IRB Assistant

List Maintenance

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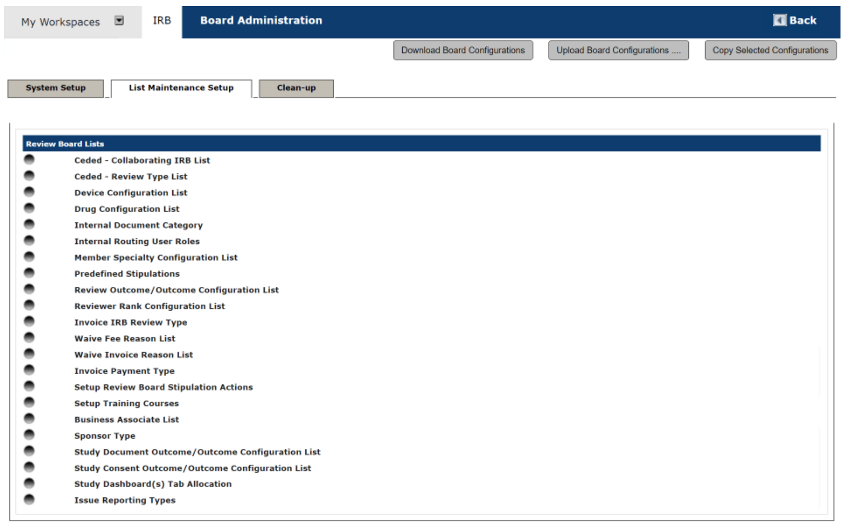
Introduction

The iRIS™ system provides numerous picklists on system pages and forms. Some of these lists exist to save users the time and trouble of manually typing in frequently used data items. Other lists exist to enforce data validation requirements.

Lists are managed on the **List Maintenance Setup** tab. To access this area navigate to IRB Assistant > Review Board Administration > **List Maintenance Setup** tab.



This manual provides details of list configuration processes and settings, and where applicable, information about where the configured lists are employed in the iRIS™ system.

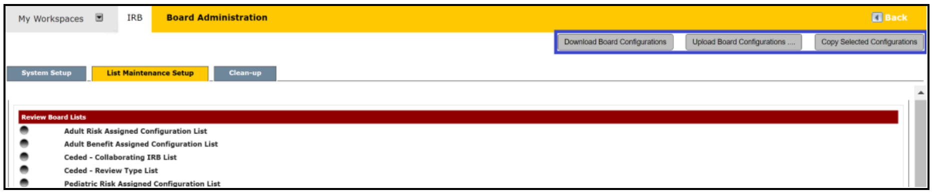
Tools for Copying Board Configuration

The iRIS™ system provides tools for duplication of an existing review board's configuration files to serve two different scenarios:

Download / Upload Board Configurations — create an identical board on a new server / in a new installation of the iRIS™ software

Copy Selected Configurations — create a new board on the same server / in an existing installation of the iRIS™ software with the same configuration settings as the source board

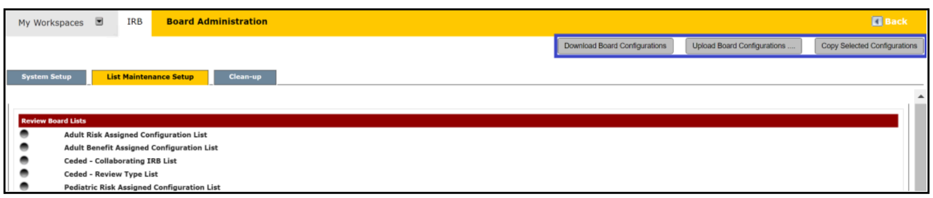
As shown in the screenshot below, both options are accessed via buttons on the **List Maintenance Setup** tab under IRB Assistant > Review Board Administration.



Note that these tools are only intended to be made available to full System Administrators (as opposed to those assigned to an Administrator role within a specific iRIS™ module) to help with initial setup of iRIS™ servers and new review boards.

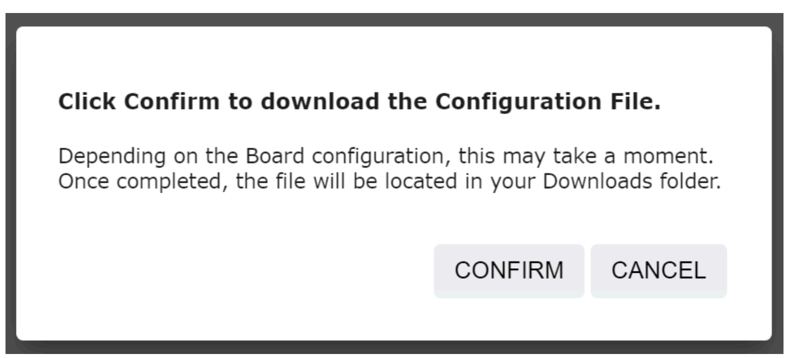
Download/Upload Board Configurations

Download/Upload Board Configurations is a tool that allows full System Administrators (as opposed to those assigned to an Administrator role within a specific iRIS™ module) to duplicate a fully configured review board from one iRIS™ system to another, such as when setting up a new server at a new facility within the same umbrella institution, in order to avoid errors and save the time and effort of manually keying in all the same data for a new board.



CAUTION: Download/Upload Configurations should not be used in a live iRIS™ system. iMedRIS recommends performing a board configuration copy to a destination review board only once.

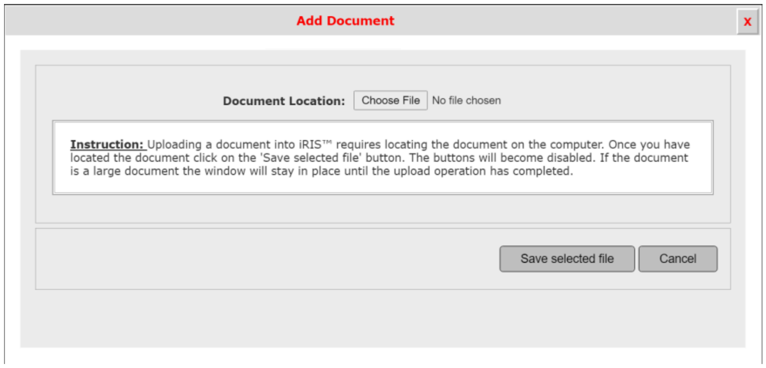
IN THE SOURCE iRIS™ SYSTEM: Click the **Download Board Configurations** button to download a file containing configuration settings for the currently selected IRB review board. A confirmation popup displays, as shown below.



Click **CANCEL** to close the popup without downloading the configuration file.

Click **CONFIRM** to complete the download. Note that as the popup indicates, the file is saved to the local computer's Downloads folder.

ON THE TARGET iRIS™ SYSTEM: Copy the downloaded configuration file to the computer where the target iRIS™ system is installed. Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Upload Board Configurations** button.



Click **Cancel** to close the popup without uploading the file.

Click **Save** selected file and follow the prompts to locate the file and upload it. Installation completes automatically.

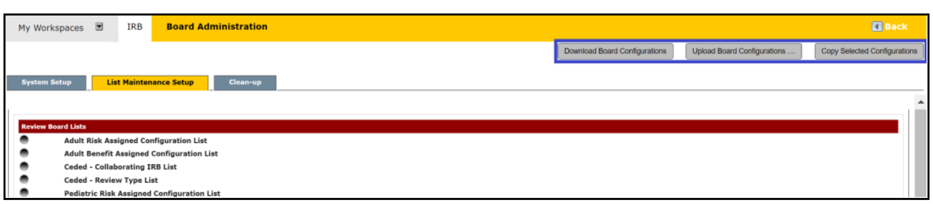
Copy Configurations

Copy Configurations is a tool that allows an iRIS™ system administrator to copy pre-existing, fully configured review board elements into a different, newly created review board within the same iRIS™ system in order to avoid errors and save the time and effort of manually keying in all the same data for a new board.

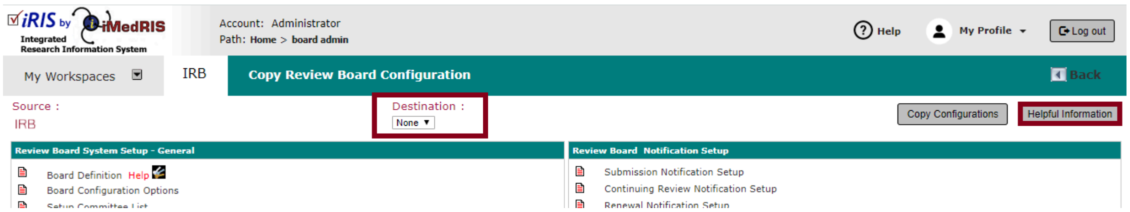
CAUTION: Copy Configurations should not be used after setup of review boards is complete, nor in a live iRIS™ system. iMedRIS recommends performing a board configuration copy to a destination review board only once.

Note that configurations cannot be copied across review boards of different types (IRB to IBC, IRB to ARC, etc.). Within IRB Assistant it is only possible to copy configurations across IRB review boards.

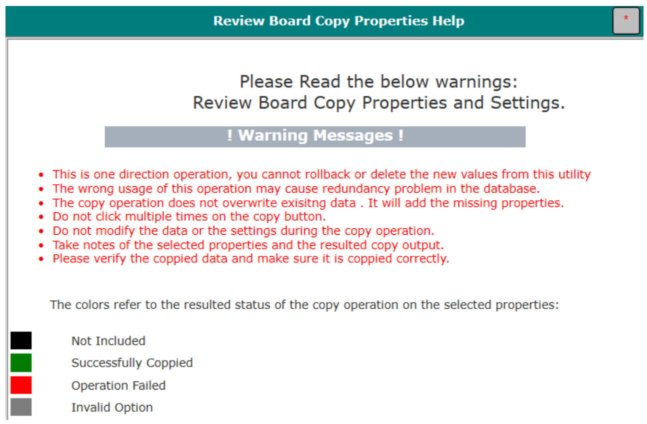
Click the **Copy Configurations** button to copy a pre-existing IRB review board configuration to another IRB review board.



The **Copy Review Board Configuration** page displays. The page contains links to configurations that can be copied to another review board. Note the **Destination** dropdown list at the top center of the page, and the **Helpful Information** button at right. The **Copy Configurations** button is non-functional until the **Destination** and at least one configuration item are selected (details follow below).



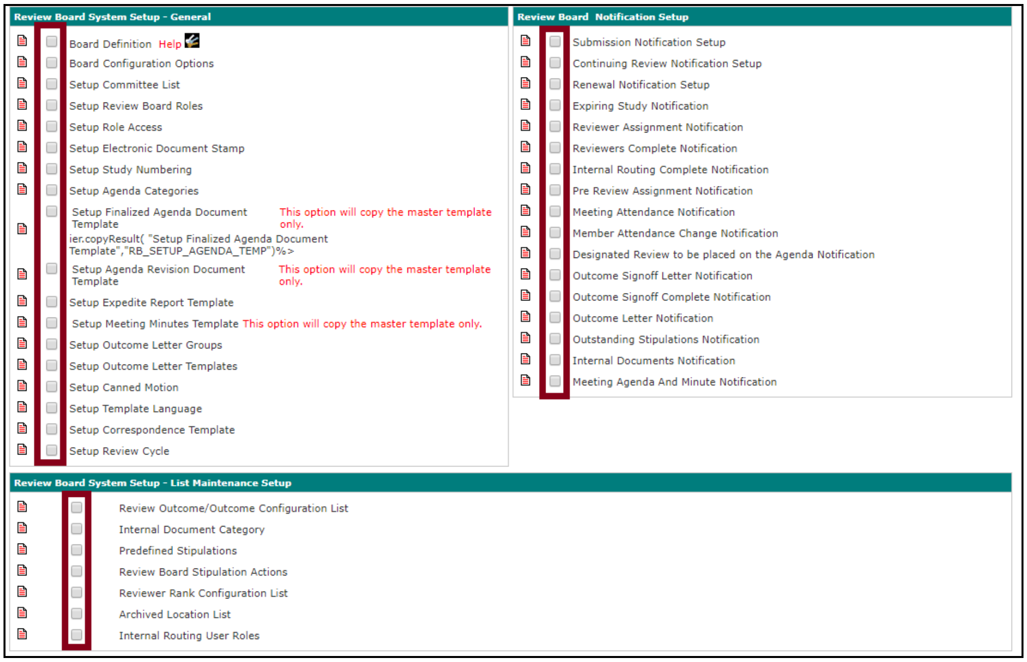
Click the **Helpful Information** button to view a popup containing important information and warnings about copying review board configurations.



Click the close window button in the upper right corner (marked with a red asterisk) to close the popup.

Back on the **Copy Review Board Configuration** page, select the target review board from the **Destination** dropdown list at the top of the page. The configuration **Source** is shown at the upper left, indicating the review board that is currently active. Only review boards of the same type will populate in the **Destination** dropdown list.

Select boxes for applicable configuration items in the setup lists are now available.



Select the configuration item(s) to be copied to the selected destination by clicking the respective checkbox(es).

Note that the following configuration items of the **Source** board cannot be copied:

— Board Definition

— Setup Review Board Roles

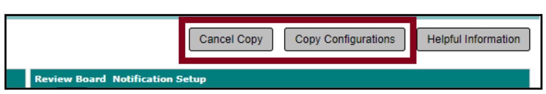
— Role Access

— Setup Correspondence Template

— Review Cycle

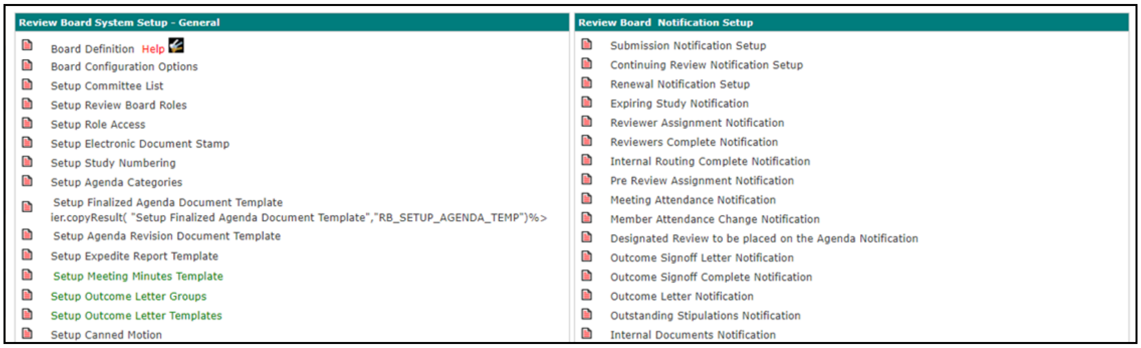
— Study Status Configuration List

Click the **Copy Configurations** button to complete the copy process. Click the **Cancel Copy** button to cancel the process without saving changes.



When the **Copy Configurations** button is clicked the copy process completes, and the **Copy Review Board Configuration** page refreshes.

Items where there is no data to copy, or where the corresponding field is not turned on in the destination review board, are not copied to the ***Destination*** *review board.*

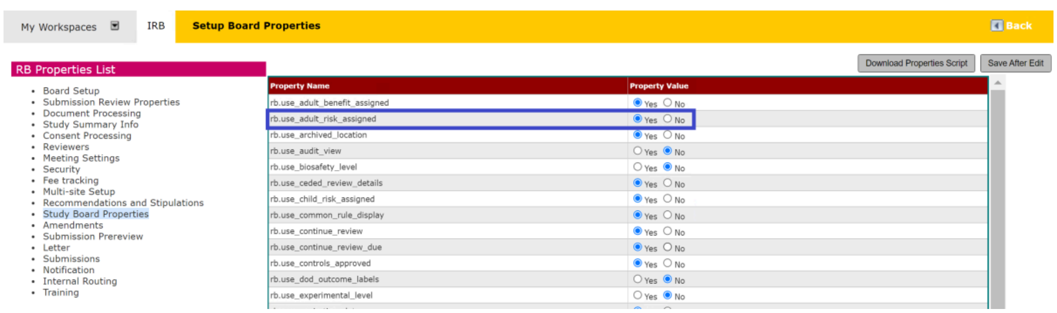


As demonstrated above, any items successfully copied are color coded with green text. Items that did not copy successfully are color coded with red text.

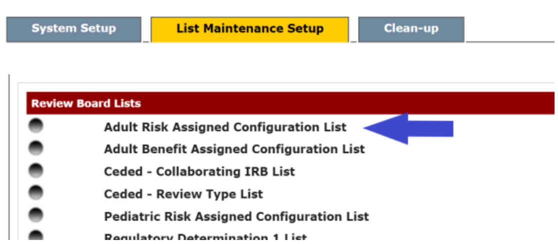
Note: When performing a review board configuration copy from one board to another, fields that were originally pre-populated in the destination board are overwritten with data copied from the source board.

Adult Risk Assigned Configuration List

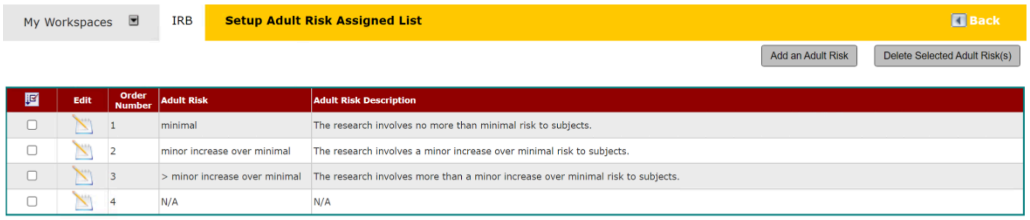
Where the property rb.use_adult_risk_assigned is set to “Yes” (under IRB Assistant > Review Board Administration > Board Configuration Options > Study Board Properties, see screenshot below), the iRIS™ system allows for setup and maintenance of an **Adult Risk Assigned Configuration List**. The list contains current risk ratings the review board can assign to rate potential risk to adults accrued from participation in a particular study.



Setting the property to “Yes” populates an **Adult Risk Assigned Configuration List** link on the List Maintenance Setup tab, as shown in the example below.

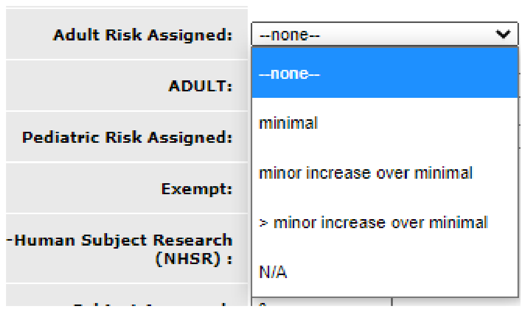


Click the link to open the **Setup Adult Risk Assigned List** page, shown below.



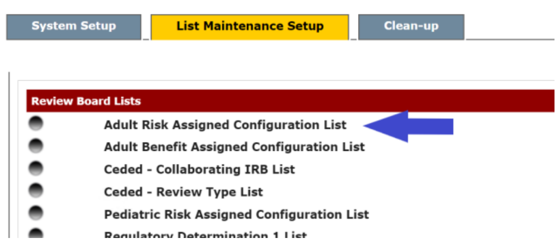
The page lists all previously configured adult risk assignments and provides controls for creating, revising and deleting adult risk assignment records.

The list defined here is used to populate the dropdown picklist for the **Adult Risk Assigned** field, which appears in both the **Outcome** tab (shown below) and Study Summary screen (not shown).

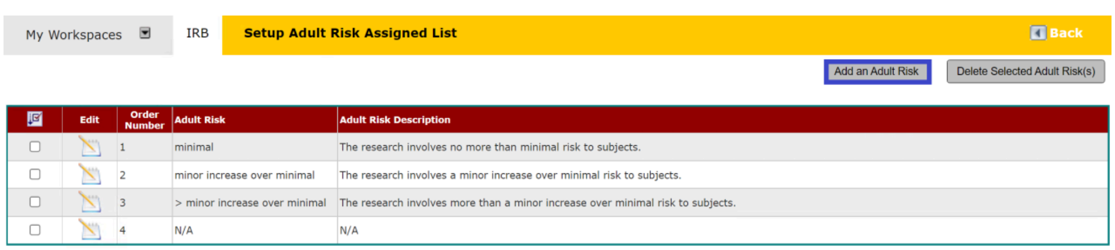


Add Adult Risk Assigned

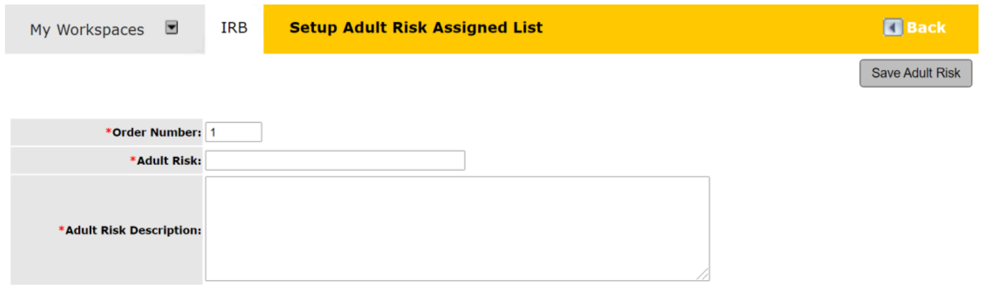
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Adult Risk Assigned Configuration List** link.



As shown below, the **Setup Adult Risk Assigned List** page opens.



Click the **Add an Adult Risk** button (blue box in screenshot above). An add form opens, as shown below.

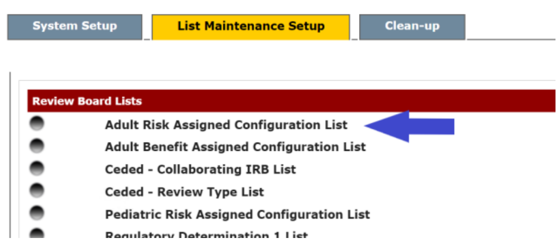


Order Number defaults to "1" (one), meaning that this entry will appear at the top of the list on the **Setup Adult Risk Assigned List** page when saved. The field is unlocked, allowing for entry of a different **Order Number**. If a duplicate **Order Number** is entered here the list is automatically reordered, with the new item taking precedence.

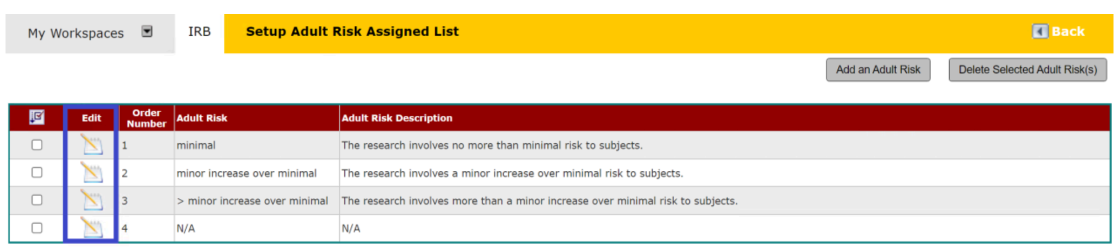
Enter desired text for **Adult Risk** and **Adult Risk Description**, and click the **Save Adult Risk** button. The add form closes and the new **Adult Risk** is added to the list on the **Setup Adult Risk Assigned List** page.

Edit Adult Risk Assigned

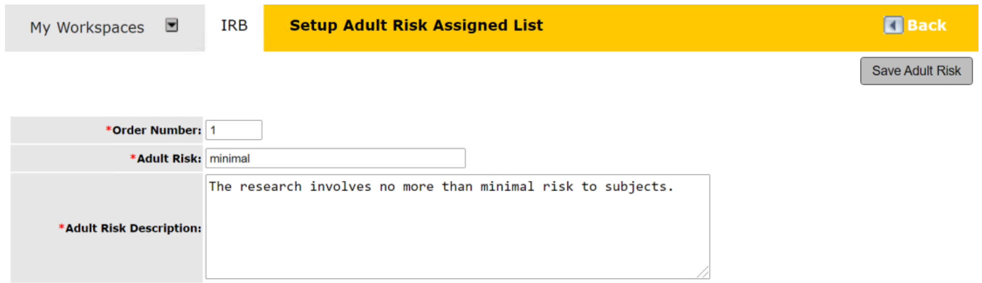
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Adult Risk Assigned Configuration List** link.



As shown below, the **Setup Adult Risk Assigned List** page opens.



Click the applicable icon in the **Edit** column (blue box in screenshot above). The selected record opens in an edit form, as shown below.



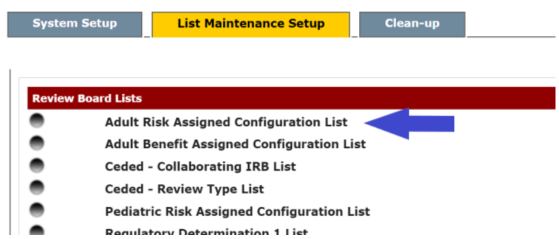
Make desired changes to **Order Number, Adult Risk** and **Adult Risk Description**.

If a duplicate **Order Number** is entered here the list is automatically reordered when changes are saved, with the new item taking precedence.

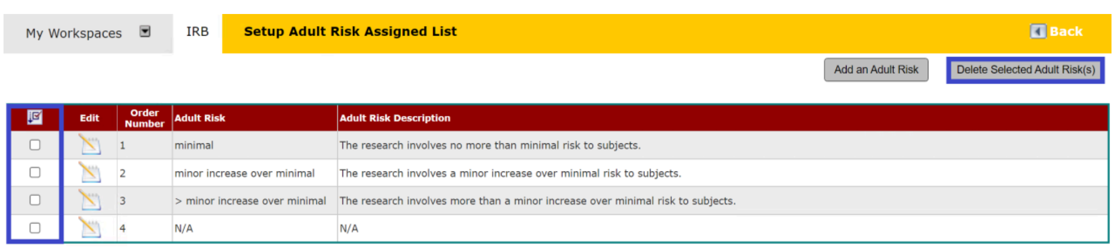
Click the **Save Adult Risk** button. The edit form closes and the **Adult Risk** is revised in the list on the **Setup Adult Risk Assigned List** page.

Delete Adult Risk Assigned

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Adult Risk Assigned Configuration List** link.

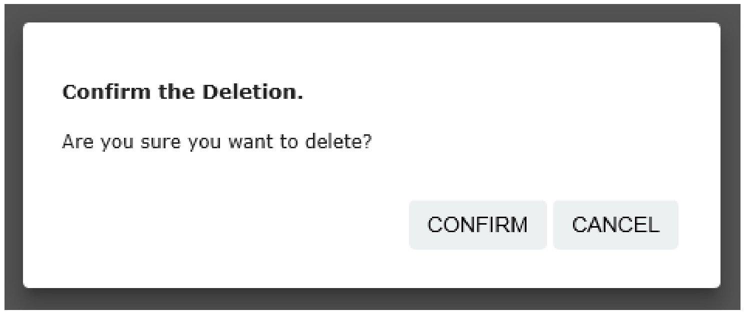


As shown below, the **Setup Adult Risk Assigned List** page opens.



Click to select the checkboxes of the item(s) to be deleted in the far left column and click the **Delete Selected Adult Risk(s)** button (blue boxes in screenshot above).

A confirmation popup window displays.

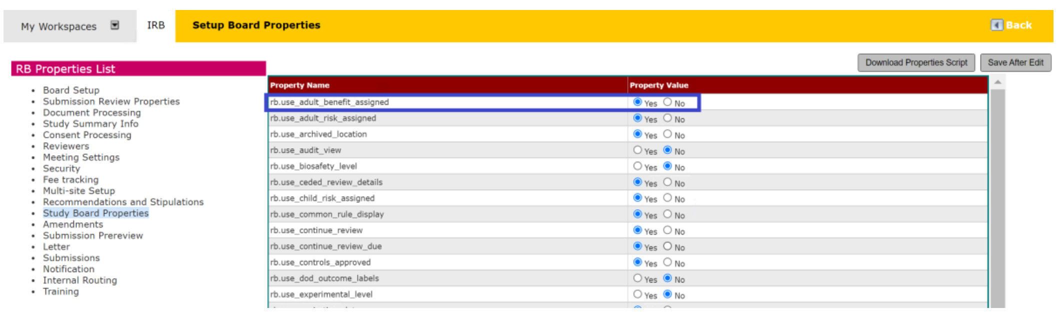


Click **CANCEL** to close the popup without deleting the record.

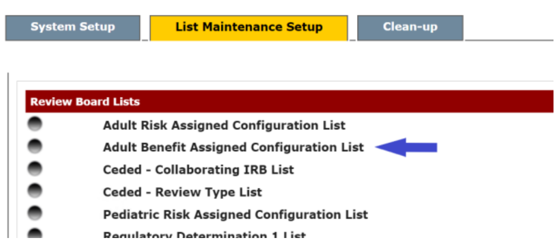
Click **CONFIRM** to complete deletion of the record. The item is deleted from the list on the **Setup Adult Risk Assigned List** page.

Adult Benefit Assigned Configuration List

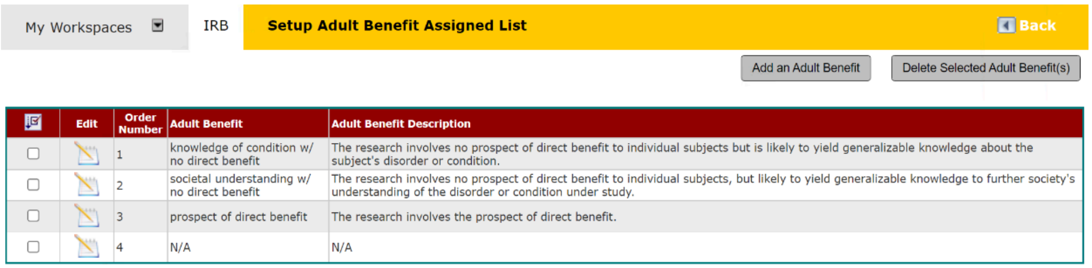
Where the property rb.use_adult_benefit_assigned is set to "Yes" (under IRB Assistant > Review Board Administration > Board Configuration Options > Study Board Properties), the iRIS™ system allows for setup and maintenance of an **Adult Benefit Assigned Configuration List**. The list contains current benefit ratings the review board can assign to rate potential benefits to adults accrued from participation in a particular study.



Setting the property to "Yes" populates an **Adult Benefit Assigned Configuration List** link on the List Maintenance Setup tab, as shown in the example below.

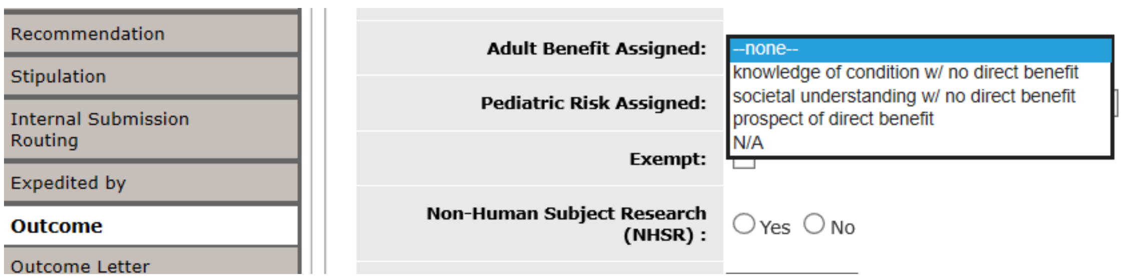


Click the link to open the **Setup Adult Benefit Assigned List** page, shown below.



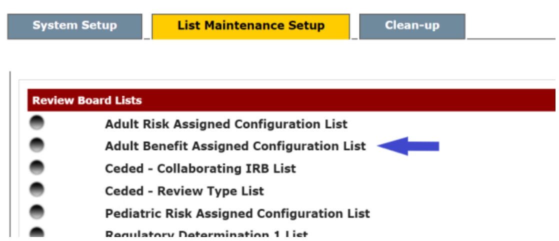
The page lists all previously configured adult benefit assignments and provides controls for creating, revising and deleting adult benefit assignment records.

The list defined here is used to populate the dropdown picklist for the **Adult Benefit Assigned** field, which appears in both the **Outcome** tab (shown below) and Study Summary screen (not shown).

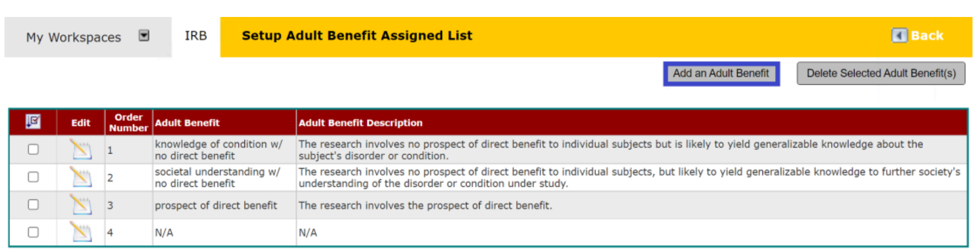


Add Adult Benefit Assigned

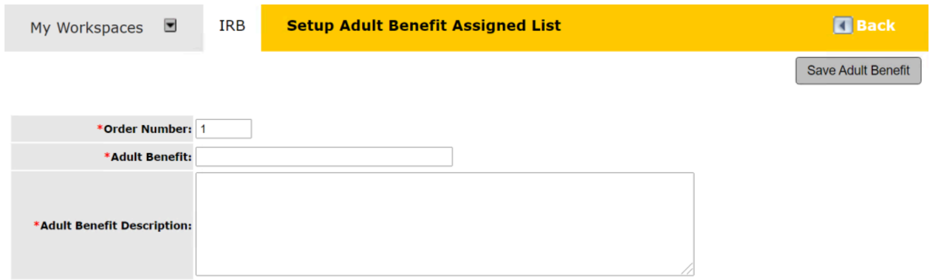
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Adult Benefit Assigned Configuration List** link.



As shown below, the **Setup Adult Benefit Assigned List** page opens.



Click the **Add an Adult Benefit** button (blue box in screenshot above). An add form opens, as shown below.



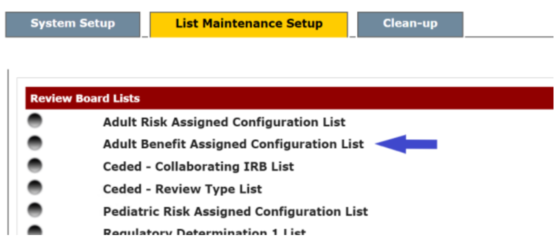
Order Number defaults to "1" (one), meaning that this entry will appear at the top of the list on the **Setup Adult Benefit Assigned List** page when saved. The field is unlocked, allowing for entry of a different **Order Number**.

If a duplicate **Order Number** is entered here the list is automatically reordered, with the new item taking precedence.

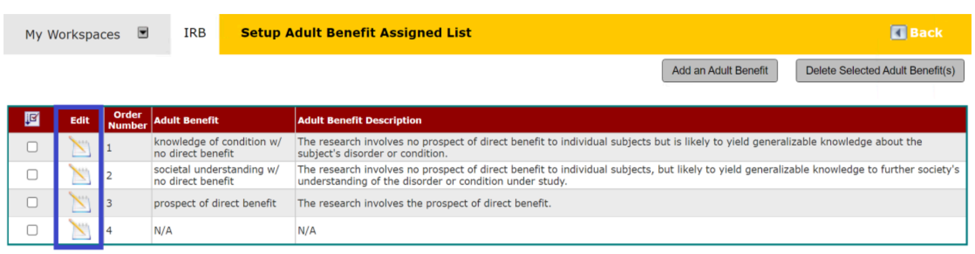
Enter desired text for **Adult Benefit** and **Adult Benefit Description**, and click the **Save Adult Benefit** button. The add form closes and the new **Adult Benefit** is added to the list on the **Setup Adult Benefit Assigned List** page.

Edit Adult Benefit Assigned

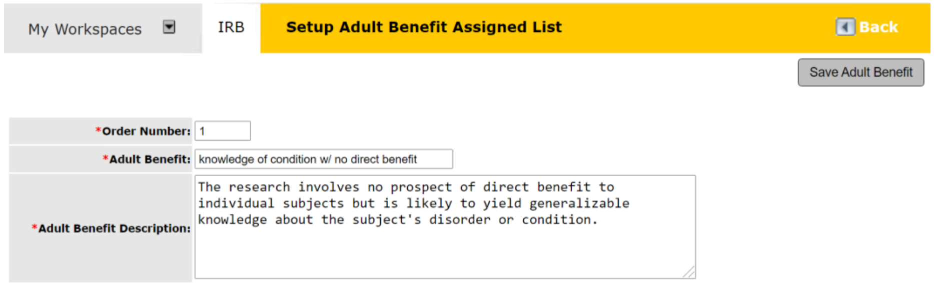
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Adult Benefit Assigned Configuration List** link.



As shown below, the **Setup Adult Benefit Assigned List** page opens.



Click the applicable icon in the **Edit** column (blue box in screenshot above). The selected record opens in an edit form, as shown below.



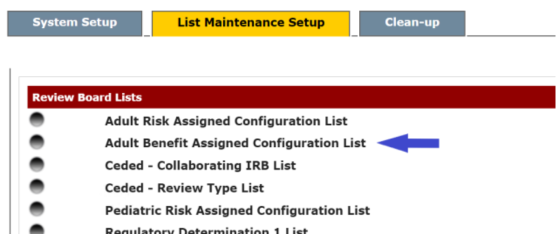
Make desired changes to **Order Number, Adult Benefit** and **Adult Benefit Description**.

If a duplicate **Order Number** is entered here the list is automatically reordered when changes are saved, with the new item taking precedence.

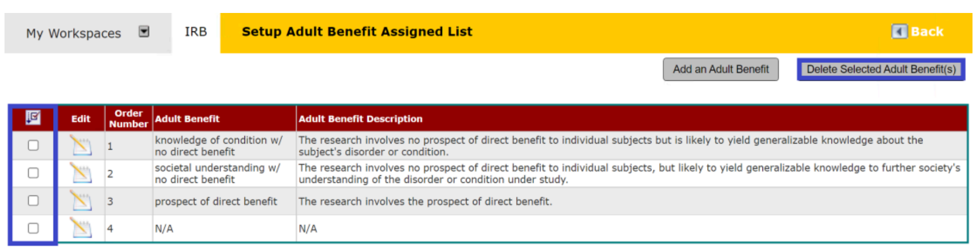
Click the **Save Adult Benefit** button. The edit form closes and the **Adult Benefit** is revised in the list on the **Setup Adult Benefit Assigned List** page.

Delete Adult Benefit Assigned

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Adult Benefit Assigned Configuration List** link.

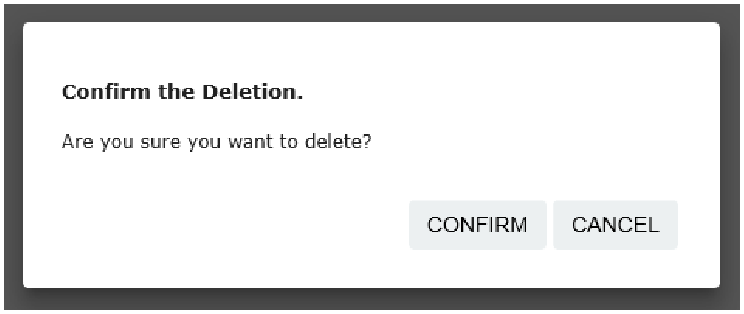


As shown below, the **Setup Adult Benefit Assigned List** page opens.



Click to select the checkboxes of the item(s) to be deleted in the far left columns and click the **Delete Selected Adult Benefit(s)** button (blue boxes in screenshot above).

A confirmation popup window displays.

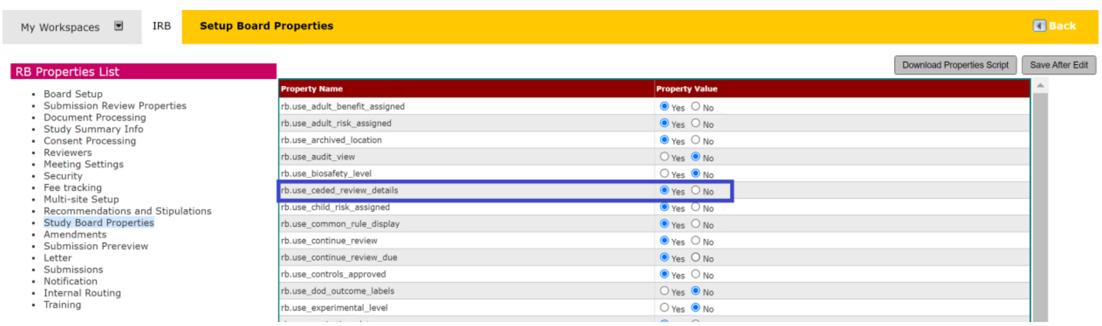


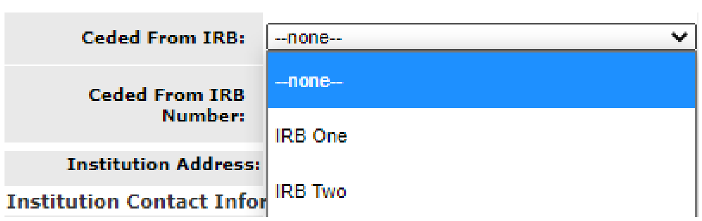
Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The item is deleted from the list on the **Setup Adult Benefit Assigned List** page.

Ceded – Collaborating IRB List

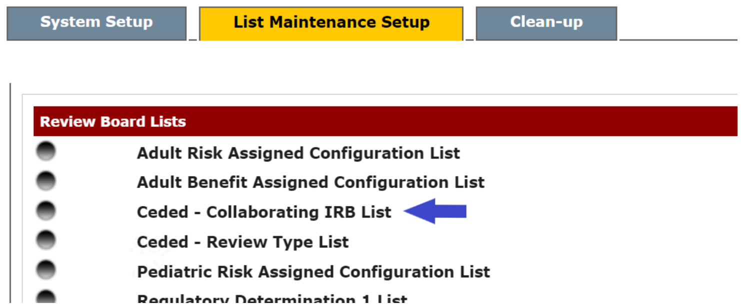
Where the property rb.use_ceded_review_details is set to "Yes" (under IRB Assistant > Review Board Administration > Board Configuration Options > Study Board Properties), the iRIS™ system allows for setup and maintenance of a **Collaborating IRB List**: a dropdown list of organizations provided in the **Ceded to IRB** field on the **Outcome** tab of a submission, as demonstrated below.



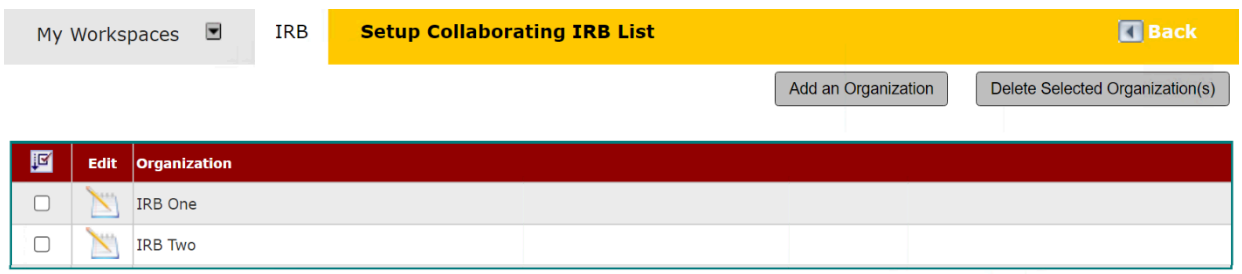


This field populates in the **Outcome** tab when the user indicates that the study has been ceded from or to another organization.

Setting the property to "Yes" populates a **Ceded - Collaborating IRB List** link on the **List Maintenance Setup** tab, as shown in the example below.



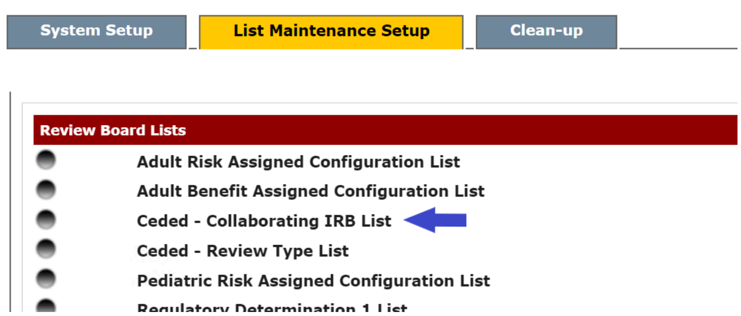
Clicking the link opens the **Setup Collaborating IRB List** page, shown below.



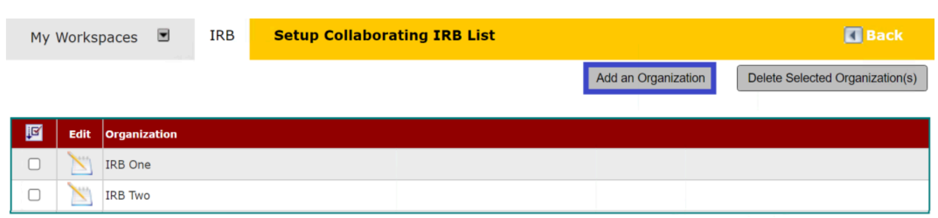
The page lists all previously configured **Collaborating IRB** records and provides controls for creating, revising and deleting **Collaborating IRB** records.

Add Collaborating IRB Organization

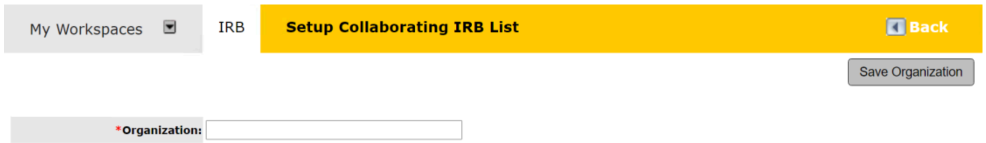
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Ceded – Collaborating IRB List** link.



As shown below, the **Setup Collaborating IRB List** page opens.



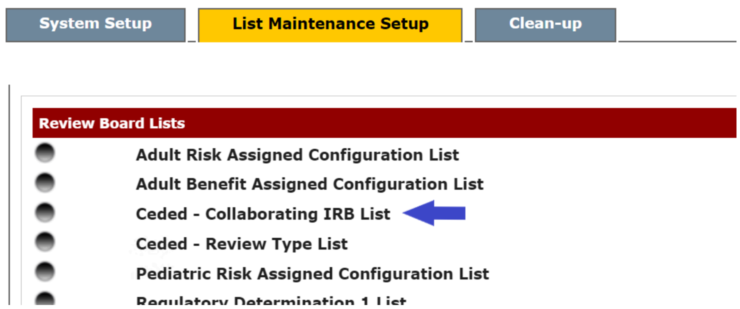
Click the **Add an Organization** button (blue box in screenshot above). An add form opens, as shown below.



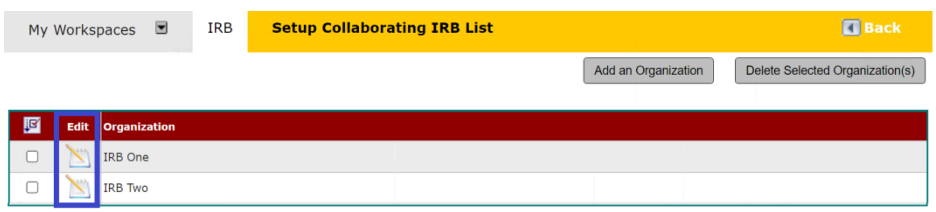
Enter the desired text for the new **Organization** and click the **Save Organization** button. The add form closes and the new **Organization** is added to the list on the **Setup Collaborating IRB List** page.

Edit Collaborating IRB Organization

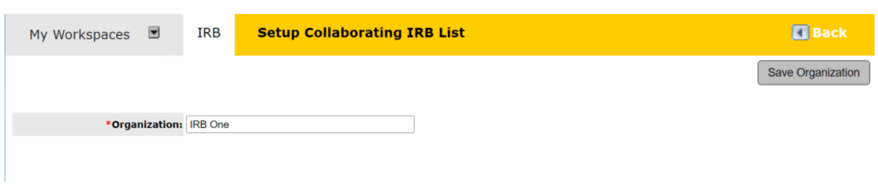
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Ceded – Collaborating IRB List** link.



As shown below, the **Setup Collaborating IRB List** page opens.



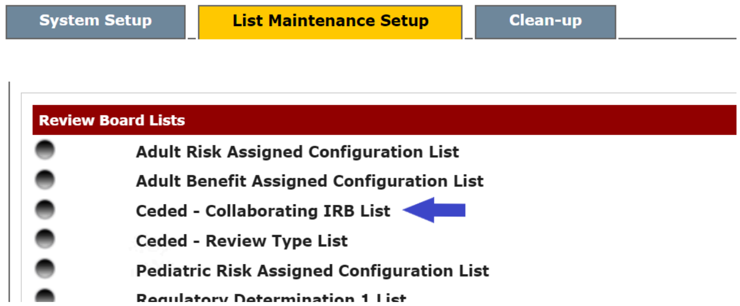
Click the applicable icon in the **Edit** column (blue box in screenshot above). The applicable record is opened in an edit form, as shown below.



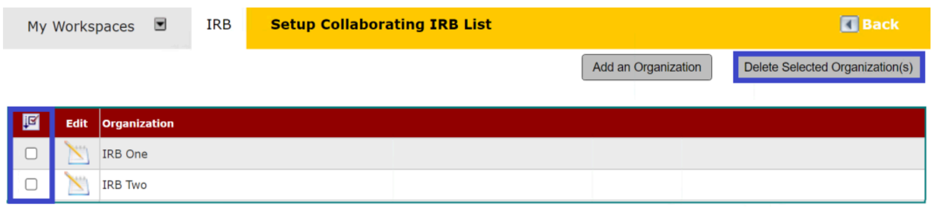
Revise text for the **Organization** as desired and click the **Save Organization** button. The edit form closes and the **Organization** is revised in the list on the **Setup Collaborating IRB List** page.

Delete Collaborating IRB Organization

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Ceded – Collaborating IRB List** link.

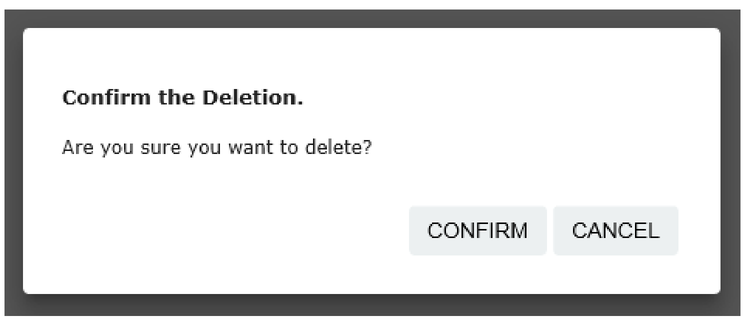


As shown below, the **Setup Collaborating IRB List** page opens.



Click to select the checkboxes of the item(s) to be deleted in the far left columns and click the **Delete Selected Organization(s)** button (blue boxes in screenshot above).

A confirmation popup window displays.

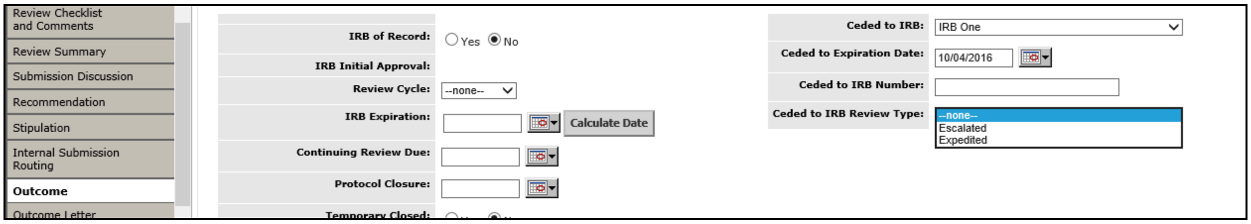


Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The **Organization** is deleted from the list on the **Setup Collaborating IRB List** page.

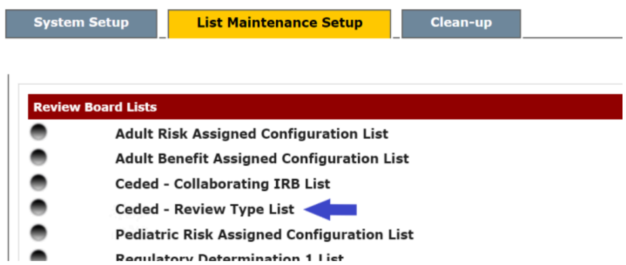
Ceded – Review Type List

The iRIS™ system allows for setup and maintenance of a **Type of Review List**: a dropdown list of review types provided in the **Ceded to IRB Review Type** field on the **Outcome** tab of a submission, as demonstrated below.

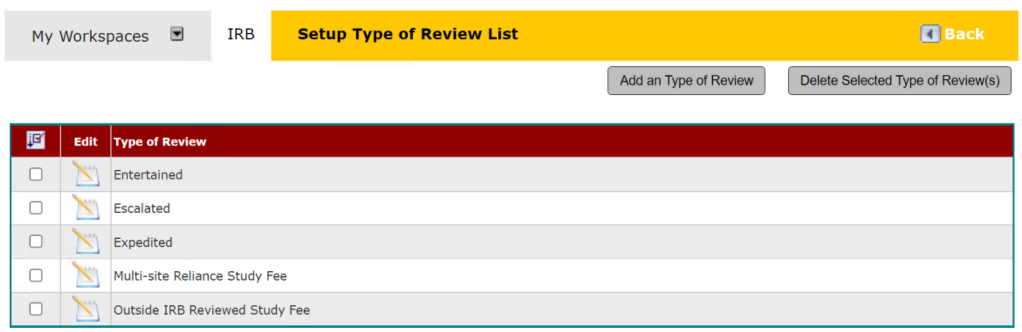


This field populates when the user indicates that the current IRB is not the IRB of Record and the study has been ceded to another IRB.

The **Type of Review List** is maintained on the **Setup Type of Review List** page, which is accessed via the **Ceded – Review Type List** link on the **List Maintenance Setup** tab, as shown in the example below.



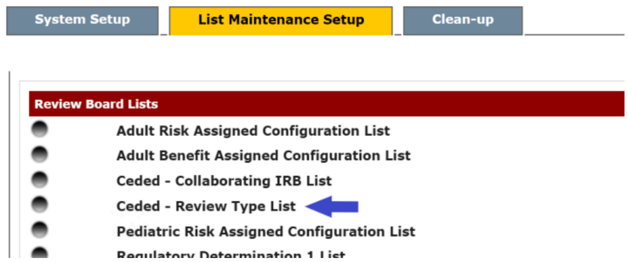
Clicking the link opens the **Setup Type of Review List** page, shown below.



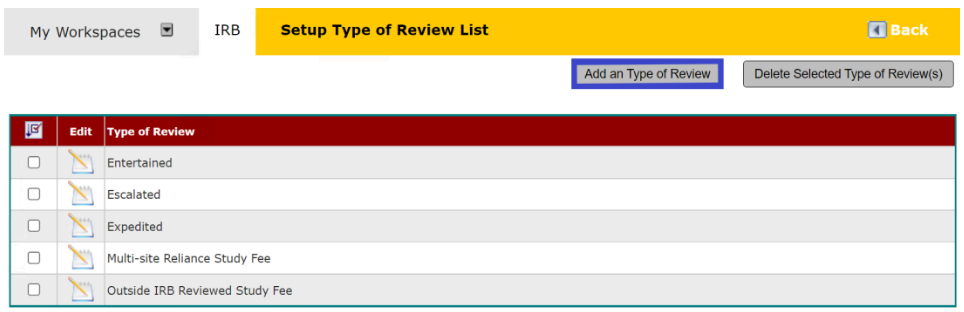
The page lists all previously configured **Type of Review** records and provides controls for creating, revising and deleting **Type of Review** records.

Add Type of Review

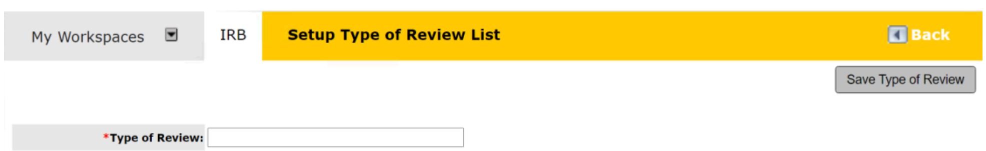
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Ceded – Review Type List** link.



As shown below, the **Setup Type of Review List** page opens.



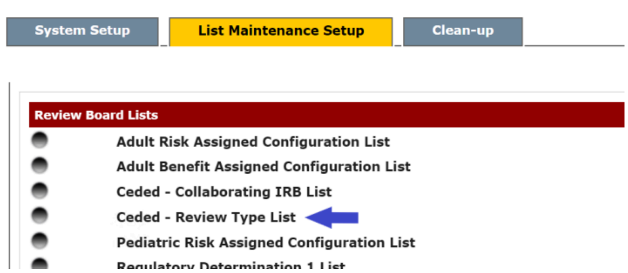
Click the **Add an Type of Review** button (blue box in screenshot above). An add form opens, as shown below.



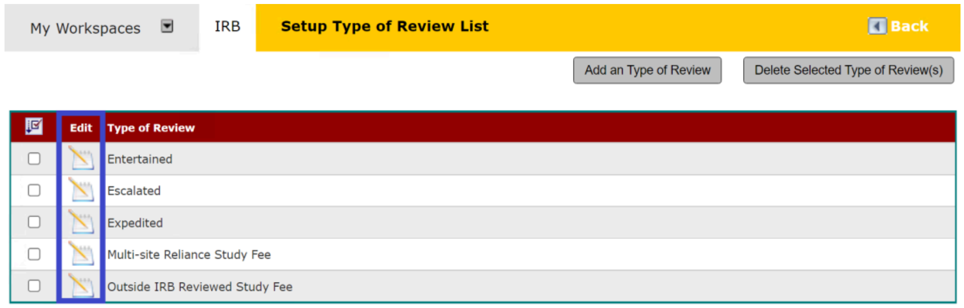
Enter the desired text for the new **Type of Review** and click the **Save Type of Review** button. The add form closes and the new **Type of Review** is added to the list on the **Setup Type of Review List** page.

Edit Type of Review

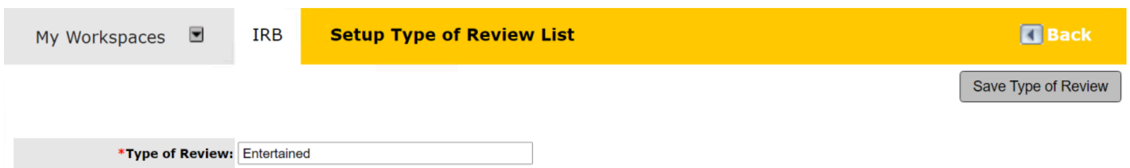
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Ceded – Review Type List** link.



As shown below, the **Setup Type of Review List** page opens.



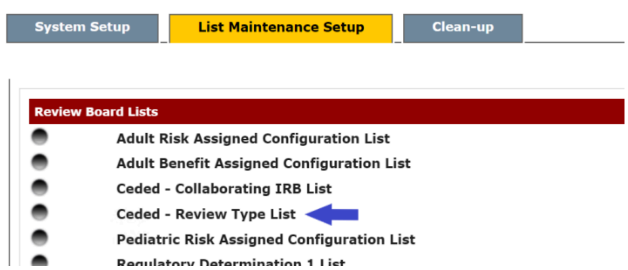
Click the applicable icon in the **Edit** column (blue box in screenshot above). The applicable record is opened in an edit form, as shown below.



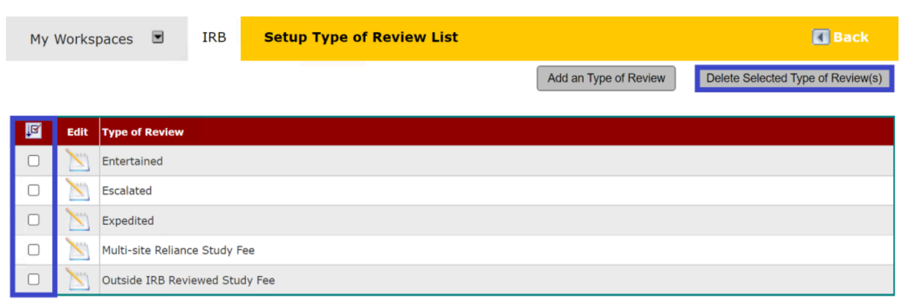
Make desired changes to **Type of Review** text and click the **Save Type of Review** button. The edit form closes and the **Type of Review** is revised in the list on the **Setup Type of Review List** page.

Delete Review Type

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Ceded – Review Type List** link.

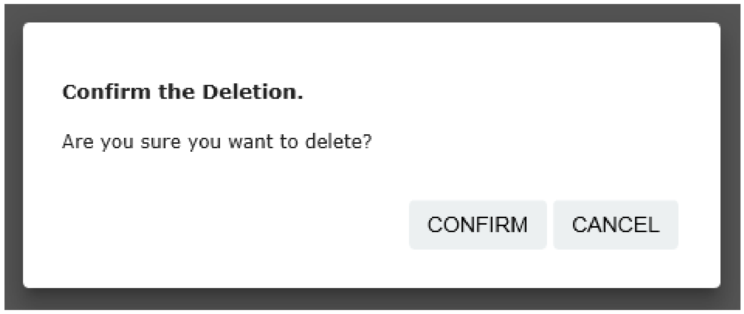


As shown below, the **Setup Type of Review List** page opens.



Click to select the checkboxes of the item(s) to be deleted in the far left columns and click the **Delete Selected Type of Review(s)** button (blue boxes in screenshot above).

A confirmation popup window displays.



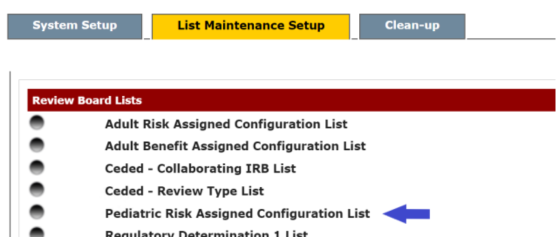
Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The **Type of Review** is deleted from the list on the **Setup Type of Review List** page.

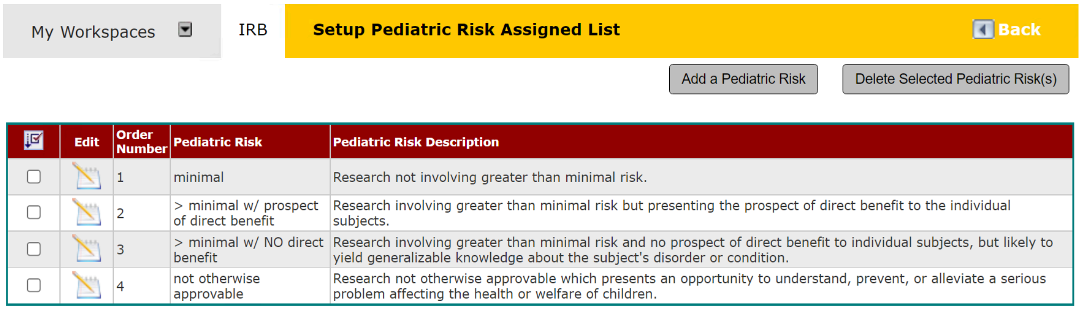
Pediatric Risk Assigned Configuration List

Where the property rb.use_child_risk_assigned is set to "Yes" (under IRB Assistant > Review Board Administration > Board Configuration Options > Study Board Properties), the iRIS™ system allows for setup and maintenance of a **Pediatric Risk Assigned Configuration List**. The list contains current risk ratings the review board can assign to rate potential risk to minors accrued from participation in a particular study.

Setting the property to "Yes" populates a **Pediatric Risk Assigned Configuration List** link on the List Maintenance Setup tab, as shown in the example below.



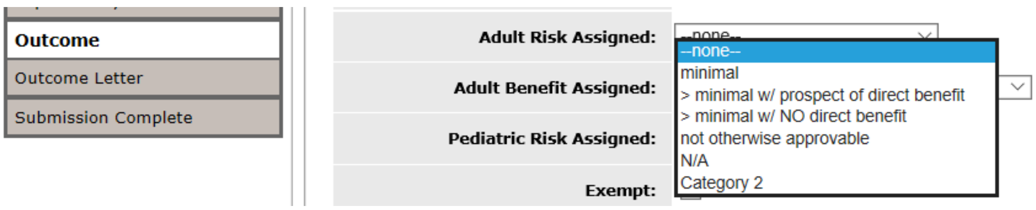
Click the link to open the **Setup Pediatric Risk Assigned List** page, shown below.



	Edit	Order Number	Pediatric Risk	Pediatric Risk Description
		1	minimal	Research not involving greater than minimal risk.
		2	> minimal w/ prospect of direct benefit	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
		3	> minimal w/ NO direct benefit	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
		4	not otherwise approvable	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

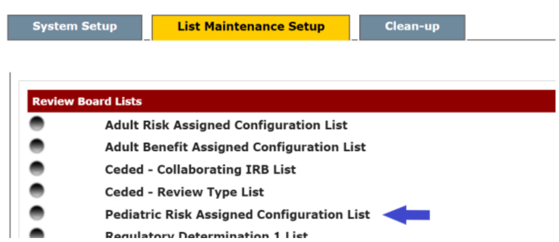
The page lists all previously configured adult risk assignments and provides controls for creating, revising and deleting adult risk assignment records.

The list defined here is used to populate the dropdown picklist for the **Pediatric Risk Assigned** field, which appears in both the **Outcome** tab (shown below) and Study Summary screen (not shown).

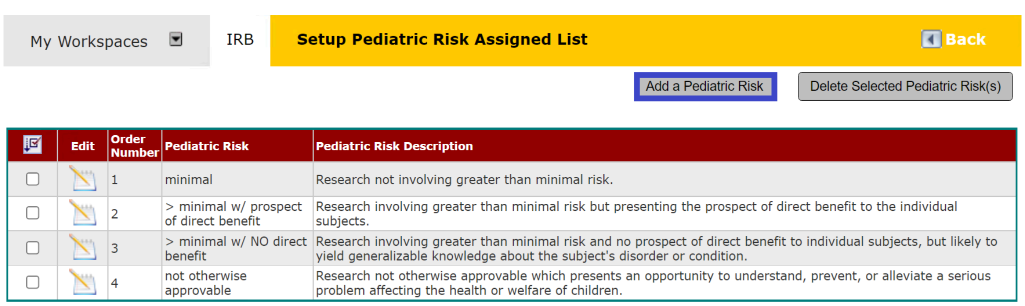


Add Pediatric Risk Assigned

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Pediatric Risk Assigned Configuration List** link.

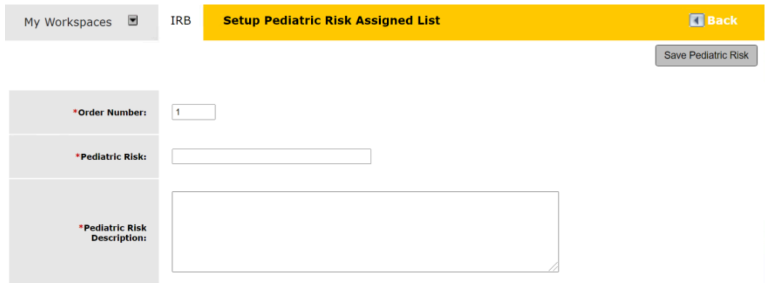


As shown below, the **Setup Pediatric Risk Assigned List** page opens.



	Edit	Order Number	Pediatric Risk	Pediatric Risk Description
		1	minimal	Research not involving greater than minimal risk.
		2	> minimal w/ prospect of direct benefit	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
		3	> minimal w/ NO direct benefit	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
		4	not otherwise approvable	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Click the **Add a Pediatric Risk** button (blue box in screenshot above). An add form opens, as shown below.

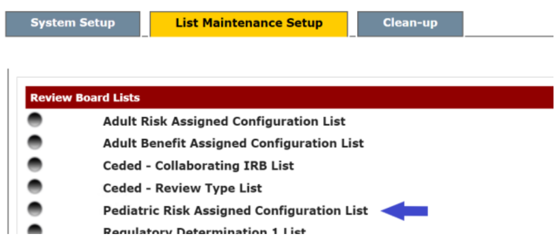


Order Number defaults to "1" (one), meaning that this entry will appear at the top of the list on the **Setup Pediatric Risk Assigned List** page when saved. The field is unlocked, allowing for entry of a different **Order Number**. If a duplicate **Order Number** is entered here the list is automatically reordered, with the new item taking precedence.

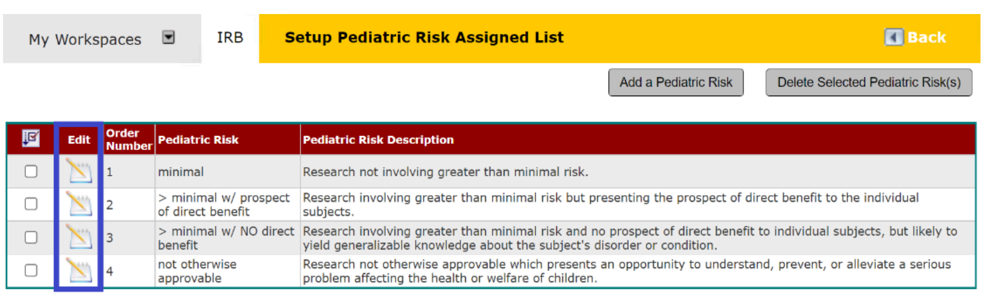
Enter desired text for **Pediatric Risk** and **Pediatric Risk Description**, and click the **Save Pediatric Risk** button. The add form closes and the new **Adult Risk** is added to the list on the **Setup Adult Risk Assigned List** page.

Edit Pediatric Risk Assigned

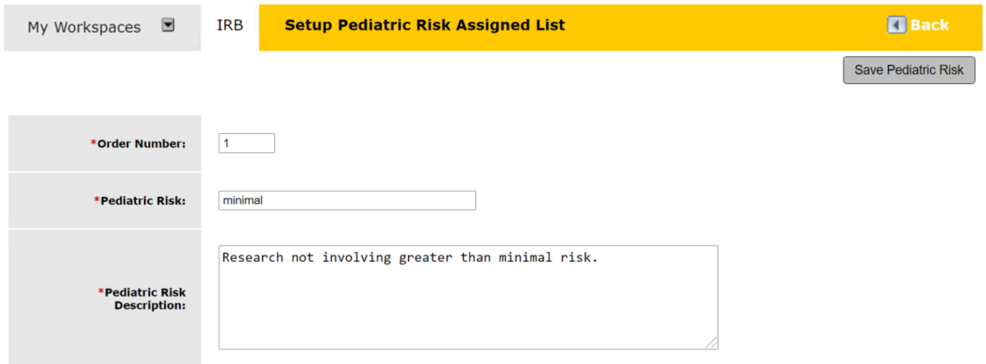
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Pediatric Risk Assigned Configuration List** link.



As shown below, the **Setup Pediatric Risk Assigned List** page opens.



Click the applicable icon in the **Edit** column (blue box in screenshot above). The selected record opens in an edit form, as shown below.



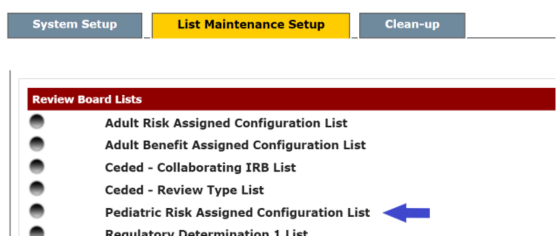
Make desired changes to **Order Number, Pediatric Risk** and **Pediatric Risk Description**.

If a duplicate **Order Number** is entered here the list is automatically reordered when changes are saved, with the new item taking precedence.

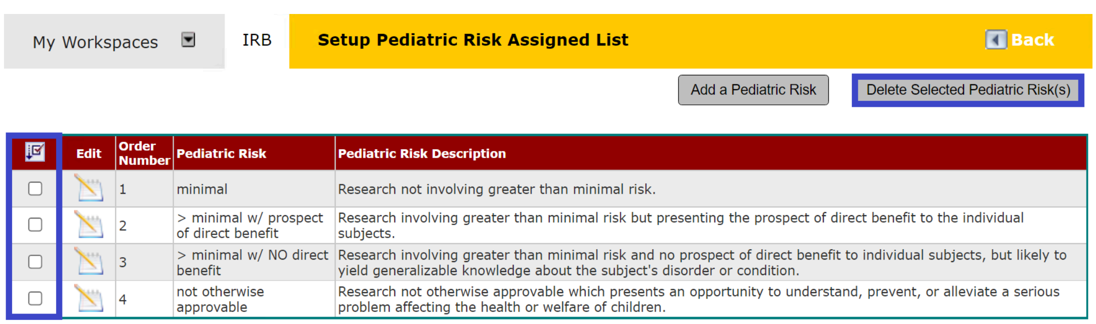
Click the **Save Pediatric Risk** button. The edit form closes and the **Pediatric Risk** is revised in the list on the **Setup Pediatric Risk Assigned List** page.

Delete Pediatric Risk Assigned

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Pediatric Risk Assigned Configuration List** link.

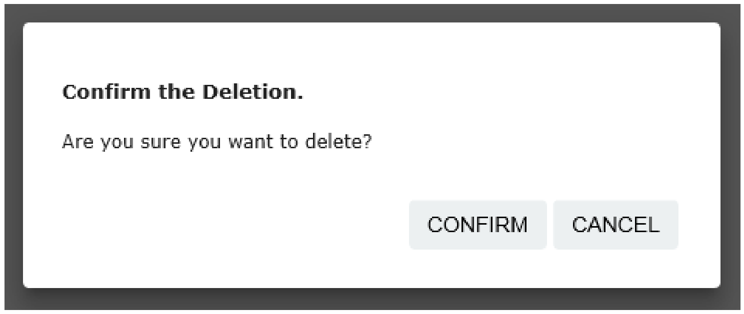


As shown below, the **Setup Pediatric Risk Assigned List** page opens.



Click to select the checkboxes of the item(s) to be deleted in the far left column and click the **Delete Selected Pediatric Risk(s)** button (blue boxes in screenshot above).

A confirmation popup window displays.



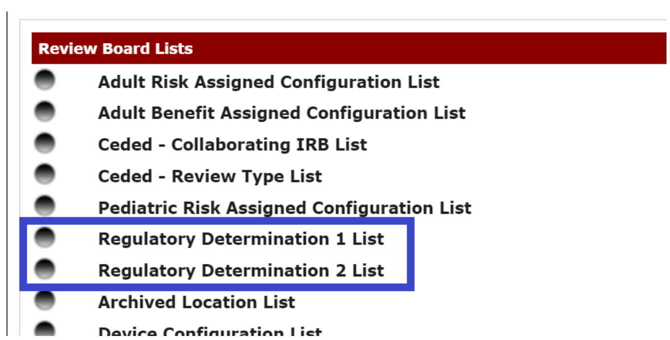
Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The item is deleted from the list on the **Setup Pediatric Risk Assigned List** page.

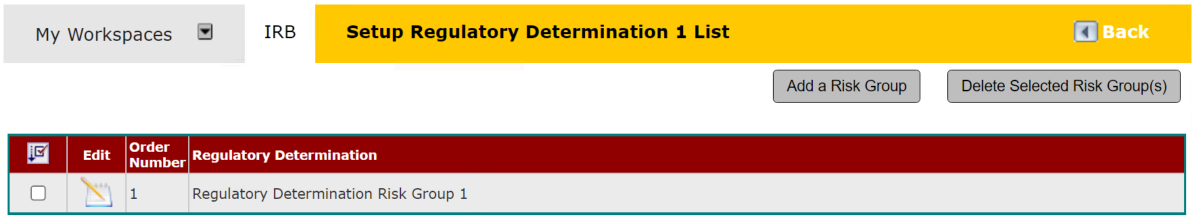
Regulatory Determination 1 List / Regulatory Determination 2 List

The **Regulatory Determination 1 List** and **Regulatory Determination 2 List** are used in the Outcome tab, to provide the IRB with preconfigured dropdown picklists of up to two regulatory determinations applicable to a given submission.

The configuration lists are accessed via the IRB Assistant > Review Board Administration > List Maintenance Setup tab > **Regulatory Determination 1 List** and **Regulatory Determination 2** List links.



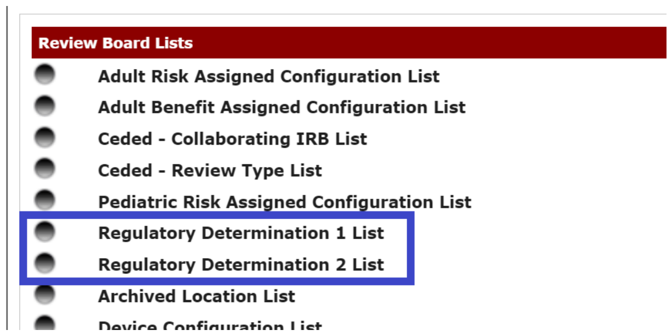
Clicking either link opens the associated **Regulatory Determination List** page (example, **Regulatory Determination 1 List** page, shown below).



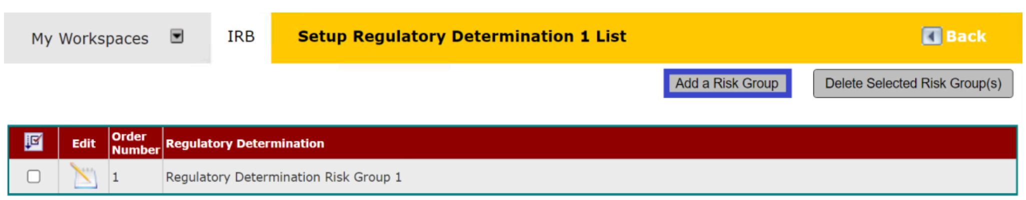
Processes for adding, revising and deleting regulatory determination items are the same for both lists, as described in the following manual subsections.

Add Regulatory Determination

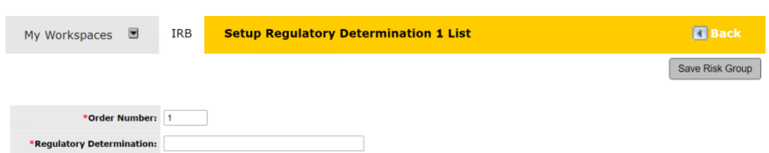
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the applicable **Regulatory Determination List** link.



As shown below, the applicable **Setup Regulatory Determination Assigned List** page opens.



Click the **Add a Risk Group** button (blue box in screenshot above). An add form opens, as shown below.

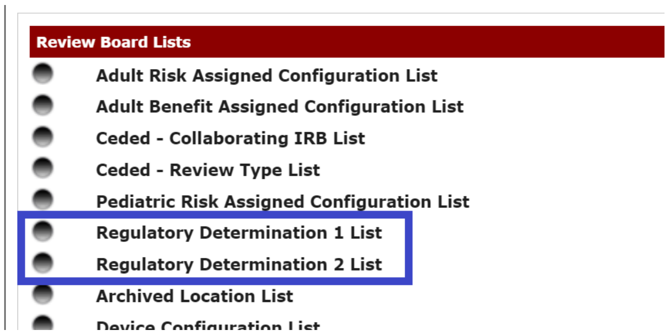


Order Number defaults to "1" (one), meaning that this entry will appear at the top of the list on the **Setup Regulatory Determination List** page when saved. The field is unlocked, allowing for entry of a different **Order Number**. If a duplicate **Order Number** is entered here the list is automatically reordered, with the new item taking precedence.

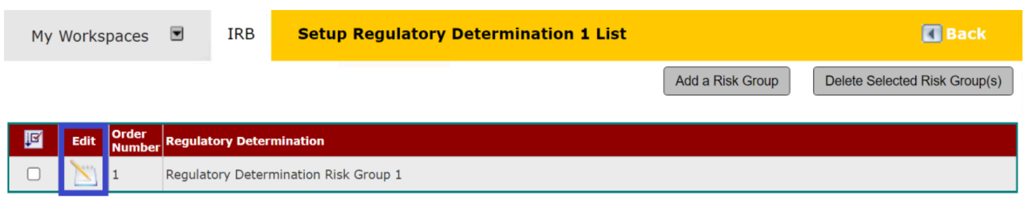
Enter desired text for **Regulatory Determination** and click the **Save Risk Group** button. The add form closes and the new **Regulatory Determination** is added to the list on the applicable **Setup Regulatory Determination List** page.

Edit Regulatory Determination

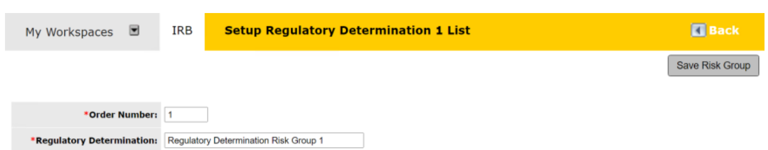
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the applicable **Regulatory Determination List** link.



As shown below, the applicable **Setup Regulatory Determination List** page opens.



Click the **Add a Risk Group** button (blue box in screenshot above). An add form opens, as shown below.



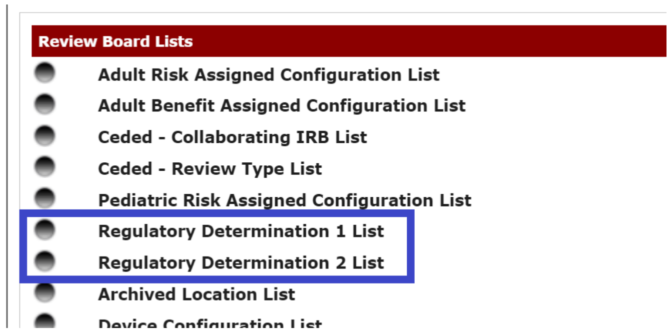
Make desired changes to **Order Number** and **Regulatory Determination** and click the **Save Risk Group** button.

If a duplicate **Order Number** is entered here the list is automatically reordered when changes are saved, with the new item taking precedence.

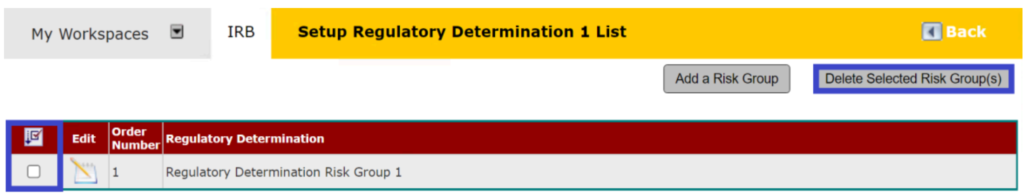
The edit form closes and the **Regulatory Determination** is revised in the list on the applicable **Setup Regulatory Determination List** page.

Delete Regulatory Determination

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the applicable **Regulatory Determination List** link.

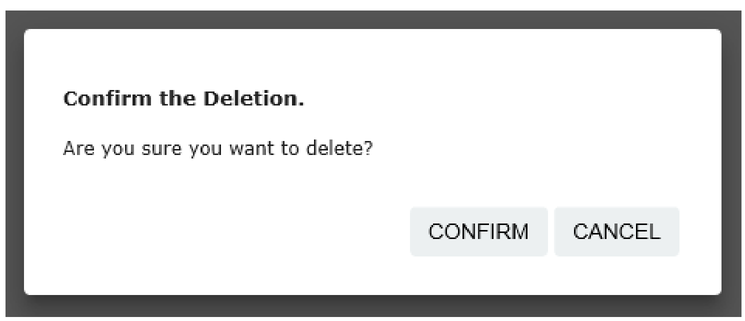


As shown below, the applicable **Setup Regulatory Determination List** page opens.



Click to select the checkboxes of the item(s) to be deleted in the far left column and click the **Delete Selected Risk Group(s)** button (blue boxes in screenshot above).

A confirmation popup window displays.

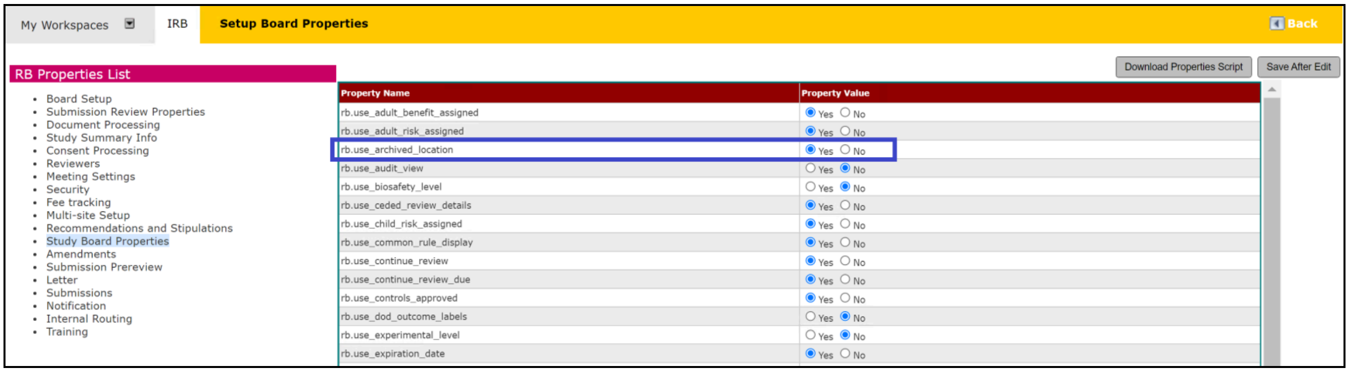


Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The item is deleted from the list on the applicable **Setup Regulatory Determination List** page.

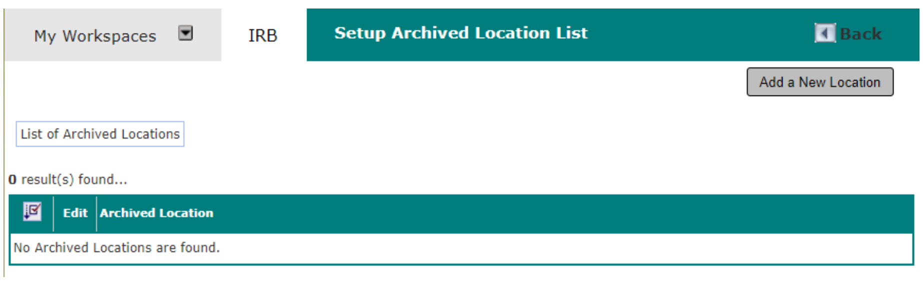
Archived Location List

Where the property rb.use_archived_location is set to “Yes” (under IRB Assistant > Review Board Administration > Board Configuration Options > Study Board Properties, see screenshot below), the iRIS™ system provides a means for tracking locations where study documentation can be archived.



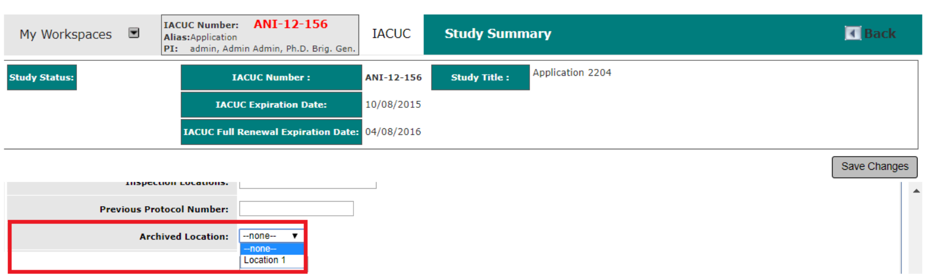
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Archived Location List** link.

The **Setup Archived Location List** page is opened.



Archived Location List Implementation – Application Side

The archived location list is provided as a dropdown picklist on the **Study Summary** page for selection of **Archived Location** when a study/submission is renewed or reactivated, as shown in the IACUC example below.



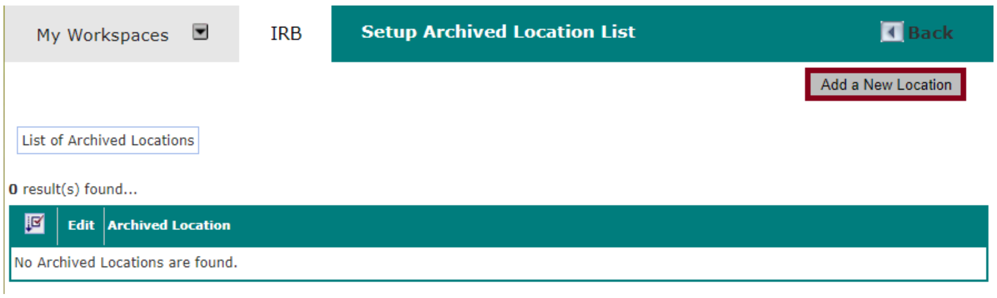
Archived Location List Implementation – Board Side

Where applicable, archive locations are specified on the application side and are not generally subject to direct revision by the board.

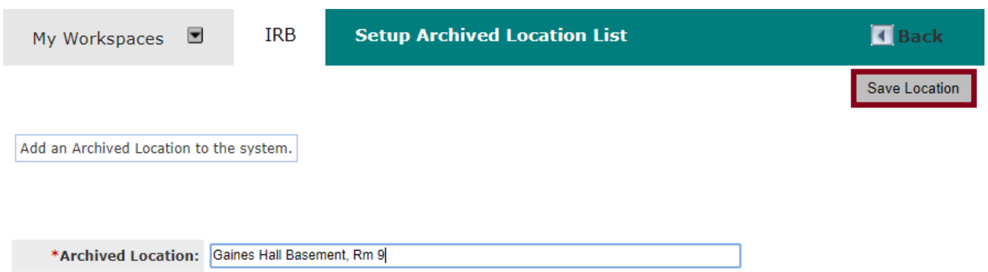
Add Archived Location

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Archived Location List** link.

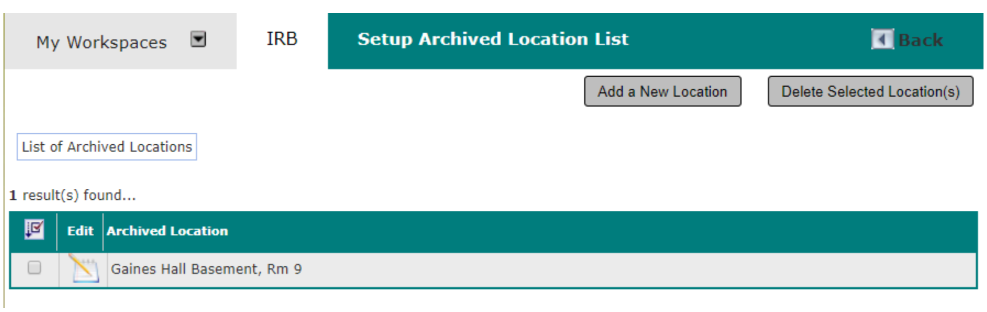
The **Setup Archived Location List** page is opened. Click the **Add a New Location** button.



Enter the desired **Archived Location** and click the **Save Location** button.



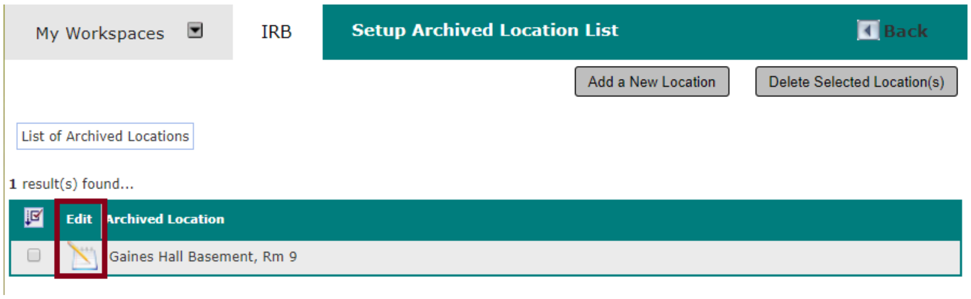
The category is added on the main **Setup Archived Location List** page.



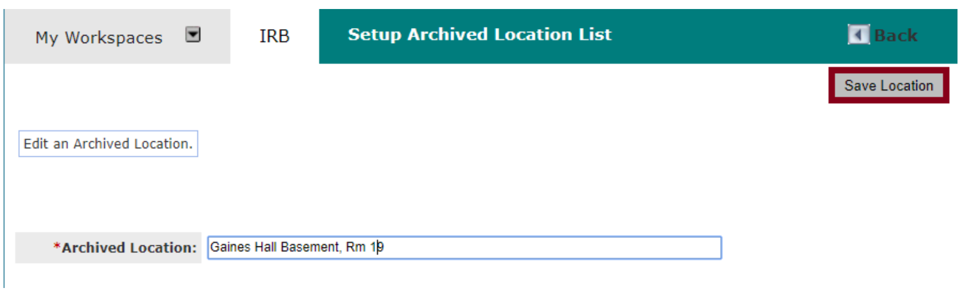
Edit Archived Location

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Archived Location List** link.

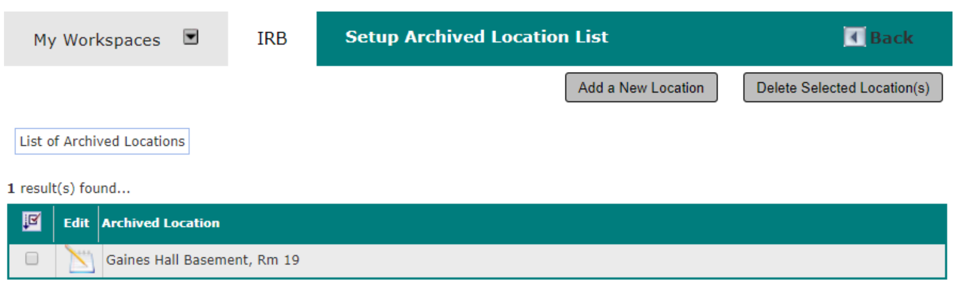
The **Setup Archived Location List** page is opened. Click the icon in the **Edit** column for the applicable item.



The record is opened for editing. Make desired changes to the **Archived Location** field and click the **Save Location** button.



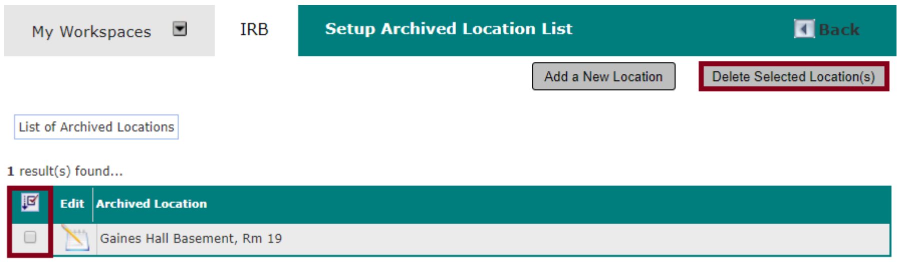
The category is revised on the main **Setup Archived Location List** page.



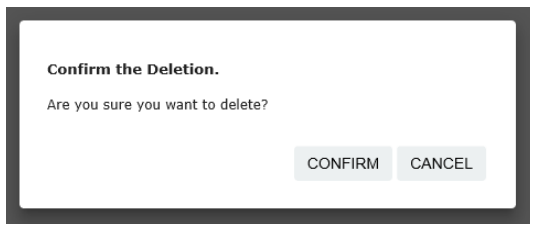
Delete Archived Location

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Archived Location List** link.

The **Setup Archived Location List** page is opened. Select the checkbox(es) for the item(s) to be deleted and click the **Delete Selected Location(s)** button.

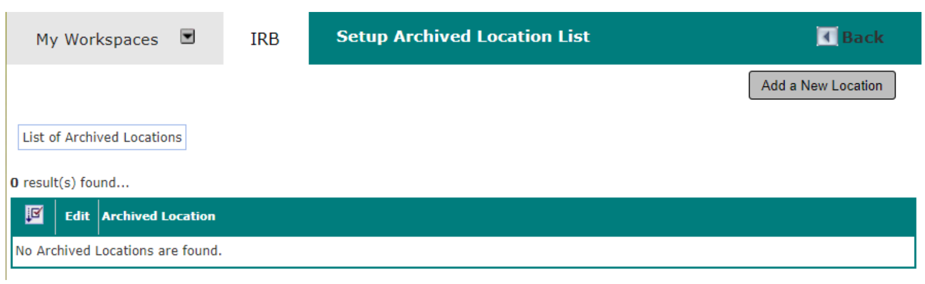


A confirmation popup window appears.



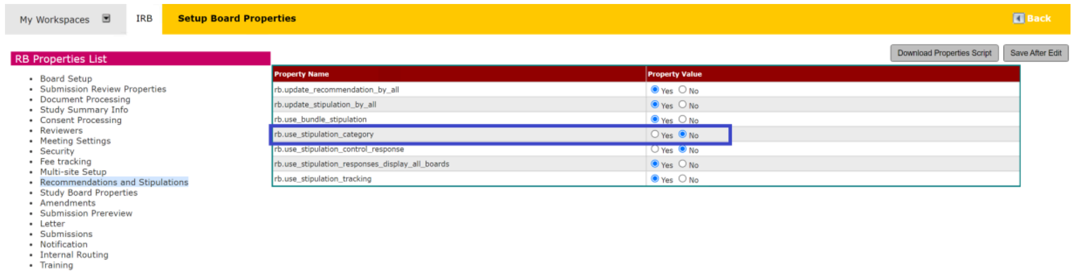
Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to delete the record and close the popup. The record is deleted from the list on the main **Setup Archived Location List** page.

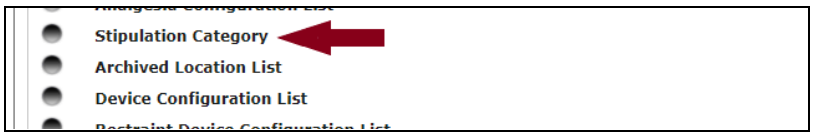


Stipulation Category

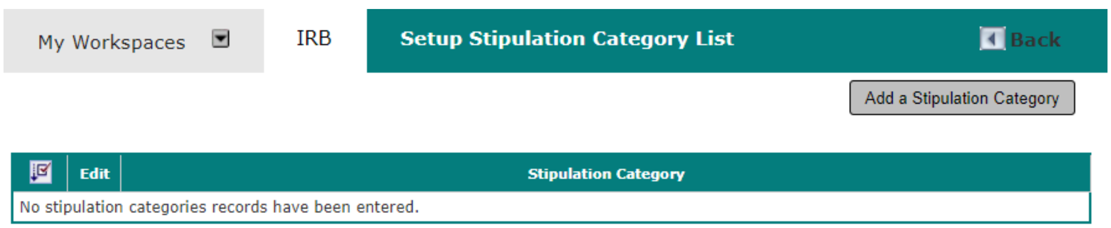
Where the property rb.use_stipulation_category is set to “Yes” (under IRB Assistant > Review Board Administration > Board Configuration Options > Recommendations and Stipulations), the review board can group stipulation items into categories.



Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Stipulation Category** link.



The **Setup Stipulation Category List** page is opened.

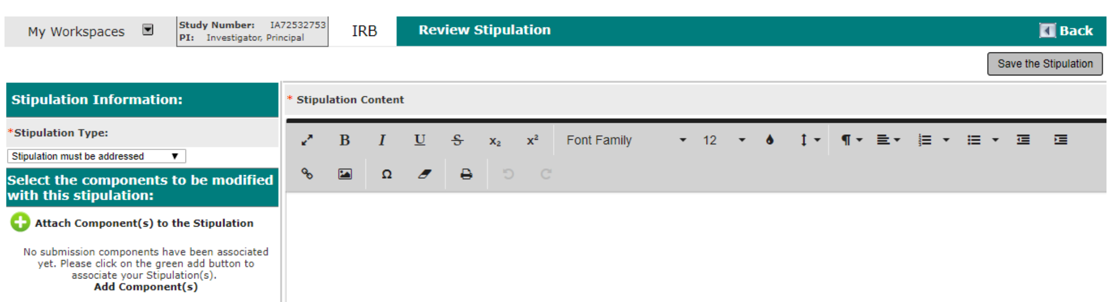


Stipulation Category List Implementation – Application Side

Where applicable, stipulations are assigned on the board review side. This list is not employed on the application side.

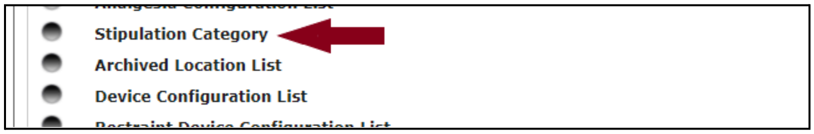
Stipulation Category List Implementation – Board Side

The stipulation category list is provided as a dropdown picklist for selection of **Stipulation Type** when a stipulation is added for a submission.

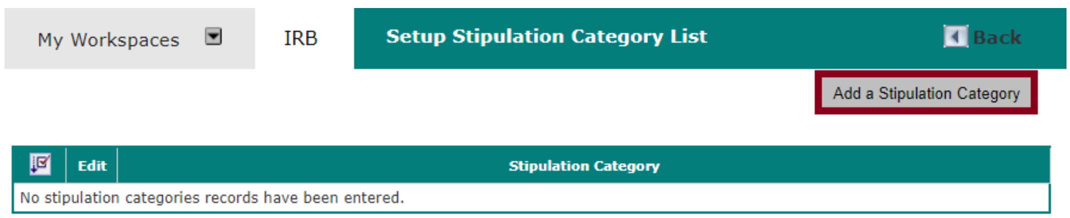


Add Stipulation Category

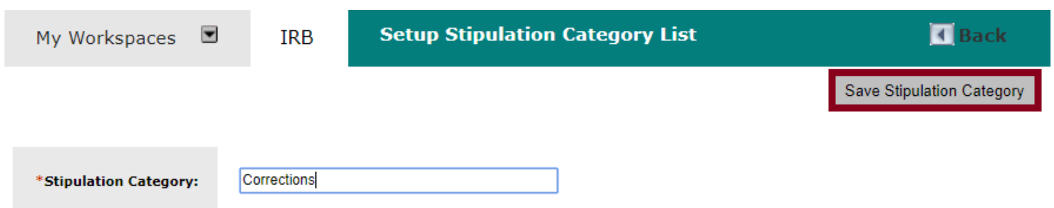
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Stipulation Category** link.



The **Setup Stipulation Category List** page is opened. Click the **Add a Stipulation Category** button.



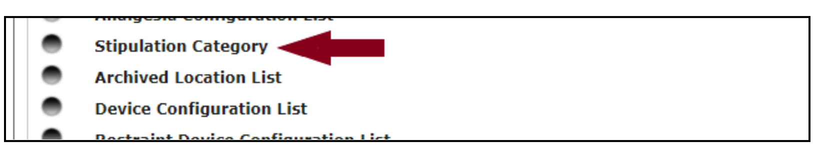
Enter a **Stipulation Category** name and click the **Save Stipulation Category** button.



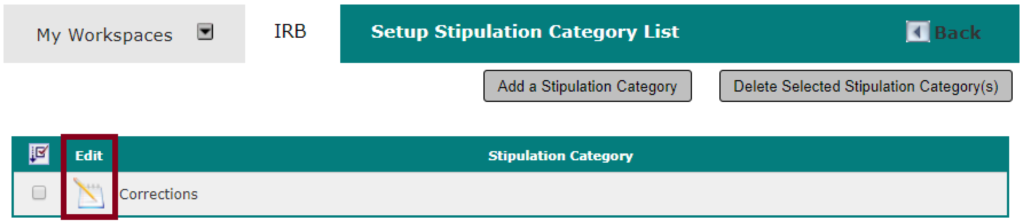
The category is added on the main **Setup Stipulation Category List** page.

Edit Stipulation Category

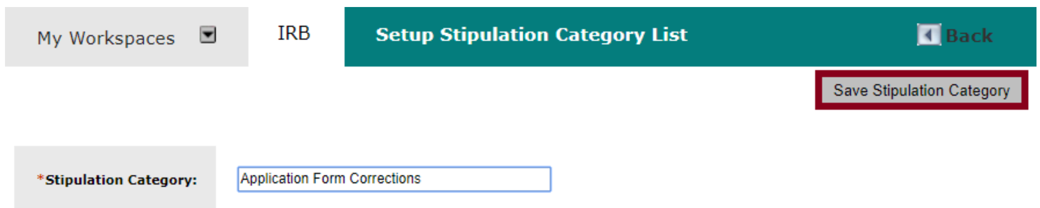
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Stipulation Category** link.



The **Setup Stipulation Category List** page is opened. Click the icon in the **Edit** column for the applicable item.



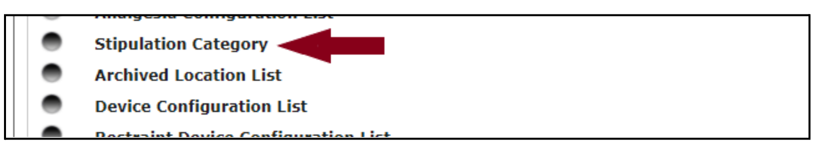
The record is opened for editing. Make desired changes to the **Stipulation Category** name and click the **Save Stipulation Category** button.



The category is revised on the main **Setup Stipulation Category List** page.

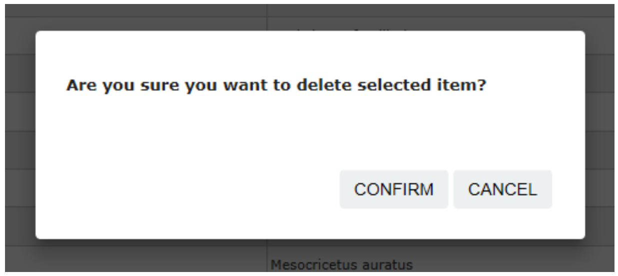
Delete Stipulation Category

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Stipulation Category** link.



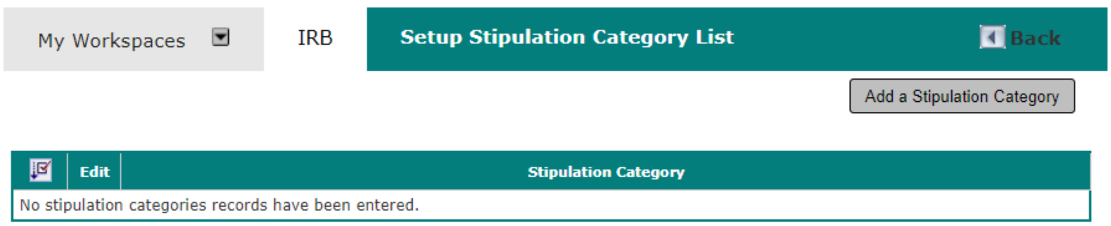
The **Setup Stipulation Category List** page is opened. Select the checkbox(es) for the item(s) to be deleted and click the **Delete Select Stipulation Category(s)** button.

A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

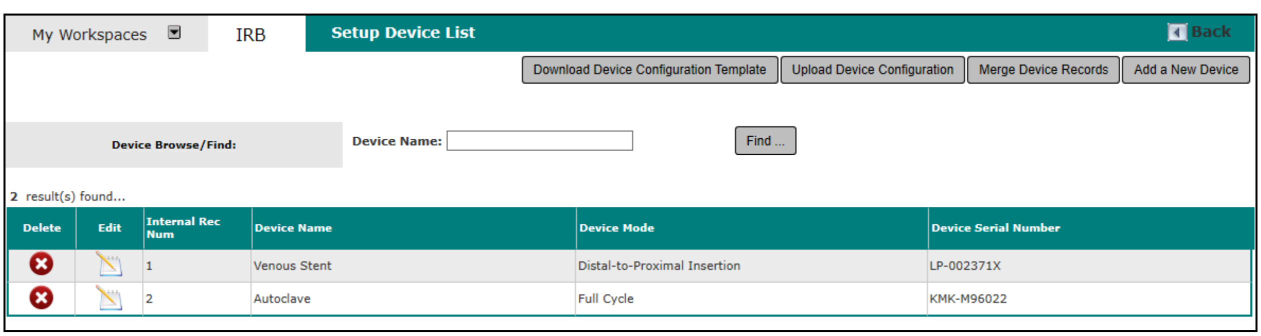
Click **CONFIRM** to complete deletion of the record. The item is deleted from the **Setup Stipulation Category List** page.



Device Configuration List

The **Device Configuration List** is where a list of devices approved by the institution for use in animal subject studies is maintained in the iRIS™ system. To access the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Device Configuration List** link.

The **Setup Device List** page is opened.

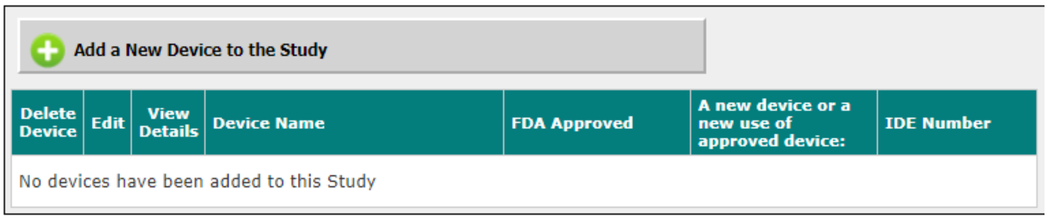


If the device list is lengthy, use the **Device Browse/Find** form above the list to search for records by **Device Name**.

Device List Implementation – Application Side

The device list is employed in the following areas on the application side of iRIS™.

Study Application — the Device Configuration List is made available in an application via an **Add a New Device to the Study** button



For more information about the study application, see the Study Assistant Manual.

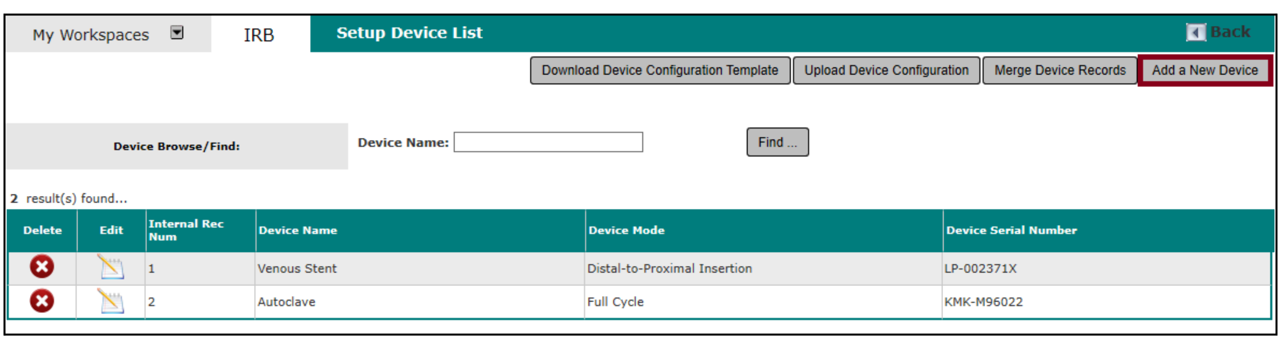
Device List Implementation – Board Side

Devices are added on the application side where required and are not generally subject to direct revision by the board.

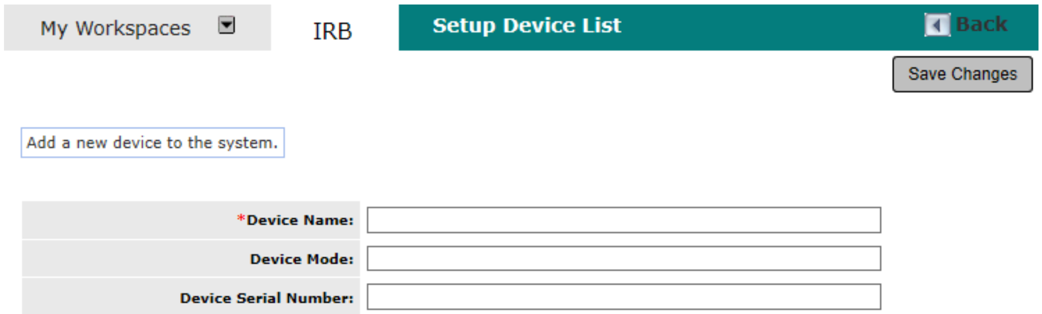
Add a New Device

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Device Configuration List** link.

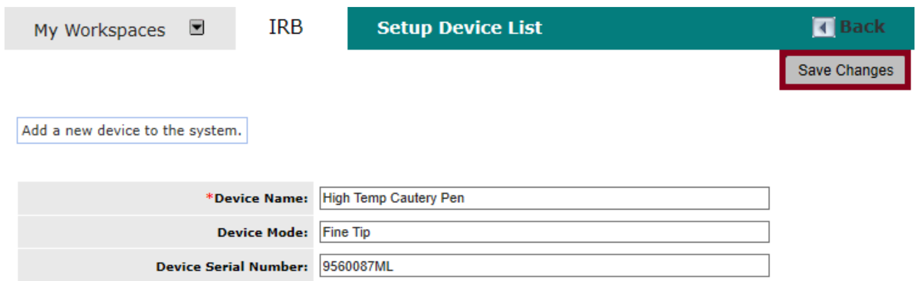
The **Setup Device List** page is opened. Click the **Add a New Device** button.



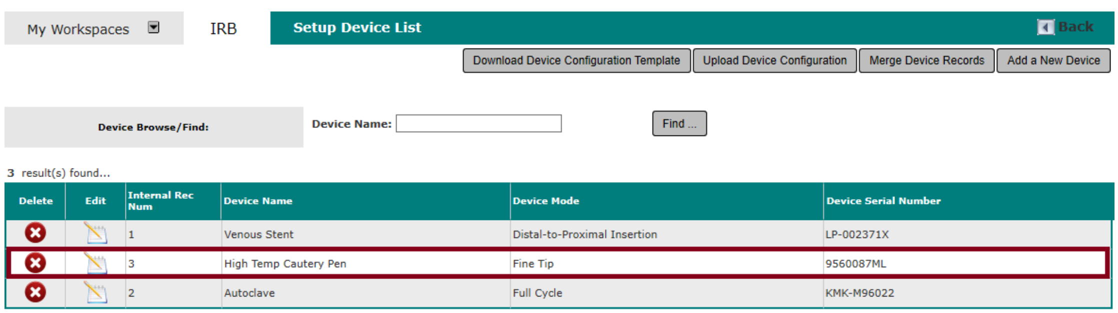
An **Add a new device to the system** panel opens for entry of the new record.



Enter a **Device Name**, **Device Mode** and **Device Serial Number**, then click the **Save Changes** button.

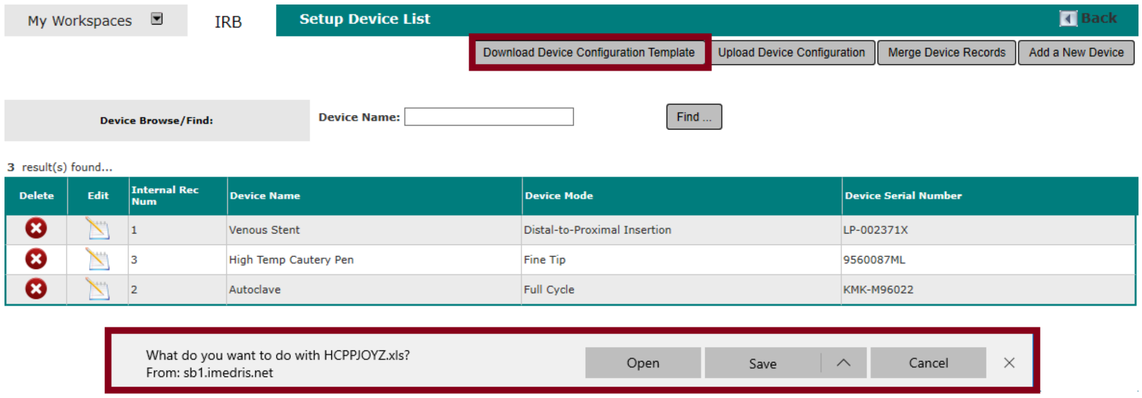


The add panel is closed and the new record is added on the **Setup Device List** page.



Download Device Configuration Template

The iRIS™ system provides a mechanism for adding a large quantity of device records at once, via population and upload of a pre-formatted Excel template. Click the **Download Device Configuration Template** button to begin. A download dialog opens at the bottom of the page.

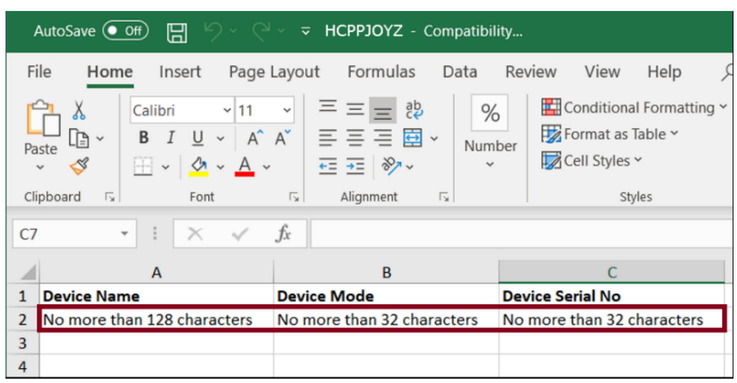


Click the **Cancel** button in the download dialog popup to close it without downloading the template.

Click the **Save** button in the download dialog popup to save the template to the default Downloads folder on the computer. Click the upward-pointing arrow to the right of the **Save** button to access Save As options, which allow for saving the template to the user's desired location on the computer.

The download dialog popup message changes when the download is complete, as shown below.

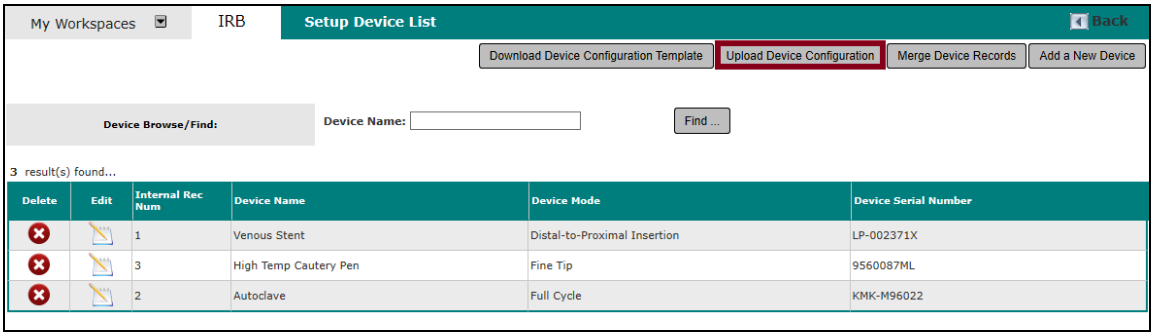
Navigate to the downloaded template file and open it.



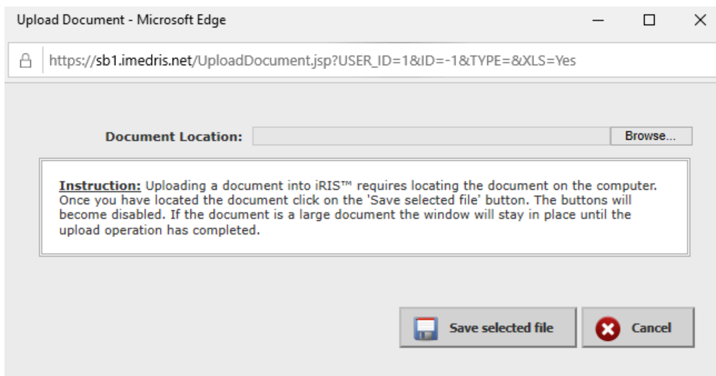
As shown in the screenshot above, field length limits are provided in the second row. Enter desired device records to complete the template and save changes to the file.

Upload Device Configuration Template

When the Device Template has been populated with all desired data, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Device Configuration List** link. The **Setup Device List** page opens. Click the **Upload Device Configuration** button.



An upload dialog popup appears.



Click the **Cancel** button to close the dialog without completing the upload.

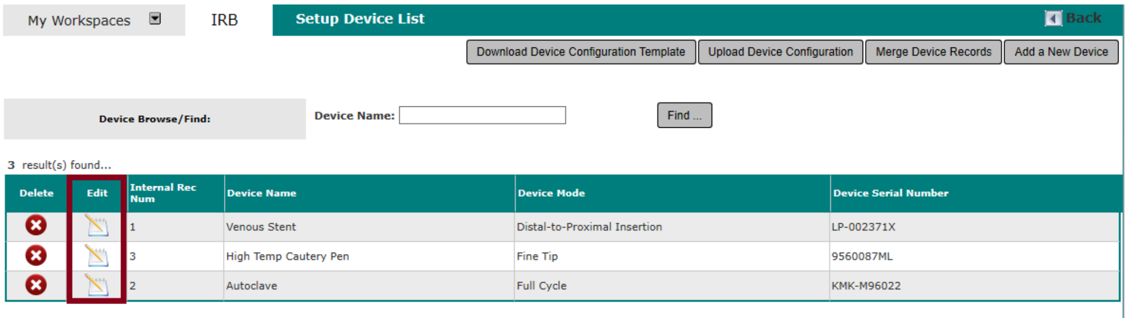
Click the **Browse…** button to navigate to the completed template and select it, then click the **Save selected file** button to complete the upload.

Review the uploaded records in the **Setup Device List** page to ensure the uploaded records have correctly populated all columns. Any records that do not meet data content requirements must be edited or deleted promptly, to ensure they cannot be mistakenly assigned to studies.

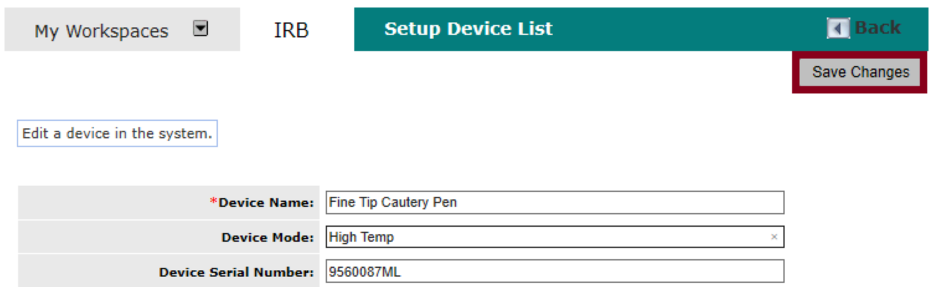
Edit Device

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Device Configuration List** link.

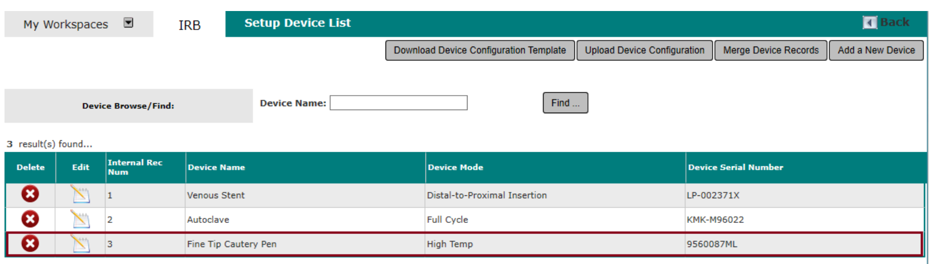
The **Setup Device List** page is opened. Click the icon in the **Edit** column for the applicable record.



The record is opened in an **Edit a device in the system** panel. Make desired changes and click the **Save Changes** button.

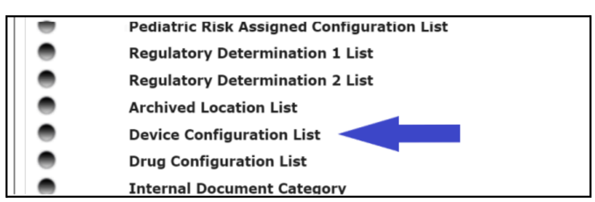


The edit panel is closed and the record is revised on the **Setup Device List** page.

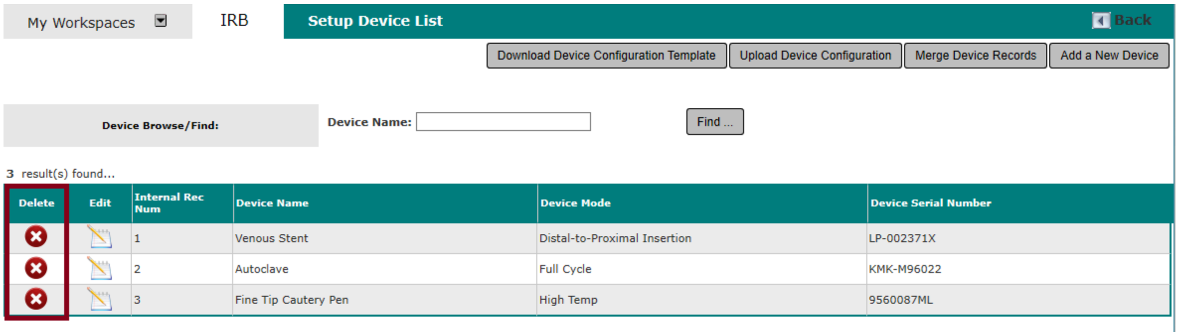


Delete Device

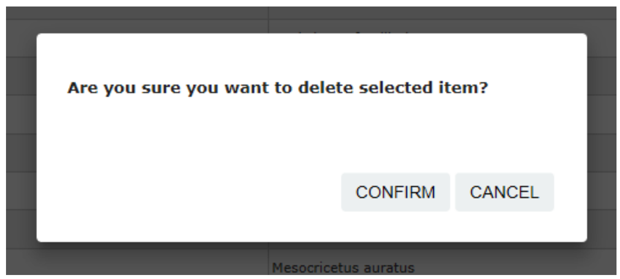
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Device Configuration List** link.



The **Setup Device List** page is opened. Click the icon in the **Delete** column for the applicable record.



A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record and return to the **Setup Device List** page.

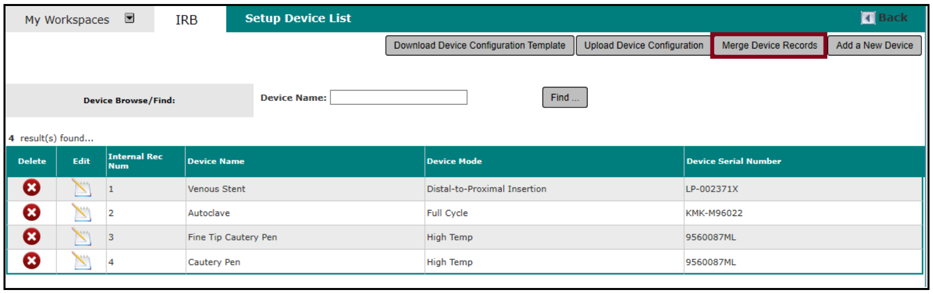
Merge Device Records

Sometimes a duplicate or erroneous device record is created and then assigned to one or more study applications before the mistake is caught.

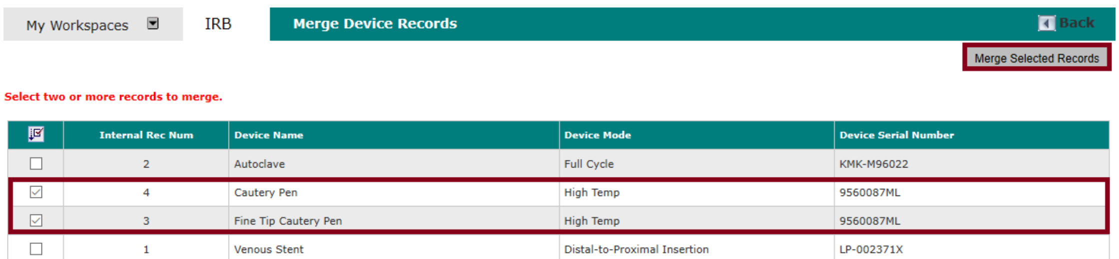
In that situation, the duplicate or erroneous device record can be merged with a valid device record. The valid device record is then substituted for the duplicate/erroneous device record previously assigned to study applications.

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Device Configuration List** link.

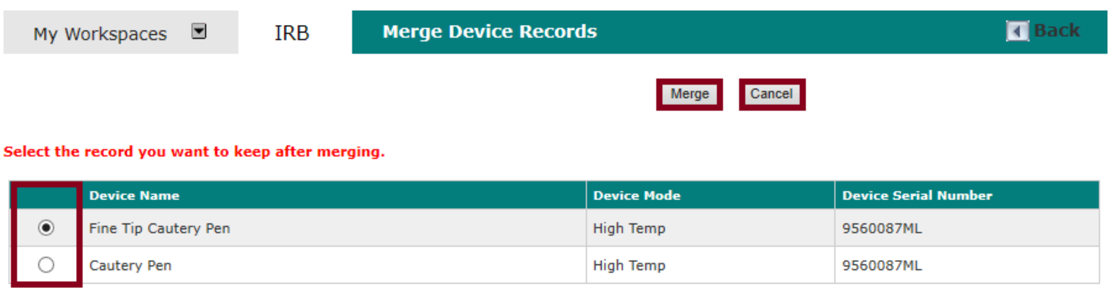
The **Setup Device List** page is opened.



In the example shown above, the second “Cautery Pen” device record in the list was created in error but may have been assigned to one or more studies. Click the **Merge Device Records** button to begin. The **Merge Device Records** page opens.

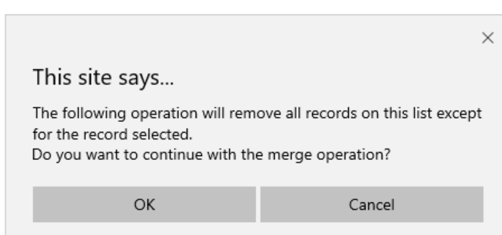


Select the checkboxes at far left for the device records to be merged and click the **Merge Selected Records** button. A new panel opens with only the selected records listed.

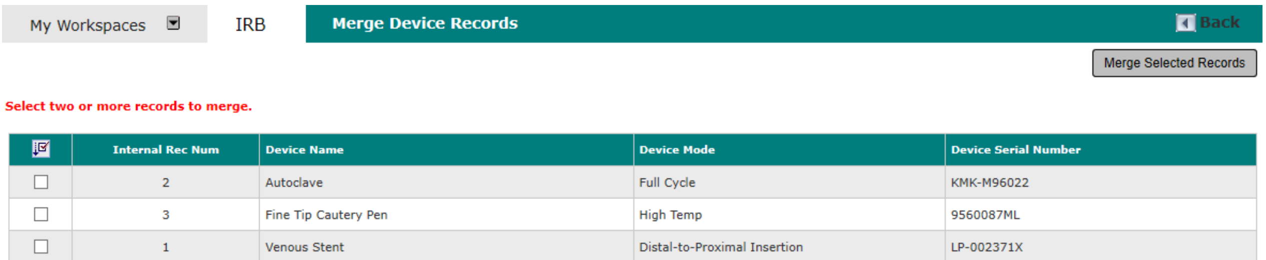


Click the **Cancel** button to close the panel without merging the records.

Note the red instruction text above the table: select the radio button at far left for the record to be KEPT, then click the **Merge** button. A confirmation popup window appears.

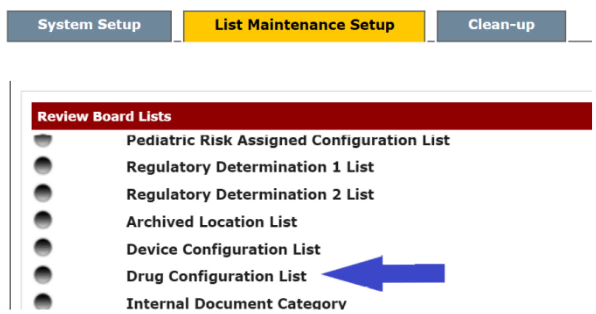


As the popup states, all records on the list will be deleted except for the selected record. Click **Cancel** to close the popup without merging the records. Click **OK** to complete the merge and return to the **Merge Device Records** page, where the merge can be confirmed.

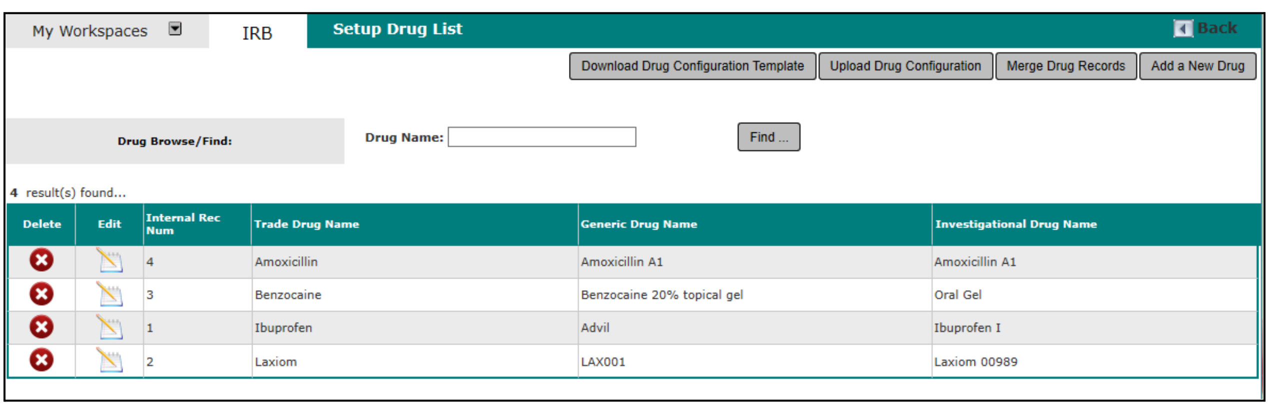


Drug Configuration List

The **Drug Configuration List** is where a list of drugs approved by the institution for use in studies is maintained in the iRIS™ system. To access the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Drug Configuration List** link.



The **Setup Drug List** page is opened.



If the drug list is lengthy, use the **Drug Browse/Find** section above the list to search for records by **Drug Name**.

Drug List Implementation – Application Side

Where this field is in use by the institution, it appears in the study application form.

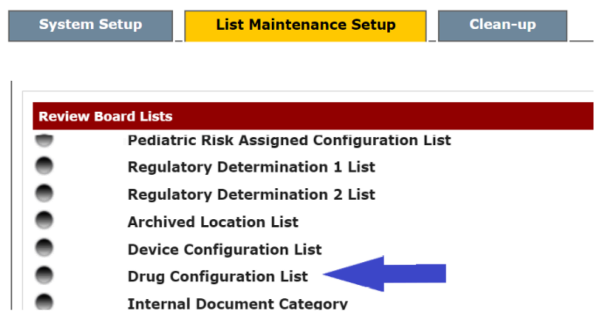
For more information about the study application, see the Study Assistant Manual.

Drug List Implementation – Board Side

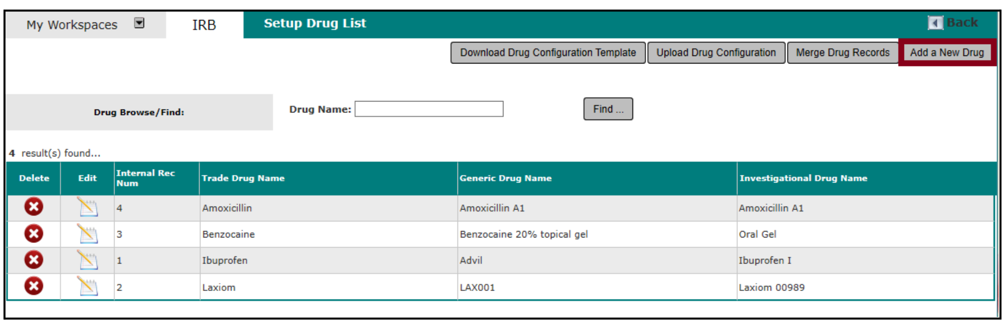
Drugs are added on the application/study side where required and are not generally subject to direct revision by the board.

Add a New Drug

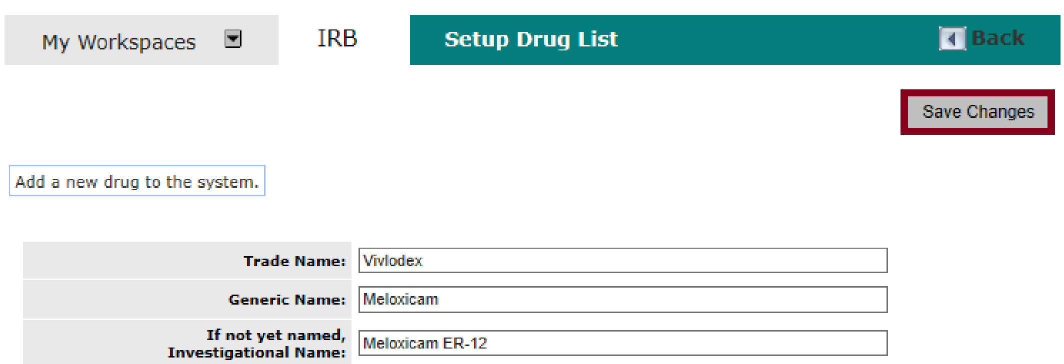
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Drug Configuration List** link.



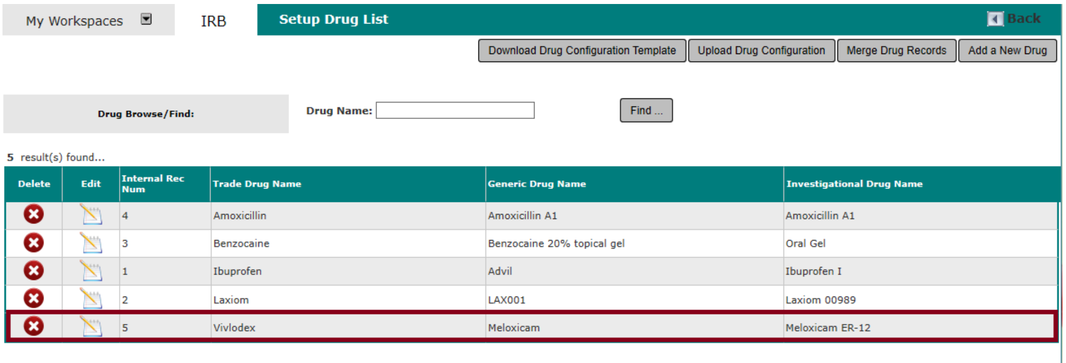
The **Setup Drug List** page is opened. Click the **Add a New Drug** button.



An **Add a new drug to the system** panel opens. Enter **Trade Name**, **Generic Name** and if not yet named, **Investigational Name** details, then click the **Save Changes** button to save the record and close the add panel.

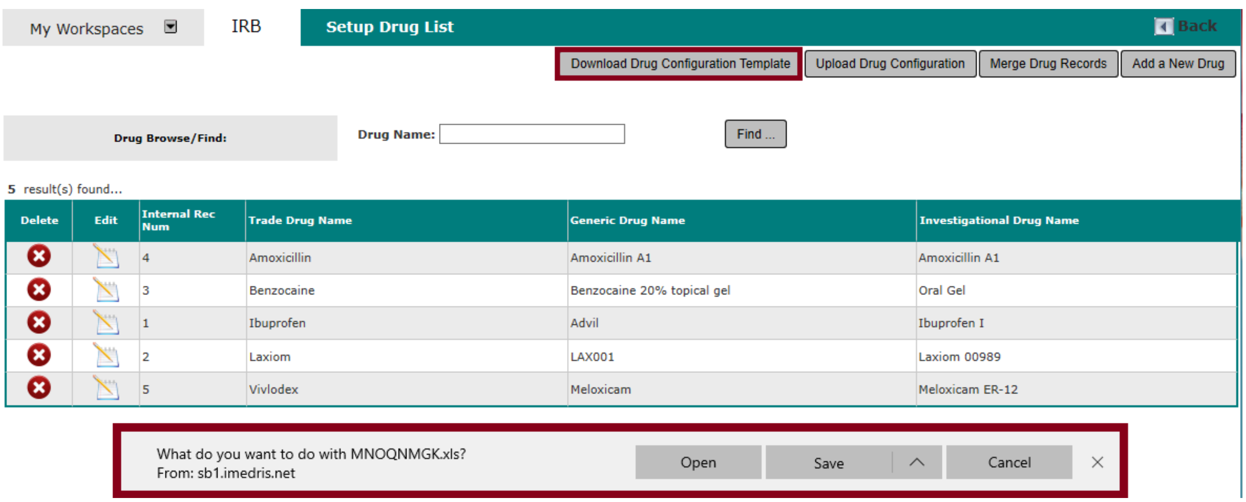


The new drug is added on the **Setup Drug List** page.



Download Drug Configuration Template

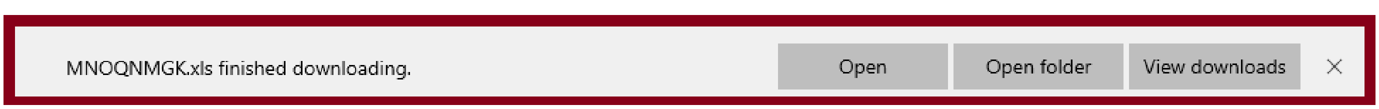
The iRIS™ system provides a mechanism for adding a large quantity of drug records at once, via population and upload of a pre-formatted Excel template. Click the **Download Drug Configuration Template** button to begin. A download dialog opens at the bottom of the page.



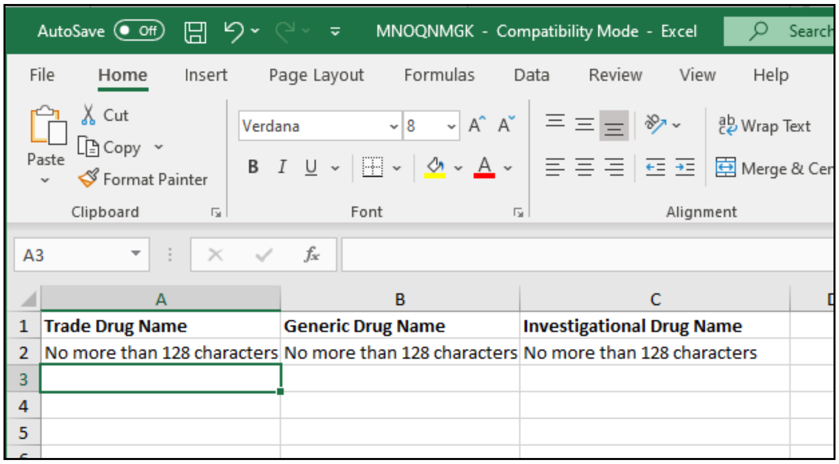
Click the **Cancel** button in the download dialog popup to close it without downloading the template.

Click the **Save** button in the download dialog popup to save the template to the default Downloads folder on the computer. Click the upward-pointing arrow to the right of the **Save** button to access Save As options, which allow for saving the template to the user's desired location on the computer.

The download dialog popup message changes when the download is complete, as shown below.



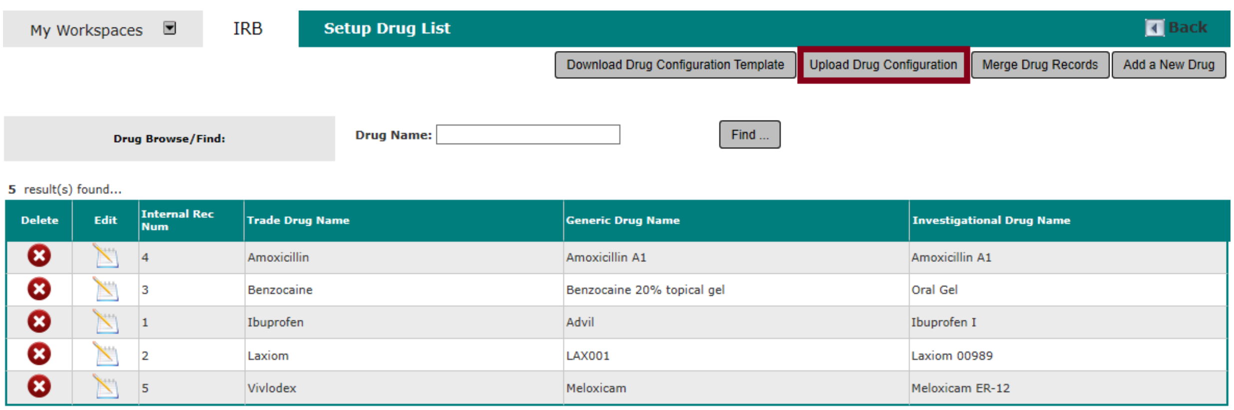
Navigate to the downloaded template file and open it.



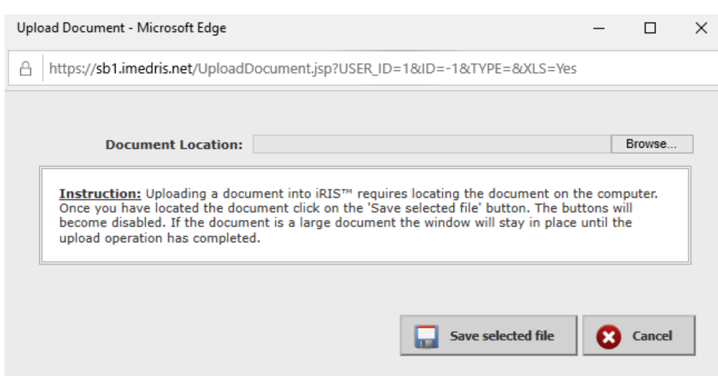
As shown in the screenshot above, field length limits are provided in the second row. Enter desired drug records to complete the template and save changes to the file.

Upload Drug Configuration Template

When the Drug Template has been populated with all desired data, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Drug Configuration List** link. The **Setup Drug List** page opens. Click the **Upload Drug Configuration** button.



An upload dialog popup appears.



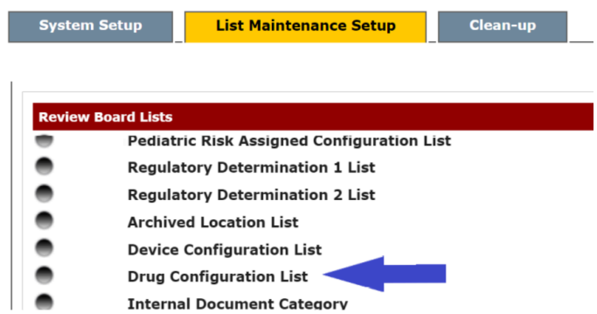
Click the **Cancel** button to close the dialog without completing the upload.

Click the **Browse…** button to navigate to the completed template and select it, then click the **Save selected file** button to complete the upload.

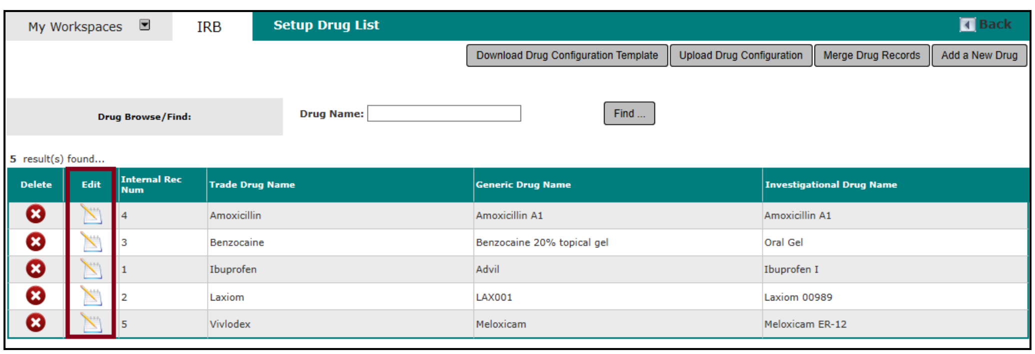
Review the uploaded records in the **Setup Drug List** page to ensure the uploaded records have correctly populated all columns. Any records that do not meet data content requirements must be edited or deleted promptly, to ensure they cannot be mistakenly assigned to studies.

Edit Drug

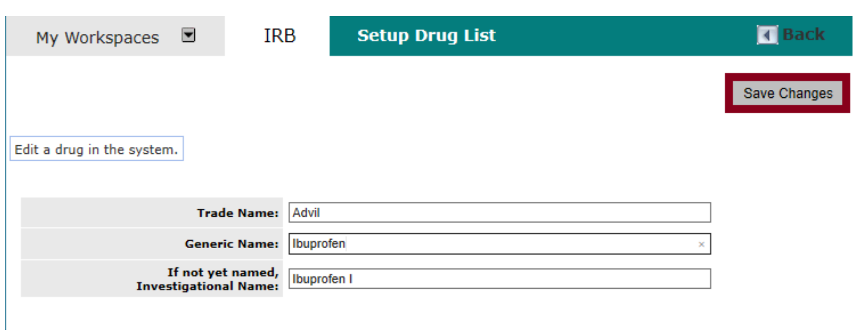
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Drug Configuration List** link.



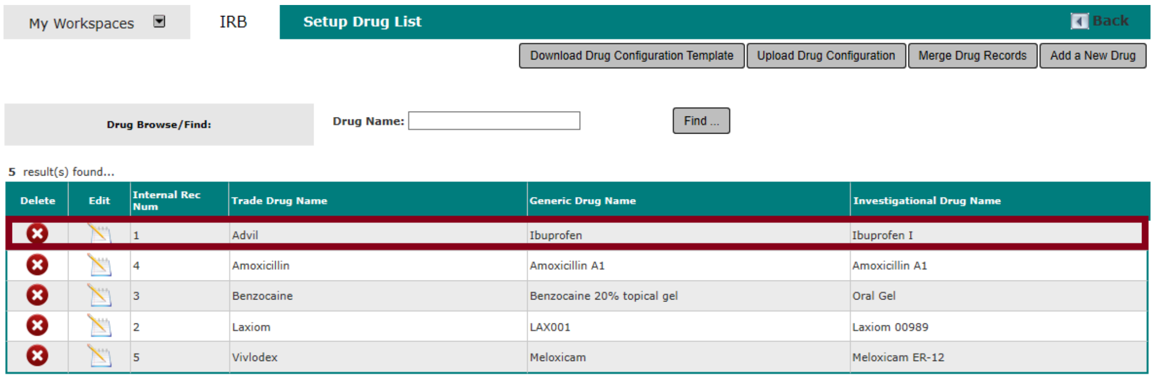
The **Setup Drug List** page is opened. Click the icon in the **Edit** column for the applicable record.



The record is opened in an **Edit a drug in the system** panel.

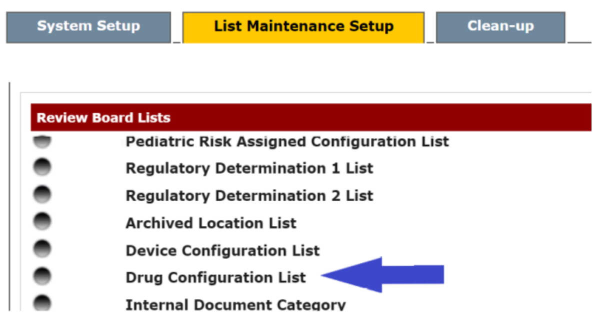


Make desired changes and click the **Save Changes** button to save the record and close the edit panel. The record is revised on the **Setup Drug List** page.

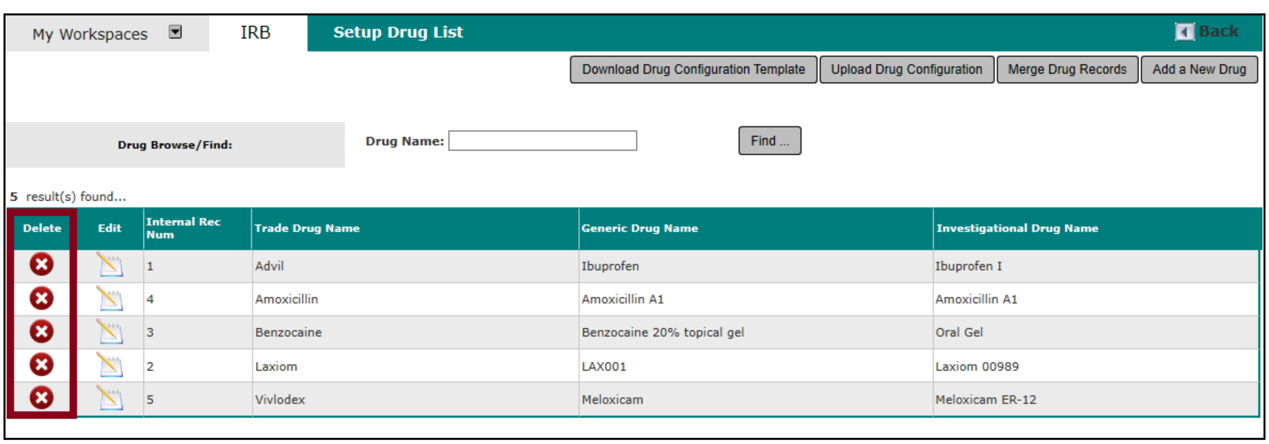


Delete Drug

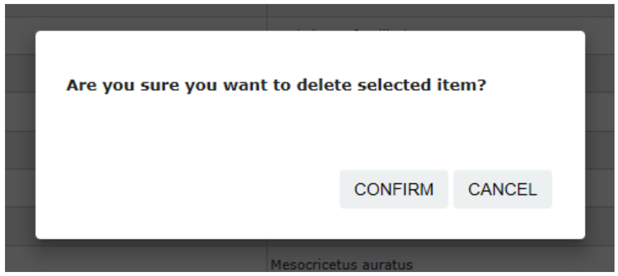
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Drug Configuration List** link.



The **Setup Drug List** page is opened. Click the icon in the **Delete** column for the applicable record.



A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

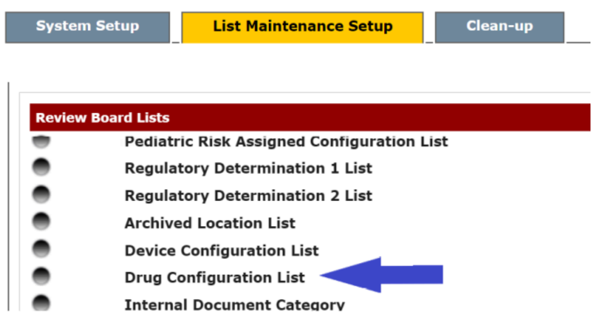
Click **CONFIRM** to complete deletion of the record and return to the **Setup Drug List** page.

Merge Drug Records

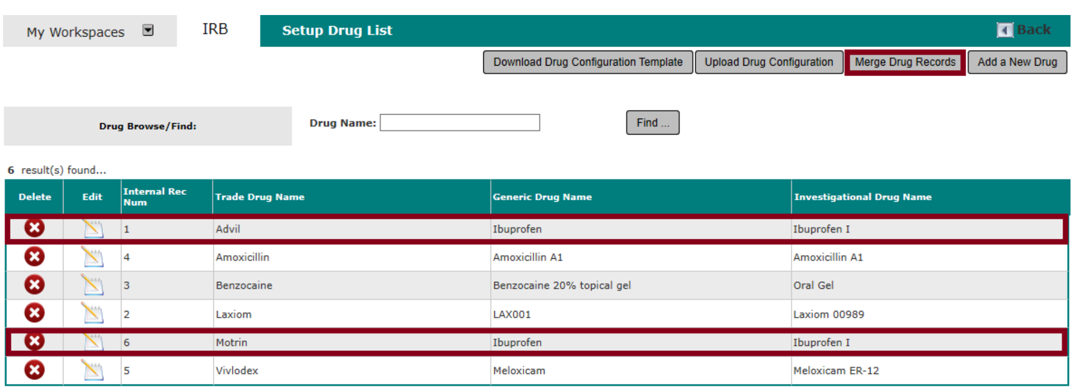
Sometimes a duplicate or erroneous drug record is created and then assigned to one or more study applications before the mistake is caught.

In that situation, the duplicate or erroneous drug record can be merged with a valid drug record. The valid drug record is then substituted for the duplicate/erroneous drug record previously assigned to study applications.

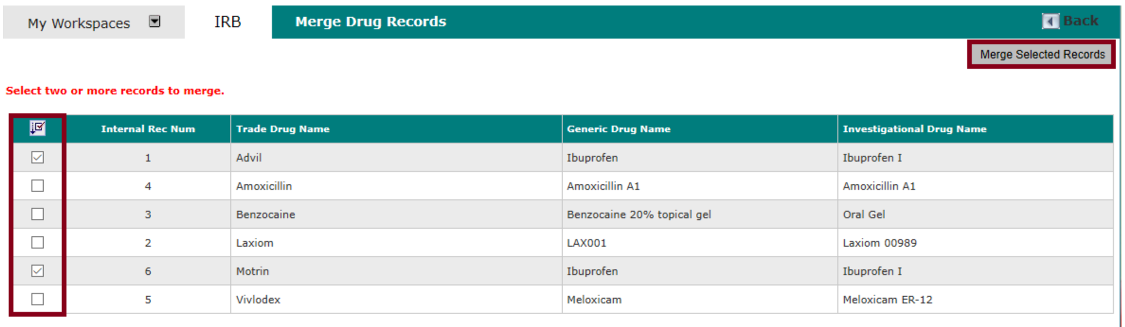
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Drug Configuration List** link.



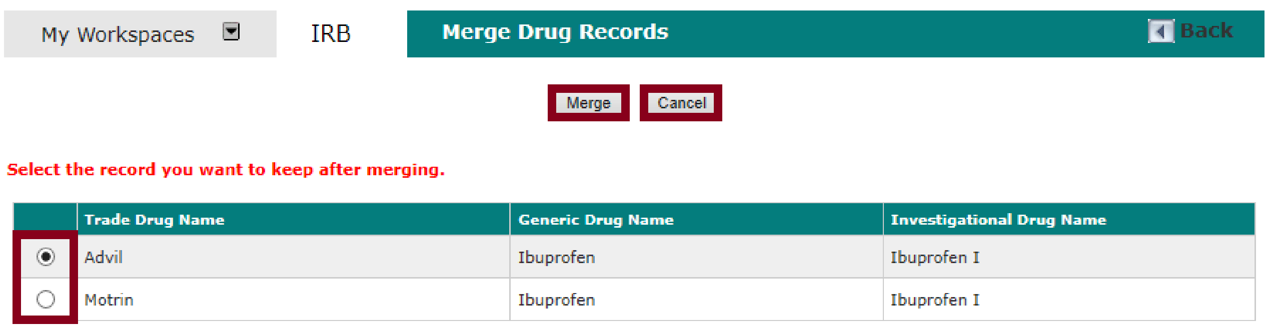
The **Setup Drug List** page is opened. Click the **Merge Drug Records** button.



In the example shown above, the “Motrin” drug record was created in error, as Motrin is another trade name for Ibuprofen and that drug is already in the list under the Trade Drug Name “Advil”. The Motrin record may have been assigned to one or more studies and must be merged with the “Advil” record. Click the **Merge Selected Records** button to begin. The **Merge Drug Records** page opens.

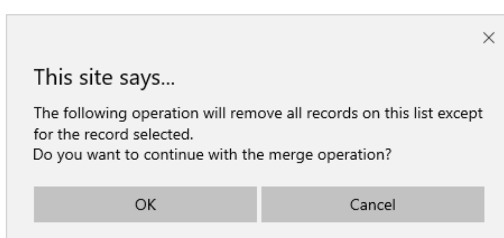


Select the checkboxes at far left for the drug records to be merged and click the **Merge Selected Records** button. A new panel opens with only the selected records listed.

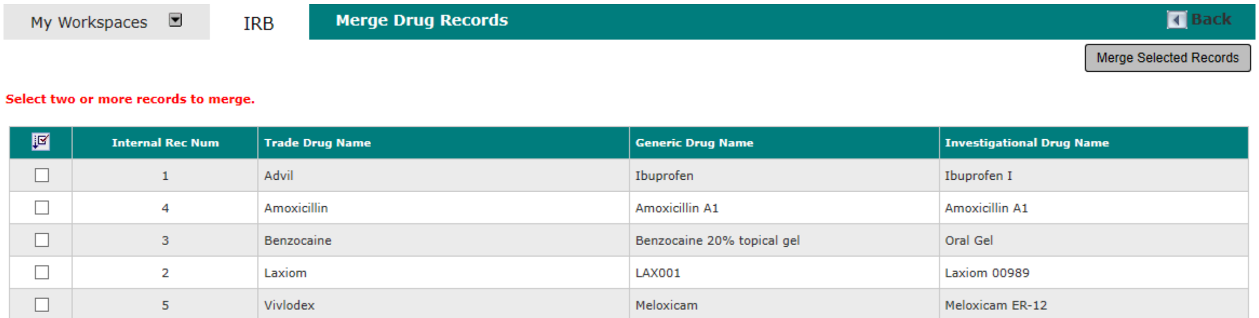


Click the **Cancel** button to close the panel without merging the records.

Note the red instruction text above the table: select the radio button at far left for the record to be KEPT, then click the **Merge** button. A confirmation popup window appears.



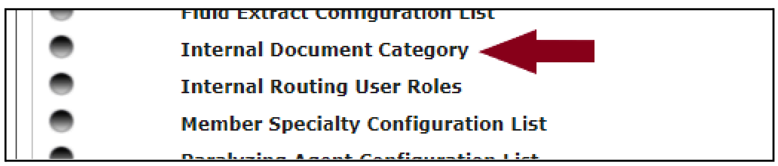
As the popup states, all records on the list will be deleted except for the selected record. Click **Cancel** to close the popup without merging the records. Click **OK** to complete the merge and return to the **Merge Drug Records** page, where the merge can be confirmed.



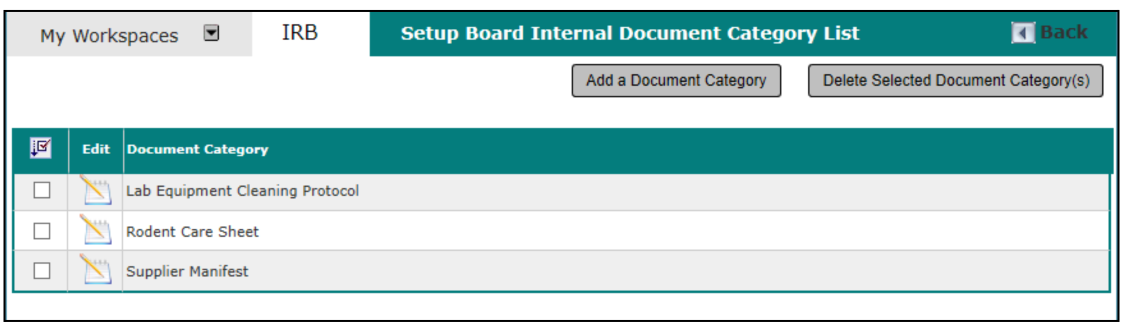
	Internal Rec Num	Trade Drug Name	Generic Drug Name	Investigational Drug Name
☐	1	Advil	Ibuprofen	Ibuprofen I
☐	4	Amoxicillin	Amoxicillin A1	Amoxicillin A1
☐	3	Benzocaine	Benzocaine 20% topical gel	Oral Gel
☐	2	Laxiom	LAX001	Laxiom 00989
☐	5	Vivlodex	Meloxicam	Meloxicam ER-12

Internal Document Category

The **Internal Document Category** list is where a list of standard, internal review board documents is maintained. To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Document Category** link.



The **Setup Board Internal Document Category List** page is opened.

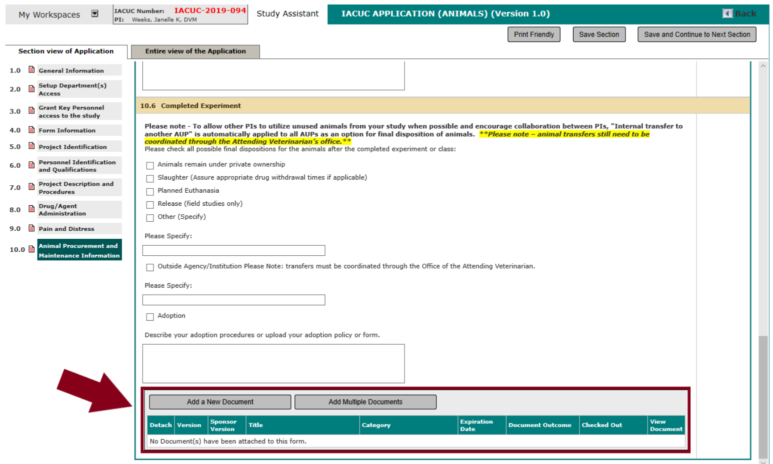


	Edit	Document Category
☐		Lab Equipment Cleaning Protocol
☐		Rodent Care Sheet
☐		Supplier Manifest

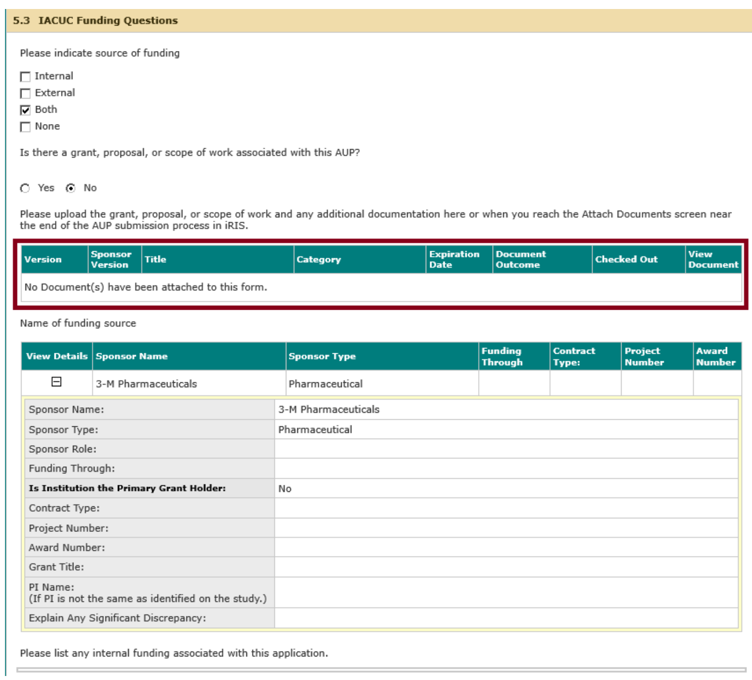
Internal Document List Implementation – Application Side

The internal document list is employed in the following areas on the application side of iRIS™.

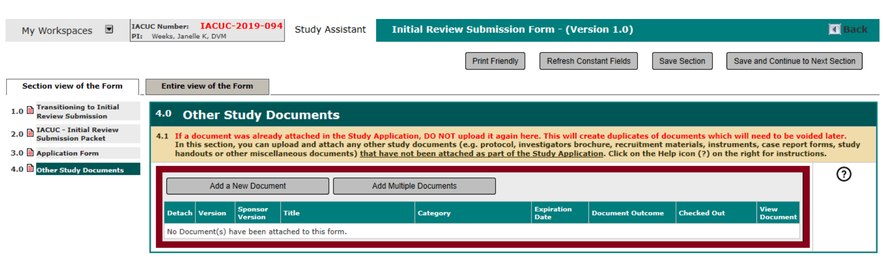
Animal Procurement and Maintenance Information section — any supporting document(s) pertaining to animal subject adoption procedures can be added to an IACUC / ARC study in the **Completed Experiment** section of the application form



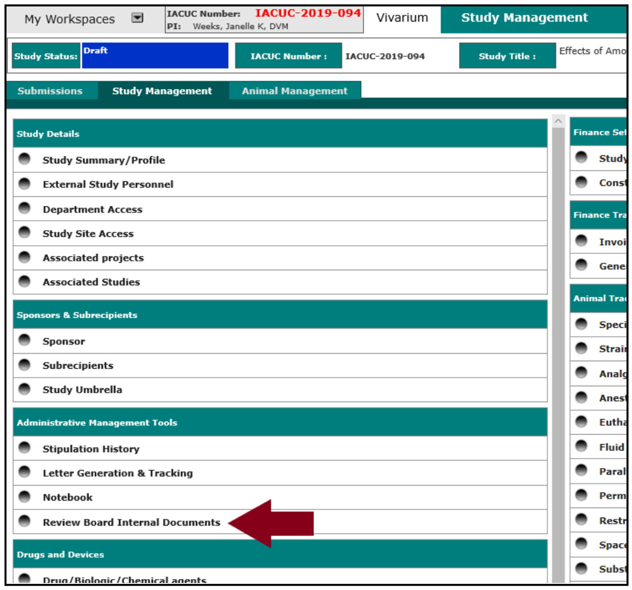
Funding Questions — any supporting document pertaining to funding can be added to a study in the **Funding Questions** section of the application form, as shown in the IACUC example below



Initial Review Submission Form — internal study documents can be attached to the application in the **Other Study Documents** section



Review Board Internal Documents — Review Board Internal Documents added to a study can be accessed on the application side via [module] > Find a Study > [study opened] > Study Management tab > Study Summary/Profile link > Study Management tab > Review Board Internal Documents link, as demonstrated in the IACUC example below

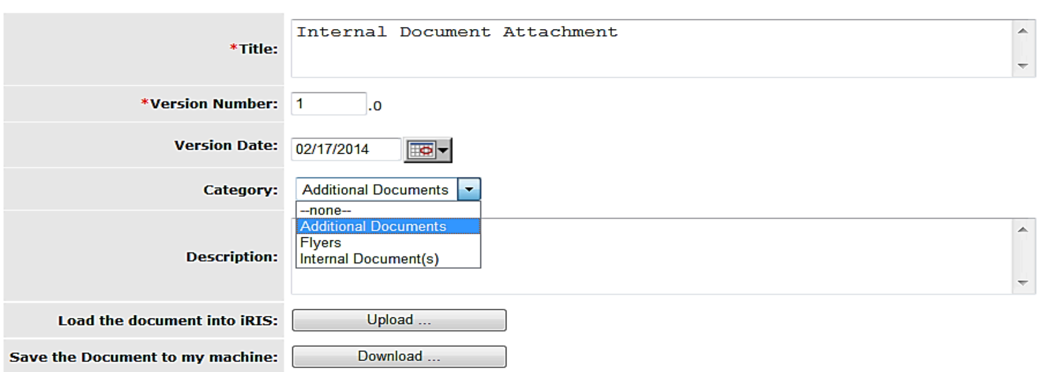


For more information about the study application, see the Study Assistant manual.

Internal Document List Implementation – Board Side

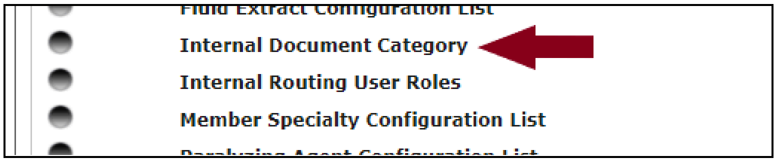
The internal document list is employed in the following areas on the review board / system setup side of iRIS™.

Review Board Internal Documents add form — board members can add internal documents via the Review Board Internal Documents add form

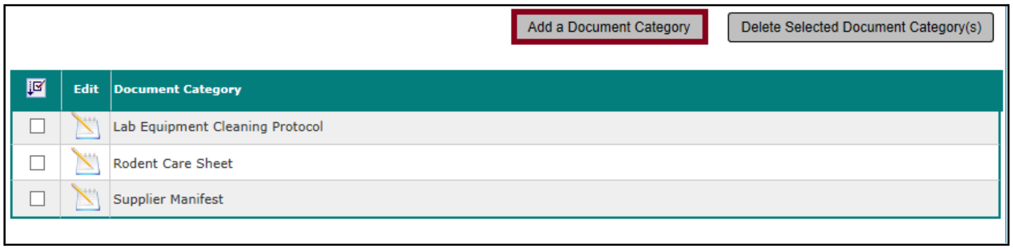


Add Internal Document Category

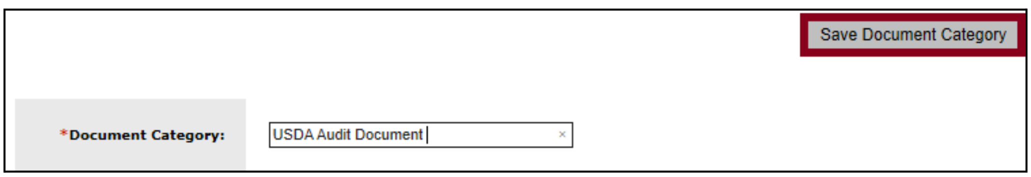
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Document Category** link.



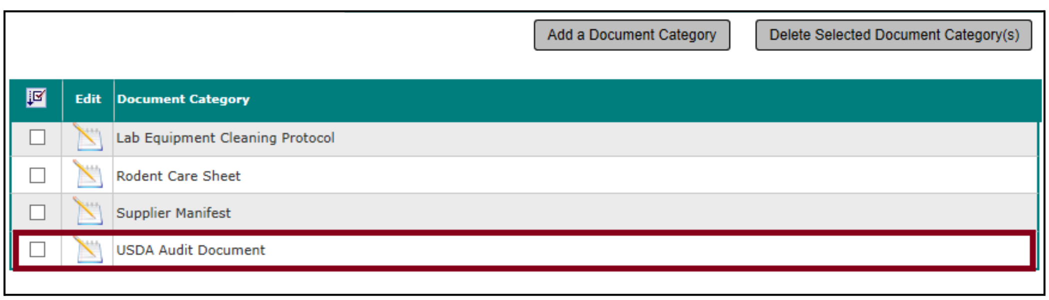
The **Setup Board Internal Document Category List** page is opened. Click the **Add a Document Category** button.



An add panel is opened for creation of the new record. Enter the new **Document Category** and click the **Save Document Category** button.

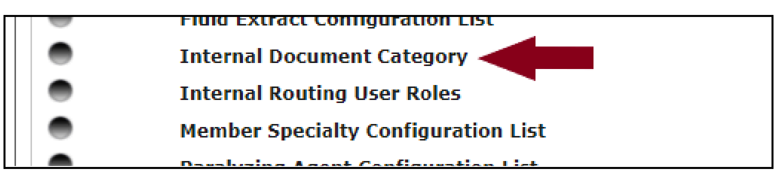


The record is added to the list on the main **Setup Board Internal Document Category List** page.

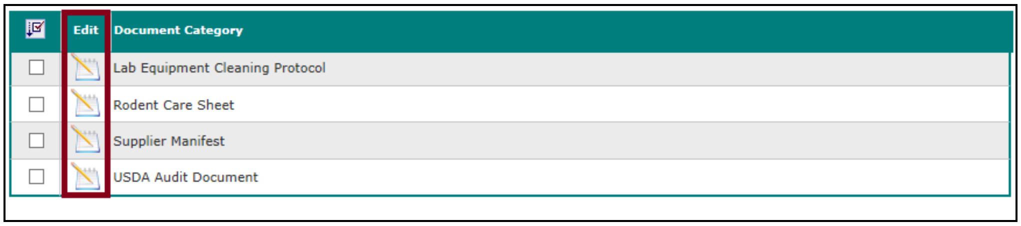


Edit Internal Document Category

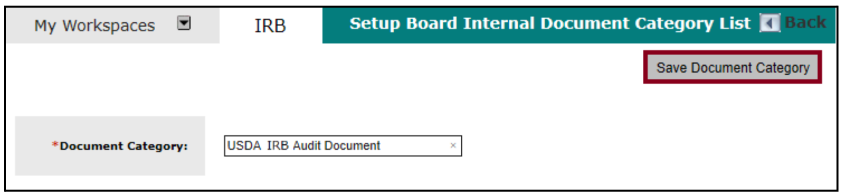
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Document Category** link.



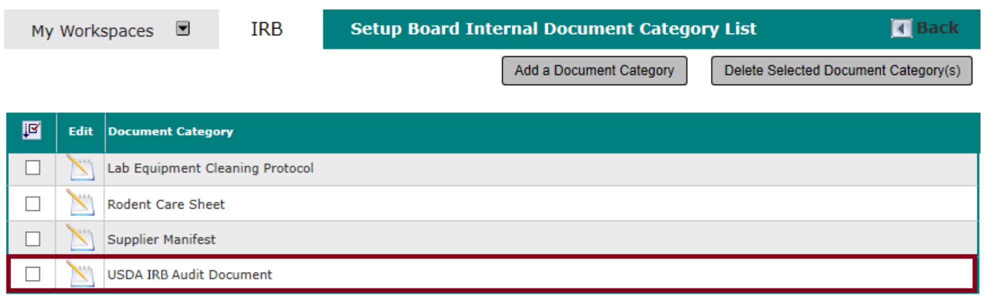
The **Setup Board Internal Document Category List** page is opened. Click the icon in the **Edit** column for the applicable record.



The record is opened in an edit panel. Enter desired changes and click the **Save Document Category** button.

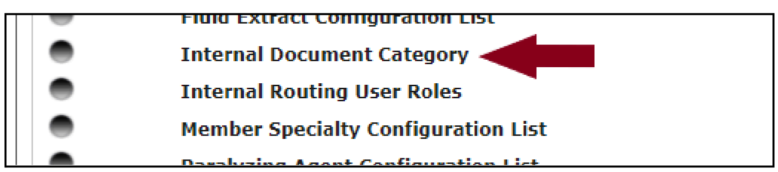


The record is revised on the main list page.

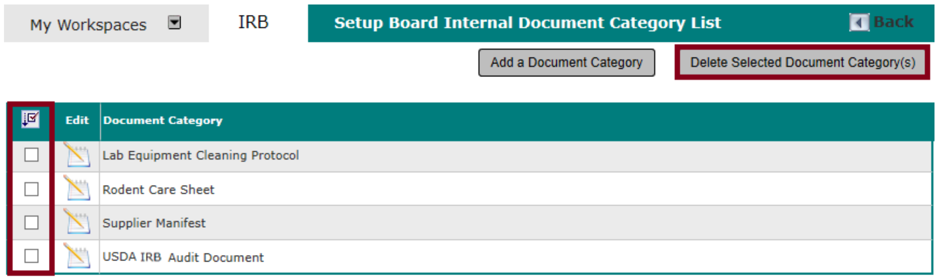


Delete Internal Document Category

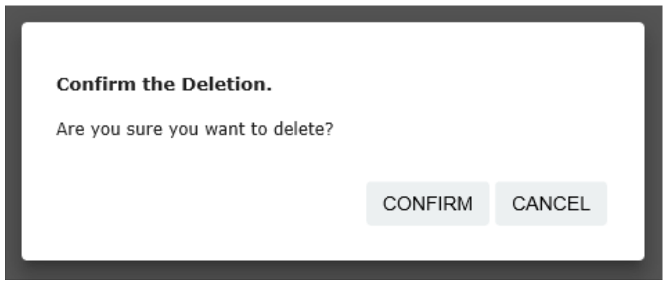
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Document Category** link.



The **Setup Board Internal Document Category List** page is opened. Select the checkbox in the far-left column for the applicable record and click the **Delete Selected Document Category(s)** button.



A confirmation popup window appears.

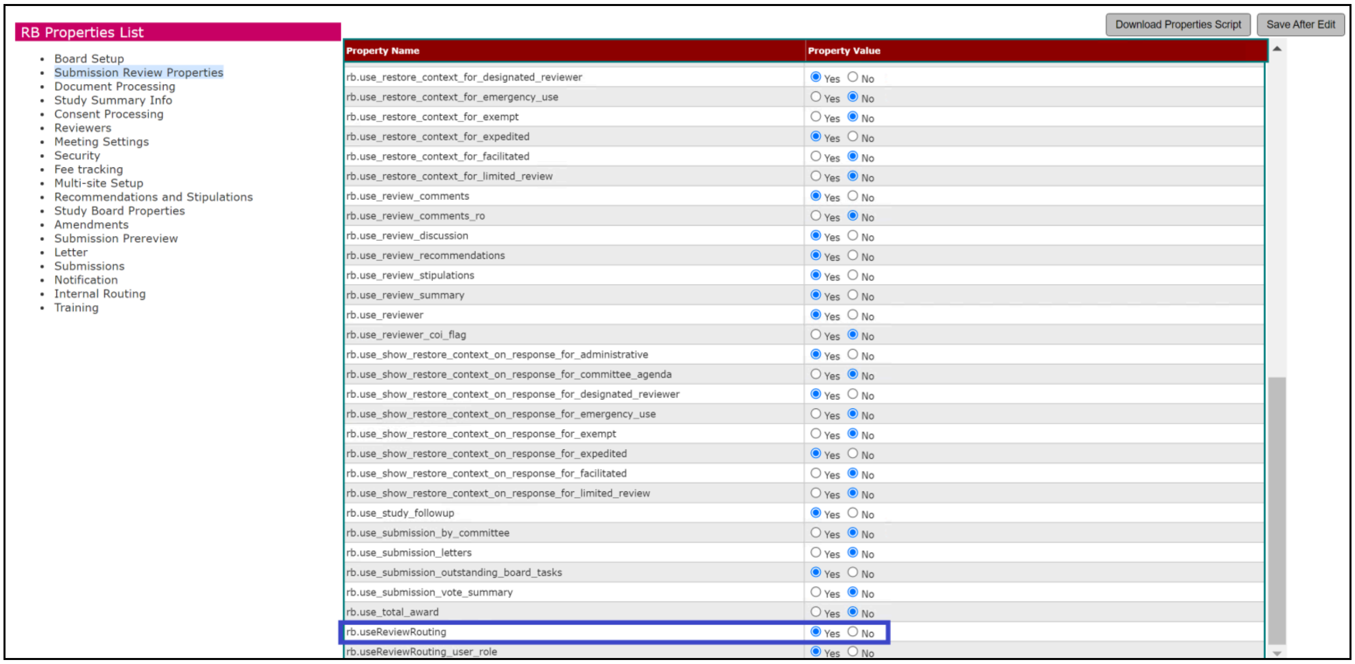


Click **CANCEL** to close the popup without deleting the record.

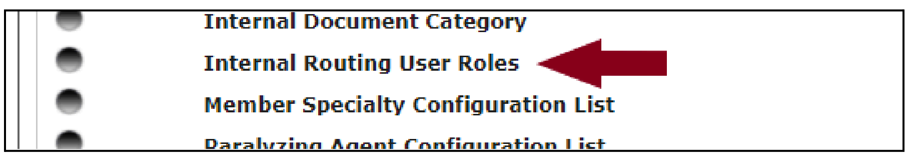
Click **CONFIRM** to delete the record and close the popup. The record is deleted from the list on the main **Setup Board Internal Document Category List** page.

Internal Routing User Roles

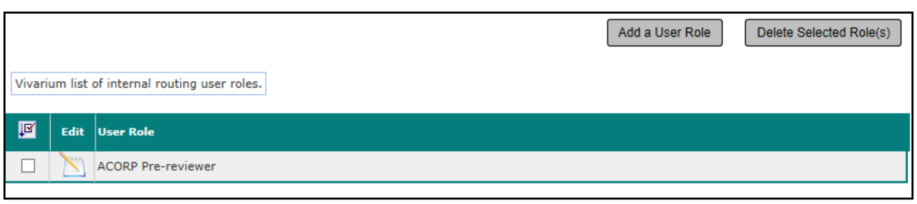
Where the property rb.useReviewRouting_user_role is set to “Yes” (under IRB Assistant > Review Board Administration > Board Configuration Options > Submission Review Properties, see screenshot below), the iRIS™ system allows for setup and maintenance of an **Internal Routing User Roles** list, consisting of roles involved in study document review and signoff.



To access the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Routing User Roles** link.



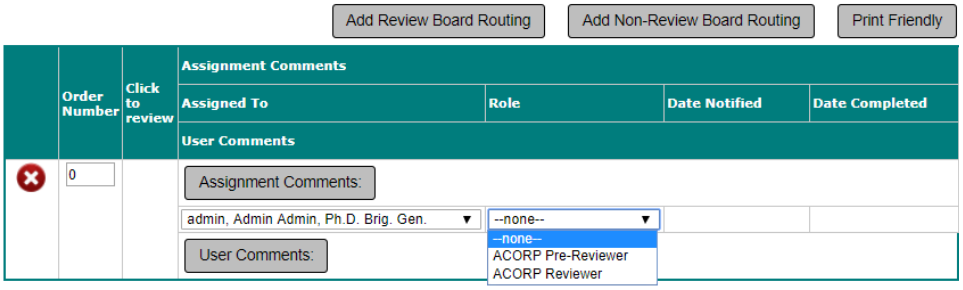
The **Setup Internal Routing User Roles List** page is opened.



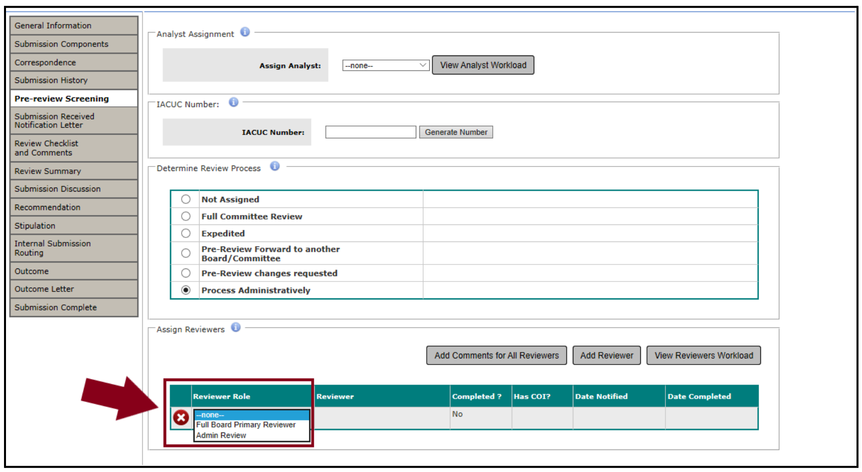
Internal Routing User Role List Implementation – Application Side

The internal routing user role list is employed in the following areas on the application side of iRIS™.

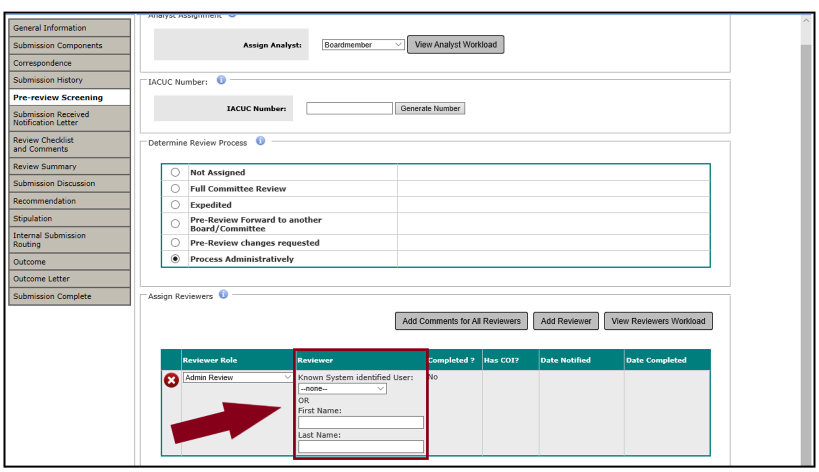
Study Application — the internal routing user role dropdown is employed when making internal routing assignments for a submission



Study Application — the internal routing user role dropdown is employed in the **Assign Reviewers** section of the **Pre-review Screening** tab



Note that selection of an Ad Hoc reviewer role unlocks fields for selection of a named reviewer.



For more information about the study application, see the Study Assistant Manual.

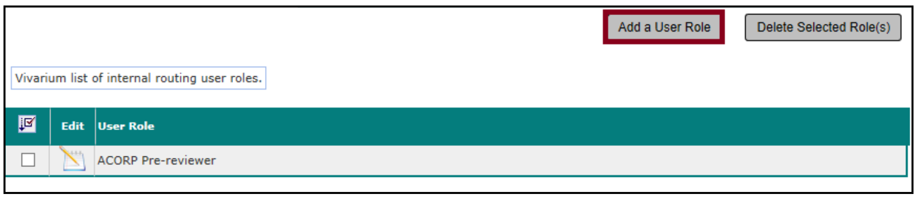
Internal Routing User Role List Implementation – Board Side

The internal routing user role list is utilized during Pre-Review screening, as described in the previous section, and routing assignments made at that time are not generally subject to direct revision by the board.

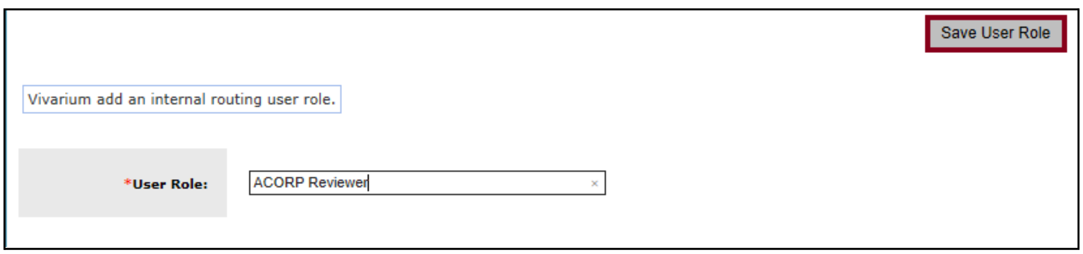
Add Internal Routing User Role

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Routing User Roles** link.

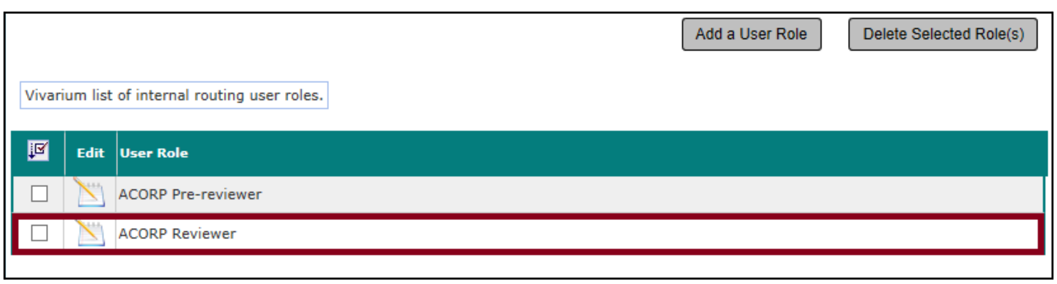
The **Setup Internal Routing User Roles List** page is opened. Click the **Add a User Role** button.



An **add an internal routing user role** panel is opened for creation of the new record. Enter the new **User Role** and click the **Save User role** button.

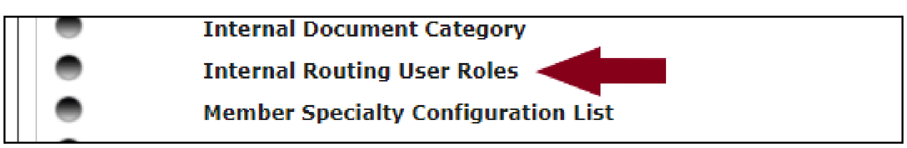


The add panel is closed and the record is added to the list on the **Setup Internal Routing User Roles List** page.

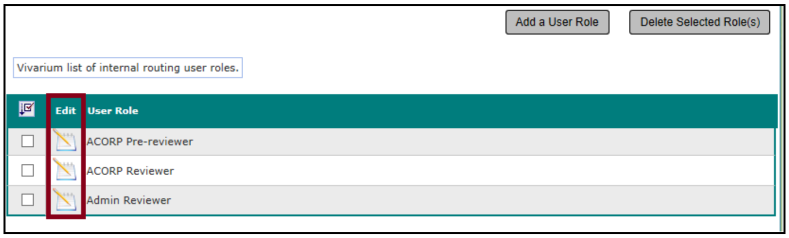


Edit Internal Routing User Role

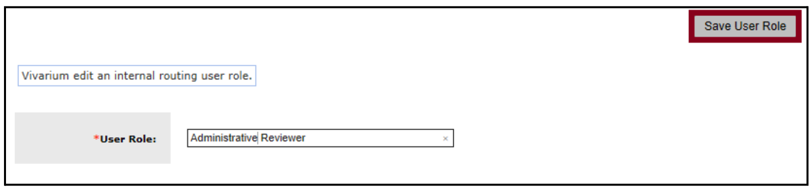
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Routing User Roles** link.



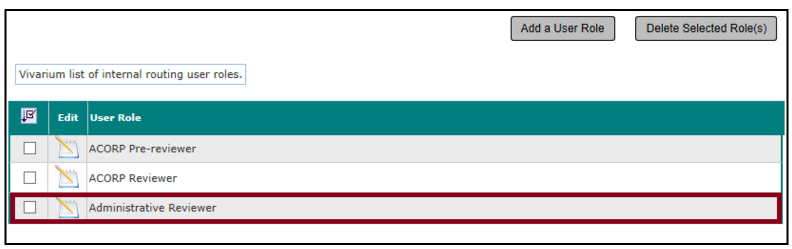
The **Setup Internal Routing User Roles List** page is opened. Click the icon in the **Edit** column for the applicable record.



An **edit an internal routing user role** panel is opened. Enter desired changes and click the **Save User Role** button.

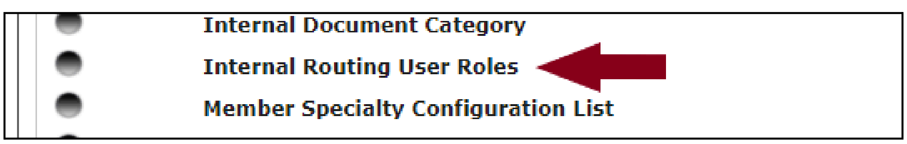


The edit panel is closed, and the record is revised on the **Setup Internal Routing User Roles List** page.

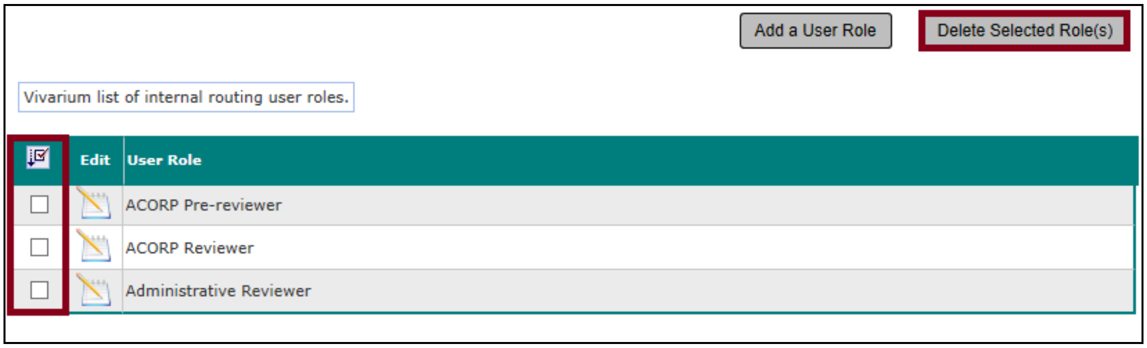


Delete Internal Routing User Role

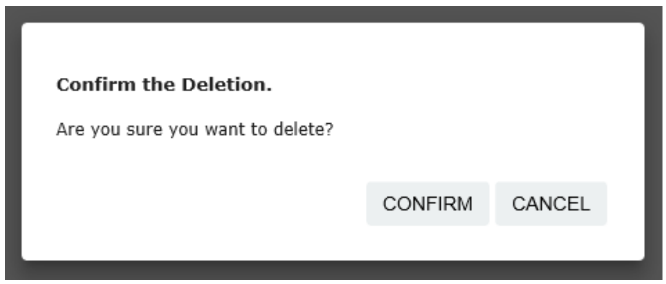
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Internal Routing User Roles** link.



The **Setup Internal Routing User Roles List** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted and click the **Delete Selected Role(s)** button.



A confirmation popup window appears.

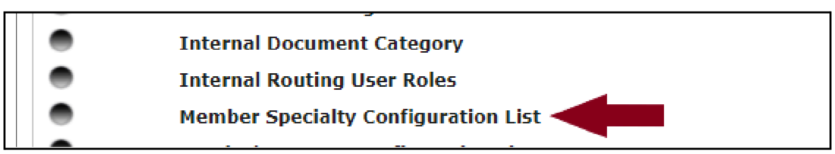


Click **CANCEL** to close the popup without deleting the record.

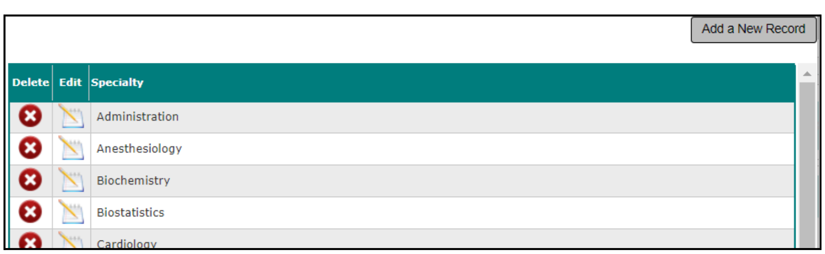
Click **CONFIRM** to delete the record and close the popup. The record is deleted from the list on the main **Setup Internal Routing User Roles List** page.

Member Specialty Configuration List

The **Member Specialty Configuration List** is where a list of review board member academic or medical specialties is maintained in the iRIS™ system. To access the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Member Specialty Configuration List** link.



The **System Administration – Member Specialty** page is opened.

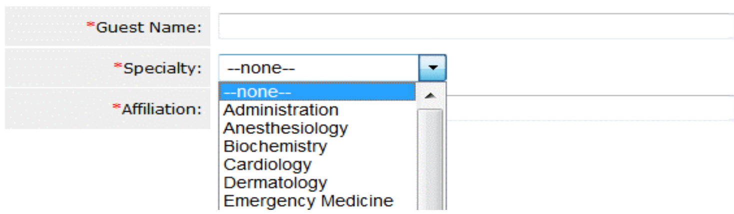


Member Specialty List Implementation – Application Side

The member specialty list is employed on the review board side only.

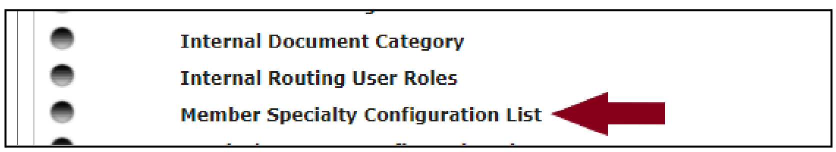
Member Specialty List Implementation – Board Side

Member specialties are added to review board member user profiles at the time the system administrator sets up their iRIS™ user accounts, and the specialty configuration list is also made available as a dropdown picklist when guests are added to the meeting attendance section for a meeting agenda (shown below).

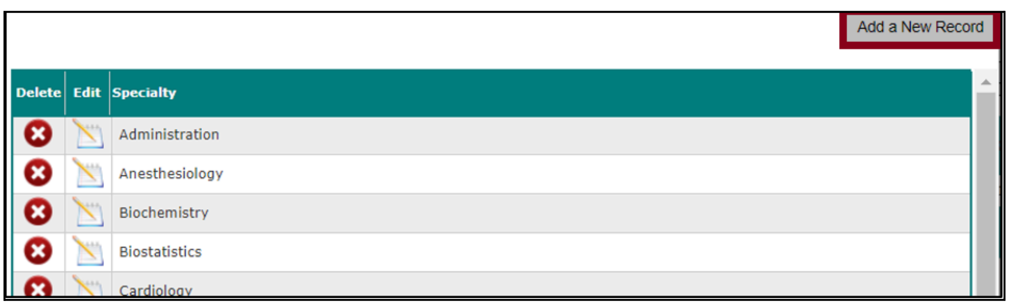


Add Member Specialty

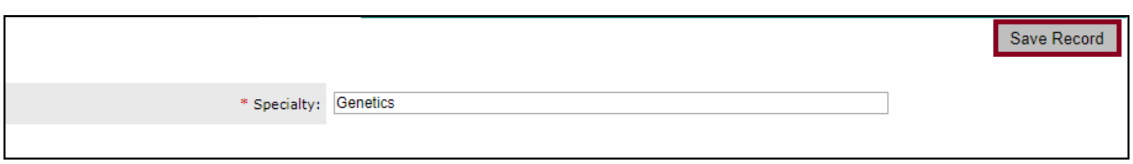
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Member Specialty Configuration List** link.



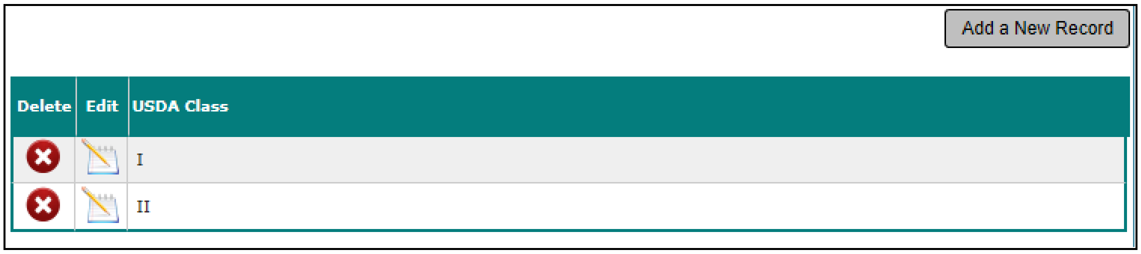
The **System Administration – Member Specialty** page is opened. Click the **Add a New Record** button.



An add panel is opened. Enter the **Specialty** and click the **Save Record** button.

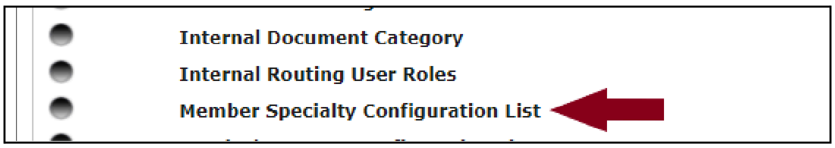


The record is added to the **System Administration – Member Specialty** list page.

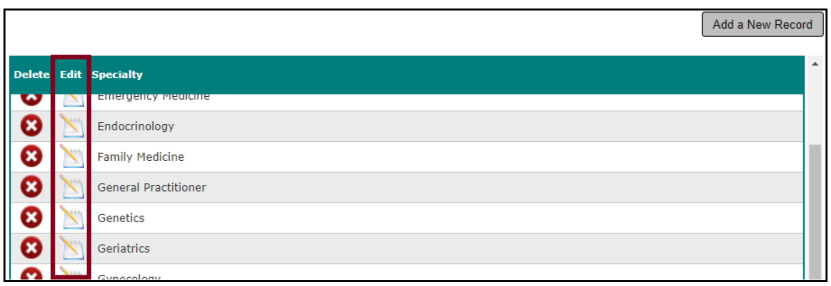


Edit Member Specialty

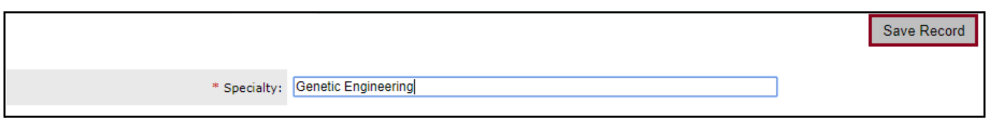
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the click the **Member Specialty Configuration List** link.



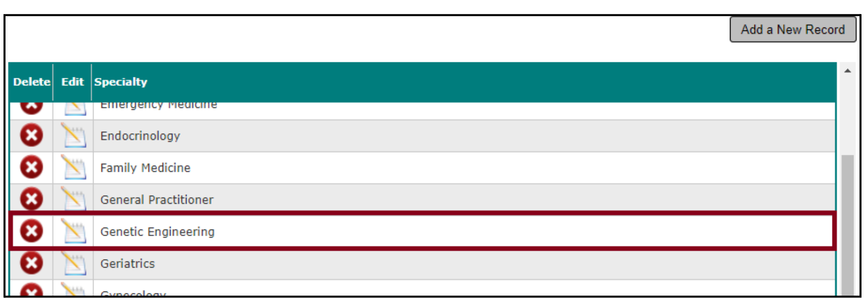
The **System Administration – Member Specialty** page is opened. Click the icon in the **Edit** column for the applicable record.



The record is opened in an edit panel.

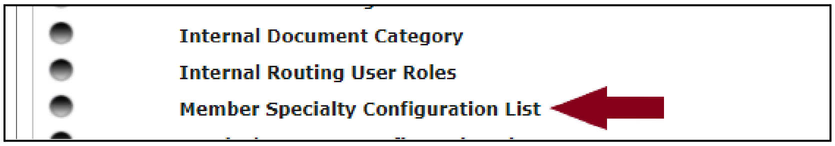


Make desired changes and click the **Save Record** button. The record is revised on the **System Administration – Member Specialty** list page.

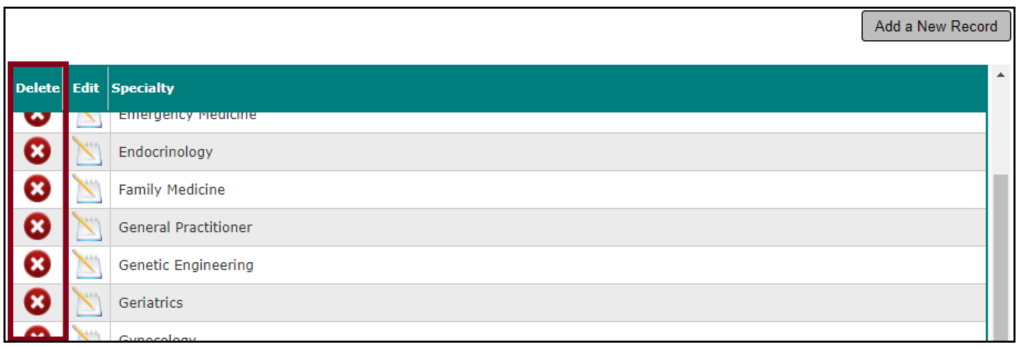


Delete Member Specialty

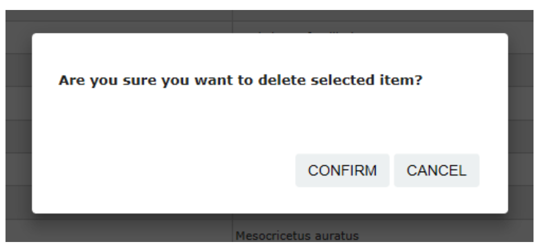
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the click the **Member Specialty Configuration List** link.



The **System Administration – Member Specialty** page is opened. Click the icon in the **Delete** column for the applicable record.

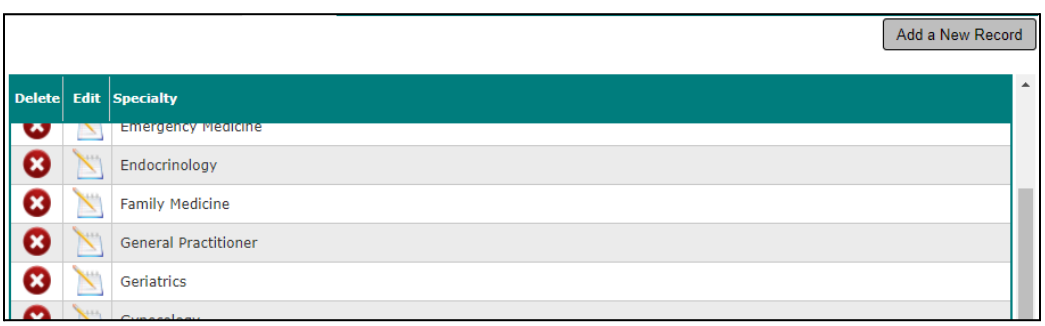


A confirmation popup window displays.



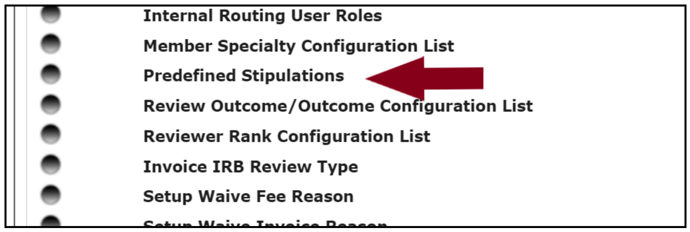
Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record and return to the **System Administration – Member Specialty** list page. The record is deleted from the list.

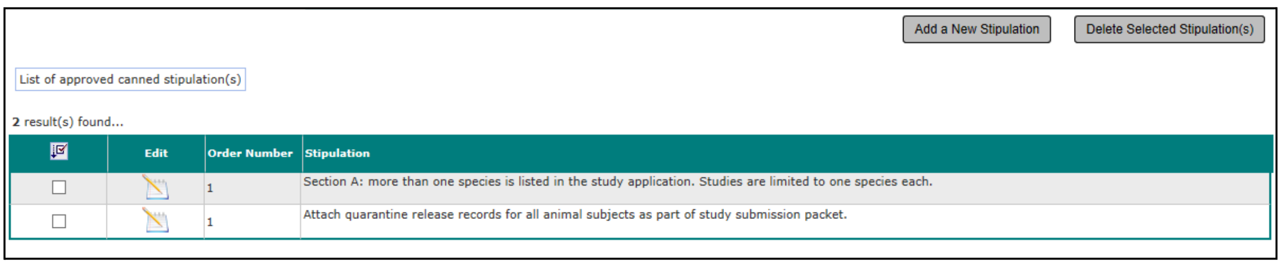


Predefined Stipulations

The Predefined Stipulations list is where boilerplate stipulations approved by the institution for use in studies is maintained in the iRIS™ system. To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Predefined Stipulations** link.

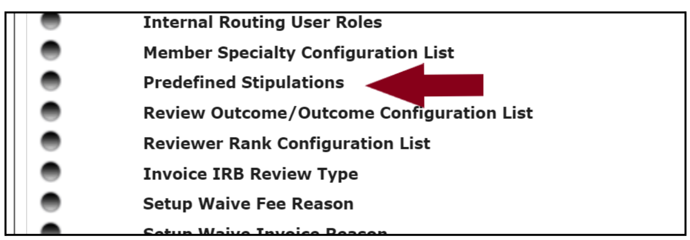


The **Setup Stipulation** page is opened.

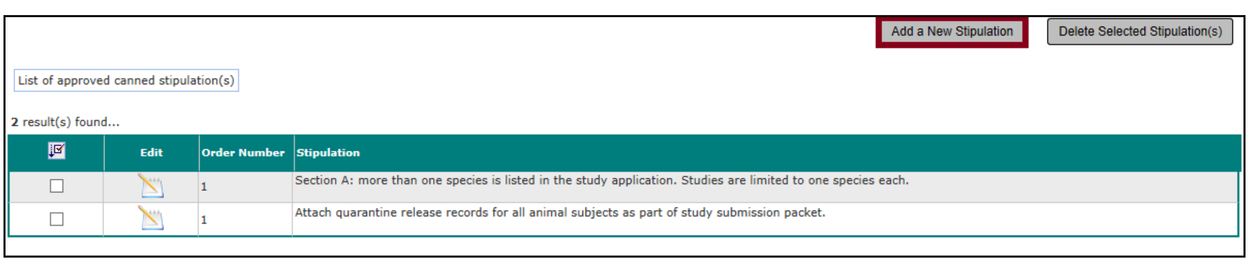


Add Predefined Stipulation

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Predefined Stipulations** link.



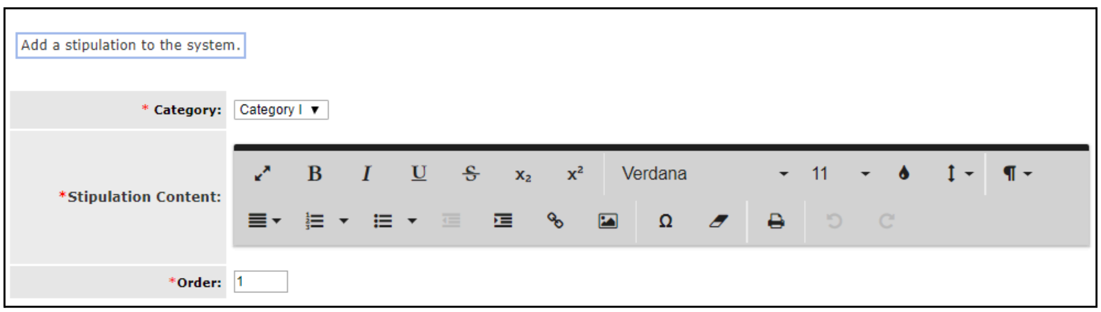
The **Setup Stipulation** page is opened. Click the **Add a New Stipulation** button.



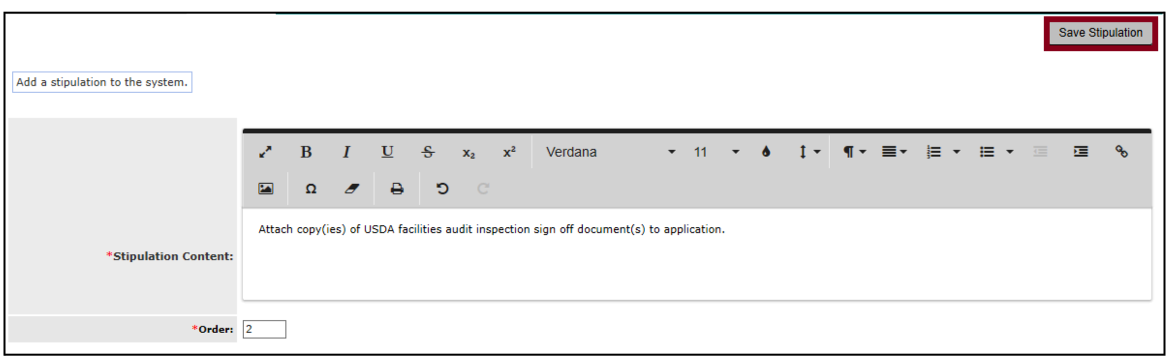
The **Add a stipulation to the system** panel is opened.

Enter desired stipulation text in the **Stipulation Content** area. Use the toolbar buttons to format the text, insert links or insert images. Enter a numeric **Order** value to indicate routing priority order for the stipulation.

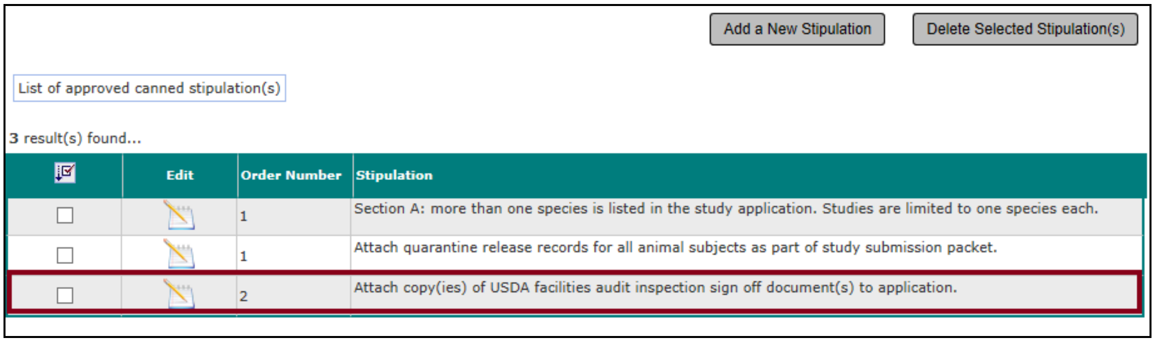
If stipulation categories are in use at the institution (property rb.use_stipulation_category set to "Yes" under IRB Assistant > Review Board Administration > Board Configuration Options > Recommendations and Stipulations) a **Category** field is also included at the top of the page, as shown below. Select the applicable **Category** from the dropdown list.



In the example below, the add panel is complete. Click the **Save Stipulation** button to save the new record and close the add panel.

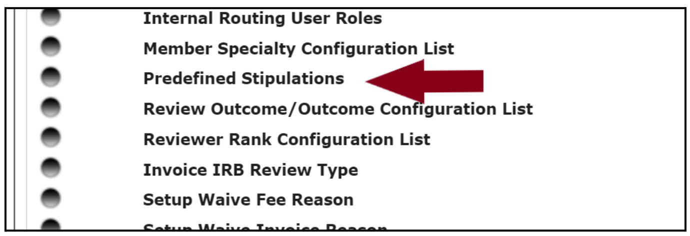


The new stipulation is added on the main **Setup Stipulation** list page.

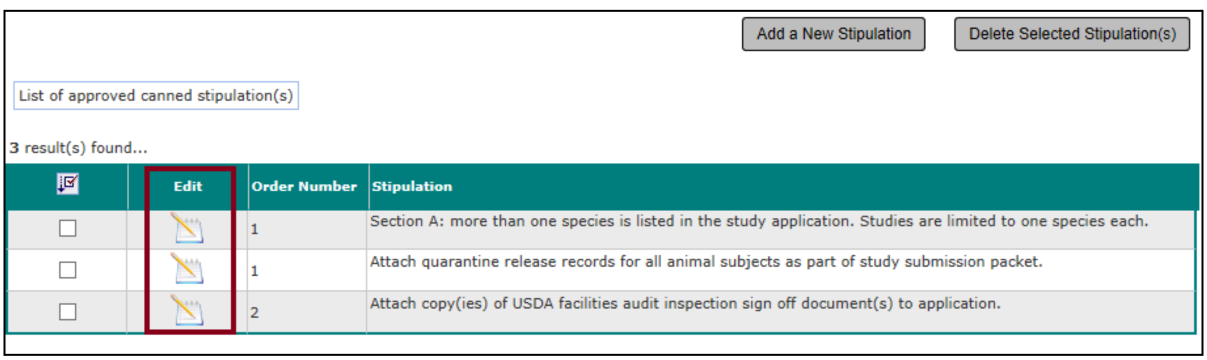


Edit Predefined Stipulation

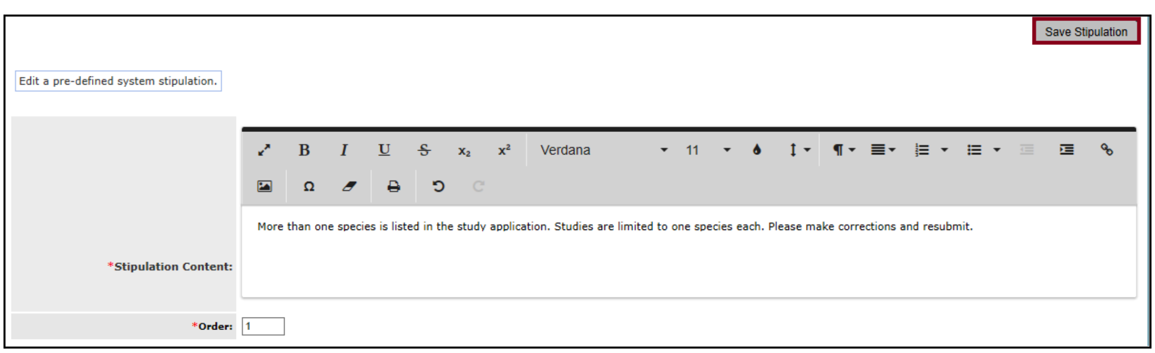
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Predefined Stipulations** link.



The **Setup Stipulation** page is opened. Click the icon in the **Edit** column for the applicable record.

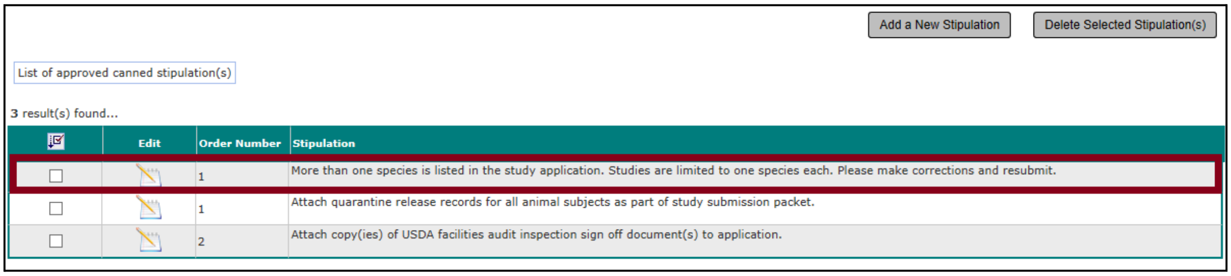


The selected record is opened in an **Edit a pre-defined system stipulation** panel.



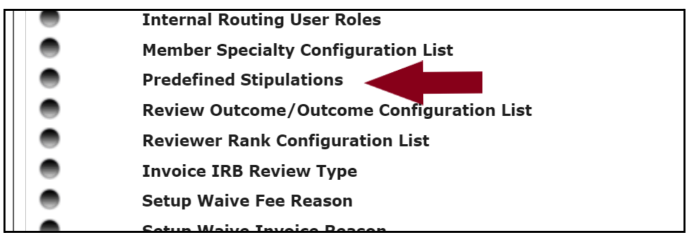
*Note that if stipulation categories are in use at the institution (property rb.use_stipulation_category set to "Yes" under IRB Assistant > Review Board Administration > Board Configuration Options > Recommendations and Stipulations) a **Category** field is included in the edit panel.*

Make desired changes and click the **Save Stipulation** button to save changes and close the edit panel. The record is updated on the **Setup Stipulation** list page.

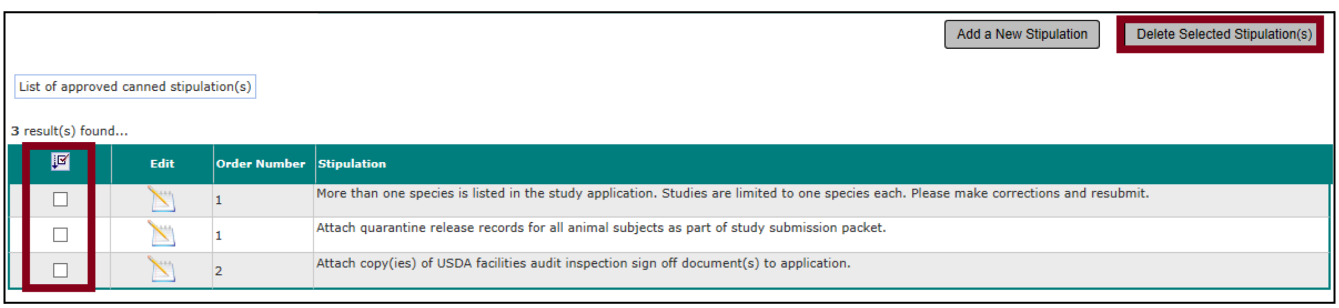


Delete Predefined Stipulation

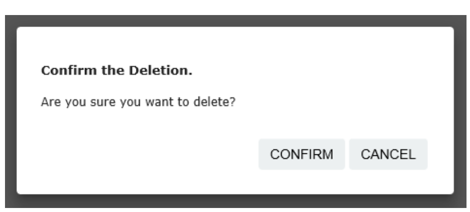
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Predefined Stipulations** link.



The **Setup Stipulation** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted and click the **Delete Selected Stipulation(s)** button.

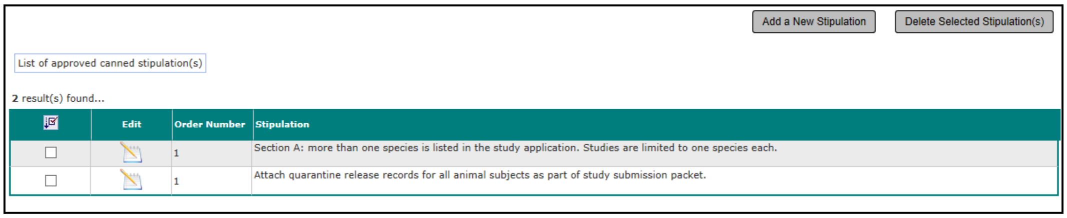


A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

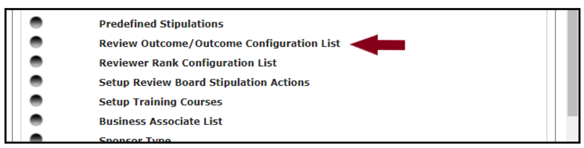
Click **CONFIRM** to complete deletion of the record and return to the **Setup Stipulation** page. The record is deleted from the **Setup Stipulation** page.



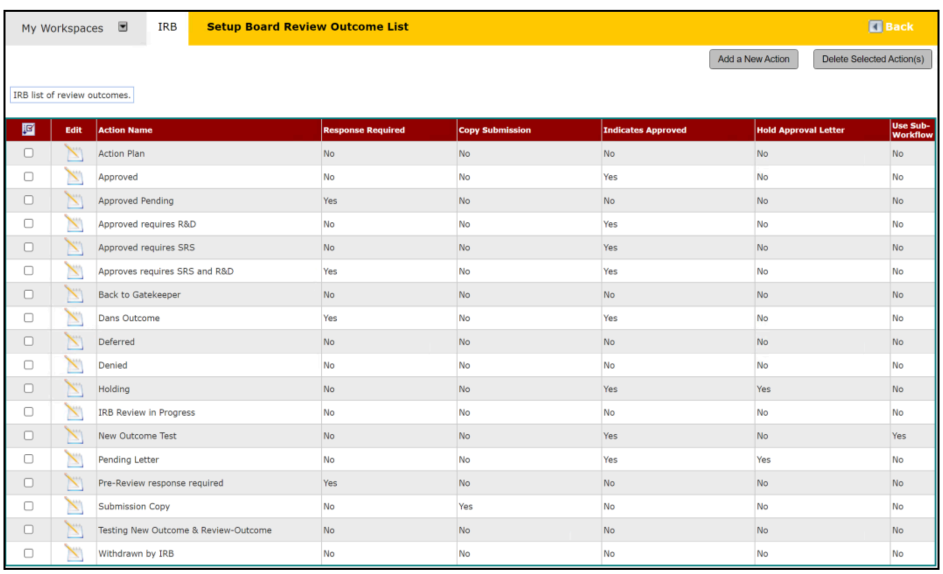
	Edit	Order Number	Stipulation
		1	Section A: more than one species is listed in the study application. Studies are limited to one species each.
		1	Attach quarantine release records for all animal subjects as part of study submission packet.

Review Outcome/Outcome Configuration List

The Review Outcome / Outcome Configuration list is where a list of predefined review outcomes is maintained in the iRIS™ system. To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Review Outcome / Outcome Configuration List** link.



The **Setup Board Review Outcome List** page is opened.



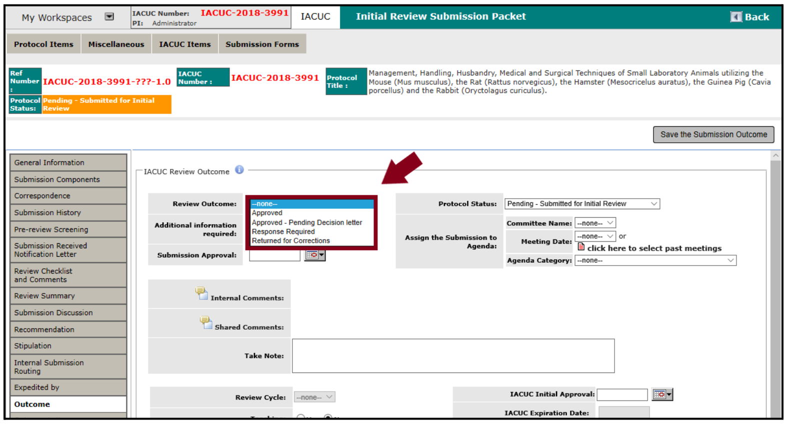
	Edit	Action Name	Response Required	Copy Submission	Indicates Approved	Hold Approval Letter	Use Sub-Workflow
		Action Plan	No	No	No	No	No
		Approved	No	No	Yes	No	No
		Approved Pending	Yes	No	No	No	No
		Approved requires R&D	No	No	Yes	No	No
		Approved requires SRS	No	No	Yes	No	No
		Approves requires SRS and R&D	Yes	No	Yes	No	No
		Back to Gatekeeper	No	No	No	No	No
		Dans Outcome	Yes	No	Yes	No	No
		Deferred	No	No	No	No	No
		Denied	No	No	No	No	No
		Holding	No	No	Yes	Yes	No
		IRB Review in Progress	No	No	No	No	No
		New Outcome Test	No	No	Yes	No	Yes
		Pending Letter	No	No	Yes	Yes	No
		Pre-Review response required	Yes	No	No	No	No
		Submission Copy	No	Yes	No	No	No
		Testing New Outcome & Review-Outcome	No	No	No	No	No
		Withdrawn by IRB	No	No	No	No	No

Review Outcome List Implementation – Application Side

Review outcomes are generally assigned by the applicable review board, making this functionality inapplicable on the application side.

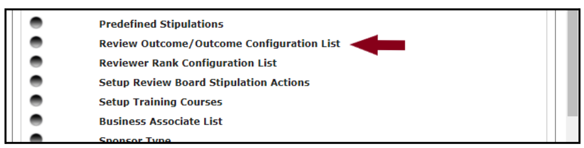
Review Outcome List Implementation – Board Side

The review outcome list is employed in the Outcome tab within submission processing screens, as shown in the IACUC example below.

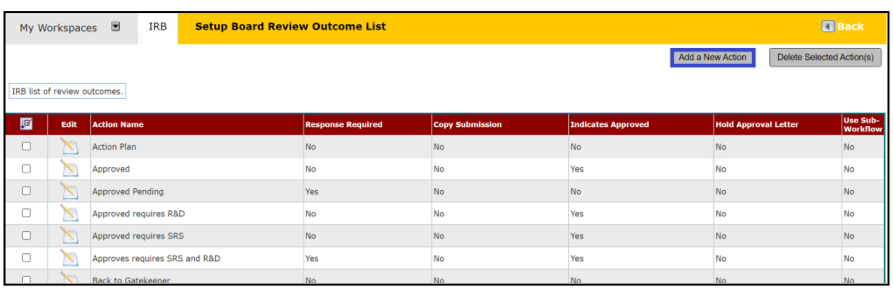


Add Review Outcome

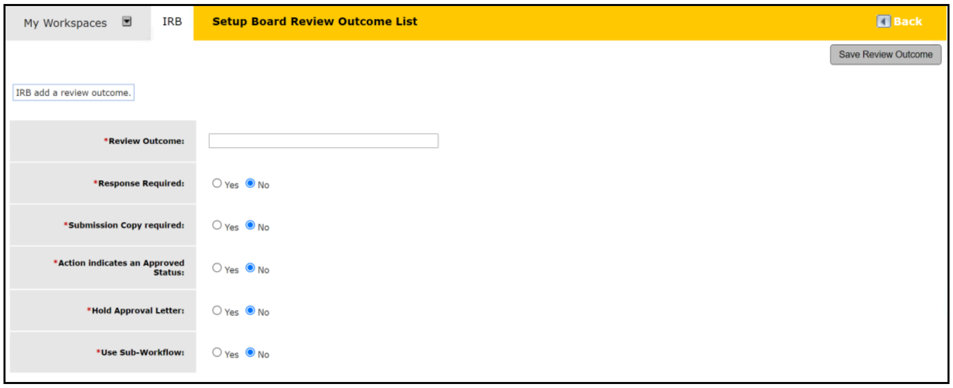
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Review Outcome / Outcome Configuration List** link.



The **Setup Board Review Outcome List** page is opened. Click the **Add a New Action** button.



The **add a review outcome** panel is opened. Note that all fields default to a selection of "No".



A selection of "Yes" for **Response Required** means that where this outcome is assigned, an application / submission will be returned and held from further progress until the required response is received.

A selection of "Yes" for **Submission Copy Required** means that where this outcome is assigned, a copy of the submission will be added to the Not Assigned queue. This option is typically used for tabled submissions that are to be assigned to a future meeting.

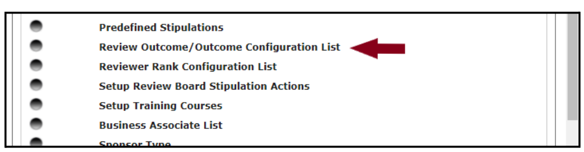
A selection of "Yes" for **Use Sub-Workflow** means that where this outcome is assigned, the system will trigger a sub-workflow that must be completed before submission for final approval.

Enter a **Review Outcome** and click to select "Yes" or "No" for **Response Required**, **Submission Copy required** and **Use Sub-Workflow**, then click the **Save Review Outcome** button.

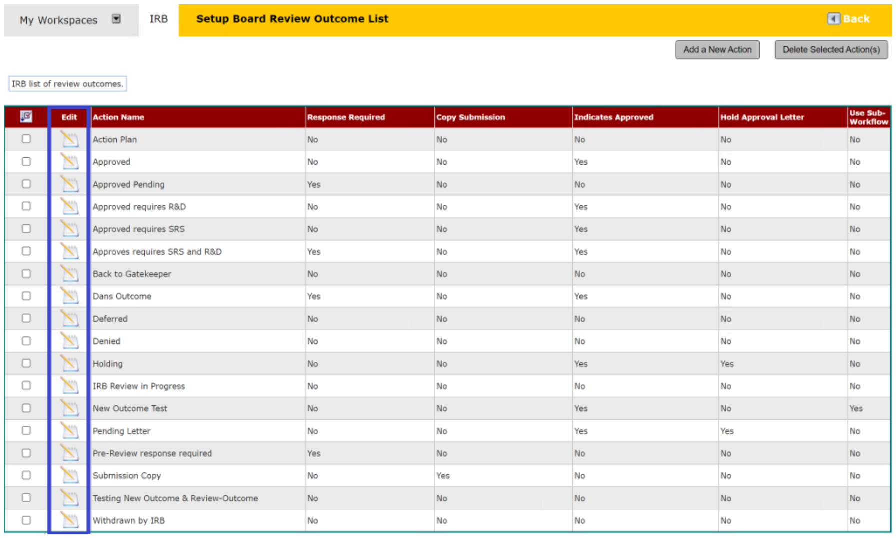
The record is added on the main **Setup Board Review Outcome List** page.

Edit Review Outcome

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Review Outcome / Outcome Configuration List** link.

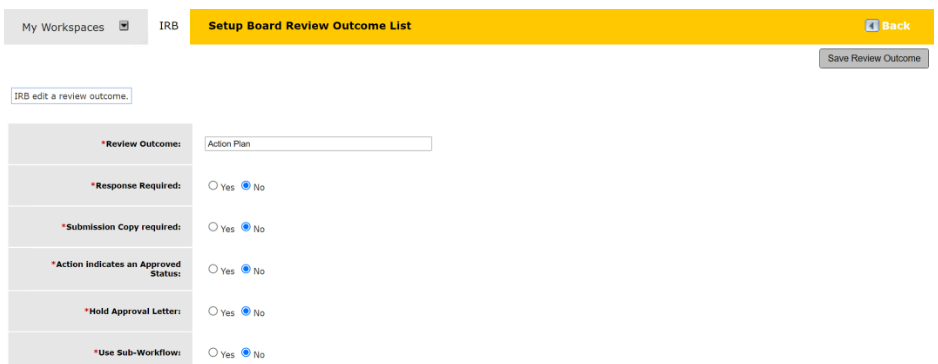


The **Setup Board Review Outcome List** page is opened. Click the icon in the **Edit** column for the applicable record.



Edit	Action Name	Response Required	Copy Submission	Indicates Approved	Hold Approval Letter	Use Sub-Workflow
	Action Plan	No	No	No	No	No
	Approved	No	No	Yes	No	No
	Approved Pending	Yes	No	No	No	No
	Approved requires R&D	No	No	Yes	No	No
	Approved requires SRS	No	No	Yes	No	No
	Approves requires SRS and R&D	Yes	No	Yes	No	No
	Back to Gatekeeper	No	No	No	No	No
	Dans Outcome	Yes	No	Yes	No	No
	Deferred	No	No	No	No	No
	Denied	No	No	No	No	No
	Holding	No	No	Yes	Yes	No
	IRB Review in Progress	No	No	No	No	No
	New Outcome Test	No	No	Yes	No	Yes
	Pending Letter	No	No	Yes	Yes	No
	Pre-Review response required	Yes	No	No	No	No
	Submission Copy	No	Yes	No	No	No
	Testing New Outcome & Review-Outcome	No	No	No	No	No
	Withdrawn by IRB	No	No	No	No	No

The record is opened in an **edit a review outcome** panel.



A selection of "Yes" for **Response Required** means that where this outcome is assigned, an application / submission will be returned and held from further progress until the required response is received.

A selection of "Yes" for **Submission Copy Required** means that where this outcome is assigned, a copy of the submission will be added to the Not Assigned queue. This option is typically used for tabled submissions that are to be assigned to a future meeting.

A selection of "Yes" for **Use Sub-Workflow** means that where this outcome is assigned, the system will trigger a sub-workflow that must be completed before submission for final approval.

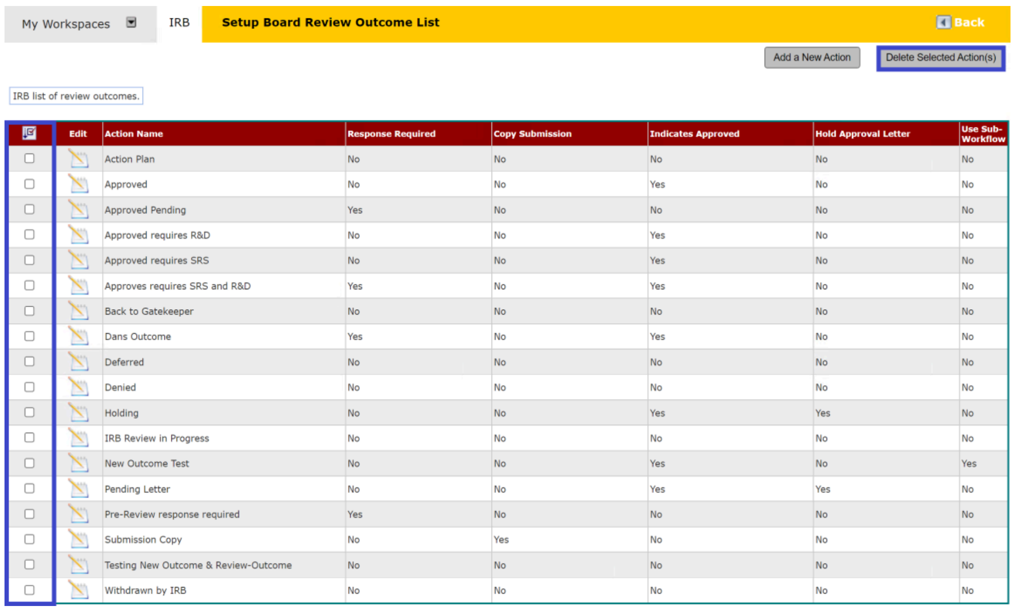
Make desired changes and click the **Save Review Outcome** button.

The edit panel is closed, and the record is updated on the **Setup Board Review Outcome List** page.

Delete Review Outcome

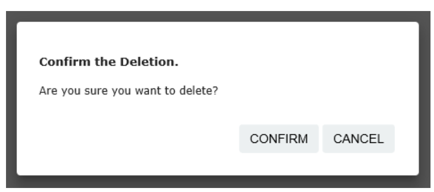
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Review Outcome / Outcome Configuration List** link.

The **Setup Board Review Outcome List** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted, then click the **Delete Selected Action(s)** button.



	Edit	Action Name	Response Required	Copy Submission	Indicates Approved	Hold Approval Letter	Use Sub-Workflow
		Action Plan	No	No	No	No	No
		Approved	No	No	Yes	No	No
		Approved Pending	Yes	No	No	No	No
		Approved requires R&D	No	No	Yes	No	No
		Approved requires SRS	No	No	Yes	No	No
		Approves requires SRS and R&D	Yes	No	Yes	No	No
		Back to Gatekeeper	No	No	No	No	No
		Dans Outcome	Yes	No	Yes	No	No
		Deferred	No	No	No	No	No
		Denied	No	No	No	No	No
		Holding	No	No	Yes	Yes	No
		IRB Review in Progress	No	No	No	No	No
		New Outcome Test	No	No	Yes	No	Yes
		Pending Letter	No	No	Yes	Yes	No
		Pre-Review response required	Yes	No	No	No	No
		Submission Copy	No	Yes	No	No	No
		Testing New Outcome & Review-Outcome	No	No	No	No	No
		Withdrawn by IRB	No	No	No	No	No

A confirmation popup window displays.

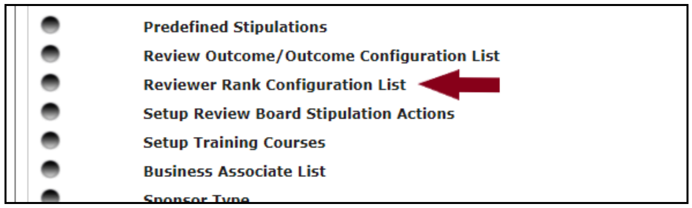


Click **CANCEL** to close the popup without deleting the record.

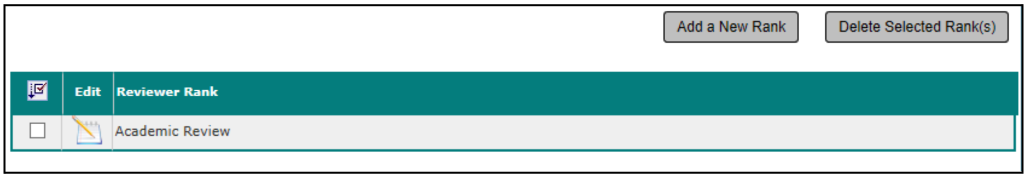
Click **CONFIRM** to complete deletion of the record. The popup closes and the record is deleted from the **Setup Board Review Outcome List** page.

Reviewer Rank Configuration List

The Reviewer Rank Configuration List is where a list of predefined reviewer ranks is maintained in the iRIS™ system. To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Reviewer Rank Configuration List** link.



The **Setup Reviewer Rank List** page is opened.



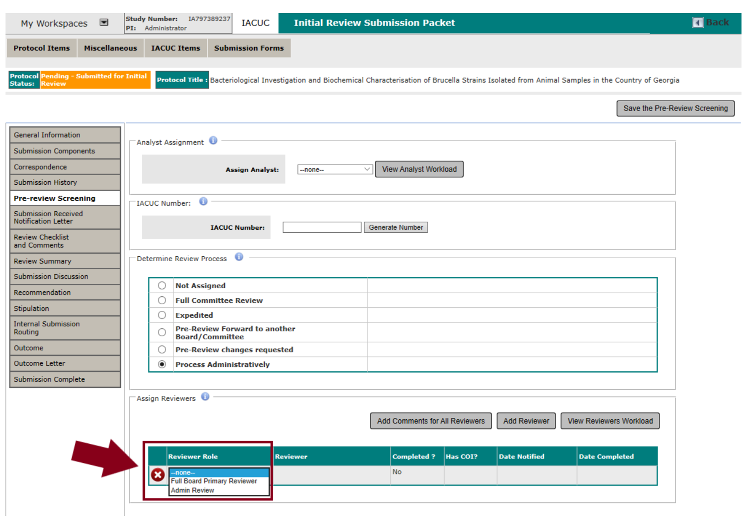
Reviewer Rank List Implementation – Application Side

Reviewer ranks are generally assigned and tracked by the Coordinator and/or applicable review board, making this functionality inapplicable on the application side.

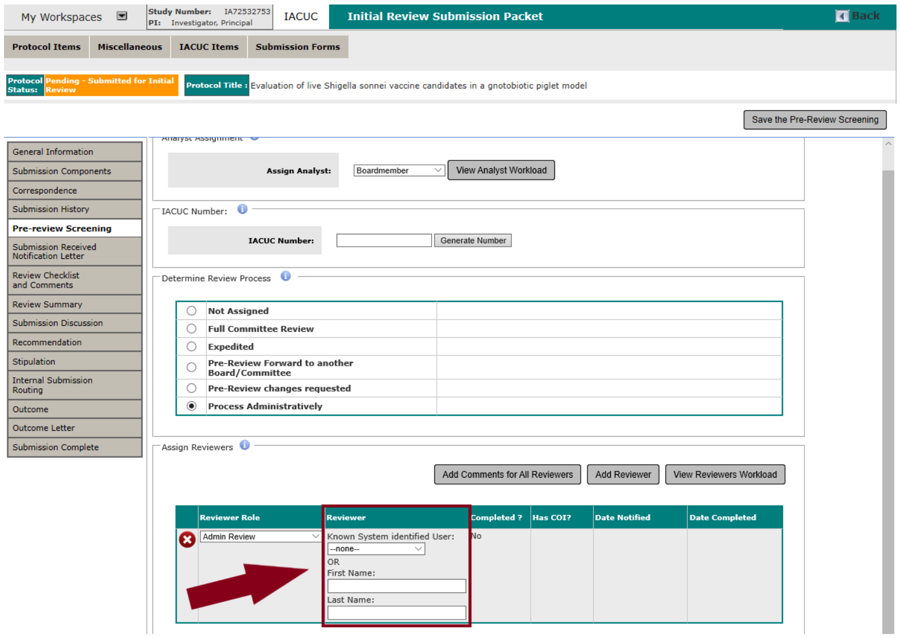
Reviewer Rank List Implementation – Board Side

The reviewer rank list is employed in the following areas on the review board / system setup side of iRIS™.

Study Application — the Reviewer Rank List is employed on the **Pre-review Screening** tab of the **Initial Review Submission Packet**, which is accessed via [module name] > Submissions > [submission opened for editing], as shown in the IACUC example below

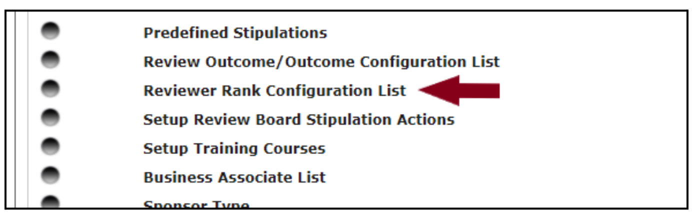


If the reviewer rank selected in the **Reviewer Role** column is an Ad Hoc rank, additional fields populate in the **Reviewer** column for entry of the reviewer name.

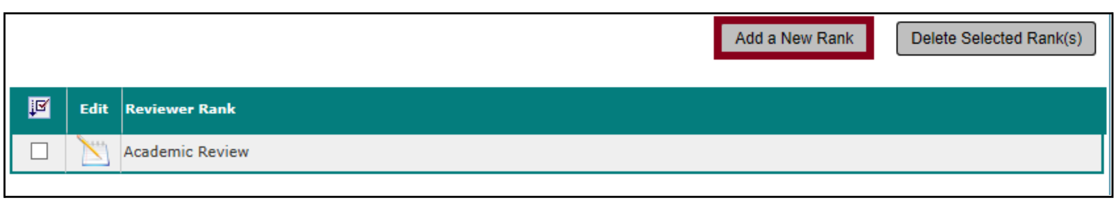


Add Reviewer Rank

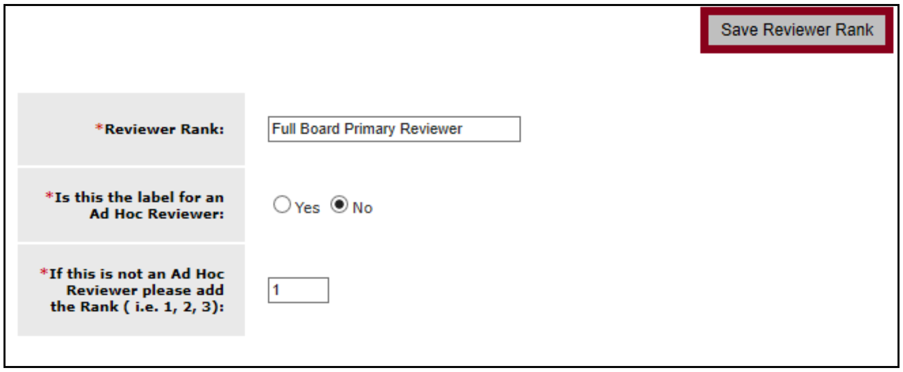
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Reviewer Rank Configuration List** link.



The **Setup Reviewer Rank List** page is opened. Click the **Add a New Rank** button.



An add panel is opened for creation of the new record.



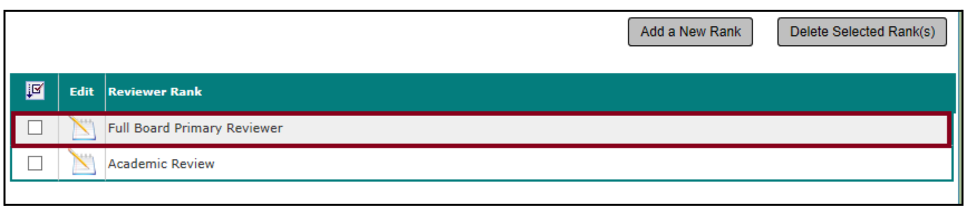
Enter a **Reviewer Rank**.

Click to select "Yes" or "No" for **Is this the label for an Ad Hoc reviewer**. Note that the field defaults to "Yes".

In the **If this is not an Ad Hoc Review please add the Rank (e.g., 1, 2, 3)** field, enter a single digit from zero (0) through three (3). "0" indicates an Ad Hoc reviewer. "1" indicates a Primary Reviewer. "2" indicates a Secondary Reviewer. "3" indicates any other review level. "0" indicates Ad Hoc.

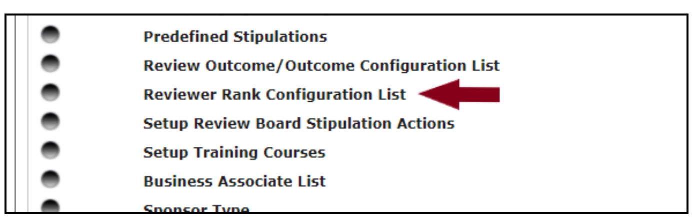
*Note that if no entry is made in the **If this is not an Ad Hoc Review please add the Rank (e.g., 1, 2, 3)** field a default value of "0" will be stored by the system, indicating this is an Ad Hoc Reviewer role.*

Click the **Save Reviewer Rank** button to close the add panel. The record is added on the **Setup Reviewer Rank List** page.

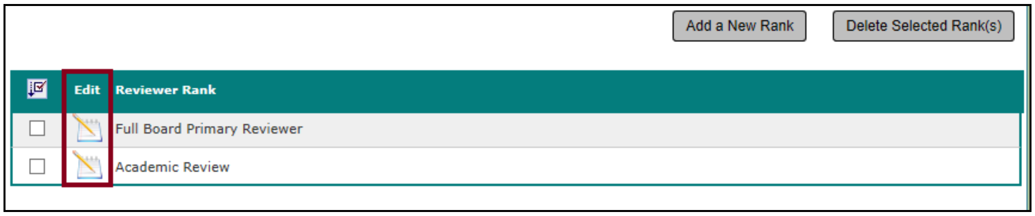


Edit Reviewer Rank

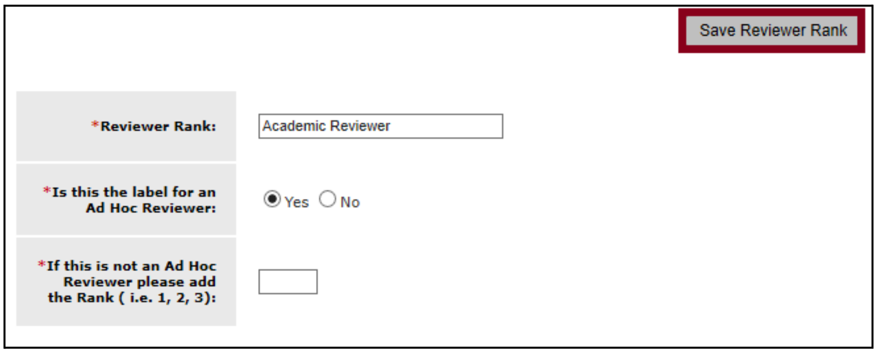
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Reviewer Rank Configuration List** link.



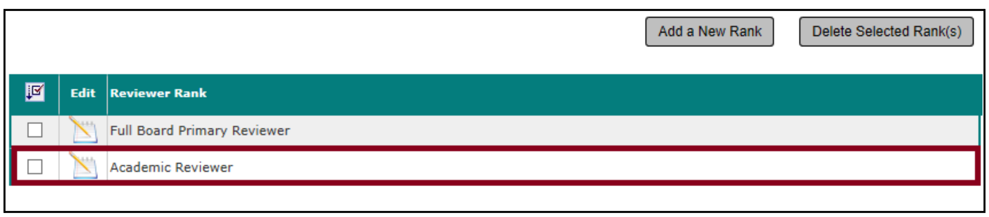
The **Setup Reviewer Rank List** page is opened. Click the icon in the **Edit** column for the applicable record.



The record is opened in an edit panel. Make desired changes and click the **Save Reviewer Rank** button.

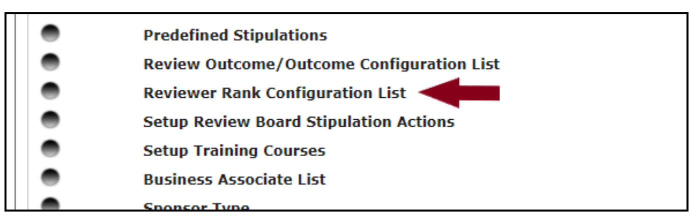


The edit panel is closed, and the record is revised on the **Setup Reviewer Rank List** page.

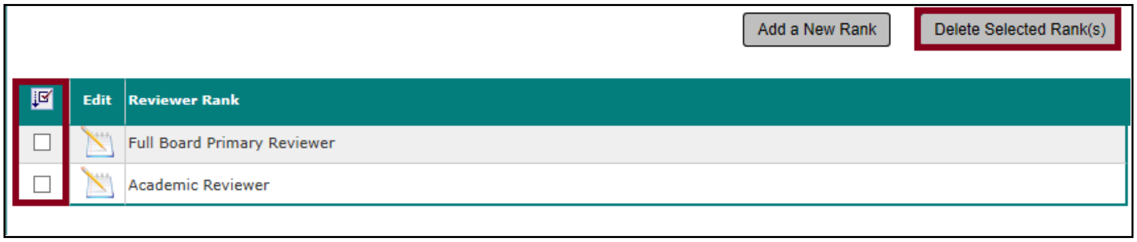


Delete Reviewer Rank

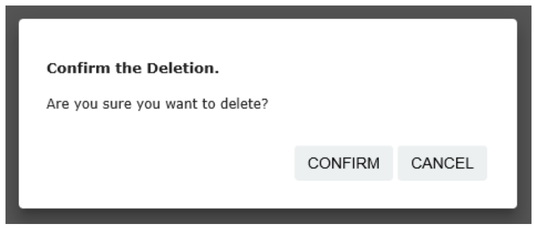
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Reviewer Rank Configuration List** link.



The **Setup Reviewer Rank List** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted and click the **Delete Selected Rank(s)** button.



A confirmation popup window displays.

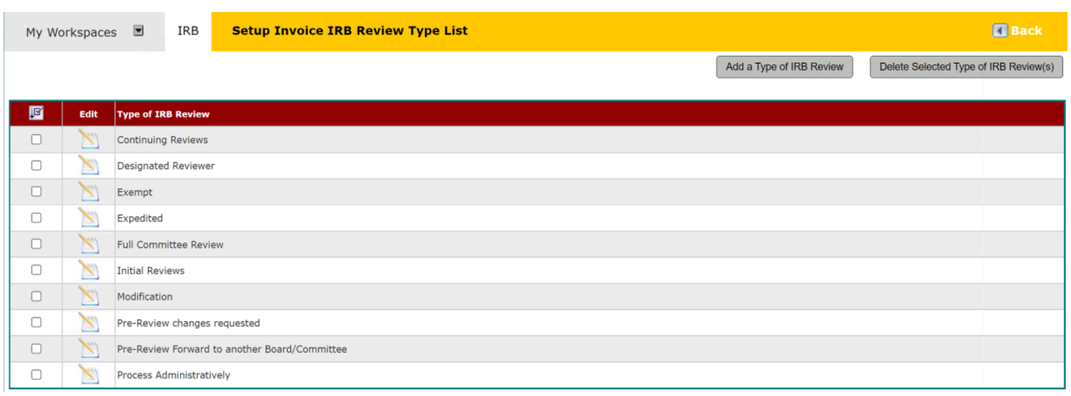


Click **CANCEL** to close the popup without deleting the record.

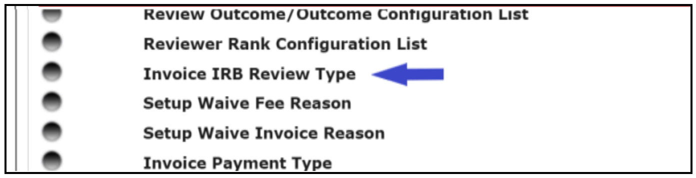
Click **CONFIRM** to complete deletion of the record. The popup closes and the record is deleted from the **Setup Reviewer Rank List** page.

Invoice IRB Review Type

The iRIS™ system provides invoicing and accounting tools for use during processing of fee-based submissions. Categories for fee based review types are configured via the **Setup Invoice IRB Review Type List** page, shown below.

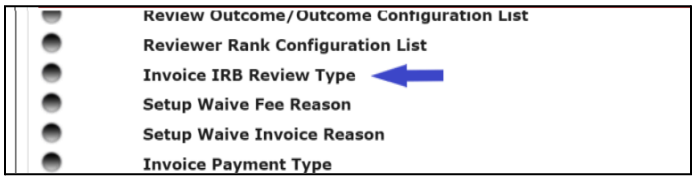


The configuration list is accessed via the IRB Assistant > Review Board Administration > List Maintenance Setup tab > **Invoice IRB Review Type** link.

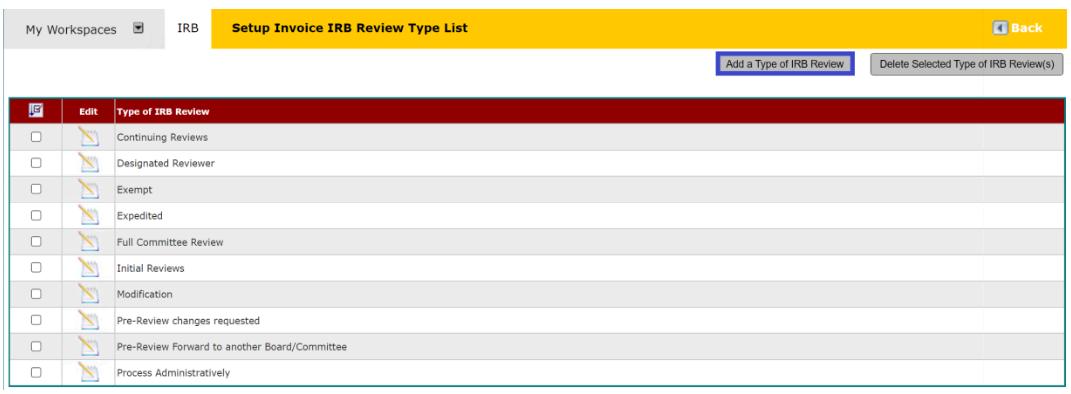


Add Review Type

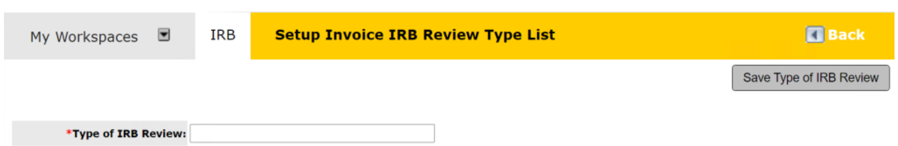
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice IRB Review Type** link.



As shown below, the **Setup Invoice IRB Review Type List** page opens.



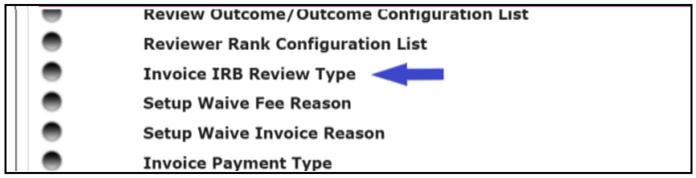
Click the **Add a Type of IRB Review** button (blue box in screenshot above). An add form opens, as shown below.



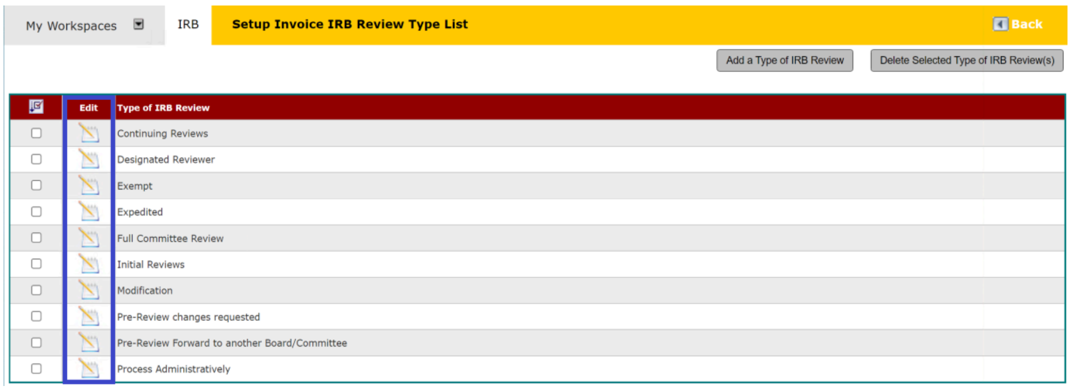
Enter the desired text for the new **Type of IRB Review** and click the **Save** button. The add form closes and the new **Review Type** is added to the list on the **Setup Invoice IRB Review Type List** page.

Edit Review Type

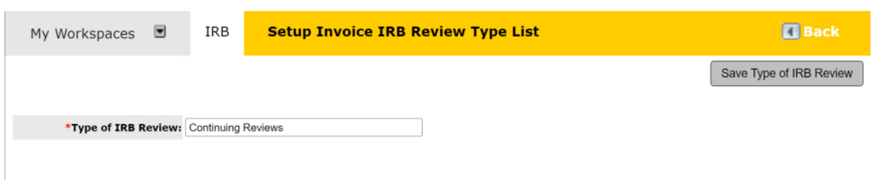
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice IRB Review Type** link.



As shown below, the **Setup Invoice IRB Review Type List** page opens.



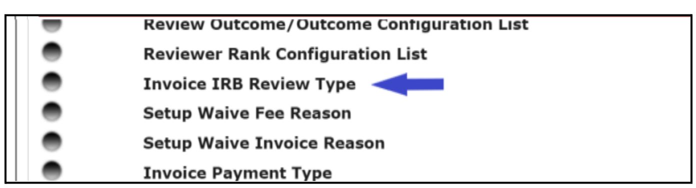
Click the applicable icon in the **Edit** column (blue box in screenshot above). The selected record is opened in an edit form, as shown below.



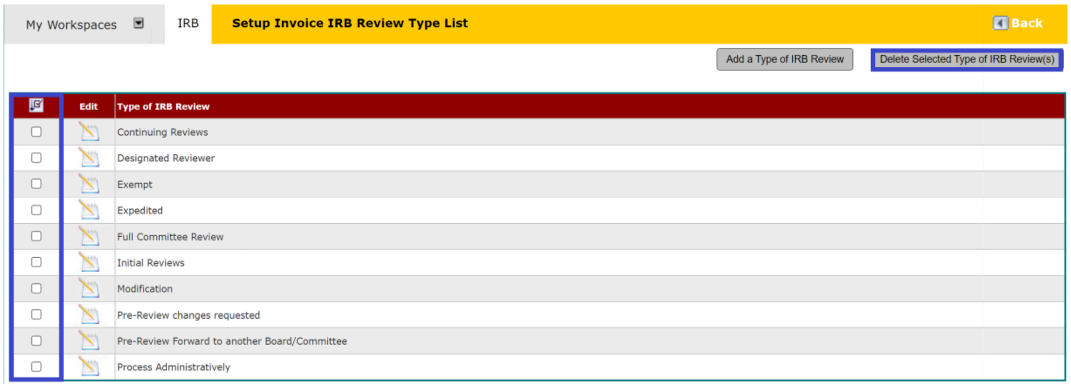
Revise the **Type of IRB Review** text as desired and click the **Save** button. The edit form closes and the **Review Type** is revised in the list on the **Setup Invoice IRB Review Type List** page

Delete Review Type

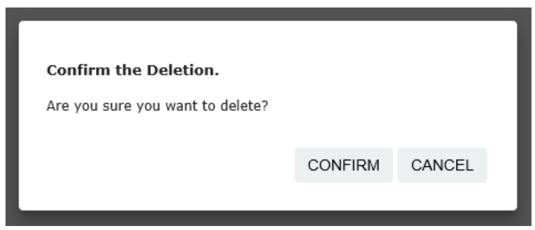
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice IRB Review Type** link.



As shown below, the **Setup Invoice IRB Review Type List** page opens.



Click to select the checkbox(es) of the type(s) to be deleted and click the **Delete Selected Type of IRB Review(s)** button (blue boxes in screenshot above). A confirmation popup window displays.



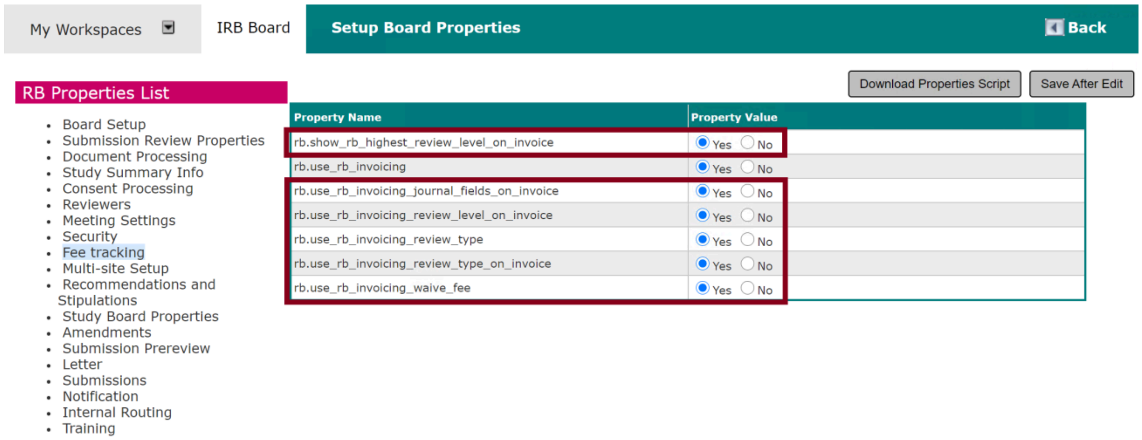
Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The popup closes and the record is deleted from the **Setup Invoice IRB Review Type List** page.

Waive Fee Option

Beginning with iRIS™ version 12.01, it is possible to waive invoice fees and maintain a configurable list of reasons for doing so. This functionality for situations where it is useful or necessary to generate an invoice for recordkeeping purposes, but no fee is to be charged. This feature is property based.

As shown below, six new properties have been added within the **Fee tracking** category under IRB Assistant > Review Board Administration > Board Configuration (red boxes in screenshot below).



The new properties are:

rb.show_rb_highest_review_level_on_invoice

rb.use_rb_invoicing_journal_fields_on_invoice

rb.use_rb_invoicing_review_level_on_invoice

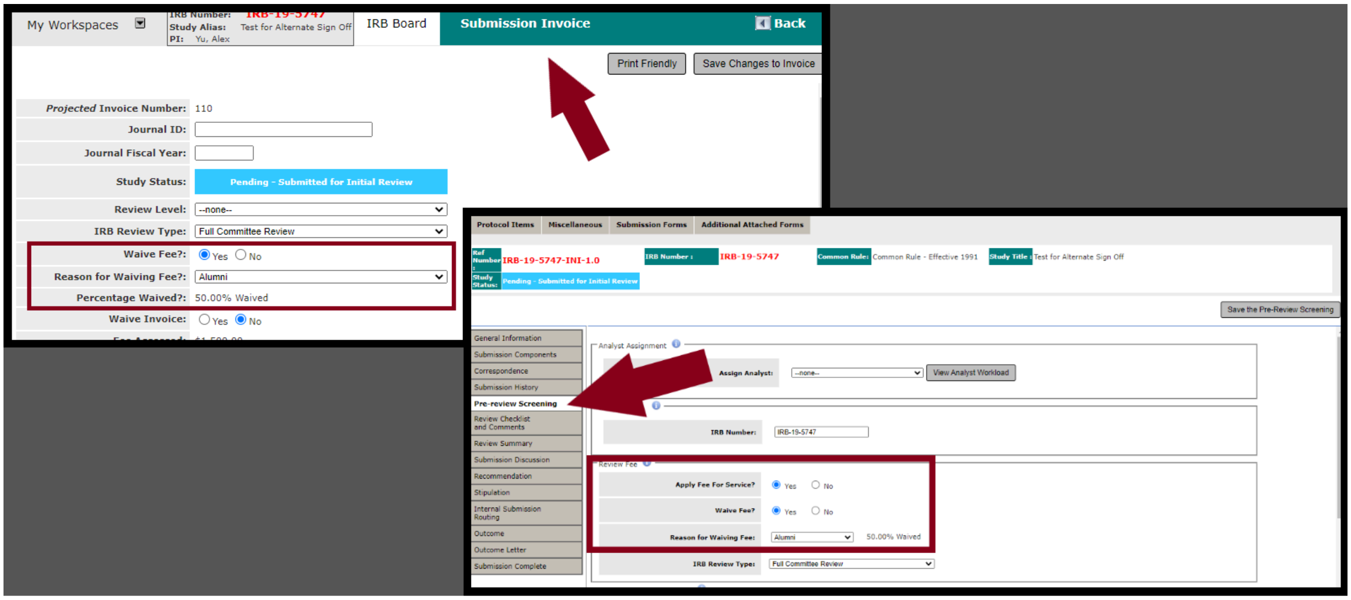
rb.use_rb_invoicing_review_type

rb.use_rb_invoicing_review_type_on_invoice

rb.use_rb_invoicing_waive_fee

By default, “No” is selected for all of these properties. Invoicing must be enabled within the module by selecting “Yes” for the rb.use_rb_invoicing property in order for the new fields to function, as that property turns the entire invoicing feature off and on.

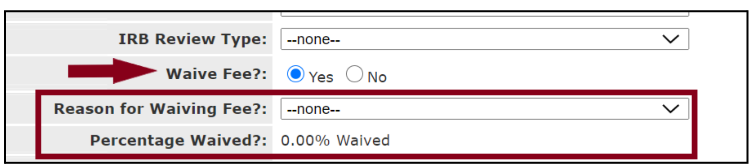
As demonstrated in the screenshot below, setting ALL SIX (6) properties to “Yes” adds a **Waive Fee** Y/N field, **Reason for Waiving Fee** field and auto-populating **Percentage Waived** field on the **Submission Invoice** page, and entries made there carry through to the submissions **Pre-review Screening** tab, below the **Apply Fee for Service** field.



Note that the **Waive Fee** and **Reason for Waiving Fee** fields remain active on the **Pre-review Screening** tab and can be updated there.

With the properties enabled, new fields populate on the **Submission Invoice** page as follows:

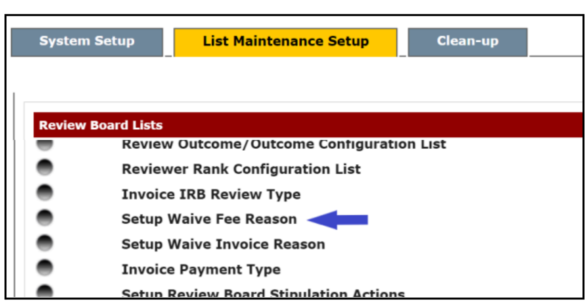
Waive Fee? — select “Yes” to waive the fee; this selection populates **Reason for Waiving Fee?** and **Percentage Waived** fields, as shown below



Reason for Waiving Fee? — click in the field to open a drop down pick list of reasons; click the desired item to select it, automatically populating the associated **Percentage Waived?** field

Setup Waive Fee Reason

The preconfigured list of acceptable reasons for waiving fees is maintained via the **Setup Waive Fee Reason List** page. To access the page, navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Fee Reason** link.



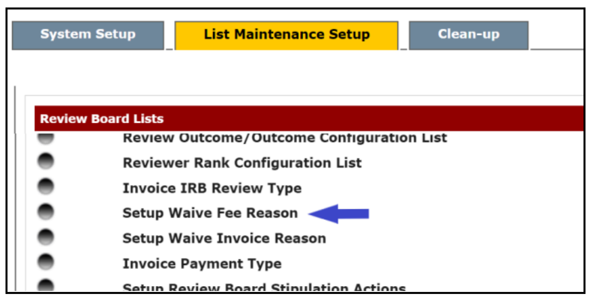
Click the link to open the **Setup Waive Fee Reason List** page, shown below.

	Edit	Waive Fee Reason	% Waived
		Alumni	50.00%
		Complete Fee Waiver	99.99%
		Fee Waived	12.00%
		Fee Waived Reason 2	42.00%
		Veteran	65.00%

Previously configured **Wave Fee Reason**s are listed in a table. Buttons and controls are provided to add, edit or delete **Waive Fee Reason**s.

Add Waive Fee Reason

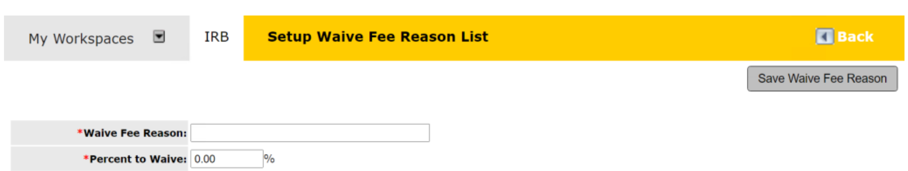
Navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Fee Reason** link.



Click the link to open the **Setup Waive Fee Reason List** page, shown below.

	Edit	Waive Fee Reason	% Waived
		Alumni	50.00%
		Complete Fee Waiver	99.99%
		Fee Waived	12.00%
		Fee Waived Reason 2	42.00%
		Veteran	65.00%

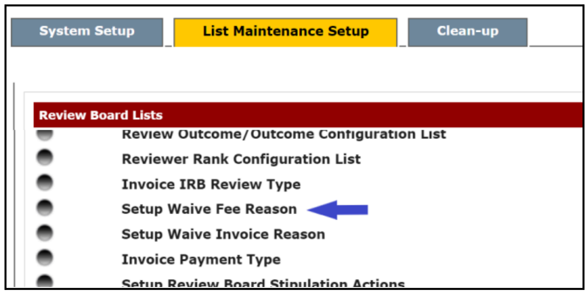
Click the **Add a Waive Fee Reason** button (blue box in screenshot above). An add form opens, as shown below.



Enter the desired text for the new **Waive Fee Reason** and the desired **Percent to Waive**, then click the **Save Waive Fee Reason** button. The add form closes and the new **Waive Fee Reason** is added to the **Waive Fee Reason** list.

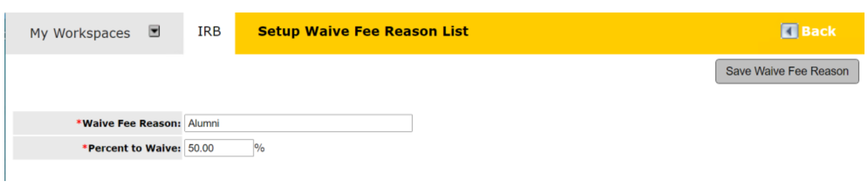
Edit Waive Fee Reason

Navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Fee Reason** link.



Click the link to open the **Setup Waive Fee Reason List** page, shown below.

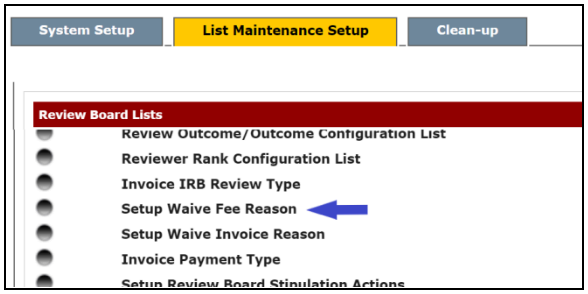
Click the applicable icon in the **Edit** column (blue box in screenshot above) to open the corresponding **Waive Fee Reason** record for editing. The record is opened in an edit panel, as shown below.



Make desired changes to the text for **Waive Fee Reason** and **Percent to Waive**, then click the **Save** button. The edit form closes and the **Waive Fee Reason** is revised in the **Waive Fee Reason** list.

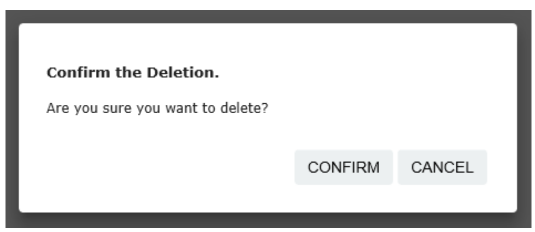
Delete Waive Fee Reason

Navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Fee Reason** link.



Click the link to open the **Setup Waive Fee Reason List** page, shown below.

Click to select the applicable checkbox(es) in the far left column (blue box in screenshot above) for the **Waive Fee Reason** record(s) to be deleted and click the **Delete Selected Waive Fee Reason(s)** button. A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

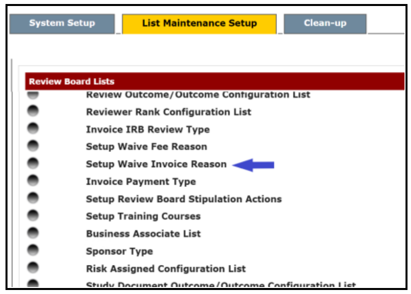
Click **CONFIRM** to complete deletion of the record. The popup closes and the record is deleted from the **Setup Waive Fee Reason List** page.

Waive Invoice Option

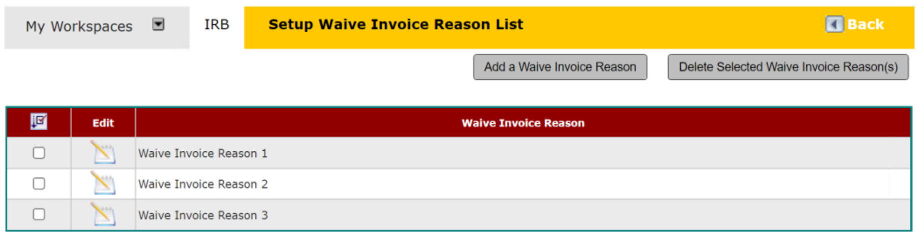
Beginning with iRIS™ version 12.01, it is possible to waive the issuance of an invoice while still capturing fee data, and maintain a configurable list of reasons for waiving the issuance of the invoice.

Setup Waive Invoice Reason

The preconfigured list of acceptable reasons for waiving invoices is maintained via the **Setup Waive Invoice Reason List** page. To access the page, navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Invoice Reason** link.



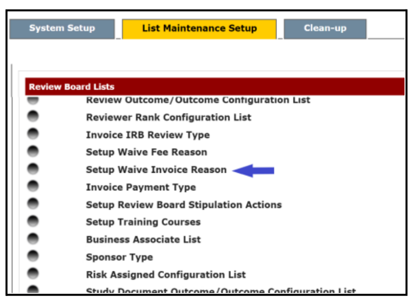
Click the link to open the **Setup Waive Invoice Reason List** page, shown below.



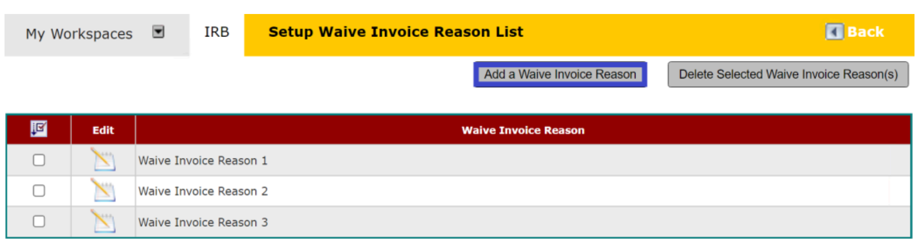
Previously configured **Wave Invoice Reason**s are listed in a table. Buttons and controls are provided to add, edit or delete **Waive Invoice Reason**s.

Add Waive Invoice Reason

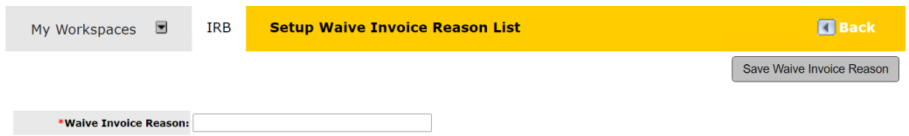
Navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Invoice Reason** link.



Click the link to open the **Setup Waive Invoice Reason List** page, shown below.



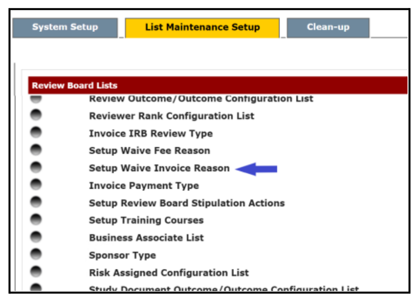
Click the **Add a Waive Invoice Reason** button (blue box in screenshot above). An add form opens, as shown below.



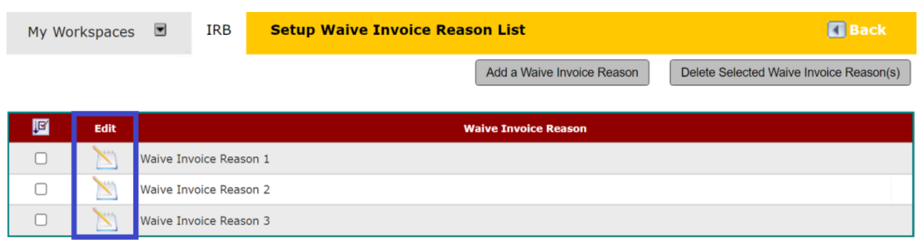
Enter the desired text for the new **Waive Invoice Reason** and click the **Save Waive Invoice Reason** button. The add form closes and the new **Waive Invoice Reason** is added to the **Waive Invoice Reason** list.

Edit Waive Invoice Reason

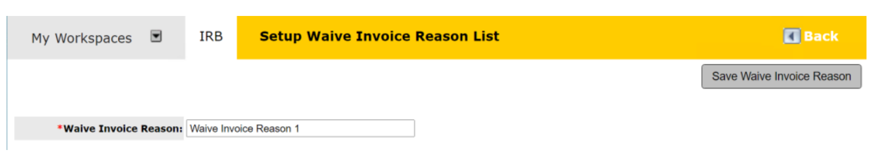
Navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Invoice Reason** link.



Click the link to open the **Setup Waive Invoice Reason List** page, shown below.



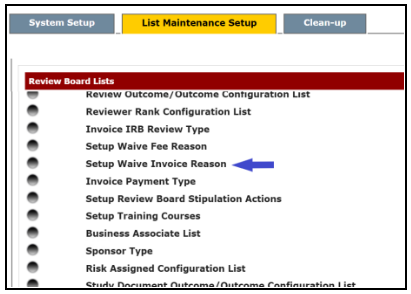
Click the applicable icon in the **Edit** column (blue box in screenshot above) to open the corresponding **Waive Invoice Reason** record for editing. The record is opened in an edit panel, as shown below.



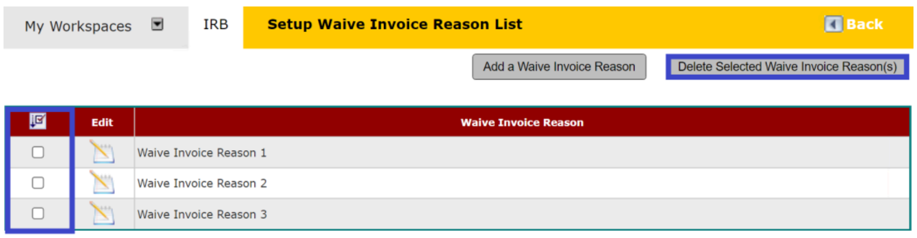
Make desired changes to the text for **Waive Invoice Reason** and click the **Save** button. The edit form closes and the **Waive Invoice Reason** is revised in the **Waive Invoice Reason** list.

Delete Waive Invoice Reason

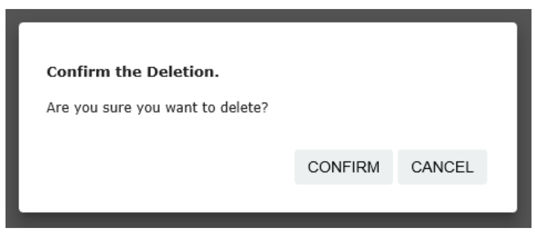
Navigate to Review Board Administration > List Maintenance Setup > **Setup Waive Invoice Reason** link.



Click the link to open the **Setup Waive Invoice Reason List** page, shown below.



Click to select the applicable checkbox(es) in the far left column (blue box in screenshot above) for the **Waive Invoice Reason** record(s) to be deleted and click the **Delete Selected Waive Invoice Reason(s)** button. A confirmation popup window displays.

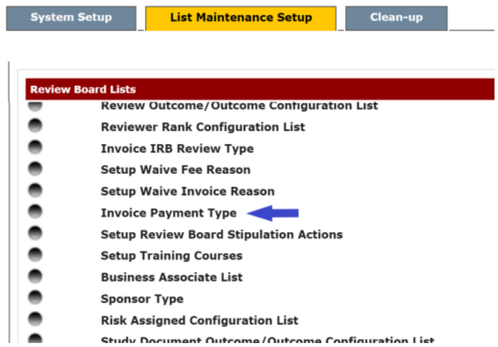


Click **CANCEL** to close the popup without deleting the record.

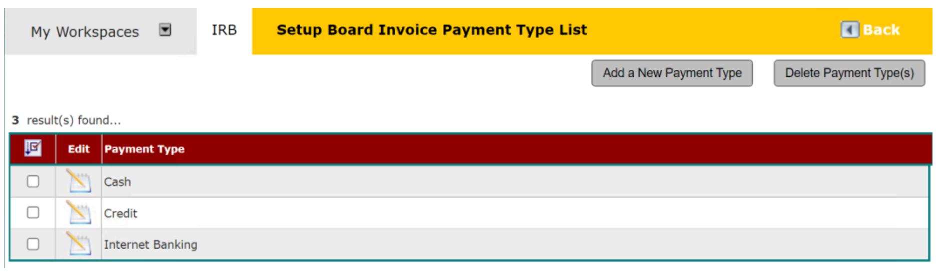
Click **CONFIRM** to complete deletion of the record. The popup closes and the record is deleted from the **Setup Waive Invoice Reason List** page.

Invoice Payment Type

A predefined list of invoice payment methods (e.g., cash, credit card, etc.) is maintained via the invoice payment type list, which is maintained via the **Setup Board Invoice Payment Type List** page. To access the page, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice Payment Type** link.



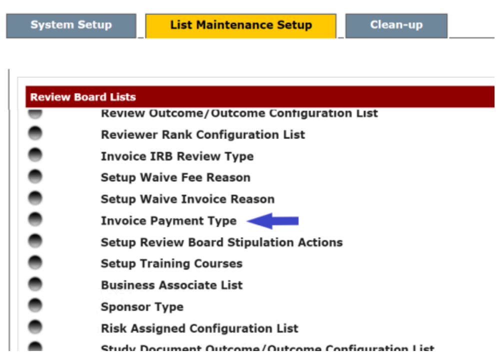
As shown below, the **Setup Board Invoice Payment Type List** page opens.



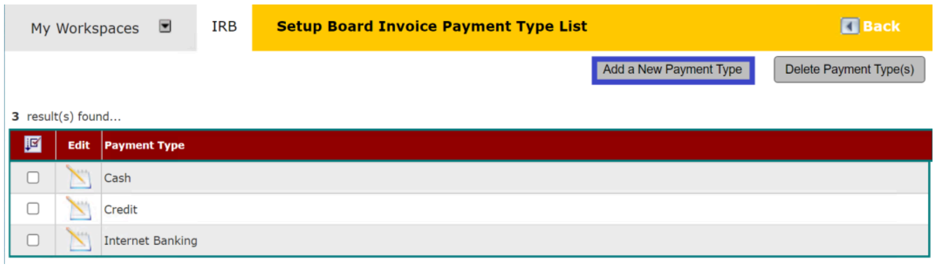
Previously configured **Payment Type**s are listed in a table. Buttons and controls are provided to add, edit or delete **Payment Type**s.

Add Invoice Payment Type

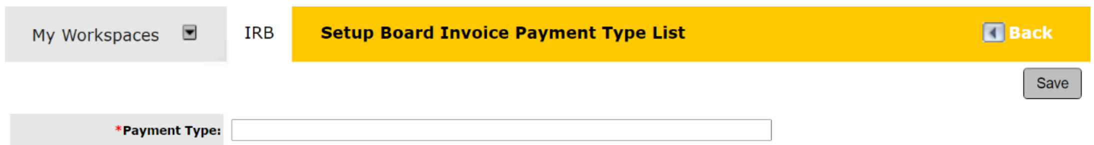
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice Payment Type** link.



As shown below, the **Setup Board Invoice Payment Type List** page opens.



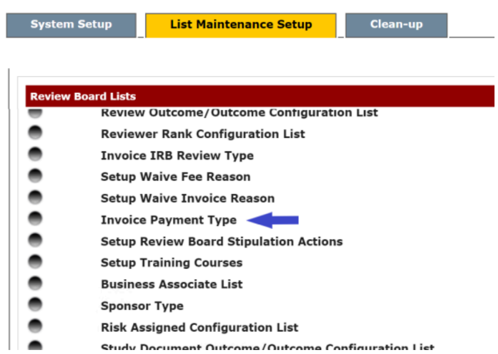
Click the **Add a New Payment Type** button (blue box in screenshot above). An add form opens, as shown below.



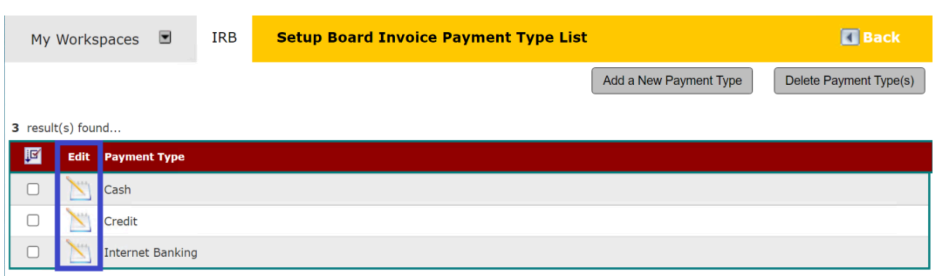
Enter the desired text for the new **Payment Type** and click the **Save** button. The add form closes and the new **Payment Type** is added to the invoice **Payment Type** list.

Edit Invoice Payment Type

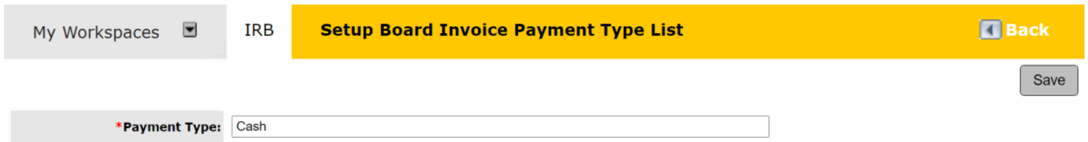
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice Payment Type** link.



As shown below, the **Setup Board Invoice Payment Type List** page opens.



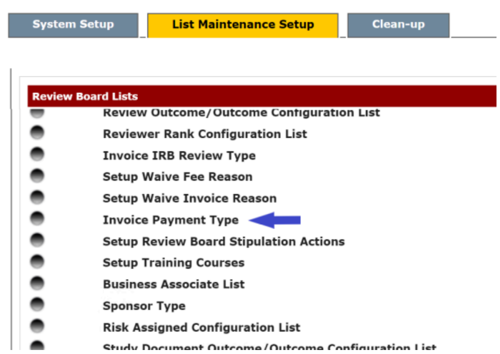
Click the applicable icon in the **Edit** column (blue box in screenshot above) to open the corresponding **Payment Type** record for editing. The record is opened in an edit panel, as shown below.



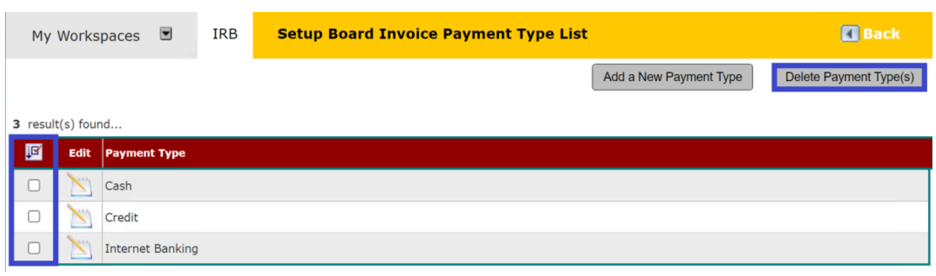
Make desired changes to the **Payment Type** text and click the **Save** button. The edit form closes and the **Payment Type** is revised in the invoice **Payment Type** list.

Delete Invoice Payment Type

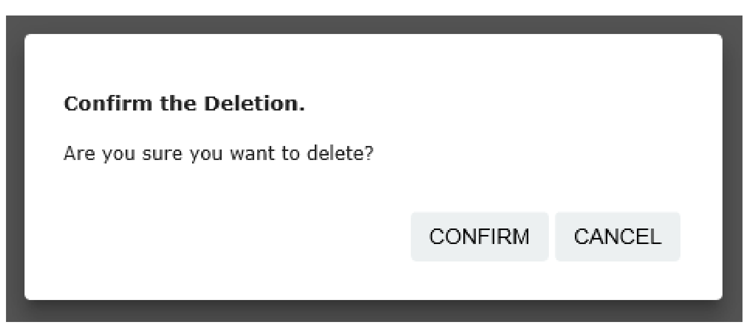
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Invoice Payment Type** link.



As shown below, the **Setup Board Invoice Payment Type List** page opens.



Click to select the applicable checkbox(es) in the far left column (blue box in screenshot above) for the **Payment Type** record(s) to be deleted. A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record and return to the **Setup Protocol Document Outcome** page.

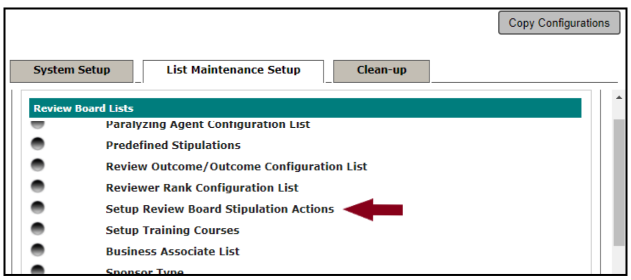
Click **CONFIRM** to complete deletion of the record. The **Payment Type** is deleted from the **Setup Board Invoice Payment Type List** page.

Setup Review Board Stipulation Actions

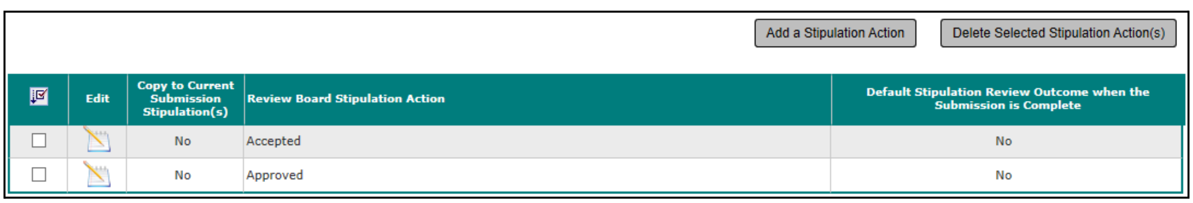
The Review Board Stipulation Actions List is where a list of boilerplate review board stipulation actions approved for use in studies is maintained in the iRIS™ system.

These actions are applied to stipulations when a study submits its response to the review board. Review board stipulation actions determine if the incoming stipulation can be closed as complete or must be retained as an outstanding item to the study.

To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Setup Review Board Stipulation Actions** link.



The **Setup Stipulation Review Board Actions** page is opened.

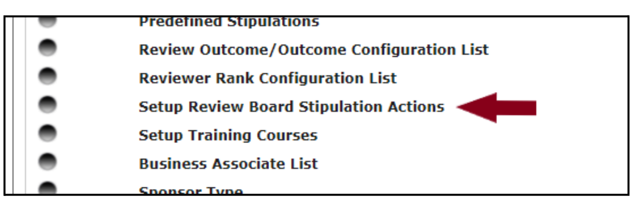


Add a Stipulation Action | Delete Selected Stipulation Action(s)

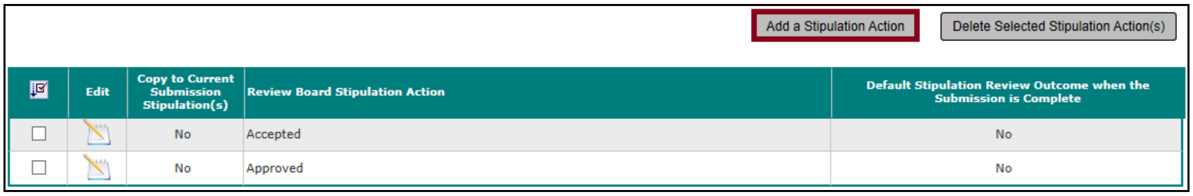
	Edit	Copy to Current Submission Stipulation(s)	Review Board Stipulation Action	Default Stipulation Review Outcome when the Submission is Complete
		No	Accepted	No
		No	Approved	No

Add Review Board Stipulation

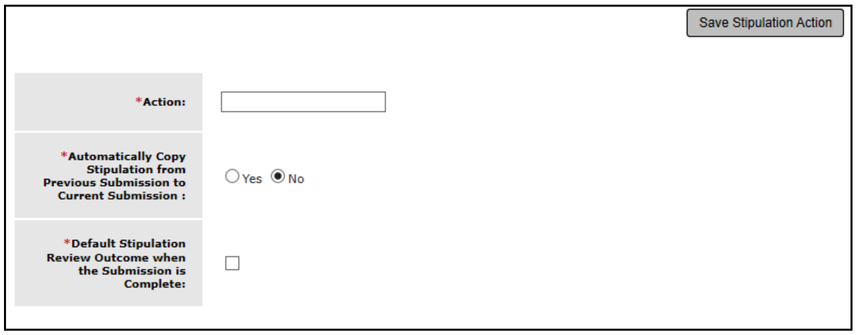
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Setup Review Board Stipulation Actions** link.



The **Setup Stipulation Review Board Actions** page is opened. Click the **Add a Stipulation Action** button.



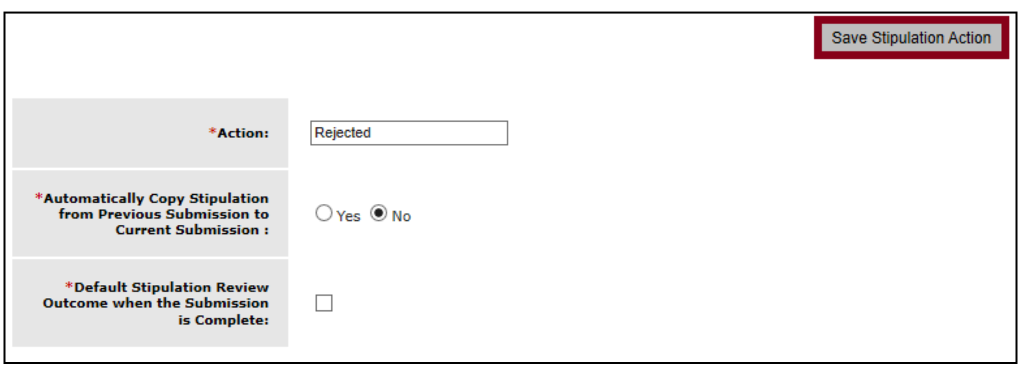
An add panel is opened for creation of the new record.



The **Automatically Copy Stipulation from Previous Submission to Current Submission** setting controls whether the stipulation is to be closed as completed or copied to the current submission and remain as an outstanding item to the study. “No” indicates the stipulation is to be closed. “Yes” indicates the stipulation will remain as an outstanding item to the study.

The **Default Stipulation Review Outcome when the Submission is Complete** selection dictates whether a closed status is to be automatically assigned to the stipulation. Click the **Save Stipulation Action** button to add the record to the list.

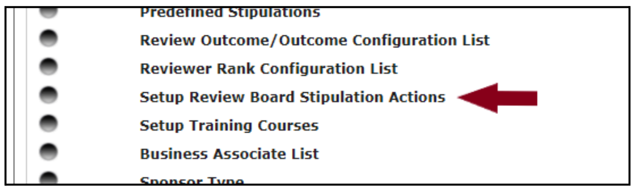
Complete the form as desired and click the **Save Stipulation Action** button.



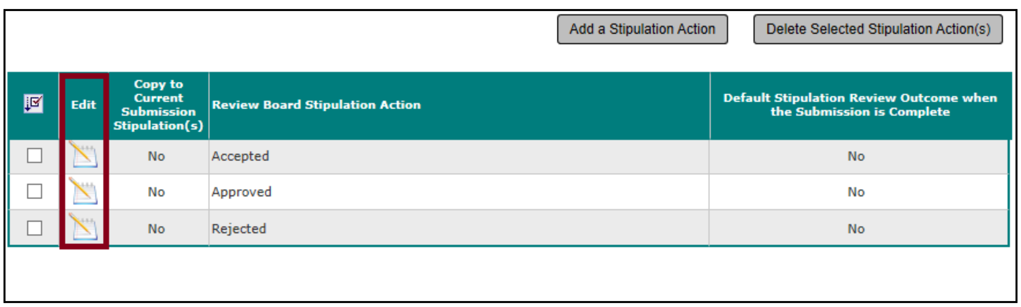
The record is added to the **Setup Stipulation Review Board Actions** list page.

Edit Review Board Stipulation

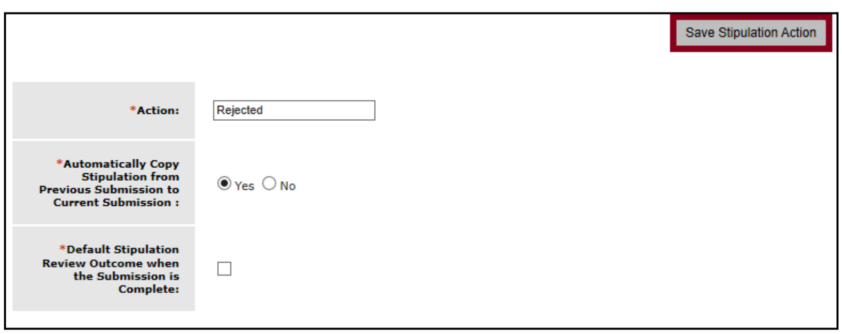
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Setup Review Board Stipulation Actions** link.



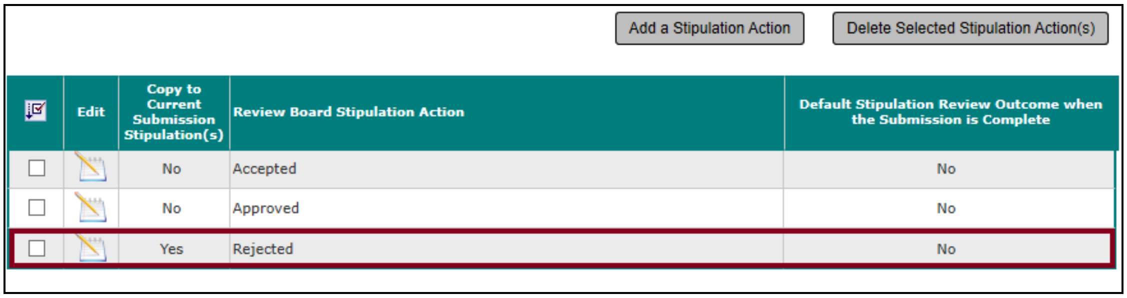
The **Setup Stipulation Review Board Actions** page is opened. Click the icon in the Edit column for the applicable record.



The record is opened in an edit panel. Make desired changes and click the **Save Stipulation Action** button.

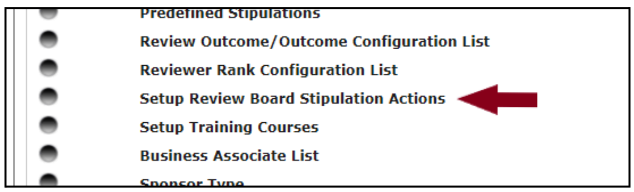


The edit panel is closed, and the record is revised on the **Setup Stipulation Review Board Actions** list page.

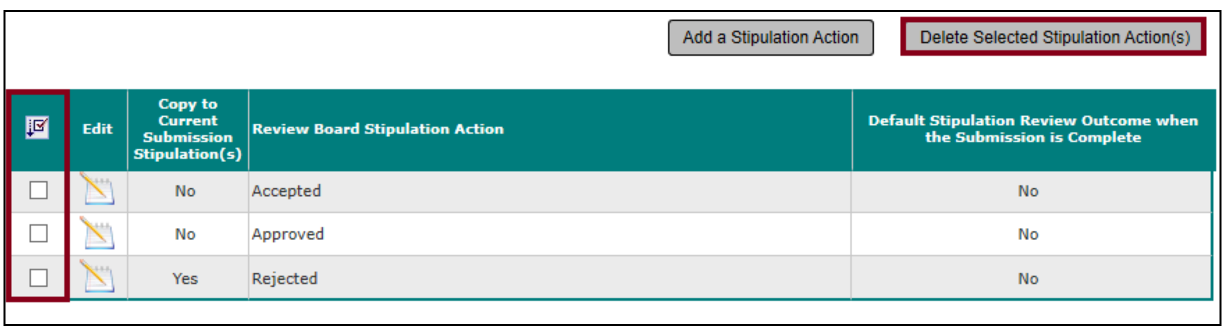


Delete Review Board Stipulation

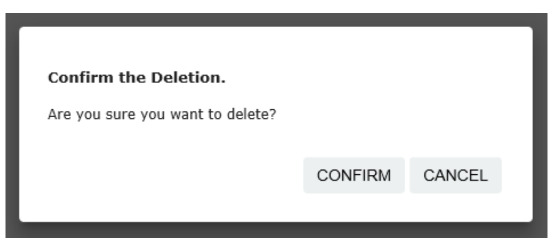
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Setup Review Board Stipulation Actions** link.



The **Setup Stipulation Review Board Actions** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted and click the **Delete Selected Stipulation Action(s)** button.



A confirmation popup window displays.

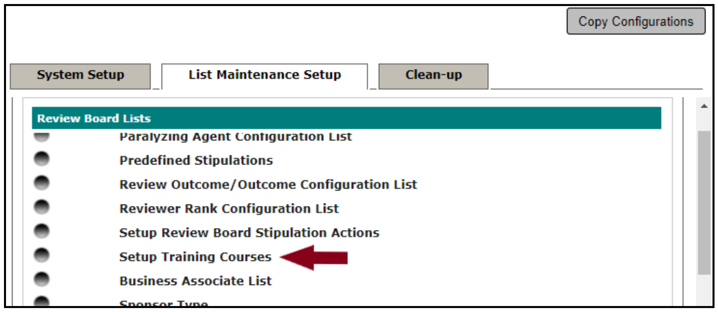


Click **CANCEL** to close the popup without deleting the record and return to the **Setup Stipulation Review Board Actions** page.

Click **CONFIRM** to complete deletion of the record and return to the **Setup Stipulation Review Board Actions** page. The record is deleted from the **Setup Stipulation Review Board Actions** page.

Setup Training Courses

Direct access to the Define Training Courses area under iRIS™ System Administration > List Configuration and Maintenance > System Setup tab > User Training Setup section is provided for the review board under IRB Assistant > Review Board Administration > List Maintenance Setup tab > Setup Training Courses link.



See the List Configuration and Maintenance section of the System Administration – User Training Manual for more information about configuring and tracking iRIS™ user training.

Business Associate List

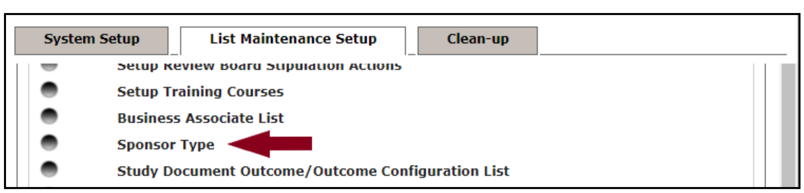
The Business Associate List link is used to access system functions related to business associates. In this context, a business associate is an institution or business which interacts with the institution where iRIS™ is in use.

Within the iRIS™ system, business associate entities can be added as a study sponsor, vendor or subrecipient, or as a third party in a conflict of interest.

For more information about business associate list management activities, see the Business Associate List manual.

Sponsor Type

The Sponsor Type configuration list is where a list of predefined sponsor types is maintained in the iRIS™ system. To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Sponsor Type** link.



The **Setup Sponsor Type** page is opened.

Add a New Category

13 result(s) found... 1 - 13

Delete	Edit	Sponsor Type	Sort Order Number	Include in Disclosure Search	Description
		01 - Federal	1	Yes	Federal Government: Departments, agencies, etc. of the United States government.
		02 - State	2	Yes	State Government: Departments, agencies, etc. of the State of California
		03 - Other Government	3	Yes	Other Government Agency: Other governmental agencies, including: cities; counties; other states; foreign governments or governmental agencies; multi-national organizations such as the United Nations; or, quasi-governmental agencies or special districts, such as a water or pest control district.
		04 - Business/Profit Entity	4	Yes	Business/Profit Entity: Business or other entity engaged in activities for profit.
		05 - Non-profit	5	Yes	Non-Profit, Business Related: Non-profit organization sponsored by one or more business or other entities engaged in activities for profit, including: corporate foundations, industry or trade associations; and professional, union, or lobbying organizations.
		06 - Foundation/Charitable Trust	6	Yes	Foundation/Charitable Trust: Non-profit foundations or charitable trusts, as defined in The Foundation Directory; excluding corporate foundations; and, including funds or endowments designated by the Internal Revenue Service as private grant-making foundations, community foundations, family foundations, and charitable trusts.
		07 - Higher Education	7	Yes	Higher Education: Higher education institution or association such as: Harvard Institution/Association University, University of Michigan, or the American Association of Colleges of Pharmacy.
		08 - Campus Organization	8	Yes	Campus-Related Organization: Campus-related organization, including student groups, University support groups, alumni associations, etc.
		09 - Individual	9	Yes	Individual: Individuals, excluding incorporated professionals who should be coded 'Business/Profit Entity'.
		10 - Marketing Orders	10	Yes	Marketing Orders: Regulated Agricultural Marketing Order Boards
		11 - Unfunded	11	No	
		12 - Departmental	12	No	Carried out with either actual funding from Departmental funding source or by faculty and staff who receive salary support from Departmental funding.
		99 - Unassigned	99	Yes	Unassigned: Sponsor not yet assigned to one of the above categories

Sponsor Type Implementation: Application Side

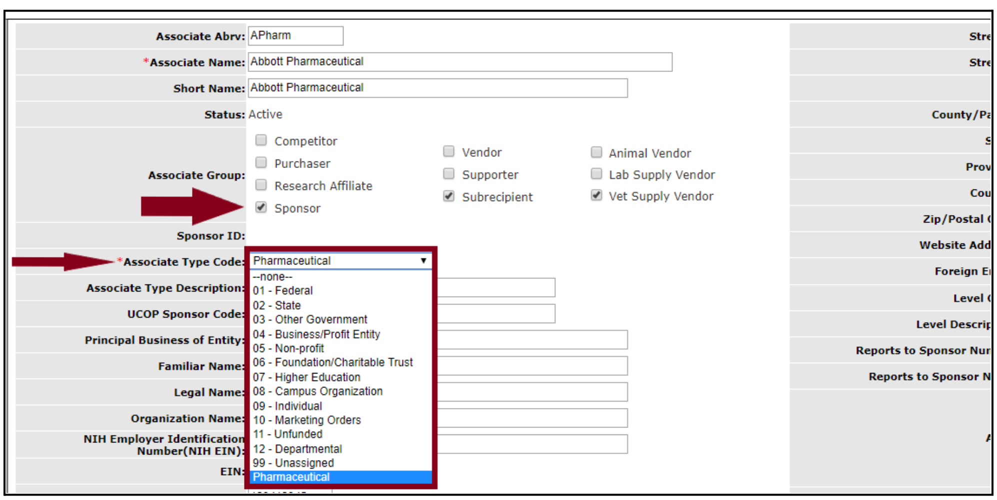
The sponsor type list is employed when a sponsor is added to the study application via the **Add a New Sponsor to the Study** button. As shown below, any sponsor listed in the table beneath the add button includes the Sponsor Type designation selected when the sponsor is added to the application.

Add a New Sponsor to the Study

Delete	Edit	View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number Modified
No Sponsor has been added to this Study								

Sponsor Type Implementation: Board Side

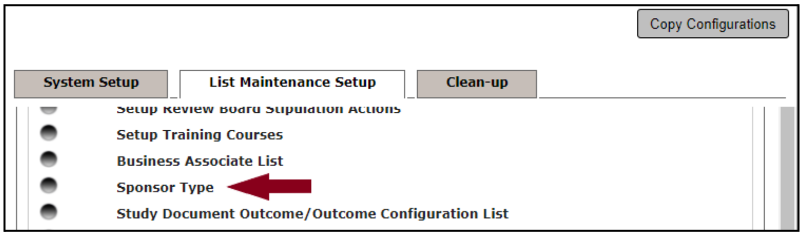
The sponsor type list is employed in the **System Setup of Business Associate List** page, as shown below.



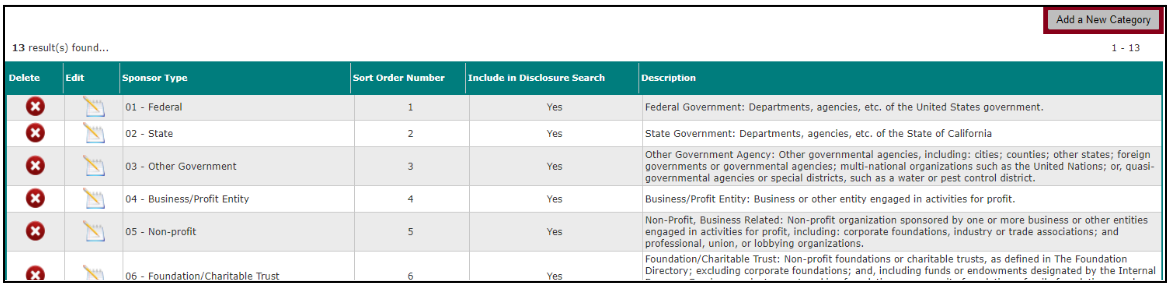
When "Sponsor" is selected from among the **Associate Group** options (large red arrow in screenshot above), new fields populate for selection of the sponsor type (small red arrow and red box in screenshot above) and entity details.

Add Sponsor Type

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Sponsor Type** link.



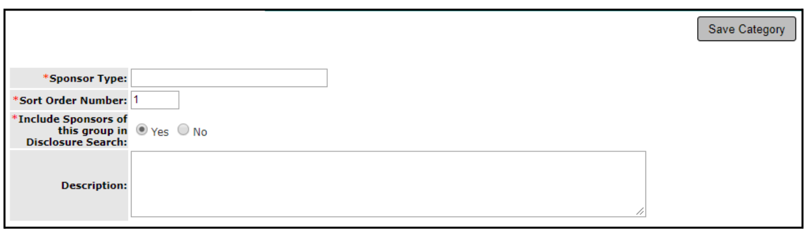
The **Setup Sponsor Type** page is opened. Click the **Add a New Category** button.


Add a New Category

13 result(s) found... 1 - 13

Delete	Edit	Sponsor Type	Sort Order Number	Include in Disclosure Search	Description
		01 - Federal	1	Yes	Federal Government: Departments, agencies, etc. of the United States government.
		02 - State	2	Yes	State Government: Departments, agencies, etc. of the State of California
		03 - Other Government	3	Yes	Other Government Agency: Other governmental agencies, including: cities; counties; other states; foreign governments or governmental agencies; multi-national organizations such as the United Nations; or, quasi-governmental agencies or special districts, such as a water or pest control district.
		04 - Business/Profit Entity	4	Yes	Business/Profit Entity: Business or other entity engaged in activities for profit.
		05 - Non-profit	5	Yes	Non-Profit, Business Related: Non-profit organization sponsored by one or more business or other entities engaged in activities for profit, including: corporate foundations, industry or trade associations; and professional, union, or lobbying organizations.
		06 - Foundation/Charitable Trust	6	Yes	Foundation/Charitable Trust: Non-profit foundations or charitable trusts, as defined in The Foundation Directory; excluding corporate foundations; and, including funds or endowments designated by the Internal

An add panel is opened for creation of the new record.



Enter a **Sponsor Type** name. At some institutions a numeric code is included in the name, as shown in the previous screenshot. The name should be distinct from any pre-existing items in the configuration list.

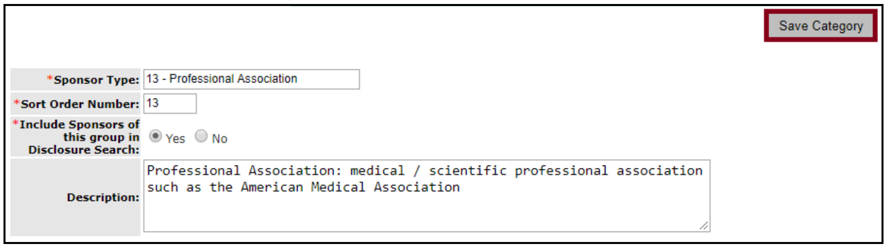
Enter the desired **Sort Order Number**. This number specifies the order in which sponsors appear in the configuration list and dropdown picklist of sponsors.

*Note: If a number that is already in use is selected, when this record is saved its **Sort Order Number** overrides any pre-existing item with the same sort order. The overridden item and all items that follow it in the list are incremented by one (1) and moved down one (1) position in the configuration list.*

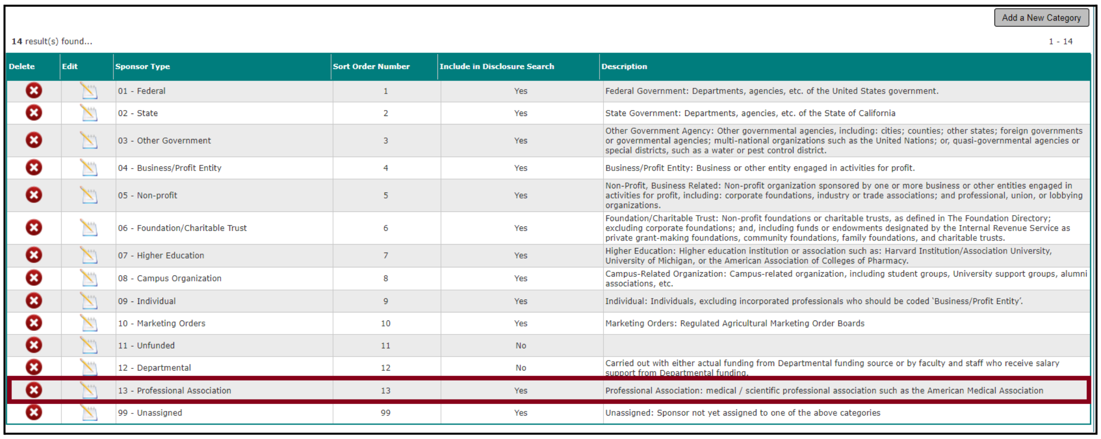
Select “Yes” or “No” for **Include Sponsors of this group in Disclosure Search** field.

Enter a **Description** of the sponsor to assist system users in distinguishing it from other sponsors in the list.

An example of the filled add panel is shown below. Click the **Save Category** button.



The record is added on the **Setup Sponsor Type** page.



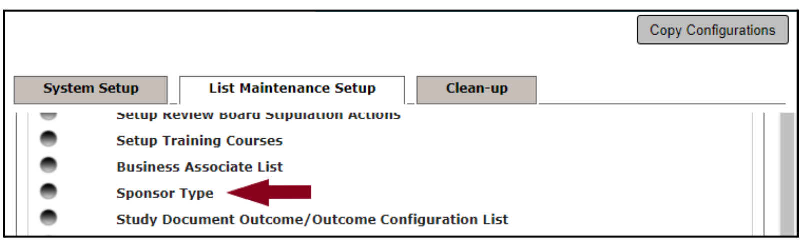
Add a New Category

14 result(s) found... 1 - 14

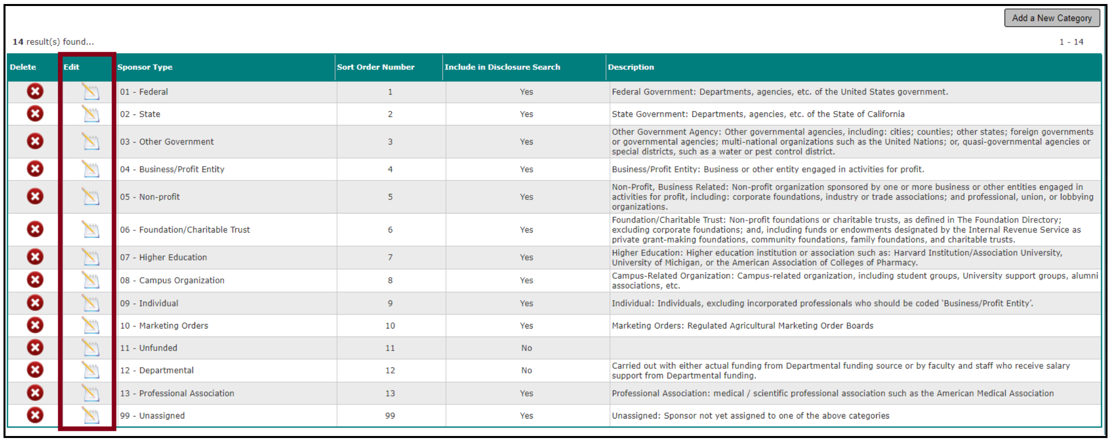
Delete	Edit	Sponsor Type	Sort Order Number	Include in Disclosure Search	Description
		01 - Federal	1	Yes	Federal Government: Departments, agencies, etc. of the United States government.
		02 - State	2	Yes	State Government: Departments, agencies, etc. of the State of California
		03 - Other Government	3	Yes	Other Government Agency: Other governmental agencies, including: cities; counties; other states; foreign governments or governmental agencies; multi-national organizations such as the United Nations; or, quasi-governmental agencies or special districts, such as a water or pest control district.
		04 - Business/Profit Entity	4	Yes	Business/Profit Entity: Business or other entity engaged in activities for profit.
		05 - Non-profit	5	Yes	Non-Profit, Business Related: Non-profit organization sponsored by one or more business or other entities engaged in activities for profit, including: corporate foundations, industry or trade associations; and professional, union, or lobbying organizations.
		06 - Foundation/Charitable Trust	6	Yes	Foundation/Charitable Trust: Non-profit foundations or charitable trusts, as defined in The Foundation Directory; excluding corporate foundations; and, including funds or endowments designated by the Internal Revenue Service as private grant-making foundations, community foundations, family foundations, and charitable trusts.
		07 - Higher Education	7	Yes	Higher Education: Higher education institution or association such as: Harvard Institution/Association University, University of Michigan, or the American Association of Colleges of Pharmacy.
		08 - Campus Organization	8	Yes	Campus-Related Organization: Campus-related organization, including student groups, University support groups, alumni associations, etc.
		09 - Individual	9	Yes	Individual: Individuals, excluding incorporated professionals who should be coded 'Business/Profit Entity'.
		10 - Marketing Orders	10	Yes	Marketing Orders: Regulated Agricultural Marketing Order Boards
		11 - Unfunded	11	No	
		12 - Departmental	12	No	Carried out with either actual funding from Departmental funding source or by faculty and staff who receive salary support from Departmental funding.
		13 - Professional Association	13	Yes	Professional Association: medical / scientific professional association such as the American Medical Association
		99 - Unassigned	99	Yes	Unassigned: Sponsor not yet assigned to one of the above categories

Edit Sponsor Type

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Sponsor Type** link.



The **Setup Sponsor Type** page is opened. Click the icon in the **Edit** column for the applicable record.



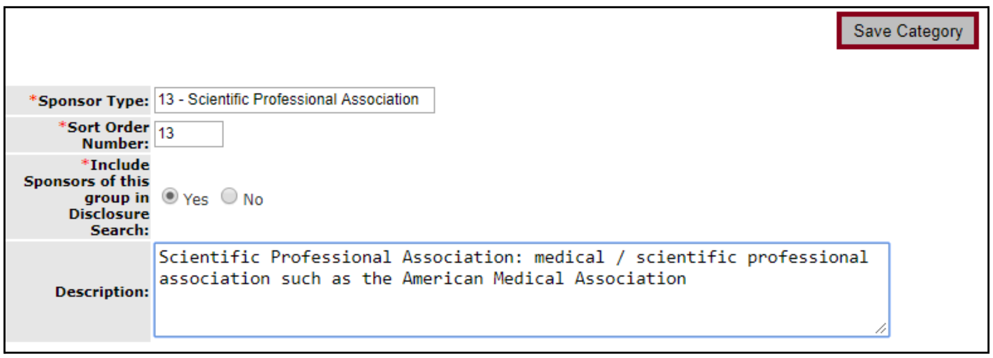
Add a New Category

14 result(s) found...

1 - 14

Delete	Edit	Sponsor Type	Sort Order Number	Include in Disclosure Search	Description
		01 - Federal	1	Yes	Federal Government: Departments, agencies, etc. of the United States government.
		02 - State	2	Yes	State Government: Departments, agencies, etc. of the State of California
		03 - Other Government	3	Yes	Other Government Agency: Other governmental agencies, including: cities; counties; other states; foreign governments or governmental agencies; multi-national organizations such as the United Nations; or, quasi-governmental agencies or special districts, such as a water or pest control district.
		04 - Business/Profit Entity	4	Yes	Business/Profit Entity: Business or other entity engaged in activities for profit.
		05 - Non-profit	5	Yes	Non-Profit, Business Related: Non-profit organization sponsored by one or more business or other entities engaged in activities for profit, including: corporate foundations, industry or trade associations; and professional, union, or lobbying organizations.
		06 - Foundation/Charitable Trust	6	Yes	Foundation/Charitable Trust: Non-profit foundations or charitable trusts, as defined in The Foundation Directory; excluding corporate foundations; and, including funds or endowments designated by the Internal Revenue Service as private grant-making foundations, community foundations, family foundations, and charitable trusts.
		07 - Higher Education	7	Yes	Higher Education: Higher education institution or association such as: Harvard Institution/Association University, University of Michigan, or the American Association of Colleges of Pharmacy.
		08 - Campus Organization	8	Yes	Campus-Related Organization: Campus-related organization, including student groups, University support groups, alumni associations, etc.
		09 - Individual	9	Yes	Individual: Individuals, excluding incorporated professionals who should be coded 'Business/Profit Entity'.
		10 - Marketing Orders	10	Yes	Marketing Orders: Regulated Agricultural Marketing Order Boards
		11 - Unfunded	11	No	
		12 - Departmental	12	No	Carried out with either actual funding from Departmental funding source or by faculty and staff who receive salary support from Departmental funding.
		13 - Professional Association	13	Yes	Professional Association: medical / scientific professional association such as the American Medical Association
		99 - Unassigned	99	Yes	Unassigned: Sponsor not yet assigned to one of the above categories

The selected record is opened in an edit panel. Make desired changes to the fields in the panel.



At some institutions a numeric code is included in the **Sponsor Type** name, as shown above. The name should be distinct from any pre-existing items in the configuration list.

The **Sort Order Number** specifies the order in which sponsors appear in the configuration list and dropdown picklist of sponsors.

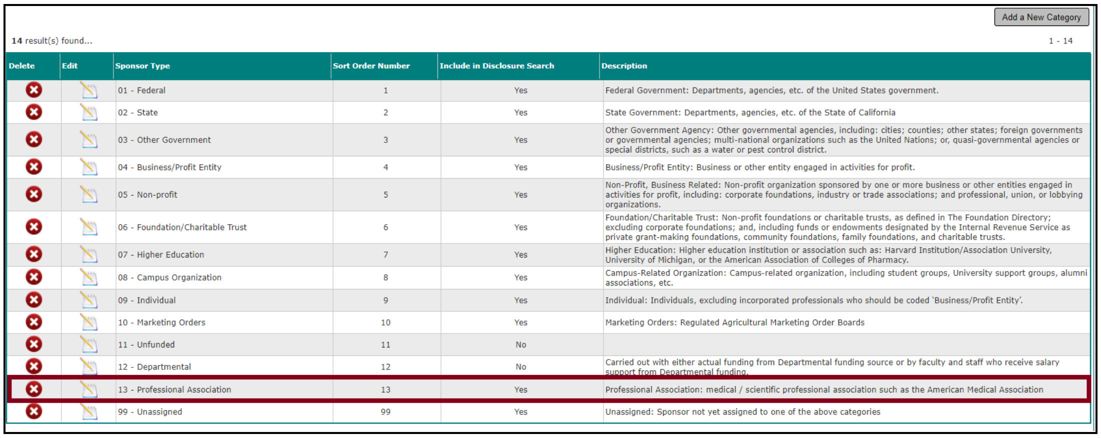
*Note: If a number that is already in use is selected, when this record is saved its **Sort Order Number** overrides any pre-existing item with the same sort order. The overridden item and all items that follow it in the list are incremented by one (1) and moved down one (1) position in the configuration list.*

Select "Yes" or "No" for **Include Sponsors of this group in Disclosure Search** field.

Enter a **Description** of the sponsor to assist system users in distinguishing it from other sponsors in the list.

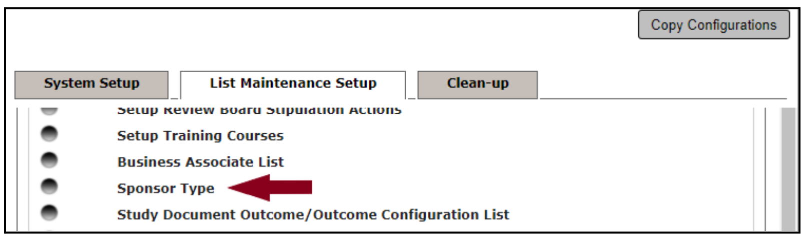
Click the **Save Category** button to save changes.

The record is revised on the **Setup Sponsor Type** page.

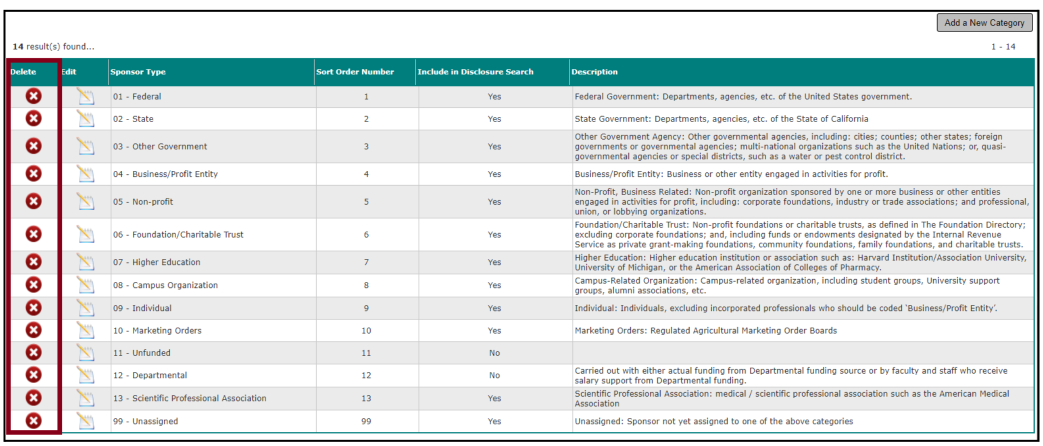


Delete Sponsor Type

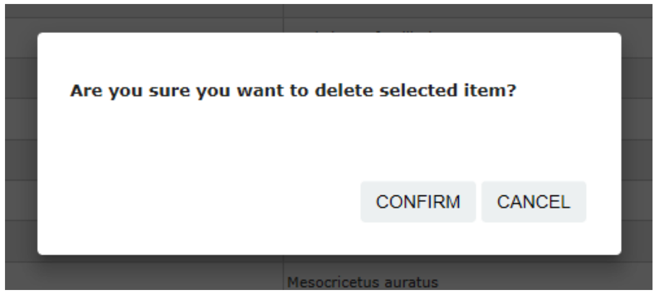
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Sponsor Type** link.



The **Setup Sponsor Type** page is opened. Click the icon in the **Delete** column for the applicable record.



A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The record is deleted from the list on the **Setup Sponsor Type** page.

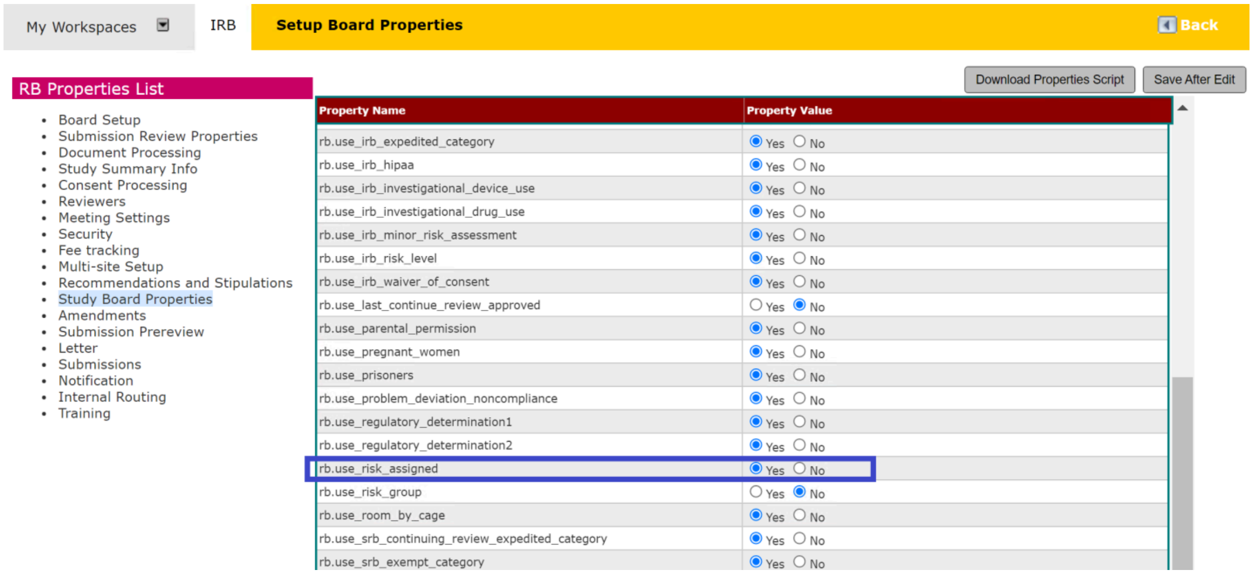
Add a New Category

13 result(s) found... 1 - 13

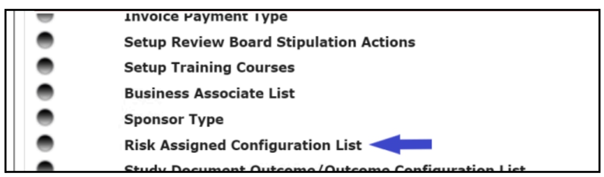
Delete	Edit	Sponsor Type	Sort Order Number	Include in Disclosure Search	Description
		01 - Federal	1	Yes	Federal Government: Departments, agencies, etc. of the United States government.
		02 - State	2	Yes	State Government: Departments, agencies, etc. of the State of California
		03 - Other Government	3	Yes	Other Government Agency: Other governmental agencies, including: cities; counties; other states; foreign governments or governmental agencies; multi-national organizations such as the United Nations; or, quasi-governmental agencies or special districts, such as a water or pest control district.
		04 - Business/Profit Entity	4	Yes	Business/Profit Entity: Business or other entity engaged in activities for profit.
		05 - Non-profit	5	Yes	Non-Profit, Business Related: Non-profit organization sponsored by one or more business or other entities engaged in activities for profit, including: corporate foundations, industry or trade associations; and professional, union, or lobbying organizations.
		06 - Foundation/Charitable Trust	6	Yes	Foundation/Charitable Trust: Non-profit foundations or charitable trusts, as defined in The Foundation Directory; excluding corporate foundations; and, including funds or endowments designated by the Internal Revenue Service as private grant-making foundations, community foundations, family foundations, and charitable trusts.
		07 - Higher Education	7	Yes	Higher Education: Higher education institution or association such as: Harvard Institution/Association University, University of Michigan, or the American Association of Colleges of Pharmacy.
		08 - Campus Organization	8	Yes	Campus-Related Organization: Campus-related organization, including student groups, University support groups, alumni associations, etc.
		09 - Individual	9	Yes	Individual: Individuals, excluding incorporated professionals who should be coded 'Business/Profit Entity'.
		10 - Marketing Orders	10	Yes	Marketing Orders: Regulated Agricultural Marketing Order Boards
		11 - Unfunded	11	No	
		12 - Departmental	12	No	Carried out with either actual funding from Departmental funding source or by faculty and staff who receive salary support from Departmental funding.
		99 - Unassigned	99	Yes	Unassigned: Sponsor not yet assigned to one of the above categories

Risk Assigned Configuration List

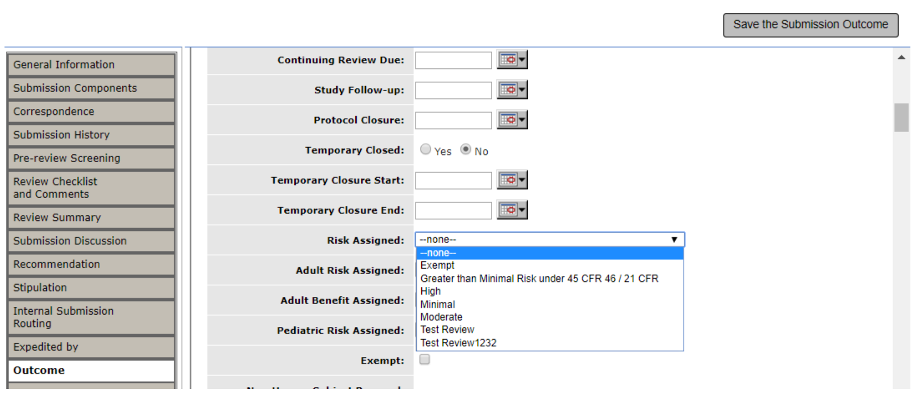
Where the property rb.use_risk_assigned is set to "Yes" (under IRB Assistant > Review Board Administration > Board Configuration Options > Study Board Properties, see screenshot below), the iRIS™ system allows for setup and maintenance of a **Risk Assigned Configuration List**. The list contains current risk ratings the review board can assign to studies.



Setting the property to “Yes” populates a **Risk Assigned Configuration List** link on the List Maintenance Setup tab, as shown in the example below.

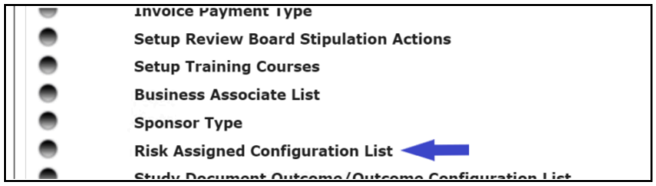


The list defined here is available for assigning risk to a study within the **Outcome** tab of the submission processing screens, as shown below.

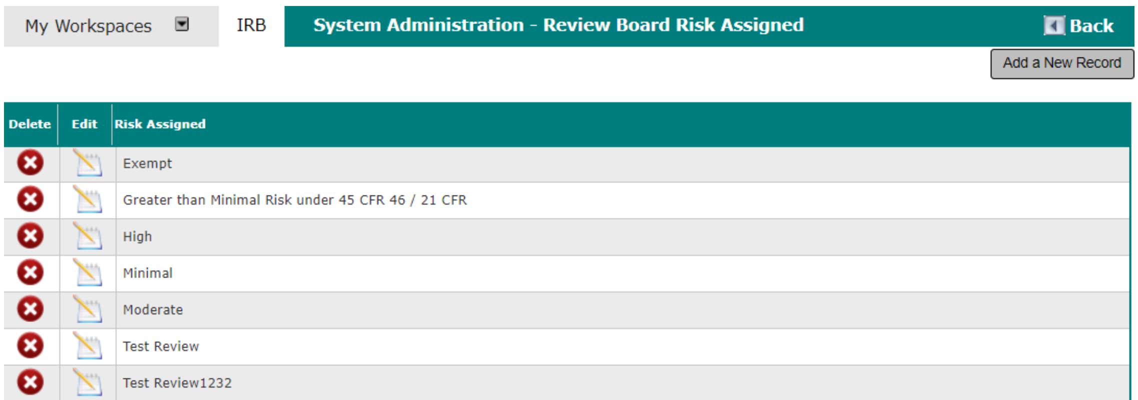


Add Risk

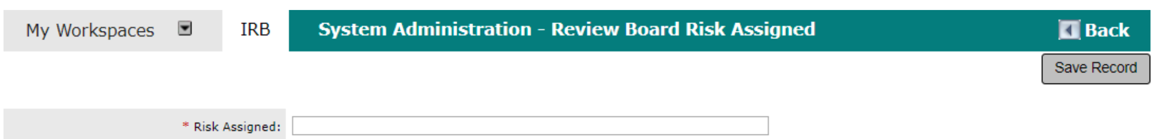
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Risk Assigned Configuration List** link.



As shown below, the **Review Board Risk Assigned** page opens.



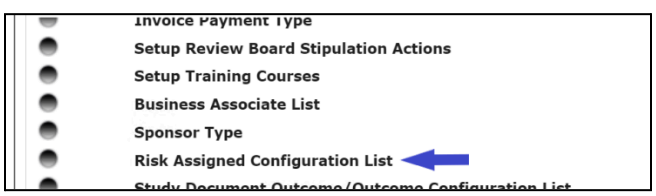
Click the **Add a New Record** button. An add form opens, as shown below.



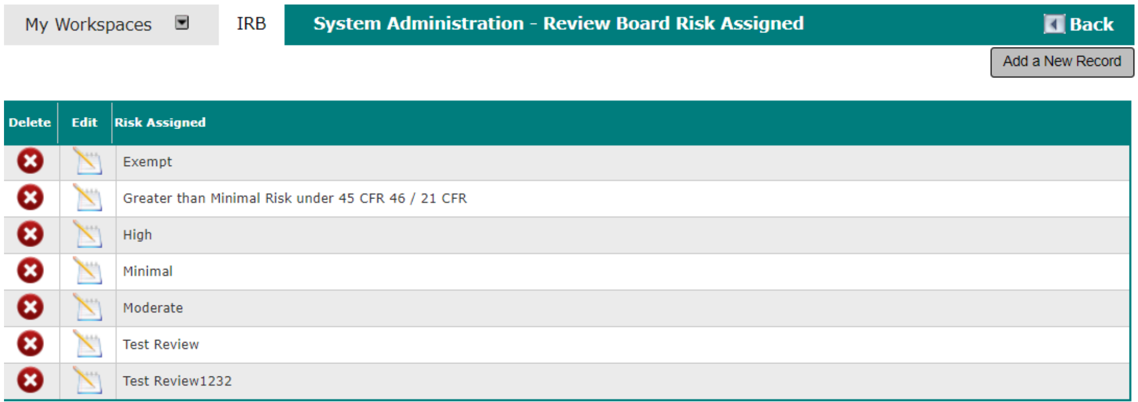
Enter desired text for **Risk Assigned** and click the **Save Record** button. The add form closes and the new **Risk** is added to the list on the **Review Board Risk Assigned** page.

Edit Risk

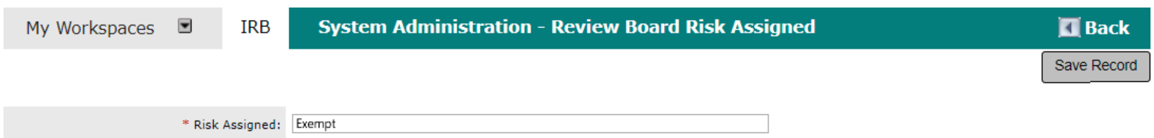
Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Risk Assigned Configuration List** link.



As shown below, the **Review Board Risk Assigned** page opens.



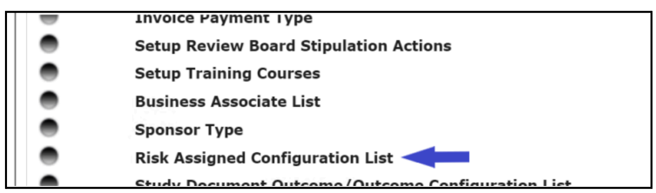
Click the applicable icon in the **Edit** column. The applicable record is opened in an edit form, as shown below.



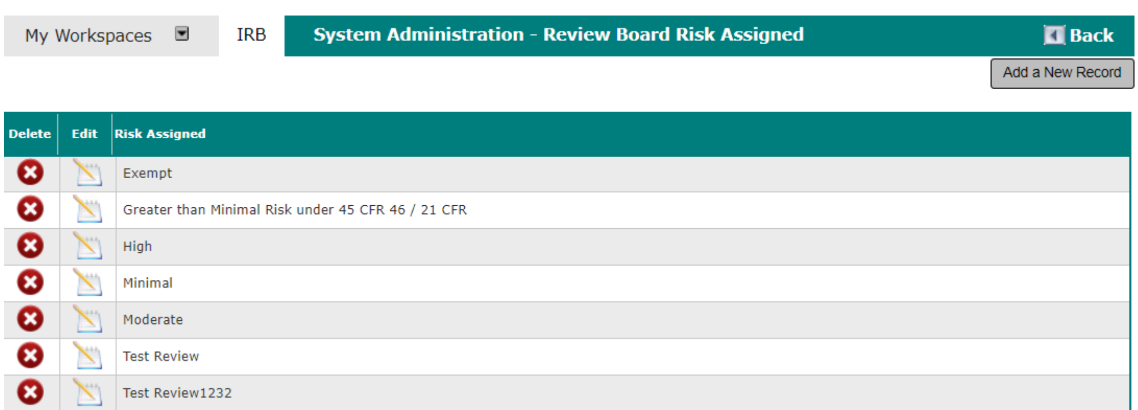
Revised the **Risk Assigned** text as desired and click the **Save Record** button. The edit form closes and the new **Risk** is revised in the list on the **Review Board Risk Assigned** page.

Delete Risk

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Risk Assigned Configuration List** link.

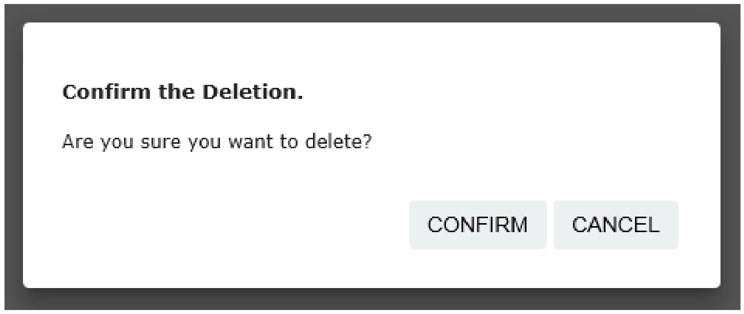


As shown below, the **Setup Adult Risk Assigned List** page opens.



Click the **Delete** column icon for the item to be deleted.

A confirmation popup window displays.

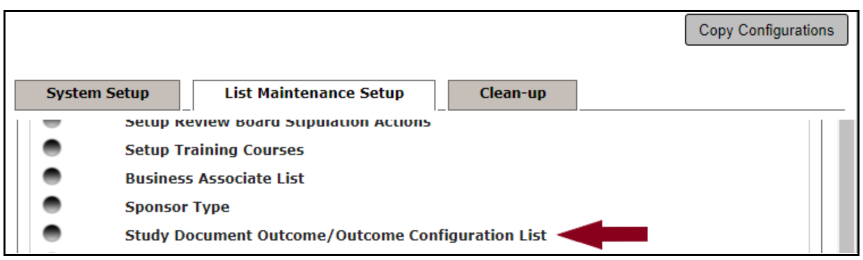


Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The item is deleted from the list on the **Review Board Risk Assigned** page.

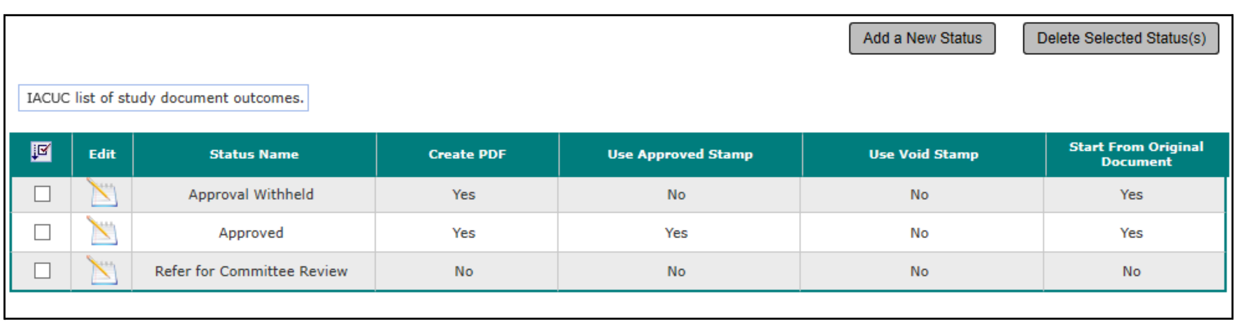
Study Document Outcome/Outcome Configuration List

The Document Outcome/Outcome Configuration List is where a list of boilerplate outcome statuses approved for use in studies is maintained in the iRIS™ system. To view the list, navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Study Document Outcome / Outcome Configuration List** link.



The **Setup Protocol Document Outcome** page is opened.

Note that at some institutions, the term "Study" is substituted for "Protocol". These terms may be used interchangeably in manual text and screenshots.



	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Document
		Approval Withheld	Yes	No	No	Yes
		Approved	Yes	Yes	No	Yes
		Refer for Committee Review	No	No	No	No

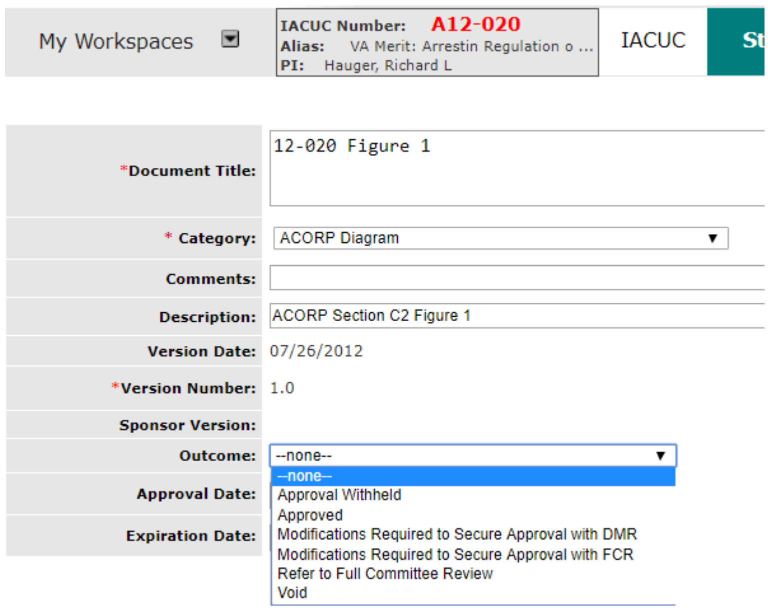
Study Document Outcome List Implementation – Application Side

Study document outcomes are assigned by the applicable review board, making this functionality inapplicable on the application side.

Study Document Outcome List Implementation – Board Side

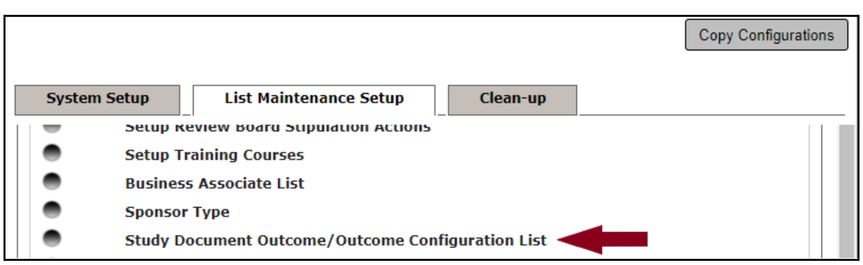
The study document outcome list is employed in the following areas on the review board / system setup side of iRIS™.

Submission processing — the Study Document Outcome list is employed as a dropdown picklist in the **Outcome** field when approving a study document within submission processing screens, as shown in the IACUC example below

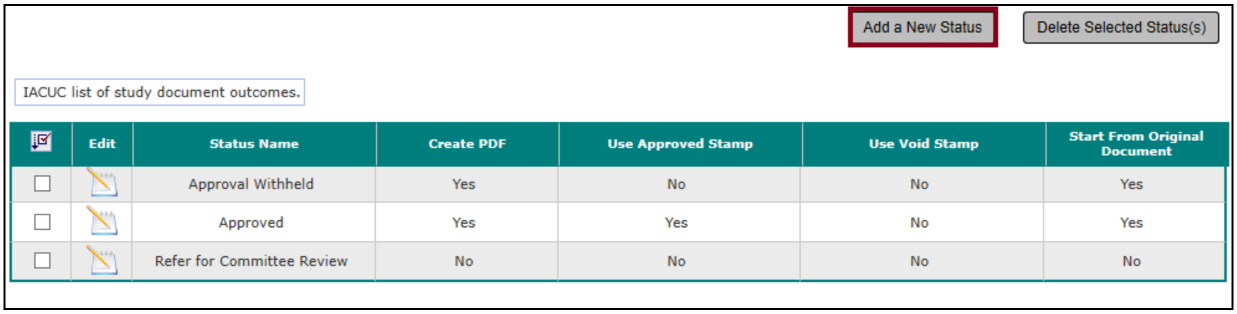


Add Study Document Outcome

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Study Document Outcome / Outcome Configuration List** link.

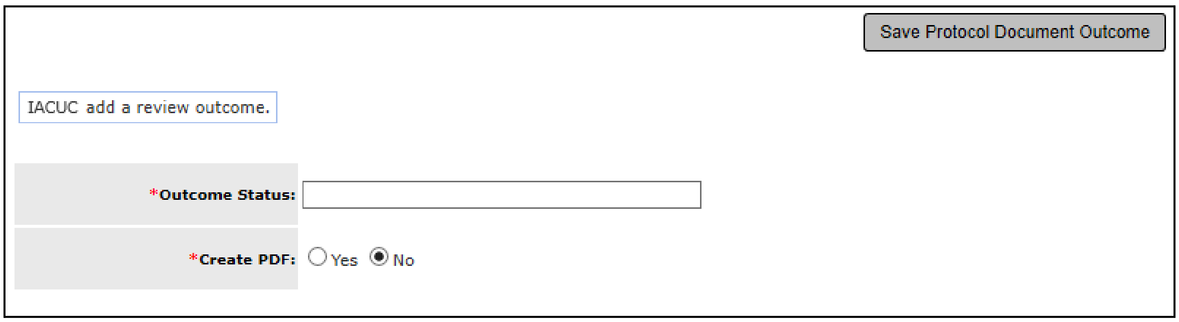


The **Setup Protocol Document Outcome** page is opened. Click the **Add a New Status** button.



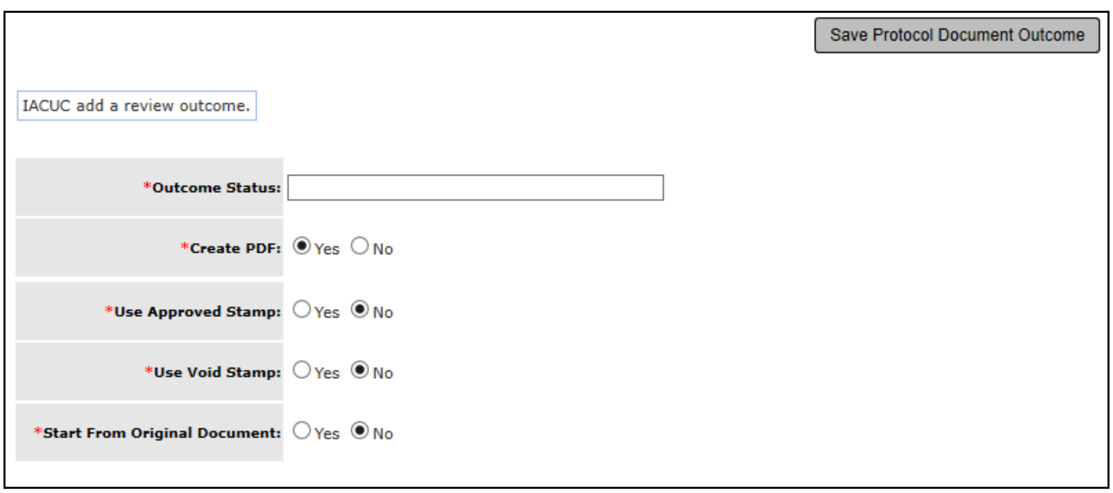
	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Document
		Approval Withheld	Yes	No	No	Yes
		Approved	Yes	Yes	No	Yes
		Refer for Committee Review	No	No	No	No

An **add a review outcome** panel is opened for creation of the new record. Below, the blank form is shown with the default selection of “No” in place for **Create PDF**.



When “Yes” is selected for **Create PDF**, indicating that the document given this outcome is to be converted to a PDF, three additional fields pertaining PDF settings are unlocked with default selections set to “No”.

*Note that **Create PDF** must be set to “Yes” for any document to which an electronic document stamp will be applied.*



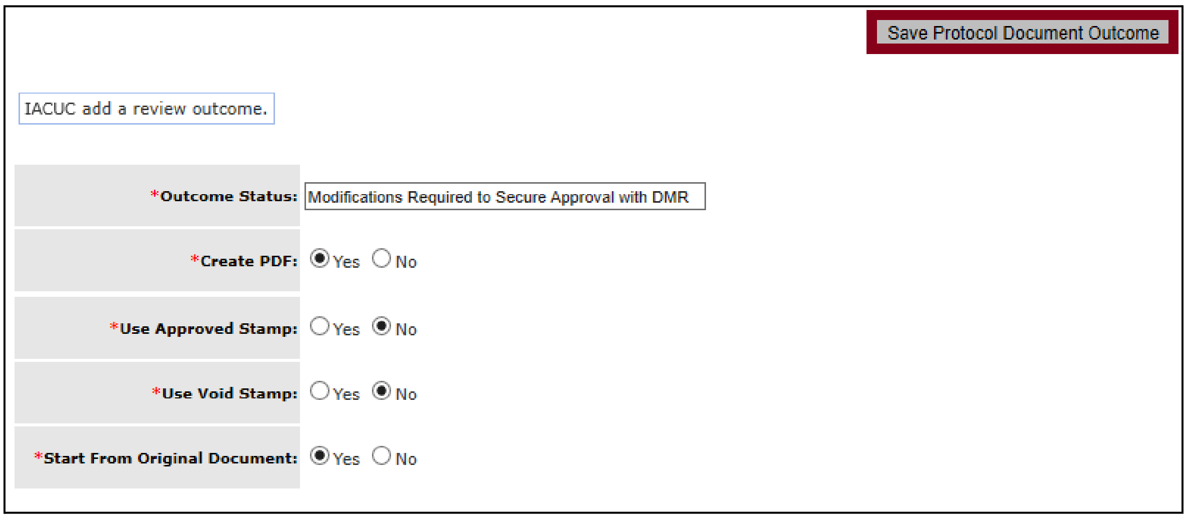
Use Approved Stamp – This option is only available where the review board property “rb.stamp_study_doc” (under IRB Assistant > Review Board Administration > Board Configuration Options > Document Processing) is turned on. When this option is set to “Yes”, the study document PDF with this outcome assigned will have an electronic approval stamp applied.

Use Void Stamp – When this option is set to "Yes", the study document PDF with this outcome assigned will have an electronic VOID watermark applied.

Start From Original Document - When this option is set to "Yes", the assigned outcome is applied to the original document. When this option is set to "No", the assigned outcome is applied to a PDF of the original document that was previously created as part of a prior outcome.

This setting is useful in cases where the review board needs to revisit a study document and assign a different outcome. For example, when a PDF document with a VOID watermark is subsequently approved, ***Start from Original Document*** *must be set to "Yes" to ensure the VOID watermark is removed from the document.*

Fill the form as desired and click the **Save Study Document Outcome** button.


Save Protocol Document Outcome

IACUC add a review outcome.

*Outcome Status: Modifications Required to Secure Approval with DMR

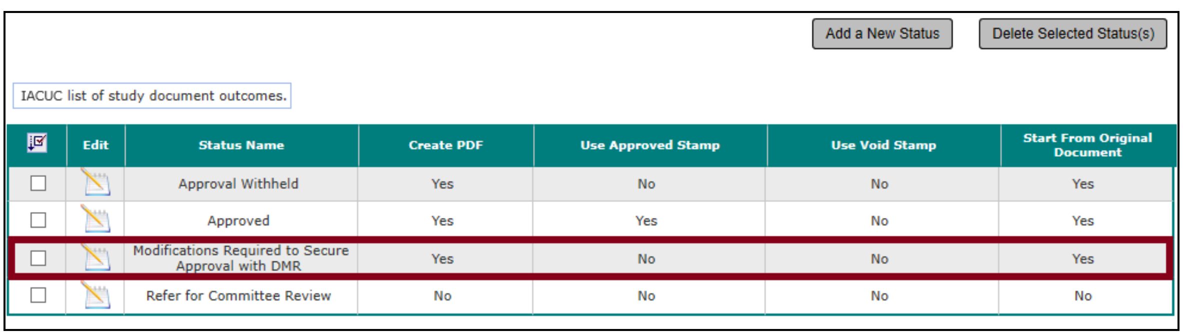
*Create PDF: Yes No

*Use Approved Stamp: Yes No

*Use Void Stamp: Yes No

*Start From Original Document: Yes No

The outcome is added on the **Setup Protocol Document Outcome** list page.

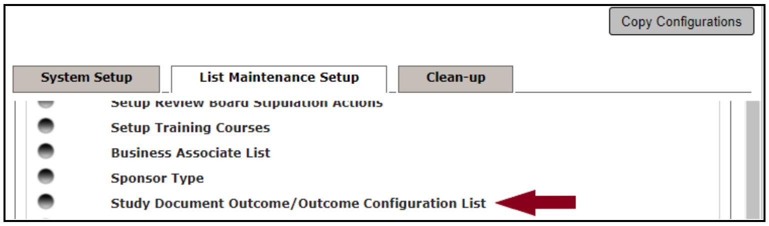

Add a New Status | Delete Selected Status(s)

IACUC list of study document outcomes.

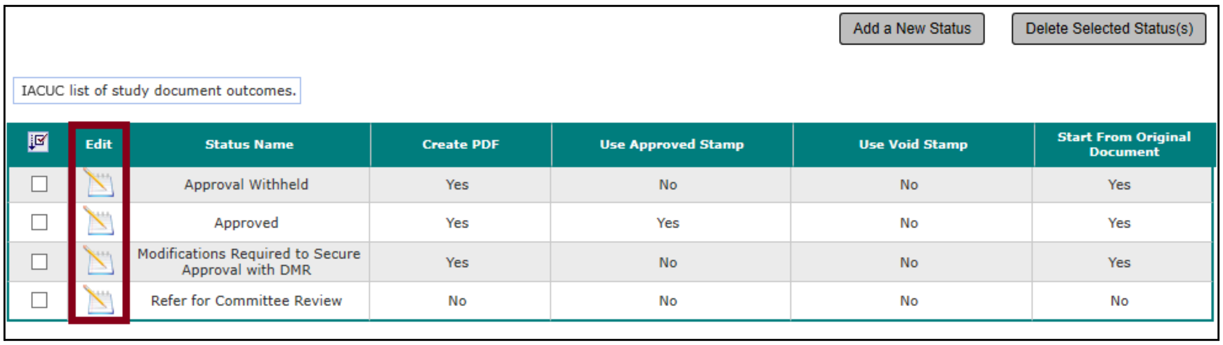
	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Document
		Approval Withheld	Yes	No	No	Yes
		Approved	Yes	Yes	No	Yes
		Modifications Required to Secure Approval with DMR	Yes	No	No	Yes
		Refer for Committee Review	No	No	No	No

Edit Study Document Outcome

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Study Document Outcome / Outcome Configuration List** link.

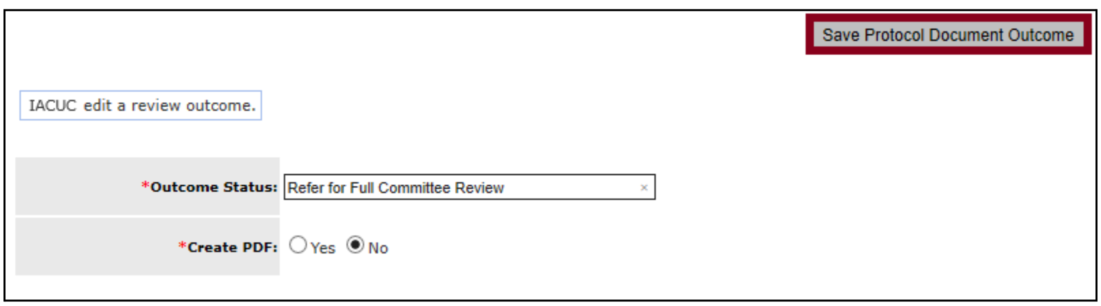


The **Setup Protocol Document Outcome** page is opened. Click the icon in the **Edit** column for the applicable record.



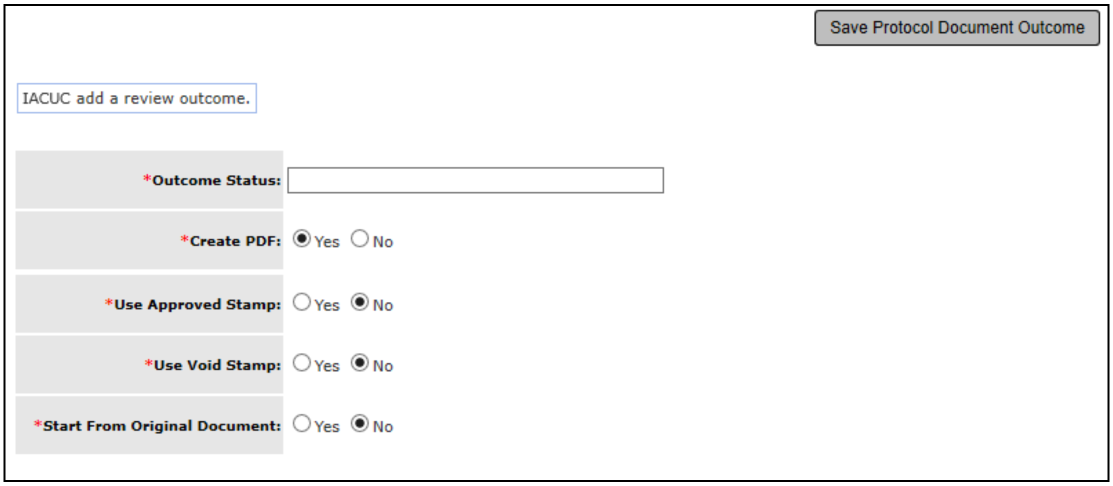
	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Document
		Approval Withheld	Yes	No	No	Yes
		Approved	Yes	Yes	No	Yes
		Modifications Required to Secure Approval with DMR	Yes	No	No	Yes
		Refer for Committee Review	No	No	No	No

The record is opened in an **edit a review outcome** panel.



When “Yes” is selected for **Create PDF**, indicating that the document given this outcome is to be converted to a PDF, three additional fields pertaining PDF settings are unlocked with default selections set to “No”.

*Note that **Create PDF** must be set to “Yes” for any document to which an electronic document stamp will be applied.*



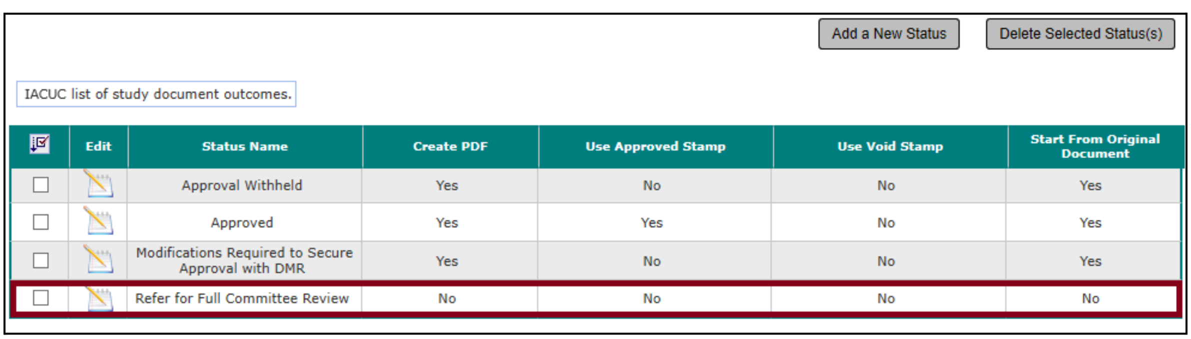
Use Approved Stamp – This option is only available where the Review Board Property "rb.stamp_study_doc" (under IRB Assistant > Review Board Administration > Board Configuration Options > Document Processing) is turned on. When this option is set to "Yes", the study document PDF with this outcome assigned will have an electronic approval stamp applied.

Use Void Stamp – When this option is set to "Yes", the study document PDF with this outcome assigned will have an electronic **VOID** watermark applied.

Start From Original Document - When this option is set to "Yes", the assigned outcome is applied to the original document. When this option is set to "No", the assigned outcome is applied to a PDF of the original document that was previously created as part of a prior outcome.

*This setting is useful in cases where the review board needs to revisit a study document and assign a different outcome. For example, when a PDF document with a VOID watermark is subsequently approved, **Start from Original Document** must be set to "Yes" to ensure the VOID watermark is removed from the document.*

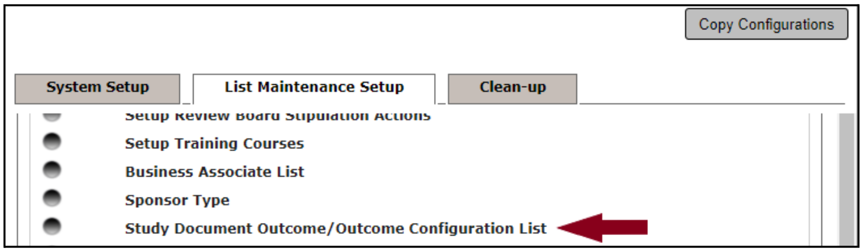
Edit the record as desired and click the **Save Protocol Document Outcome** button. The edit panel is closed, and the record is revised on the **Setup Protocol Document Outcome** list page.



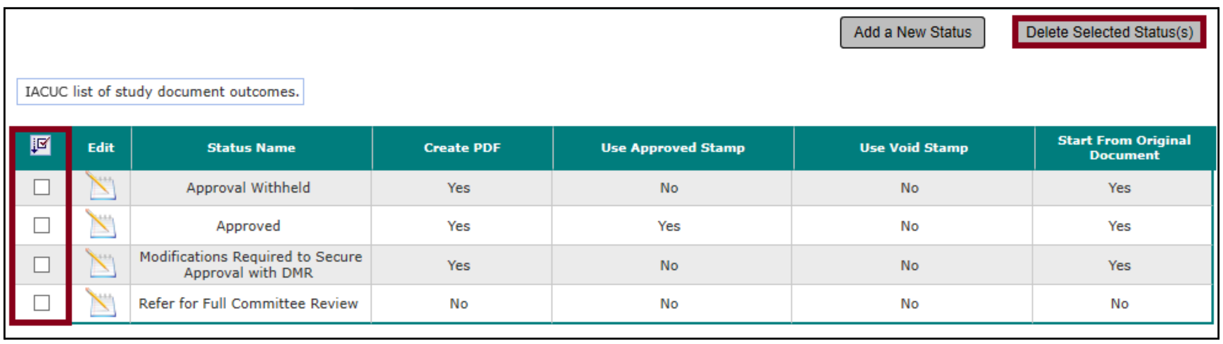
	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Document
		Approval Withheld	Yes	No	No	Yes
		Approved	Yes	Yes	No	Yes
		Modifications Required to Secure Approval with DMR	Yes	No	No	Yes
		Refer for Full Committee Review	No	No	No	No

Delete Study Document Outcome

Navigate to IRB Assistant > Review Board Administration > List Maintenance Setup tab and click the **Study Document Outcome / Outcome Configuration List** link.

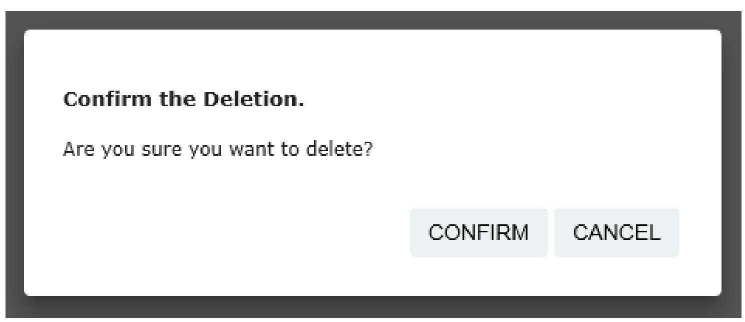


The **Setup Protocol Document Outcome** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted and click the **Delete Selected Status(s)** button.



	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Document
		Approval Withheld	Yes	No	No	Yes
		Approved	Yes	Yes	No	Yes
		Modifications Required to Secure Approval with DMR	Yes	No	No	Yes
		Refer for Full Committee Review	No	No	No	No

A confirmation popup window displays.

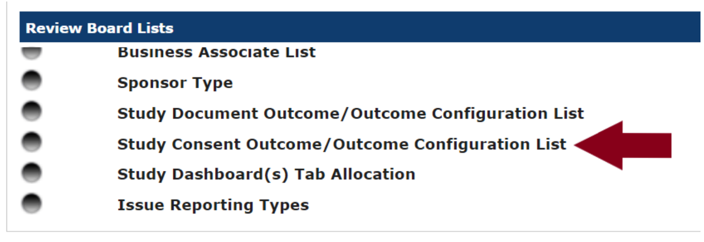


Click **CANCEL** to close the popup without deleting the record.

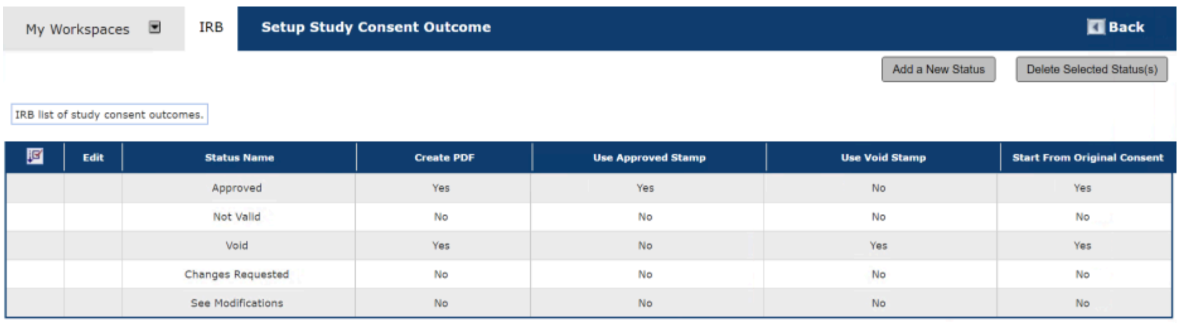
Click **CONFIRM** to complete deletion of the record. The record is deleted from the **Setup Protocol Document Outcome** page.

Study Consent Outcome/Outcome Configuration List

A list of preconfigured Consent outcomes is maintained on the Setup Study Consent Outcome page. To access the page, navigate to Review Board Administration > [List Maintenance Setup tab] > **Study Consent Outcome/Outcome Configuration List** link.



Click the link to open the **Setup Study Consent Outcome** page, shown below.

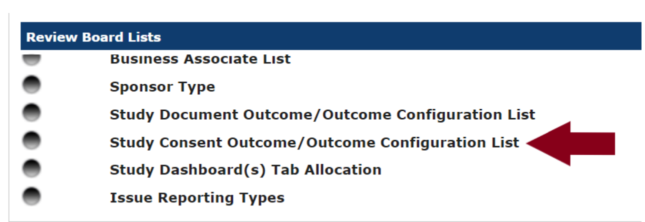


All previously configured Consent outcomes are listed on the page.

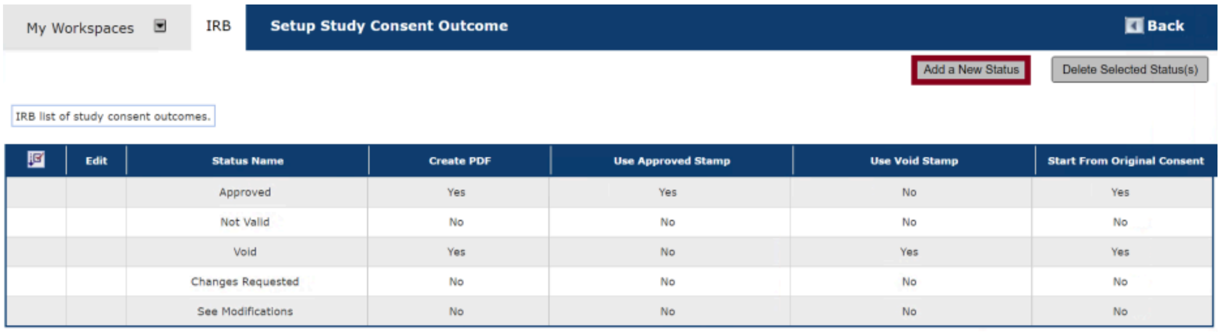
Notice that outcomes of “Approved”, “Not Valid”, “Void”, “Changes Requested” and “See Modifications” are pre-populated in the list by default. These outcomes are reserved, and cannot be revised or deleted.

Add Study Consent Outcome

Navigate to Review Board Administration > [List Maintenance Setup tab] > **Study Consent Outcome/Outcome Configuration List** link.

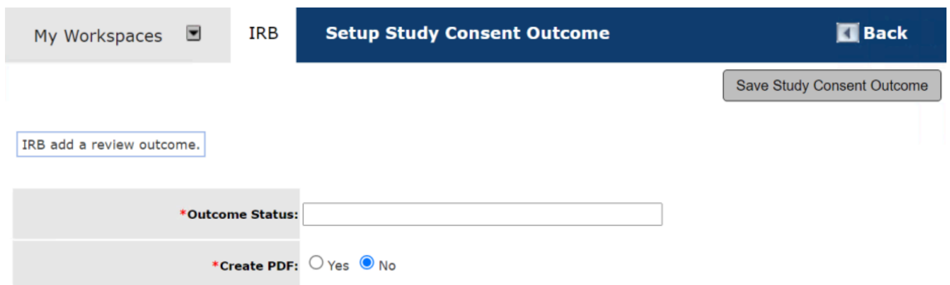


Click the link to open the **Setup Study Consent Outcome** page, shown below.

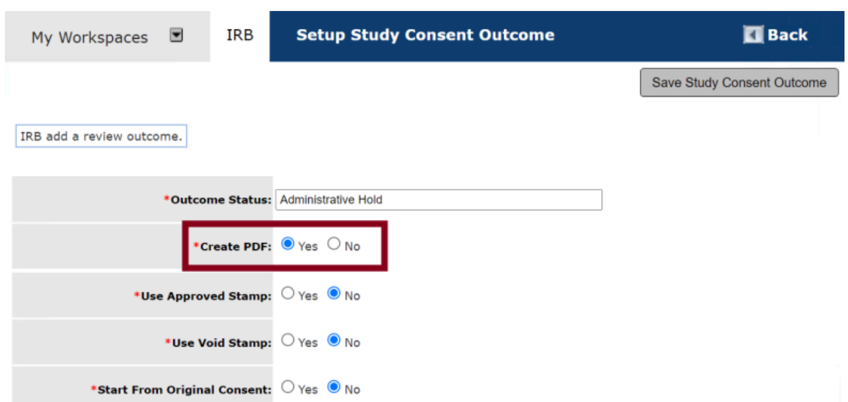


	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Consent
		Approved	Yes	Yes	No	Yes
		Not Valid	No	No	No	No
		Void	Yes	No	Yes	Yes
		Changes Requested	No	No	No	No
		See Modifications	No	No	No	No

Click the **Add a New Status** button.



Enter the desired **Outcome Status**.



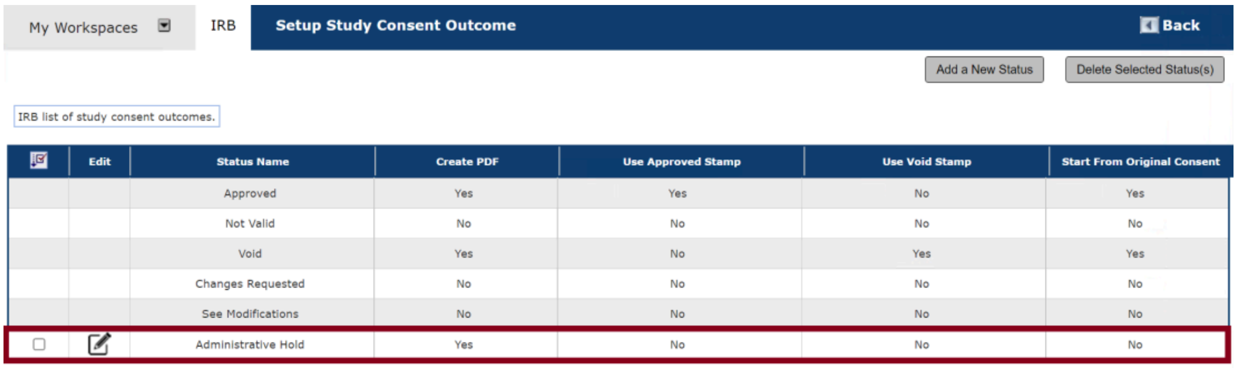
The **Create PDF** field is set to “No” by default. As shown above, changing the selection to “Yes” populates the following fields, which all default to “No”:

Use Approved Stamp – select “Yes” to include the Approved stamp on the PDF; this option is appropriate for Consent outcomes of an ‘approved’ type ONLY

Use Void Stamp – select “Yes” to include the Void stamp on the PDF; this option is appropriate for Consent outcomes OTHER than an ‘approved’ type

Start From Original Consent – select “Yes” to default to the original Consent document when the PDF is printed; this option is appropriate in cases where it is desirable to revert to the original Consent document during review

When all selections are complete, click the **Save Study Consent Outcome** button.

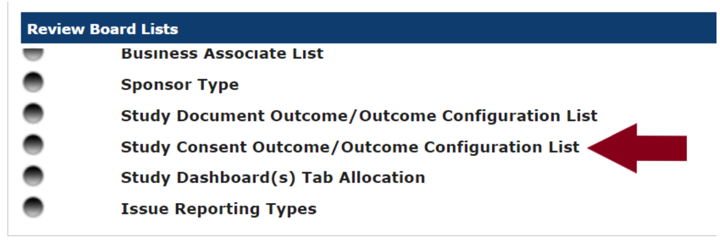


	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Consent
		Approved	Yes	Yes	No	Yes
		Not Valid	No	No	No	No
		Void	Yes	No	Yes	Yes
		Changes Requested	No	No	No	No
		See Modifications	No	No	No	No
		Administrative Hold	Yes	No	No	No

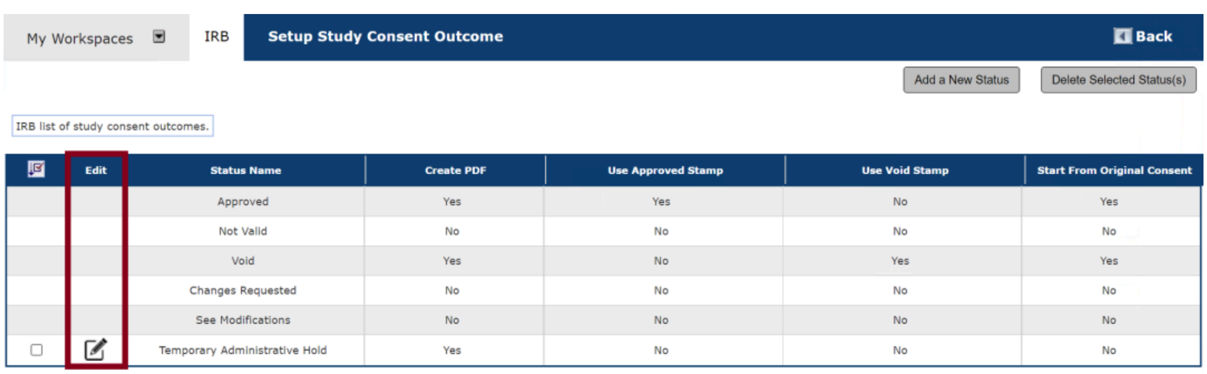
As shown above, the new outcome is added to the list on the **Setup Study Consent Outcome** page.

Edit Study Consent Outcome

Navigate to Review Board Administration > [List Maintenance Setup tab] > **Study Consent Outcome/Outcome Configuration List** link.

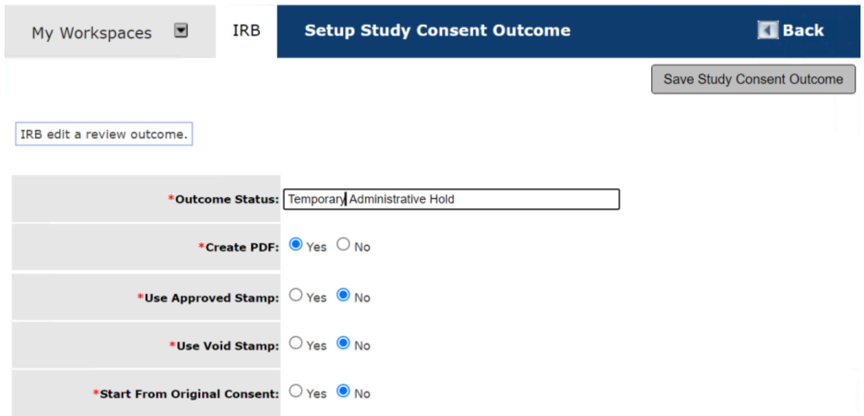


Click the link to open the **Setup Study Consent Outcome** page, shown below.

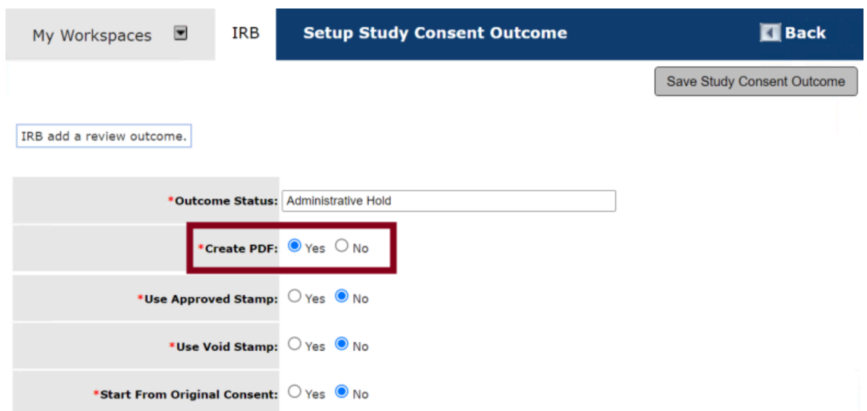


	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Consent
		Approved	Yes	Yes	No	Yes
		Not Valid	No	No	No	No
		Void	Yes	No	Yes	Yes
		Changes Requested	No	No	No	No
		See Modifications	No	No	No	No
		Temporary Administrative Hold	Yes	No	No	No

Click the icon in the **Edit** column for the applicable Consent outcome. The record is opened in an edit form, as shown below.



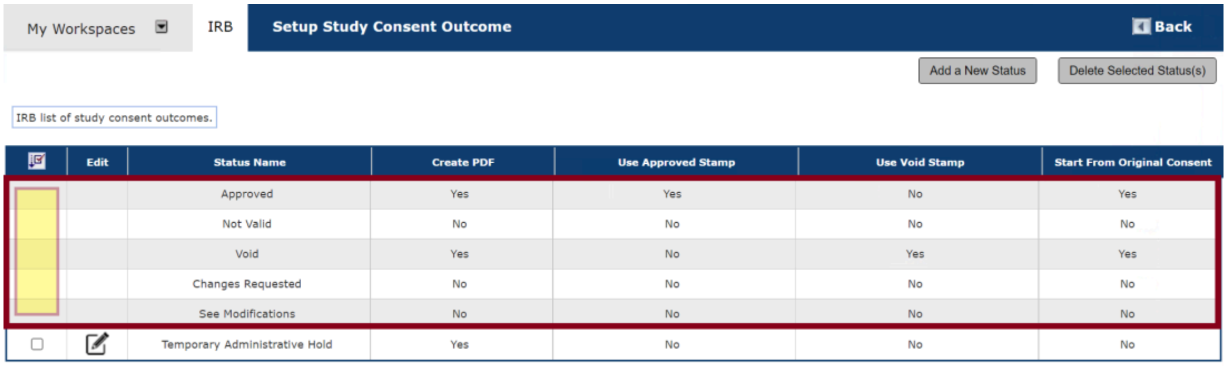
Make desired changes to the **Outcome Status**, as shown above.



Where the **Create PDF** field is set "No", no other fields appear on the page. As shown above, setting the selection to "Yes" populates the following fields, which all default to "No":

- **Use Approved Stamp** – select "Yes" to include the Approved stamp on the PDF; this option is appropriate for Consent outcomes of an 'approved' type ONLY
- **Use Void Stamp** – select "Yes" to include the Void stamp on the PDF; this option is appropriate for Consent outcomes OTHER than an 'approved' type
- **Start From Original Consent** – select "Yes" to default to the original Consent document when the PDF is printed; this option is appropriate in cases where it is desirable to revert to the original Consent document during review

When all selections are complete, click the **Save Study Consent Outcome** button.

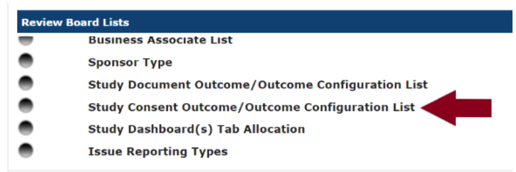


As shown above, the Consent outcome is revised in the list on the **Setup Study Consent Outcome** page.

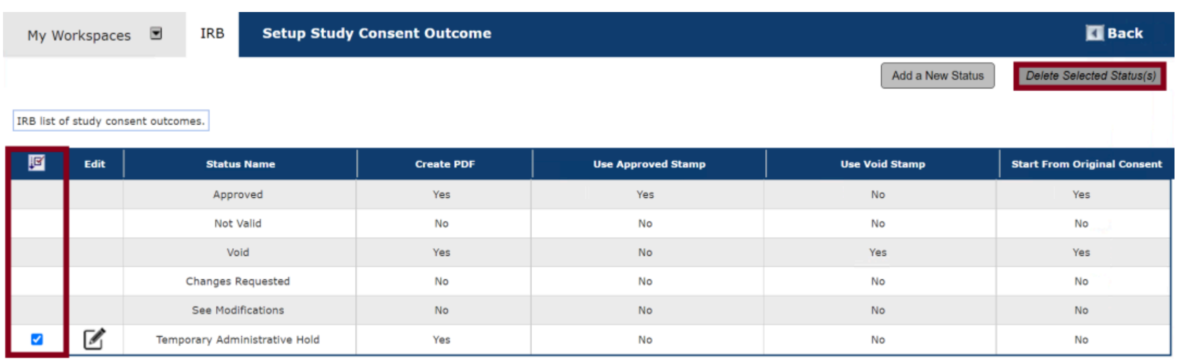
Notice that the revised item has an icon in the **Edit** column and a select checkbox in the far left column to be used for deleting the record, if desired. Pre-existing, default Consent outcomes do not have icons in the **Edit** column or select checkboxes for deletion, as they cannot be revised or deleted.

Delete Study Consent Outcome

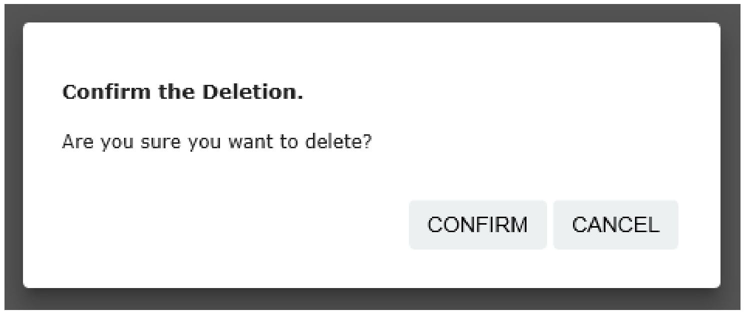
Navigate to Review Board Administration > [List Maintenance Setup tab] > **Study Consent Outcome/Outcome Configuration List** link.



Click the link to open the **Setup Study Consent Outcome** page, shown below.

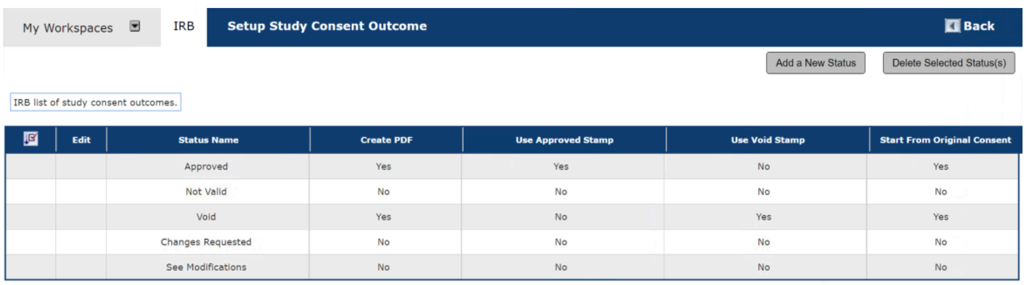


Click to select the applicable checkbox(es) in the far-left column and click the **Delete Selected Status(es)** button, as shown above. A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record.

Click **CONFIRM** to complete deletion of the record. The record is deleted from the **Setup Study Consent Outcome** page.

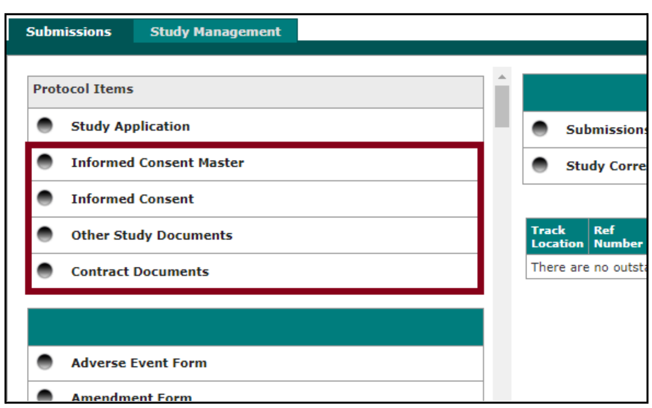


	Edit	Status Name	Create PDF	Use Approved Stamp	Use Void Stamp	Start From Original Consent
		Approved	Yes	Yes	No	Yes
		Not Valid	No	No	No	No
		Void	Yes	No	Yes	Yes
		Changes Requested	No	No	No	No
		See Modifications	No	No	No	No

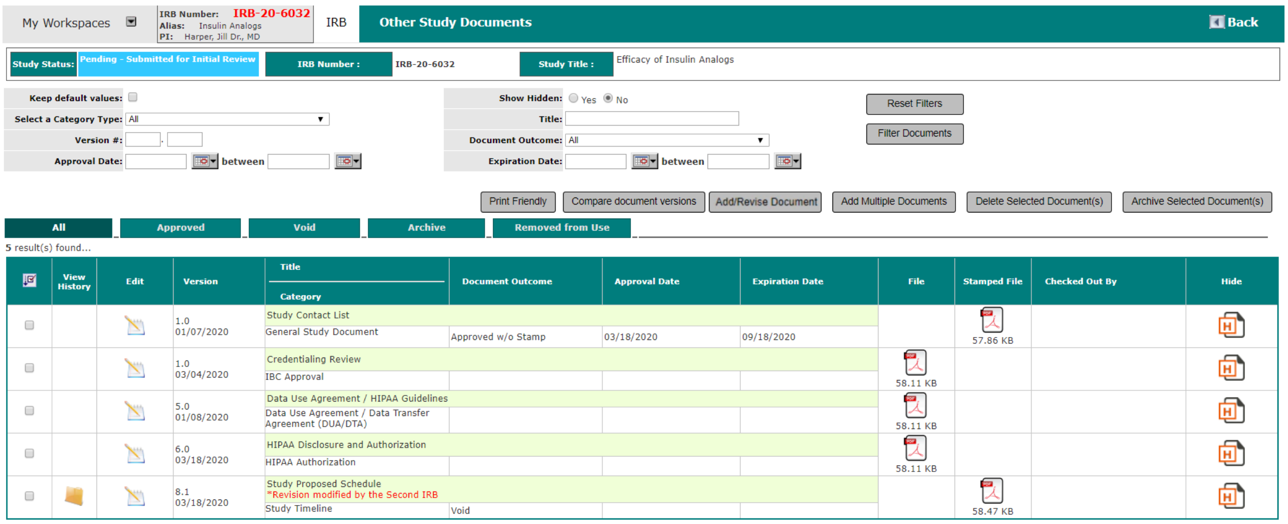
Study Dashboard(s) Tab Allocation

A central dashboard page for document upload and management is provided for each major type of document as configured by the institution. Most institutions use Consent and Other Study Documents document types, but some have additional document types configured.

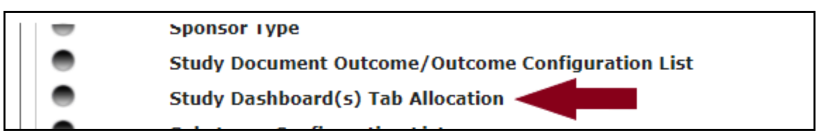
The screenshot below demonstrates an institution with four major document types configured, and therefore four document management dashboards: Informed Consent Master, Informed Consent, Other Study Documents and Contract Documents.



The dashboard pages are shared across the study submission and board sides of processing, as well as across review boards, ensuring that all personnel at all stages of submission processing have visibility of, and access to, the same versions of attached documents at all times. As shown below for the **Other Study Documents** type, each new dashboard contains a tabbed list table.



The iRIS™ system allows institutions to configure the order in which study status tabs appear on study dashboards. Configuration of this feature is accessed via RB Assistant > Review Board Administration > List Maintenance Setup tab > **Study Dashboard(s) Tab Allocation** link.

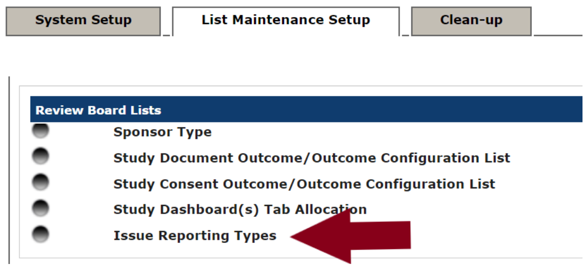


See the Document Management manual for more information about this feature.

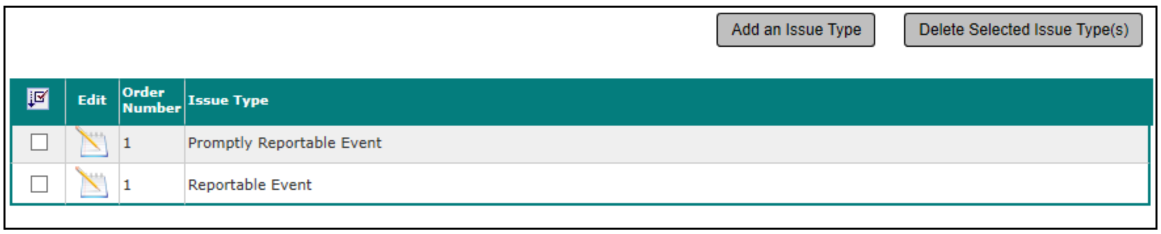
Issue Reporting Types

Institutions involved in IRB or IACUC research activity must report any issues that arise and have the potential to impact on any aspect of research activities. Each institution has its own internal policies for issue reporting, categorization, management and resolution.

The **Issue Reporting Types** list is where a list of issue reporting types can be maintained by institutions in the iRIS™ system. To access the list, navigate to IRB Assistant > Review Board Administration > **List Maintenance Setup** tab and click the **Issue Reporting Types** link.



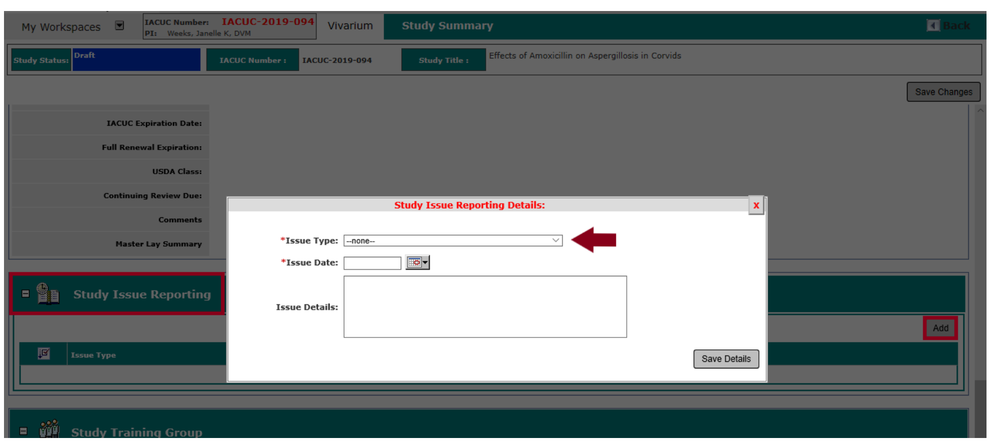
The **Setup Issue Type List** page is opened.



Issue Type Implementation – Application Side

The issue type list is employed in the following areas on the application side of iRIS™.

Issue reporting functionality on the application side is accessed via Find a Study > [study opened] > Study Management tab > Study Summary/Profile link.



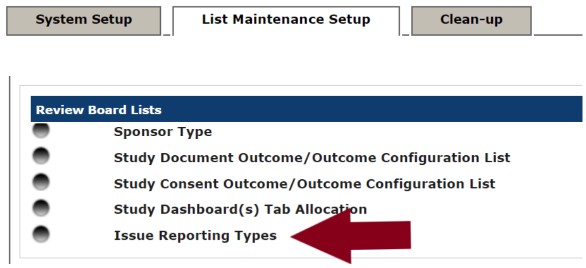
For more information about the study application, see the Study Assistant Manual.

Issue Type Implementation – Board Side

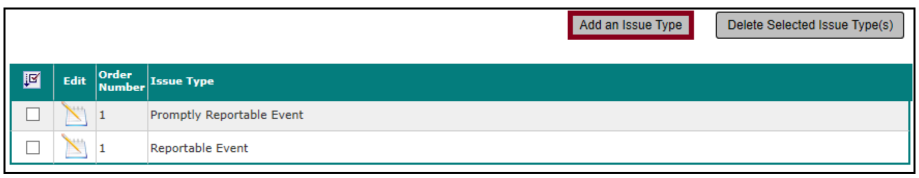
Issues are reported on the application/study side at the time they occur. This list is not applicable to the board side of processing.

Add Issue Type

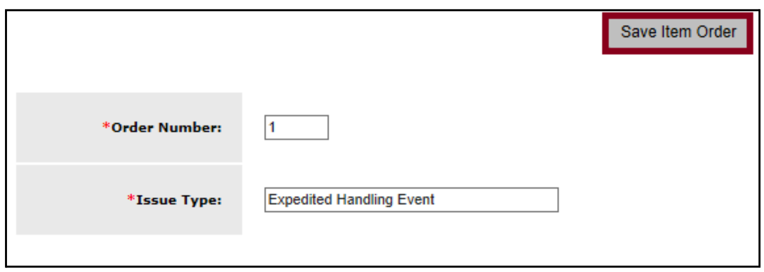
Navigate to IRB Assistant > Review Board Administration > **List Maintenance Setup** tab and click the **Issue Reporting Types** link.



The **Setup Issue Type List** page is opened. Click the **Add an Issue Type** button.



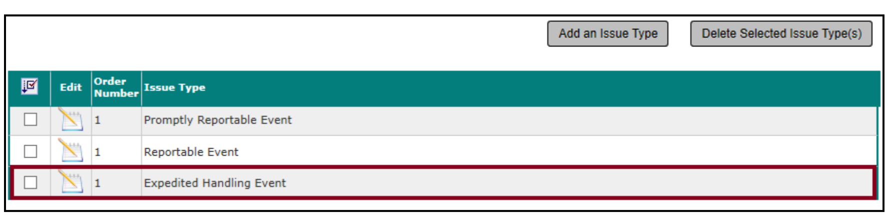
An add panel is opened for creation of the new record.



Enter an **Order Number** and enter the desired designation in the **Issue Type** field, then click the **Save Item Order** button to save the record and close the add panel.

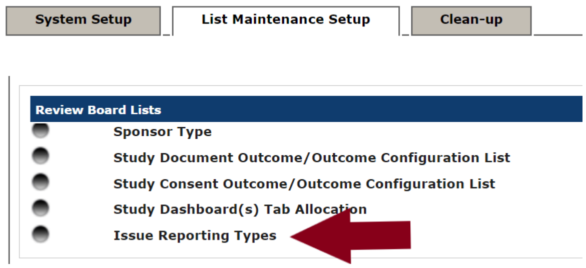
*Note that the **Order Number** field is generally used to indicate the priority level of the **Issue Type**, according to the institution's internal policies.*

The record is added to the **Setup Issue Type List**.

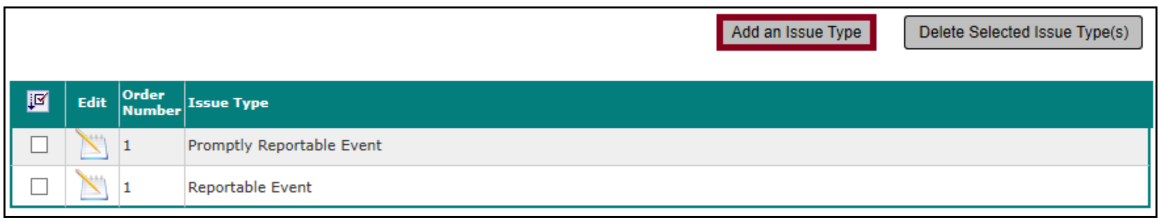


Edit Issue Type

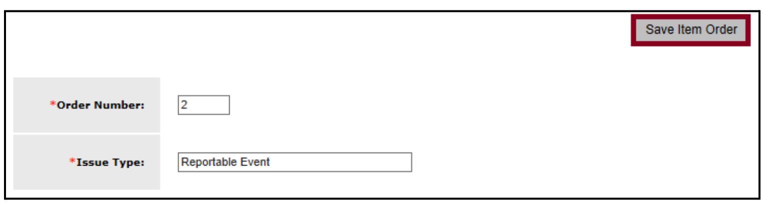
Navigate to IRB Assistant > Review Board Administration > **List Maintenance Setup** tab and click the **Issue Reporting Types** link.



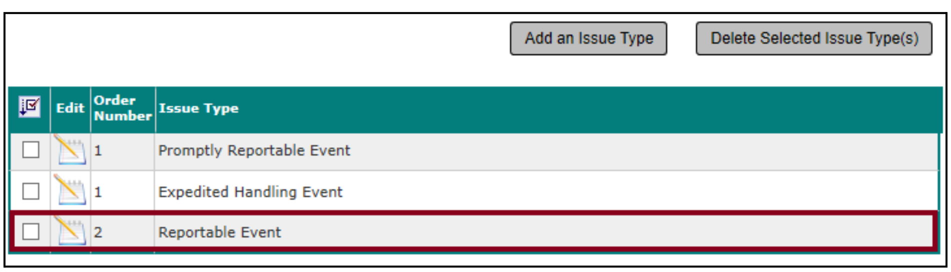
The **Setup Issue Type List** page is opened. Click the **Add an Issue Type** button.



The record is opened in an edit panel.

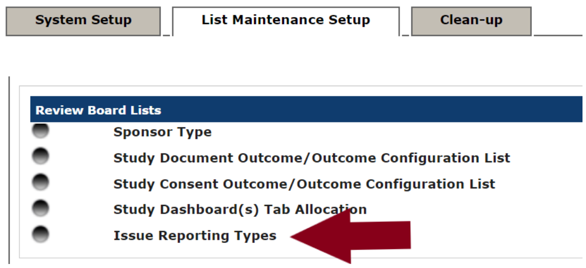


Make desired changes and click the **Save Item Order** button to save the record and close the edit panel. The record is revised on the **Setup Issue Type List**.

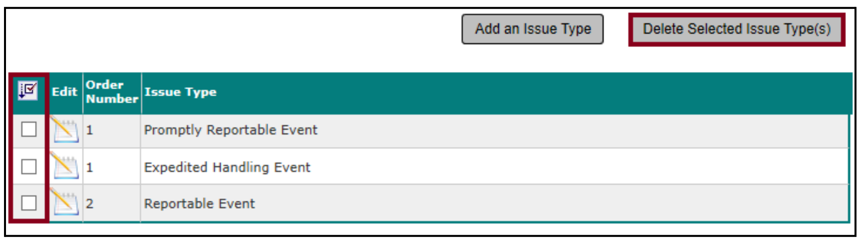


Delete Issue Type

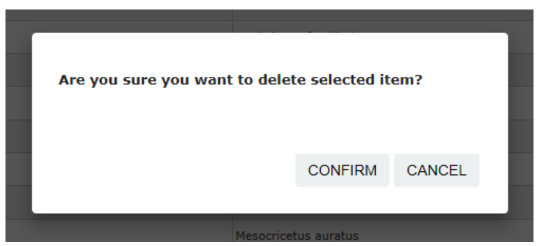
Navigate to IRB Assistant > Review Board Administration > **List Maintenance Setup** tab and click the **Issue Reporting Types** link.



The **Setup Issue Type List** page is opened. Select the checkbox(es) in the far-left column for the record(s) to be deleted and click the **Delete Selected Issue Type(s)** button.



A confirmation popup window displays.



Click **CANCEL** to close the popup without deleting the record and return to the **Setup Issue Type List** page.

Click **CONFIRM** to complete deletion of the record and return to the **Setup Issue Type List** page. The record is deleted from the list on the **Setup Issue Type List** page.