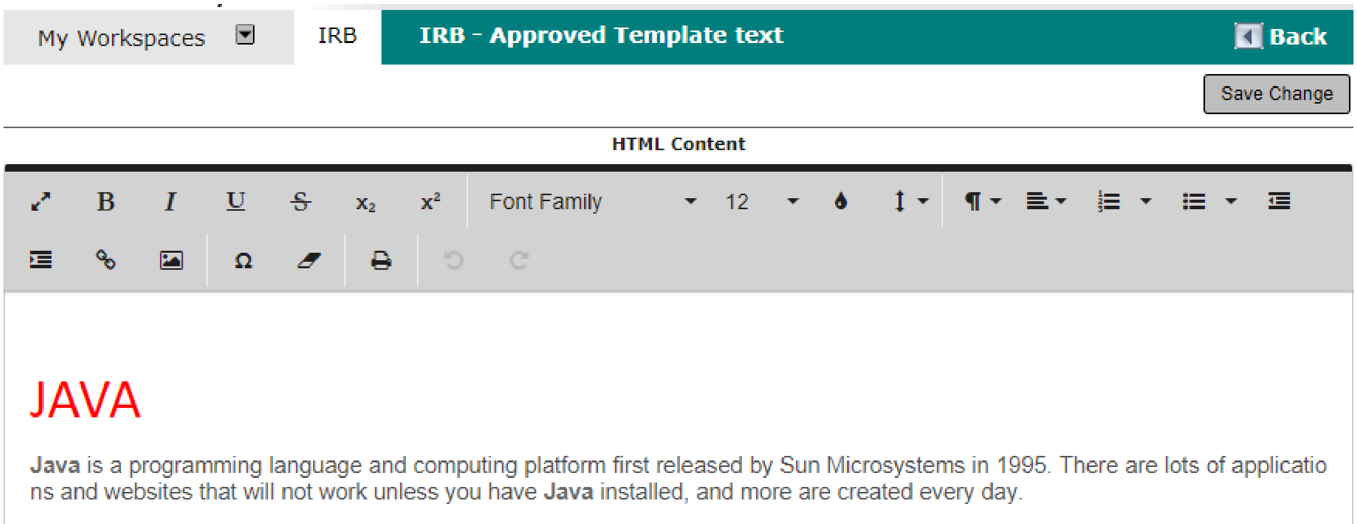


When you open the page, a list of any template language that has already been defined will display. If template language has not yet been added, this page will not list any records.

You can click the **Add a New Approved Text** button to add new template language to the list. You can also edit an existing letter by clicking on the icon.

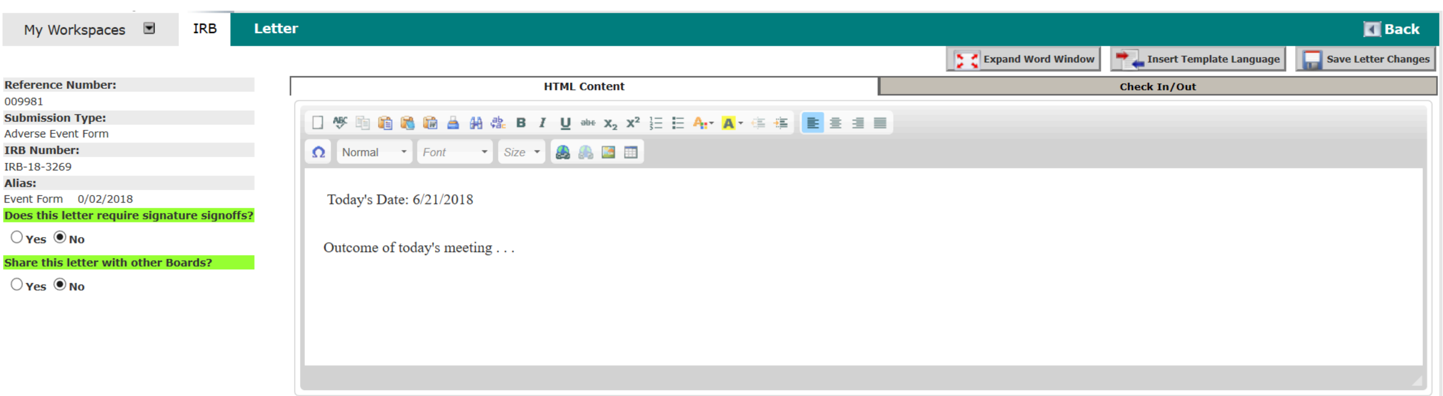


When you add a new template language, you will need to provide the Name of the template language as well as the Code (the merge code iRIS uses to insert language into a document). The Code must be alphanumeric and cannot contain spaces or special characters. To add the content of the template language, click on **Click here to add the language text.**

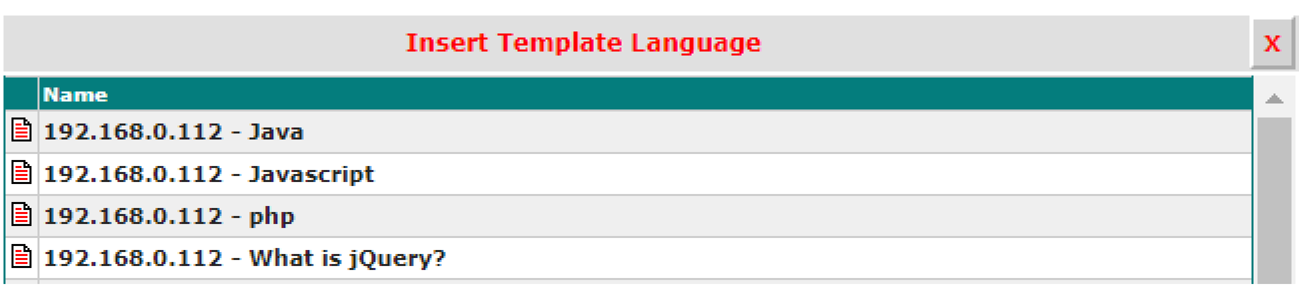


This will open a new page containing an embedded Word editor. You can copy and paste or type in your template language. Click the **Save Change** button when you are ready to save the text and return to the previous screen.

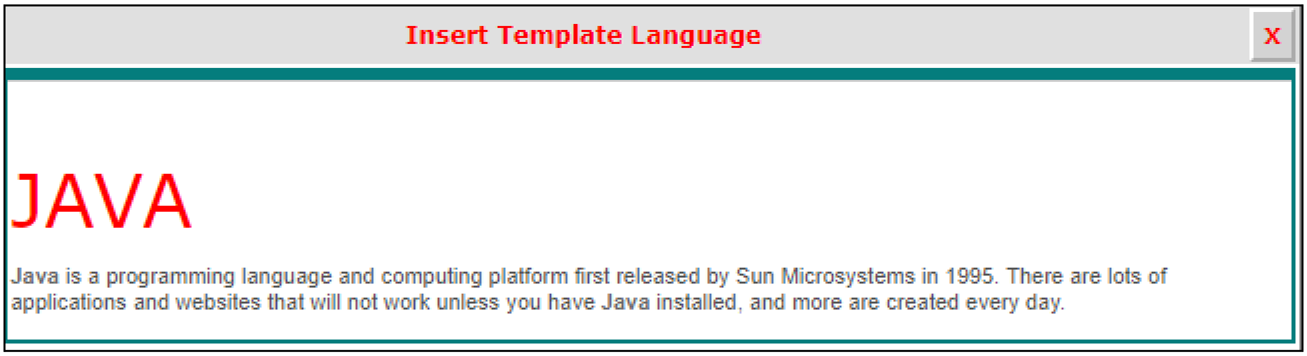
After adding the Name, Code, and text for the template language, click the **Save Approved Text** button and the record will be added to the list of template language.



Template Language can be inserted into Outcome Letters, Meeting Minutes, and Meeting Agendas. Above the embedded Word editor of the generated letter, agenda, or minutes you will see an **Insert Template Language** button. First, position your mouse cursor in the document where you would like to insert the language.



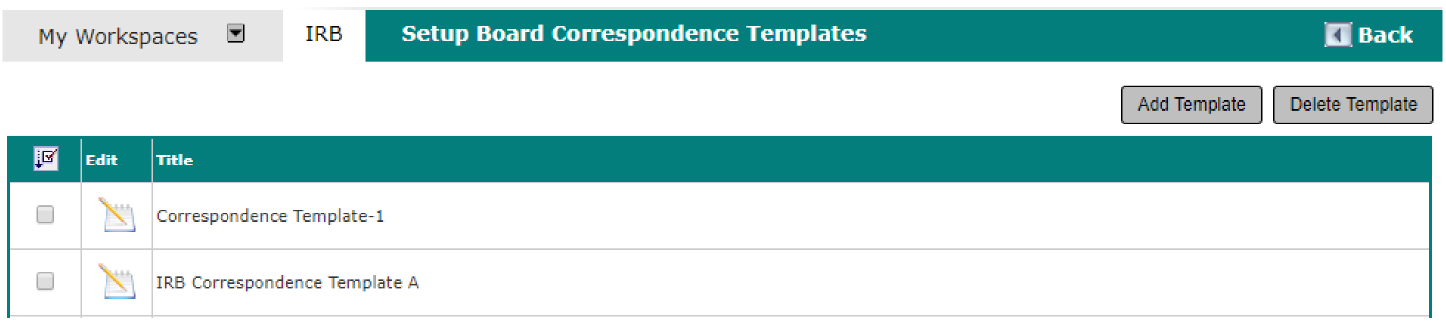
Clicking the **Insert Template Language** button will open a small popup window that will link to your list of template languages. Click on the language you wish to insert into the document.



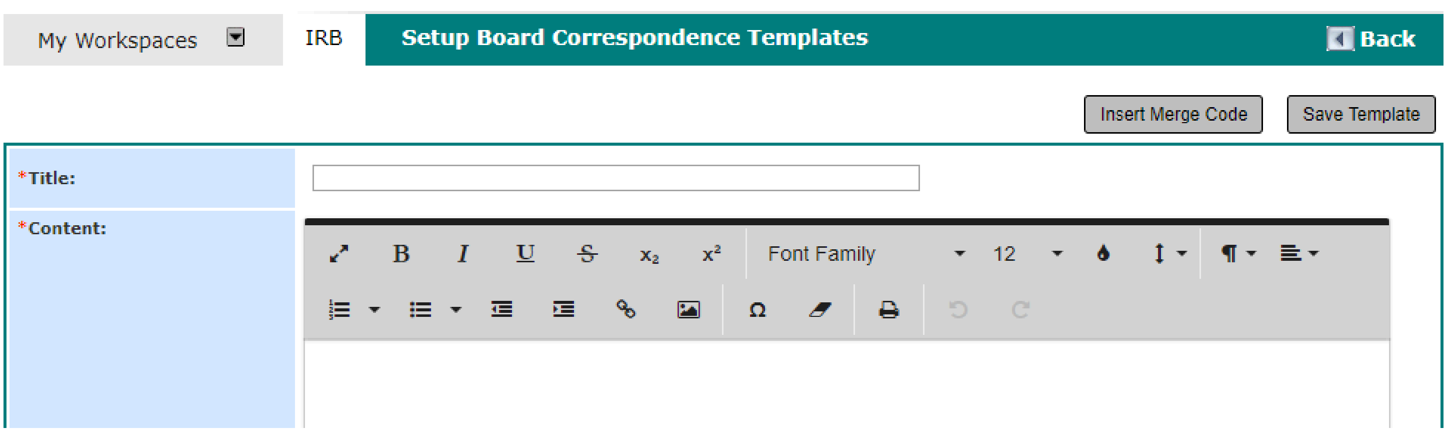
The popup will refresh, displaying the text of the template language. You can highlight the text of the language and copy and paste it into your document, or you can click on the **Insert Template Language** button in the window.

Setup Correspondence Template

You can set up templates that you can pull into correspondence generated for a submission. You can have any number of templates and pull any template into a correspondence within the submission processing screens.



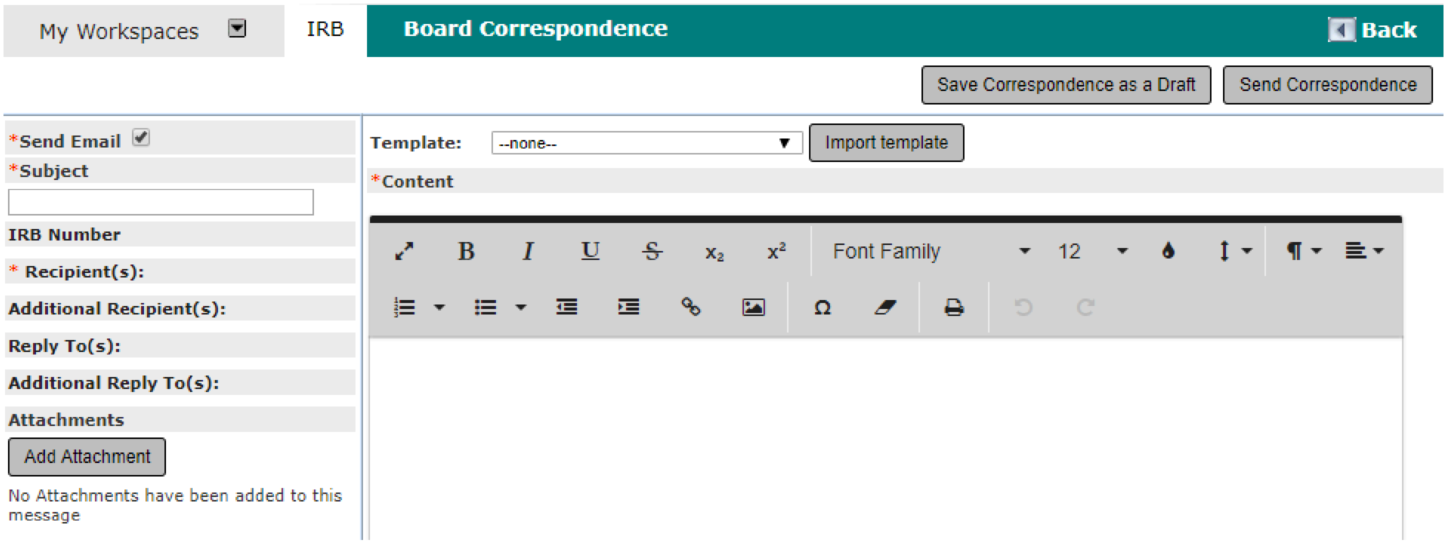
When you open the page, a list of any defined correspondence templates will display. If templates have not yet been added, this page will not list any records. You can click **Add Template** to add a new template to the list.



When you add a new correspondence template, you will need to provide the Title of the template language. Beneath the Title field is an embedded rich text editor where you can copy and paste or type in the content of your correspondence template. You can also insert merge codes that will pull in specific information when the correspondence template is added to a specific submission. To insert a merge code, position your mouse cursor in the document where you would like the code to be inserted, click the **Insert Merge Code** button, and then click the code you want to insert.

When you are finished adding content to the correspondence template, click the **Save Template** button.

Correspondence Templates are used on the Correspondence tab of the submission processing screens when you create a correspondence record. Above the embedded rich text editor, a drop-down menu will contain the available templates.

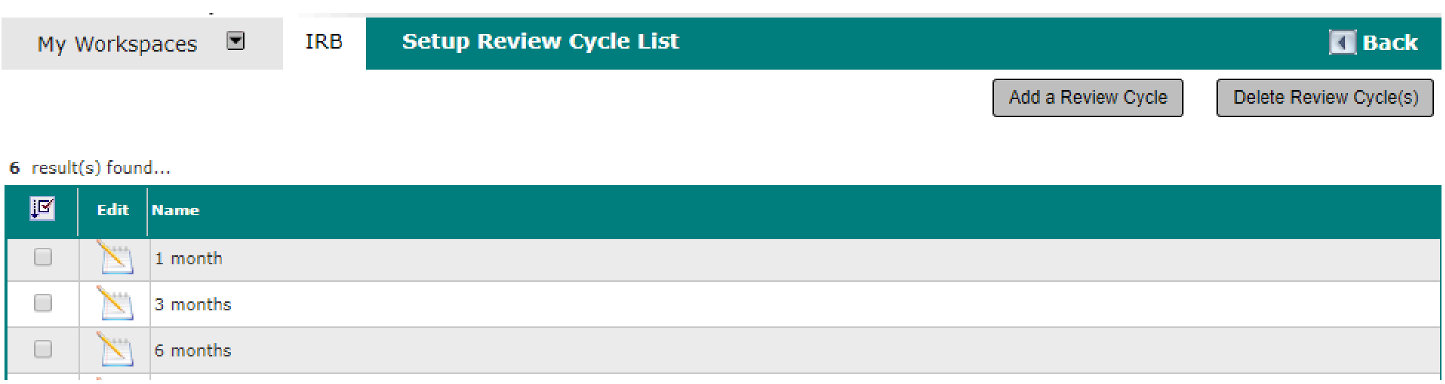


Setup Review Cycle

From this screen, you have the ability to create review cycles that can be used to calculate the IRB expiration date on the Outcome tab of the submission processing screens. If you have an IRB submission approval date, the IRB expiration date can be calculated based on your pre-defined review cycles. Please note that the review cycle calculates based on “x” amount of months.

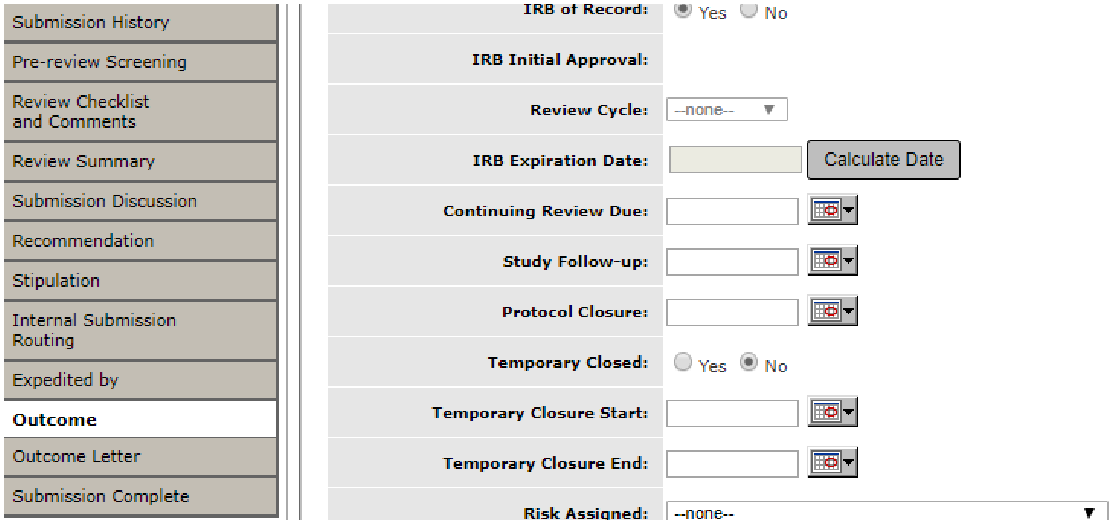
When you open the page, a list of any review cycles defined will display. If review cycles have not yet been added, this page will not list any records.

You can click **Add a Review Cycle** to add a new record to the list.

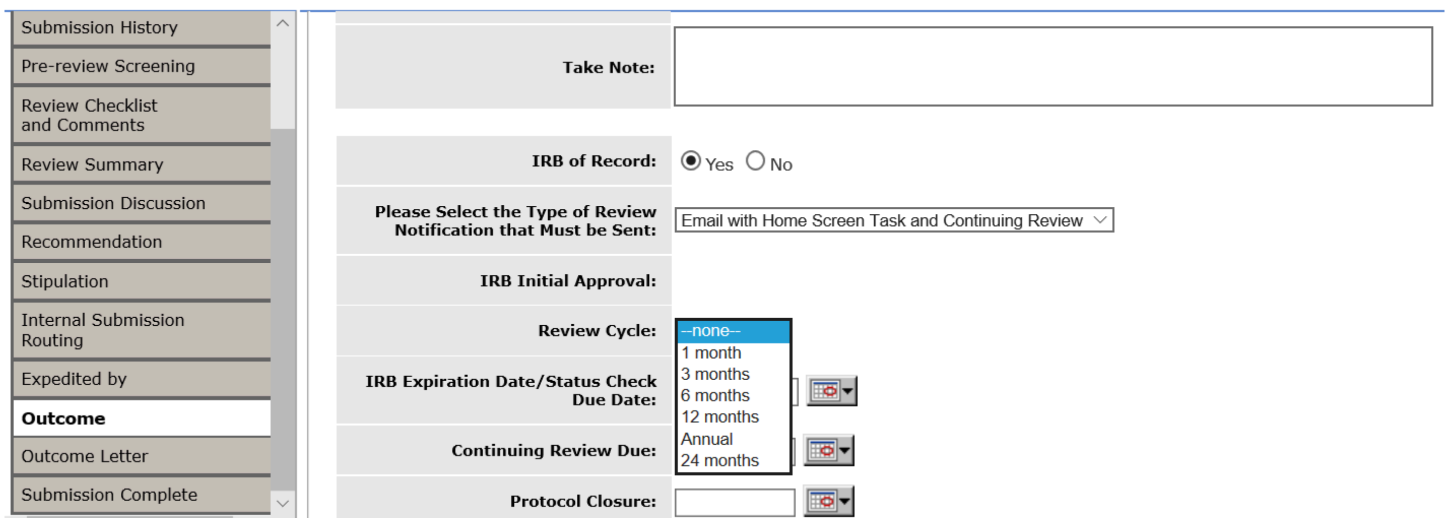


This will open a new page where you can enter information related to the review cycle.

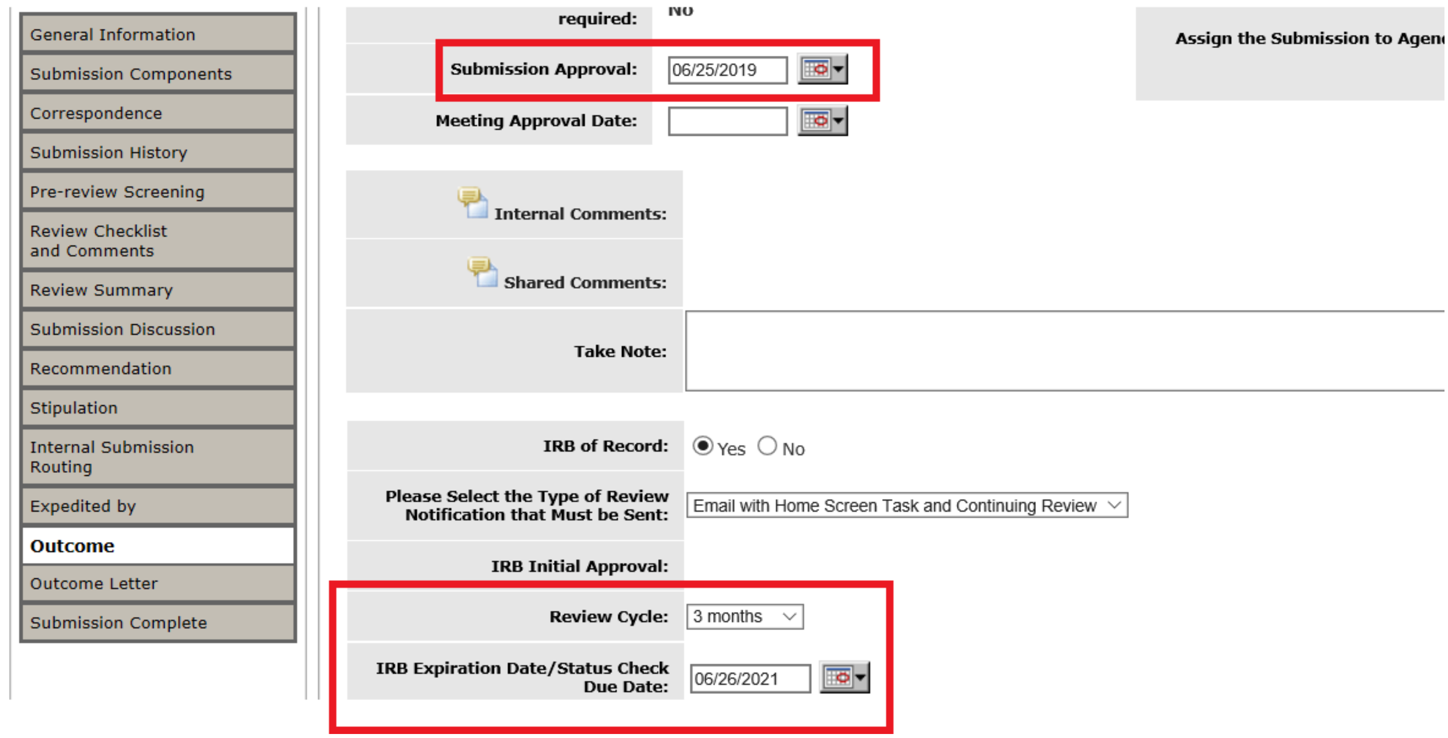
Enter the Name of the Review Cycle and the number of months in the Review Cycle Number in Months field. Click the **Save Review Cycle** button and the record will be added to the list of review cycles.



The Review Cycle is available on the Outcome tab within the submission processing screens. Once the approval information is entered, you may select a Review Cycle from the drop-down list, as shown in the screenshot below.

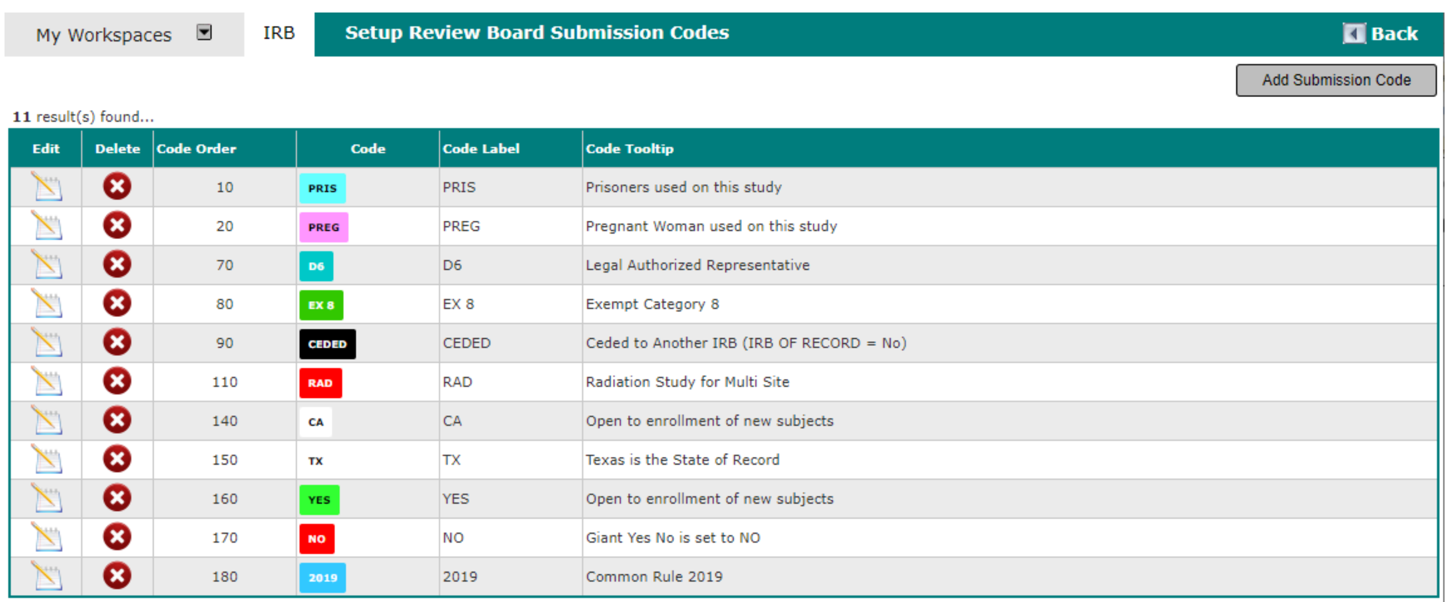


Based on the Submission Approval and the number of months associated to the Review Cycle selected, the IRB Expiration will auto-populate if *rb.use_autocal_expiration* is set to yes.



Setup Submission Codes (Not Applicable Unless Purchased)

This feature in iRIS is not available for general use, only an iMedRIS employee can adjust this information. Please contact your Project Manager or Customer Support Representative if you have any questions regarding the properties for this setup.



Edit	Delete	Code Order	Code	Code Label	Code Tooltip
		10	PRIS	PRIS	Prisoners used on this study
		20	PREG	PREG	Pregnant Woman used on this study
		70	D6	D6	Legal Authorized Representative
		80	EX 8	EX 8	Exempt Category 8
		90	CEDED	CEDED	Ceded to Another IRB (IRB OF RECORD = No)
		110	RAD	RAD	Radiation Study for Multi Site
		140	CA	CA	Open to enrollment of new subjects
		150	TX	TX	Texas is the State of Record
		160	YES	YES	Open to enrollment of new subjects
		170	NO	NO	Giant Yes No is set to NO
		180	2019	2019	Common Rule 2019

This area of the system will allow you to configure System Submission Codes essential to the operation for submissions. Create and maintain the submission codes for submission in the Setup Submissions Codes page. These codes will allow you identify characteristic of a protocol easily. When the properties: system.use_IRB_identifying_codes and "rb.use_identifying codes are set to yes, the Setup Submission Codes list will be available in the System Setup tab.

The Review Board Submission Codes are used for every single criteria described in Submission Form, Outcome tab or study application. The review board will maintain the submission codes of a particular study; however, the system will also default the appropriate code depending on the criteria selected.

The **Edit** column contains icons that you can click to open information about the submission code and **Edit.**

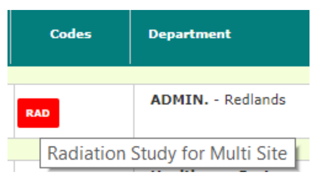
The **Delete** column is used to delete a submission code. To delete a submission code, click the icon next to the submission code desired.

The **Code Order** column determines sets the order of the submission code. The Code Order can be changed by typing in the new section order then clicking on the **Save Section Order** button.

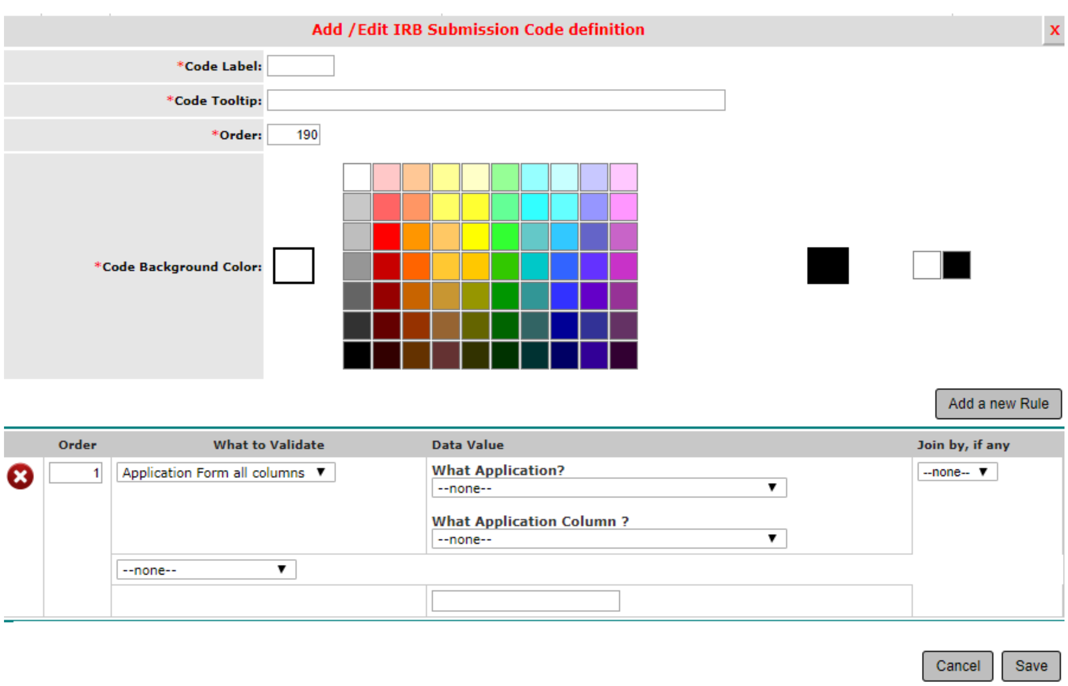
The **Code** column contains a sample of the assigned color and code label for the code.

The **Code Label** column is used when using the code, this is used as a reference point, so be sure to label it with an accurate description. The code label entered will display in the code column which will be associated to a specific color.

The **Code Tooltip** column is used to describe the code. This area allows you to create a help popup for specific words. By hovering the mouse cursor over the code, the tooltip text you entered in this column will display. This feature is helpful for complicated areas where providing additional explanations will be beneficial.

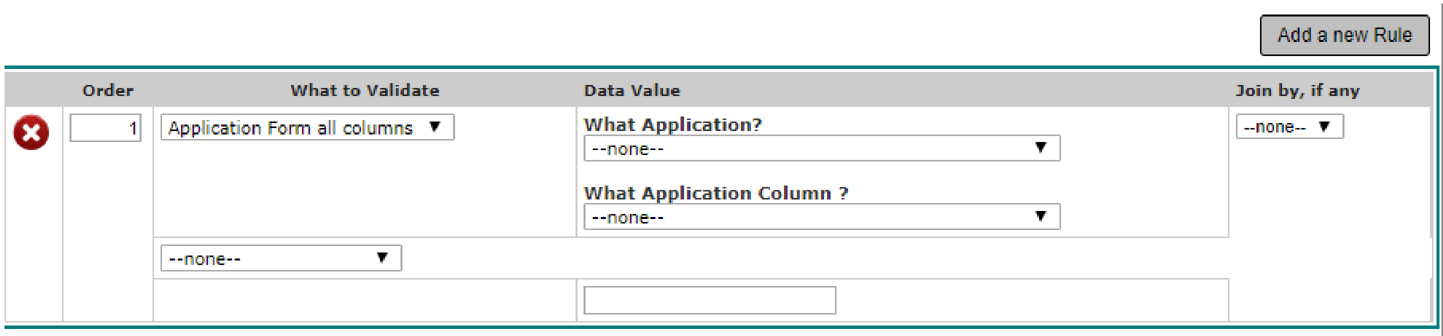


To create a new submission code, click the **Add Submission Code** button. The Add/Edit IRB Submission Code Definition page will open. All the field on this page are required fields.



You can use the bottom section of the page to setup rules within the application and submission form. Selecting the Add a New Rule button in this area will allow you to build rules for the inclusion of the section based on the criteria selected on the application form, IRB outcome fields and submission form.

Any code with an included rule defined will only display that code if the rules defined are met.



Order – This order field determines in which order the rules will be checked against the value entered by the user.

What to Validate column has a list of options from which to select from. You may select an application, a submission form or IRB outcome fields from the drop-down menu.

The **Data Value** column populates based on what was selected in the “What to Validate” column.

> **What Application** – This selection will pull in the names of all the application. This is used when you want your rule to reflect a value completed in the application form for the study or project. The Data Value column will first ask “What Application?” you are setting this rule for. Once this is selected, the “Data Type” column will update and ask which application to pull data from, then it will update with the database column name from the selected application.
>
> **What Application Column?** – Once an application is selected, the system will update database column name selected from that specific application selected to apply the code rule to.
>
> Note: The What Application Column populates based on what was selected in the “What to Validate” column. Keep in mind the Data Value is pulling the database column names that were created when the data value was created in System Forms Designer.
>
> **Setting the Validate Action** – After selecting the Data Value, you can indicate how the data value relates to the rule. In most cases, the “EQUAL” action will adequately capture the rule, however in some cases the other options need to be selected.
>
> EQUAL – This action is used to indicate that the value entered in the form for the specified Data Value must be equal to the selection.
>
> NOT EQUAL – This action is used to indicate that the value entered in the form for the specified Data Value must not equal the selection.

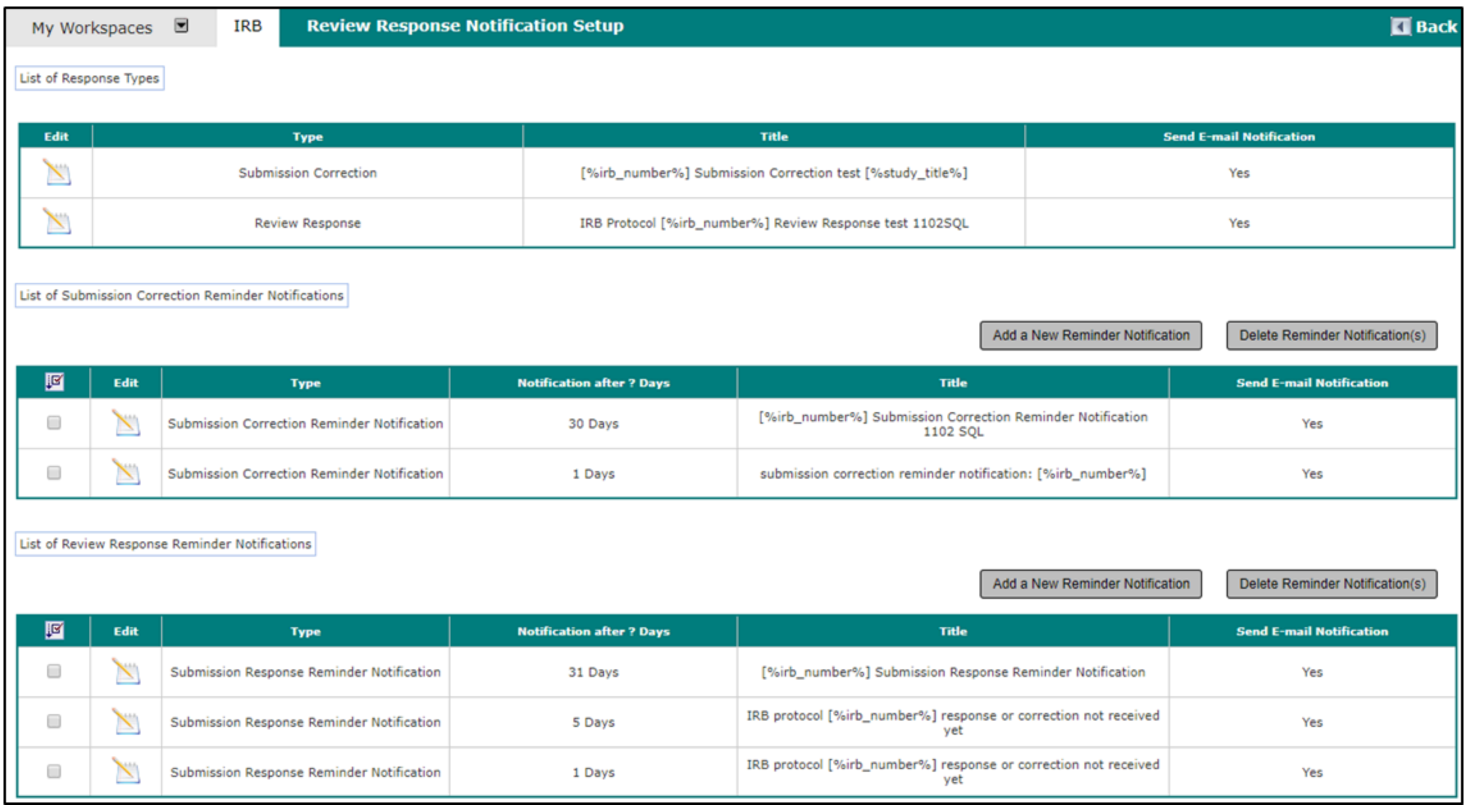
LESS THAN, LESS THAN EQUAL, GREATER THAN, GREATER THAN EQUAL – These actions can only be used when the Data Value selected is a numeric value. If this is the case, you can build a rule that will only trigger if the specified value for the data value is less than, less than or equal to, greater than, or greater than or equal to the value specified in this rule.

Join by, if any – This column will be used if your Validation determination is based on more than one value.

Review Board Notification Setup

Review Response Notification Setup

The Review response, or submission notifications, will generate and send to the study when a review board returns a submission for pre-review or post-review changes. You can also define reminder notifications to be sent when the study does not respond within a certain amount of time to these changes.



My Workspaces | IRB | Review Response Notification Setup | Back

List of Response Types

Edit	Type	Title	Send E-mail Notification
	Submission Correction	[%irb_number%] Submission Correction test [%study_title%]	Yes
	Review Response	IRB Protocol [%irb_number%] Review Response test 1102SQL	Yes

List of Submission Correction Reminder Notifications

Add a New Reminder Notification | Delete Reminder Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		Submission Correction Reminder Notification	30 Days	[%irb_number%] Submission Correction Reminder Notification 1102 SQL	Yes
		Submission Correction Reminder Notification	1 Days	submission correction reminder notification: [%irb_number%]	Yes

List of Review Response Reminder Notifications

Add a New Reminder Notification | Delete Reminder Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		Submission Response Reminder Notification	31 Days	[%irb_number%] Submission Response Reminder Notification	Yes
		Submission Response Reminder Notification	5 Days	IRB protocol [%irb_number%] response or correction not received yet	Yes
		Submission Response Reminder Notification	1 Days	IRB protocol [%irb_number%] response or correction not received yet	Yes

Response Types

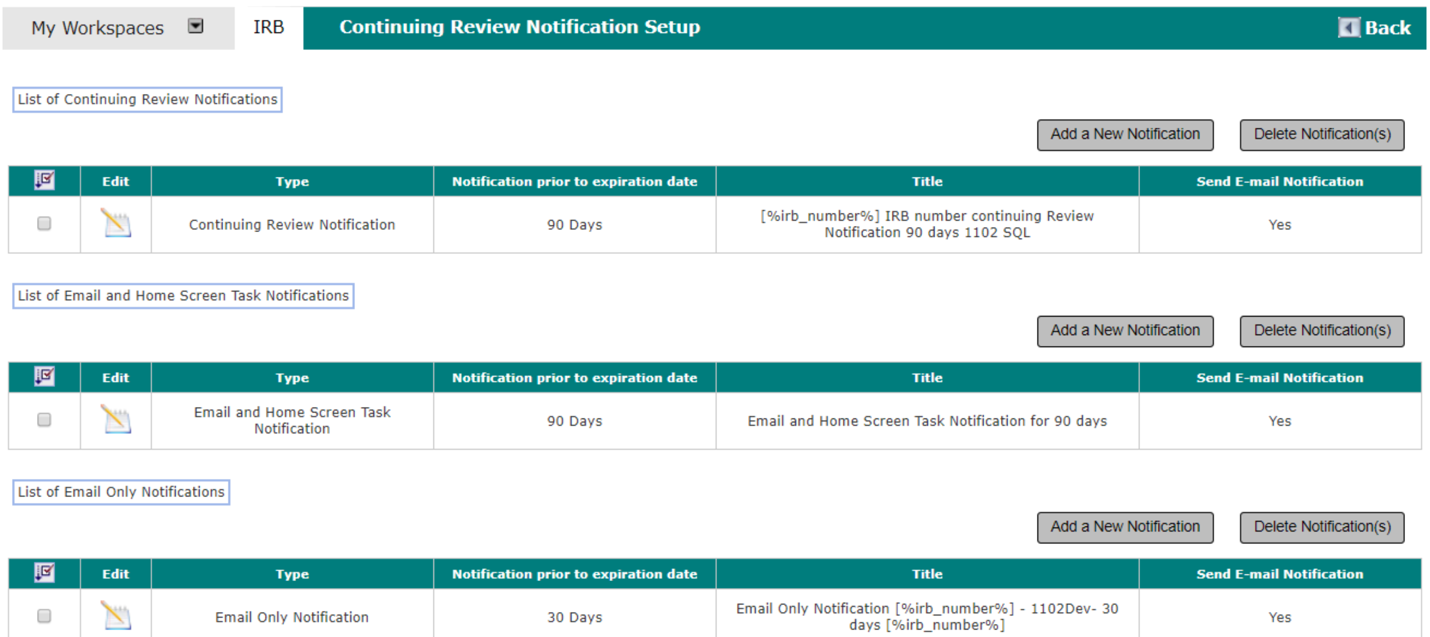
These two notifications will generate and send when the review board requests changes. The Submission Correction will generate and send when the review board indicates there are pre-review changes. The Review Response will generate and send when the review board adds stipulations and sets the Submission Outcome to an outcome that will return to the study.

Response Reminder Notifications

The Response Reminder notification will send to the study a certain amount of days after a submission has been returned to the study and works with the Submission Correction/Review Response. This notification will send x amount of days after the Submission Correction/Review Response has been sent, if the study has not responded.

Continuing Review Notification Setup

The Continuing Review Notification will alert selected users of an upcoming Continuing Review. An email will be sent out as specified in the screenshot below. Continuing Review notifications are sent to the Principal Investigator, and to the additional recipients configured to receive them by the board administrator. There are currently three notifications set up: one to be sent 90 days prior to the expiration date, one 60 days prior, and one 30 days prior. These can be modified and deleted, and new notifications can be added.



The notifications will be sent out on the amount of days specified before the Review Board Expiration Date set for the study by the IRB on the Outcome Tab.

Email and Home Screen Task Notification

These notifications will generate and send when the review board assigns a task. The Email and Home Screen Task Notification will send a notification to the home screen and send an email to the PI and Study Contact.

Email Only Notification

The Email Only notification will send an email to the study of upcoming Continuing Review but will not send a notification in iRIS. This notification will send x amount of days after the Submission Correction/Review Response has been sent, if the study has not responded.

Follow-up Study Notification Setup

When a Review Notification Type is select for a study status in System Administration > Setup System Status, the review notification type selected for the status will automatically display within the "Please Select the Type of Review Notification that Must be Sent" drop-down menu in the Outcome tab. This will allow a notification to be sent out for a study follow-up date, if the property “system.IRB_allow_cont_review_notification_selection_No’ is set to “Yes’ and the appropriate fields- Study Follow-up" and "Send Follow-up Notification?" fields have been selected in the Outcome tab.

You must select a Study Follow-up date and select the Yes Radio button for Send Follow-up Notification? In order for the notification to be sent out.

My Workspaces IRB **Follow-up Notification Setup** **Back**

List of Follow-up Notifications

Add a New Notification Delete Notification(s)

	Edit	Type	Notification After Follow-Up	Title	Send E-mail Notification
		Follow-up Notification	24 Months	Year 2 Follow-up [%irb_number%]	Yes

Expiring Study Notification

When the Expiring Study Notification property: rb.send_expiring_study_notification_to_PI_contact is set to “Yes”, the notification for the expiring study will be sent to the PI, and study contact. If the property is set to “No”, then it will be sent to the assigned analyst. If there is no analyst assigned, the notification will be sent to the coordinator(s).

Reviewers Notification Setup

Reviewers Notifications are sent to the assigned reviewers of a submission. There is also a notification you can set up to let the assigned analyst of a submission know when the reviewers have completed their reviews.

Reviewers Complete Notification

This notification will trigger and send to the assigned Analyst when reviewers are complete with their reviews on a submission.

List of RB Reviewers Complete Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Reviewers Complete Notification	Reviewers Complete Notification/10032	Yes	Delete Notification

Reviewer Assignment Notifications

These notifications will generate and send to an assigned reviewer based on the review process of the submission. You can also setup a notification to send to the reviewer if they have been removed from the review.

ist of Reviewer Assignment Notifications

Edit	Type	Title	Send E-mail Notification	Action
	Agenda Reviewer Assignment Notification	IRB Reviwer Assignment (10032 testing)	Yes	Delete Notification
	Expedited Reviewer Assignment Notification	Expedited VA & IRB Review Assignment	Yes	Delete Notification
	Designated Reviewer Assignment Notification	Designated Reviewer Assignment Notification/10032	Yes	Delete Notification
	Designated Review Member Assignment Notification	Designated Review Member Assignment Notification/10032	Yes	Delete Notification
	Exempt Reviewer Assignment Notification	Exempt Review-1102 SQL	Yes	Delete Notification
	Limited Review Reviewer Assignment Notification	Limited Reviewer Assignment Notification -1102 SQL	Yes	Delete Notification
	Process Administrative Reviewer Assignment Notification	VA IRB Administrative Review Assignment	Yes	Delete Notification
	Reviewer Unassignment Notification	VA IRB Reviewer Assignment Change	Yes	Delete Notification

Agenda Reviewer Assignment Notification

This notification will send to a full board reviewer. Note that you must also have Enable Reviewer Notifications set to Yes for the Meeting Date in Meeting Manager before any full board review notifications will send.

Expedited Reviewer Assignment Notification

This notification will send to an expedited reviewer as soon as you assign them to review an Expedited submission.

Exempt Reviewer Assignment Notification

This notification will send to a reviewer as soon as you assign them to review the Exempt submission.

Designated Reviewer Assignment Notification

This notification will send to a reviewer if you assign them to review a submission with the Designated Reviewer review process.

Designated Review Member Assignment Notification

This notification will be sent to a board member if they have been assigned to review a Designated Reviewer submission.

Process Administrative Reviewer Assignment Notification

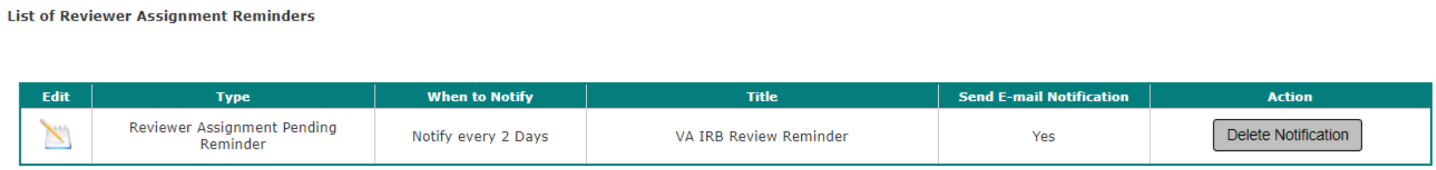
This notification will send to a reviewer as soon as you assign them to review a submission that has been given a review process of Process Administratively.

Reviewer Unassignment Notification

This notification will send if you delete a reviewer assignment task.

Reviewer Assignment Reminder

You can set up a notification that will send out a specified number of days after the review assignment to remind the reviewer of their task.

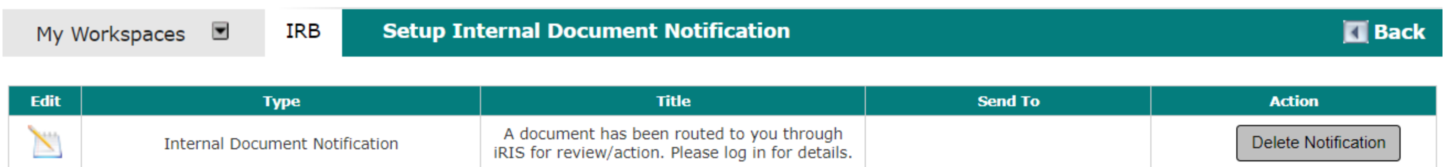


List of Reviewer Assignment Reminders

Edit	Type	When to Notify	Title	Send E-mail Notification	Action
	Reviewer Assignment Pending Reminder	Notify every 2 Days	VA IRB Review Reminder	Yes	Delete Notification

Internal Documents Notification

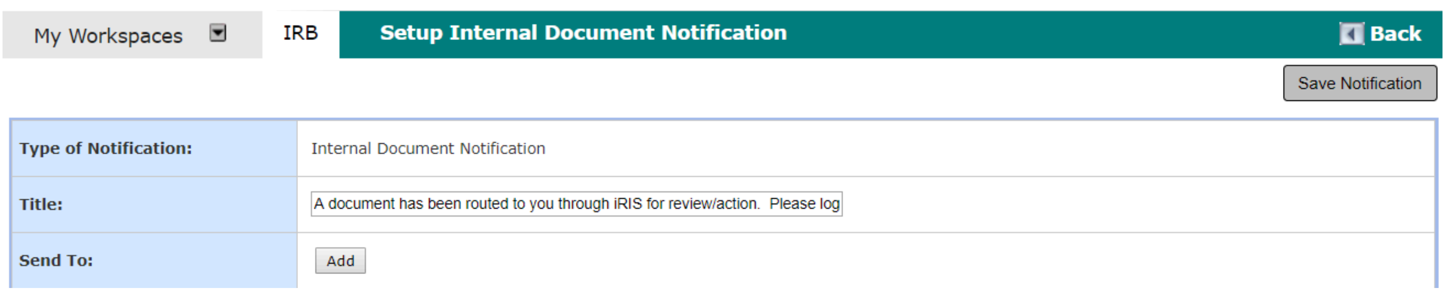
The review board has the ability to upload documents to a study record that are specific to the study and internal to the review board. When documents are uploaded, you have the ability to email that document to another user of the system. Notifications defined here will attach the uploaded document and send to the selected recipient.



My Workspaces | IRB | Setup Internal Document Notification | Back

Edit	Type	Title	Send To	Action
	Internal Document Notification	A document has been routed to you through iRIS for review/action. Please log in for details.		Delete Notification

From this page you will be able to add the title and define the recipient(s) for the notification.

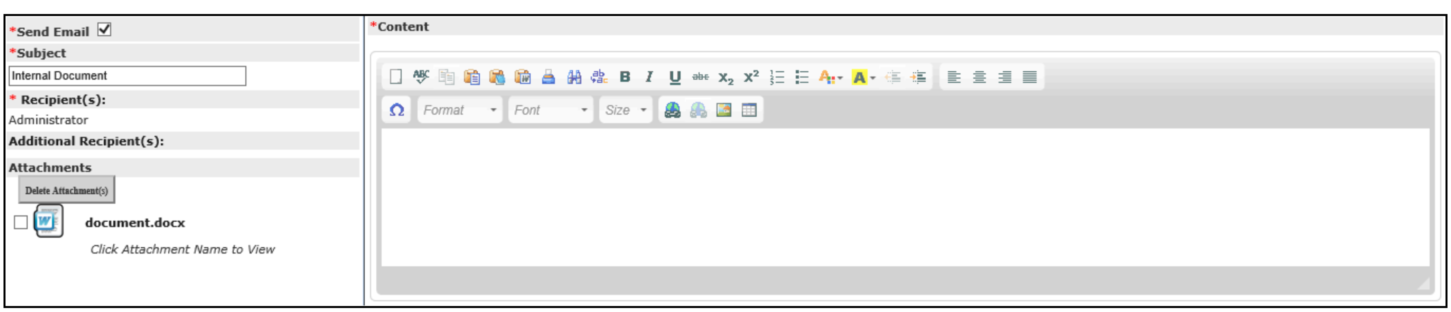


My Workspaces | IRB | Setup Internal Document Notification | Back

Save Notification

Type of Notification:	Internal Document Notification
Title:	A document has been routed to you through iRIS for review/action. Please log
Send To:	Add

The recipient of this notification is specified within the notification template, or any additional recipients manually added at the time you send the notification. The screenshot below shows an example of a template about to be sent from a study within the IRB board. The Recipients column pulled in the recipient as defined in the notification setup, and you can manually add additional recipients here.



The notification will send when you access Review Board Internal Documents within a study record within the IRB board. Select the checkbox next to the document you wish to send and then click the **Send Email** button.

This will cause the Internal Document Correspondence page to open. You can type in content for the notification, change the recipient list, or change the Subject line for the email. When you are done and ready to send the notification, click on the **Save & Send Correspondence** button.

Internal Routing Notification

These notifications will send to a user assigned an Internal Routing task and also to the Assigned Analyst when an Internal Routing task is completed.

My Workspaces | IRB | **Internal Routing Notification** | Back

Edit	Type	Title	Send E-mail Notification	Action
	RB Internal Submission Routing Signoff Notification	Notice of Internal Routing Assignment	Yes	Delete Notification

Edit	Type	Title	Send E-mail Notification	Action
	RB Internal Submission Routing Complete Notification	RB Internal Routing Complete Notification	Yes	Delete Notification

Internal Routing Assignment Notification

This notification sends to a user assigned an Internal Routing task.

Internal Routing Complete Notification

This notification will send to the Assigned Analyst when all assigned users have completed their Internal Routing tasks for a submission.

Pre-Review Assignment Notification

The Pre-Review Assignment Notifications will email to the study when a submission has been assigned a certain review process. Each notification listed on this page matches a process in the Pre-Review Screening tab of the submission processing screens.

My Workspaces | IRB | **Prereview Notification Setup** | Back

Edit	Type	Title	Send E-mail Notification	Action
	Prereview Agenda Assignment Notification	NOTICE OF AGENDA REVIEW ASSIGNMENT	Yes	Delete Notification
	Prereview Expedite Notification	Notice of Expedited Review Assignment	Yes	Delete Notification
	Prereview Exempt Notification	NOTICE OF EXEMPT ASSIGNMENT	Yes	Delete Notification
	Prereview Exempt Notification	Not Defined	Not Defined	Add Notification
	Prereview Administrative Notification	NOTICE OF PREREVIEW ADMINISTRATIVE ASSIGNMENT	Yes	Delete Notification

Pre-Review Agenda Assignment Notifications

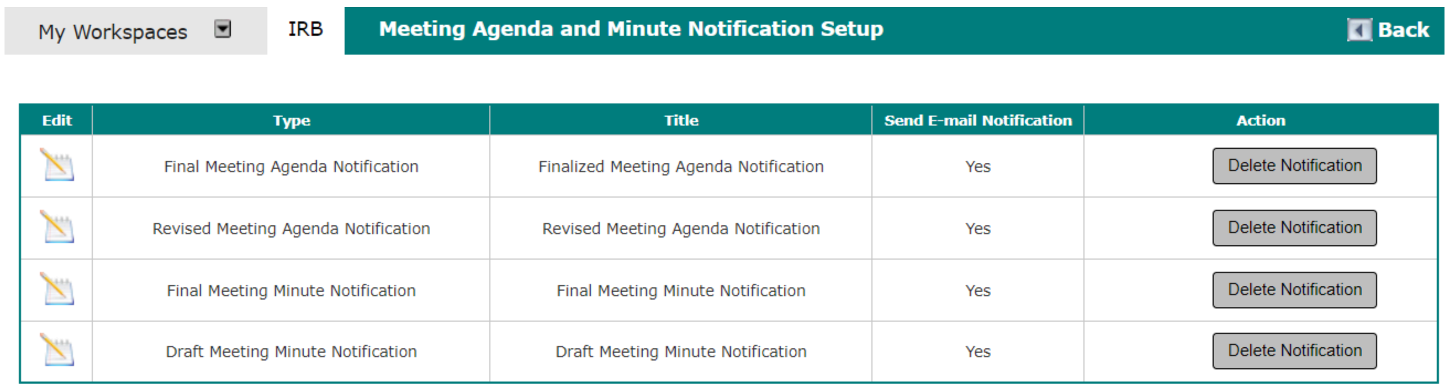
Pre-Review Agenda Assignment Notification is sent when a submission has been placed on the agenda for full board review.

Pre-Review Expedited, Exempt, and Administrative Notifications

The Pre-Review Expedited, Facilitated, Exempt, and Emergency Use Notifications are sent when a submission has been set to Expedited, Facilitated Review, Exempt, Emergency Use by the IRB. Depending on your system settings, you may or may not have all these notification types listed on this page.

Meeting Agenda and Minute Notification

The Meeting Agenda and Minutes notifications send out to board members when you generate, publish, and then indicate to the system to send out the agenda template or minutes template for a specific meeting date in the Meeting Manager. These notifications generate and will attach the PDF-published versions of the appropriate document. They will send to all board members or to members present at a specific meeting, depending on what notification is sending out.



Edit	Type	Title	Send E-mail Notification	Action
	Final Meeting Agenda Notification	Finalized Meeting Agenda Notification	Yes	Delete Notification
	Revised Meeting Agenda Notification	Revised Meeting Agenda Notification	Yes	Delete Notification
	Final Meeting Minute Notification	Final Meeting Minute Notification	Yes	Delete Notification
	Draft Meeting Minute Notification	Draft Meeting Minute Notification	Yes	Delete Notification

Final Meeting Agenda Notification

This notification will generate when you send the published Meeting Agenda for a specific meeting date in the Meeting Manager. It will attach the PDF Meeting Agenda and send to all board members.

Revised Meeting Agenda Notification

This notification will generate when you send a published Revised Meeting Agenda for a specific meeting date in the Meeting Manager. It will attach the PDF Meeting Agenda Revision and send to all board members.

Final Meeting Minute Notification

This notification will generate when you send the published Meeting Minutes for a specific meeting date in the Meeting Manager. It will attach the PDF Meeting Minutes and send to all board members present at the meeting.

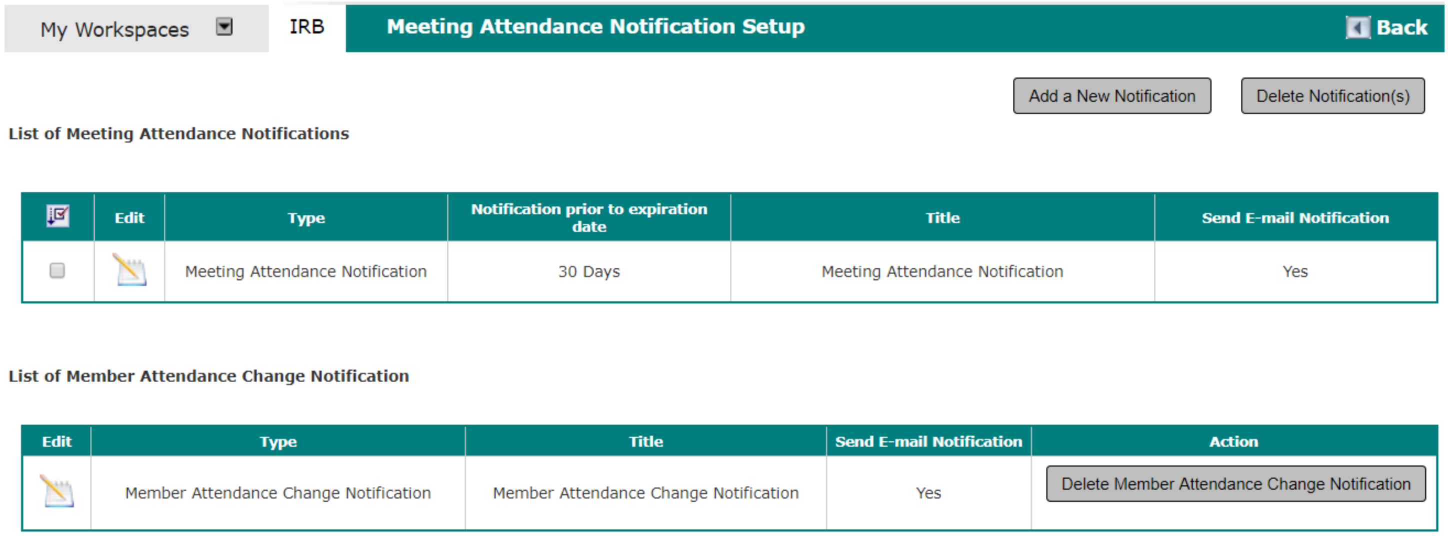
Draft Meeting Minute Notification

This notification will generate when you send a copy of the Draft Meeting Minutes for a specific meeting date in the Meeting Manager. It will attach the PDF Draft Meeting Minutes and send to all board members present at the meeting.

Meeting Attendance Notification

You can set up notifications that will send to board members a certain amount of days prior to a meeting date, asking them to log in to the system and set their meeting availability. You can also setup a notification that will send to IRB

Coordinators if any member changes their availability within a certain amount of time prior to a meeting date.


My Workspaces | IRB | Meeting Attendance Notification Setup | Back

Add a New Notification | Delete Notification(s)

List of Meeting Attendance Notifications

	Edit	Type	Notification prior to expiration date	Title	Send E-mail Notification
		Meeting Attendance Notification	30 Days	Meeting Attendance Notification	Yes

List of Member Attendance Change Notification

Edit	Type	Title	Send E-mail Notification	Action
	Member Attendance Change Notification	Member Attendance Change Notification	Yes	Delete Member Attendance Change Notification

Meeting Attendance Notifications

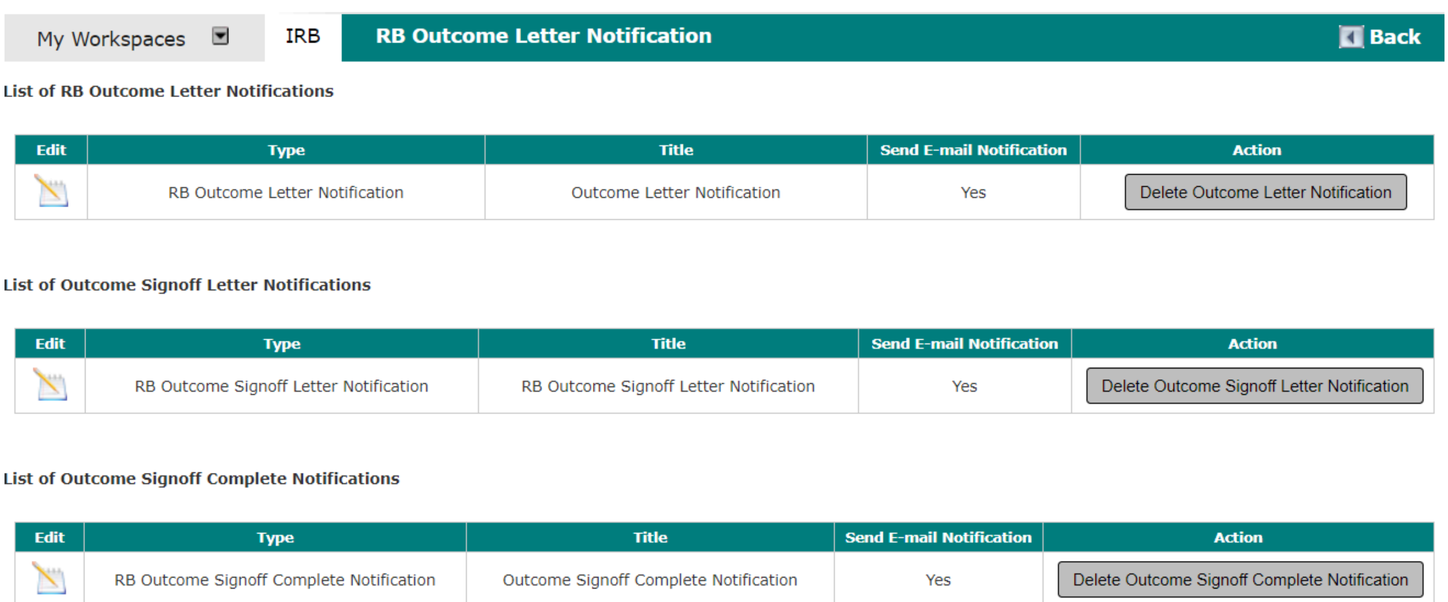
If you would like to send notifications to board members to alert them to set their availability for upcoming meetings, you can set up reminders here. These notifications will send a certain amount of days prior to a meeting date to let the member know they need to set their availability. You can have any number of notifications set up.

Member Attendance Change Notification

This notification will send to IRB Coordinators a certain amount of time prior to the meeting date if any member has changed their availability.

Outcome Letter Notification

Notifications related to Outcome Letters are set up here. These notifications send to Outcome Letter recipients, to users assigned to sign an Outcome Letter, and to alert analysts that signoffs on letters have been completed.


My Workspaces | IRB | RB Outcome Letter Notification | Back

List of RB Outcome Letter Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Outcome Letter Notification	Outcome Letter Notification	Yes	Delete Outcome Letter Notification

List of Outcome Signoff Letter Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Outcome Signoff Letter Notification	RB Outcome Signoff Letter Notification	Yes	Delete Outcome Signoff Letter Notification

List of Outcome Signoff Complete Notifications

Edit	Type	Title	Send E-mail Notification	Action
	RB Outcome Signoff Complete Notification	Outcome Signoff Complete Notification	Yes	Delete Outcome Signoff Complete Notification

Outcome Letter Notification

This is the notification that will generate and send to the recipients selected when you send an Outcome Letter. This notification will attach the PDF Outcome Letter.

Outcome Signoff Letter Notification

This is the notification that will generate and send to a user assigned to sign off on an Outcome Letter.

Outcome Signoff Complete Notification

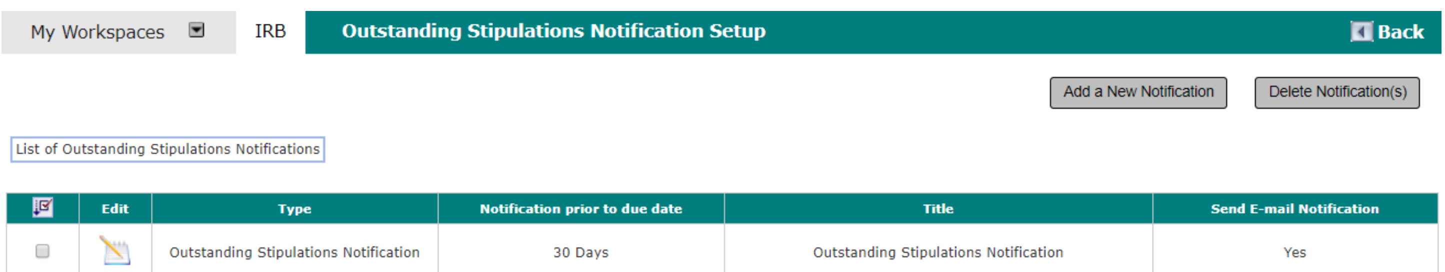
This is the notification that will generate and send to an assigned analyst when all signoff tasks for the letter have been completed.

Designated Review Agenda Assistant Notification

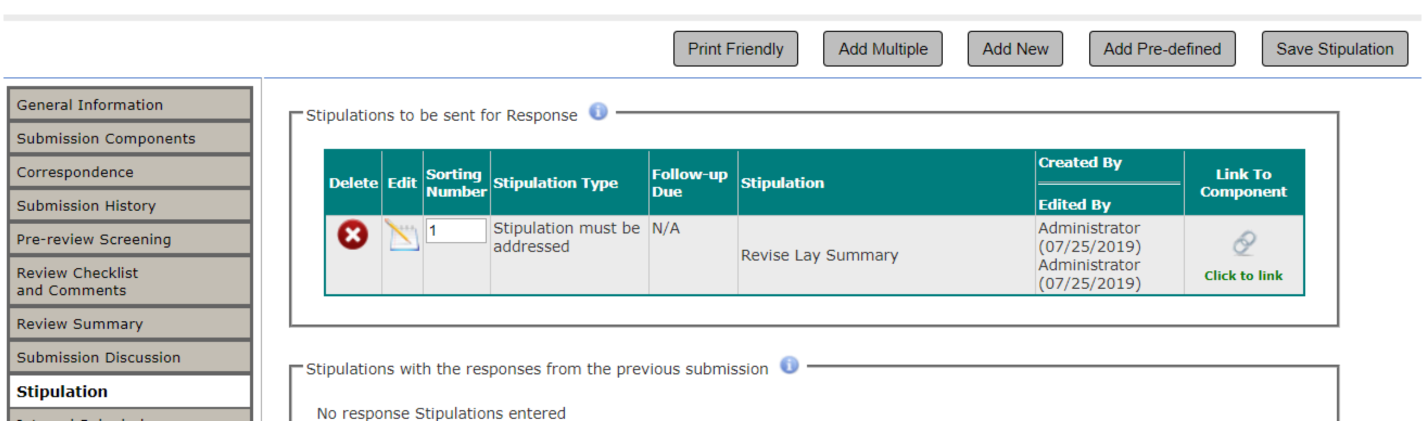
The review agenda notification will be sent when a user has been assigned the role of a Designated Reviewer for a study and the reviewer need to submit their review comments within a specific amount of time.

Outstanding Stipulations Notification

These notifications are sent to the PI, Study Contact, and assigned analyst on the defined number of days before the follow-up due date defined by the IRB in a stipulation. There are three notifications shown below as examples in this group of notifications. One is designed to be sent 1 day before the due date of the stipulation and the others are designed to be sent 5 days and 30 days before the due date of the stipulation. These notifications will not be sent if the Review Board has closed the stipulation and assigned a Date Closed prior to the day the notification would be triggered.



When the IRB defines a stipulation, the stipulation type "Comments that must be addressed" causes the follow up date field to appear. When this is defined, then the number of days defined in the notification before this follow-up date is when the notifications will be sent.

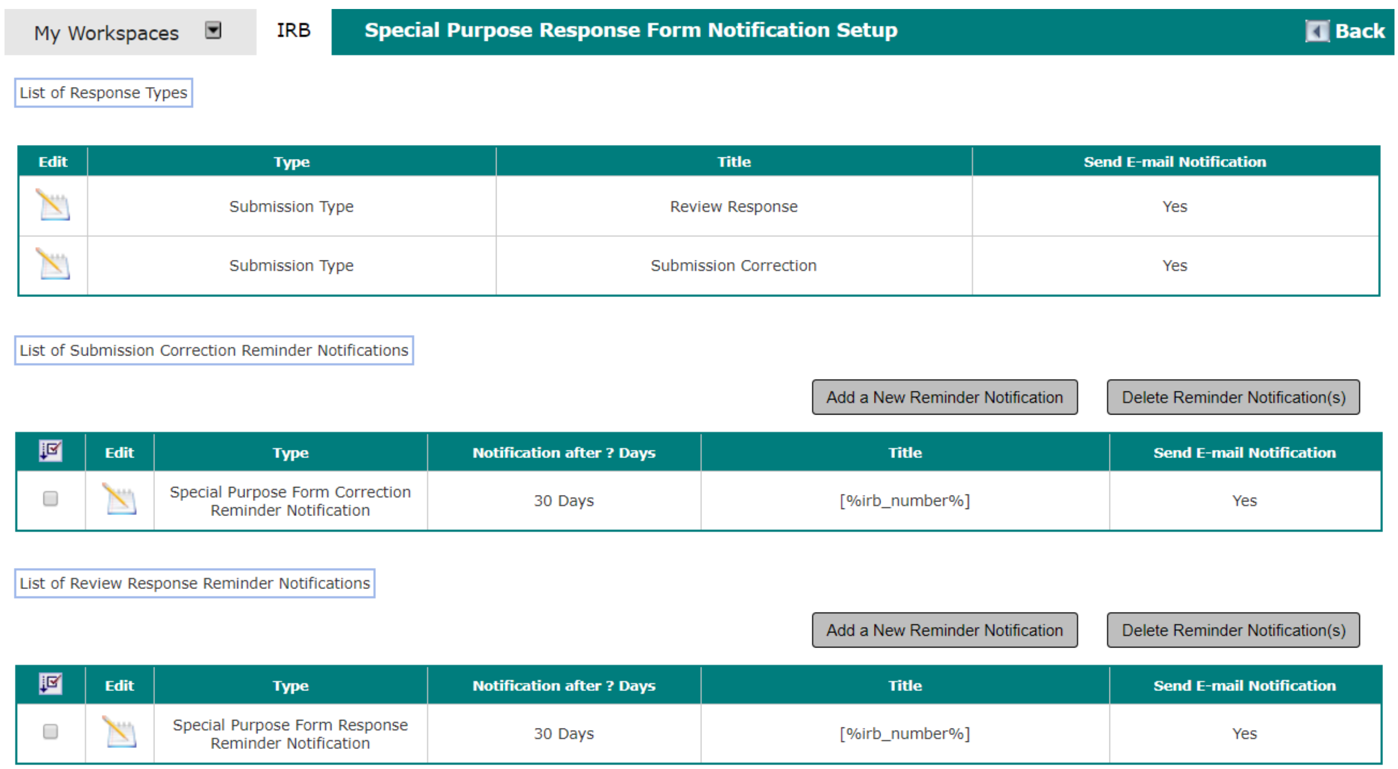


If the study returns the submission correction form with the stipulations addressed, and the review board takes an action and assigns a Date Closed before the day that the notification has been set up to send out, then the notification will not be triggered.

In order to add an outstanding stipulation notification, simply click the Add a New Notification button and fill in the Title, the Notification if within number of days, the Send Email Notification, and the E-mail Content. Merge codes can be inserted into the email as defined in Submission Notification Setup.

Special Purpose Forms Response Notification Setup

Here, you can configure notifications, including reminder notifications, for Submission Correction and Review Response forms for Special Purpose submissions.


My Workspaces | IRB | Special Purpose Response Form Notification Setup | Back

List of Response Types

Edit	Type	Title	Send E-mail Notification
	Submission Type	Review Response	Yes
	Submission Type	Submission Correction	Yes

List of Submission Correction Reminder Notifications

Add a New Reminder Notification | Delete Reminder Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		Special Purpose Form Correction Reminder Notification	30 Days	[%irb_number%]	Yes

List of Review Response Reminder Notifications

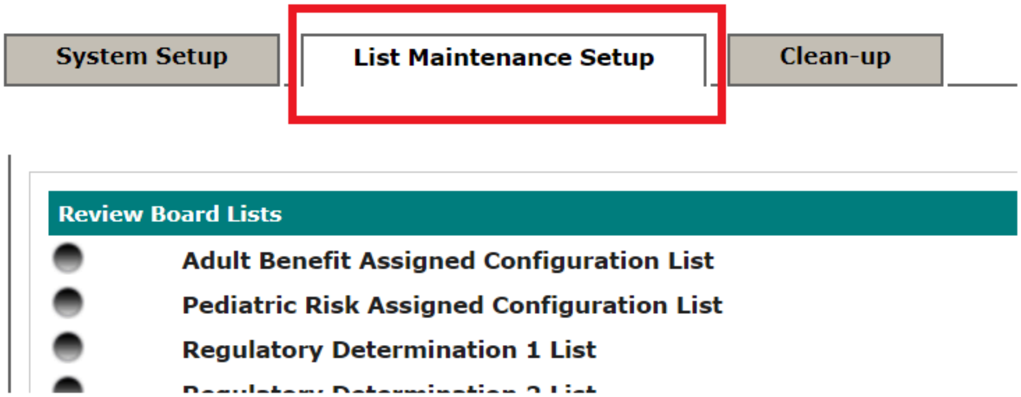
Add a New Reminder Notification | Delete Reminder Notification(s)

	Edit	Type	Notification after ? Days	Title	Send E-mail Notification
		Special Purpose Form Response Reminder Notification	30 Days	[%irb_number%]	Yes

When configuring these notifications, the “Form Author” merge codes described in the previous section are available for use.

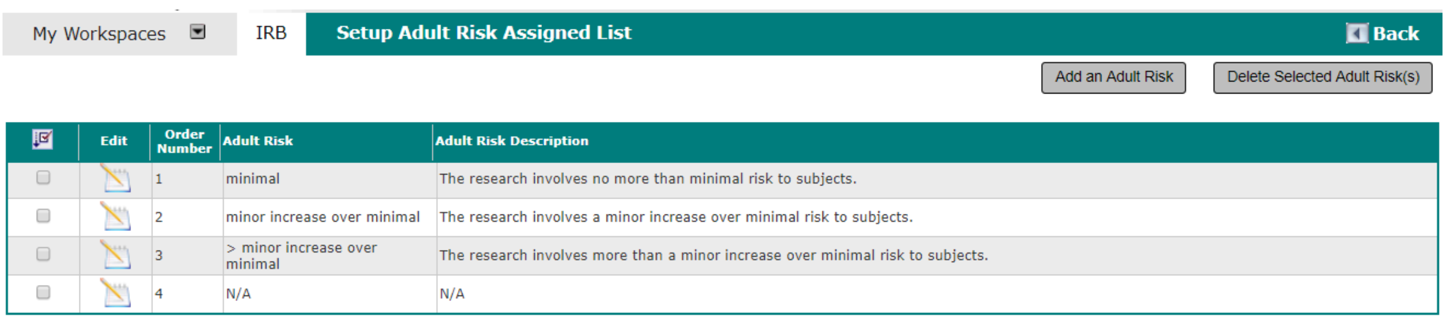
List Maintenance Setup

List Maintenance Setup is where you set up the information that will appear in review board drop-down lists.



Adult Risk Assigned Configuration List

The Adult Risk Assigned Configuration List allows you to set up a list of current risk ratings that the review board uses to rate the adult risk for a particular study. Depending on whether the rb.use_adult_risk_assigned property is turned on, this configuration list may not appear.



	Edit	Order Number	Adult Risk	Adult Risk Description
		1	minimal	The research involves no more than minimal risk to subjects.
		2	minor increase over minimal	The research involves a minor increase over minimal risk to subjects.
		3	> minor increase over minimal	The research involves more than a minor increase over minimal risk to subjects.
		4	N/A	N/A

To delete one or more Adult Risk Assigned record(s), check the boxes next to the record(s) to be deleted, and then click the **Delete Selected Adult Risk(s)** button. A dialog box will open. Click the **OK** button to continue and delete the record(s). Click the **Cancel** button and the record(s) will not be deleted.

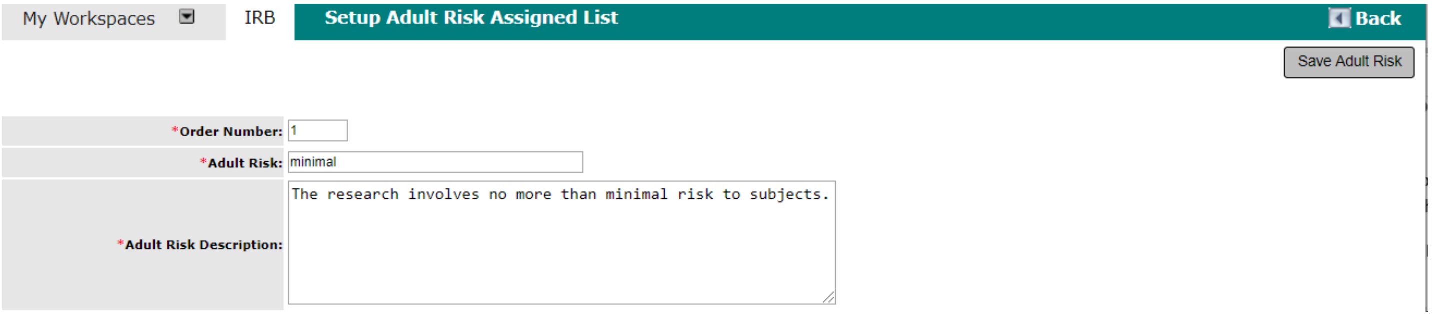
To edit a risk, click the icon next to the risk to be edited. After a new page opens, you may change the name, order, and description of the risk. Click the **Save Adult Risk** button to save the changes.

The Order Number indicates the order in which these risk categories will appear in the actual drop-down list on the Outcome tab.

The Adult Risk field displays the name of the risk that will be displayed for the reviewer to choose.

The Adult Risk Description explains when this Adult Risk category might be assigned.

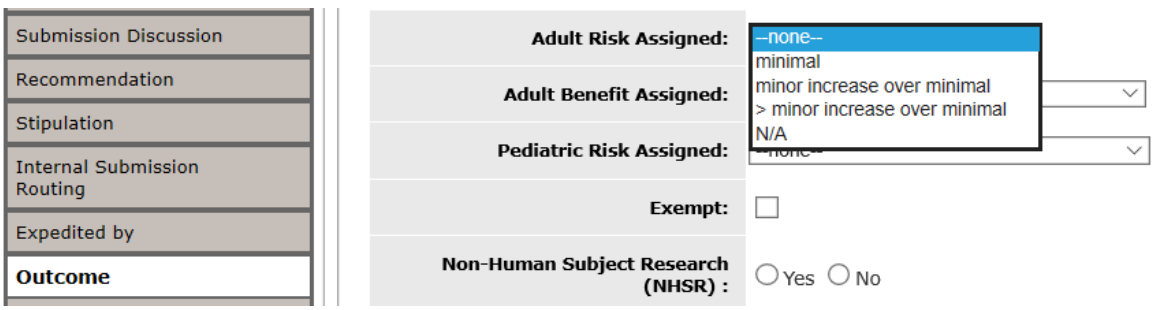
After returning to the main Setup Adult Risk Assigned List screen, click the **Add Adult Risk** button to add a record to the list.



Enter the order of the risk, the Adult Risk name and enter a detailed description of this risk category.

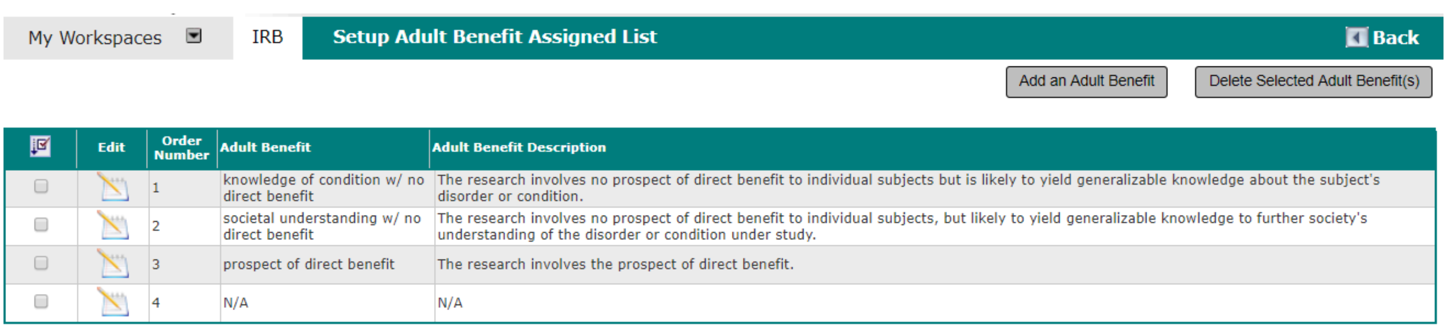
Click the **Save Adult Risk** button to add the risk to the Adult Risk Assigned page.

The list that is defined here is available to choose from when assigning the Adult Risk to a study. The screenshot below shows where this feature is used on the Outcome tab. It also appears on the Study Summary screen.



Adult Benefit Assigned Configuration List

The Adult Benefit Assigned Configuration List lists the current benefit ratings the review board uses to rate the benefit for a particular study. Depending on whether the rb.use_adult_benefit_assigned property is turned on, this configuration list may not appear.



	Edit	Order Number	Adult Benefit	Adult Benefit Description
		1	knowledge of condition w/ no direct benefit	The research involves no prospect of direct benefit to individual subjects but is likely to yield generalizable knowledge about the subject's disorder or condition.
		2	societal understanding w/ no direct benefit	The research involves no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society's understanding of the disorder or condition under study.
		3	prospect of direct benefit	The research involves the prospect of direct benefit.
		4	N/A	N/A

To delete one or more Adult Benefit Assigned record(s), click the box(es) next to the record(s) to be deleted, and then click the **Delete Selected Adult Benefit(s)**. A dialog box will open. Click the **OK** button to continue and delete the record(s). Click the **Cancel** button and the record(s) will not be deleted.

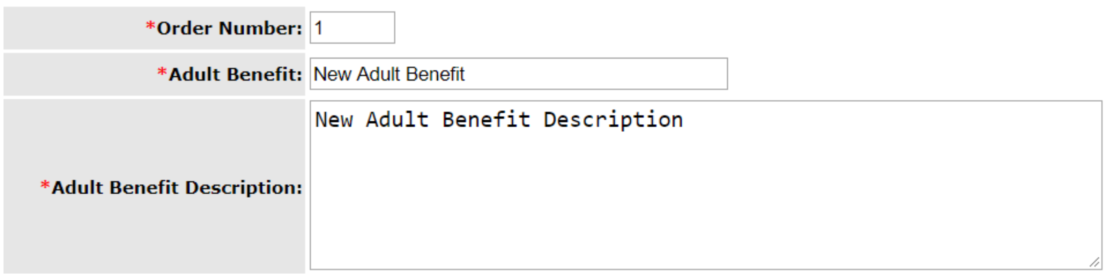
To edit a benefit, click the icon next to the risk to be edited. After a new page opens, you may change the name, order, and description of the benefit, and then click the **Save Adult Benefit** button to save the changes.

The Order Number indicates the order that these risk categories will appear in the actual drop-down list on the Outcome tab.

The Adult Benefit field displays the name of the risk that will be displayed for the reviewer to choose.

The Adult Benefit Description explains when this Adult Benefit category might be assigned.

After returning to the main Setup Adult Benefit Assigned List screen, click the **Add an Adult Benefit** button to add a record to the list.

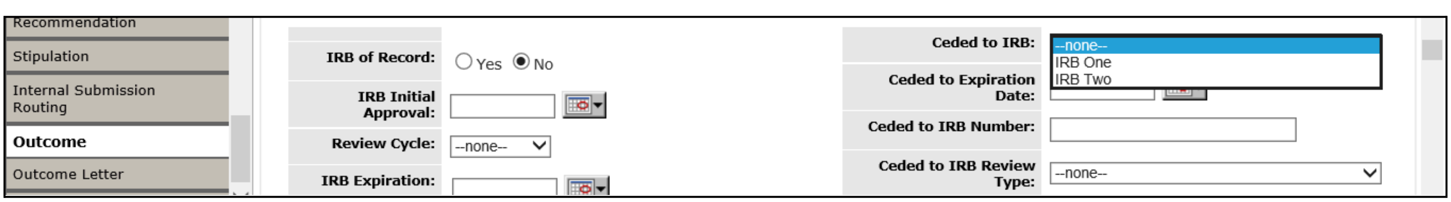


Enter the order of the Benefit, the Adult Benefit name, and enter a detailed description of this Benefit category. Click the **Save Adult Benefit** button to add the risk to the Adult Benefit Assigned page.

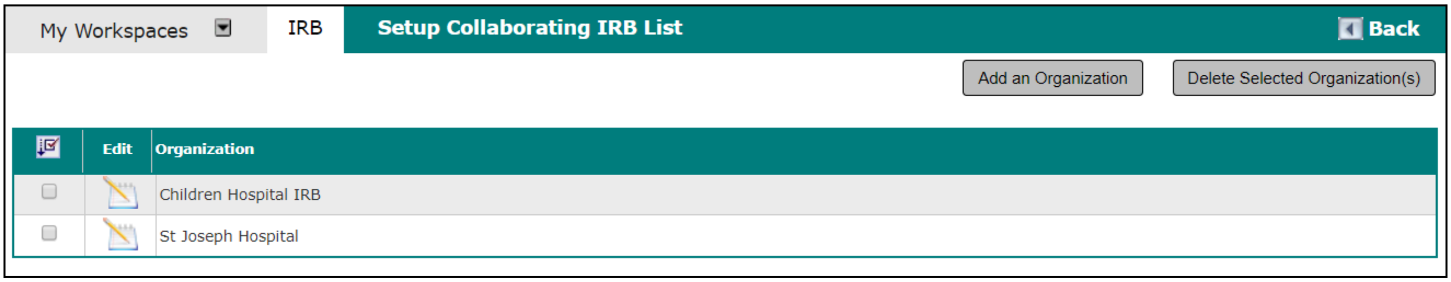
The list that is defined here is available on the Outcome tab for the reviewers to choose from to assign the Adult Benefit to a study. The screen shot below shows where this feature is used, and it also appears on the Study Summary screen.

Ceded – Collaborating IRB List

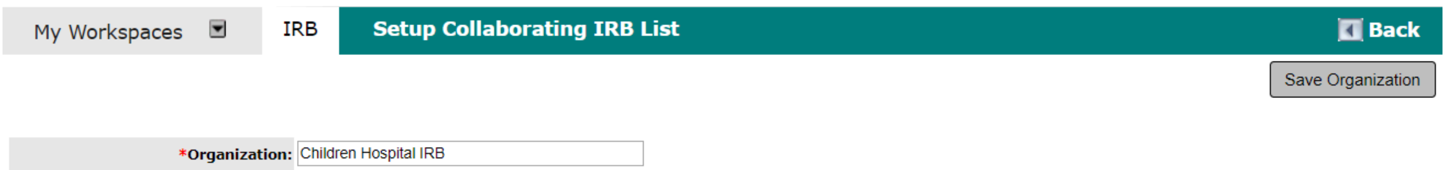
The Collaborating IRB List is used to configure the organizations that will appear in the Ceded From/Ceded To IRB lists on the Outcome tab of a Submission. When rb.use_ceded_review_details is set to yes, you will be able to enter information about an IRB that the study has been ceded from or to. The Collaborating IRB List displays when you indicate that the study has been ceded from or to another organization.



To delete an organization entered on the Collaborating IRB List, check the box(es) next to the organization(s) you wish to delete and click Delete **Selected Organizations**.



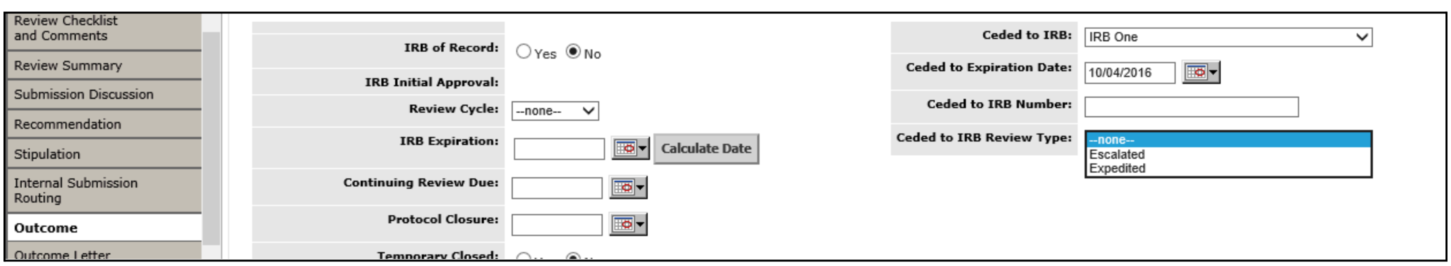
To edit an organization, click the  icon next to the organization you wish to edit. The following screen will open, and you will be able to edit the organization name in the Organization field. Click **Save Organization** to save your changes and return to the main Collaborating IRB List screen.



To add a new organization, click the **Add an Organization** button. You will be brought back to the screen seen in the screenshot above, and you will be able to enter the name of the new organization in the Organization field. Click **Save Organization** to save the new organization and return to the main Collaborating IRB List screen.

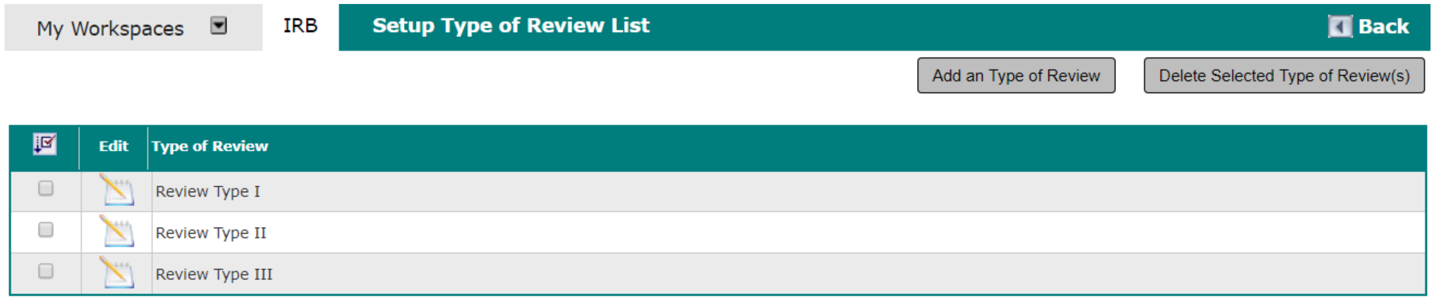
Ceded – Review Type List

The Review Types added in this list will appear in the Ceded to IRB Review Type drop-down list on the Outcome tab of a submission.

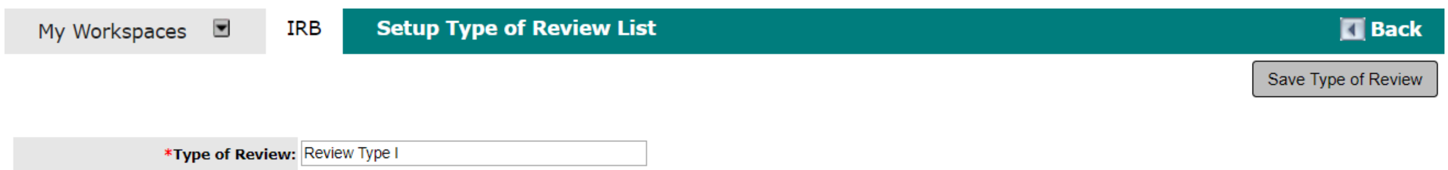


This list is available when you have indicated that the current IRB is not the IRB of Record and the study has been ceded to another IRB.

To delete a type of review entered on the Type of Review List, check the box(es) next to the review type(s) you wish to delete and click **Delete Selected Type of Review(s)**.



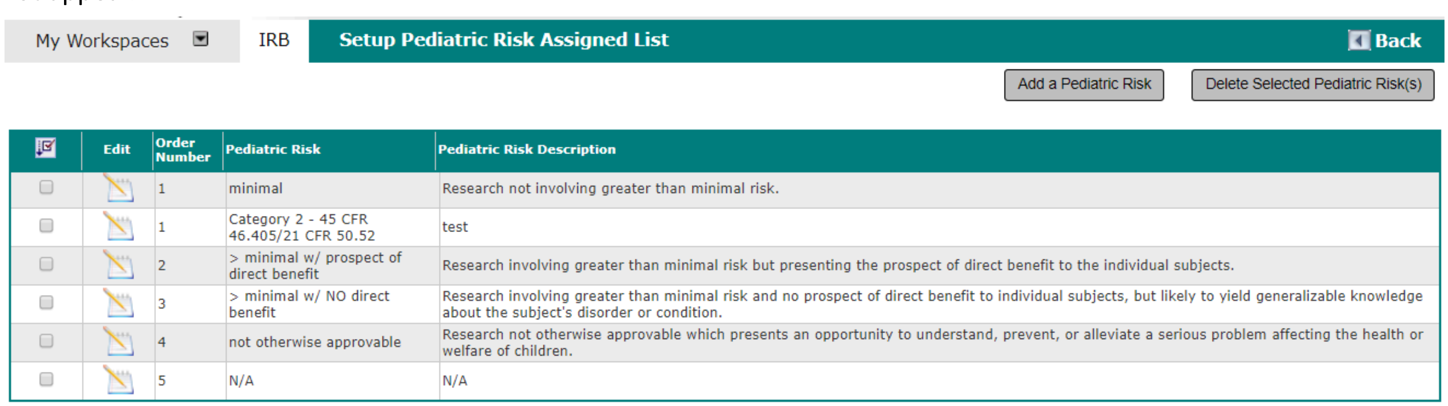
To edit a review type, click the icon next to the type of review you wish to edit. The following screen will open, and you will be able to edit the type of review name in the Type of Review field. Click **Save Type of Review** to save your changes and return to the main Type of Review List screen.



To add a new organization, click the **Add a Type of Review** button. You will be brought back to the screen seen in the screenshot above, and you will be able to enter the name of the new type of review in the Type of Review field. Click **Save Type of Review** to save the new organization and return to the main Type of Review List screen.

Pediatric Risk Assigned Configuration List

The Pediatric Risk Assigned Configuration List lists the current risk ratings the review board can use to rate the risk for a particular study. Depending on whether the rb.use_child_risk_assigned property is turned on, this configuration list may not appear.



To delete one or more Pediatric Risk Assigned record(s), check the box(es) next to the record(s) to be deleted, and then click the **Delete Selected Pediatric Risk(s)** button. A dialog box will open. Click the **OK** button to continue and delete the record(s). Click the **Cancel** button and the record(s) will not be deleted.

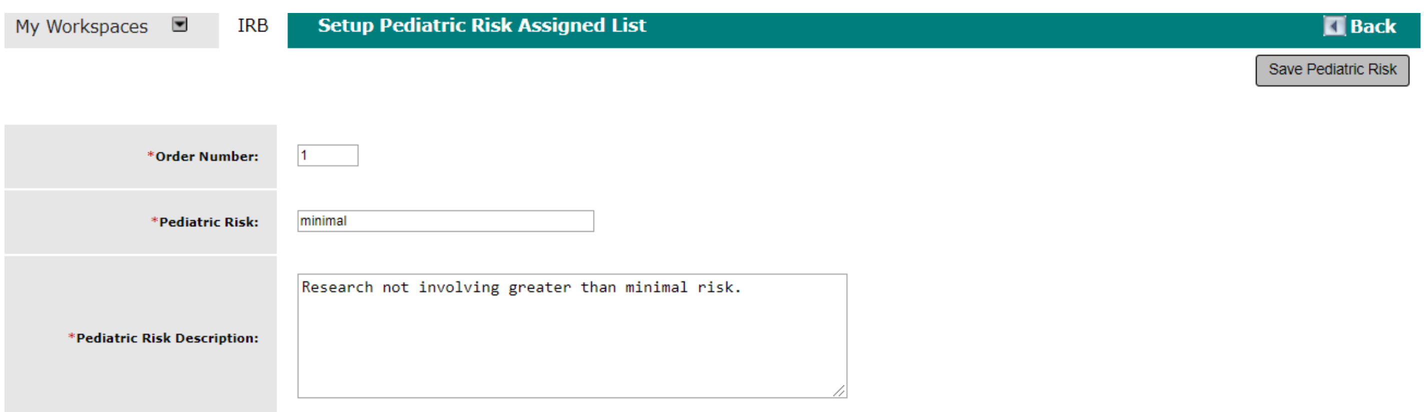
To edit a risk, click the icon next to the risk to be edited. After a new page opens, you may change the name, order, and description of the risk. Click the **Save Pediatric Risk** button to save the changes.

The Order Number indicates the order that these risk categories will appear in the actual drop-down list on the Outcome tab.

The Pediatric Risk field displays the name of the risk that will be displayed for the reviewer to choose from.

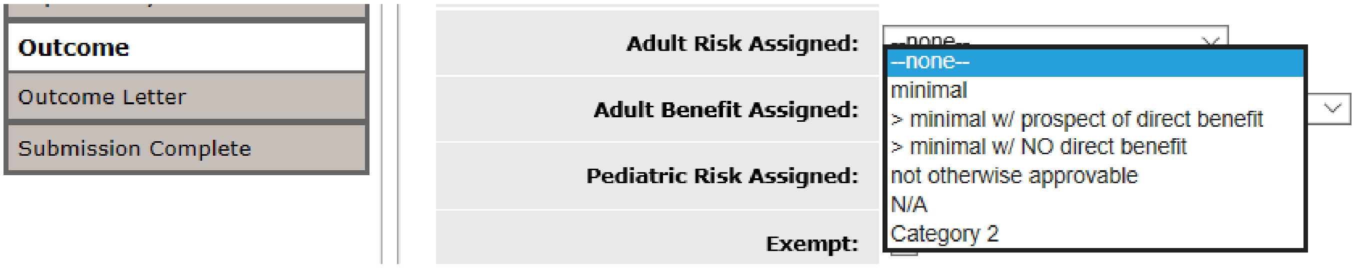
The Pediatric Risk Description explains when this Pediatric Risk category might be assigned.

After returning to the main Setup Pediatric Risk Assigned List screen, click the **Add a Pediatric Risk** button to add a record to the list.



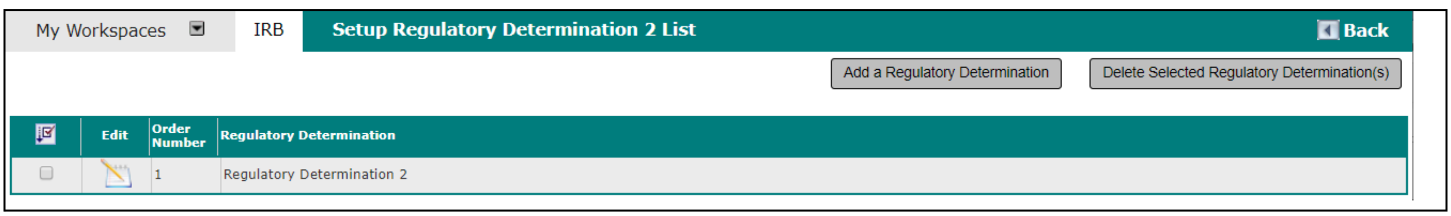
Enter the order of the risk, the Pediatric Risk name, and a detailed description of this risk category. Click **Back** to return to the Pediatric Risk Assigned page without saving any changes. Click the **Save Pediatric Risk** button to add the risk to the Pediatric Risk Assigned page.

The list that is defined here is available for the reviewers to assign the Pediatric Risk to a study. The screen below shows where this feature is used, and also appears in the Study Summary.



Regulatory Determination 1/ Regulatory Determination 2 List

This list allows you to set up a list of regulatory determinations for your IRB to select on the Outcome tab of a submission. If you need a second list of regulatory determinations, you can also use the Regulatory Determination 2 List functionality. After clicking on a Regulatory Determination 1 or 2 List link, you will be brought to a screen where you can create, edit, and delete regulatory determinations for your review board.



To delete existing Regulatory Determinations, check the box(es) next to the record(s) you wish to delete and click **Delete Selected Risk Group(s)**.

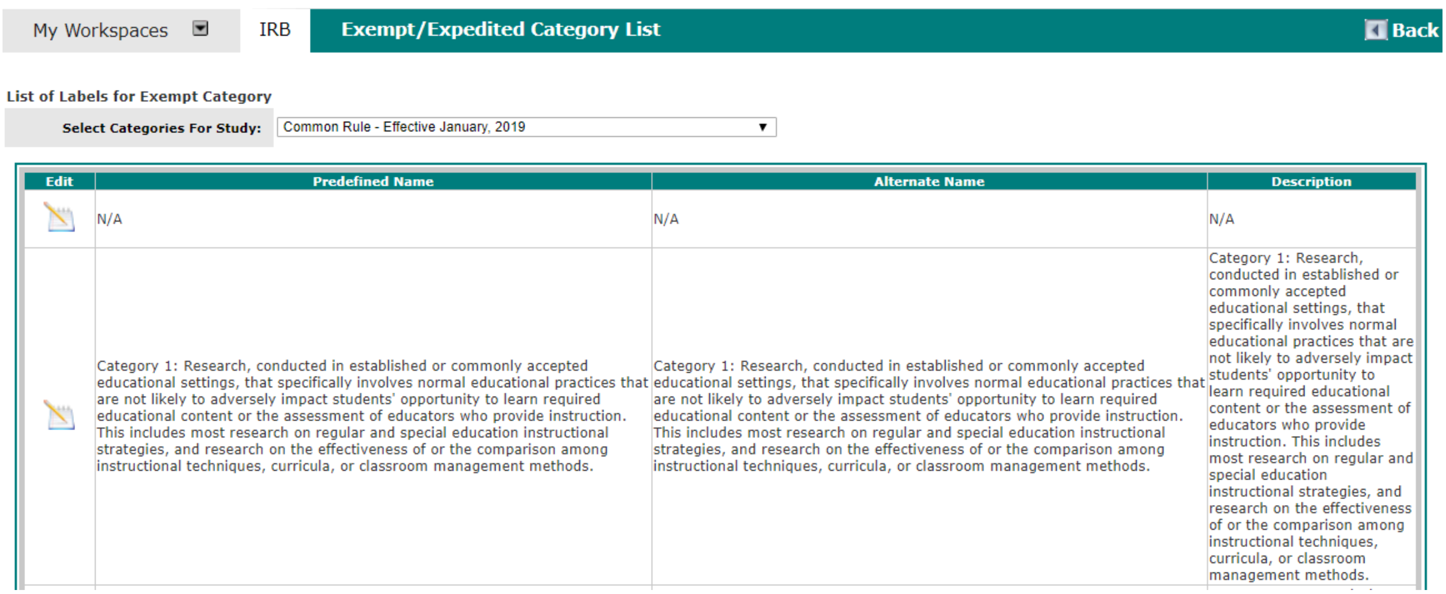
To edit an existing Regulatory Determination, click the  icon next to the record. You will be brought to a screen where you can edit the order number (indicating in what order the items will appear in the list) and the name of the Regulatory Determination. Click **Save Risk Group** to return to the main Setup Regulatory Determination 1 List screen with your edits saved or click **Back** to return with no edits.

On the main screen, click **Add a Risk Group** to return to the screen shown in the above screenshot, where you can enter the Order Number and Regulatory Determination. Click **Save Risk Group** to return to the main Setup Regulatory Determination 1 List screen with your new group saved or click **Back** to cancel.

The Regulatory Determination 1 and 2 Lists appear on the Outcome tab of a Submission as shown below, as well as the Study Summary:

Exempt/ Expedited Category List

This section will allow you to change the Exempt and Expedited categories which are hard- coded labels in the Outcome tab. Once the link is selected, an extensive list of broken down into several sections.

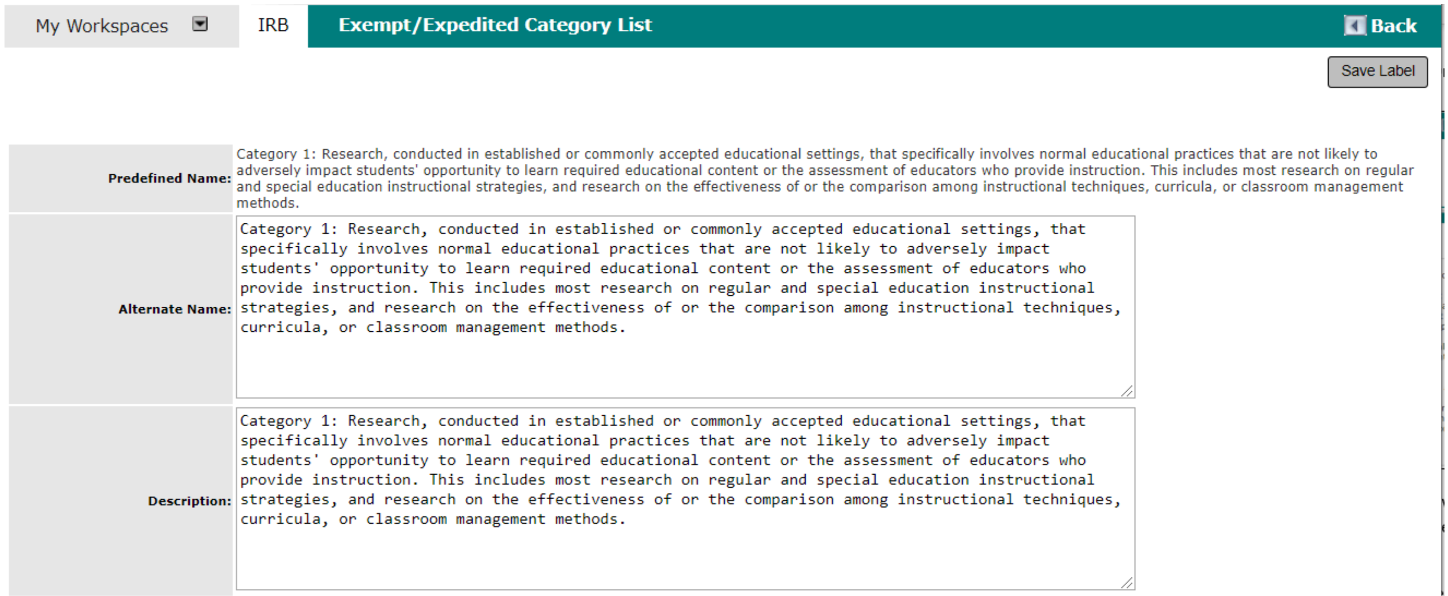


Select Categories for Study– Using the field "Select Categories for Study" will allow you to control which Common Rule list to display within the Exempt/Expedited Category List page from the drop-down.

"Common Rule- Effective 1991" selecting this option allows for users to use the old Common Rule.

"Common Rule – Effective January 2018" this prompt for the generation of the revised Common Rule. The "Common Rule – Effective January 2018" is set as the default selection in the drop-down bar. The Exempt/ Expedited Category List shows both the new and old Common Rule options now available in iRIS.

Edit – If a label needs to be adjusted, select the Edit icon next to the applicable label. From the following screen you will be able to make the needed adjustment(s). Be sure to **save** your work, labels can be adjusted as many times as needed.

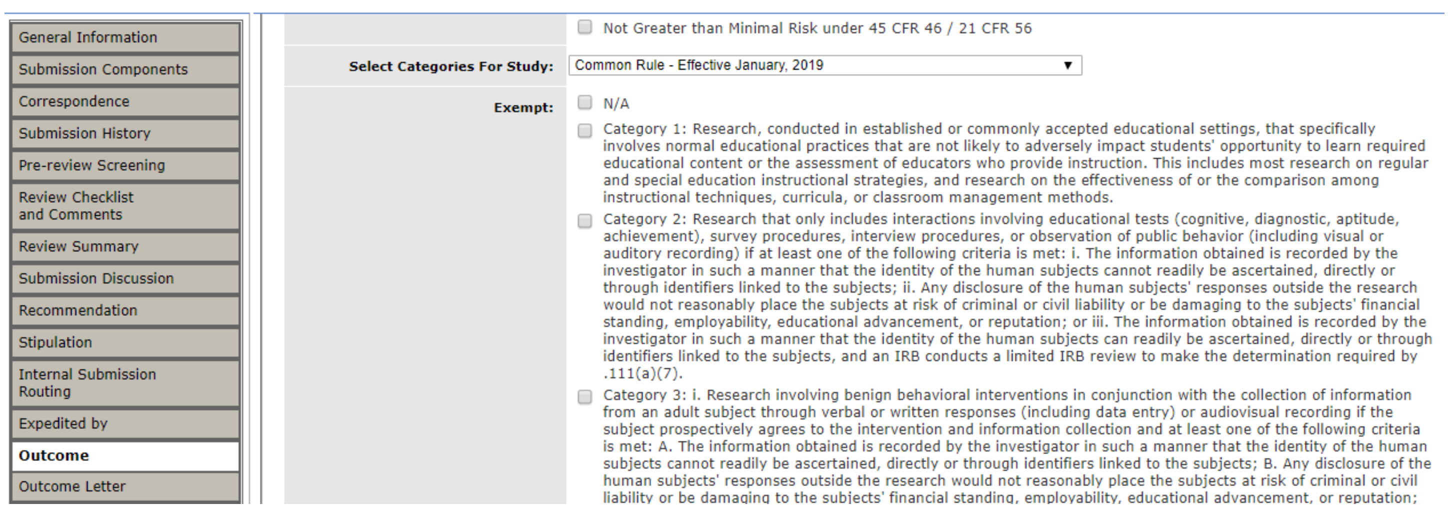


Predefined Name – This field will display the name that the label was originally set as within iRIS. This field is read-only.

Alternate Name – Displays the current name for the label. This means this is what the system is using in place of the Predefined Name, if different.

Description – Displays the applicable description of how or where the label is displayed within iRIS.

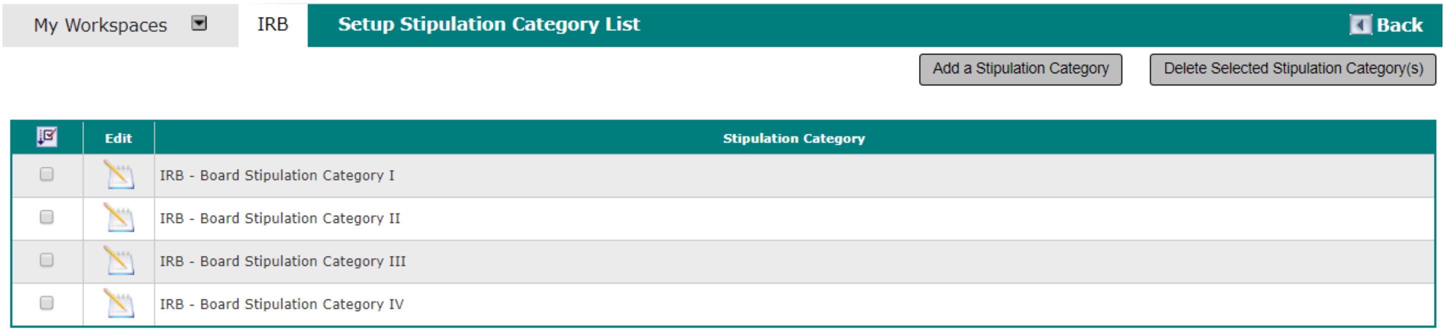
Once labels are configured, board members will be able to see the new category label changes in the Outcome tab.



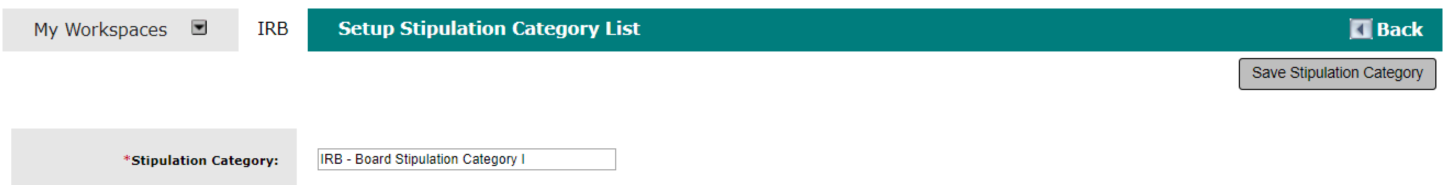
Stipulation Category

If you would like to categorize your stipulations, you can create a list of categories you can assign to stipulations when you create them. To use categories for stipulations, the review board property rb.use_stipulation_category must be set to Yes.

When you click the Stipulation Category link, a list of any categories that have already been added to the system will display. If you have not set up any categories, the page will not list any records. You can add a new category by clicking on the **Add a Stipulation Category** button.



Type the **Stipulation Category** name and click the **Save Stipulation Category** button to add the new category to the list.

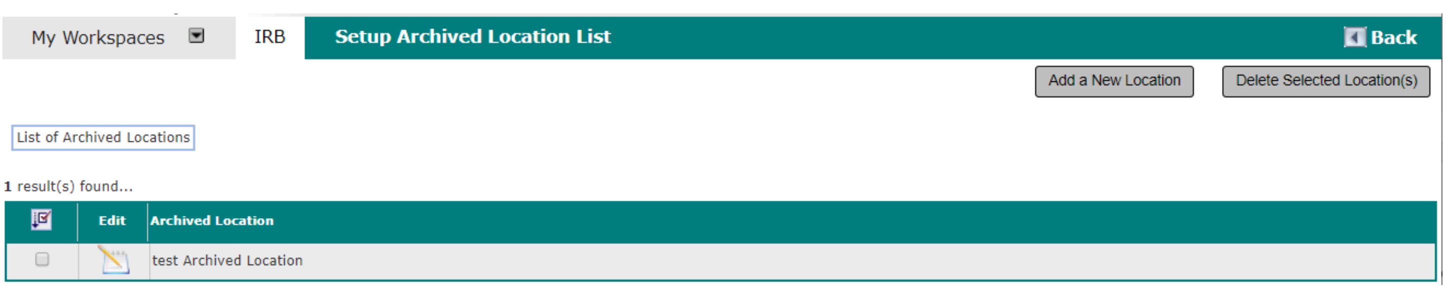


You can edit existing categories by clicking the  icon next to the category name. This will open a page that will allow you to modify the name.

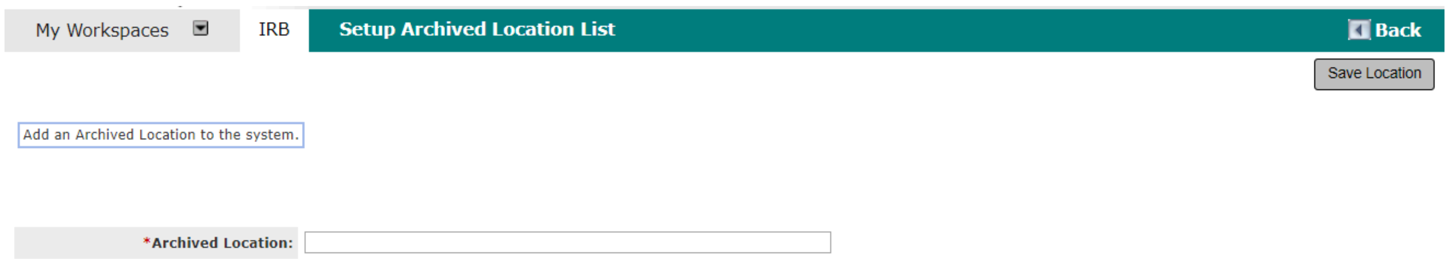
Any category you add to the list will populate in the Stipulation Category drop-down list when creating a Stipulation for a submission.

Archived Location List

The Archived Location List allows you to create a list of Archived Locations that you will be able to select from a drop-down menu on the Outcome tab of a submission. Click the Archived Location List link to open the Archived Location Setup screen.



Click **Add a New Location** to open a screen where you can enter the name of the location and add it to the list.

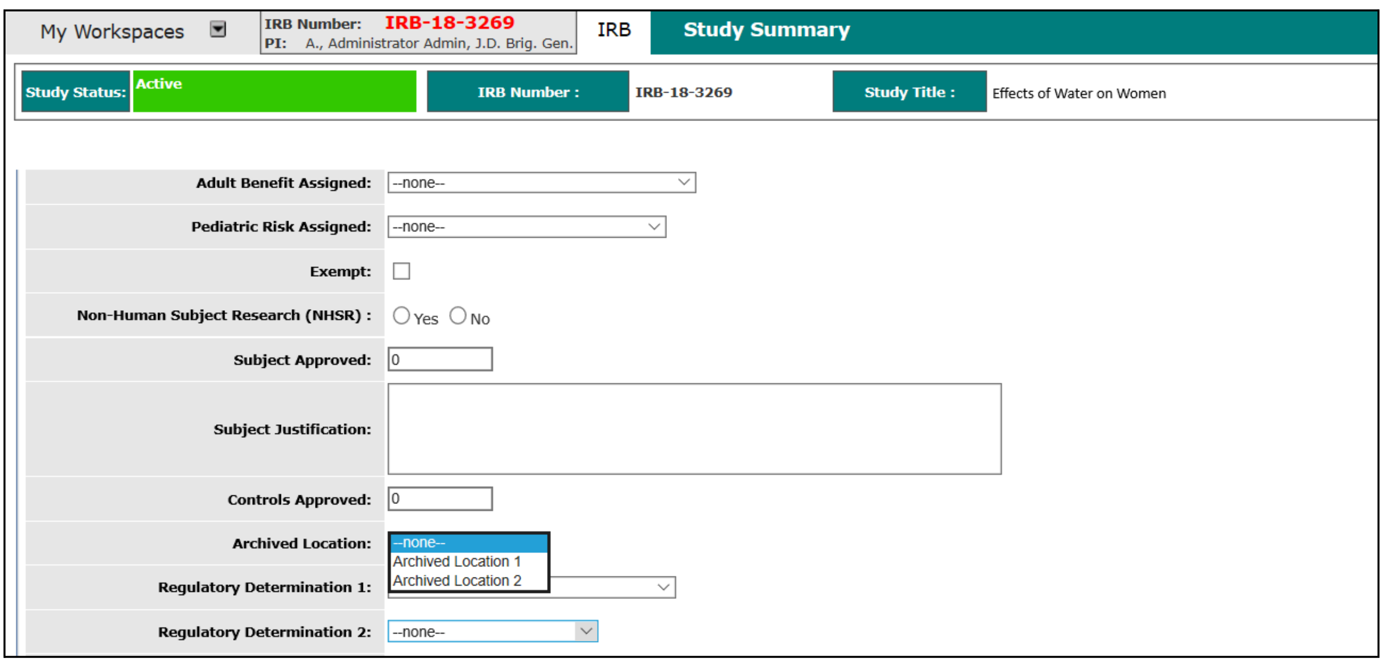


Enter text in the Archived Location field and click **Save Location** to add the new location to the list and return to the main Archived Location Setup screen. Click **Back** to return to the main screen without creating a new entry.

If you wish to delete Archived Locations from your list, check the box(es) next to the location(s) you wish to delete and click **Delete Selected Location(s)**. A popup will display; click **OK** to delete the location or **Cancel** to proceed without deleting.

To edit an Archived Location, click the  icon next to the location you wish to edit. This will open the screen shown in the above screenshot, and you will be able to change the name of the Archived Location.

The Archived Location drop-down list appears on the Study Summary page of a submission.

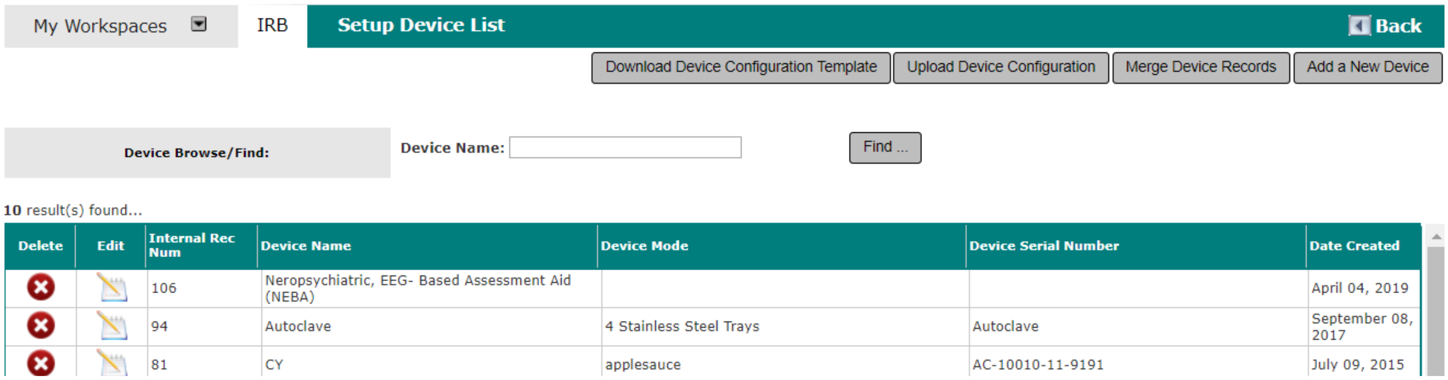


Device Configuration List

The Device Configuration List allows you to add or edit all of the devices within iRIS that will be available to be associated to a study.

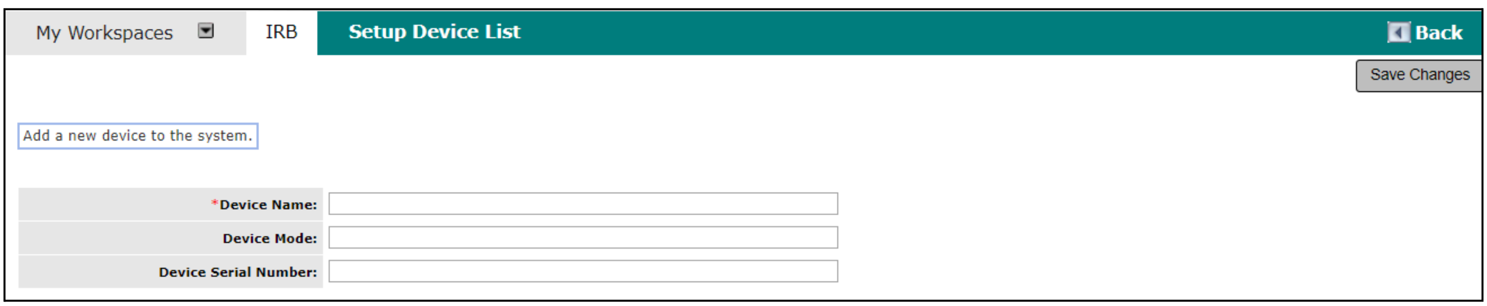
After selecting this link, the master list of existing devices will display. You will have the ability to **Edit** existing devices, as well as **Download / Upload Device Configurations, Merge Device Records**, **Add a New Device** and **Delete Device(s)**.

This page contains a Device Name filter which allows you to search for specific devices that have been previously added.



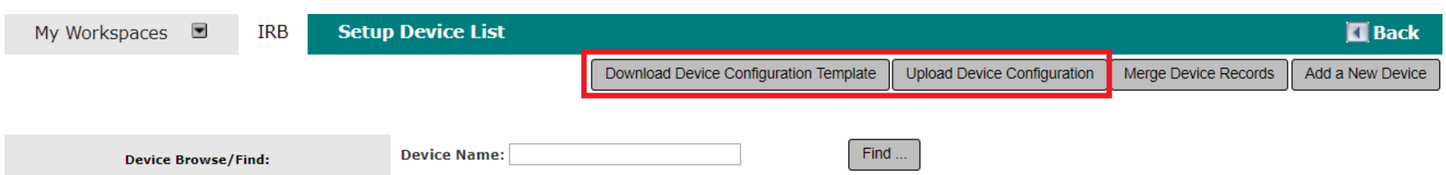
Add a New Device

Add a New Device will allow you to add a new device to the master device list within iRIS. To add a new device, you will need to provide the Device Name. Optionally, you may include the Device Mode and Device Serial Number. After entering the device details, click the **Save Changes** button. Saving the record will update the master device list with the new entry.

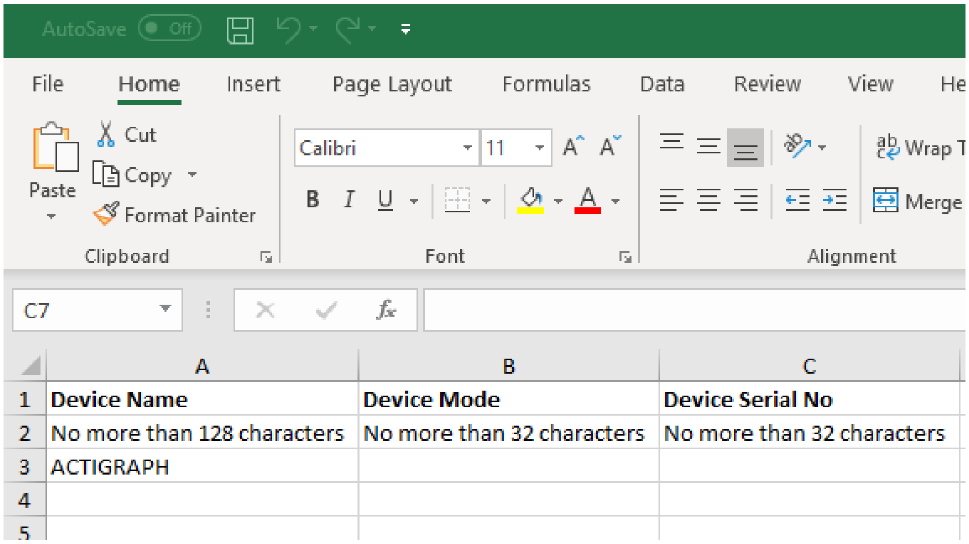


Download/Upload Device

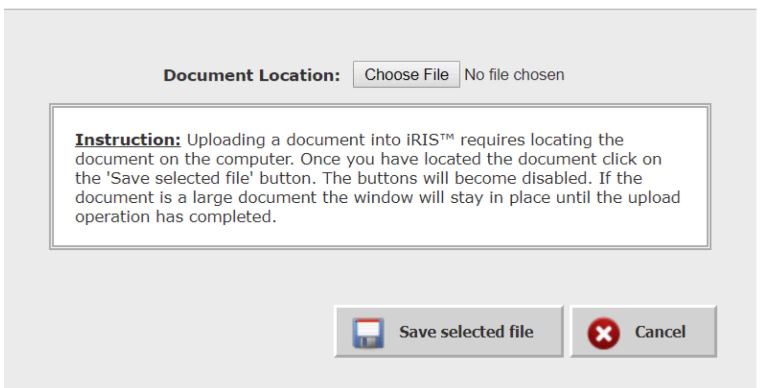
Download/Upload Device Configuration gives you the ability to easily upload an Excel file with as many device records as needed at one time.



Download Device Configuration Template – This feature will allow you to download a spreadsheet template; this template is set up in the proper format for uploading device records, with instructions for the input of data in each field. When downloading, be sure to **Save** the file to a known location on your computer, so the data can be input and saved for future uploading. Below you will find a screenshot of this spreadsheet template.

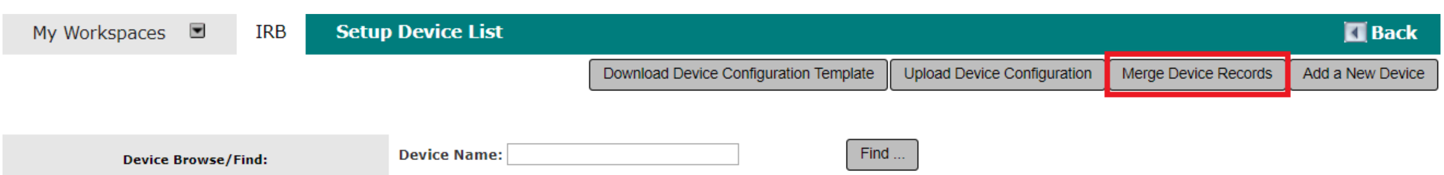


Upload Device Configuration– Selecting to upload the device configuration will open a popup window, where you will be able to browse for the correct Excel file containing the device records you wish to upload.

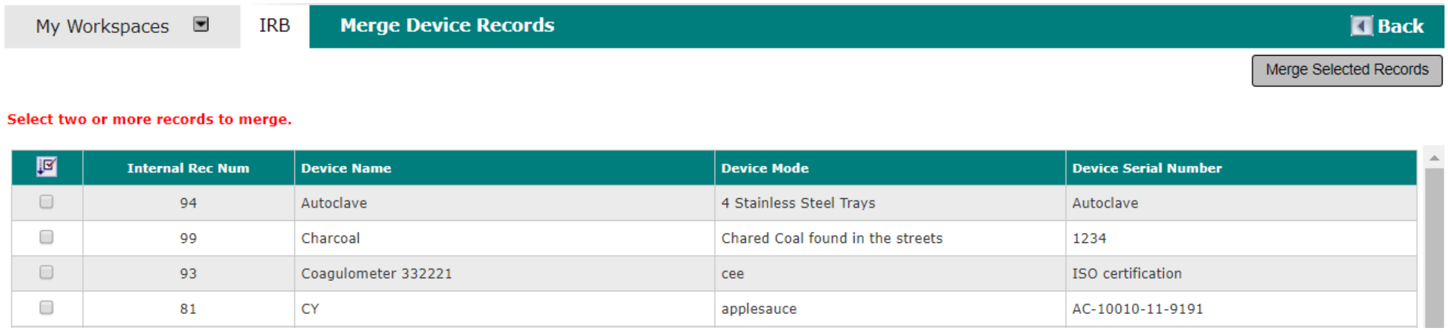


Merge Device Records

Merge Device Records - This feature will allow you to merge duplicate records within the system.



After making this selection a list of the existing records will populate. Selecting two or more records will allow you to merge and select the record that you wish to keep. After making your selection, click **Merge Selected Records**.



My Workspaces | IRB | Merge Device Records | Back

Merge Selected Records

Select two or more records to merge.

	Internal Rec Num	Device Name	Device Mode	Device Serial Number
	94	Autoclave	4 Stainless Steel Trays	Autoclave
	99	Charcoal	Chared Coal found in the streets	1234
	93	Coagulometer 332221	cee	ISO certification
	81	CY	applesauce	AC-10010-11-9191

A popup will appear ensuring that you wish to continue with the merge operation. Click OK to proceed with the merge or Cancel to proceed without merging.

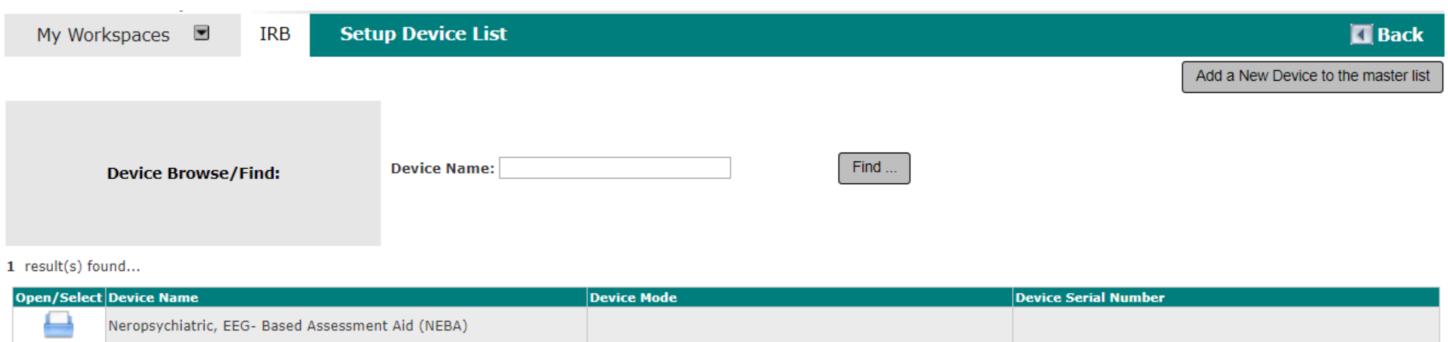
Note: Merging device records will update existing studies with the most current record.

Once devices have been added to the master list, they can be associated to study applications through a data value.

Add a New Device to the Study

Delete Device	Edit	View Details	Device Name	Is the Device FDA Approved	Is this a new device or a new use of an already approved device	IDE Number
No devices have been added to this Study						

Selecting **Add a New Device to the Study** will open a popup window, which will allow the user to search for the applicable device.



My Workspaces | IRB | Setup Device List | Back

Add a New Device to the master list

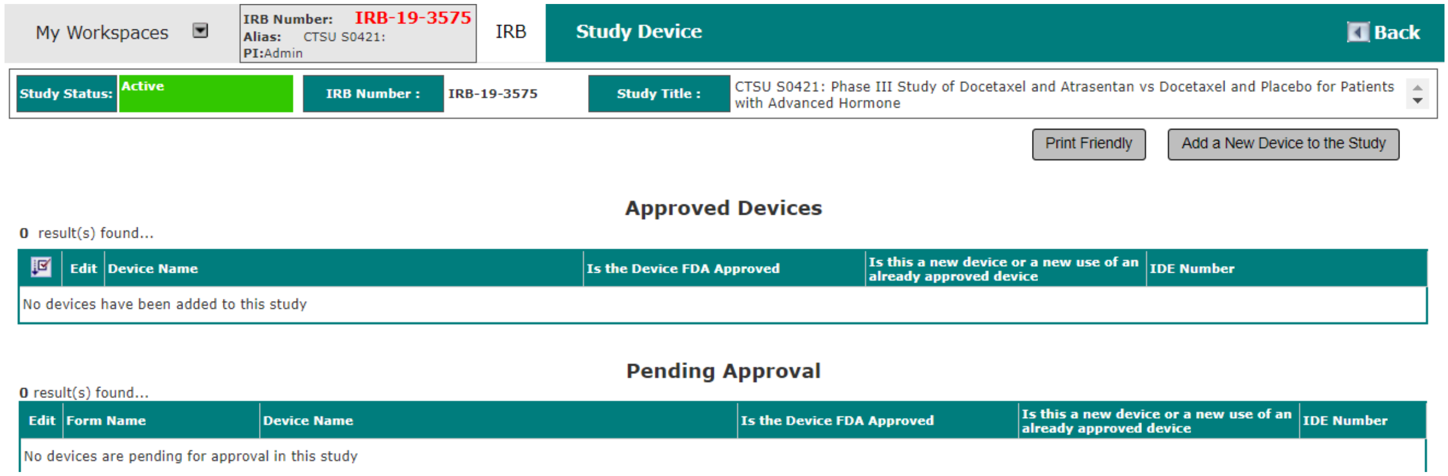
Device Browse/Find: Device Name: Find ...

1 result(s) found...

Open/Select	Device Name	Device Mode	Device Serial Number
	Neropsychiatric, EEG- Based Assessment Aid (NEBA)		

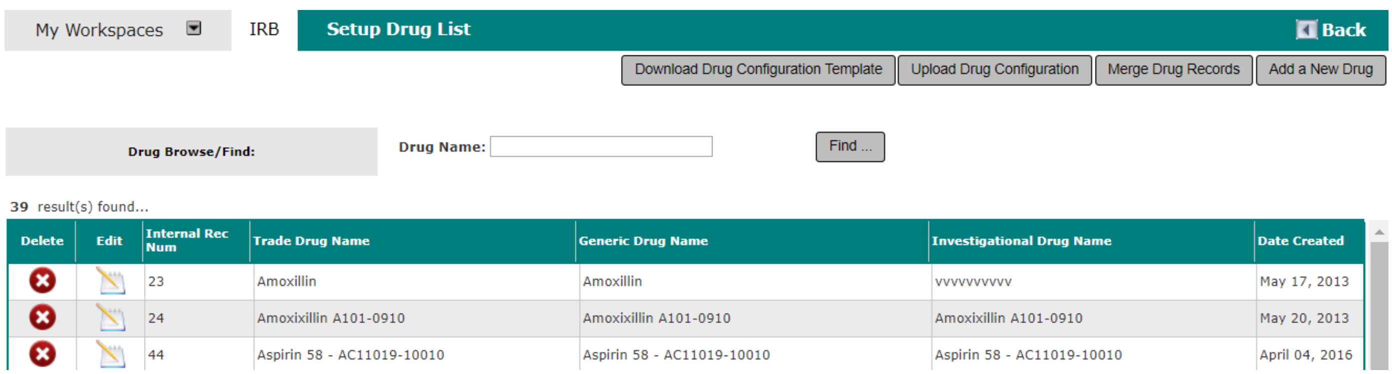
If the board approves a submission with an attached device, the device(s) applicable to the submission then display as approved in the Study Management area for that particular study.

If any new devices need to be added, or existing devices need to be modified, the study will need to submit an amendment or modification to the review board of record for approval. Any modifications or new device requests will populate in the Pending Approval table, shown in the image below. Once the review board approves the modification or addition, the device record will populate in the Approved Devices table.



Drug Configuration List

The Drug Configuration List allows you to add to or edit the list of drugs within iRIS. After selecting this link, the master list of existing drugs will display. You will have the ability to **Edit** existing drugs as well as **Download / Upload Drug Configurations, Merge Drug Records**, **Add a New Drug,** and **Delete Drug(s),** as seen in the image below. This page also contains a Drug Name filter which allows you to search for a specific drug that has been previously added.



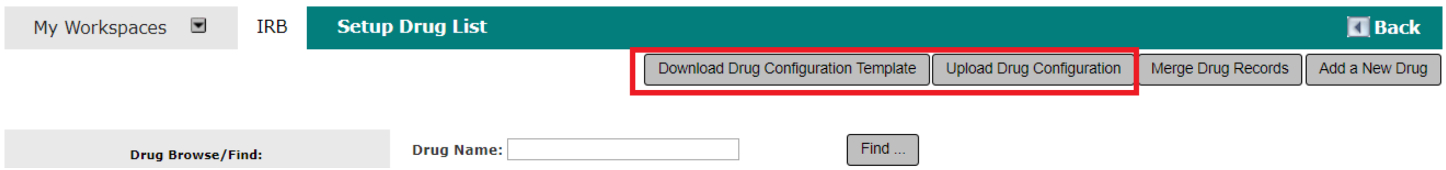
Add a New Drug

Add a New Drug will allow you to add a new drug to the master drug list within iRIS. To add a new drug, you must enter the Trade Name, Generic Name, or Investigational Name. Only one of the three drug names is needed to add a new record to the system. Clicking the **Save Changes** button will add this drug record and update the master drug list.

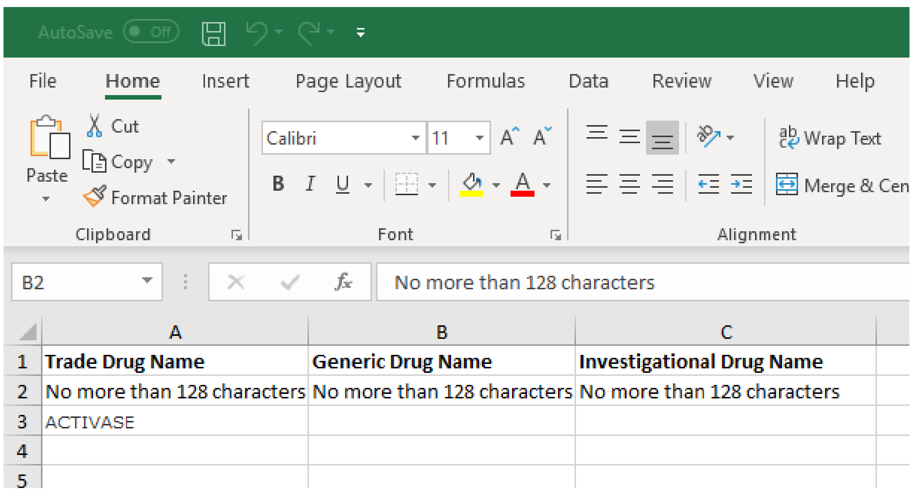
11.02

Download/Upload Drug

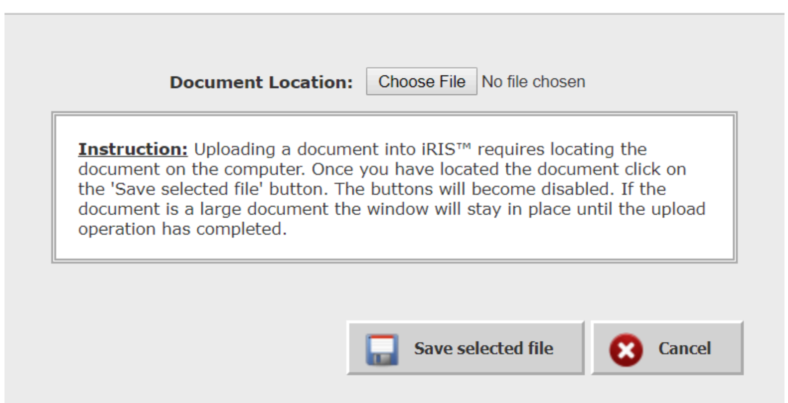
The **Download/Upload Drug** features give you the ability to upload an Excel file with as many drug records as needed at one time.



Download Drug Configuration Template – This feature will allow you to download an Excel spreadsheet template. This template is setup in the proper format for uploading drug records, with instructions for the input of data in each field. When downloading, be sure to **Save** the file to a known location on your computer, so the data can be input and saved for future uploading. Below you will find a screenshot of this spreadsheet template.



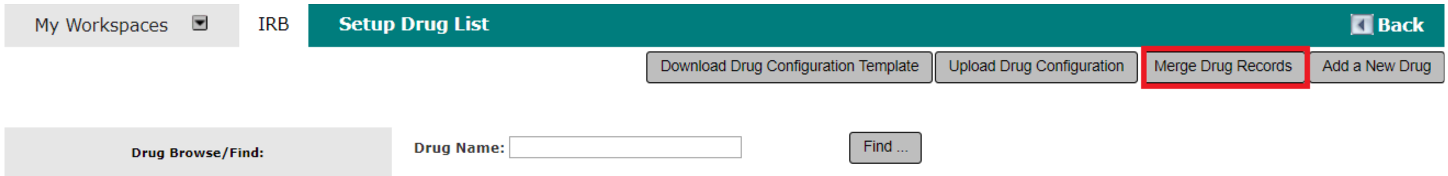
Upload Drug Configuration– Selecting to upload will open a popup window, where you will be able to browse for the correct Excel file containing the drug records you wish to upload.



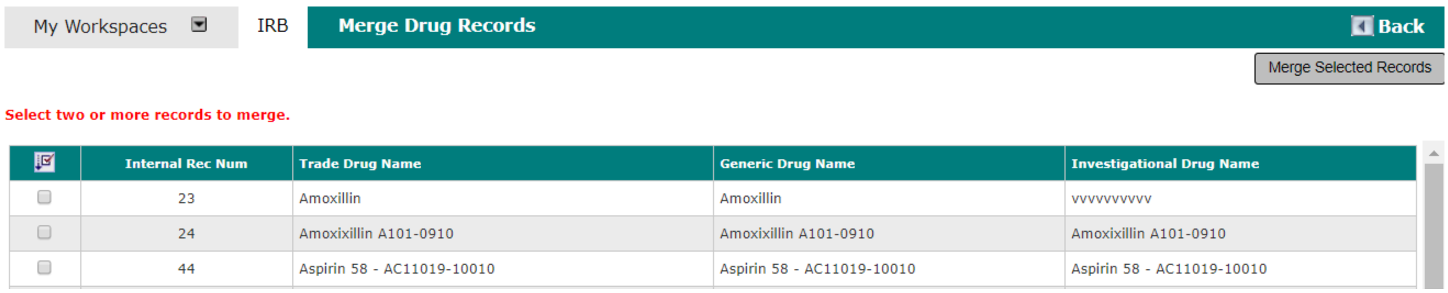
Merge Drug Records

Merge Drug Records Feature - This feature will allow you to merge duplicate drug records within the system.

11.02
Clicking the **Merge Drug Records** button will populate the list of existing drugs in the system.



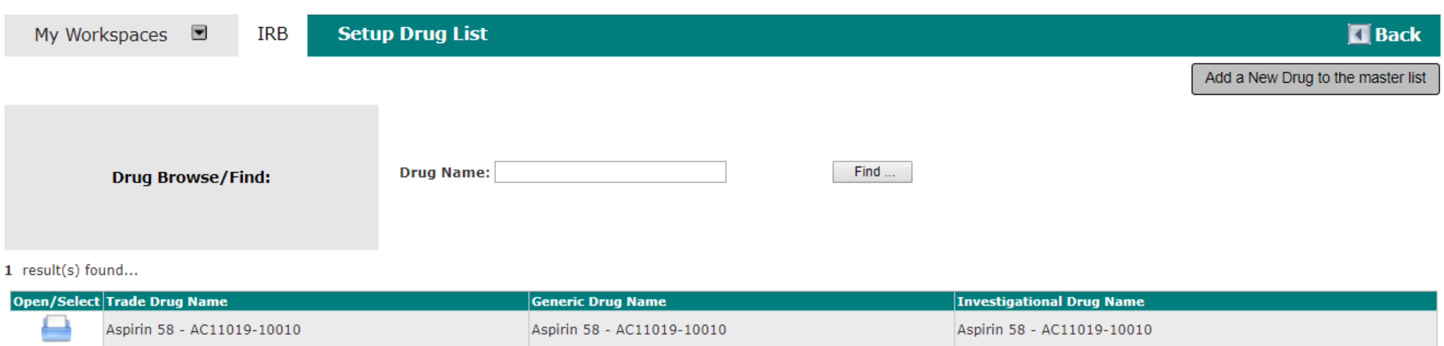
Selecting two or more records will allow you to merge and select the record that you wish to keep. After making your selection, click **Merge Selected Records**.



Note: Merging drug records will update existing studies with most current drug record.

Once drugs have been added to the master list, they become available to be associated to study applications through a data value.

Selecting to **Add a New Drug to the Study** will open a popup window, which will allow you to search for the applicable drug.



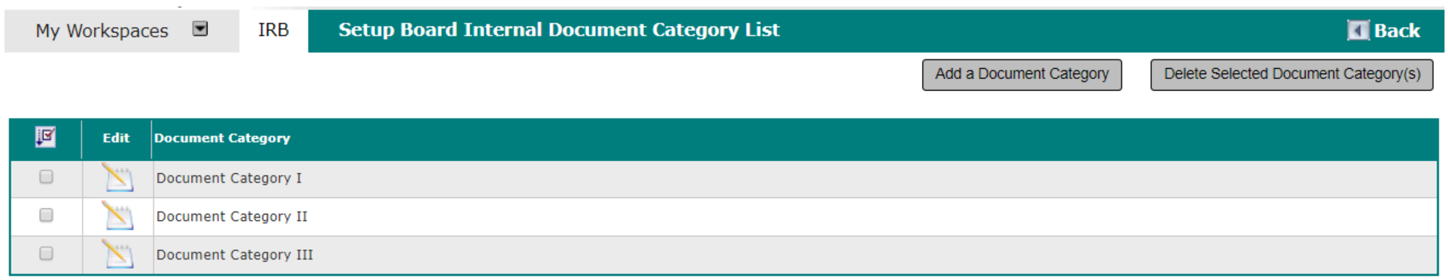
If the board approves a submission with an attached drug, the drugs applicable to the submission then display as approved in the Study Management area for that particular study.

11.02
If any new drugs need to be added or existing drugs need to be modified, the study will need to submit an amendment or modification to the review board of record for approval. Any modifications or new drug requests will populate in the Pending Drugs table, shown in the image below. Once the review board approves the modification or addition, the drug record will populate in the Approved Drugs table.

Internal Document Category

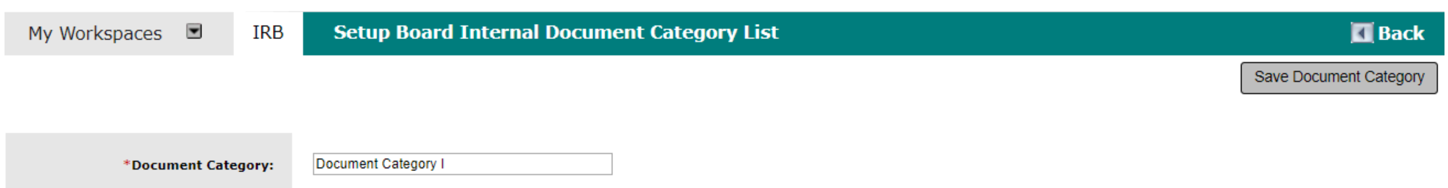
You can create categories for any Internal Documents you upload to a study from within the review board.

When you open the Setup Review Board Internal Document Category page, a list of any categories that have already been created will display. If you have not set up any categories, the page will not list any records. You can add a new category by clicking on the **Add a Document Category** button.

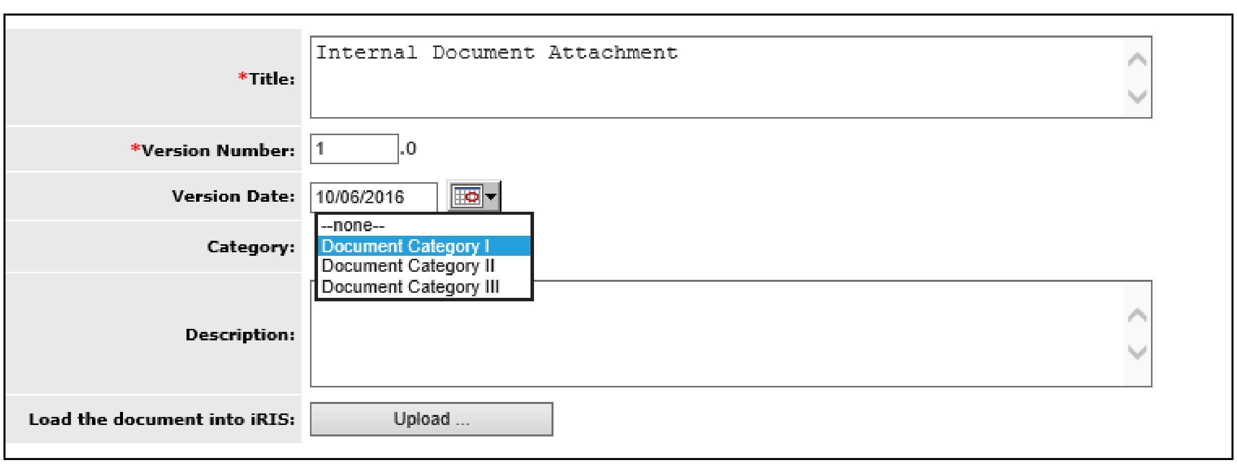


Type in the Document Category name and click the **Save Document Category** button to add the new category to the list.

You can edit existing categories by clicking the  icon next to the category name. This will open a page that will allow you to modify the name.



Any category you add will populate in the Category drop-down list when you are uploading a document in the Review Board Internal Documents area within a study in the IRB board.

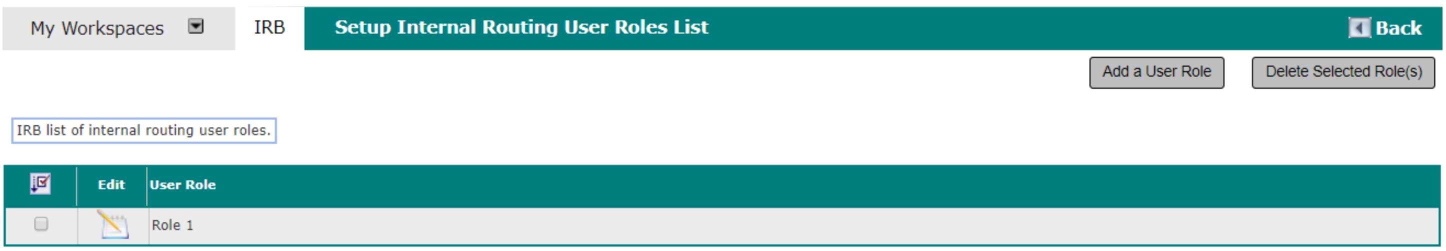


Internal Routing User Roles

When you are assigning a user to an Internal Routing task, you can specify a role for that user. To use the roles feature, the review board property rb.useReviewRouting_user_role must be set to Yes. See the IRB Assistant - Properties manual for more details.

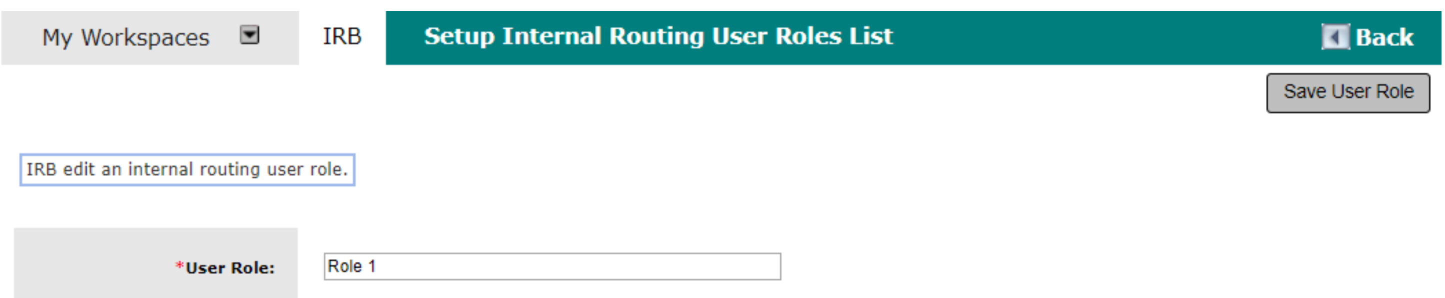
When you open the page, a list of any roles that have already been created will display. If you have not set up any roles, the page will not list any records.

You can add a new role by clicking on the **Add a User Role** button.

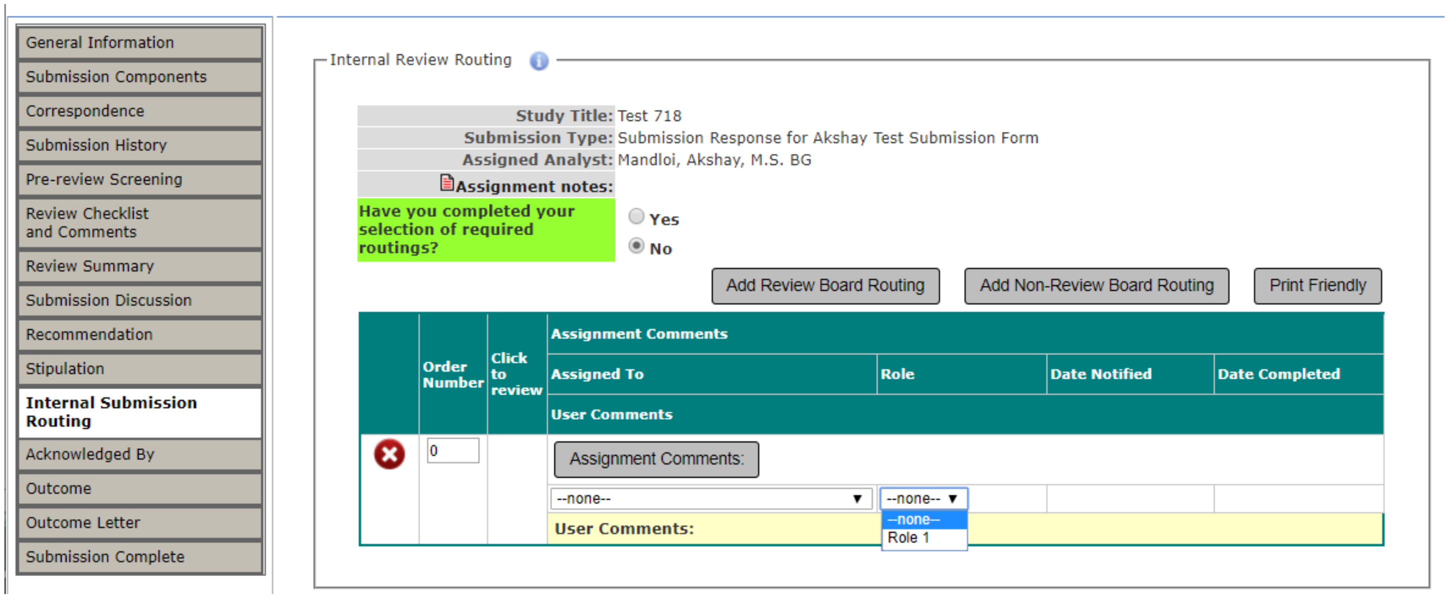


Type in the User Role name, and then click the **Save User Role** button to add the new role to the list.

You can edit existing roles by clicking the  icon next to the role name. This will open a page that will allow you to modify the name.

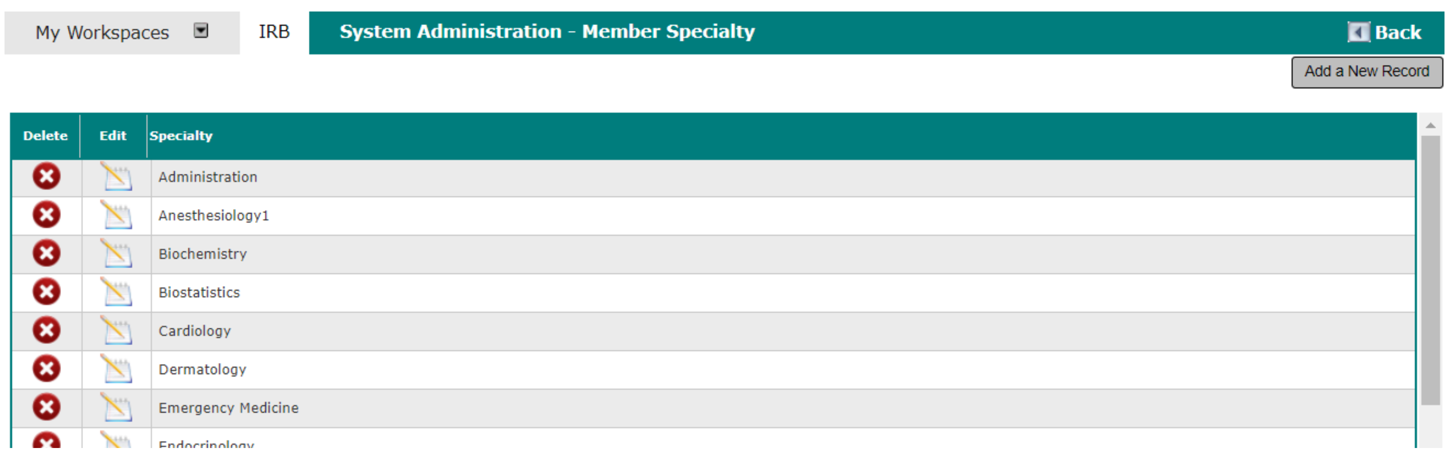


Any role you add to the list will populate in the drop-down list next to the user assignment when you are making an Internal Routing assignment for a submission.

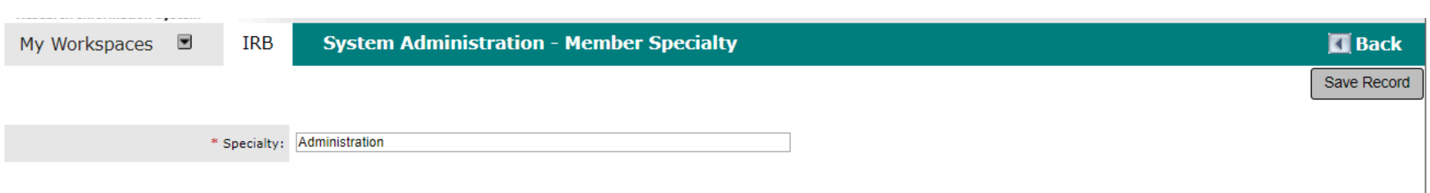


Member Specialty Configuration List

This is where you define specialties that can be assigned to review board members.



You can add a new specialty by clicking the **Add a New Record** button. You will be able to enter in the title of the specialty. Once you are finished, click the **Save Record** button to have the review board member specialty added to the list.



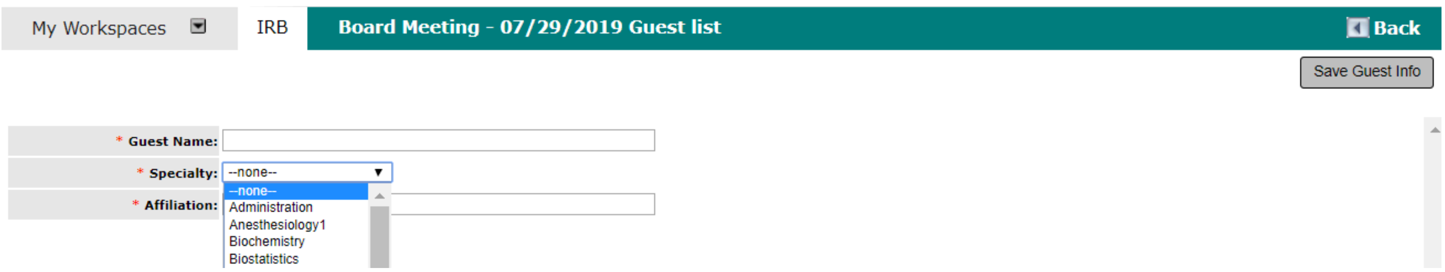
The specialties can also be edited or deleted from the main list.

To delete a specialty from this list, click the icon in the Delete column. A dialog box will open confirming the deletion. Click the **OK** button to continue and delete the record(s). Click the **Cancel** button to cancel the deletion.

To edit a speciality, click the icon next to the specialty to be edited, and a new page will open. Change the name of the specialty, and then click the **Save Record** button. The changes will be saved to the record. To return to the list without saving the changes, click the **Back** button.

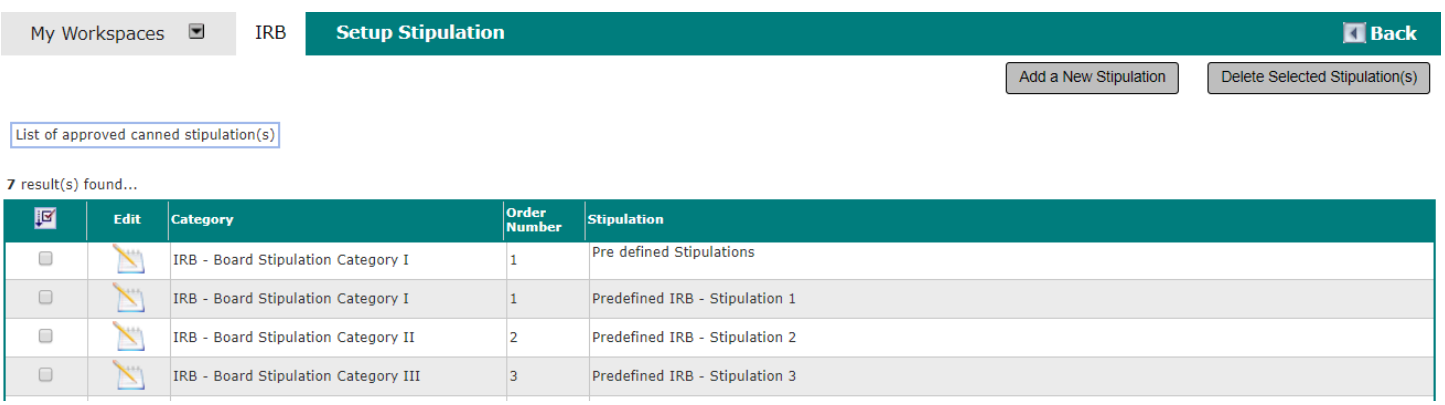
The Specialty column displays the title of the specialty as it will display for the reviewers to choose from.

The member specialty list is available when adding a guest to the meeting attendance on an agenda (see below).

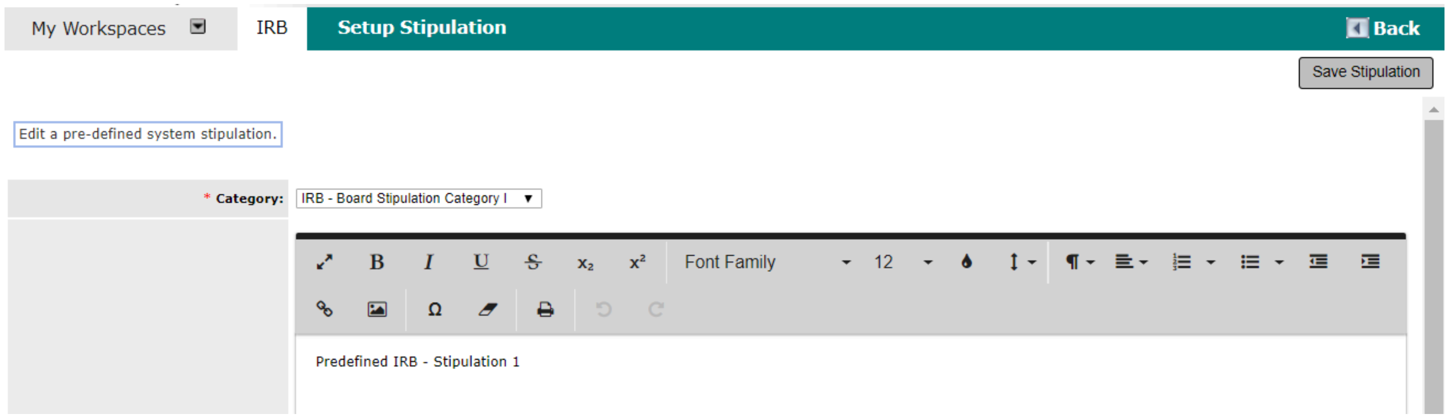


Predefined Stipulations

If you have a list of commonly used stipulations, you can set them up under Predefined Stipulations and use them for submissions as needed.



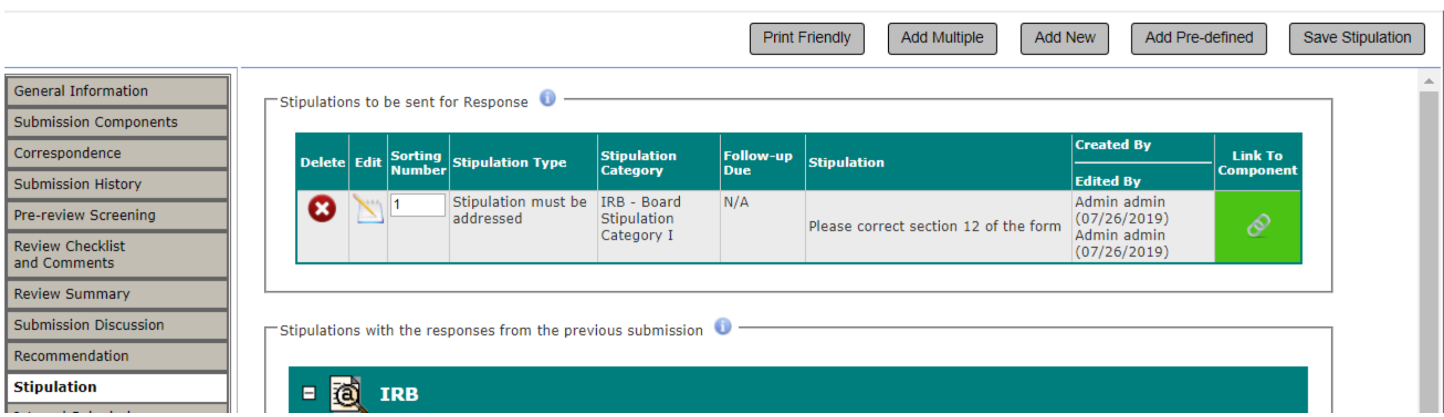
When you open the page, a list of any predefined stipulations that have already been created will display. If you have not set up any stipulations, the page will not list any records. You can add a new predefined stipulation by clicking on the **Add a New Stipulation** button.



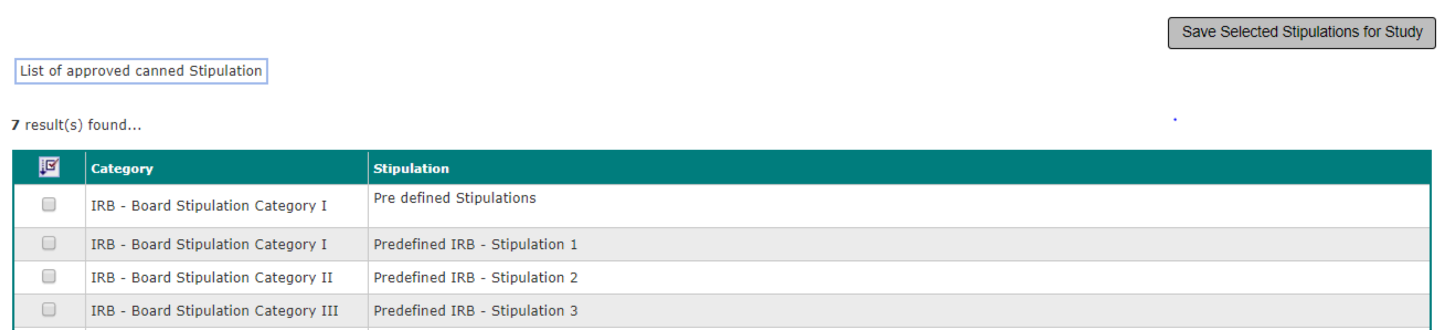
Type in the Stipulation Content and specify an Order, and then click the **Save Stipulation** button to add the predefined stipulation to the list.

You can edit existing stipulations by clicking the  icon next to the record. This will open a page that will allow you to modify the Stipulation Content and the Order.

When you are creating a stipulation for a submission, you will be able to select the option to **Add a Pre-defined** stipulation.

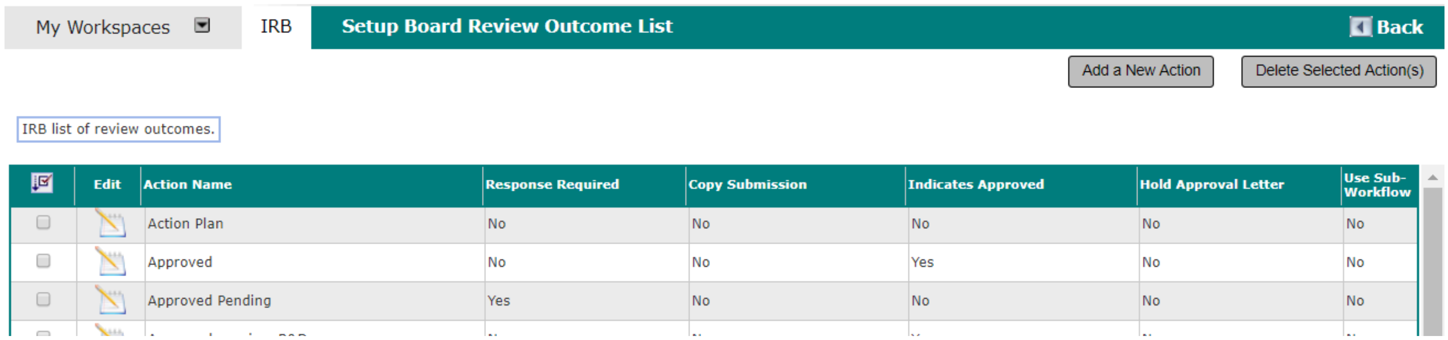


Clicking the **Add Pre-defined** button will open the list of predefined stipulations that have been added to the configuration list.

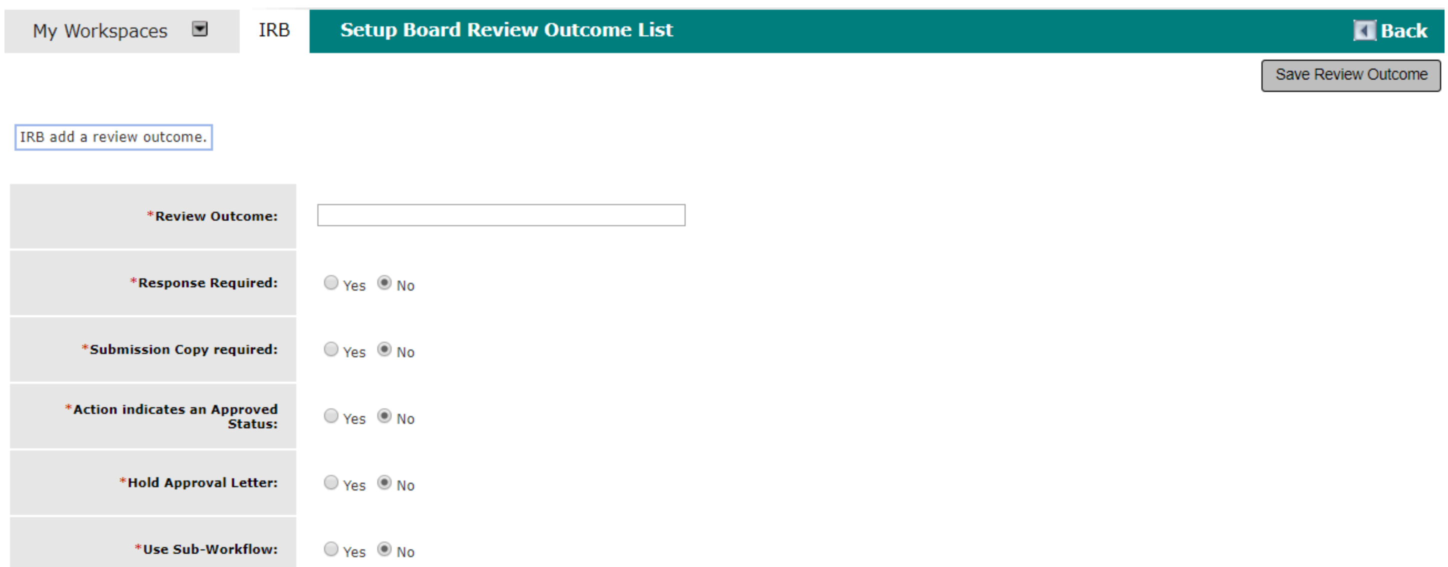


11.02
Review Outcome / Outcome Configuration List
Set up the Outcome list for submissions here.

When you open the page, a list of any review outcomes that have already been added to the system will display. If you have not set up any review outcomes, the page will not list any records.



You can add a new review outcome by clicking on the **Add a New Action** button.



Enter in the Review Outcome name.

You can also specify which flags to apply to this Outcome.

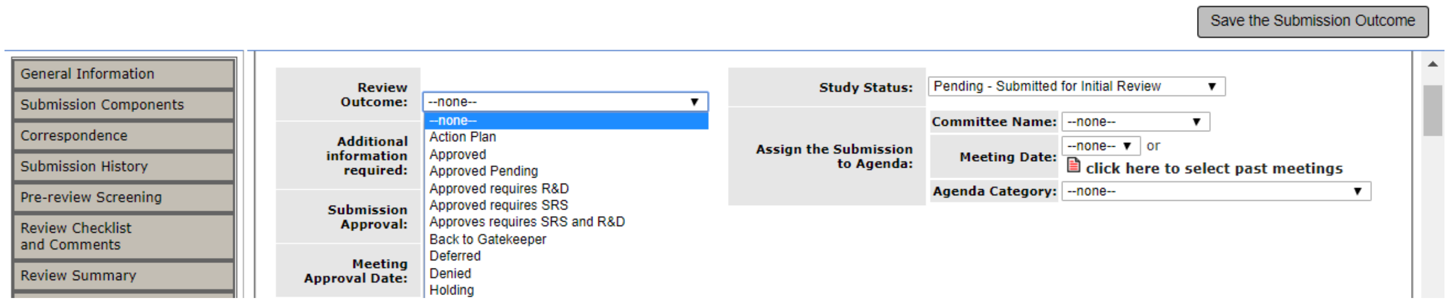
Submission Copy Required – When this option is set to Yes, the system will place a copy of the submission back into the Not Assigned queue. This setting is typically used to flag tabled submissions so you can assign a tabled submission to another meeting from the Not Assigned queue.

Action indicates an Approved Status - When this option is set to Yes, the system will flag this submission as Approved and mark any submission form associated to the submission as approved. Note: This does not include consent forms and other study documents; those must be approved and stamped separately.

Hold Approval Letter – When this option is set to Yes, the system will hold the approval letter from being sent out.

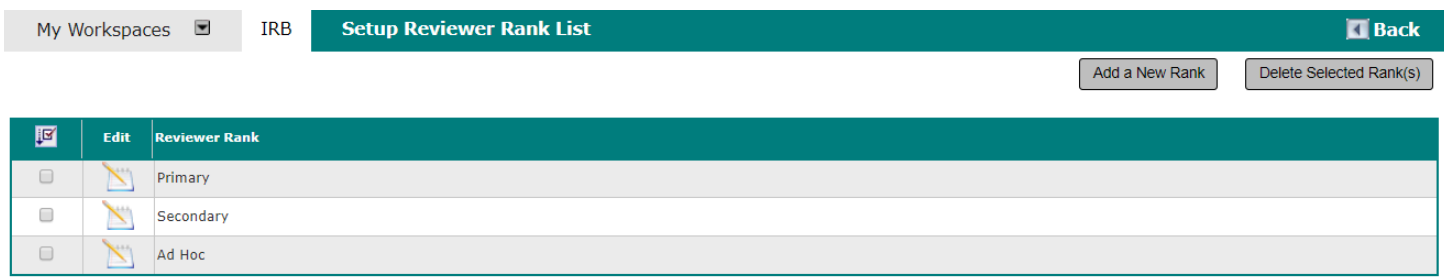
After returning to the main list of icons, you can edit existing review outcomes by clicking the  icon next to the record. This will open a page that will allow you to modify the Review Outcome and other associated decisions.

The list of Review Outcomes will populate in the Review Outcome list in the Outcome tab within the submission processing screens.



Reviewer Rank Configuration list

You can define your reviewer ranks here.

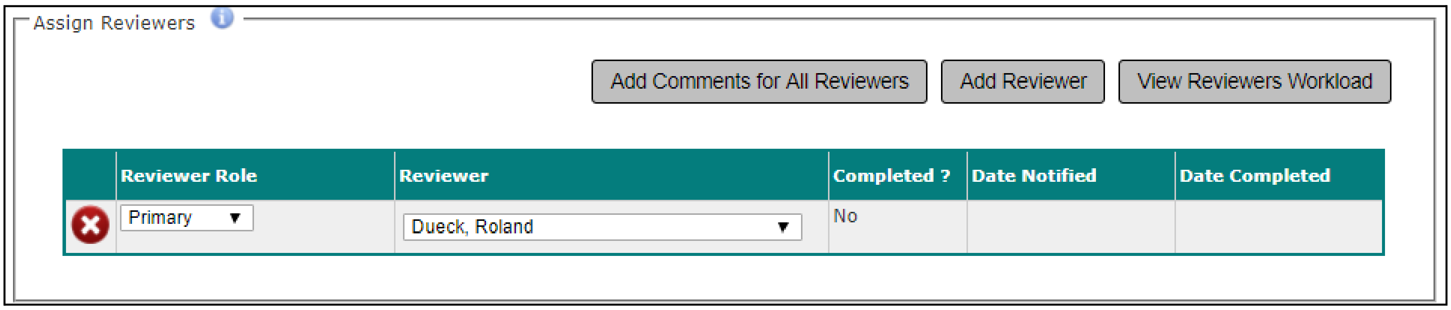


When you open the page, a list of any reviewer ranks that have already been created will display. If you have not set up any reviewer ranks, the page will not list any records.

You can add a new reviewer rank by clicking on the **Add a New Rank** button.

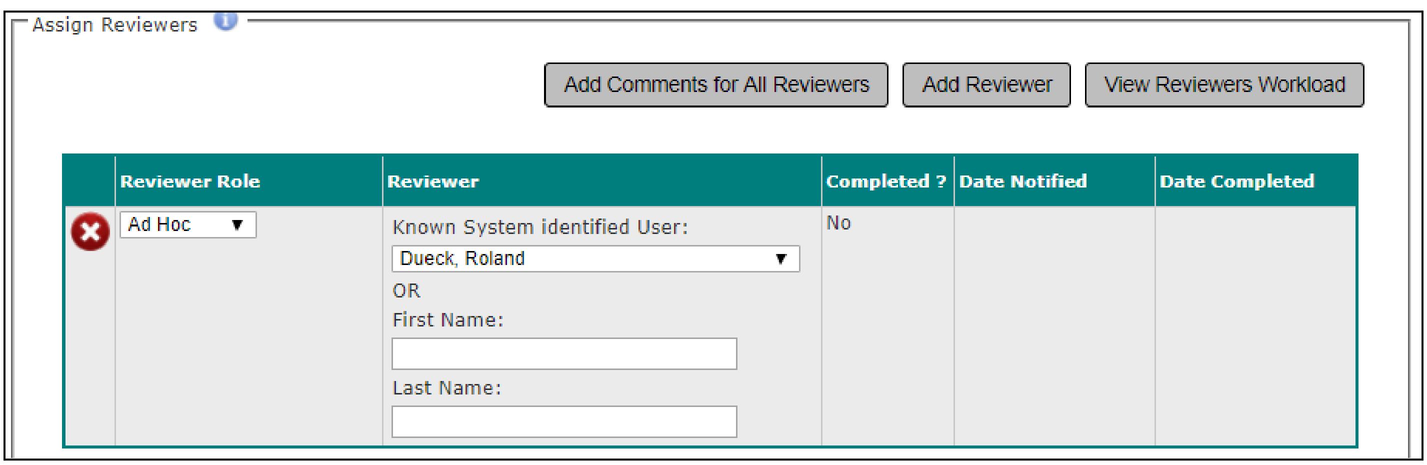
Type in the Reviewer Rank and specify whether the rank represents an Ad Hoc reviewer by selecting Yes or No. You must also specify a number for the rank. Specify 1, 2, 3 or 0 (for Ad Hoc reviewer ranks). These numbers tell the system how to treat the reviewer rank. “1” indicates a Primary Reviewer in the system. “2” indicates a Secondary Reviewer. “3” indicates any other review level. “0” indicates Ad Hoc. Click the **Save Reviewer Rank** button to add the record to the list.

You can edit existing reviewer ranks by clicking the  icon next to the record. This will open a page that will allow you to modify the record. To delete an existing rank(s), check the box(es) next to their name(s) and click **Delete Selected Rank(s)**.



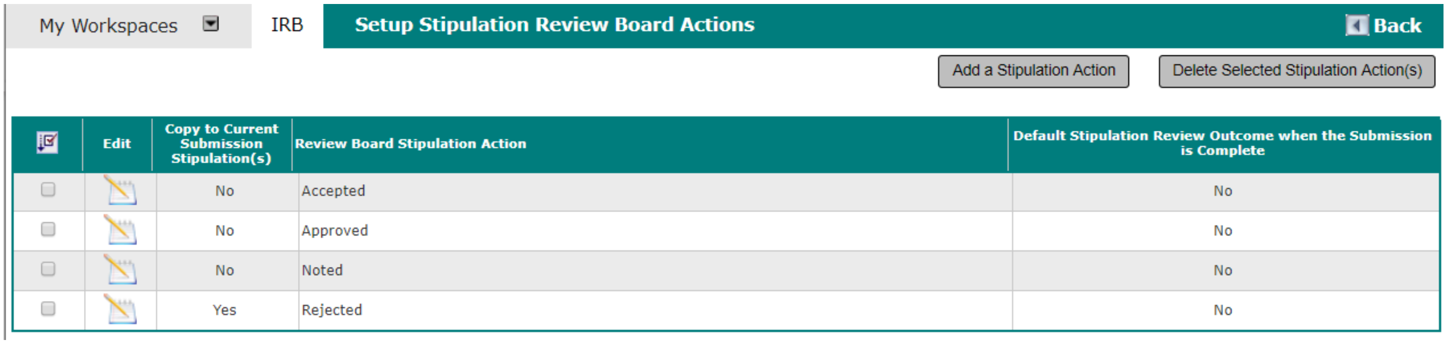
Reviewer rank populates in the Reviewer Role column when you are assigning a reviewer to a submission.

If the reviewer rank you selected is an Ad Hoc rank, you will be able to select a named board member from the drop-down list in the Reviewer column, or you can type in the first name and last name of the user (for specialty reviewers who do not have a user account in iRIS).



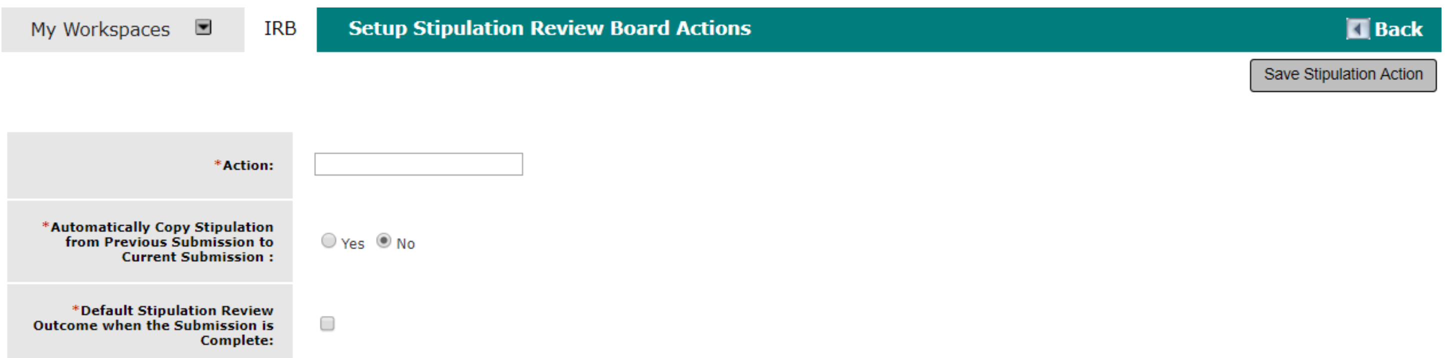
Setup Review Board Stipulation Actions

Here, you will be able to set up the list of Stipulation Actions that can be taken on existing stipulations.



	Edit	Copy to Current Submission Stipulation(s)	Review Board Stipulation Action	Default Stipulation Review Outcome when the Submission is Complete
		No	Accepted	No
		No	Approved	No
		No	Noted	No
		Yes	Rejected	No

To delete existing stipulation actions, click the checkbox next to the item desired and click the **Delete Selected Stipulation Action(s)** button. To edit a stipulation action, click the icon next to the desired stipulation action. To add a new stipulation action, click the **Add a Stipulation Action** button.



Enter the Action and define the additional details, then click **Save Stipulation Action**. To return without saving the action, click the **Back** button. A saved stipulation action will appear in the list of stipulation actions.

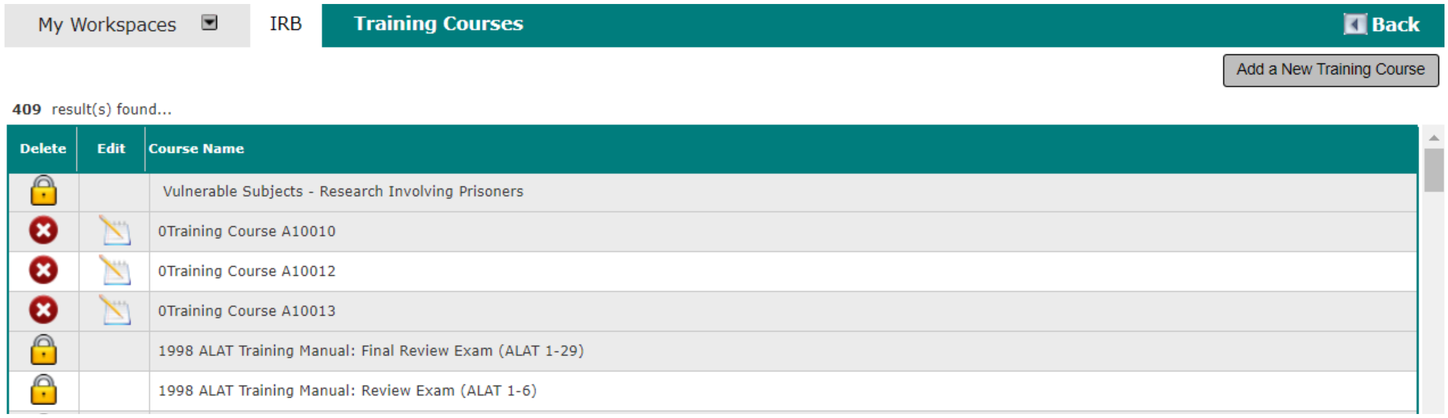
Automatically Copy Stipulation from Previous Submission to Current Submission – If this option is set to Yes, the stipulation will be copied to the current round when this Stipulation Action is applied. This means that the stipulation was not adequately addressed by the study and will be returned to the study again. If this option is set to No, the stipulation will post as "Closed" when the action is applied.

Default Stipulation Review Outcome when the Submission is Complete – Only one Stipulation Action can have this flag set. If you do not post actions to stipulations and complete the processing for the submission, the action with this flag will be applied to the stipulations. This typically means that the stipulations were all adequately addressed and can be closed.

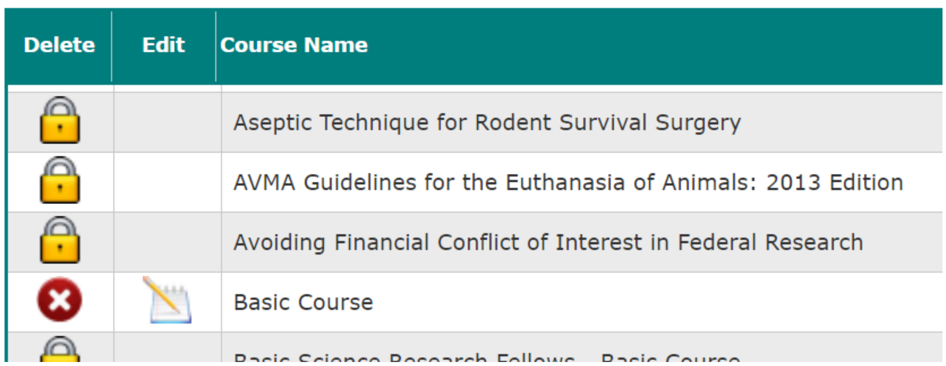
When a stipulation is modified in the Stipulations Tracking Screen in the review board assistant, the list of Review Board Actions will populate with the actions set up.

Setup Training Courses

The Setup Training Courses page lists the current training courses that a user can be assigned. Note: If your system imports the CITI feed, courses are imported automatically and will appear as locked, unable to be deleted or edited.



To delete courses that have been added manually, click the icon in the Delete column. A dialog box will open. Click the **OK** button to continue and delete the record. Click the **Cancel** button and the record will not be deleted.



To edit courses that have been added manually, click the icon next to the course to be edited. After a new page opens, you may change the name of the course, and then click the **Save Training Course** button to save the changes. Click **Back** to return to the list without saving any changes.

The Course Name column displays the name of the course that will be displayed.

Click the **Add New Training Course** button to add a course to the list.

Enter the name of the course. Click the **Back** button to return to the Training Course list page without saving any changes. Click the **Save Training Course** button to add the course to the Training Course list page.

When the Review Board Administrator adds a training record for a particular board member, the training courses added in this configuration list will populate in the Course Name drop-down list when the Administrator is adding a new course for a user.

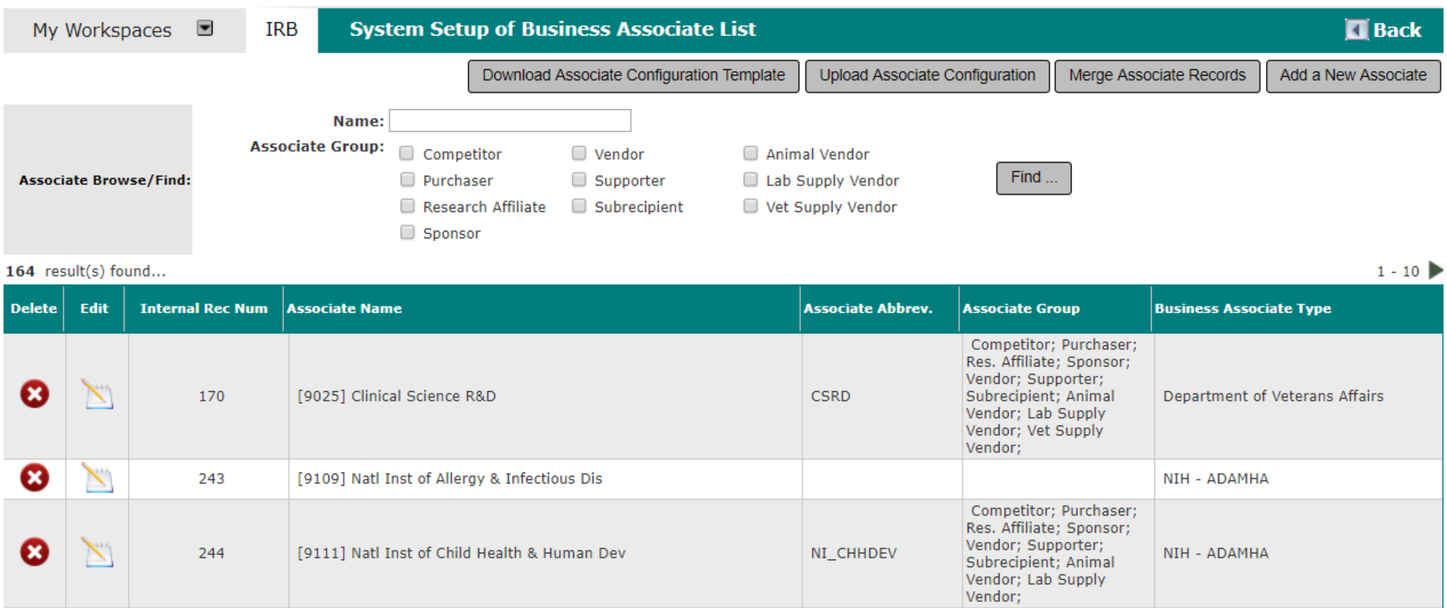
11.02
Business Associate List

The Business Associate List contains a list of institutions you may need to track as a Sponsor, Subrecipient, Vendor, etc. Records added to the Business Associate list can be used in a variety of ways in the system. They can be added as a study sponsor, as a third party for a conflict of interest, and as a sponsor or subrecipient on a study.

Clicking the Business Associate List link will populate the existing Associates in the system. You will have the ability to **Add a New Associate, Download** a template that will allow you to add multiple business associates at one time, **Upload** a template to add the associates to the system, edit the existing business associates, **Merge Associate Records**, and delete associates**.** Additionally, this page contains search filters that will allow you to search for a specific record.

Add a New Associate

Selecting **Add a New Associate** will prompt you to enter the below fields. Saving this information will add the record to the list of Associates/Sponsors within iRIS.



Associate Abrv – Allows the designation of an abbreviation for the particular associate.

Associate Name – In this required field, you must specify the business associate's name.

Status – Displays the internal status of the record. Once the record is saved, this status will change to "Active."

Associate Group – Allows the designation of the group the associate should be labeled as. Depending on the answer given in this list, additional fields below will populate, and be available for entry. Note: The Associate Group list is a configurable list.

Associate Type – Allows the type of association to be labeled and chosen from a drop-down menu.

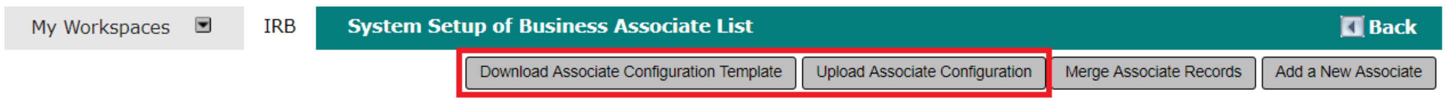
Street 1 & 2, City, County/Parish, State, Province, Country, Zip/Postal Code – Allows the input of the Associate/Sponsor's address or location information.

Clicking **Save Changes** will add the new Business Associate to the master list.

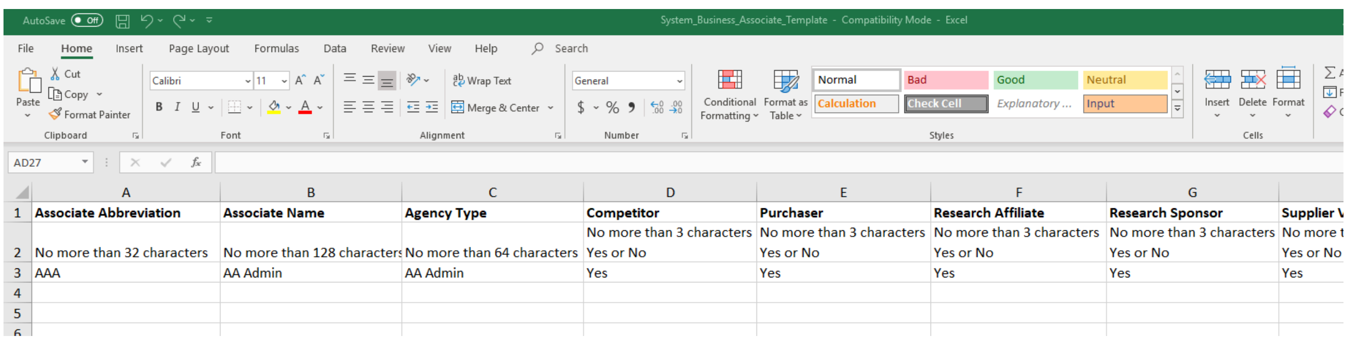
11.02

Download/Upload Associates

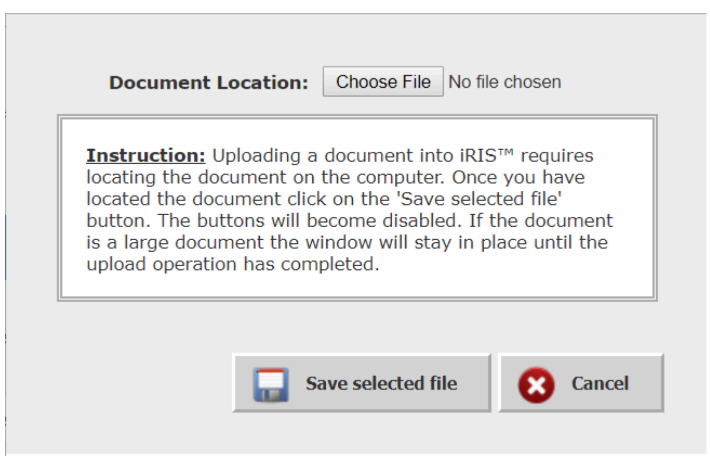
The **Download/Upload Associate** features give you the ability to upload an Excel file with as many business associate records as needed at one time.



Download Associate Configuration Template – This feature will allow you to download an Excel spreadsheet template. This template is setup in the proper format for uploading business associate records, with instructions for the input of data in each field. When downloading, be sure to **Save** the file to a known location on your computer, so the data can be input and saved for future uploading. Below you will find a screenshot of this spreadsheet template.

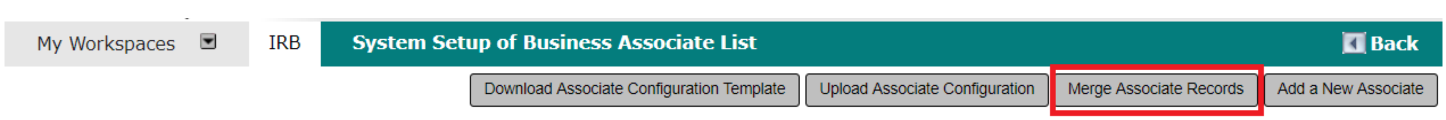


Upload Associate Configuration– Selecting to upload will open a popup window, where you will be able to browse for the correct Excel file containing the drug records you wish to upload.



Merge Associate Records

Selecting to **Merge Associate Records** allows you to merge duplicate records within the system.

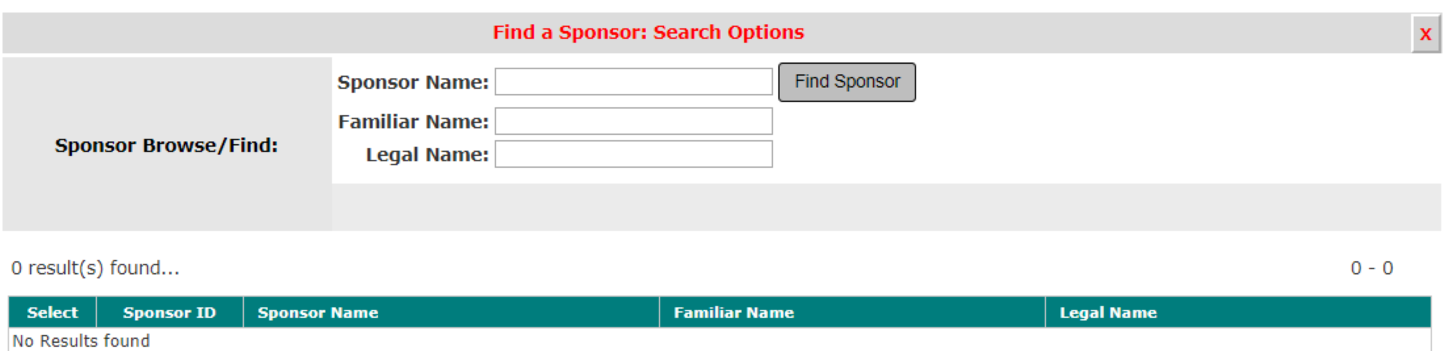


After making this selection, a list of the existing records will populate. Selecting two or more records will allow you to merge the records and select the record that you wish to keep.

Note: For records already existing on studies, the record that was kept will replace the deleted record within the study.

Once a Business Associate / Sponsor has been added to the master list, they become available to be associated to study applications through a data value.

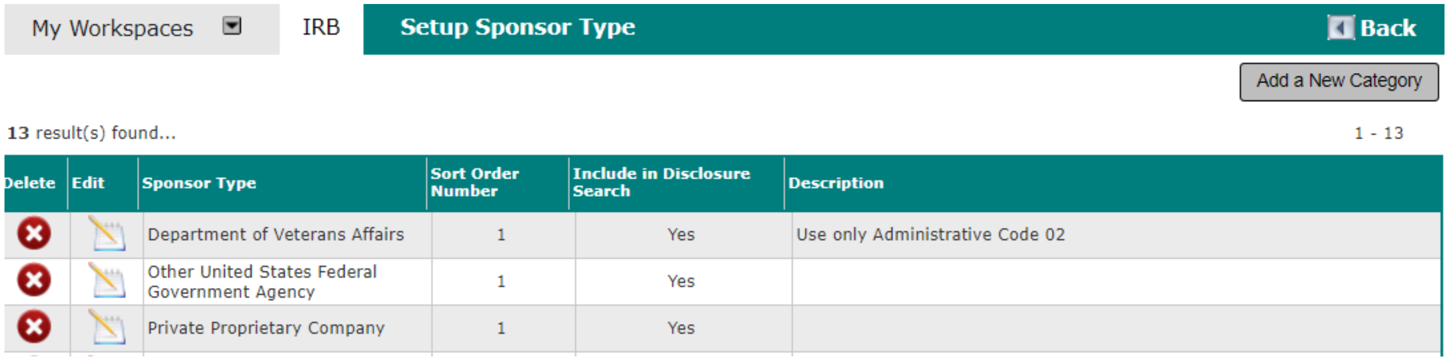
Selecting **Add a New Sponsor to the Study** will display a popup window, which will allow the user to search for the applicable sponsor.



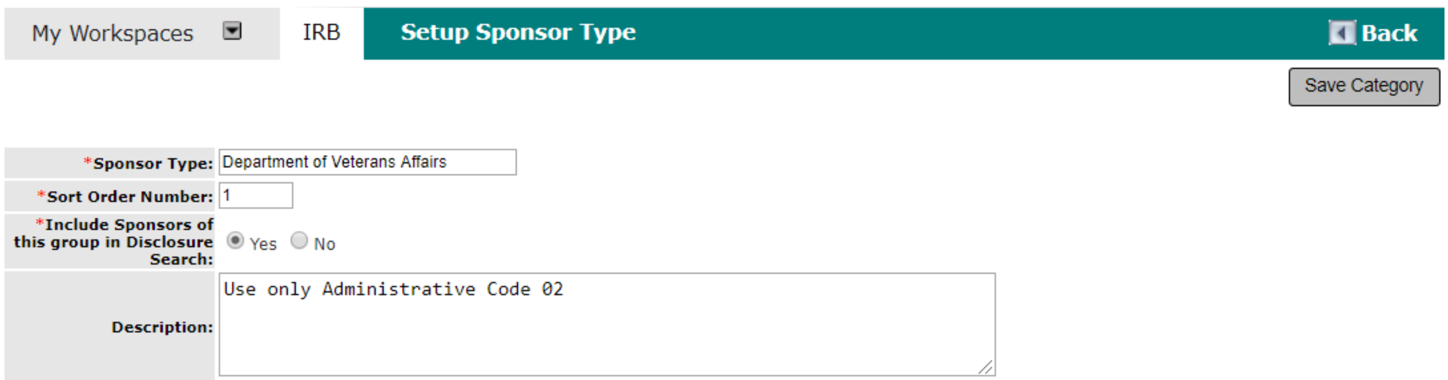
Sponsor Type

This is a list of available Sponsor Types that you can associate to a Sponsor record.

After selecting this link, the master list of existing Sponsor Types will display. You will have the ability to edit the existing records, as well as add new categories and delete categories.



Clicking the **Add a New Category** button will direct you to the following screen:



Sponsor Type – In this field, you are required to designate the display name for the Sponsor Type record.

Sort Order Number – Enter a number to set the order in which you want the Sponsor Types to display.

Include Sponsors of this group in Disclosure Search – This setting is used for the COI module. Any sponsor associated to a Sponsor Type with this flag set to Yes will be included in the conflict of interest check. This means when a Covered Person submits a conflict of interest form, with a conflict match listing a sponsor with this type, the system will flag a COI match and report it to the Conflict of Interest board.

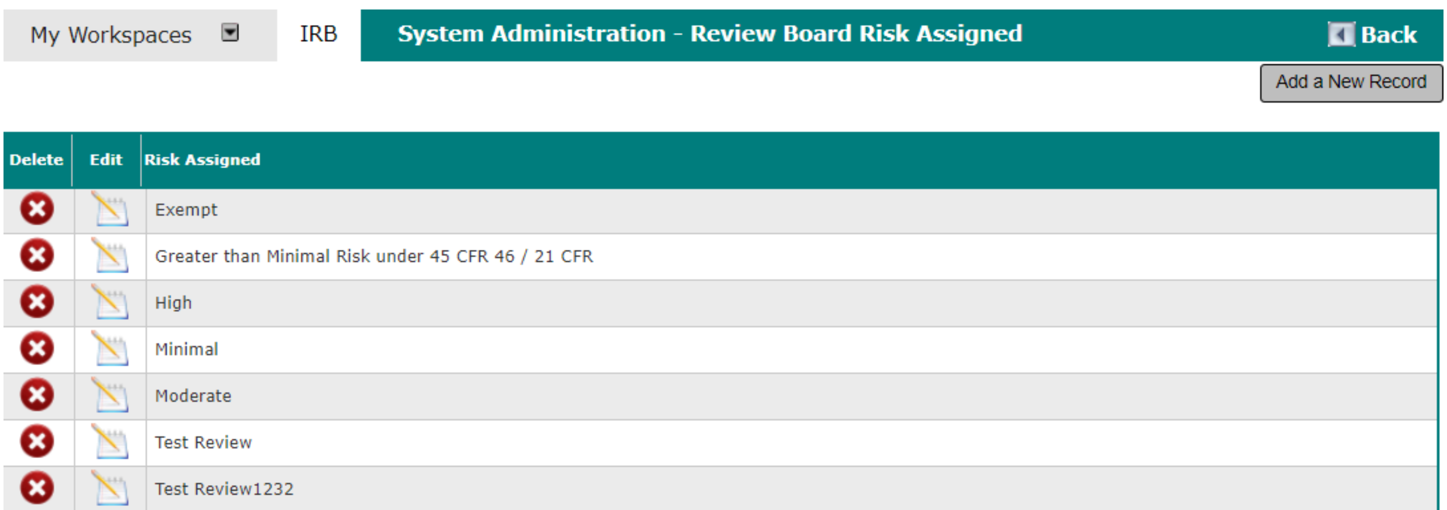
Description – You can enter a description of the Sponsor Type here. This field is for internal purposes and will not be displayed to end users.

Click **Save Category** to add the Sponsor Type to the master list and make it available to be applied to sponsors in the system.

To delete an existing Sponsor Type, click the icon next to the corresponding record in the list of Sponsor Types.

Risk Assigned Configuration List

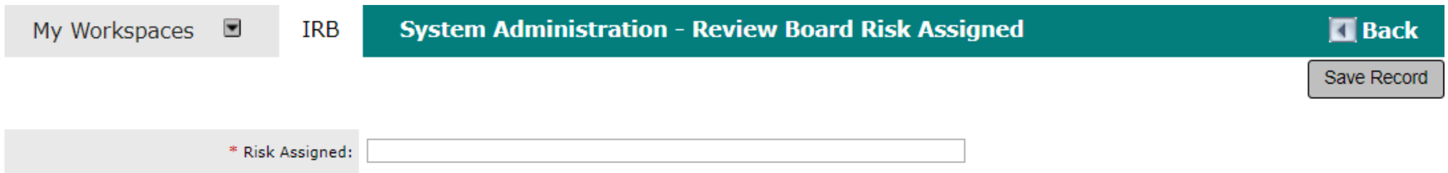
The Risk Assigned Configuration List contains the current risk ratings the review board uses to rate the risk for a particular study. Depending on whether the rb.use_risk_assigned property is turned on, this configuration list may not appear.



To delete Risk Assigned record(s), click the icon in the Delete column. A dialog box will open. Click the **OK** button to continue and delete the record(s). Click the **Cancel** button and the record(s) will not be deleted.

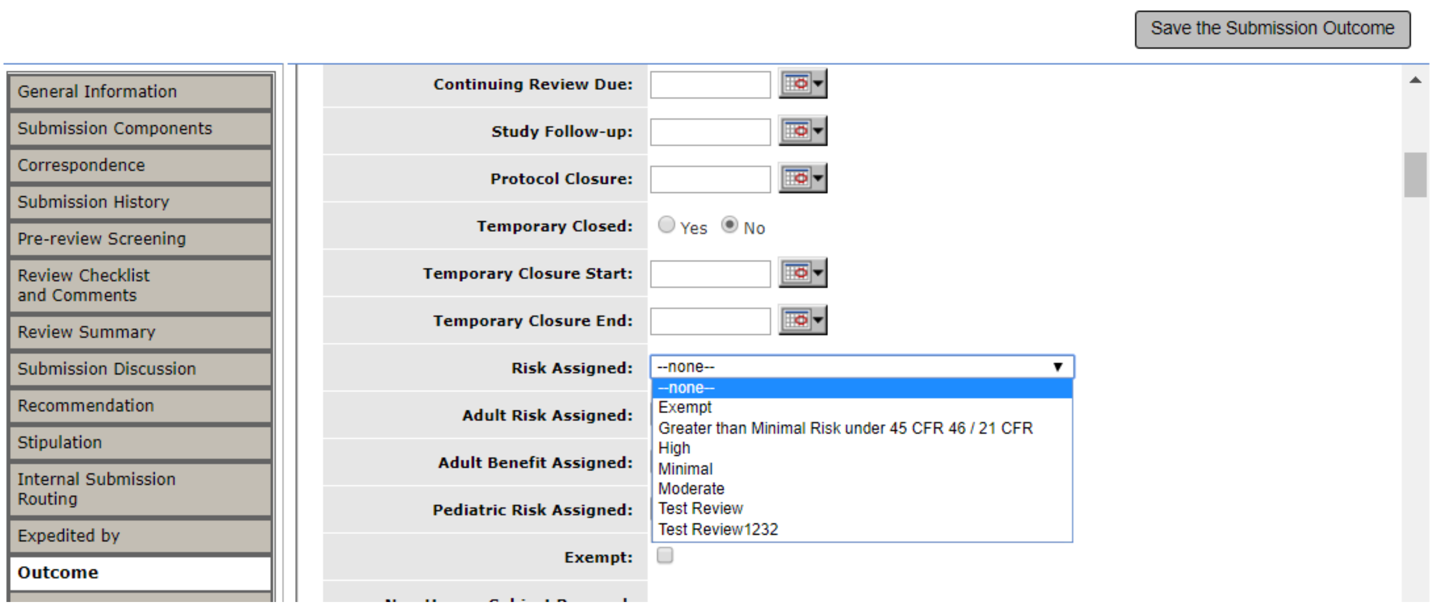
To edit a risk, click the icon next to the risk to be edited. After a new page opens, you may change the name in the Risk Assigned field, and then click the **Save Record** button to save the changes.

11.02
Click the **Add a New Record** button to add a record to the list.



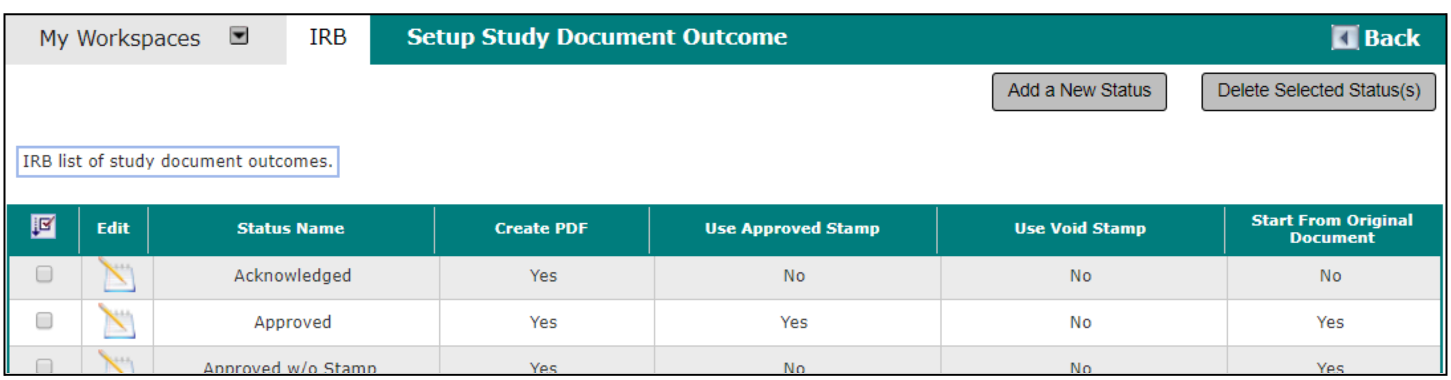
Enter the risk name, and then click the **Save Record** button.

The list that is defined here is available to choose from when assigning the Risk to a study within the Outcome tab of the submission processing screens.

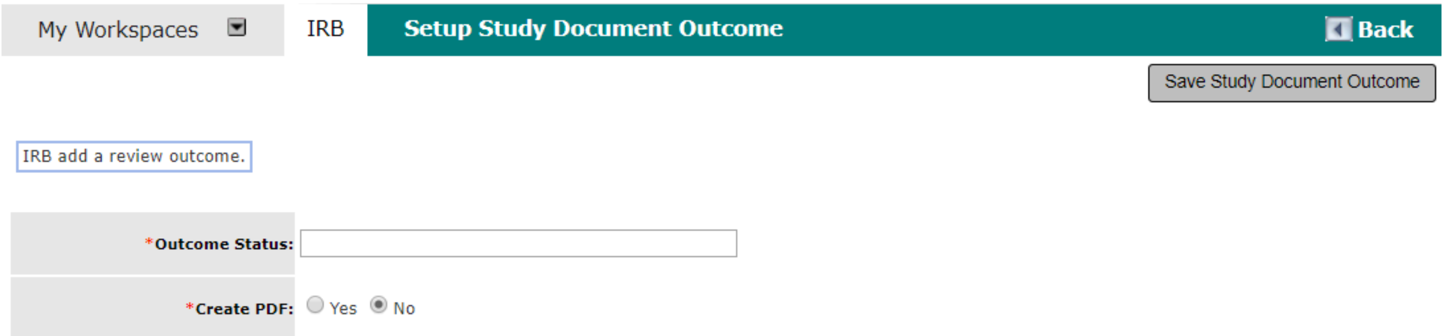


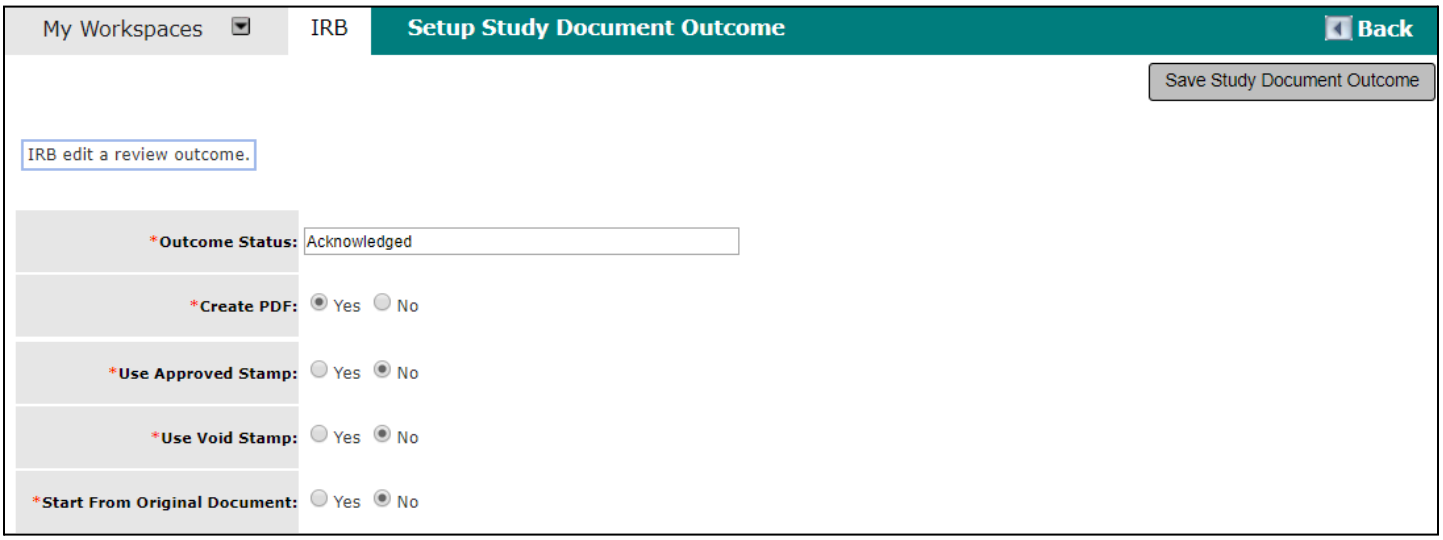
Study Document Outcome/Outcome Configuration List

This list will contain a list of Study Document Outcomes for the review board.



To add a new Outcome Status, click the **Add a New Status** button.



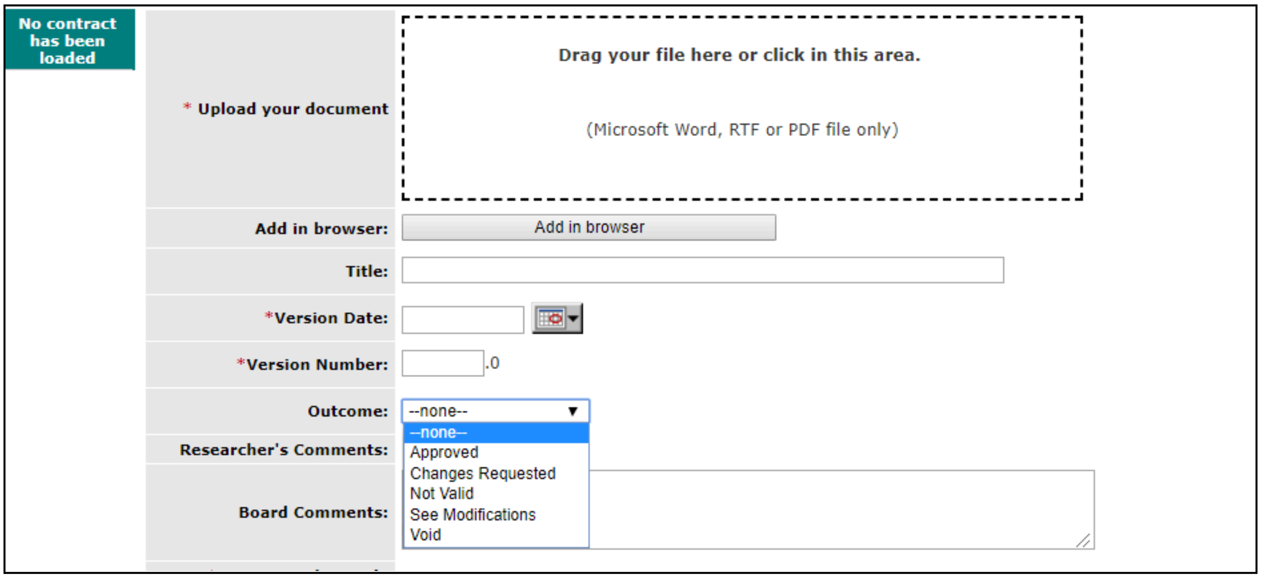


The Outcome Status name is a required field. When the Create PDF option is set to No, the outcome status will leave the document as is. When it is set to Yes, when a study document is giving this outcome and saved it will be converted to PDF. In addition, three more options will populate. The three additional options are titled Use Approved Stamp, Use Void Stamp, and Start Fom Original Document.

The Use Approved Stamp option will not be available if the Review Board Property rb.stamp_study_doc property under the Document Processing Category is set to No. When this property is on, and the option here is set to Yes, then a study document assigned with this outcome will be stamped with an Approval Stamp.

The Use Void Stamp option will create a “VOID” watermark on the study document when it is converted to PDF.

The Start From Original Document option will specify whether the outcome set and saved will apply to the original document or to a PDF that has already been created from the study document outcome having already been set in the past. This option is applicable if review boards often return to the study document to re-process it and assign it another outcome. For example, when setting a document stamp to void, and a void watermark is stamped, then later on approving the document, the Start from Original Document option should be set to Yes so that the VOID watermark is no longer present.

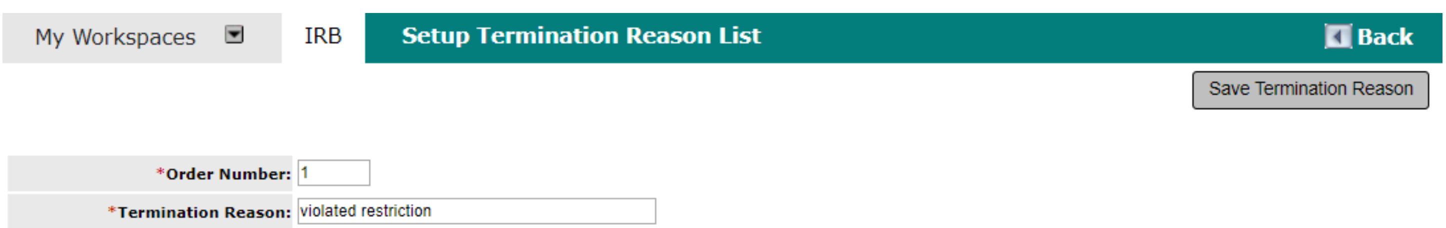


The Study Document Outcomes will populate in the Outcome drop-down list when you are approving a study document on the Submission Components tab within the submission processing screens.

Termination Reason List

The Setup Termination Reason List screen allows you to add, edit, and delete termination reasons for a study.

Click **Add a Termination Reason** to add a new termination reason to the list. You will see the following screen, which allows you to enter an Order Number and the name of the Termination Reason.

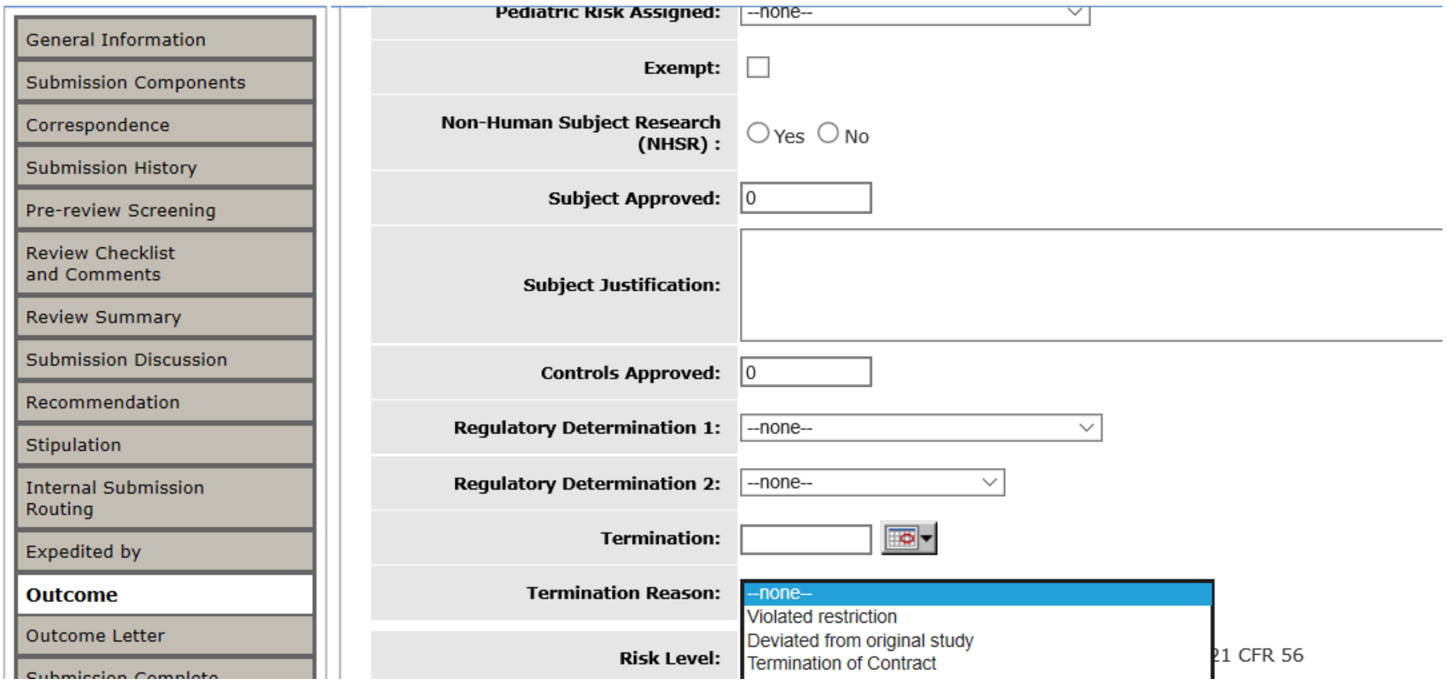


To save the new Termination Reason, click **Save Termination Reason**. To return to the main list without saving, click **Back**.

To delete Termination Reason(s), check the box(es) next to the reason(s) and click **Delete Selected Termination Reason(s)**. A dialog will appear to confirm the deletion. Click **OK** to proceed with the deletion or **Cancel** to return without deleting.

Click the  icon next to a Termination Reason to edit it. This will bring you to the screen shown in the above screenshot, where you can edit the Order Number and name of the Termination Reason.

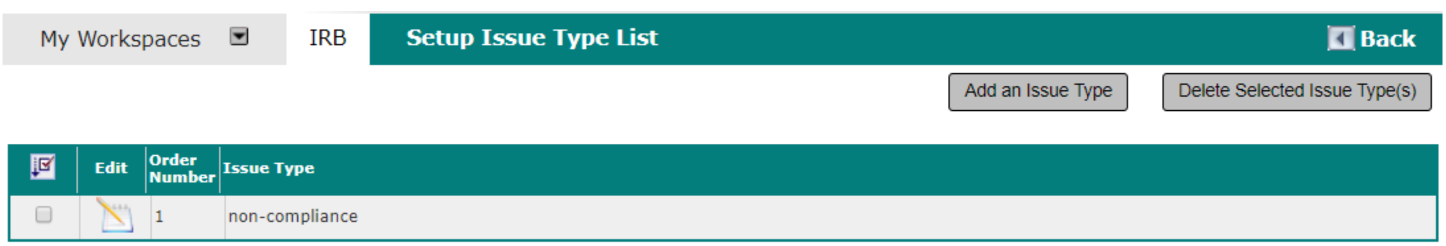
The Termination Reason drop-down list appears on the Outcome tab of submissions, as well as in the Study Summary.



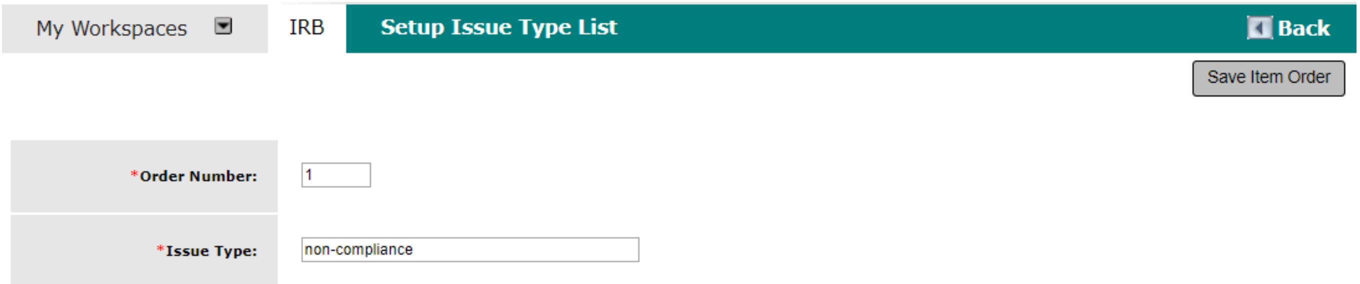
Issue Reporting Types

The Issue Type List page lists the current issue types that can be assigned to a study.

You can add a new Issue Type by clicking the **Add an Issue Type** button.

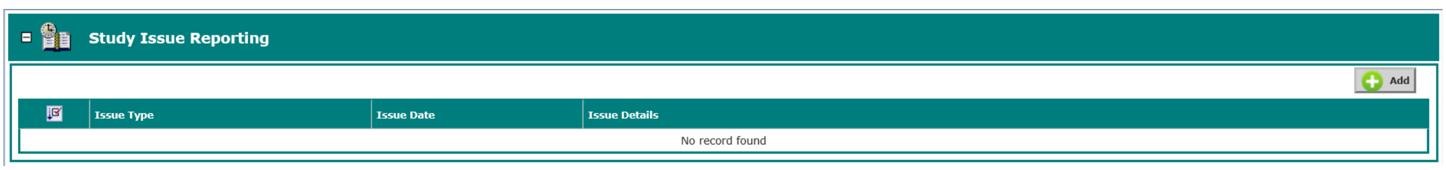


This will bring you to the Issue Type setup page. You will be required to enter the Order Number and the Issue Type. Once you have entered this information, click the **Save Item Order** button and the issue will be added to the Issue Type List.

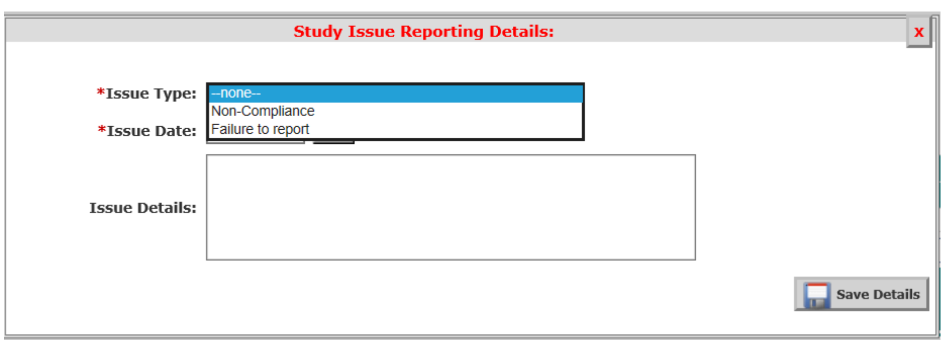


To delete Issue Type(s), check the box(es) next to the Issue Type(s) you want to delete and click the **Delete Selected Issue Type(s)** button. To edit an issue, click the icon next to an Issue Type, and you will be brought to the screen shown above, where you can edit the Order Number and Issue Type.

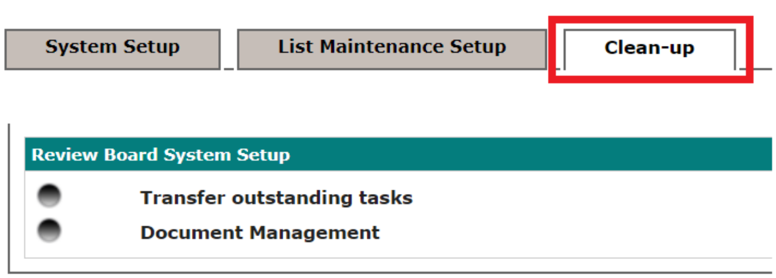
You can add the issue to a study from the Study Summary Information page from the Miscellaneous menu tab on the submission processing screens. Once you are on the Study Summary page, click the **Add** button next to the Study Issue Report section.



This will open the Study Issue Reporting Details window, where you can specify the Issue Type, Issue Date, and Issue Details. After you are done entering the issue details, click the **Save Details** button to add the issue to the study.



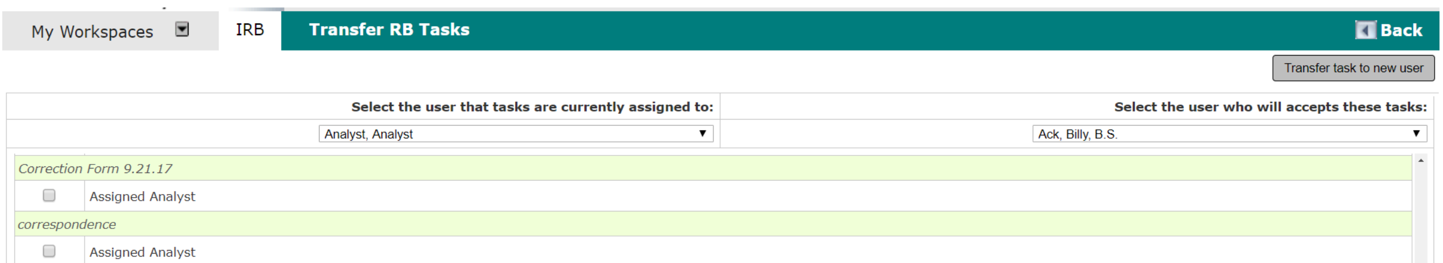
Clean-up



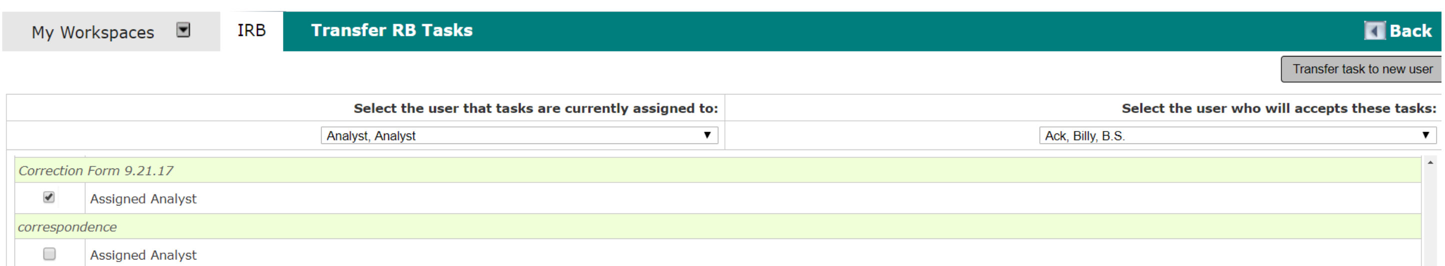
Transfer Outstanding Tasks

In Review Board Administration under the Clean-up tab, there is a feature titled Transfer Outstanding Tasks. This allows you to reassign a particular user's incomplete tasks to another user. This can be used, for example, when an IRB Coordinator leaves the institution and all their tasks needed to be transferred to their replacement.

To use this option, click the **Transfer outstanding tasks** link. This will open a new page where you can select the user whose tasks need to be transferred. The system will pull all of their incomplete tasks and put them in a list:



Then, check the box(es) next to the tasks desired for transfer and select the user that will accept these tasks from the drop-down menu. Then click the **Transfer Task to New User** button at the top right of the screen.

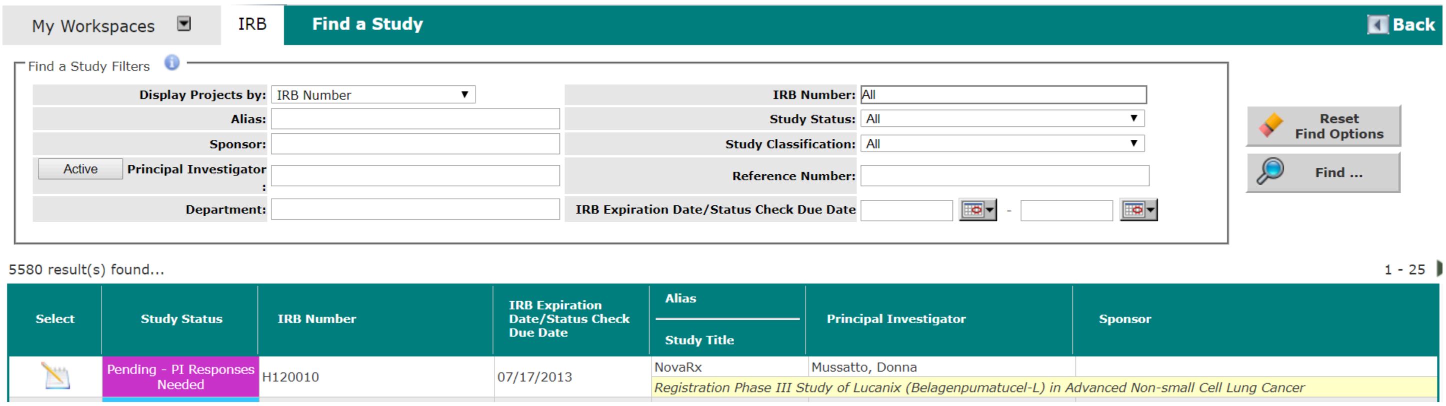


The user who has accepted the tasks will be able to open and complete the task from their home screen.

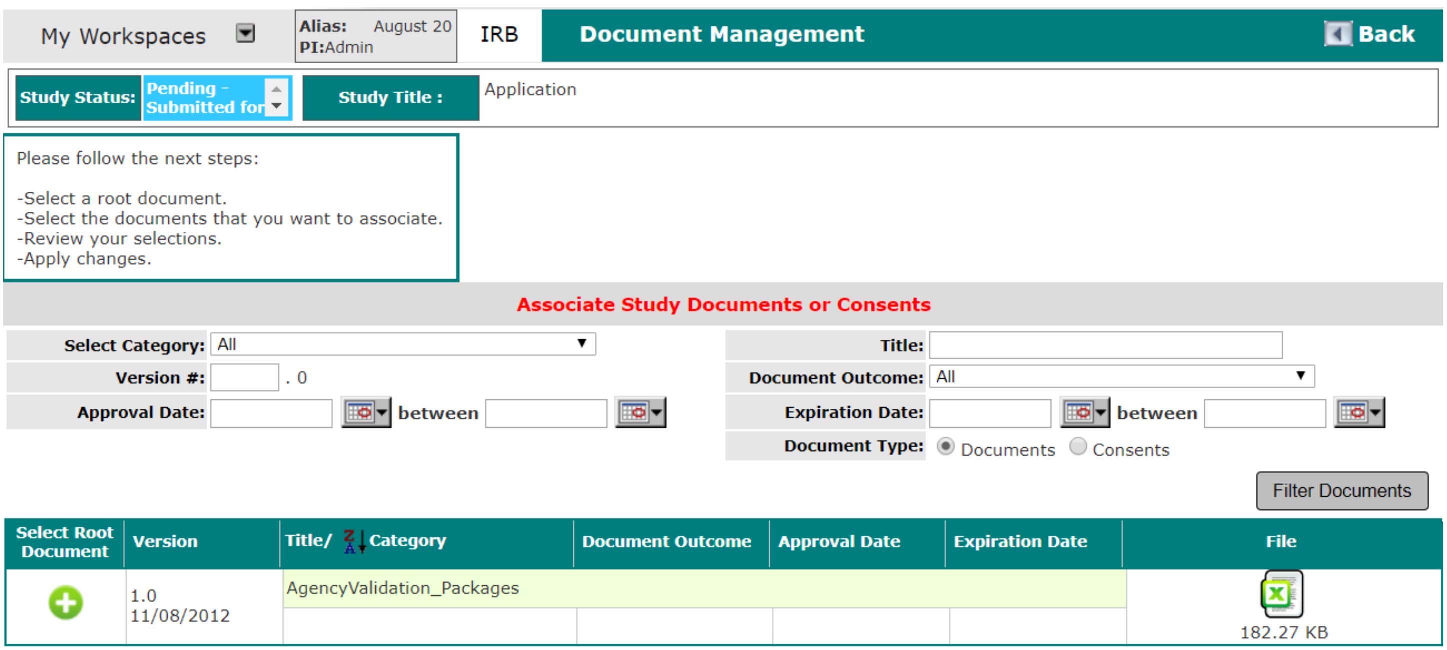
Document Management

The Document Management functionality allows you to manage the documents and consent forms associated with a study.

When you click the link, you will be brought to the IRB – Find a Study screen. You can use the filters at the top of the screen to locate the study you wish to manage documents for. In the screenshot below, the IRB Number filter was used to find a study. Enter the desired search terms in the Find a Study Filters and click **Find**.

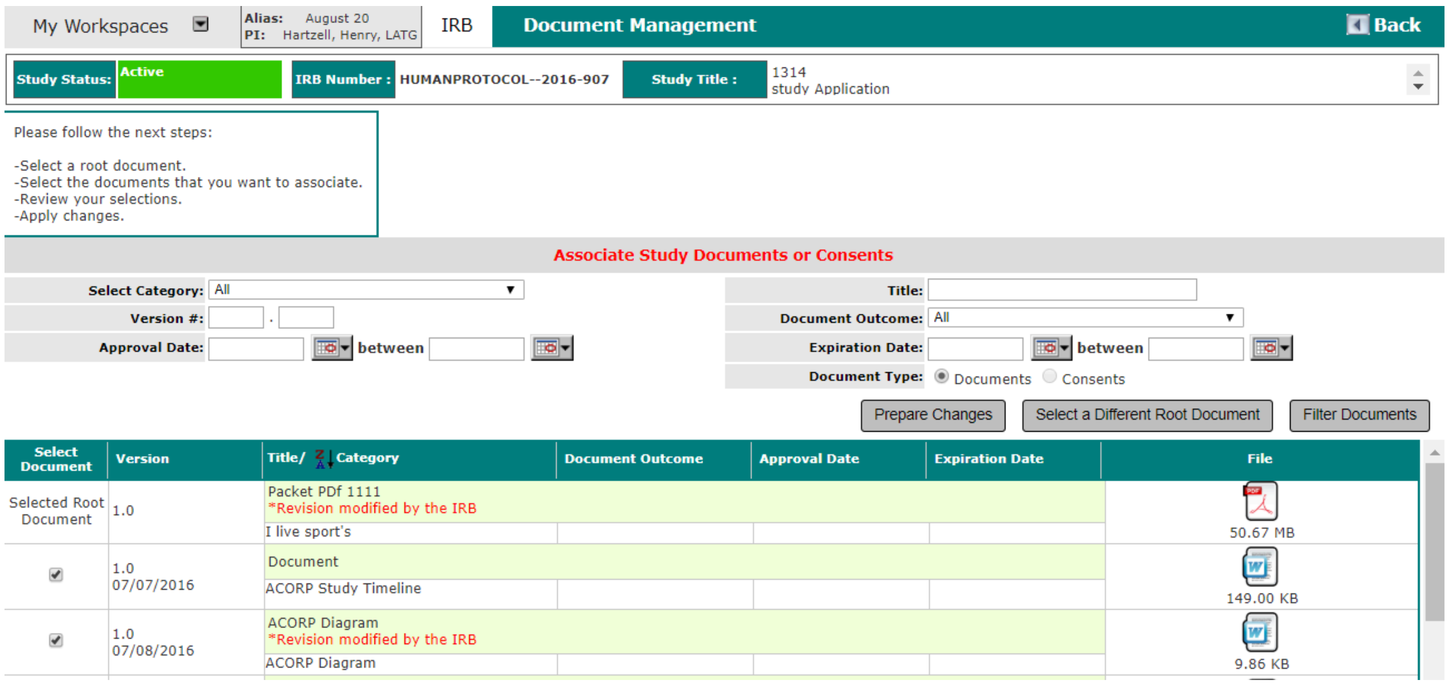


Click the in the record for the study you wish to open. This will bring you to the Document Management screen. In this example, Consents have been selected in the Document Type filter as the type of document to manage. You can also filter by document/consent Category, Version Number, Approval Date range, document Title, Document Outcome, and Expiration Date range.

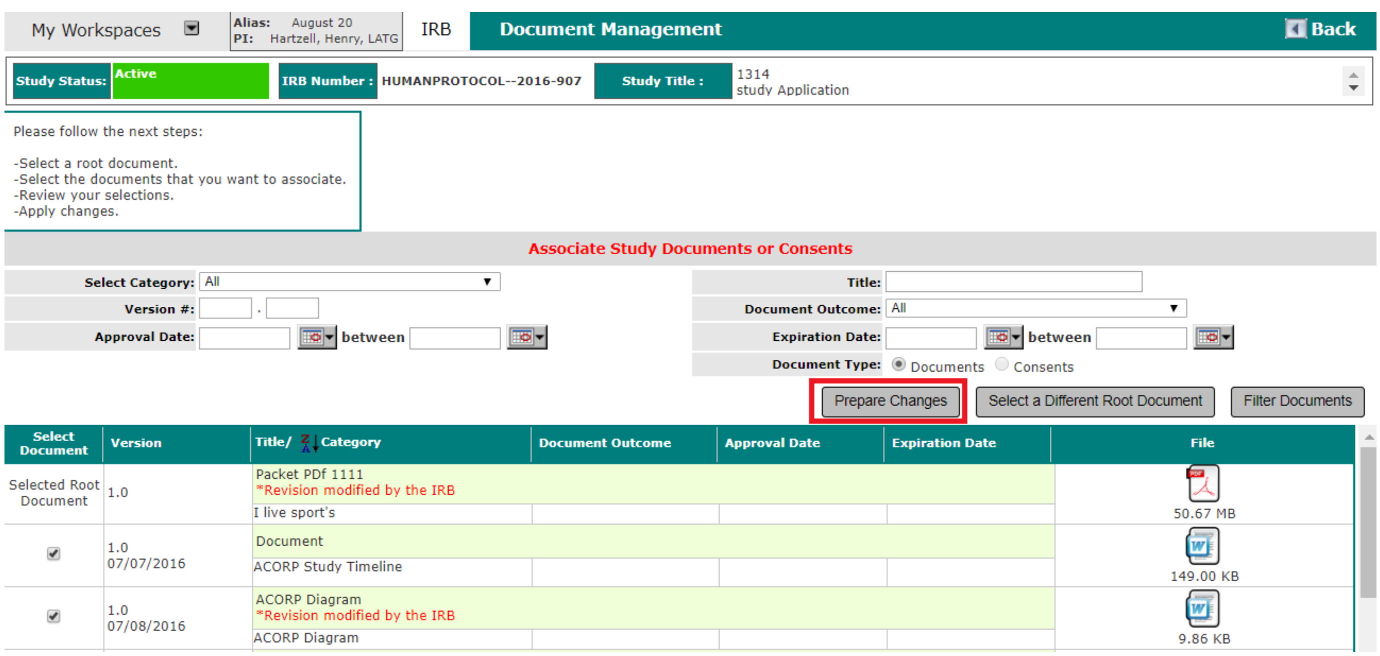


In the Select Root Consent column, you will see all of the consent documents associated with the study you selected that are version 1.0. These are the root documents that you will be merging other documents into. Click the icon next to the document that you wish to be your root document.

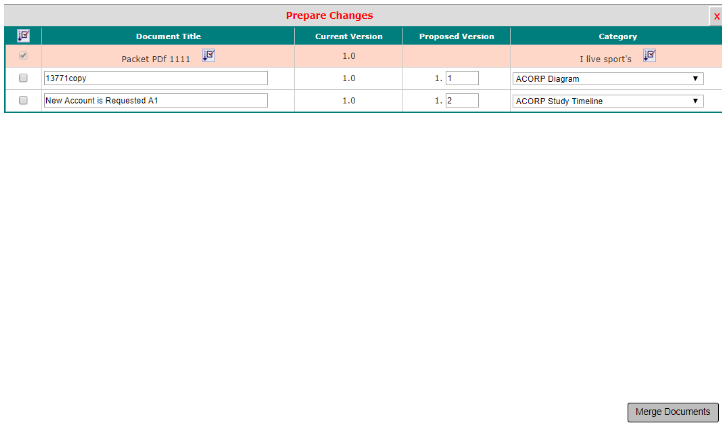
Checkboxes will populate in the Select Consent column, allowing you to select the consent document(s) that you wish to merge with the root document.



Make your selection(s) and click **Prepare Changes**.



The following window will open. Here, you can see that the versions of the document you selected as your root consent form are already selected for you. The documents called “Informed Consent”, which you selected with checkboxes in the previous step, are listed below the root versions with unchecked boxes next to them, which you can select if you decide to merge these documents into the root document.



The columns in this window are as follows:

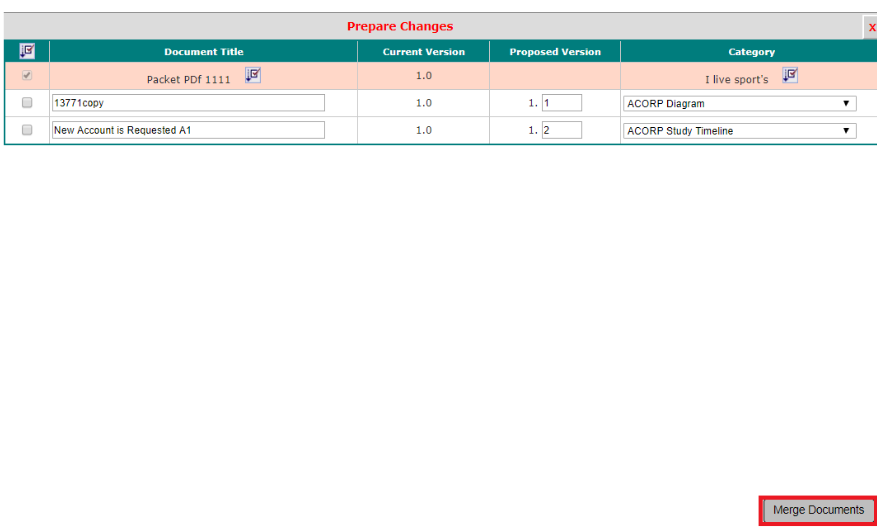
Document Title – When the window first opens, this field displays the original names of the documents. These are editable if you wish to change the name of any of your document versions.

Current Version – This column lists the current versions of the documents in the list.

Proposed Version – This column displays the suggested versions of the documents once they have been merged. These are editable if you wish to change any of the current version numbers.

Category – This column shows that all listed documents have been associated with the category of the root document.

In the scenario in the screenshot above, you can check the boxes next to the two documents titled Informed Consent to select them to merge with the versions of the root document. If you wish for these versions to have the same name as the root document, change their names in the Document Title field.



Click **Merge Documents** to proceed.

This opens the Prepare Changes window, where you can view the proposed changes to the documents. Click **Confirm** to continue with the merge, or **Cancel** if you do not wish to proceed. A dialog will open; click **OK** to confirm the action or **Cancel** if you do not wish to reorganize the documents.

Study Status Configuration List

Note: In previous versions, the link “Study Status Configuration List” was under the Review Board Administration > List Configuration and Maintenance, however it has now been removed and moved from every module’s “Review Board Administration”. Users with full system administration access can access the “Study Status Configuration List” from System Administration > List Configuration and Maintenance > Setup Study Status.