



IRB ASSISTANT

Review Board Administration

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Contents

- Introduction..... 1
- Review Board Limited Administrative Rights..... 1
- Review Board Member History.....3
- Common Rule Display.....7
- Sync Documents with Other Boards When Doing Parallel Submissions..... 9
- System Setup Tab.....10
 - Download/Upload Board Configurations..... 11
 - Copy Configurations..... 12
- Board Definition.....16
 - Board Configuration Options..... 17
- Broadcast Notice.....19
 - Add a Broadcast Notice..... 19
 - Draft Notice..... 23
 - Edit a Broadcast Notice.....24
 - Delete a Broadcast Notice..... 26
- Setup Committee List..... 27
 - Edit Committee.....27
 - Add Committee.....28
 - Delete Committee..... 29
- Setup Review Board Roles..... 30
 - Edit Board Role..... 32
 - Add Board Role..... 35
 - Delete Board Role..... 37
- Setup Role Access..... 38
- Setup Consent Checklist..... 40
 - Change Consent Checklist Item Order..... 41
 - Add Consent Checklist Item.....41
 - Edit Consent Checklist Item..... 42
 - Delete Consent Checklist Item.....44
- Setup Electronic Document Stamp..... 45

Add Electronic Document Stamp.....	45
Edit Electronic Document Stamp.....	49
Delete Electronic Document Stamp.....	52
Setup Study Numbering.....	53
Setup Agenda Categories.....	55
Agenda Filter.....	56
Add Agenda Filter.....	57
Edit Agenda Filter.....	58
Delete Agenda Filter.....	59
Filter User Defined.....	60
Add Agenda Category.....	66
Edit Agenda Category.....	69
Delete Agenda Category.....	71
Document Templates.....	72
Using Merge Codes in Document Templates.....	73
Merge Code List.....	75
Merge Codes Applicable to Animal Resource Center (ARC).....	76
Merge Codes Applicable to Meetings.....	76
Setup Consent Template.....	77
Add Consent Template.....	78
Edit Consent Template.....	83
Delete Consent Template.....	88
Setup Consent Builder Template.....	88
Add Consent Builder Template.....	89
Edit Consent Builder Template.....	91
Delete Consent Builder Template.....	93
Setup Bundle Email Template.....	94
Setup Finalized Agenda Document Template.....	99
Setup Agenda Revision Document Template.....	104
Setup Expedite Report Template.....	105
Setup Meeting Minutes Template.....	106
Setup Outcome Letter Groups.....	107

Add Outcome Letter Group.....	109
Edit Outcome Letter Group.....	112
Delete Outcome Letter Group.....	114
Setup Outcome Letter Templates.....	114
Add Outcome Letter Template.....	115
Edit Outcome Letter Template.....	118
Delete Outcome Letter Template.....	120
Setup Invoice Template.....	121
Add Invoice Template.....	121
Edit Invoice Template.....	123
Delete Invoice Template.....	124
Setup Correspondence Templates.....	125
Add Correspondence Template.....	126
Edit Correspondence Template.....	127
Delete Correspondence Template.....	129
Setup Invoice Type.....	130
Add Invoice Type.....	130
Edit Invoice Type.....	131
Delete Invoice Type.....	132
Setup Canned Motion.....	133
Add Canned Motion.....	134
Edit Canned Motion.....	136
Delete Canned Motion.....	138
Setup Template Language.....	139
Add Template Language.....	141
Edit Template Language.....	142
Delete Template Language.....	144
Setup Review Cycle.....	145
Add Review Cycle.....	146
Edit Review Cycle.....	147
Delete Review Cycle.....	148
Setup Submission Codes.....	150

Setup Submission Outcome Validation.....	153
Add Submission Outcome Validation.....	154
Edit Submission Outcome Validation.....	163
Delete Submission Outcome Validation.....	170
Setup COI Status KSP / KPP Display.....	171
Setup Review Board Metrics Teams.....	173
Add Review Board Metrics Team.....	173
Edit Review Board Metrics Team.....	177
Delete Review Board Metrics Team.....	179
Setup Submission Status Graph.....	181
Setup Review Board Groups.....	183
Add Review Board Group.....	184
Edit Review Board Group.....	188
Delete Review Board Group.....	191
Review Board Notification Setup.....	192
List Maintenance Setup Tab.....	193
Clean-up Tab.....	193
Transfer outstanding tasks.....	193
Document Management.....	195
Find a Study Results Section.....	197
Merging Document Versions.....	198

Introduction

The designated Review Board Administrator sets up and manages IRB configuration lists, review board options and roles, notifications, various types of document templates and module settings under IRB **Board Administration**, accessed via IRB Assistant > Review Board Administration.

The screenshot displays the IRB Assistant interface for Board Administration. At the top, there is a navigation bar with 'My Workspaces' (dropdown), 'IRB', and 'Board Administration' (with a 'Back' button). Below this are three buttons: 'Download Board Configurations', 'Upload Board Configurations ...', and 'Copy Selected Configurations'. A secondary navigation bar features three tabs: 'System Setup', 'List Maintenance Setup', and 'Clean-up'. The main content area is split into two columns:

- Review Board System Setup:**
 - Board Definition
 - Board Configuration Options
 - Broadcast Notice
 - Setup Committee List
 - Setup Review Board Roles
 - Setup Role Access
 - Setup Consent Template
 - Setup Consent Builder Template
 - Setup Consent Checklist
 - Setup Electronic Document Stamp
 - Setup Study Numbering
 - Setup Agenda Categories
 - Setup Finalized Agenda Document Template
 - Setup Agenda Revision Document Template
 - Setup Expedite Report Template
 - Setup Meeting Minutes Template
 - Setup Management Plan
 - Setup Outcome Letter Groups
 - Setup Outcome Letter Templates
 - Setup Invoice Template
 - Setup Invoice Type
 - Setup Canned Motion
 - Setup Correspondence Template
 - Setup Review Cycle
 - Setup Submission Codes
 - Setup Submission Outcome Validation
 - Setup COI Status KSP/KPP Display
 - Setup Review Board Metrics Teams
 - Setup Submission Status Graph
 - Setup Review Board Groups
- Review Board Notification Setup:**
 - Review Response Notification Setup
 - Continuing Review Notification Setup
 - Follow-up Study Notification Setup
 - Reviewers Notification Setup
 - Internal Documents Notification
 - Internal Routing Notification
 - Pre Review Assignment Notification
 - Submission Meeting Assignment Notification Setup
 - Meeting Agenda And Minute Notification
 - Meeting Attendance Notification Setup
 - Designated Review to be placed on the Agenda Notification
 - Outcome Letter Notification
 - Outstanding Stipulations Notification
 - Special Purpose Forms Response Notification Setup
 - Inactivity Submission Notification Setup
 - Task Inactivity Submission Notification Setup

Review Board Limited Administrative Rights

The rb.use_limited_admin_rights property under Board Configuration > Board Setup toggles the limited administrator rights option off and on.

My Workspaces ▾ IRB Setup Board Properties Back

RB Properties List Download Properties Script Save After Edit

- Board Setup
- Submission Review Properties
- Document Processing
- Study Summary Info
- Consent Processing
- Reviewers
- Meeting Settings
- Security
- Fee tracking
- Multi-site Setup
- Recommendations and Stipulations
- Study Board Properties
- Amendments
- Submission Prereview
- Letter
- Submissions
- Notification
- Internal Routing
- Training

Property Name	Property Value
rb.allow_change_of_study_status_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_child_risk_assigned_list	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_document_outcome_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_grants_gov_revisions	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_issue_reporting_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_regulatory_determination1_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_regulatory_determination2_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_review_outcome_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_reviewer_rank_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_risk_assigned_list	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_SRB_approval	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_termination_reason_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.Auto_expire_exempt_protocols	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.display_dashboard_tab_allocation	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_date_board_rec_column	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.Edit_Master_Lay_Summary	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.Master_Lay_Summary_Label	Master Lay Summary
rb.notify_use_continuing_review_due	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.number_of_days_to_lock_submission	7
rb.restrict_change_of_rb_number	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.restrict_user_training_to_board_member	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.show_coi_status_table	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.stamp_no_clinic_use	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_auto_expiration	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_auto_select_PI_and_Contact	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_bundle_to_external_source	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_continuing_review_notif_when_full_renewal	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_create_study	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_duplicate_rb_number	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_full_expiration_calculation	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_full_renewal_expiration	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_limited_admin_rights	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_rb_number	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_revise_last_approved_app_on_change_personnel	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_sticky_filters	<input checked="" type="radio"/> Yes <input type="radio"/> No

When this property is set to “Yes” a Limited Administrator Rights selection is made available when granting users administrative board level access.

- Grant IRB Administrative rights
- Grant IRB Junior Administrative rights
- Grant IRB Limited Administrative Rights

Users assigned Limited Administrative Rights have access to the items shown below under Review Board Administration. Board members can be assigned access to view and edit notifications and letter templates when board level role access is set.

My Workspaces ▾ IRB **Board Administration** ⌵ Back

System Setup

Review Board System Setup	Review Board Notification Setup
<ul style="list-style-type: none"> ● Setup Role Access ● <u>Setup Finalized Agenda Document Template</u> ● Setup Agenda Revision Document Template ● Setup Expedite Report Template ● Setup Meeting Minutes Template ● Setup Outcome Letter Templates ● Setup Invoice Template ● Setup Invoice Type ● Setup Canned Motion ● Setup Correspondence Template ● Setup COI Status KSP/KPP Display ● Setup Review Board Metrics Teams ● Setup Submission Status Graph ● Setup Review Board Groups 	<ul style="list-style-type: none"> ● Review Response Notification Setup ● Continuing Review Notification Setup ● Follow-up Study Notification Setup ● Reviewers Notification Setup ● Internal Routing Notification ● Submission Meeting Assignment Notification Setup ● Meeting Agenda And Minute Notification ● Meeting Attendance Notification Setup ● Outcome Letter Notification ● Outstanding Stipulations Notification ● Special Purpose Forms Response Notification Setup ● Inactivity Submission Notification Setup ● Task Inactivity Submission Notification Setup

As shown below, users granted this rights level are granted access to the **Review Board Administration** icon in their main workspace, as well as the corresponding menu link.

The screenshot shows the IRB workspace header with a gear icon. Below the header is a large white area containing a circular icon with three people and a gear, labeled "Review Board Administration". Below this icon is a dropdown menu with the following items:

- Review Board Workspace ⌵
- IRB Assistant ▶
- Administration
- IRB Assistant Workspace
- Review Board Administration

Review Board Member History

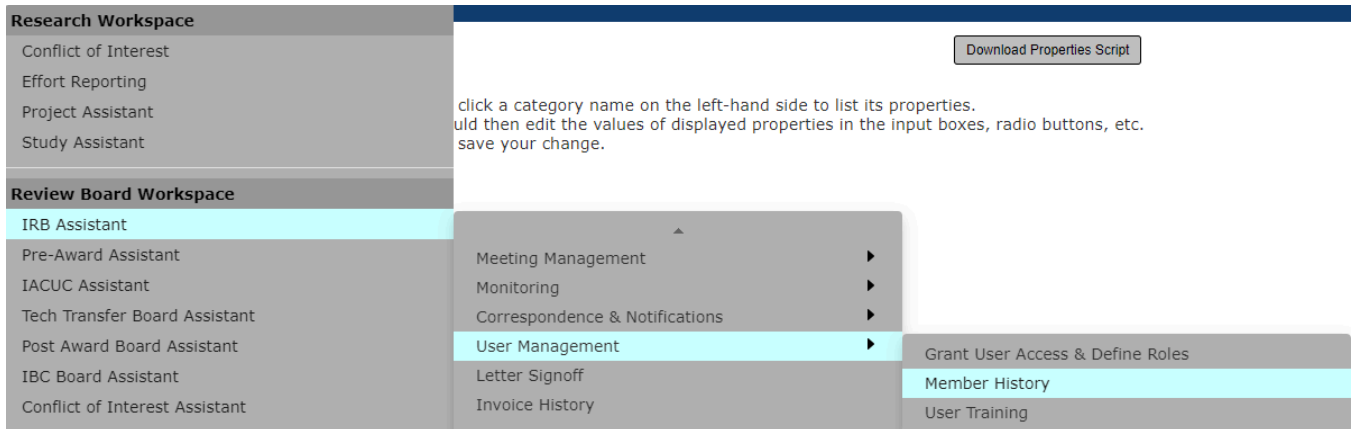
Review board role assignments and changes are recorded in an audit log, regardless of where the assignment or role change was made in the system.

When a user is added to a review board the system creates an audit log entry that includes the username, the start and end dates for the role assignment, the role title, and the name of the user who made the role assignment.

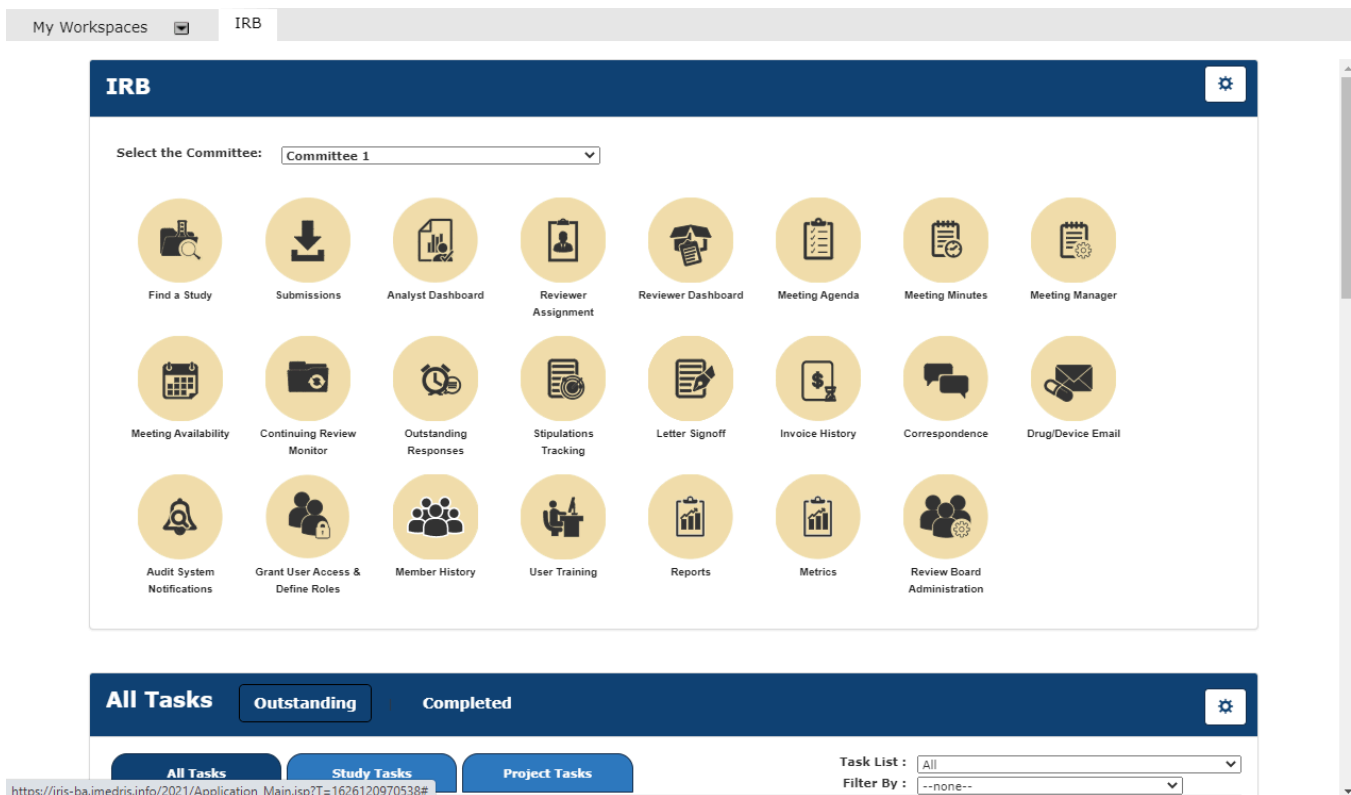
When an existing board member is assigned to a different role on the same board, the system automatically enters the date of the new assignment as the end date for the user’s previous review board role and as the start date for the new review board role. These dates are then saved to the audit log, along with the name of the user being reassigned, the new role title, and the name of the user who made the change.

Review board role assignment history for users is accessible via the [Board Name] Assistant > User Management > **Member History** link, as shown below.

Note: availability of this feature is controlled under Review Board Administration > User Roles and Access, and the menu item shown only populates for users in roles that are granted access.



A **Member History** icon/link is also available in the workspace for users with access to the **Member History** page.



When either link is clicked the **Member History** page opens to the **Active** tab displaying users that are currently active within the board as shown below.

My Workspaces ▾ IRB **Member History** Back

Last Name:

First Name:

Username:

Role:

Specialty:

Group:

Find ...

Active **History** Print Display by Committee: Adverse Event ▾

10 results found... 100 records per page Displaying 1 to 7 >

Name	Role	Specialty	Group
Reviewer, OSF	Board Member		
Smith, Betty	Board Member		Neurology NHLBI
Smith, John	Coordinator	Anesthesiology	Neurology NHLBI
Stewart, Andrew	Coordinator		
Ramirez, Yvette	Coordinator		Neurology Oncology
Administrator	Board Member		
Coordinator, OSF	Coordinator		

Clicking on the **History** tab allows the user to lookup user role assignment history. The search form on the page defaults to a range from the current date going back one year, but the dates can be changed.

My Workspaces ▾ IRB **Member History** Back

Last Name:

First Name:

Username:

Role:

Specialty:

Group:

Status:

Active Between: -

Find ...

Active **History** Print Display by Committee: Adverse Event ▾

10 results found... 100 records per page Displaying 1 to 7 >

Name	Role	Specialty	Group	Status	Start Date	End Date
Reviewer, OSF	Board Member			Active	04/21/2021	
Smith, Betty	Board Member		Neurology NHLBI	Active	02/15/2021	
Smith, John	Coordinator	Anesthesiology	Neurology NHLBI	Active	01/28/2020	
Stewart, Andrew	Coordinator			Active	06/24/2021	
Ramirez, Yvette	Coordinator		Neurology Oncology	Active	06/16/2021	
Administrator	Board Member			Active	10/29/2019	
Coordinator, OSF	Coordinator			Active	04/21/2021	

Enter desired search criteria (**Last Name, First Name, Username, Specialty, Group, Role, Status**, date range) and click the Find button to run the search. Use the **Display by Committee** drop down list at the upper right of the page to filter search results further.

Notice that each user can have multiple history entries, one for each role assignment on each board. A user may also have multiple entries for a role if they held that role for two periods of time.

Click the **Print** button to print the results displayed on the screen. To print all of the records in the result set, change the **records per page** drop down to "All". It is also possible to print to PDF using that browser function.

There are two areas in the system where board role assignments and changes can be entered. The first is the **Grant User Access & Define Roles** page within a review board module, as shown below.

Grant User Access & Define Roles

Name: Analyst, John

Highest Degree Earned:

Specialty:

Relationship to the Institution: Affiliated Non-Affiliated

Affiliations:

Representational Capacity: Scientist Non-Scientist

Representative of Specific Entity:

Group: Oncology

Address:

Primary Number:
Cell Number:
Pager Number:
Fax Number:
Primary Email:

Grant IRB Administrative Rights
 Grant IRB Junior Administrative Rights

Committee Access	Committee Name	Voting Member	Experienced Member
<input checked="" type="checkbox"/>	Committee 1	<input type="checkbox"/>	<input type="checkbox"/>

Roles

- Board Member
- Coordinator
- Chairperson
- Data Entry Member
- Non-Voting Member
- Vice-Chairperson
- Expediting Board Member
- Administrative Assistant
- Ex-Officio Member
- Consultant/Ad Hoc Reviewer
- Alternate Member
 - For: Administrator
 - Member, RB
 - Coordinator
 - michelle, meeche
 - Pithavath, Suchitra
 - Rands, Jeffery, PhD
 - Reviewer, IRB
 - Reviewer, Luke, Ph.D
 - Reviewer, Leia
 - Reviewer, OSF
 - Smith, Betty
 - Stewart, Andrew

Committee Access	Committee Name	Voting Member	Experienced Member
<input type="checkbox"/>	Adverse Event	<input type="checkbox"/>	<input type="checkbox"/>

Roles

- Board Member
- Coordinator
- Vice-Chairperson
- Expediting Board Member

The second is at the System Administration level and is accessed via System Administration > System Administration Workspace > User Accounts > **Assign Access** link for applicable user.

My Workspaces | System Administration | **User Accounts** |

Last Name:

First Name:

User ID:

Status:

Email Address:

Institution:

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

Delete	Switch to User	User Name	Assign Access	User Training	User ID	Primary Department	Login Enabled	Status	Date Created	Notes
<input type="checkbox"/>		1, Coordinator			excoordinator	None Selected	Yes	Active	09/05/2018	
<input type="checkbox"/>		Aarons, Emily			eaarons	GUR - Oncology	Yes	Active	10/15/2020	
<input type="checkbox"/>		Aballay, Alejandro			aaballay	GUR - Oncology	Yes	Active	10/15/2020	
<input type="checkbox"/>		abar, Bijan			abijan	GUR - Pediatric	Yes	Active	10/15/2020	
<input type="checkbox"/>		accpunt1, account			useraccount1	None Selected	Yes	Active	12/18/2018	
<input type="checkbox"/>		Admin, ORA			ORAdmin	GHOSP - Grants Office	Yes	Active	02/22/2018	
<input type="checkbox"/>		Administrator			grant_admin	GHOSP - Grants Office	Yes	Active	10/29/2019	
<input type="checkbox"/>		Analyst, John			john_reviewer	HCRH - Pediatric	Yes	Active	09/06/2018	
<input type="checkbox"/>		Bartz, Raquel			rbartz	None Selected	Yes	Active	10/15/2020	
<input type="checkbox"/>		Boardmember			Mboardmember	GCH - Office of Human Protection	Yes	Active	02/21/2018	

Clicking that icon opens the role assignment page for the applicable user, as shown below.

My Workspaces ▾ System Administration **Assign System Access and Roles for Analyst, John** Back

Full System Administrator: Timesheet Administrator: Designated Department Reviewer:
 System Administrator I: Timekeeper Role: Report Administrator:
 Auditor: CFR Form Designer: Grants Submission Authority:
 Institution Signatory Contact: Department/Site Administrator: Effort Report Administrator:
 Institution Principal Investigator: Global Study Access: Conflict of Interest Form Initiation Role:
 Institution Research Staff: Global Subject Access:
 Global Project Access:
 Veterinarian:

Allow User Access	Default Review Board	Review Board Name	
<input checked="" type="checkbox"/>	<input type="radio"/>	Animal Management Center	<input type="button" value="User Role"/>
<input type="checkbox"/>	<input type="radio"/>	Conflict of Interest	<input type="button" value="User Role"/>
<input type="checkbox"/>	<input type="radio"/>	Export Control	<input type="button" value="User Role"/>
<input type="checkbox"/>	<input type="radio"/>	Flex Board	<input type="button" value="User Role"/>
<input type="checkbox"/>	<input type="radio"/>	IACUC	<input type="button" value="User Role"/>
<input type="checkbox"/>	<input type="radio"/>	IBC Board	<input type="button" value="User Role"/>
<input checked="" type="checkbox"/>	<input type="radio"/>	IRB	<input type="button" value="User Role"/>
<input type="checkbox"/>	<input type="radio"/>	Post Approval Monitoring	<input type="button" value="User Role"/>

Clicking on User Role will allow the user to manage the user’s role on that board.

My Workspaces ▾ System Administration **Assign IRB Roles for Analyst, John** Back

Grant IRB Administrative Rights
 Grant IRB Junior Administrative Rights

Committee Access	Committee Name	Voting Member
<input checked="" type="checkbox"/>	Committee 1	<input type="checkbox"/>

Roles

<input type="radio"/> Board Member	<input type="radio"/> Non-Voting Member	<input type="radio"/> Administrative Assistant
<input checked="" type="radio"/> Coordinator	<input type="radio"/> Vice-Chairperson	<input type="radio"/> Ex-Officio Member
<input type="radio"/> Chairperson	<input type="radio"/> Expediting Board Member	<input type="radio"/> Consultant/Ad Hoc Reviewer
<input type="radio"/> Data Entry Member		<input type="radio"/> Alternate Member

Alternate for:

<input type="checkbox"/> Administrator	<input type="checkbox"/> Reviewer, Luke, Ph.D
<input type="checkbox"/> Member, RB Coordinator	<input type="checkbox"/> Reviewer, Leia
<input type="checkbox"/> michelle, meecho	<input type="checkbox"/> Reviewer, OSF
<input type="checkbox"/> Pithavath, Suchitra	<input type="checkbox"/> Smith, Betty
<input type="checkbox"/> Rands, Jeffery, PhD	<input type="checkbox"/> Stewart, Andrew
<input type="checkbox"/> Reviewer, IRB	

Deactivating, terminating or retiring a user account also places an end date(s) for any role(s) the user holds at that time.

Common Rule Display

A property is available to toggle the display of Common Rule applicability on or off in the system. This feature allows review board members and reviewers to easily identify whether a study is subject to the new 2019 Common Rule or is under the 1991 Common Rule, based on the option chosen in the **Select Categories for Study** drop down select field on the **Outcome** tab.

A new property, rb.use_common_rule_display, has been added under IRB > Review Board Administration > System Configuration. The property defaults to “No” and must be changed to “Yes” in order to enable the changes described in this section.

Find a Study Filters

Display Projects by: IRB Number

Study Alias: [text box]

Sponsor: [text box]

Active Principal Investigator: [text box]

Department: [text box]

IRB Numbers: [text box]

Study Status: All

Study Classification: All

Reference Numbers: [text box]

IRB Expiration Date: [calendar icon] - [calendar icon]

Common Rules: All

Advanced Find Options

Application Find Options

Reset Find Options

Find ...

Download Result(s)

71 result(s) found...

1 - 25

Open	Study Status	IRB Number	2019 Common Rule?	IRB Expiration Date	Study Alias	Principal Investigator	Sponsor
	Open	IRB-19-135	Yes	07/09/2021	BALANCE Trial <i>The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE)trial</i>	Investigator, John	
	Draft	IRB-19-141	Yes		Question Title Alignment <i>Question Title Alignment</i>	Smith, John	
	Draft	IRB-19-173	Yes		Trauma in older population <i>Trauma in older population</i>	Smith, Betty	
	Pending - Submitted for Initial Review	IRB-19-174	Yes		BA 12323 <i>Benefit of Amoxicillin for tonsillitis, bronchitis, and pneumonia</i>	Smith, John	
	Pending - Submitted for Initial Review	IRB-19-175	Yes		Validation <i>Validation</i>	Smith, John	
	Open	IRB-19-180	No	07/29/2021	USCSD -13323 <i>Use of stem cells on subjects currently being treated for Diabetes Type 2</i>	Investigator, John	

As shown in the screenshot above, a column indicating whether the study is under the **2019 Common Rule** (Yes/No displayed depending on the drop down from the **Outcome** tab, shown below) has been added to the **Find a Protocol** page.

Select Categories For Study: Common Rule - Effective January, 2019

New studies being submitted should display “Yes” for the **2019 Common Rule** column.

A new **Common Rule** filter has been added to the search box at the top of the **Find a Study** page. The drop down list includes options to display only “2019 Common Rule Studies”, only “1991 Common Rule Studies”, or “All”. The default setting for this field is “All”.

As shown in the screenshot below, the same changes have been applied to the **Board Submissions** page.

My Workspaces ▾ IRB Board Submissions Back

Close Search

Submission Types: All IRB Expiration Date: [] - []

Active Principal Investigator: [] Reset Find Options

Date Board Received: [] - [] Find ...

IRB Number: All

Ref Number: []

Common Rule: All

Not Assigned Pre-Review Review in Progress Review Complete Returned from Researchers Pending Response Completed Submissions Agendas Print Friendly

Pending Action Outstanding Board Tasks

1 result(s) found. Display Submissions by: IRB Number 1 - 1

Open	Codes	IRB Number	Ref Number	Type	2019 Common Rule?	Date Board Received	IRB Expiration Date	Principal Investigator	Assigned Analyst
	B10 Exmpt	Use of stem cells on subjects currently being treated for Diabetes Type 2 IRB-19-180	001318	Unanticipated Events Form	No	07/12/2021 12:49:34 PM PDT	07/29/2021	Investigator, John	

As shown in the screenshot below, the applicable rule now displays in the Study / Submission header.

My Workspaces ▾ IRB Numbers: IRB-21-464 IRB Unanticipated Events Form Back

PI: Investigator, John

Protocol Items Miscellaneous Submission Forms

Ref Number: 001290 IRB Expiration Date: 06/18/2022 **Common Rule: Common Rule - Effective January, 2019** Study Title: NIH - FD - 94445 - Efficacy and safety of Coronary splints over 180 weeks in USA patients with Multiple Sclerosis

Study Status: Active

Submission Details

- Submission Component(s)
- Pre-review Screening
- Submission Review
- Submission Outcome

Submission Correspondence

Submission Review Status

Submission Received	Analyst Assigned	Analyst Checklist Completed	Review Process Assigned	Reviewer(s) Assigned	All Reviewer(s) Complete	Submission Items Reviewed/Approved	Submission Outcome Assigned	Response Letter Generated	Submission Completed
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General Information

Study Alias: NIH - FD - 94445

Codes: B10 DRG Cov19

Edit the Master Lay Summary

Edit the submission summary

Internal Comments:

Archive Reference Num: 001290

An associated Merge Code (“Common Rule”) has also been added to the system for use in Meeting Minutes, Meeting Agendas and Outcome Letters. The Merge Code field populates with the applicable rule.

Sync Documents with Other Boards When Doing Parallel Submissions

The `rb.use_latest_component_parallel_submission` property, under Review Board Administration > Board Configuration > Submission Review Properties, provides the option to keep documents synchronized across boards in parallel submissions. The default value of this new property is “Yes”, meaning that by default documents are synchronized across boards in parallel submissions.

My Workspaces ▾ IRB Setup Board Properties Back

Download Properties Script Save After Edit

RB Properties List

- Board Setup
- **Submission Review Properties**
- Document Processing
- Study Summary Info
- Consent Processing
- Reviewers
- Meeting Settings
- Security
- Fee Tracking
- Multi-site Setup
- Recommendations and Stipulations
- Study Board Properties
- Amendments
- Submission Previewer
- Letter
- Submissions
- Notification
- Internal Routing
- Training

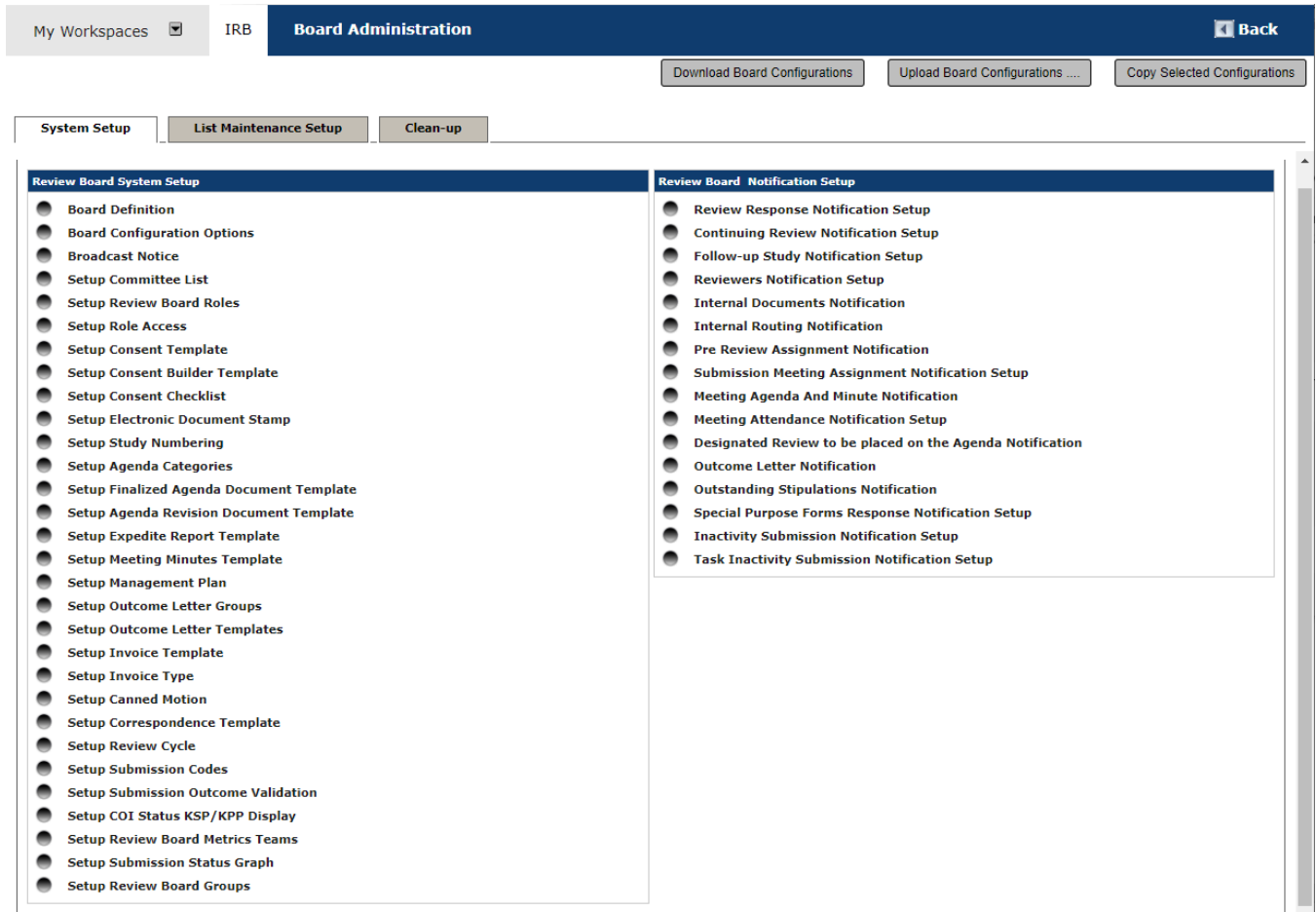
Property Name	Property Value
rb.allow_all_rounds_deletion	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_checkout_on_revised_items_only	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_delete_auto_removed	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_submission_component_revise	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_submission_doc_add	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_submission_doc_delete	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.auto_assign_analyst_on_response	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_exempt	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_irb_of_record	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_master_study_summary	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_Subject_Approved	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_Subject_Justification	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_submission_summary	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.send_expiring_study_notification_to_PI_contact	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.show_contracts_on_outcome_tab	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_agenda_state	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_autocal_expiration	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_conflict_tracking	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_Continuing_Review_notification_if_IRB_Record_NO	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_Continuing_Review_notification_if_SRB_Record_NO	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_coord_view_all_comments	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_DMR_FCR_Polling	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_expiration_calculation_restriction	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_expiration_calculation_restriction_initial_review_only	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_group_matchobjects_prereview	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_latest_component_parallel_submission	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_meeting_approval_date	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_meeting_vote_summary	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_meetings	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_member_checklist	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_member_comments	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_nonhuman_subject_research	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_outcome_letter	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_past_meetings	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_require_meeting_date_for_board_review	<input type="radio"/> Yes <input checked="" type="radio"/> No

When the property is set to “Yes” and the submission goes to multiple boards, any new components attached to the submission by Board A will automatically appear under submission components for Board B as well. This ensures all applicable boards always have the latest components in the submission. Setting this value to “No” maintains the previous functionality, where Board B keeps the original components received in the submission.

Note: When this property is set to “Yes” and Board A returns the submission for corrections at the same time as Board B, study members will always see the latest components in the submission and stipulations, no matter what was returned for corrections.

System Setup Tab

System Setup is the first tab on the IRB **Board Administration** page. This section allows review board administrators to manage general IRB Assistant module setup, define review board details, set up review board roles and access, create document templates and notifications, change labels for data fields within the IRB module, and perform similar module configuration and data management tasks.

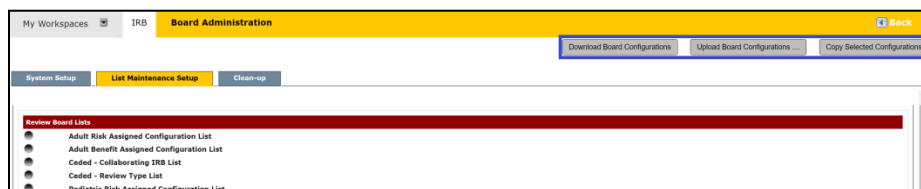


This manual provides information about system configuration items under **Review Board System Setup** (left column in screenshot above).

See the Notifications manual for more information about **Review Board Notification Setup** items (right column in screenshot above).

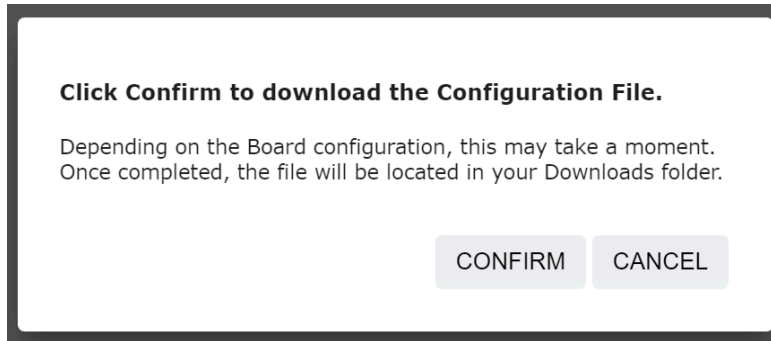
Download/Upload Board Configurations

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.

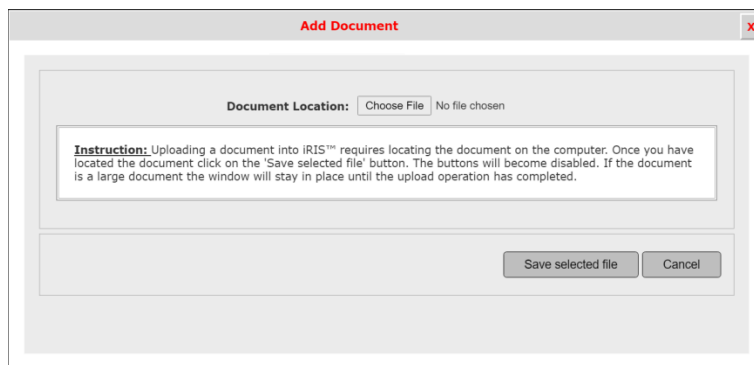
IN THE SOURCE iRIS™ SYSTEM: Click the **Download Board Configurations** button to download a file containing configuration settings for the currently selected IRB review board. A confirmation popup displays, as shown below.



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

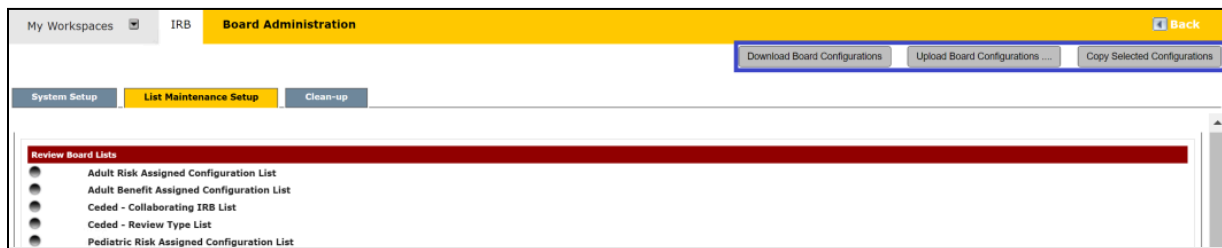
Copy Configurations is a tool that can be made available to full System Administrators (as opposed to those assigned to an Administrator role within a specific iRIS™ module) to help with initial setup of iRIS™ when two or

more similar review boards are needed. The copy tool allows an iRIS™ system administrator to copy pre-existing, fully configured review board elements into a different, newly created review 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.

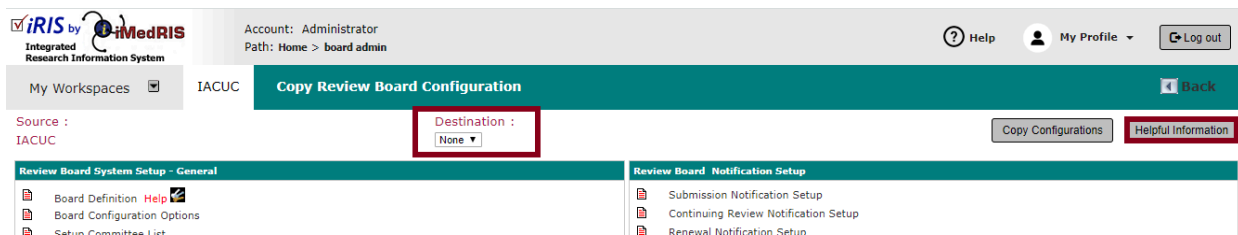
Note that configurations cannot be copied across review boards of different types (IRB to IBC, IRB to ARC, etc.). Within IRB it is only possible to copy configurations across IRB review boards.

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

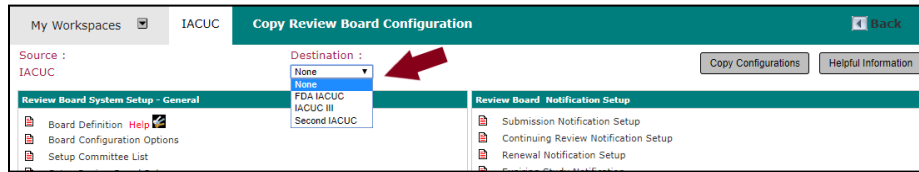


Click the **Helpful Information** button to view a popup containing important information and warnings about copying review board configurations.

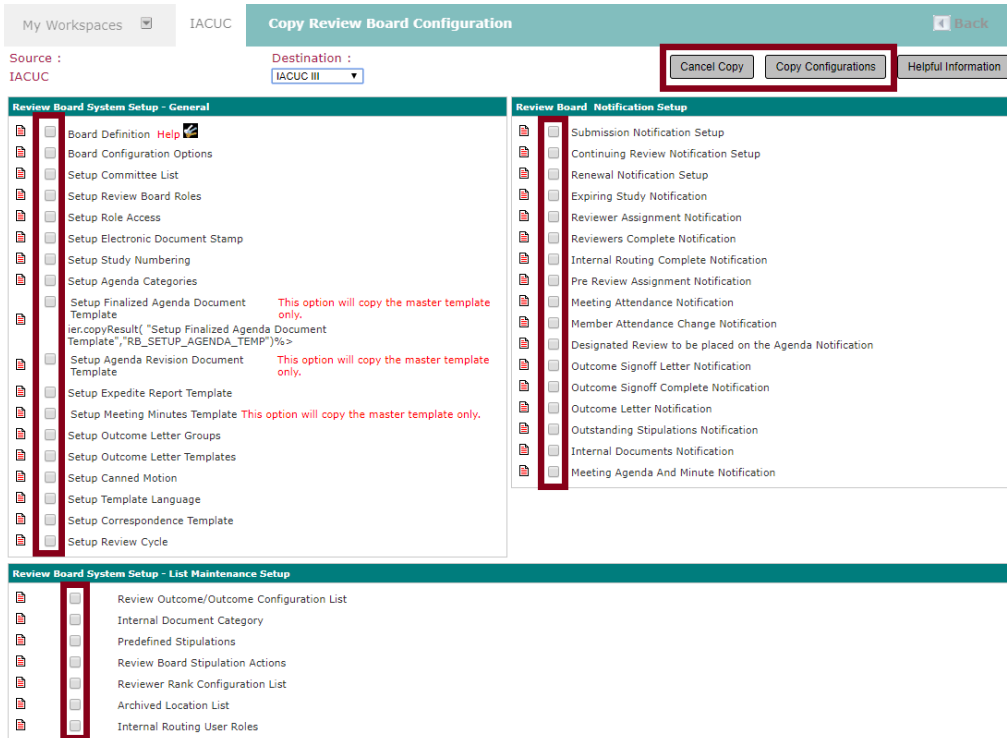


Click the close window button in the upper right corner (marked with a red asterisk) to close the popup.

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).

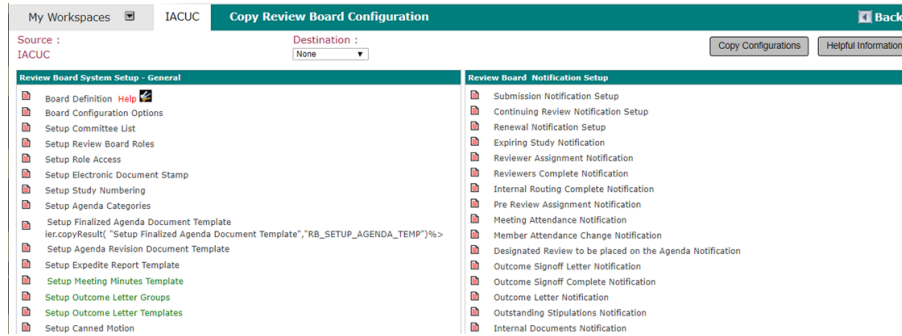
Note that the following configuration items of the **Source** board cannot be copied:

- 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.*

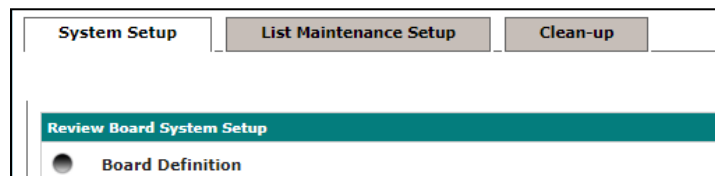


Any items successfully copied are color coded with green text. Items that did not copy successfully are color coded with red text.

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

Board Definition

Review boards are defined, edited and deleted in the Review Board Administration area of IRB Assistant. To define a board, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Board Definition** link.



The **Setup Board** page is opened.

***Review Board Name:**

***Review Board Type:**

Assurance Number:

Assurance Expiration:

Comments:

Primary Address:

Street:

City:

State:

Zip/Postal Code:

Country:

Primary Phone:

Phone Number:

Primary E-mail:

E-mail:

There are two required fields: **Review Board Name** and **Review Board Type**. The **Review Board Type** dropdown list contains predefined board types as specified in the institution’s contract with iMedRIS Data Corporation. The dropdown is disabled on this page, as the review board type has already been pre-defined in System Administration.

An Institutional Review Board (IRB) must have any required Assurance registered in order to receive research support from various funding and resource institutions. For example, an institution must have a Federalwide Assurance (FWA) registered in order to receive Health and Human Services (HHS) support for research involving human subjects.

Where applicable, enter the registered **Assurance Number** and **Assurance Expiration** date. If no Assurance is applicable to the board, skip these fields.

Use the **Comments** field to enter additional notes or comments about the board.

In the **Primary Address** section, enter **Street, City, State, Zip/Postal Code** and **Country**. This is the address that will appear on board documents and correspondences that include a board address.

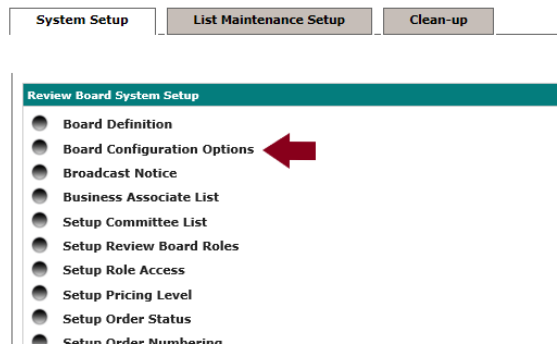
In the **Primary Phone** section, enter the **Phone Number** designated for contacting the board.

In the **Primary E-Mail** section, enter the **E-mail** address designated for contacting the board.

Click the **Save Definition** button at the upper right to save the record.

Board Configuration Options

To set or revise board configuration options, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Board Configuration Options** link.



The **Setup Board Properties** page is opened. This page lists properties the administrator can set within the review board module.

RB Properties List
Download Properties Script

- Board Setup
- Document Processing
- Study Summary Info
- Submission Review Properties
- Reviewers
- Meeting Settings
- Security
- Multi-site Setup
- Recommendations and Stipulations
- Study Board Properties
- Amendments
- Submission Prereview
- Letter
- Submissions
- Notification
- Fee tracking
- Internal Routing
- Training

- Please click a property name on the left-hand side to read its content.
- When it is not read-only, you could edit the value of a property.
- Please save your change.

It is the System Administrator’s responsibility to determine the property settings that best align with the organization’s preferences before making changes.

If assistance is needed to ensure optimal settings, discuss intended changes with iMedRIS personnel before making the changes.

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

Click an item in the **RB Properties List** to load an editable panel containing all properties related to that category.

My Workspaces ▾ IRB
Setup Board Properties
Back

RB Properties List

Download Properties Script
Save After Edit

Property Name	Property Value
rb.allow_adult_benefit_assigned_list	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_adult_risk_assigned_list	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_change_of_business_associate_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_change_of_business_associate_type	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_change_of_device_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_change_of_drug_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_change_of_study_status	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_change_of_study_status_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_child_risk_assigned_list	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_document_outcome_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_grants_gov_revisions	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_issue_reporting_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_regulatory_determination1_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_regulatory_determination2_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_review_outcome_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_reviewer_rank_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.allow_risk_assigned_list	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_SRB_approval	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.allow_termination_reason_list	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.Auto_expire_exempt_protocols	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.display_dashboard_tab_allocation	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.display_date_board_rec_column	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.Edit_Master_Lay_Summary	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.Master_Lay_Summary_Label	Master Lay Summary
rb.notify_use_continuing_review_due	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.number_of_days_to_lock_submission	7
rb.restrict_change_of_rb_number	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.restrict_user_training_to_board_member	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.show_col_status_table	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.stamp_no_clinic_use	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_auto_expiration	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_auto_select_PI_and_Contact	<input checked="" type="radio"/> Yes <input type="radio"/> No
rb.use_bundle_to_external_source	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_continuing_review_notif_when_full_renewal	<input type="radio"/> Yes <input checked="" type="radio"/> No
rb.use_create_study	<input type="radio"/> Yes <input checked="" type="radio"/> No

Where available, Yes/No radio buttons turn the property “on” or “off”. A property with any **Property Value** other than Yes/No radio buttons is a variable.

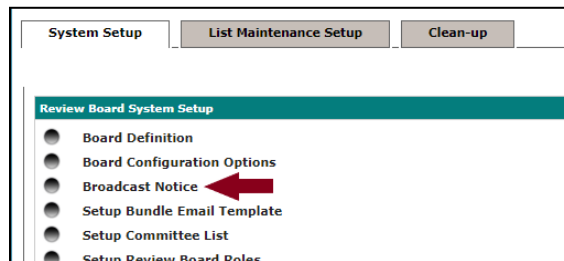
See the IRB Assistant — Properties manual for more information on each individual property.

Broadcast Notice

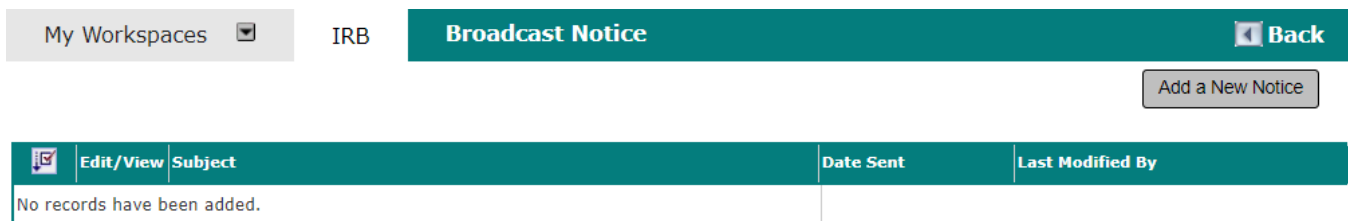
Broadcast Notice allows the system administrator to send an email to review board members and to users on studies associated with the review board. This is a useful tool for sending group alerts and messages.

*Note that the **Broadcast Notice** tool under iRIS™ System Administration—as opposed to System Administration within a module like IRB—can send a message to all users in the iRIS™ system. The System Administrator must be cautious to use the correct **Broadcast Notice** tool for their purposes.*

To access **Broadcast Notice** options, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Broadcast Notice** link.

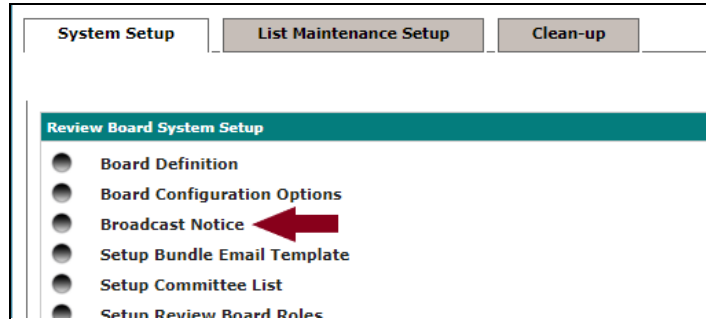


The **Broadcast Notice** page displays any broadcasts previously set up/sent out. The list is empty the first time the page is opened.

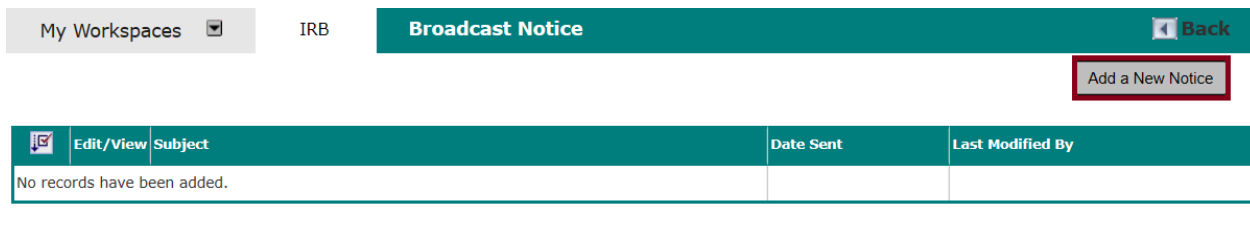


Add a Broadcast Notice

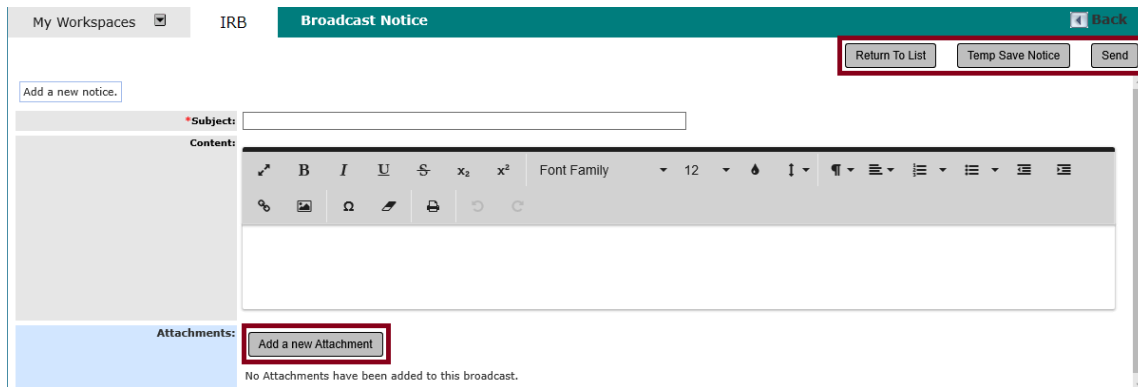
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Broadcast Notice** link.



The **Broadcast Notice** page displays any broadcasts previously set up/sent out. The list is empty the first time the page is opened.



Click the **Add a New Notice** button to create and send a message. The **Add a new notice** panel opens.



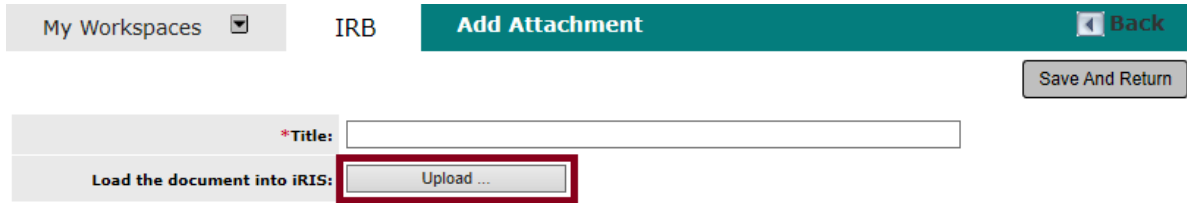
Click the **Return to List** button to cancel and return to the list of broadcast notices.

The **Temp Save Notice** button is used to save a notice draft, explained in greater detail in the Draft Notice subsection of this manual, immediately following the current subsection.

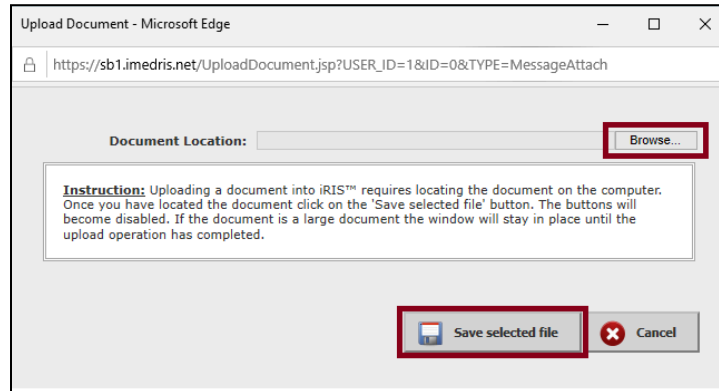
Enter a **Subject** and type, or copy and paste, desired text in the **Content** area. Use the toolbar to format text as desired. Notice that tools for insertion of hyperlinks and images are included.

Click the **Add a new Attachment** button to attach a document file to the notice.

An upload panel opens. Enter the **Title** of the document and click the **Upload** button.



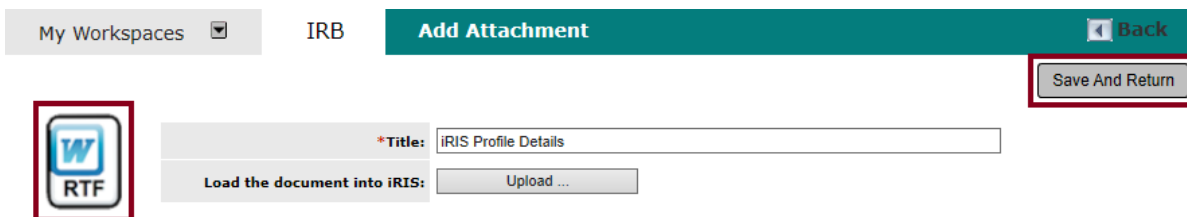
An upload dialog popup window displays.



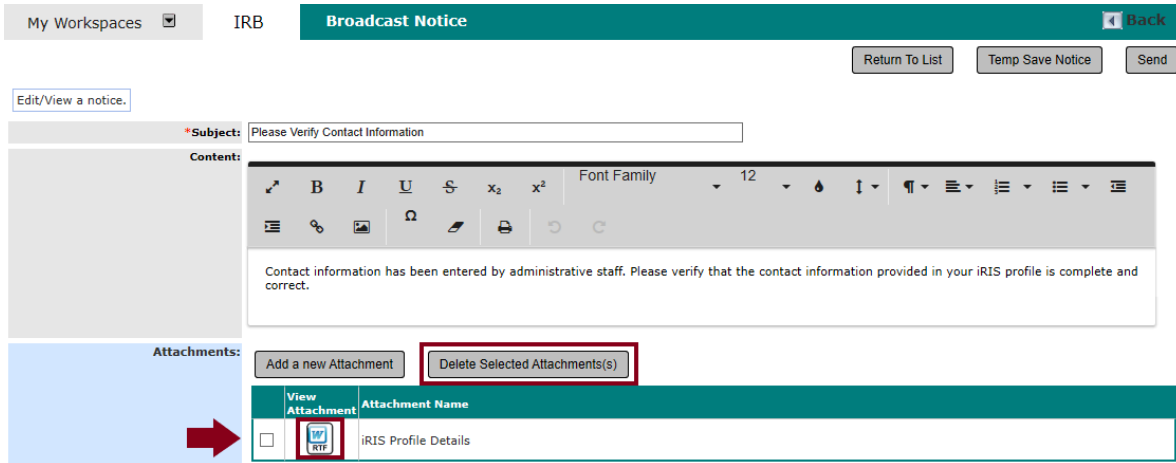
Click the **Cancel** button to close the popup without uploading a document.

Click the **Browse** button to navigate to the document to be uploaded. When the file path is displayed in the **Document Location** field, click the **Save selected file** button to attach it to the notice record.

The **Add Attachment** panel refreshes, displaying an icon for the attachment to the left of the **Title**. Click the **Save and Return** button save the notice and attachment.



The attached document icon displays in a table in the **Attachments** area of the **Edit/View a notice** panel.



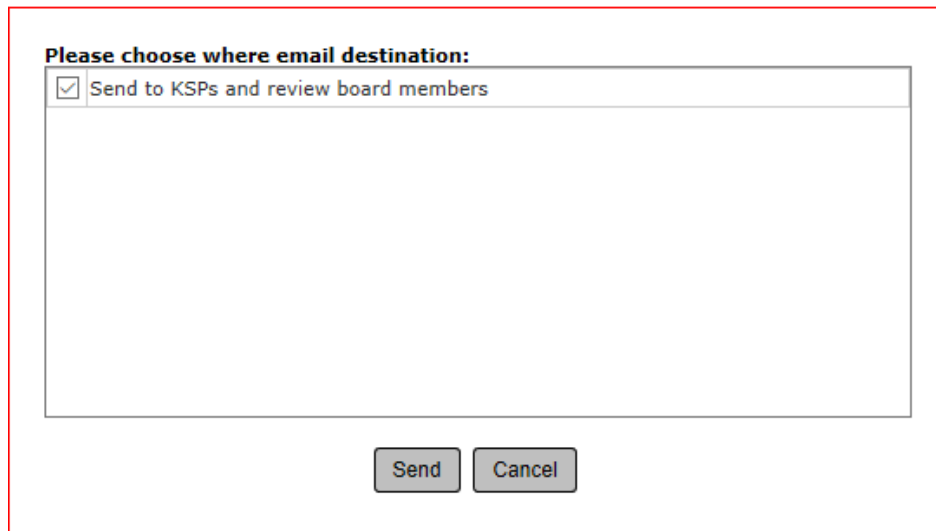
To view an attachment, click its icon.

To remove an attachment, click the select checkbox to the left of the document icon and click the **Delete Selected Attachment(s)** button.

Note that multiple attachments can be added, but users are still subject to institution or email server restrictions on file size for email attachments.

Click the **Send** button at the upper right corner of the **Edit/View a notice** panel to send the notice. A popup email distribution window opens for selection of notice recipients.

Click the **Cancel** button to exit without sending.



Note that **Send to KSPs and review board members** is selected by default when the popup opens. Click the checkbox to deselect that option and unlock the other two options: **Send to all KSPs** and **Send to review board members**.

Please choose where email destination:

<input type="checkbox"/>	Send to KSPs and review board members
<input type="checkbox"/>	Send to all KSPs
<input type="checkbox"/>	Send to review board members

Select the applicable checkbox, then click the popup window **Send** button.

After the notice is sent the **Broadcast Notice** page displays, with the sent broadcast notice added to the list and its **Date Sent** field populated.

My Workspaces	IRB	Broadcast Notice	Back	
		<input type="button" value="Add a New Notice"/>	<input type="button" value="Delete Selected Notice"/>	
	Edit/View	Subject	Date Sent	Last Modified By
		Please Verify Contact Information	August 20, 2019	Administrator

Note that the **Edit/View** icon is still present but the select box at the far left, for notice deletion, is gone. Sent notices can be viewed but cannot be edited or deleted.

Draft Notice

When creating a new notice in the **Add a new notice** panel, it is possible to save the notice as a draft.

My Workspaces	IRB	Broadcast Notice	Back	
		<input type="button" value="Return To List"/>	<input type="button" value="Temp Save Notice"/>	<input type="button" value="Send"/>
Add a new notice.				
*Subject: <input type="text"/>				
Content: <div style="border: 1px solid gray; padding: 5px;"><p>Font Family 12</p><p>B I U </p><p> </p></div>				
Attachments: <input type="button" value="Add a new Attachment"/>				
No Attachments have been added to this broadcast.				

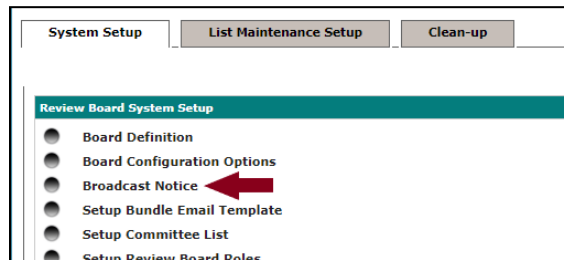
Enter a **Subject** line and desired content, then click the **Temp Save Notice** button to save a draft of the notice and return to the **Broadcast Notice** page. Note that draft notices do not have a **Date Sent** value in the list on the **Broadcast Notice** page.

My Workspaces		IRB	Broadcast Notice		Back
				Add a New Notice	Delete Selected Notice
<input checked="" type="checkbox"/>	Edit/View	Subject	Date Sent	Last Modified By	
		Please Verify Contact Information	September 17, 2019	Administrator	
<input type="checkbox"/>		Please Confirm Office Mail Drop Code		Administrator	

Edit a Broadcast Notice

Draft broadcast notices can be edited (and sent) or deleted. Notices that have been sent cannot be deleted or edited, but they can be viewed.

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Broadcast Notice** link.



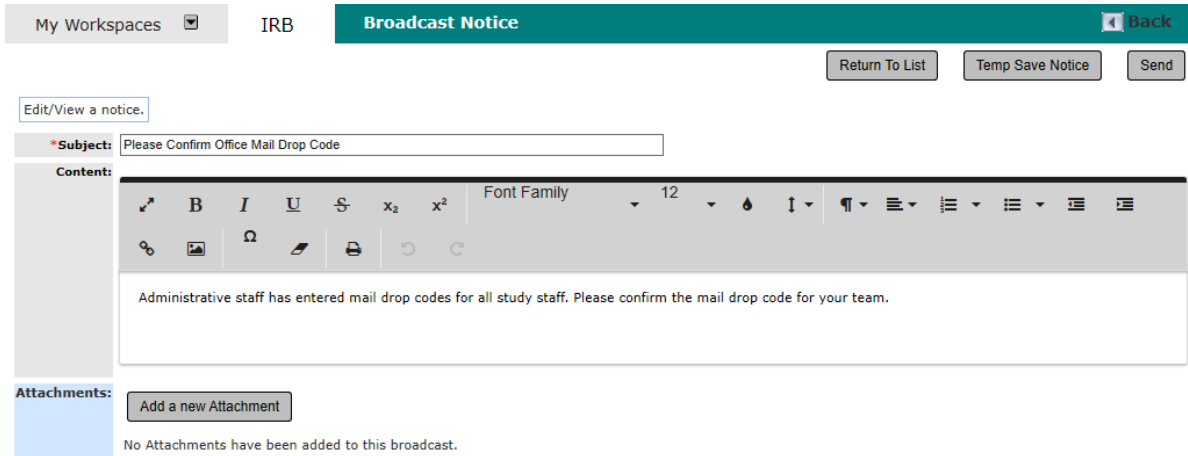
The **Broadcast Notice** page displays any broadcasts previously set up/sent out.

My Workspaces		IRB	Broadcast Notice		Back
				Add a New Notice	Delete Selected Notice
<input checked="" type="checkbox"/>	Edit/View	Subject	Date Sent	Last Modified By	
		Please Verify Contact Information	September 17, 2019	Administrator	
<input type="checkbox"/>		Please Confirm Office Mail Drop Code		Administrator	

Draft notices do not have a value in the **Date Sent** column (see screenshot above), which is how they can be easily identified in the **Broadcast Notice** list.

Click the icon in **Edit/View** column to the left of a draft title to open the draft and resume work on it.

The title of the **Add a new notice** panel changes to **Edit/View a notice** when a draft is opened.

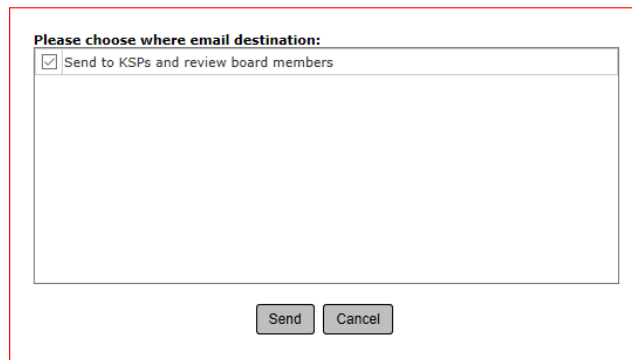


Click the **Return to List** button to return to the Broadcast Notice list page without saving changes.

Click the **Temp Save Notice** button to save changes and keep the notice as a draft.

Click the **Send** button to save changes and send the notice.

A popup email distribution window opens for selection of notice recipients. Click **Cancel** to exit without sending.



Note that **Send to KSPs and review board members** is selected by default when the popup opens. Click the checkbox to deselect that option and unlock the other two options: **Send to all KSPs** and **Send to review board members**.

Please choose where email destination:

<input type="checkbox"/>	Send to KSPs and review board members
<input type="checkbox"/>	Send to all KSPs
<input type="checkbox"/>	Send to review board members

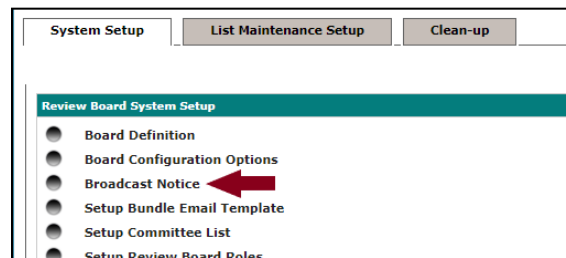
Select the applicable checkbox, then click the popup window **Send** button.

After the notice is sent the **Broadcast Notice** page displays, with the **Date Sent** field populated for the sent notice. Recall that sent notices cannot be edited or deleted.

Delete a Broadcast Notice

Draft broadcast notices can be edited (and sent) or deleted. Notices that have been sent cannot be deleted.

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Broadcast Notice** link.

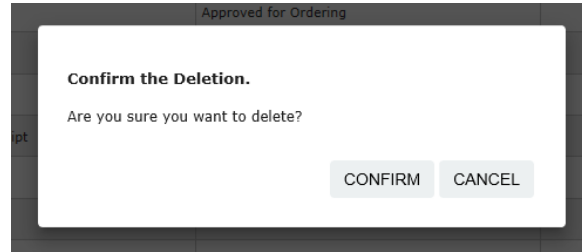


The **Broadcast Notice** page displays any broadcasts previously set up/sent out. Note that the **Date Sent** column is blank for draft notices listed here.

My Workspaces		IRB		Broadcast Notice		Back	
				Add a New Notice		Delete Selected Notice	
<input type="checkbox"/>	Edit/View	Subject	Date Sent	Last Modified By			
<input type="checkbox"/>		Please Verify Contact Information	September 17, 2019	Administrator			
<input type="checkbox"/>		Please Confirm Office Mail Drop Code		Administrator			

Select the checkbox at far left for the applicable notice and click the **Delete Selected Notice** button.

A confirmation popup window displays.

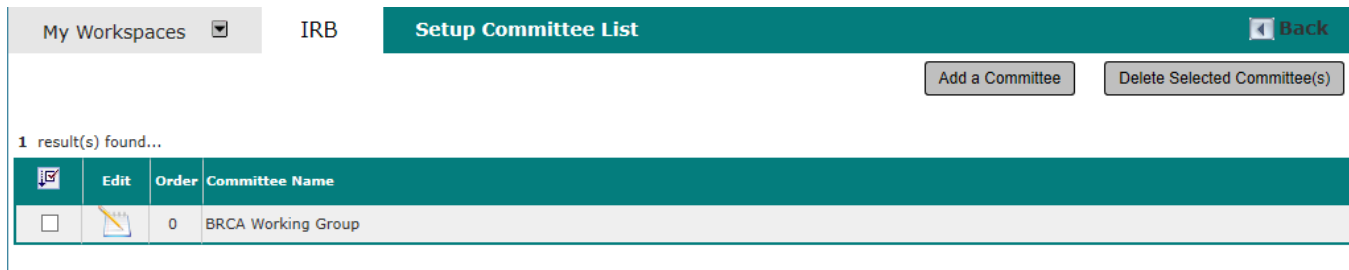


Click **CONFIRM** to delete the notice and return to the **Broadcast Notice** page.

Click **CANCEL** to return to the **Broadcast Notice** page without deleting the notice.

Setup Committee List

The **Setup Committee List** page is where current review board committees can be viewed, edited or deleted, and new committees added.

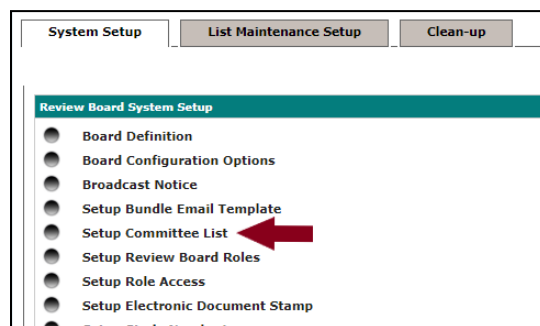


Where the property `rb.use_submission_by_committee` is set to “Yes” the review board is set up for Committee Submissions. In this configuration submissions are routed to individual committees instead of the review board. In addition, members of one committee are unable to access submissions sent to other committees.

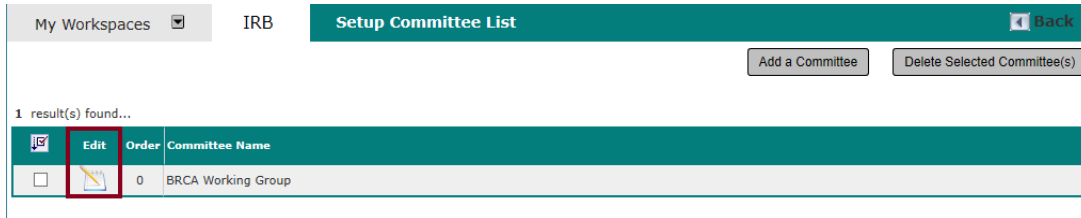
Where the property `rb.use_submission_by_committee` is set to “No” all submissions are routed to the review board submission queue, where they are processed and added to the appropriate committee meeting date. *Note that each committee has its own set of meeting dates.*

Edit Committee

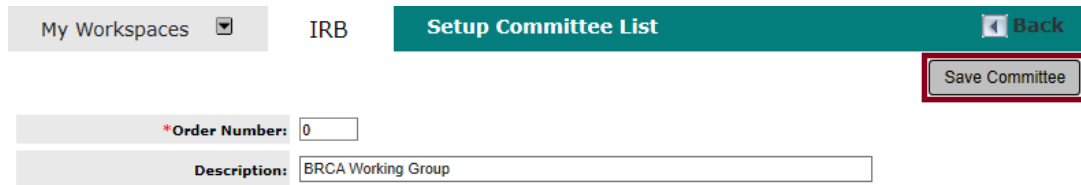
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Committee List** link.



The **Setup Committee List** page is opened. Committees currently assigned to the review board are listed here. Click the icon in the **Edit** column for the applicable committee.



An edit panel opens.



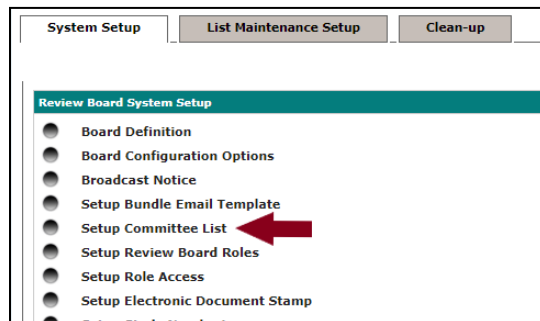
The **Order Number** defines routing priority order for the committee. Routing priority goes in ascending order, beginning with zero. If there is only one committee defined its **Order Number** will always be zero.

The **Description** is the committee name.

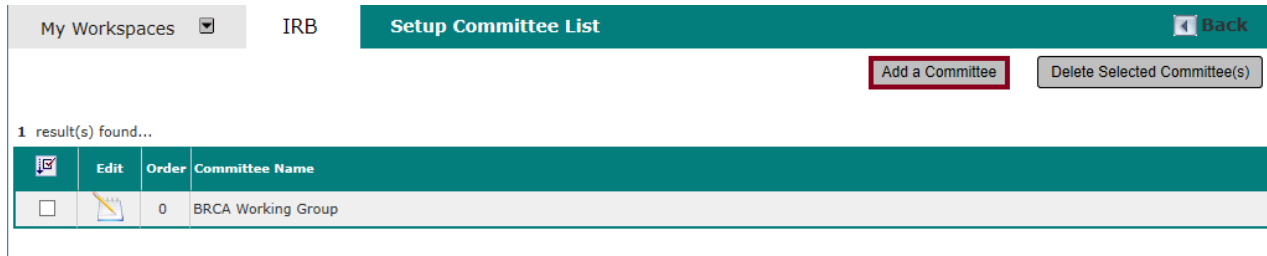
When changes are complete click the **Save Committee** button to save changes and close the edit panel.

Add Committee

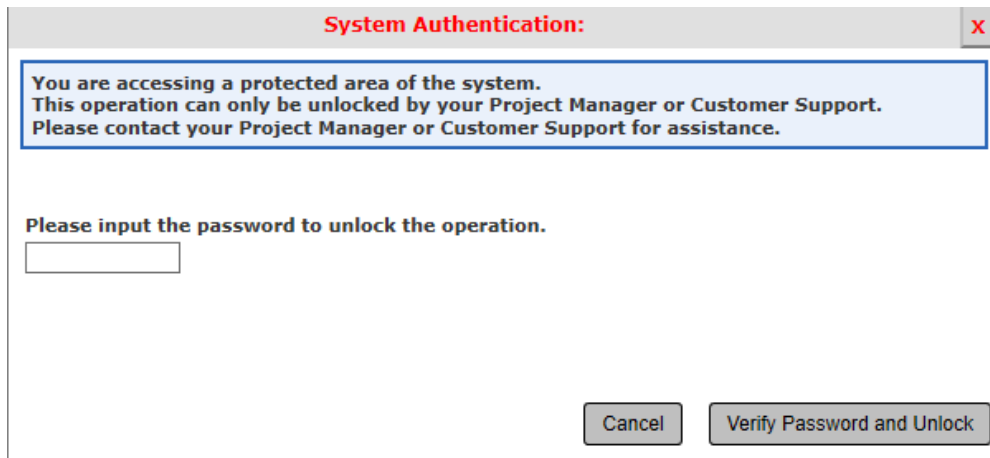
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Committee List** link.



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

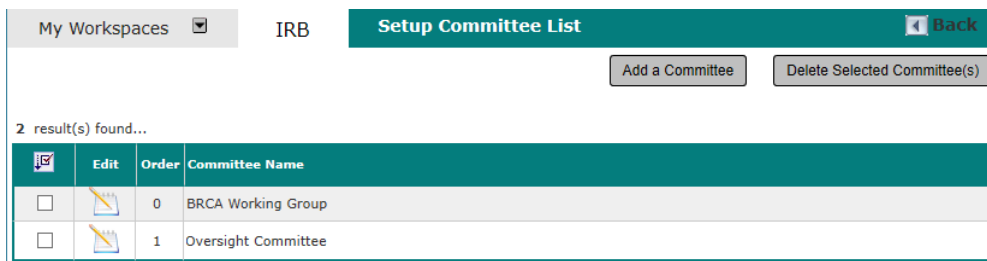


A **System Authentication** popup displays, warning that only iMedRIS Project Managers and Customer Support personnel have the necessary rights to add new review board committees.

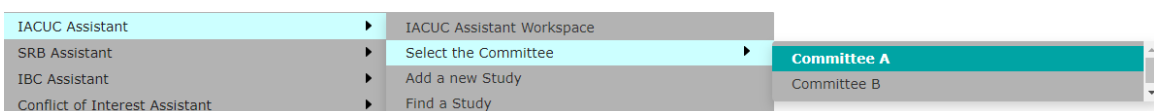


This area is locked because there are costs to the institution for each review board and committee defined in their iRIS™ system.

When an iMedRIS Project Manager or Customer Support representative adds a new committee, it is added to the **Setup Committee List** page.

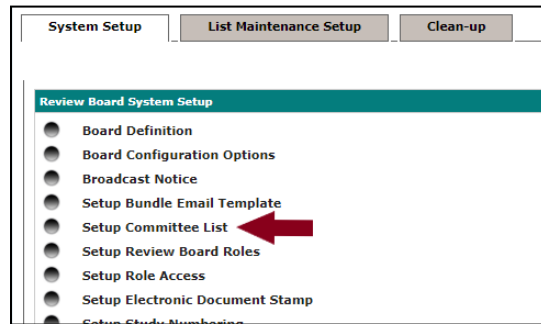


User accounts assigned to more than one review board committee will have a slightly modified main menu, enabling them to select the applicable committee for various tasks.

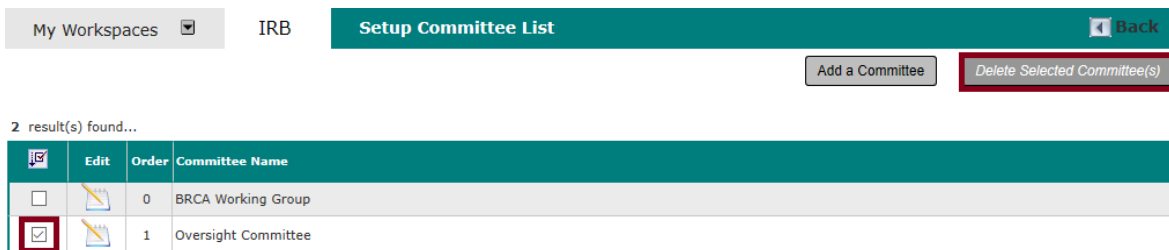


Delete Committee

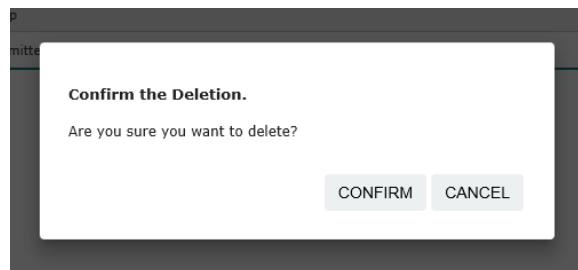
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Committee List** link.



The **Setup Committee List** page is opened. Select the checkbox for the applicable committee(s) and click the **Delete Selected Committee(s)** button.



A confirmation popup displays.



Click the **CANCEL** button to return to the **Setup Committee List** page without deleting the selected committee(s).

Click the **CONFIRM** button to confirm the deletion and return to the **Setup Committee List** page.

Note: caution must be exercised when deleting committees, as deleting a committee with review tasks assigned to it will disrupt and potentially orphan those tasks.

Also recall that review board committees can only be added by designated iMedRIS personnel, so if a needed committee is deleted in error there may be some delay in recreating it.

Setup Review Board Roles

The **Setup Roles List** page is where review board member roles can be viewed, edited or deleted, and new roles added. Each member role can be customized to allow for inclusion or exclusion on agenda and correspondence routing, as well as to allow for or prohibit designation of an alternate iRIS™ user to fulfill the duties of the role when the assigned user is unavailable.

My Workspaces ▾ IRB Setup Roles List ◀ Back

[Add a New Board Role](#)

Filter By In Use: Yes No Find

11 result(s) found... 1 - 10 ▶

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

Filter By In Use is set to “Yes” by default. Select “No” here to display roles that are not currently in use. *Note that this is a toggled setting, it is not possible to view both in use and not in use roles in a single list.*

Columns in the **Setup Roles List** table are:

- **Delete:** where it is possible to delete a role, click the icon in this column to delete a role record; note that the icon does not appear for roles that cannot be deleted
- **Edit:** click the icon in this column to open a role record for editing
- **Order:** priority number of the role for review, signoff and correspondence routing; note that priority numbers are ranked in ascending order from highest to lowest, beginning with one (1) as the highest priority number
- **Role Name:** name assigned to the role; note that role names can be modified by the institution
- **Reserved:** a “Yes” in this column indicates the role is **Reserved** and cannot be deleted; a “No” here indicates the role is not **Reserved** and *can* be deleted, provided it is not currently in use (see next item, below)

- **In-Use:** a “Yes” in this column indicates the role is currently in use on one or more studies / protocols and cannot be deleted; a “No” here indicates the role is not currently in use and can be deleted
- **Allow Alternate:** a “Yes” in this column indicates an alternate person who is included in the Alternate For list under IRB Assistant > User Management > Grant User Access & Define Roles can be selected to fulfill the meeting duties of this role when the primary assignee is unavailable; a “No” here indicates no alternate can be specified for the role
- **Include on Agenda:** a “Yes” in this column indicates users assigned to the role are selectable in the list of Attendees for a meeting date; where the flag is set to “No” users assigned to the role do not display in the meeting Attendees list for a meeting date and are not included in notifications related to the meeting
- **Include in Correspondence:** a “Yes” in this column indicates persons assigned to this role is/are to be included on the correspondence routing list; a “No” here indicates persons assigned to this role is/are not included on the correspondence routing list

As shown below, ten **Reserved** review board roles are predefined by default.

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

Reserved roles are always designated as **In-Use** regardless of whether the applicable role is currently assigned to any studies/protocols.

In the example below, **Filter By In Use** is toggled to “No” to limit the list to **Roles** not currently in use. Notice that the role is not **Reserved**, as indicated by a “No” in that column, and a **Delete** icon is provided for the role.

My Workspaces IRB **Setup Roles List** Back

Add a New Board Role

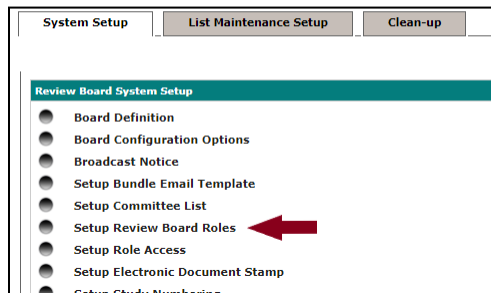
Filter By In Use: Yes No Find

1 result(s) found...

Delete	Edit	Order	Role Name	Reserved	In-Use	Allow Alternate	Include on Agenda	Include in Correspondence
		12	NIH Auditor	No	No	Yes	Yes	Yes

Edit Board Role

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Board Roles** link.



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

My Workspaces IRB **Setup Roles List** [Back](#) [Add a New Board Role](#)

Filter By In Use: Yes No [Find](#)

11 result(s) found... 1 - 10 [▶](#)

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

Filter By In Use is set to “Yes” by default. Select “No” here to display roles that are designated as not in use. *Note that this is a toggled setting, it is not possible to view both in use and not in use roles in a single list.*

Click the icon in the **Edit** column for the role.

My Workspaces ▾ IRB Setup Roles List [Back](#)

[Add a New Board Role](#)

Filter By In Use: Yes No [Find](#)

11 result(s) found... 1 - 10 ▶

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

The role is opened for editing in the **Edit a Board Role** panel. Edit each item in the panel as desired.

My Workspaces ▾ IRB Setup Roles List [Back](#)

[Back To List](#) [Save](#)

Edit a Board Role.

*Order Number:

*In Use: Yes No

*Role Name:

*Allow Alternate for Meetings: Yes No

*Include in Minutes and Agenda?: Yes No

*Include in Correspondence?: Yes No

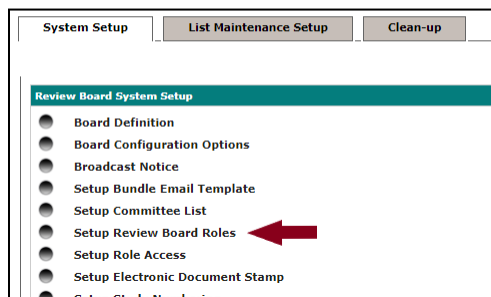
- **Order Number:** priority number of the role for review, signoff and correspondence routing; note that priority numbers are ranked in ascending order from highest to lowest, beginning with one (1) as the highest priority number
- **In-Use:** a selection of “Yes” indicates the role is currently in use on one or more studies / protocols and cannot be deleted; a selection of “No” here indicates the role is not currently in use and can be deleted
- **Role Name:** name assigned to the role; note that role names can be modified by the institution
- **Allow Alternate for Meetings:** a selection of “Yes” indicates an alternate person who is included in the **Alternate Member For** list under IRB Assistant > User Management > Grant User Access & Define Roles can be selected to fulfill the meeting duties of this role when the primary assignee is unavailable, as shown below; a “No” here indicates no alternate can be specified for the role

- **Include in Minutes and Agenda?:** a selection of “Yes” indicates users assigned to the role are selectable in the list of Attendees for a meeting date; where the flag is set to “No” users assigned to the role do not display in the meeting Attendees list for a meeting date and are not included in notifications related to the meeting
- **Include in Correspondence:** a selection of “Yes” indicates persons assigned to this role is/are to be included on the correspondence routing list; a “No” here indicates persons assigned to this role is/are not included on the correspondence routing list

Make desired edits and click the **Save** button to save changes, close the edit panel and return to the **Setup Roles List** page. Click the **Back To List** button to return to the **Setup Roles List** page without saving changes.

Add Board Role

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Board Roles** link.



The **Setup Roles List** page is opened. Click the **Add a New Board Role** button.

My Workspaces ▾ IRB Setup Roles List Back

Add a New Board Role

Filter By In Use: Yes No Find

11 result(s) found... 1 - 10 ▶

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

The **Add a Board Role** panel opens for the role, with the same fields and buttons as the edit panel.

My Workspaces ▾ IRB Setup Roles List Back

Back To List Save

Add a Board Role.

*Order Number:

*In Use: Yes No

*Role Name:

*Allow Alternate for Meetings: Yes No

*Include in Minutes and Agenda? Yes No

*Include in Correspondence? Yes No

*Allow viewing of KSP's COI status? Yes No

Default selections for the **Add a Board Role** panel are shown above. *Note that the **Order Number** field defaults to the next available **Order Number**, based on the existing list of roles.*

Enter the desired **Role Name** and edit other items as desired.

- **Order Number:** priority number of the role for review, signoff and correspondence routing; note that priority numbers are ranked in ascending order from highest to lowest, beginning with one (1) as the highest priority number
- **In-Use:** a selection of “Yes” indicates the role is currently in use on one or more studies / protocols and cannot be deleted; a selection of “No” here indicates the role is not currently in use and can be deleted
- **Allow Alternate for Meetings:** a selection of “Yes” indicates an alternate person who is included in the Alternate For list under IRB Assistant > User Management > Grant User Access & Define Roles can be selected to fulfill the meeting duties of this role when the

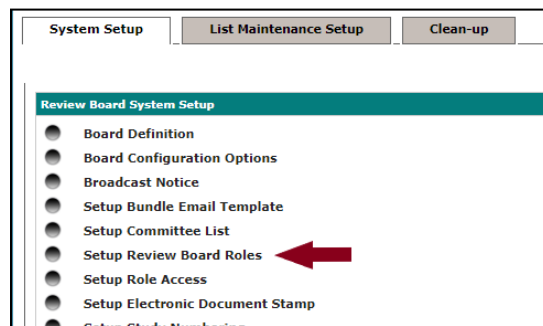
primary assignee is unavailable; a “No” here indicates no alternate can be specified for the role

- **Include in Minutes and Agenda?**: a selection of “Yes” indicates users assigned to the role are selectable in the list of Attendees for a meeting date; where the flag is set to “No” users assigned to the role do not display in the meeting Attendees list for a meeting date and are not included in notifications related to the meeting
- **Include in Correspondence**: a selection of “Yes” indicates persons assigned to this role is/are to be included on the correspondence routing list; a “No” here indicates persons assigned to this role is/are not included on the correspondence routing list
- **Allow viewing of KSP’s COI status**: a selection of “Yes” indicates persons assigned to this role will have access to view the COI status of KSP on a study while reviewing submissions from the Submission Details (Submission Processing) or COI Status page. Information presented is configurable as reviewed later in this document.

Click the **Save** button to save changes and return to the **Setup Roles List** page. Click the **Back To List** button to return to the **Setup Roles List** page without saving changes.

Delete Board Role

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Board Roles** link.



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

My Workspaces ▾ IRB Setup Roles List Back

Add a New Board Role

Filter By In Use: Yes No Find

11 result(s) found... 1 - 10 ▶

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

Because **Reserved** roles and in-use roles cannot be deleted, there are no icons in the **Delete** column for those roles on the **Setup Roles List** page.

Change the **Filter By In Use** option to “No” and click the **Find** button to view a list of roles that can be deleted. Click the icon in the **Delete** column to delete a role.

My Workspaces ▾ IRB Setup Roles List Back

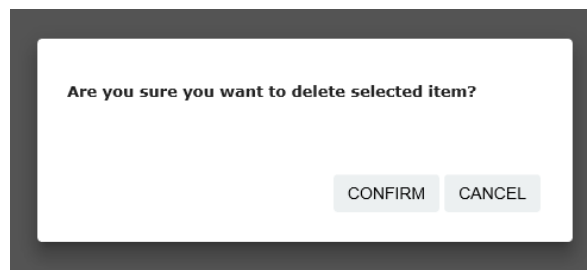
Add a New Board Role

Filter By In Use: Yes No Find

1 result(s) found...

Delete	Edit	Order	Role Name	Reserved	In-Use	Allow Alternate	Include on Agenda	Include in Correspondence
		12	NIH Auditor	No	No	Yes	Yes	Yes

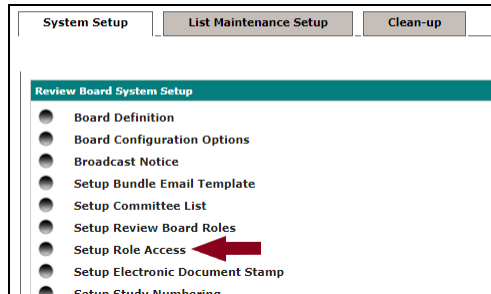
A confirmation popup window appears. Click **CANCEL** to return to the **Setup Roles List** page without saving changes. Click **CONFIRM** to delete the role and return to the **Setup Roles List** page.



Setup Role Access

The **Setup Role Access** page is where the System Administrator assigns read and write access privileges to review board roles for applicable iRIS™ pages.

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Role Access** link.



The **Setup Role Access** page is opened.

The screenshot shows the 'Setup Role Access' page with a 'Save Changes' button in the top right. The main area is a matrix with the following columns: Screen Name, Board Member (Read, Write), Coordinator (Read, Write), Chairperson (Read, Write), Data Entry Member (Read, Write), Non-Voting Member (Read, Write), Alternate Member (Read, Write), Vice-Chairperson (Read, Write), Expanding Board Member (Read, Write), Administrative Assistant (Read, Write), Ex-Officio Member (Read, Write), and Consultant/Ad Hoc Reviewer (Read, Write). The rows list various system pages such as 'Review Board Assistant', 'Submissions Not Assigned', 'Submissions Assigned', 'Submissions Completed', 'Submissions Agenda', 'Submission General Tab', 'Submission Preview Screening Tab', 'Submission Correspondence Tab', 'Submission Review Summary Tab', 'Submission Vote/Ack Tab', 'Submission Outcome Tab', 'Meeting Agenda', 'Find Study', 'Meeting Manager', 'Meeting Manager Set-up Availability', 'Meeting Manager Set-up Schedule', 'Reviewer Assignments', 'Outcome Letter Sign-off', 'Outstanding Response Due', 'Correspondence', and 'User Training'. Each cell in the matrix contains a checkbox for 'Read' and 'Write' permissions.

All applicable iRIS™ pages for the module are listed in a column at the left side of the matrix. Column headers display all applicable review board roles.

The System Administrator assigns **Read** and **Write** privileges for each page by role. The applicable system page is shown in the column at left, and the System Administrator clicks the **Read** and/or **Write** select checkboxes in the role columns at right to assign the applicable rights.

If both are selected, users assigned to the role can view and update records on the applicable page. If the page allows for record deletion, users assigned to a role with both **Read** and **Write** access for the page can delete records on the page as well.

If **Read** is selected but **Write** is not, users assigned to the role can view the applicable page but cannot modify or delete records on the page.

Note that any role with **Write** access must also have **Read** access assigned.

The first two **Read** and **Write** columns do not have an associated role. These columns are used to turn access on or off for the applicable page, regardless of user role. Settings in these columns override settings in the role-specific columns to the right.

Screen Name			Board Member		Coordinator	
	Read	Write	Read	Write	Read	Write
Review Board Assistant	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submissions Not Assigned	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submissions Assigned	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submissions Completed	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submissions Agenda	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submission General Tab	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submission Preview Screening Tab	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submission Correspondence Tab	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Submission Review Summary Tab	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

To make a given page read-only for *all* iRIS™ users, the system administrator selects the **Read** checkbox and de-selects the **Write** checkbox for the page.

To hide a page entirely the System Administrator de-selects both checkboxes for the page.

Where both checkboxes are selected for a given page, the system administrator can assign **Read** and **Write** access per role using the checkboxes in the columns at the right.

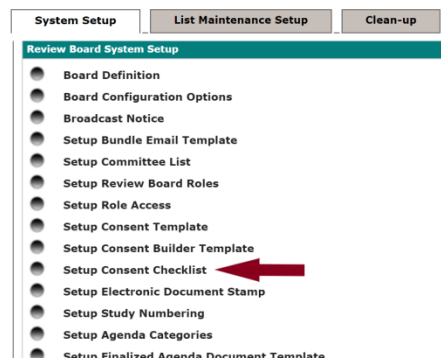
Click the **Save Changes** button to save changes.

Note: The page may take a few moments to save; wait for the page to finish loading before navigating away.

Setup Consent Checklist

The **Setup Consent Checklist** page allows for creation of a consent checklist for the review board to use when evaluating consent forms. Users can also order, edit, and delete existing checklist items.

To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Checklist** link.



The **Setup Consent Checklist** page opens, as shown below.

My Workspaces		IRB	Setup Consent Checklist	Back
				<input type="button" value="Add a New Item"/> <input type="button" value="Delete Selected Item(s)"/> <input type="button" value="Save Checklist"/>
<input type="checkbox"/>	Edit	Checklist Item	Checklist Item	
<input type="checkbox"/>		1	Consent 1	
<input type="checkbox"/>		1	Use a study design to describe all procedures.	

Change Consent Checklist Item Order

The **Checklist Item** column contains the priority order number for items in the list. When the checklist is viewed items appear in ascending order by **Checklist Item**, beginning with “0” (zero).

In the example below, both items have a **Checklist Item** order number of “1” (one), meaning neither is higher priority than the other. These items appear in the checklist in the same order they are shown on this page.

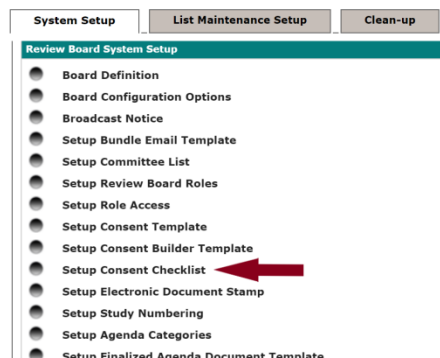
My Workspaces		IRB	Setup Consent Checklist	Back
				<input type="button" value="Add a New Item"/> <input type="button" value="Delete Selected Item(s)"/> <input type="button" value="Save Checklist"/>
<input type="checkbox"/>	Edit	Checklist Item	Checklist Item	
<input type="checkbox"/>		1	Consent 1	
<input type="checkbox"/>		1	Use a study design to describe all procedures.	

To change the priority order, enter the desired order number in the **Checklist Item** column and click the **Save Checklist** button. For example, to make “Use a study design to describe all procedures” the first item in the checklist:

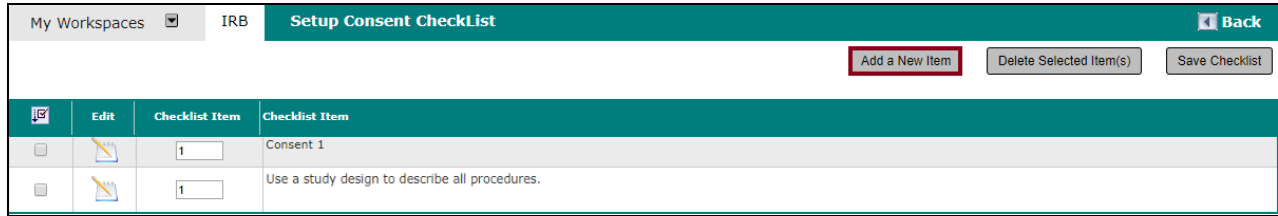
- change the **Checklist Item** number for “Consent 1” from “1” (one) to “2” (two) — OR —
- change the **Checklist Item** number for “Use a study design to describe all procedures” to “0” (zero)

Add Consent Checklist Item

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Checklist** link.

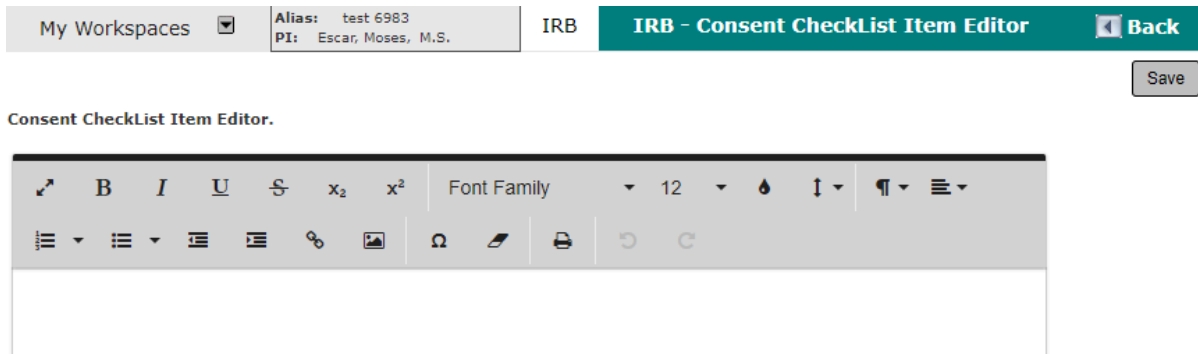


The **Setup Consent Checklist** page opens, as shown below.

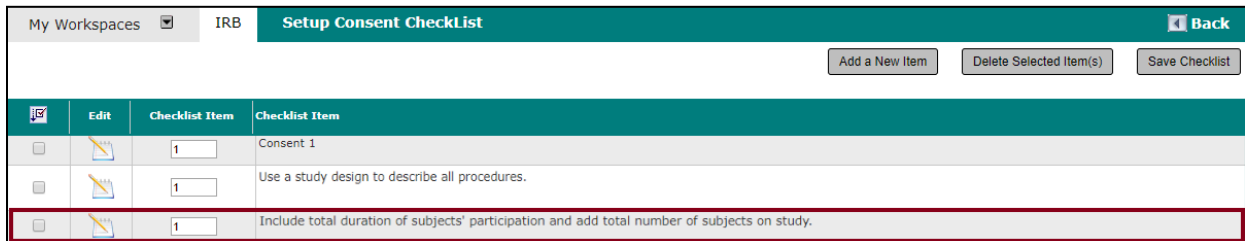


Click the **Add a New Item** button.

The **Consent Checklist Item Editor** opens, as shown below. Enter consent item text and format it as desired, then click the **Save** button (upper right corner) to save changes and close the text editor.

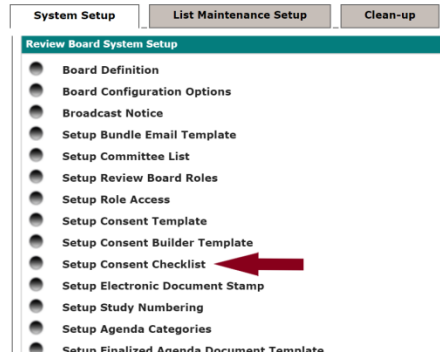


The new item is added to the list of checklist items, as shown below. Notice that it is automatically assigned a **Checklist Item** number of “1” (one), so it is added to the bottom of the list. *See the Change Consent Checklist Item Order section of this manual for details of how to change checklist item order.*

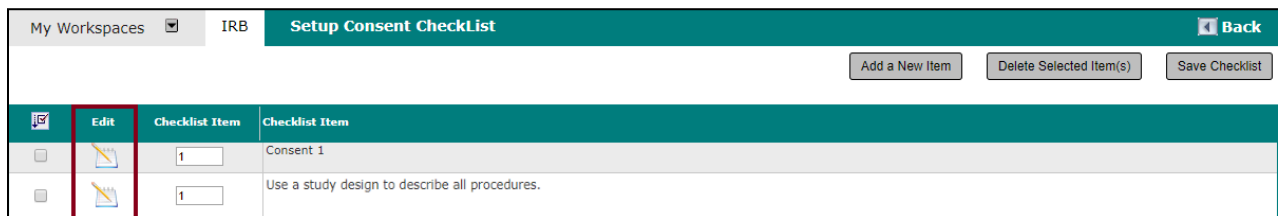


Edit Consent Checklist Item

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Checklist** link.

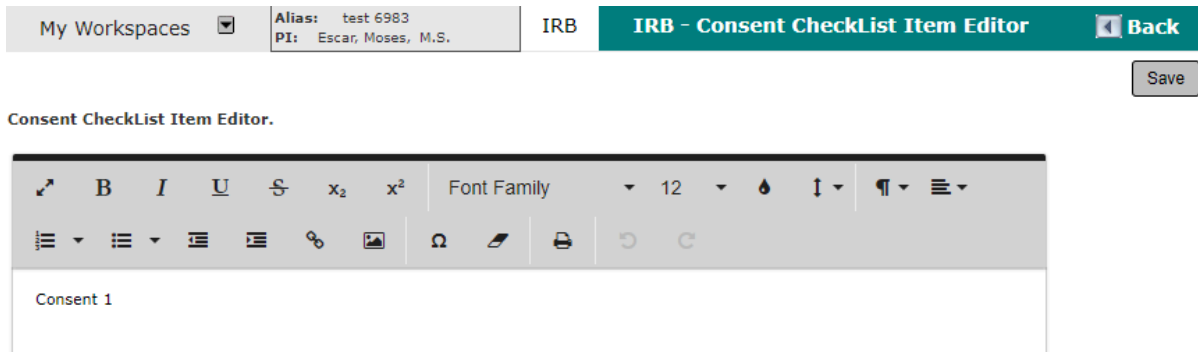


The **Setup Consent Checklist** page opens, as shown below.

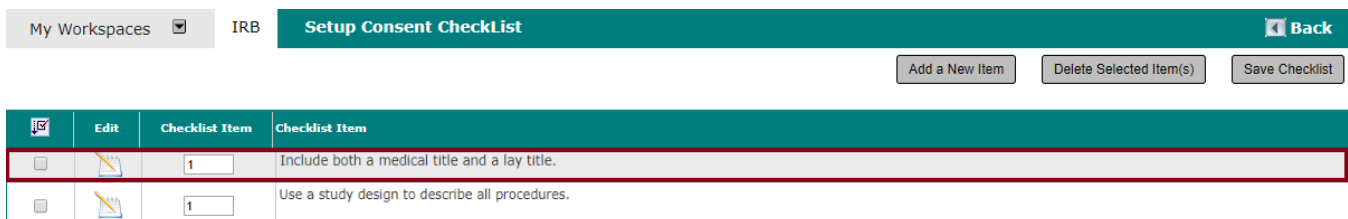


Click the applicable icon in the **Edit** column (see screenshot above).

The **Consent Checklist Item Editor** opens, as shown below. Revise consent item text and format it as desired, then click the **Save** button (upper right corner) to save changes and close the text editor.



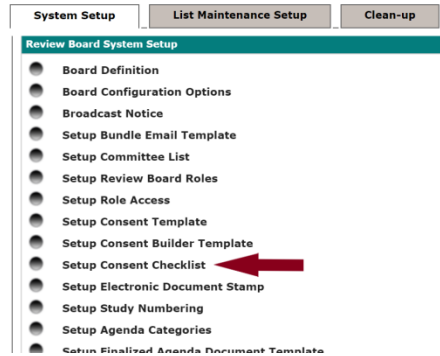
The item is revised in the list of checklist items, as shown below.



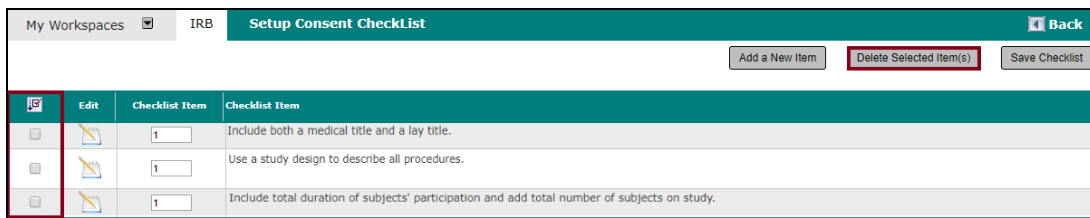
Notice that the revised item retains its **Checklist Item** number of “1” (one), so it remains in the same position in the list. See the *Change Consent Checklist Item Order* section of this manual for details of how to change checklist item order.


Delete Consent Checklist Item

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Checklist** link.

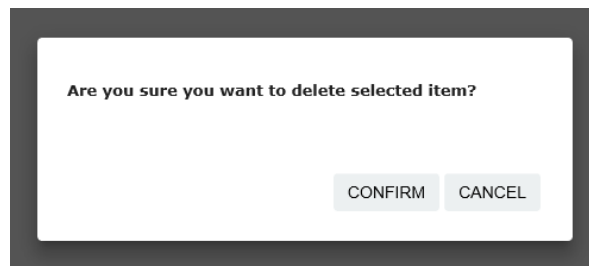


The **Setup Consent Checklist** page opens, as shown below.



Select the checkbox(es) in the far-left column for the item(s) to be deleted. To select or deselect ALL items, click the select icon in the far-left column header (). Click the **Delete Selected Item(s)** button.

A confirmation popup window appears. Click **CANCEL** to close the popup without saving changes. Click **CONFIRM** to delete the checklist item and close the popup.



As shown below, the item is deleted from the list.

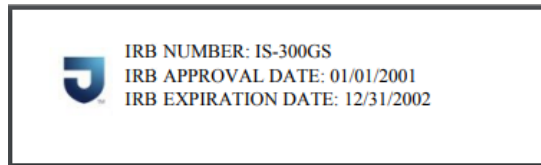
My Workspaces ▾ IRB **Setup Consent Checklist** Back

Add a New Item Delete Selected Item(s) Save Checklist

<input type="checkbox"/>	Edit	Checklist Item	Checklist Item
<input type="checkbox"/>		1	Include both a medical title and a lay title.
<input type="checkbox"/>		1	Use a study design to describe all procedures.

Setup Electronic Document Stamp

The electronic document stamp applies pre-configured review board outcome details to documents in a pre-designated location, as shown in the example below.



Electronic document stamps are configured on the **Setup Document Stamp** page, shown below.

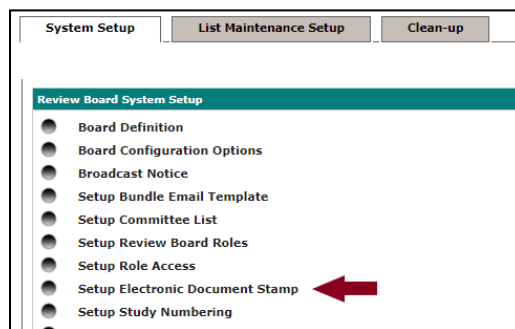
My Workspaces ▾ IRB **Setup Document Stamp** Back

Add a New Stamp Delete Stamp(s)

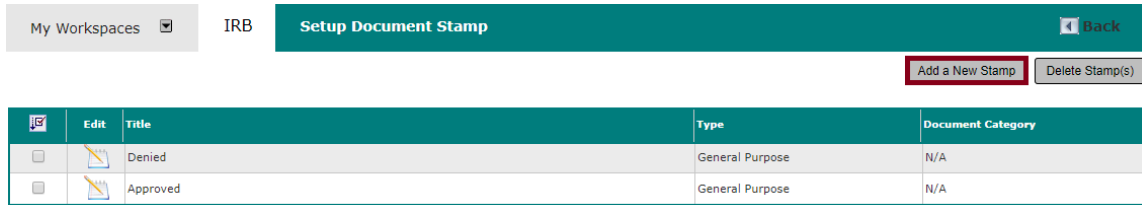
<input type="checkbox"/>	Edit	Title	Type	Document Category
<input type="checkbox"/>		Denied	General Purpose	N/A
<input type="checkbox"/>		Approved	General Purpose	N/A

Add Electronic Document Stamp

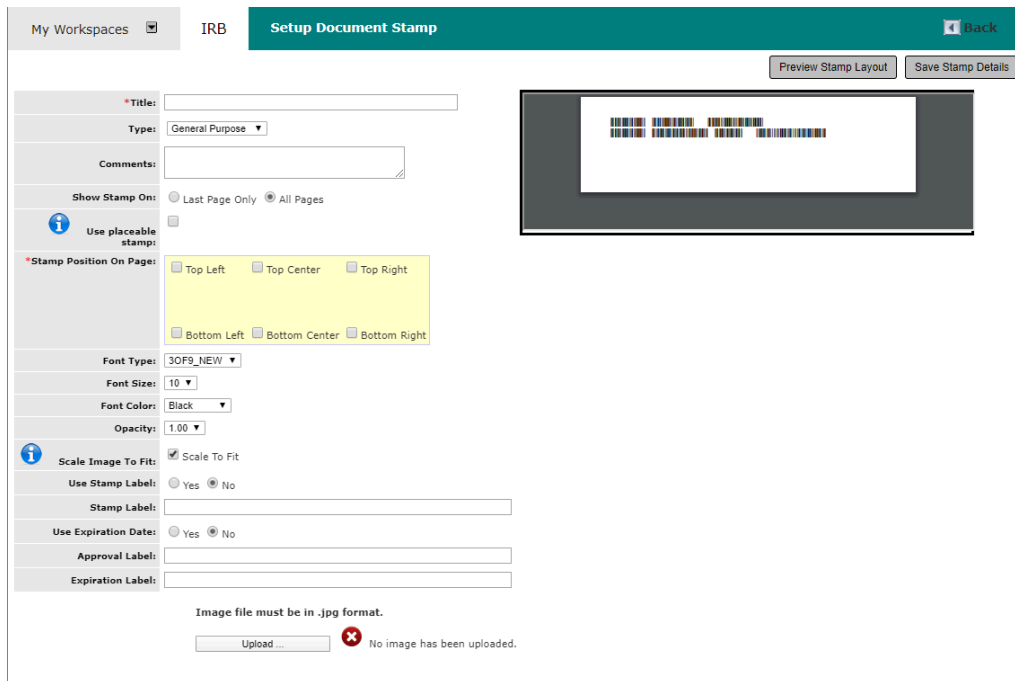
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Electronic Document Stamp** link.



The **Setup Document Stamp** page opens.



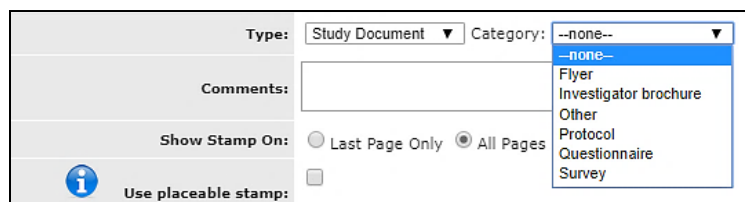
Click the **Add a New Stamp** button. An add panel opens for creation of the new stamp, as shown below.



Notice that some of the fields in the add panel contain default values. Complete the add panel fields as follows.

Title — enter the desired title of the stamp as it will appear in the list on the main **Setup Document Stamp** page list

Type — click in the field to open a dropdown picklist of options, then click on the desired option to select it: General Purpose (used for all documents, including consent and other study documents), Informed Consent (used only on consent forms), and Study Document (used only for other study documents); when Study Document is selected a **Category** dropdown list field appears for selection of the specific document type, as shown below



Note that the study document **Category** list is configured under My Workspaces > System Administration > List Configuration and Maintenance > Site List Setup tab > Study Document Category.

Also note that while it is not visible in the screenshot above, “Consent form” can be included in the configuration list at institutions performing research with human study subjects, or where animal owners are required to provide consent for the use of their animals in research.

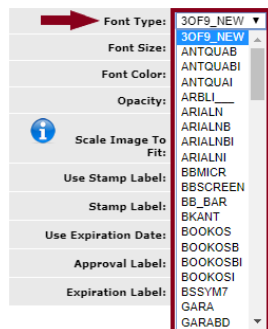
Comments — add any desired comments, such as a description of the stamp type

Show Stamp On —select “Last Page Only” to display the stamp only on the last page, or leave the default value of “All Pages” selected to display the stamp on all pages

Use placeable stamp — select this box to unlock the **Coordinate (from bottom left)** fields, shown below, which allow for exact placement on the document page; entire the desired X/Y coordinates to specify where the stamp should appear relative to the bottom left corner of the document page

Stamp Position On Page — use this field as an alternative to the **Use placeable stamp** option for stamp placement on the page; click to select “Top Left”, “Top Center”, “Top Right”, “Bottom Left”, “Bottom Center” or “Bottom Right”

Font Type — click in the field to open a dropdown list of available font options, then click the desired list item to select it



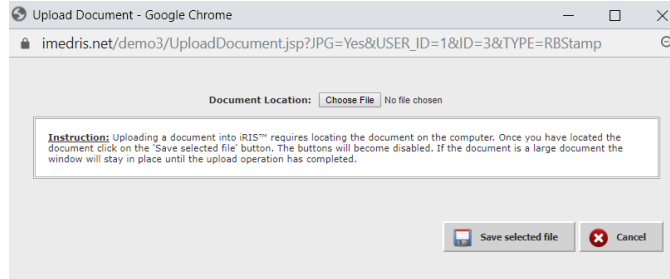
Font Size — click in the field to open a dropdown list of available font size options, then click the desired list item to select it

Font Color — click in the field to open a dropdown list of available font colors, then click the desired list item to select it

Opacity — enter an opacity value between .01 and 1.0, where 1.0 indicates 100% opaque, to set the relative transparency of the stamp

Scale Image to Fit — select this checkbox to automatically scale any uploaded images to fit within the stamp

Click the **Upload** button. An upload dialog box opens, as shown below.



Browse to the desired image file and select it, then click the **Save selected file** button to complete the upload. *Note that the image file must be in JPEG (.jpg, .jpeg) format.*

An example of the completed add panel is shown below.

Click the **Preview Stamp Layout** button to preview the stamp in a popup window.

Click the **Save Stamp Details** button to save the stamp after previewing it. As shown below, the stamp is added to the list on the Setup Document Stamp page.

My Workspaces ▾ IRB **Setup Document Stamp** Back

Add a New Stamp Delete Stamp(s)

<input type="checkbox"/>	Edit	Title	Type	Document Category
<input type="checkbox"/>		Approved Subject to NIH Review	General Purpose	N/A
<input type="checkbox"/>		Denied	General Purpose	N/A
<input type="checkbox"/>		Approved	General Purpose	N/A

Edit Electronic Document Stamp

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Electronic Document Stamp** link.

System Setup | List Maintenance Setup | Clean-up

Review Board System Setup

- Board Definition
- Board Configuration Options
- Broadcast Notice
- Setup Bundle Email Template
- Setup Committee List
- Setup Review Board Roles
- Setup Role Access
- Setup Electronic Document Stamp ←
- Setup Study Numbering

The **Setup Document Stamp** page opens.

My Workspaces ▾ IRB **Setup Document Stamp** Back

Add a New Stamp Delete Stamp(s)

<input type="checkbox"/>	Edit	Title	Type	Document Category
<input type="checkbox"/>		Approved Subject to NIH Review	General Purpose	N/A
<input type="checkbox"/>		Denied	General Purpose	N/A
<input type="checkbox"/>		Approved	General Purpose	N/A

Click the icon in the **Edit** column for the applicable stamp. The stamp is opened in an edit panel, as shown below.

My Workspaces ▾
IRB
Setup Document Stamp
Back

Preview Stamp Layout
Save Stamp Details

* **Title:**

Type:

Comments:

Show Stamp On: Last Page Only All Pages

i **Use placeable stamp:**

* **Stamp Position On Page:**

Top Left
 Top Center
 Top Right

Bottom Left
 Bottom Center
 Bottom Right

Font Type:

Font Size:

Font Color:

Opacity:

i **Scale Image To Fit:** Scale To Fit

Use Stamp Label: Yes No

Stamp Label:

Use Expiration Date: Yes No

Approval Label:

Expiration Label:

Image file must be in .jpg format.

✔
Image has been uploaded.

IRB NUMBER: IS-300GS

IRB APPROVAL DATE: 01/01/2001

IRB EXPIRATION DATE: 12/31/2002

Make desired changes to the stamp fields, described below.

Title — enter the desired title of the stamp as it will appear in the list on the main **Setup Document Stamp** page list

Type — click in the field to open a dropdown picklist of options, then click on the desired option to select it: General Purpose (used for all documents, including consent and other study documents), Informed Consent (used only on consent forms), and Study Document (used only for other study documents); when Study Document is selected a **Category** dropdown list field appears for selection of the specific document type, as shown below

Type:

Category:

Comments:

Show Stamp On: Last Page Only All Pages

i **Use placeable stamp:**

--none--
 --none--
 Flyer
 Investigator brochure
 Other
 Protocol
 Questionnaire
 Survey

*Note that the study document **Category** list is configured under My Workspaces > System Administration > List Configuration and Maintenance > Site List Setup tab > Study Document Category.*

Also note that while it is not visible in the screenshot above, “Consent form” can be included in the configuration list at institutions performing research with human study subjects, or where animal owners are required to provide consent for the use of their animals in research.

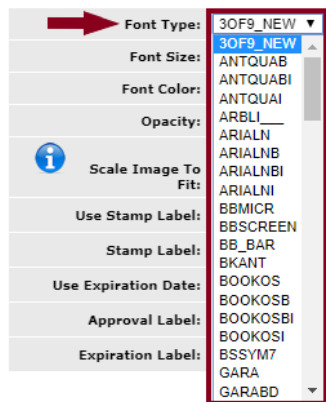
Comments — add any desired comments, such as a description of the stamp type

Show Stamp On —select “Last Page Only” to display the stamp only on the last page, or leave the default value of “All Pages” selected to display the stamp on all pages

Use placeable stamp — select this box to unlock the **Coordinate (from bottom left)** fields, shown below, which allow for exact placement on the document page; entire the desired X/Y coordinates to specify where the stamp should appear relative to the bottom left corner of the document page

Stamp Position On Page — use this field as an alternative to the **Use placeable stamp** option for stamp placement on the page; click to select “Top Left”, “Top Center”, “Top Right”, “Bottom Left”, “Bottom Center” or “Bottom Right”

Font Type — click in the field to open a dropdown list of available font options, then click the desired list item to select it



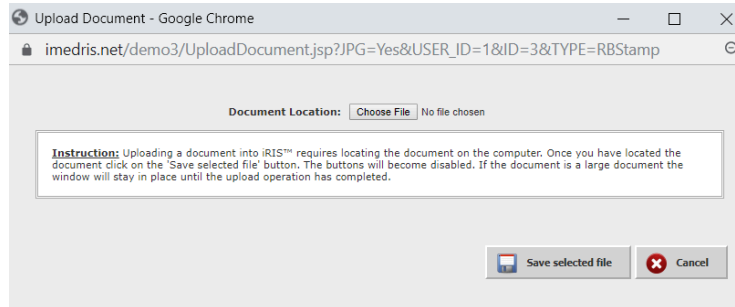
Font Size — click in the field to open a dropdown list of available font size options, then click the desired list item to select it

Font Color — click in the field to open a dropdown list of available font colors, then click the desired list item to select it

Opacity — enter an opacity value between .01 and 1.0, where 1.0 indicates 100% opaque, to set the relative transparency of the stamp

Scale Image to Fit — select this checkbox to automatically scale any uploaded images to fit within the stamp

Click the **Upload** button. An upload dialog box opens, as shown below.



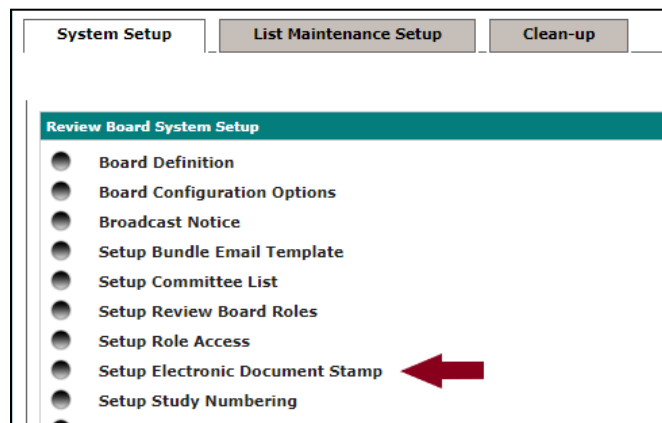
Browse to the desired image file and select it, then click the **Save selected file** button to complete the upload. *Note that the image file must be in JPEG (.jpg, .jpeg) format.*

Click the **Preview Stamp Layout** button to preview the stamp in a popup window.

Click the **Save Stamp Details** button to save the stamp after previewing it.

Delete Electronic Document Stamp

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Electronic Document Stamp** link.



The **Setup Document Stamp** page opens.

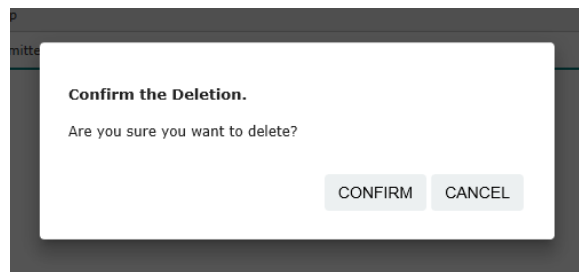
My Workspaces ▾ IRB **Setup Document Stamp** [Back](#)

[Add a New Stamp](#) [Delete Stamp\(s\)](#)

<input checked="" type="checkbox"/>	Edit	Title	Type	Document Category
<input type="checkbox"/>		Approved Subject to NIH Review	General Purpose	N/A
<input type="checkbox"/>		Denied	General Purpose	N/A
<input type="checkbox"/>		Approved	General Purpose	N/A

Select the checkbox(es) in the far-left column for the stamp(s) to be deleted and click the **Delete Stamp(s)** button.

A confirmation popup displays.



Click the **CANCEL** button to return to the **Setup Document Stamp** page without deleting the selected committee(s).

Click the **CONFIRM** button to confirm the deletion and return to the **Setup Document Stamp** page. The stamp is deleted.

My Workspaces ▾ IRB **Setup Document Stamp** [Back](#)

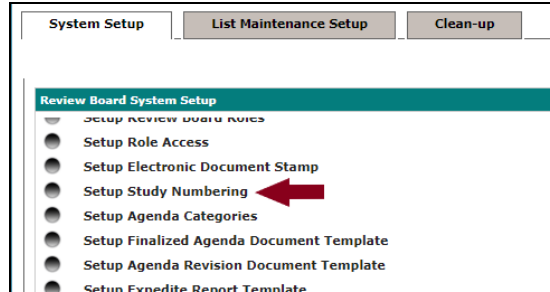
[Add a New Stamp](#) [Delete Stamp\(s\)](#)

<input checked="" type="checkbox"/>	Edit	Title	Type	Document Category
<input type="checkbox"/>		Denied	General Purpose	N/A
<input type="checkbox"/>		Approved	General Purpose	N/A

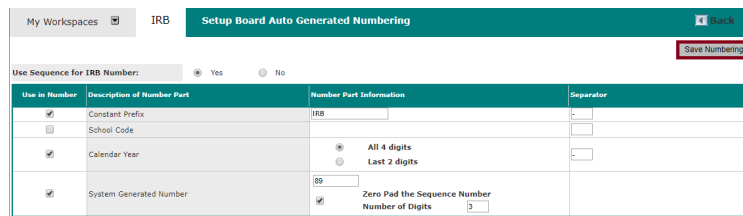
Setup Study Numbering

The iRIS™ system includes the option to generate and automatically assign pre-configured IRB study numbers.

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Study Numbering** link.



The **Setup Board Auto Generated Numbering** page opens.



Select “Yes” for **Use Sequence for IRB Number** to enable auto generated IRB study numbering.

As demonstrated in the **Description of Number Part** column, the number can be configured to include a **Constant Prefix**, **School Code**, **Calendar Year** and **System Generated Number**. Selecting the checkbox in the **Use in Number** column includes all items in that row in the numbering scheme.

Options to pad the **System Generated Number** with leading zeroes, set a fixed digit count for numbers to be generated, and insert an optional **Separator** character are also available.

In the screenshot shown above a numbering scheme that employs all options except **School Code** is configured.

The **Constant Prefix** is “IRB”.

The first **Separator** character is “-”.

The **School Code** option is not selected, indicating that no **School Code** is included in the number.

The **All 4 digits** of the current **Calendar Year** are “20”.

The second **Separator** character is “-”.

The first sequence number to be used is “89”, the checkbox for **Zero Pad the Sequence Number** is selected and **Number of Digits** is set to “3”.

The first wean number generated by this scheme would be:

IRB-2020-089

Click the **Save Numbering** button to save the numbering scheme.

Setup Agenda Categories

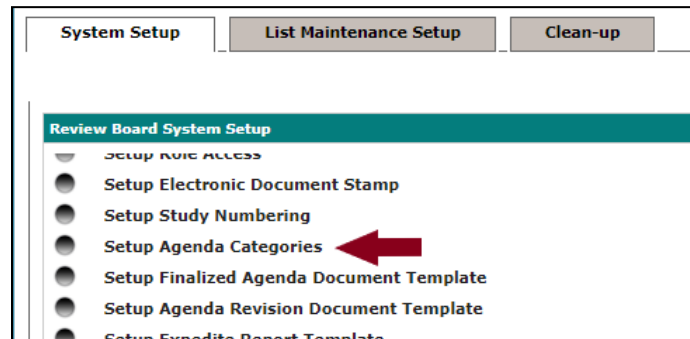
Where the property rb.use_meeting is set to “Yes” (accessed via IRB Assistant > Review Board Administration > [System Setup tab] > Board Configuration Options > Submission Review Properties link), the iRIS™ system provides the ability to configure a list of agenda topic categories that are frequently addressed in review meetings, including the ability to attach relevant forms or documents where applicable.

The configured list appears on the Meeting Agenda page, as shown below.

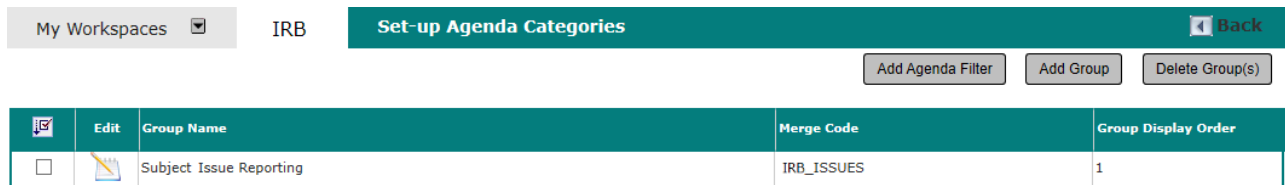


Once configured, the categories can be added to a finalized agenda template with just a few clicks rather than repetitive keystrokes (see the Setup Finalized Agenda Document Template section of this manual for more information).

This functionality is provided on the **Set-up Agenda Categories** page. To access the page, click the **Setup Agenda Categories** link under IRB Assistant > Review Board Administration > System Setup tab.



The **Set-up Agenda Categories** page opens, as shown below.



Columns and controls on this page are:

- select: far-left column, no header label; select the desired checkbox(es) here to select the corresponding record(s)
- **Edit**: click the icon in this column to open the corresponding category for editing
- **Group Name**: designated category name
- **Merge Code**: designated short text to be used in document templates, such as the Finalized Agenda Document Template, to pull the corresponding category name and any associated form or document requirements into the template
- **Group Display Order**: the order in which the applicable category is to be shown on the meeting agenda
- **Add Agenda Filter** button: click this button to open the Set-up Agenda Filter page, where rules can be configured to exclude study or review item documents from the meeting agenda that would otherwise be captured by an agenda category (see next subsection of this manual, Agenda Filter)
- **Add Group** button: click this button to open an add panel for creation of a new agenda category
- **Delete Group(s)** button: click this button to delete any agenda category selected in the far-left column

Agenda Filter

On the **Set-up Agenda Filter** page (shown below, accessed via the Add Agenda Filter button on the Set-up Agenda Categories page, see previous section of this manual), agenda filters are configured to group review document items. Once configured, agenda filters can be applied to include or exclude certain document types when assigning documents to agenda categories.

My Workspaces ▾
IRB

Set-up Agenda Filter

← Back

Add Filter
Delete Filter(s)

	Edit	Filter Type	Filter Name
<input type="checkbox"/>		Previously Reviewed Filter	Previously Reviewed Filter

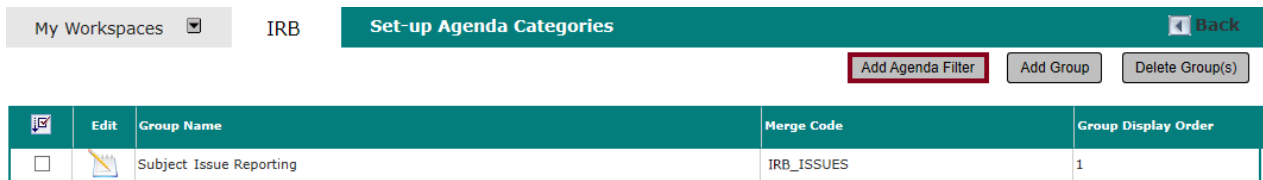
Columns and controls on this page are:

- select: far-left column, no header label; select the desired checkbox(es) here to select the corresponding record(s)
- **Edit**: click the icon in this column to open the corresponding filter for editing

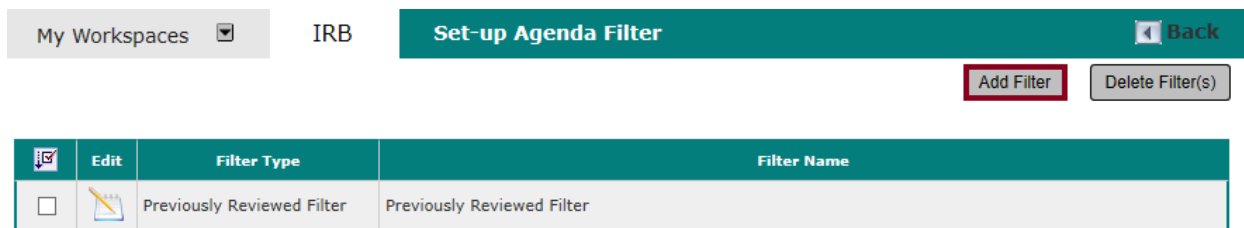
- **Filter Type:** name of category / type of exclusion
- **Filter Name:** defaults to same value as **Filter Type**
- **Add Filter** button: click this button to open an add panel for creation of a new filter
- **Delete Filter(s)** button: click this button to delete any filter selected in the far-left column

Add Agenda Filter

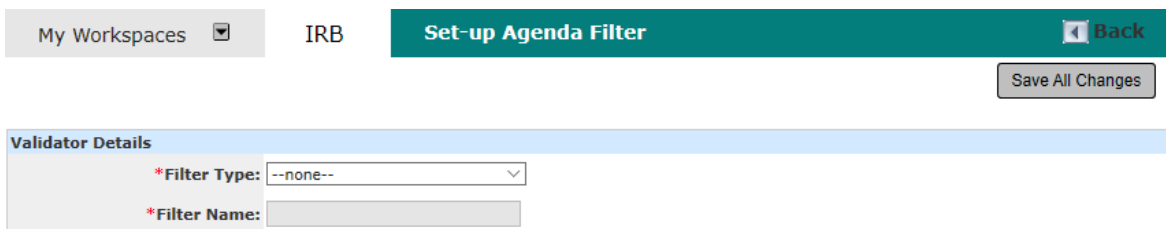
Click the **Add Agenda Filter** button on the **Set-up Agenda Categories** page.



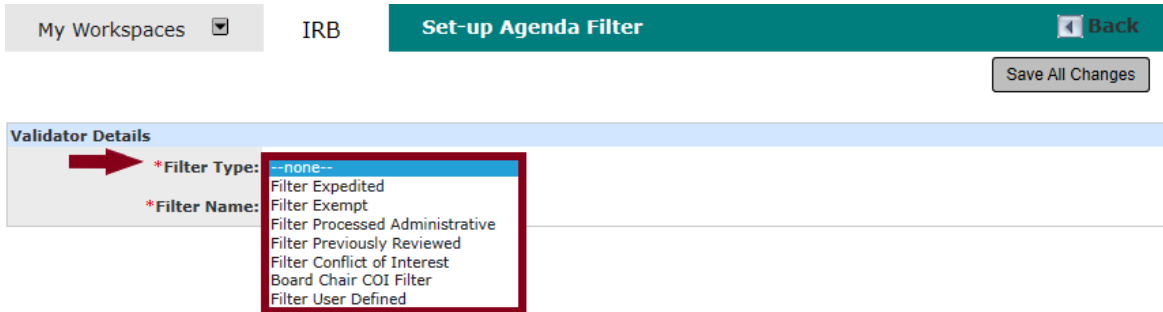
As shown below, the **Set-up Agenda Filter** page opens.



Click the **Add Filter** button. As shown below, an add panel is opened for creation of the new filter.

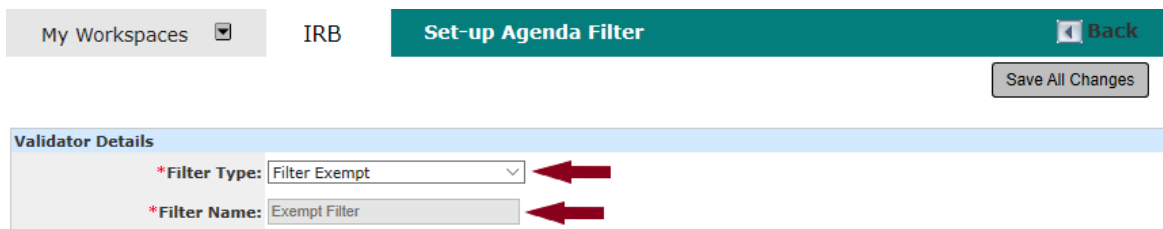


Click in the **Filter Type** field to open a dropdown picklist. Click the desired list item to select it.

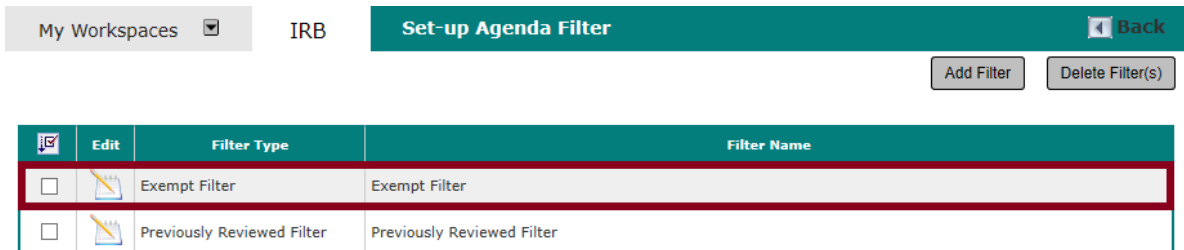


As shown below, in the case of any **Filter Type** selection other than “Filter User Defined” the **Filter Name** field automatically populates with text corresponding to the selected **Filter Type** and is set to read only.

See the Filter User Defined subsection of this manual for more information about configuring user defined filters.

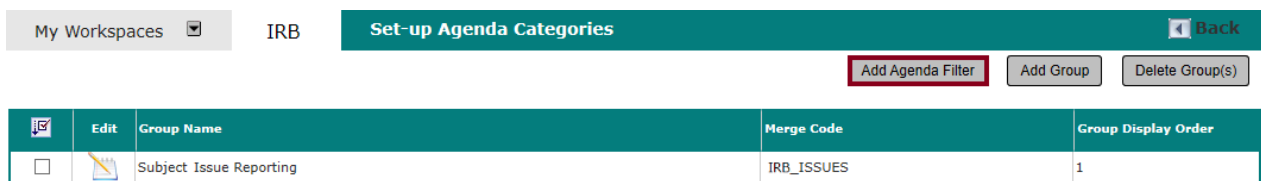


Click the **Save All Changes** button to save the filter and close the add panel. As shown below, the filter is added to the list on the **Set-up Agenda Filter** page.

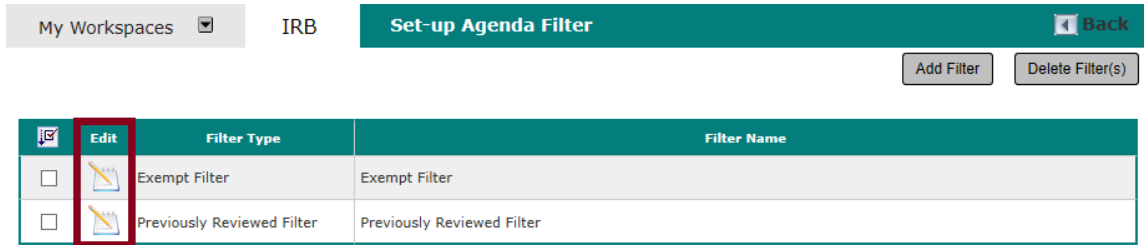


Edit Agenda Filter

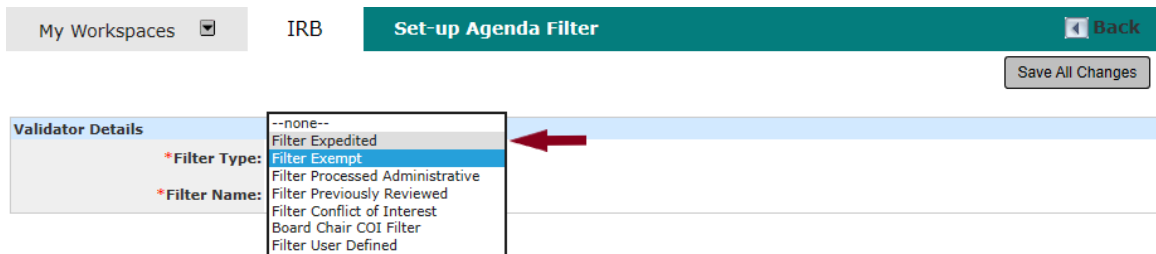
Click the **Add Agenda Filter** button on the **Set-up Agenda Categories** page.



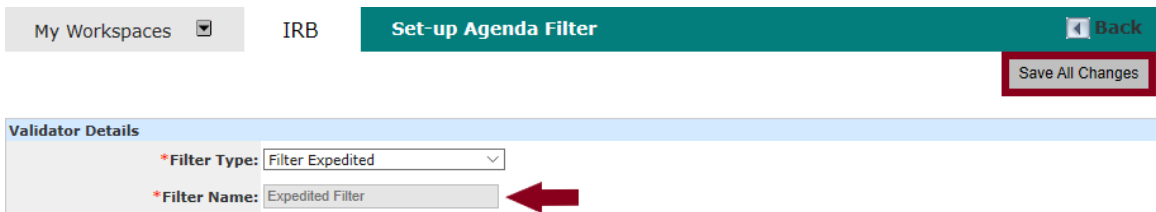
As shown below, the **Set-up Agenda Filter** page opens. Click the icon in the **Edit** column for the applicable filter.



As shown below, the record is opened in an edit panel. Click in the **Filter Type** field to expand the dropdown picklist and select the desired item.

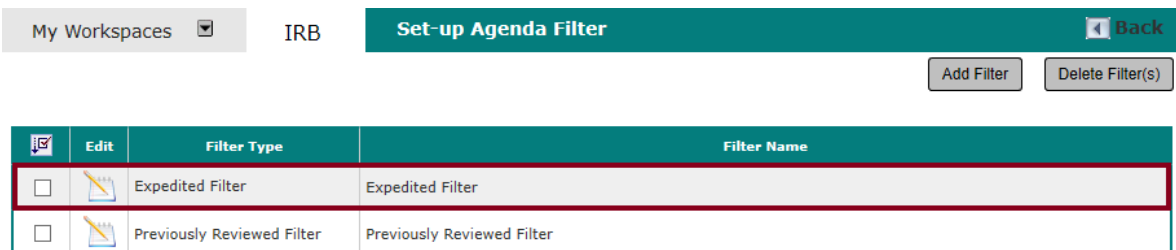


As shown below, in the case of any **Filter Type** selection other than “Filter User Defined” the **Filter Name** field automatically populates with text corresponding to the selected **Filter Type** and is set to read only.



See the Filter User Defined subsection of this manual for more information about configuring user defined filters.

Click the Save All Changes button to save changes and close the edit panel. As shown below, the filter is revised in the list on the **Set-up Agenda Filter** page.



Delete Agenda Filter

Click the **Add Agenda Filter** button on the **Set-up Agenda Categories** page.

My Workspaces ▾ IRB **Set-up Agenda Categories** ⏪ Back

Add Agenda Filter Add Group Delete Group(s)

<input type="checkbox"/>	Edit	Group Name	Merge Code	Group Display Order
<input type="checkbox"/>		Subject Issue Reporting	IRB_ISSUES	1

As shown below, the **Set-up Agenda Filter** page opens. Select the checkbox(es) in the far-left column for the filter(s) to be deleted, then click the **Delete Filter(s)** button.

My Workspaces ▾ IRB **Set-up Agenda Filter** ⏪ Back

Add Filter Delete Filter(s)

<input checked="" type="checkbox"/>	Edit	Filter Type	Filter Name
<input checked="" type="checkbox"/>		Expedited Filter	Expedited Filter
<input type="checkbox"/>		Previously Reviewed Filter	Previously Reviewed Filter

A confirmation popup window displays.

Confirm the Deletion.

Are you sure you want to delete?

CONFIRM CANCEL

Click **CANCEL** to return to the **Set-up Agenda Filter** page without deleting the filter(s).

Click **CONFIRM** to delete the filter(s) and return to the **Set-up Agenda Filter** page. As shown below, the selected filter is removed.

My Workspaces ▾ IRB **Set-up Agenda Filter** ⏪ Back

Add Filter Delete Filter(s)

<input type="checkbox"/>	Edit	Filter Type	Filter Name
<input type="checkbox"/>		Previously Reviewed Filter	Previously Reviewed Filter

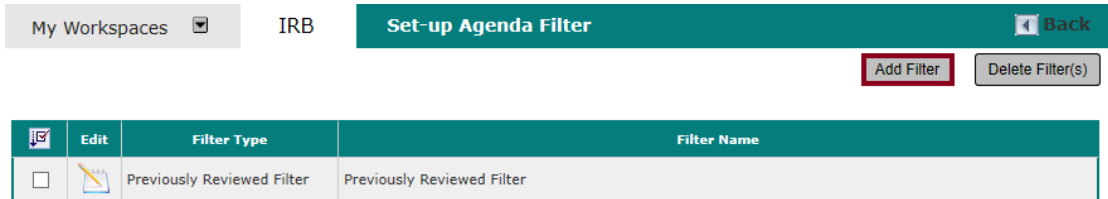
Filter User Defined

Note that familiarity with Structured Query Language (SQL), as well as a thorough knowledge of iRIS™ application modules, associated tables, custom forms and fields are required to create user defined filters using this feature. The example used in this section sets a filter for inclusion of transgenic animals, but the process described is the same regardless of specific filter selections.

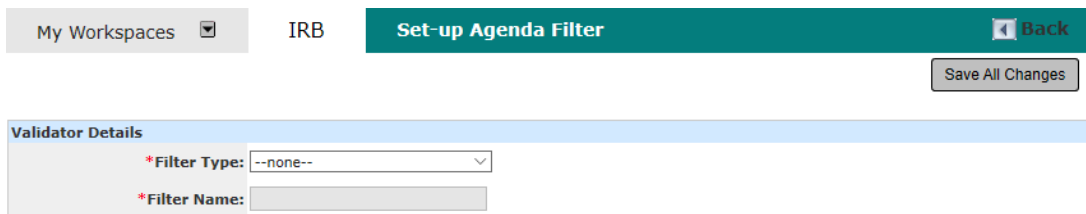
Click the **Add Agenda Filter** button on the **Set-up Agenda Categories** page.



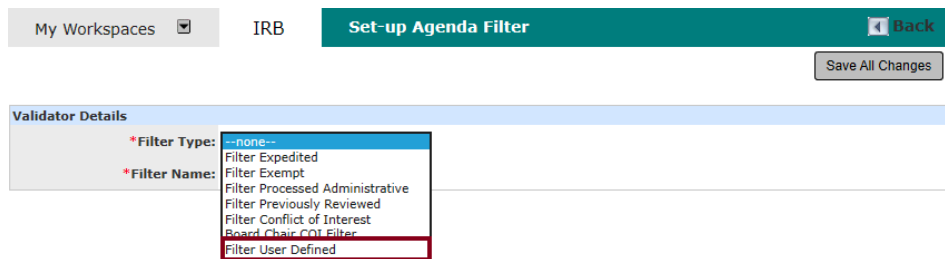
As shown below, the **Set-up Agenda Filter** page opens.



Click the **Add Filter** button. As shown below, an add panel is opened for creation of the new filter.



Click in the **Filter Type** field to open a dropdown picklist. Click "Filter User Defined" to select it.



An add panel is opened for configuration of a custom filter query.

As shown in the screenshot above, the **What to Filter** field in the query builder form defaults to “Applic. Form all columns”, and the corresponding **Data Value** fields default to **What Application?** and **What Application Column?**

In the screenshot below the **What to Filter** dropdown is expanded, showing that a second selection of “Submission Form all columns” is available.

When “Submission Form all columns” is selected the **Data Value** fields update to reflect options applicable to the Submission Form.

The **What Form?** dropdown list is populated with the names of forms configured for the specific institution, and the **What Form Column?** dropdown list is populated with items specific to the selected form.

*Note that the overall process of creating a user defined filter is the same regardless of whether “Submission Form all columns” or “Applic. Form all columns” is selected under **What to Filter**. The user selects the desired submission / application form, then selects a specific field from that form to compare against in the query.*

With the default selection of “Applic. Form all columns” in place, the **What Application?** dropdown list populates with application types. Click an application type in the list to select it.

As shown below, the **What Application Column?** dropdown list automatically populates with sections and questions applicable to the selected application.

Click the desired item in the **What Application Column?** dropdown list to select it. As shown below, the area beneath the **What Application Column?** field populates with options applicable to the selected column item.

A thorough knowledge of iRIS™ data tables is required to understand the auto-populated options provided.

Make desired selections in the area beneath the **What Application Column?** field, then select the desired comparator and data type from the dropdown lists at the lower left of the panel.

As shown below, the comparator dropdown contains all standard SQL query comparators. It is up to the user constructing the query to select a comparator type that is applicable to the selected Application Column value to the right of the comparator field.

Comparators of “NOT EQUAL” or “EQUAL” can be used for comparisons against Yes/No and text fields. The remaining comparators are used for comparisons against numeric values.

In this example a comparator of “EQUAL” is selected because the Application Column value can only be “Yes” or “No”.

Note that the second comparator field defaults to “Value” but will dynamically update with other options where such options are applicable to Application Column and comparator selections.

In the screenshot above the first clause of the user defined filter query is complete. This query returns applications where “No” is selected for option 1 of the question about whether transgenic animals are to be used in the study.

Note that when a configured filter is applied during creation of an Agenda Category, the user is prompted to choose whether to include or exclude records matching the filter’s criteria.

Click the **Add a new Clause** button to add another filter configuration panel to the page, adding another clause to the filter query.

My Workspaces ▾ IRB **Set-up Agenda Filter** ← Back

Add a new Clause Delete Clause Save All Changes

Validator Details

*Filter Type: Filter User Defined ▾
 *Filter Name:

Order	What to Filter	Data Value	Join by, if any
<input type="checkbox"/> 1	Applic. Form all columns ▾	What Application? IACUC APPLICATION (ANIMALS) ▾ What Application Column ? _400_20_TRANSGENIC_ANIMAL_MS ▾ Which Option? 1 ▾	--none-- AND OR

EQUAL ▾
 Value ▾ Yes No

When the query includes two or more clauses the **Join by, if any** field is used to specify the join type and the **Order** field is used to specify the order in which each clause is to be evaluated when the query runs.

*SQL familiarity is required to correctly configure the **Order** and **Join by, if any** fields.*

After all desired clauses have been configured for the query, enter a **Filter Name** and click the **Save All Changes** button to save the filter.

My Workspaces ▾ IRB **Set-up Agenda Filter** ← Back

Add a new Clause Delete Clause Save All Changes

Validator Details

*Filter Type: Filter User Defined ▾
 *Filter Name: Include Transgenic Animals ←

Order	What to Filter	Data Value	Join by, if any
<input type="checkbox"/> 1	Applic. Form all columns ▾	What Application? IACUC APPLICATION (ANIMALS) ▾ What Application Column ? _400_20_TRANSGENIC_ANIMAL_MS ▾ Which Option? 1 ▾	--none-- ▾

EQUAL ▾
 Value ▾ Yes No

The filter is added on the **Set-up Agenda Filter** page.

My Workspaces ▾ IRB **Set-up Agenda Filter** ← Back

Add Filter Delete Filter(s)

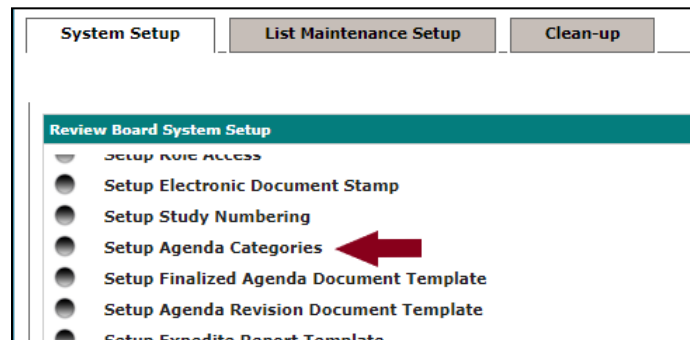
<input checked="" type="checkbox"/>	Edit	Filter Type	Filter Name
<input type="checkbox"/>		Previously Reviewed Filter	Previously Reviewed Filter
<input type="checkbox"/>		User Defined Filter	Include Transgenic Animals

Add Agenda Category

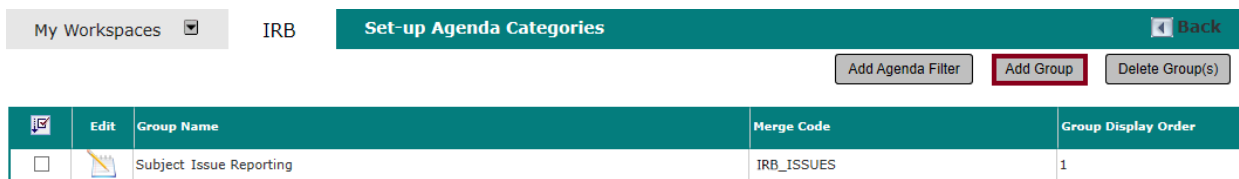
Where the property rb.use_meeting is set to “Yes” (accessed via IRB Assistant > Review Board Administration > [System Setup tab] > Board Configuration Options > Submission Review Properties link), the iRIS™ system provides the ability to configure a list of agenda topic categories. The configured list appears on the Meeting Agenda page, as shown below.



Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Agenda Categories** link.



The **Set-up Agenda Categories** page opens, as shown below.



Click the **Add Group** button. An add panel is opened for creation of the new category.

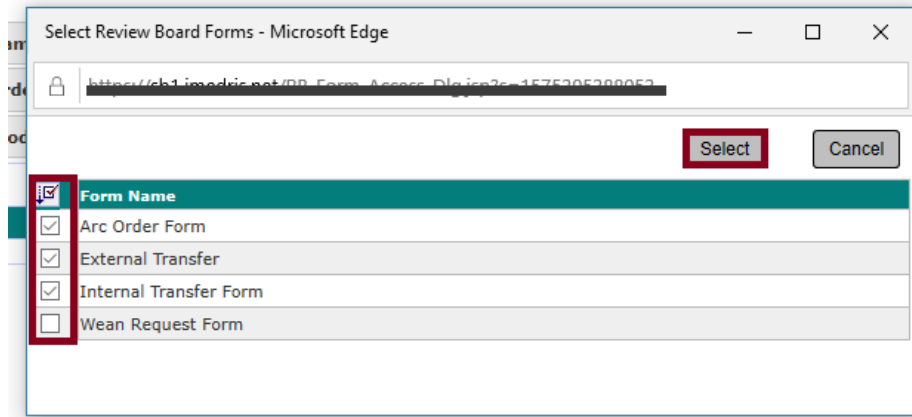
Complete the top of the add panel as follows:

- **Group Name:** enter a descriptive name for the category; recall that categories are used when creating a finalized agenda document template, so the name entered here should indicate the contents of the category
- **Group Order:** the entry in this field is shown in the Group Display Order column of the **Set-up Agenda Categories** page, and dictates the order in which this category appears in the finalized agenda document template
- **Group Merge Code:** enter the desired merge code to be used for inclusion of this category on forms and in document templates; *note that the code must include underscores where spaces occur between words, and cannot include any special characters (e.g., &, #, etc.)*

See the *Using Merge Codes in Document Templates* section of this manual for more information about working with merge codes.

An example of the filled fields is shown below. Click the **Add** button to attach forms to this category, if applicable.

The **Select Review Board Forms** popup appears, populated with all available forms for selection. *Note that because forms are custom configured for each institution, the list of forms shown here will vary.*

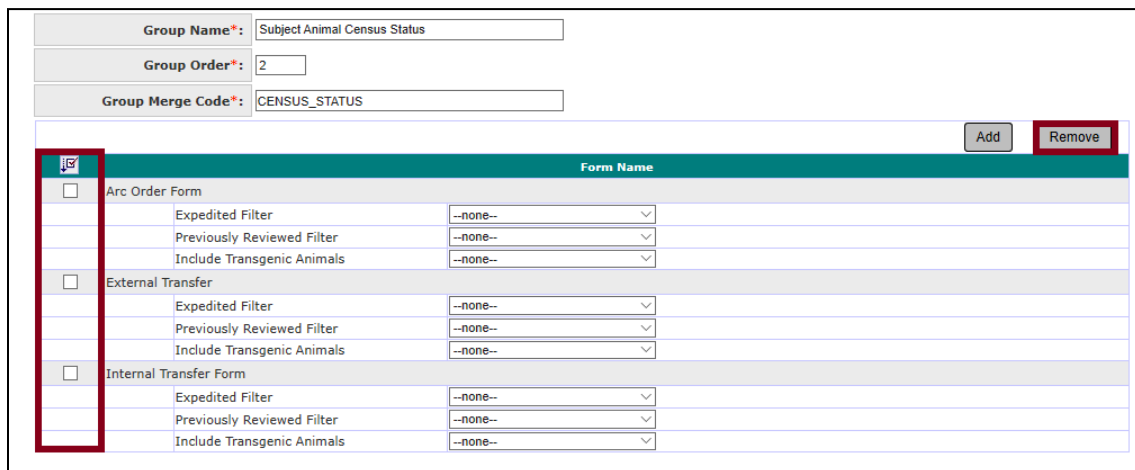


Click the **Cancel** button to close the popup without adding any forms to the category.

Select the checkbox(es) in the far-left column for forms to be attached to the category, then click the **Select** button.

The selected form(s) is(are) added to the category add panel, with options to apply previously configured filters for each form if desired. *All* previously configured filters are shown here.

See the Agenda Filter section of this manual for more information about filter configuration.



To remove any forms added to the category in error, select the checkbox(es) in the far-left column (shown in screenshot above) for forms to be deleted, then click the **Remove** button to remove the selected form(s).

In the screenshot below, the dropdown list containing options for application of the “Expedited Filter” on the “Arc Order Form” item is expanded. This dropdown list is the same for all filters.

Group Name*	Subject Animal Census Status		
Group Order*	2		
Group Merge Code*	CENSUS_STATUS		
Add Remove			
<input checked="" type="checkbox"/>	Form Name		
<input type="checkbox"/>	Arc Order Form		
	Expedited Filter	--none--	
	Previously Reviewed Filter	No Match Required	
	Include Transgenic Animals	Include if this Type is found Not Included if this Type is found	
<input type="checkbox"/>	External Transfer		
	Expedited Filter	--none--	
	Previously Reviewed Filter	--none--	
	Include Transgenic Animals	--none--	
<input type="checkbox"/>	Internal Transfer Form		
	Expedited Filter	--none--	
	Previously Reviewed Filter	--none--	
	Include Transgenic Animals	--none--	

Make all desired selections in the filter option dropdown lists, then click the **Save All Changes** button. Note that a selection is required in every dropdown list in order to save the category.

My Workspaces IRB **Set-up Agenda Categories**

Group Name*	Subject Animal Census Status		
Group Order*	2		
Group Merge Code*	ARC_CENSUS_STATUS		
Add Remove			
<input checked="" type="checkbox"/>	Form Name		
<input type="checkbox"/>	Arc Order Form		
	Expedited Filter	Not Included if this Type is found	
	Previously Reviewed Filter	Not Included if this Type is found	
	Include Transgenic Animals	Not Included if this Type is found	
<input type="checkbox"/>	External Transfer		
	Expedited Filter	Not Included if this Type is found	
	Previously Reviewed Filter	Not Included if this Type is found	
	Include Transgenic Animals	Not Included if this Type is found	
<input type="checkbox"/>	Internal Transfer Form		
	Expedited Filter	Not Included if this Type is found	
	Previously Reviewed Filter	Not Included if this Type is found	
	Include Transgenic Animals	Not Included if this Type is found	

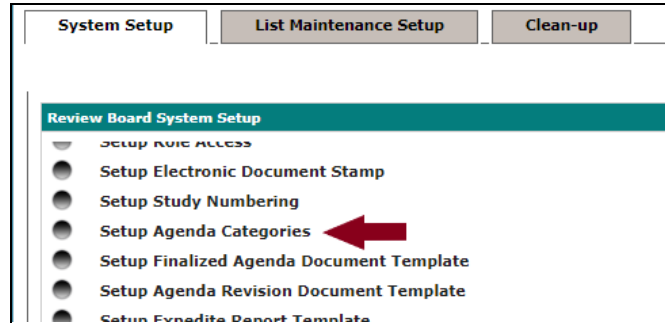
The category is added on the **Set-up Agenda Categories** page.

My Workspaces IRB **Set-up Agenda Categories**

<input checked="" type="checkbox"/>	Edit	Group Name	Merge Code	Group Display Order
<input type="checkbox"/>		Subject Issue Reporting	IRB_ISSUES	1
<input type="checkbox"/>		Subject Animal Census Status	ARC_CENSUS_STATUS	2

Edit Agenda Category

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Agenda Categories** link.



The **Set-up Agenda Categories** page opens, as shown below.

My Workspaces		IRB	Set-up Agenda Categories		Back	
				Add Agenda Filter	Add Group	Delete Group(s)
<input type="checkbox"/>	Edit	Group Name	Merge Code	Group Display Order		
<input type="checkbox"/>		Subject Issue Reporting	IRB_ISSUES	1		
<input type="checkbox"/>		Subject Animal Census Status	ARC_CENSUS_STATUS	2		

Click the icon in the **Edit** column for the applicable category. The category is opened for editing.

My Workspaces		IRB	Set-up Agenda Categories		Back
				Save All Changes	
Group Name*		Subject Animal Census Status			
Group Order*		2			
Group Merge Code*		ARC_CENSUS_STATUS			
				Add	Remove
<input type="checkbox"/>	Form Name				
<input type="checkbox"/>	Arc Order Form				
	Expedited Filter	Not Included if this Type is found			
	Previously Reviewed Filter	Not Included if this Type is found			
	Include Transgenic Animals	Not Included if this Type is found			
<input type="checkbox"/>	External Transfer				
	Expedited Filter	Not Included if this Type is found			
	Previously Reviewed Filter	Not Included if this Type is found			
	Include Transgenic Animals	Not Included if this Type is found			
<input type="checkbox"/>	Internal Transfer Form				
	Expedited Filter	Not Included if this Type is found			
	Previously Reviewed Filter	Not Included if this Type is found			
	Include Transgenic Animals	Not Included if this Type is found			

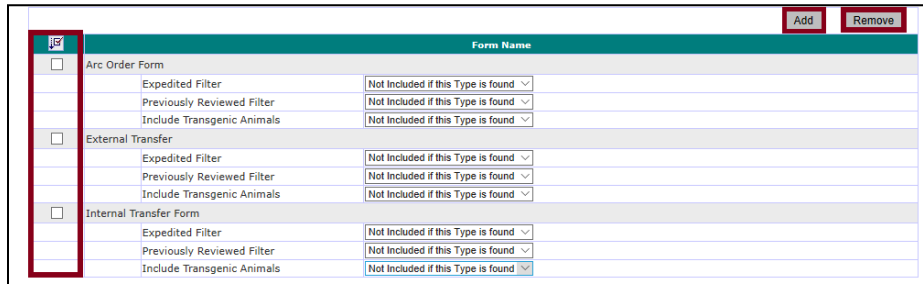
Make any desired changes to fields at the top of the edit panel as follows:

- **Group Name:** descriptive name for the category; recall that categories are used when creating a finalized agenda document template, so the name entered here should indicate the contents of the category
- **Group Order:** the entry in this field is shown in the Group Display Order column of the **Set-up Agenda Categories** page, and dictates the order in which this category appears in the finalized agenda document template

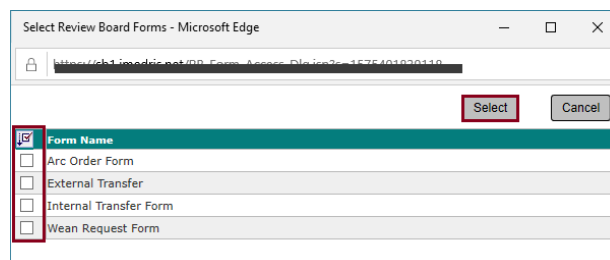
— **Group Merge Code:** enter the desired merge code to be used for inclusion of this category on forms and in document templates; *note that the code must include underscores where spaces occur between words, and special characters (e.g., &, #, etc.) are not allowed*

See the *Using Merge Codes in Document Templates* section of this manual for more information about working with merge codes.

As shown in the screenshot below, select the checkbox(es) in the far-left column for any forms to be removed from the category, then click the **Remove** button to remove the selected form(s).



Click the **Add** button to attach forms to this category, if applicable. The **Select Review Board Forms** popup appears, populated with all available forms for selection. *Note that because forms are custom configured for each institution, the list of forms shown here will vary.*



Click the **Cancel** button to close the popup without adding any forms to the category.

Select the checkbox(es) in the far-left column for forms to be attached to the category, then click the **Select** button.

Any selected form(s) is(are) added to the category add panel, with options to apply previously configured filters for each form if desired. *All* previously configured filters are shown here.

See the *Agenda Filter* section of this manual for more information about filter configuration.

My Workspaces IRB **Set-up Agenda Categories** Back

Save All Changes

Group Name*: Subject Animal Census Status

Group Order*: 2

Group Merge Code*: ARC_CENSUS_STATUS

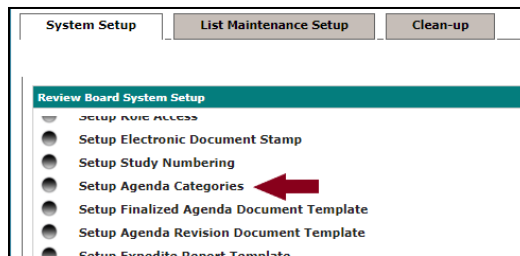
Add Remove

<input type="checkbox"/>	Form Name		
<input type="checkbox"/>	Arc Order Form		
	Expedited Filter		Not Included if this Type is found
	Previously Reviewed Filter		Not Included if this Type is found
	Include Transgenic Animals		Not Included if this Type is found
<input type="checkbox"/>	External Transfer		
	Expedited Filter		Not Included if this Type is found
	Previously Reviewed Filter		Not Included if this Type is found
	Include Transgenic Animals		Not Included if this Type is found
<input type="checkbox"/>	Internal Transfer Form		
	Expedited Filter		Not Included if this Type is found
	Previously Reviewed Filter		Not Included if this Type is found
	Include Transgenic Animals		Not Included if this Type is found

When all desired changes to the category are complete, click the **Save All Changes** button to save changes and close the edit panel.

Delete Agenda Category

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Agenda Categories** link.



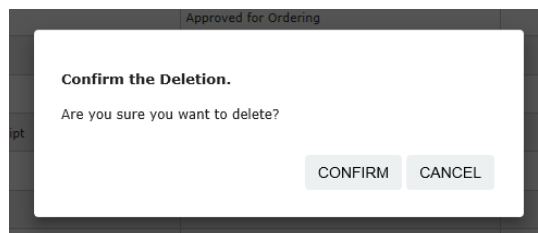
The **Set-up Agenda Categories** page opens, as shown below.

My Workspaces IRB **Set-up Agenda Categories** Back

Add Agenda Filter Add Group **Delete Group(s)**

<input type="checkbox"/>	Edit	Group Name	Merge Code	Group Display Order
<input type="checkbox"/>		Subject Animal Issue Reporting	ARC_ANIMAL_ISSUES	1
<input checked="" type="checkbox"/>		Subject Animal Census Status	ARC_CENSUS_STATUS	2

Select the checkbox in the far-left column for the applicable category(ies), then click the **Delete Group(s)** button. A confirmation popup window displays.



Click **CANCEL** to return to the **Set-up Agenda Categories** page without deleting the category(ies).

Click **CONFIRM** to delete the category(ies) and return to the **Set-up Agenda Categories** page. The category is deleted.

My Workspaces		IRB		Set-up Agenda Categories		Back	
				Add Agenda Filter	Add Group	Delete Group(s)	
<input checked="" type="checkbox"/>	Edit	Group Name		Merge Code		Group Display Order	
<input type="checkbox"/>		Subject Issue Reporting		IRB_ISSUES		1	

Document Templates

The iRIS™ system provides tools for creation of pre-formatted document templates that include commonly used boilerplate text and can pull a variety of system data into a document on the fly, when a document is generated.

The general process for template setup and use is the same, regardless of the document or correspondence type.

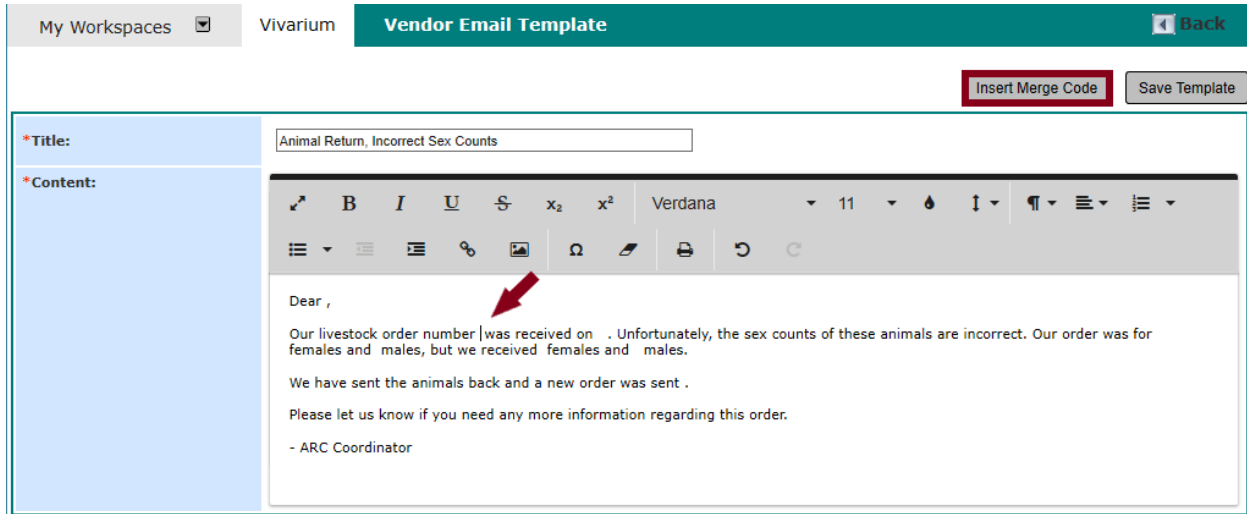
- **Template Definition:** a template containing standardized boilerplate text for the desired document or correspondence type (e.g., meeting agenda, meeting minutes, vendor email, outcome letter, etc.) is created and formatted in a rich text editor
- **Merge Code Addition:** where the document or correspondence type needs to include specific data pulled from the iRIS™ system (e.g., order number, review board name, vendor email address, quantity of animals ordered, etc.), the applicable Merge Code for each needed data item is added to the template
- **Document / Correspondence Generation:** when a template-based document / correspondence is generated by an iRIS™ user, the pre-formatted template serves as the default starting point for the document / correspondence; the user edits the document / correspondence as desired before printing or sending it

The use of templates reduces time and effort demands on the user, reduces user error, and streamlines enforcement of institutional communication standards and policies.

Using Merge Codes in Document Templates

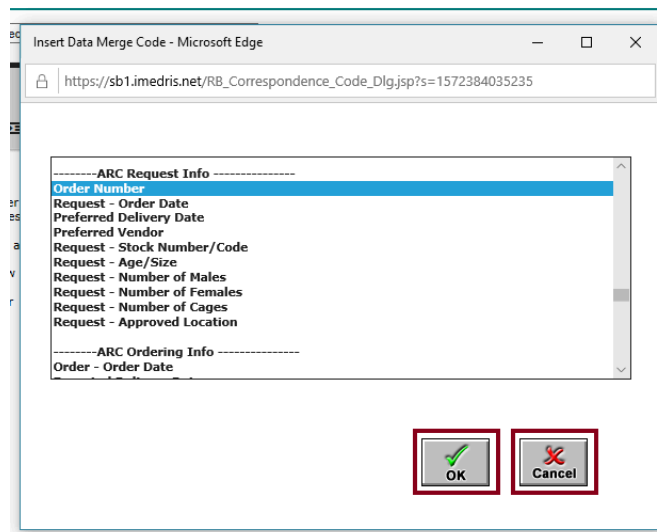
To insert a Merge Code in a document template, place the cursor in the text editor where the corresponding data value is to appear, then click the **Insert Merge Code** button to open the Merge Codes picklist.

Note that the example shown is taken from the Vivarium/ARC module, but the general process described is the same regardless of the module in use.



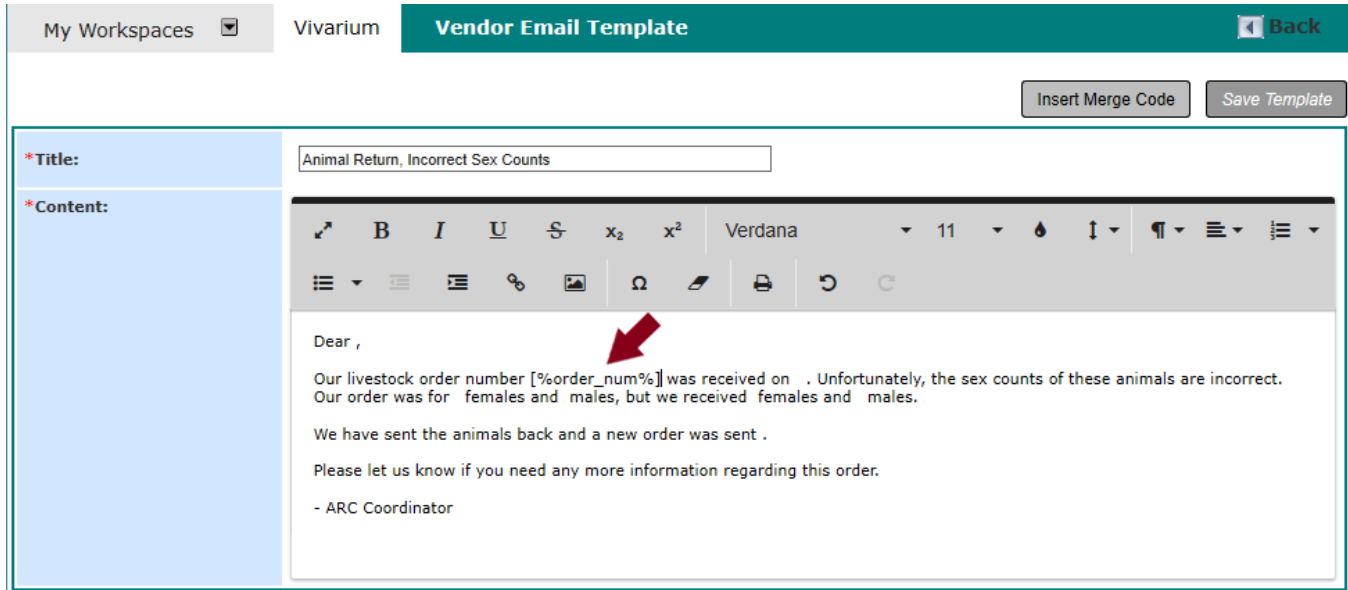
The **Insert Data Merge Code** popup window displays. Scroll down to the sections of the list labeled for ARC and select the desired Merge Code. In this example, the Merge Code for “Order Number” is selected.

Note that the list also includes sections for other modules, such as IACUC, to use in templates for documents applicable to those modules. See the Merge Code List subsection of this manual for more information.

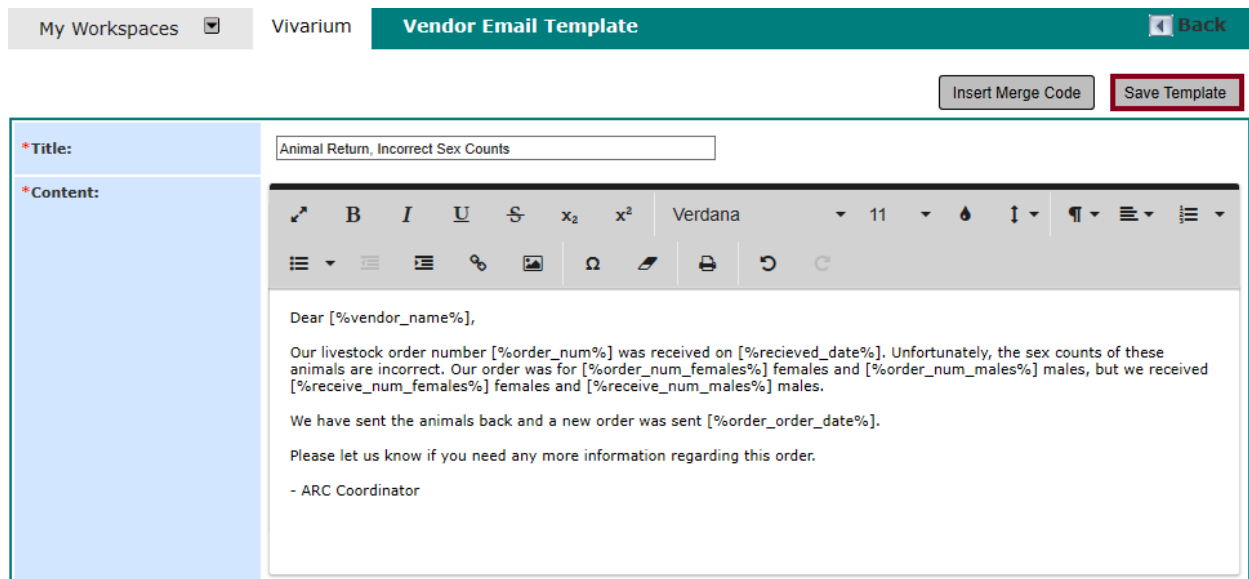


Click the **Cancel** button to close the popup without inserting the Merge Code.

Click the **OK** button to insert the Merge Code. The selected Merge Code is inserted in the template at the cursor location.



In the screenshot below, Merge Codes for “Vendor Name”, “Order Number”, “Date Received”, “Order - Number of Females”, “Order - Number of Males”, “Receive – Number of Females”, “Receive – Number of Males”, and “Order – Order Date” are inserted.



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

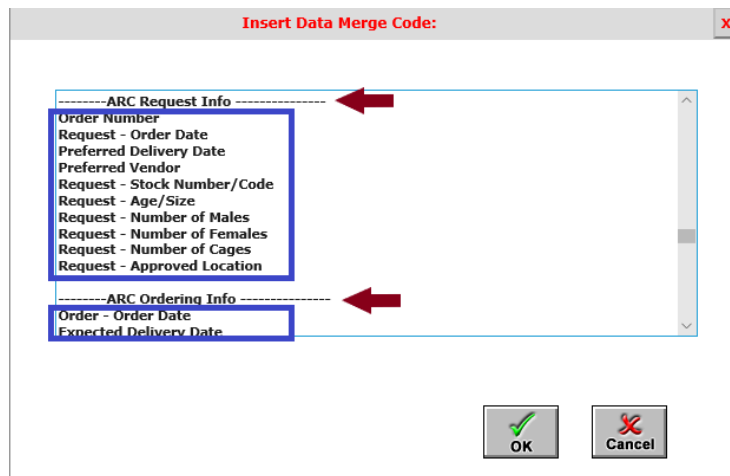
Merge Code List

Depending on the user’s data access rights and the institution’s Review Board Administration settings, the Merge Code list can include system data from the following categories:

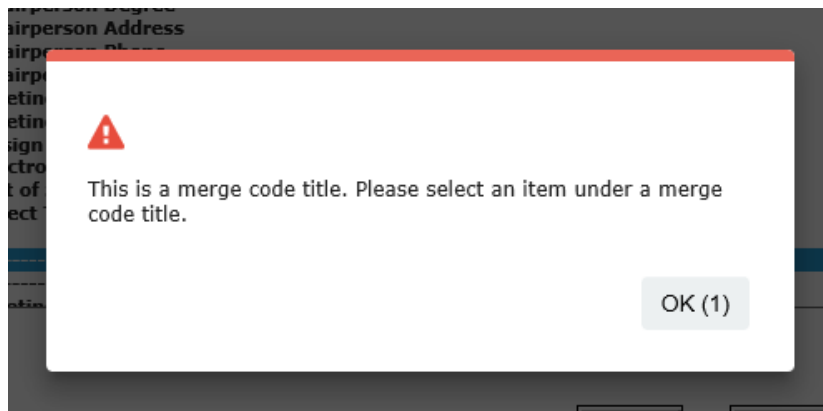
Review Board	Study Financial Information
Meetings	Submission Information

Multi-Site	ARC Request Information
Study Personnel	ARC Ordering Information
Study Contacts	ARC Receiving Information
Form Creator	ARC Cage Information
Department Reviewer and Signoff	Study/IRB/IACUC Application Information

Most of the Merge Codes in the picklist are grouped under category titles. As shown in the screenshot below, category titles are offset by dashed lines. Selectable Merge Code items are indicated by blue boxes.



Category titles are not Merge Codes and cannot be inserted in a template. If a title item is selected and the **OK** button is clicked, an error popup window displays.



Merge Codes Applicable to Animal Resource Center (ARC)

Categories and Merge Codes from the list that are most applicable to ARC are summarized in the table below.

---ARC Request Info ---	---ARC Ordering Info ---	---ARC Receiving Info ---	---ARC Cage Info ---
Number of Females	Order - Order Date	Date Received	Cage Type
Number of Males	Expected Delivery Date	Purchase Cost	Bar Code
Age Size	Confirmation Number	Service Cost	Cage - Cage ID
Species Name	Method of Ordering	Container OK	Cage - Species
Strain Name	Vendor Name	General Appearance	Cage - Strain

---ARC Request Info ---	---ARC Ordering Info ---	---ARC Receiving Info ---	---ARC Cage Info ---
Order Number	Vendor Contact	Eyes, Ears, Nose, Mouth	Cage - Number of Males
Request - Order Date	Vendor Phone	Urogenital, Anus	Cage - Number of Females
Preferred Delivery Date	Vendor Fax	Respiratory	Cage - Number of Unknown Sex
Preferred Vendor	Vendor Email	Hydration	Cage - Cage Card Comments
Request - Stock Number/Code	Order - Species	Receive - Number of Males	Cage - List of Animal IDs
Request - Age/Size	Order - Strain	Receive - Number of Females	
Request - Number of Males	Order - Stock Number/Code	Must go through Quarantine	
Request - Number of Females	Order - Age/Size	Receive - Number of Cages	
Request - Number of Cages	Order - Number of Males	Receive - Approved Location	
Request - Approved Location	Order - Number of Females		
	Order - Number of Cages		
	Order - Approved Location		

Merge Codes Applicable to Meetings

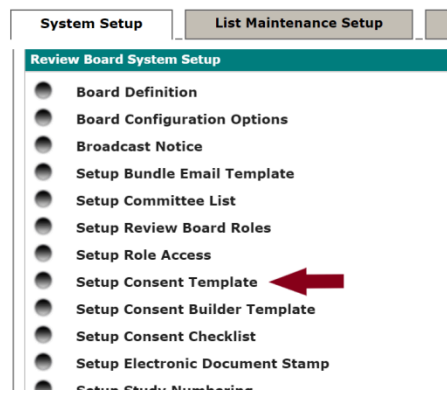
Categories and Merge Codes from the list that are most applicable to meetings are summarized in the table below.

---Review Board Info ---	---Meeting Attendance Codes ---	---Submission Info ---
Review Board Name	Meeting Call to Order	Submission Approval Date
Review Board Committee Name	Meeting New Business	Submission Type
Chairperson Name (Last Name, First Name)	Meeting Old Business	Submission List of all reviewers
Chairperson Name (First Name, Last Name)	Meeting Miscellaneous	Submission Primary Reviewer
Chairperson First Name	Meeting Closing Comments	Submission Secondary Reviewer
Chairperson Middle Name	Meeting Actual Start Time	Submission all additional reviewers over secondary
Chairperson Last Name	Meeting Actual End Time	Submission AD Hoc Reviewers
Chairperson Degree	Meeting Planned Start Time	Item Number on Agenda
Chairperson Address	Meeting Planned End Time	All Project Departments
Chairperson Phone	Meeting Chair (Last, First)	All Project Institutions
Chairperson EMAIL	Meeting Chair (First, Last)	Project Title
Electronic Signature	Total Voting Members	Project Short Title
Meeting Date	Quorum	Project Status
Meeting Location	Voting Members Present	Study Title
	Non-Voting Members Present	Study Alias
	Alternate Members Present	Study Status
	Members Absent	Sponsor/Funding Source
	Member Ex-officio Present	Proposal Number
	Administrative Staff Present	Proposal Title
	Guests Present	Proposal Short Title
	Meeting Motions	Project Award Number

---Review Board Info ---	---Meeting Attendance Codes ---	---Submission Info ---
		Project Previous Award Number
		Project Open Ended
		Is Archived
		Archived Location

Setup Consent Template

Review board Consent templates provide the ability to upload consent templates or edit existing templates for use by researchers when building their informed consent document(s). Consent templates are configured on the **Setup Consent Template** page, which is accessed via IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Template** link (shown below).

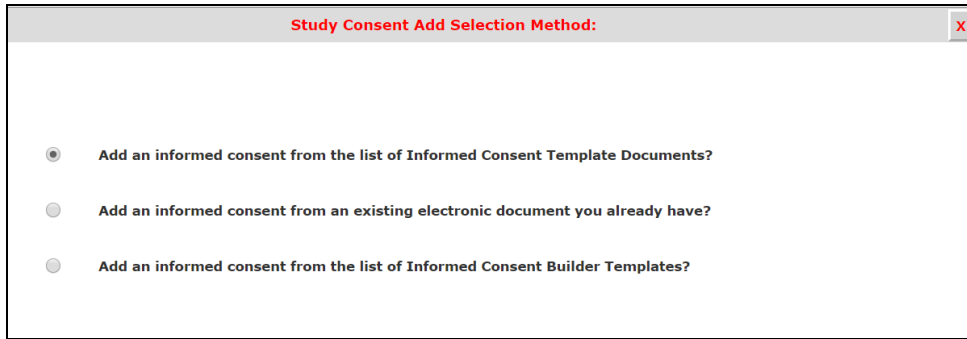


Previously configured document templates are listed on the **Setup Consent Template** page.



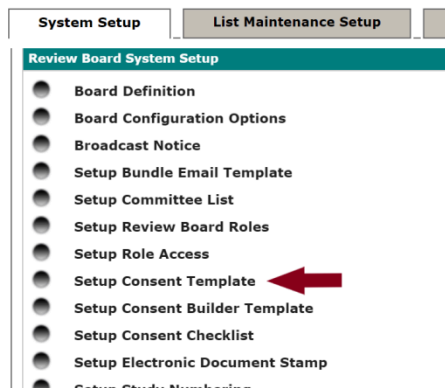
Click the icon in the **View File** column (red box in screenshot above) to view a read-only version of the corresponding template in a new tab or window of the browser.

Any templates configured on the **Setup Consent Template** page are made available to users when an Informed Consent is added to a study, as shown below.



Add Consent Template

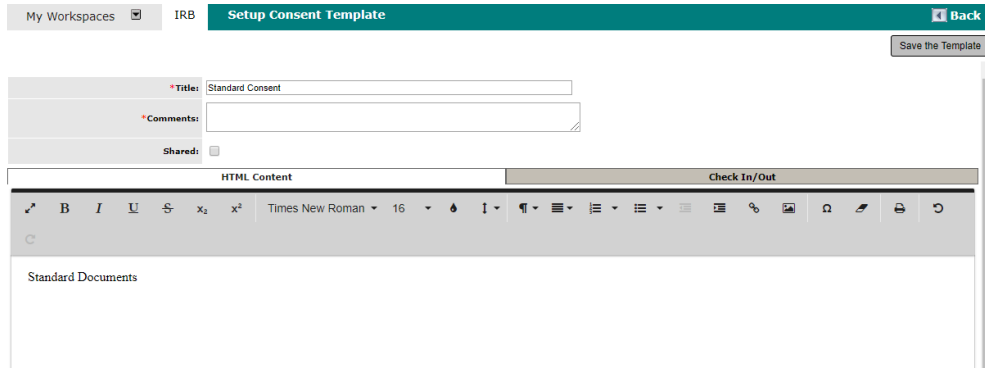
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Template** link (shown below).



The **Setup Consent Template** page opens (shown below).



Click the **Add a New Template** button (red box in screenshot above). A text editor panel (shown below) opens for creation of the template.



Complete the fields in the text editor panel as follows:

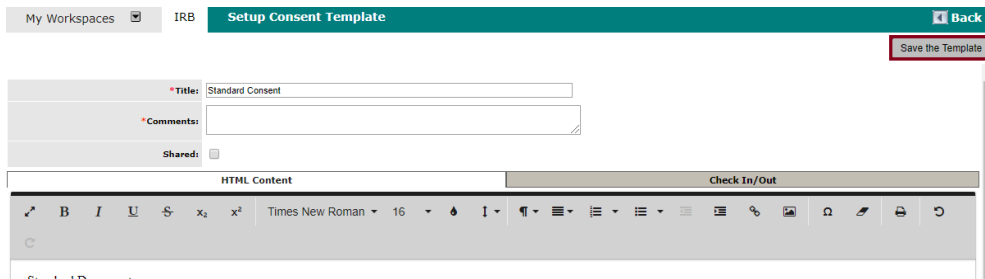
Title — enter the title of the consent template in the text box

Comments — enter any desired comments

Shared — select this box to share this Consent template with other review boards that use Consent documents

Text Editor — enter desired text and Merge Codes; *see the Using Merge Codes in Document Templates section of this manual for more information about working with Merge Codes*

When all fields are complete, click the **Save the Template** button to save changes and close the text editor panel.

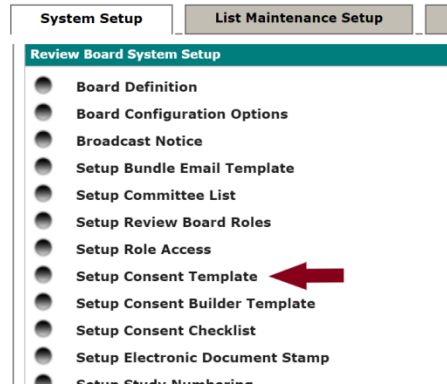


The template is added to the list on the main **Setup Consent Template** page and is made available to users for selection when an Informed Consent is added to a study.

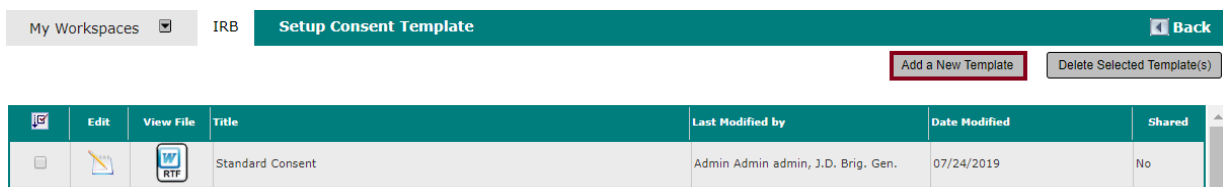
Check Out Template for Offline Revision

iRIS™ provides the option to create a Consent template file in the iRIS™ system, download the file for offline revision, and finally upload the revised document back into the system. This is a useful option in cases where extensive revisions are required, or where more sophisticated text editor tools are needed than those provided in the system.

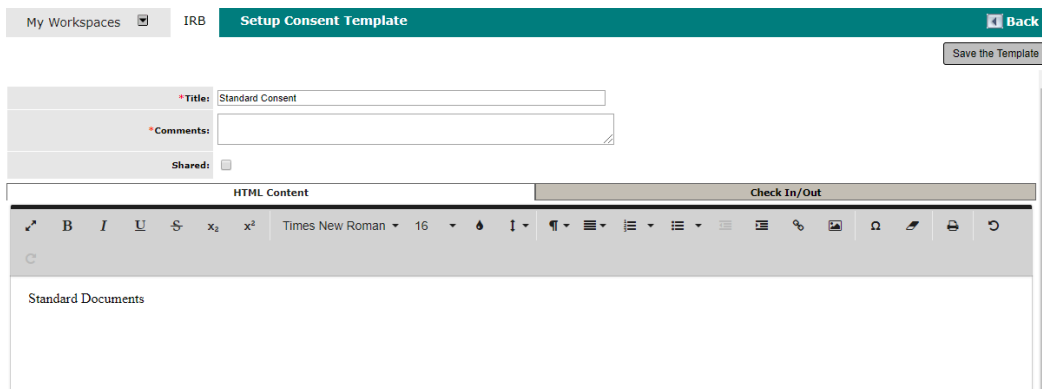
Navigate to IRB Assistant > Review Board Administration > System Setup Tab > **Setup Consent Template** link (shown below).



The **Setup Consent Template** page opens (shown below).



To create a new template file for offline revision, click the **Add a New Template** button (red box in screenshot above). A text editor panel (shown below) opens for creation of the template.



Complete the fields in the text editor panel as follows:

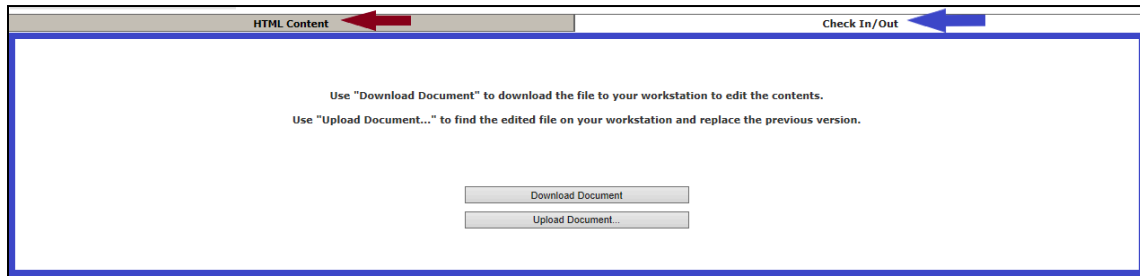
Title — enter the title of the consent template in the text box

Comments — enter any desired comments about this template

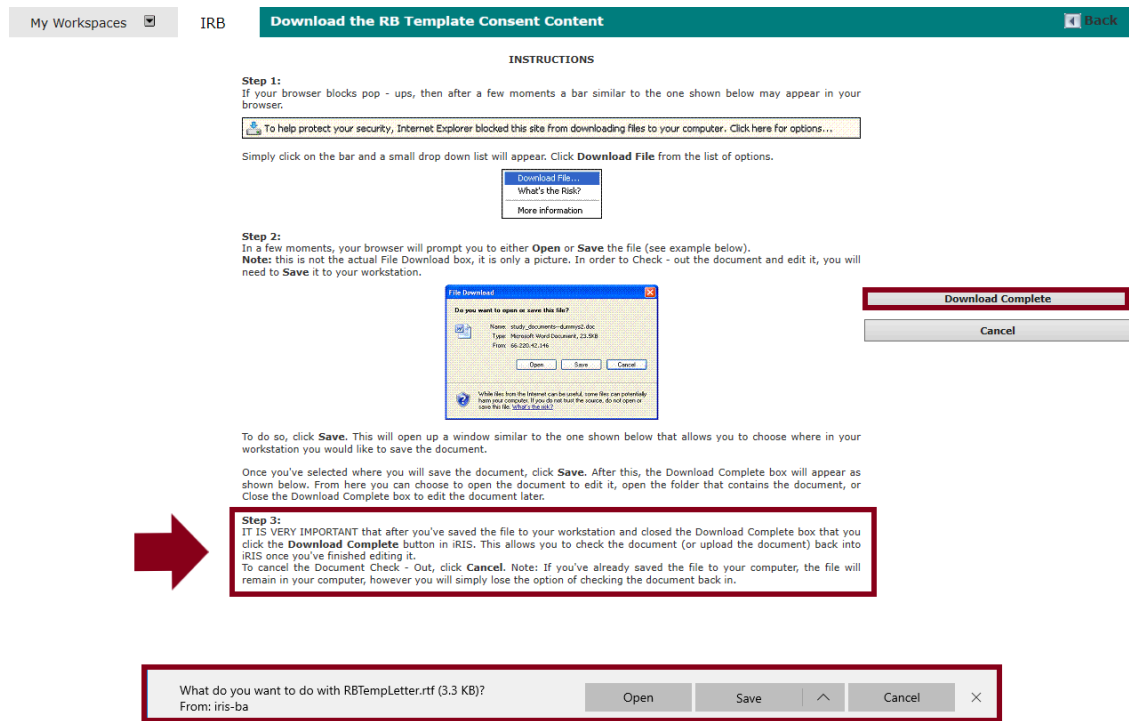
Shared — select this box to share this Consent template with other review boards that use Consent documents

Text Editor — enter placeholder text or leave blank; recall that the file will be revised offline

Click the **Check In/Out** tab (blue arrow in screenshot below) to download the template file. As shown below, the **Check In/Out** tab is opened, and the **HTML Content** tab (red arrow below) is deselected.



As per the instructions provided on this tab, click the **Download Document** button to download a copy of the letter template in RTF format. The **Download the RB Template Consent Content** page opens, as shown below.



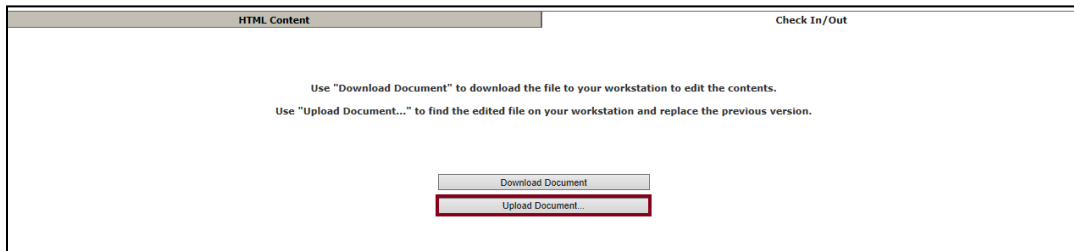
IMPORTANT: READ AND FOLLOW THE DIRECTIONS PROVIDED ON THE PAGE TO ENSURE UPLOAD OF THE REVISED DOCUMENT WILL BE ENABLED. See items boxed in red in the screenshot above.

Make desired changes to the downloaded copy of the letter template in any rich text editor and save the file under the same name as the original download.

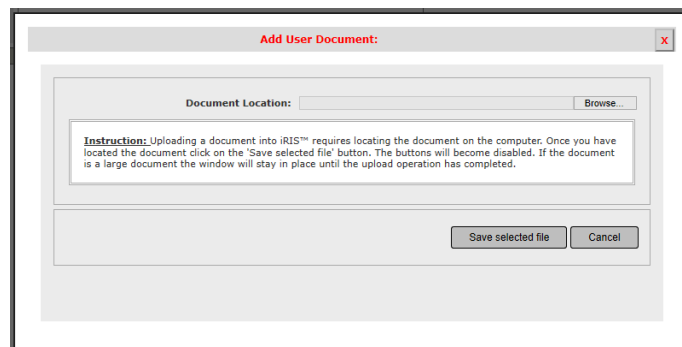
Return to the **Setup Consent Template** page and click the icon in the **Edit** column (red box in screenshot below) for the applicable template.



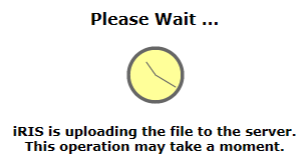
The template opens in the **HTML Content** tab of the text editor panel by default. Select the **Check In/Out** tab (shown below) and click the **Upload Document** button.



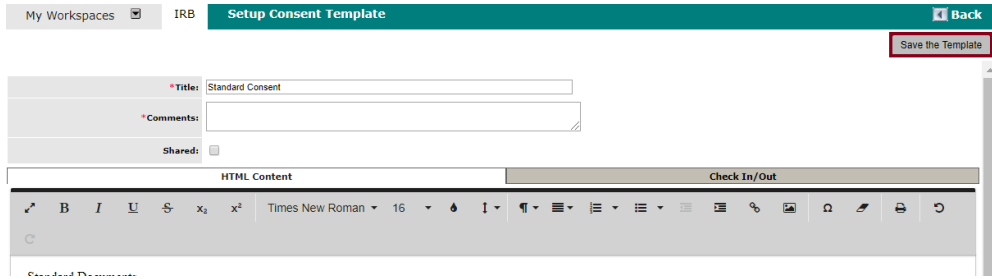
An **Add User Document** popup opens, as shown below.



Follow the directions in the popup to navigate to the revised file on the local computer and upload it to the iRIS™ system. As shown below, a countdown popup briefly appears as the upload is processed.



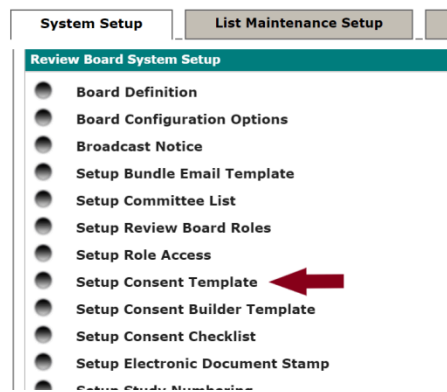
When the popup closes, back in the text editor panel of the **Setup Consent Template** page, click the **Save the Template** button to save changes and close the edit panel.



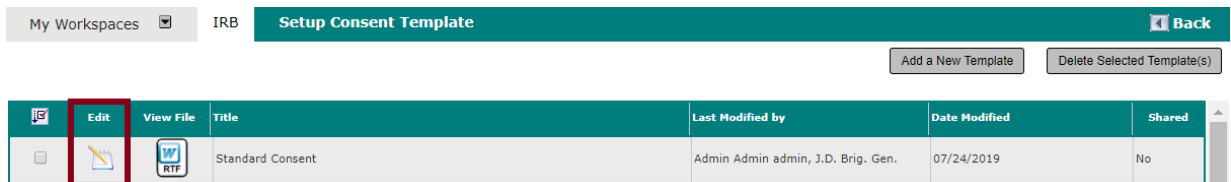
The template is added to the list on the main **Setup Consent Template** page, and is made available to users for selection when an Informed Consent is added to a study.

Edit Consent Template

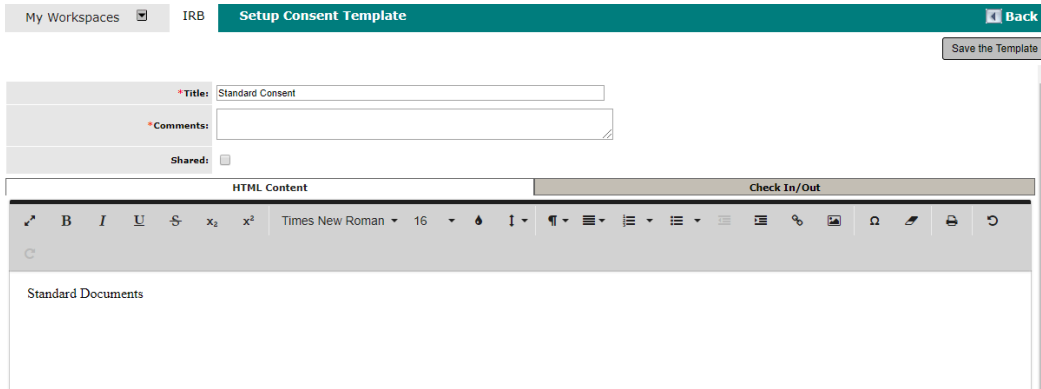
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Template** link (shown below).



The **Setup Consent Template** page opens (shown below).



Click the applicable icon in the **Edit** column. The selected template opens in a text editor panel (shown below) for revision.



Make desired changes in the upper section of the text editor panel. Fields in that section are as follows:

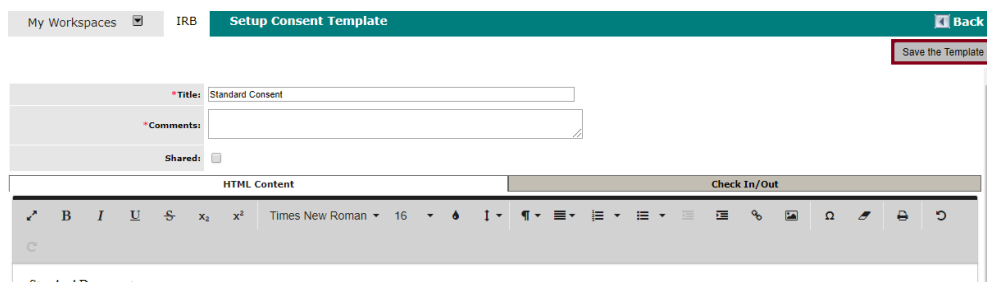
Title — title of the consent template in the text box

Comments — comments about this template

Shared — select this box to share this Consent template with other review boards that use Consent documents

Text Editor — current template content, which may include Merge Codes; *see the Using Merge Codes in Document Templates section of this manual for more information about working with Merge Codes*

When all field revisions are complete, click the **Save the Template** button to save changes and close the text editor panel.

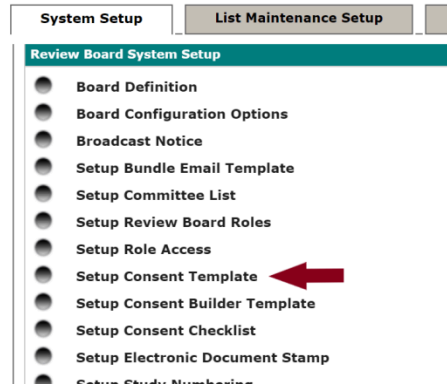


The revised template remains in the list on the main **Setup Consent Template** page, and is made available to users for selection when an Informed Consent is added to a study.

Check Out Template for Offline Revision

iRIS™ provides the option to download a Consent template file from the iRIS™ system for offline revision. This is a useful option in cases where extensive revisions are required, or where more sophisticated text editor tools are needed than those provided in the system.

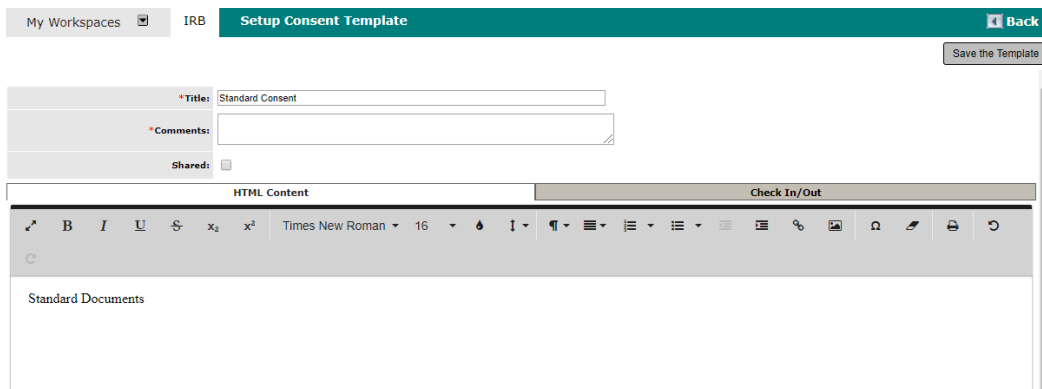
Navigate to IRB Assistant > Review Board Administration > System Setup Tab > **Setup Consent Template** link (shown below).



The **Setup Consent Template** page opens (shown below).



Click the applicable icon in the **Edit** column. The selected template opens in a text editor panel (shown below) for editing.



Make desired changes in the upper section of the text editor panel. Fields in that section are as follows:

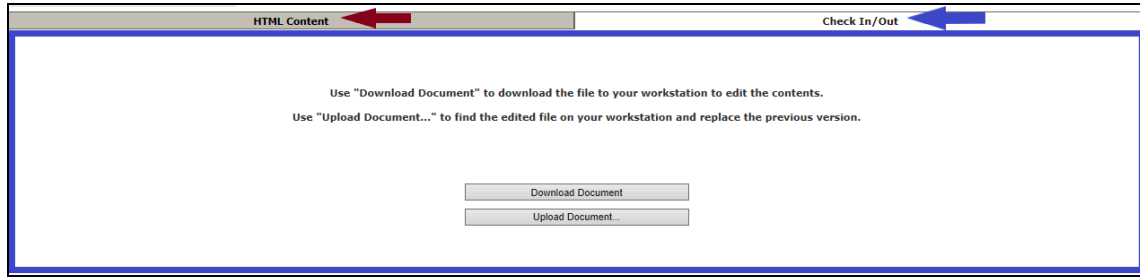
Title — title of the consent template in the text box

Comments — comments about this template

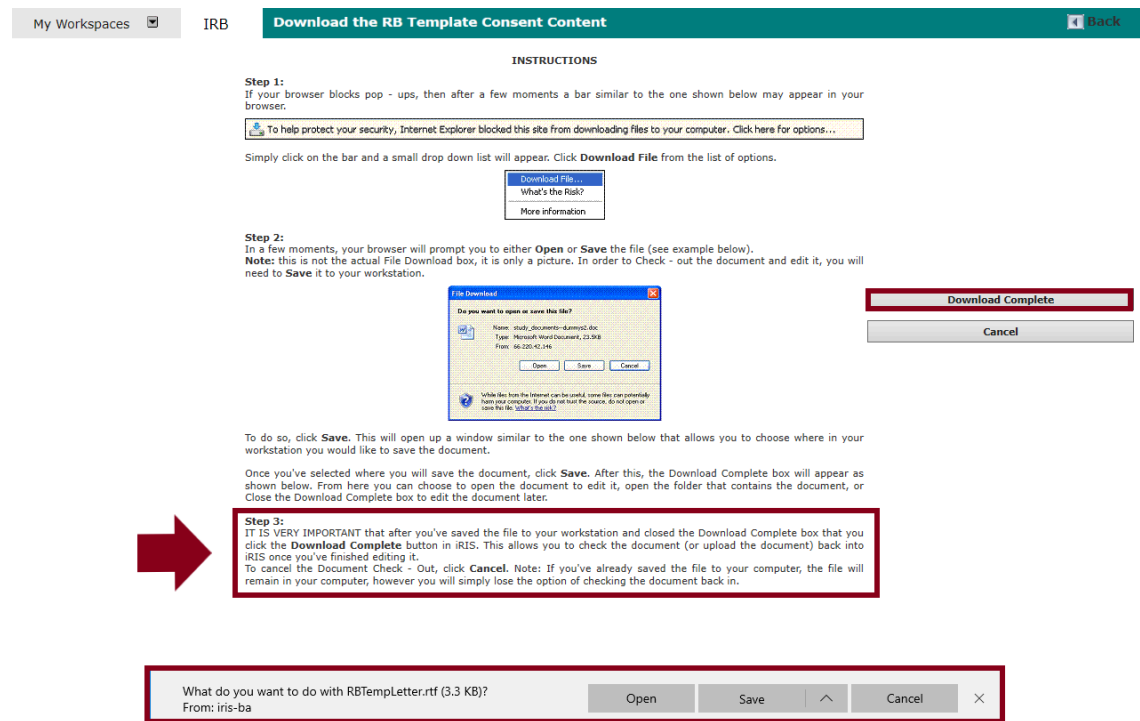
Shared — select this box to share this Consent template with other review boards that use Consent documents

Text Editor — current template content

Click the **Check In/Out** tab (blue arrow in screenshot below) to download the template file. As shown below, the **Check In/Out** tab is opened and the HTML Content tab (red arrow below) is deselected.



As per the instructions provided on this tab, click the **Download Document** button to download a copy of the letter template in RTF format. The **Download the RB Template Consent Content** page opens, as shown below.



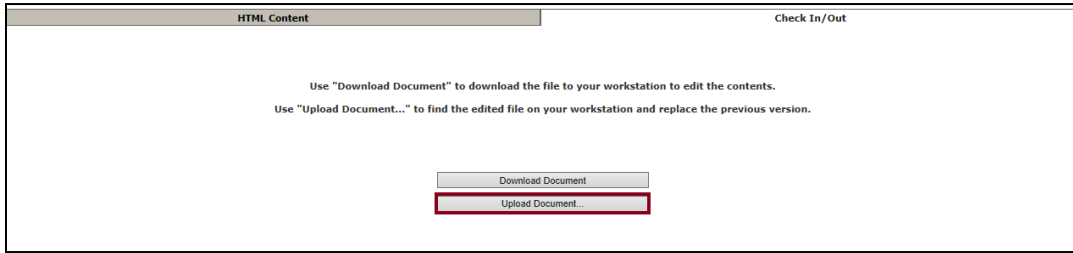
IMPORTANT: READ AND FOLLOW THE DIRECTIONS PROVIDED ON THE PAGE TO ENSURE UPLOAD OF THE REVISED DOCUMENT WILL BE ENABLED. See items boxed in red in the screenshot above.

Make desired changes to the downloaded copy of the letter template in any rich text editor and save the file under the same name as the original download.

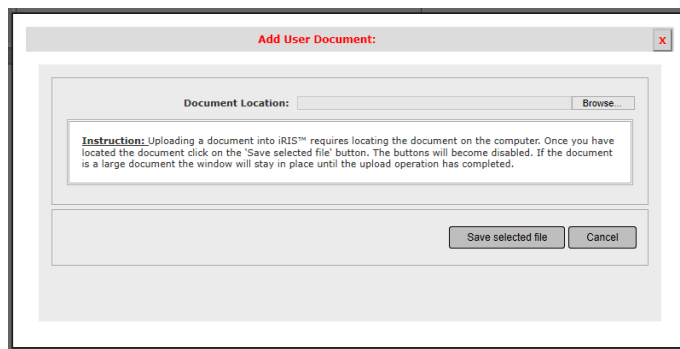
Return to the **Setup Consent Template** page and click the icon in the **Edit** column (red box in screenshot below) for the applicable template.



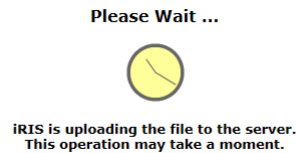
The template opens in the **HTML Content** tab of the text editor panel by default. Select the **Check In/Out** tab (shown below) and click the **Upload Document** button.



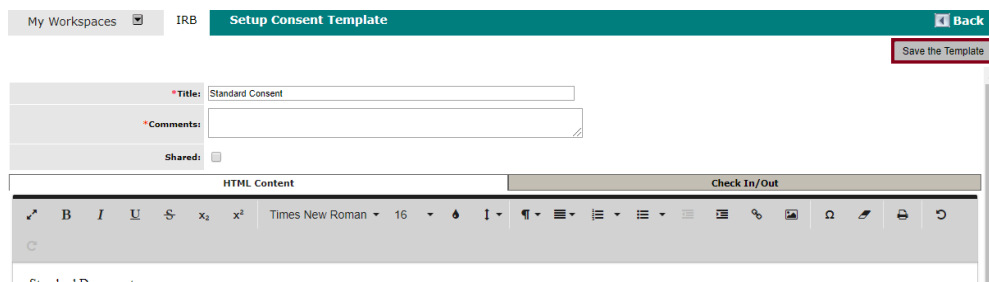
An **Add User Document** popup opens, as shown below.



Follow the directions in the popup to navigate to the revised file on the local computer and upload it to the iRIS™ system. As shown below, a countdown popup briefly appears as the upload is processed.



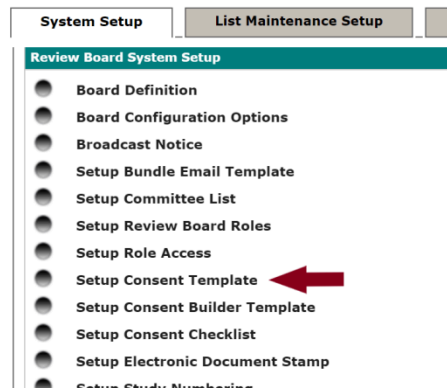
When the popup closes, back in the text editor panel of the **Setup Consent Template** page, click the **Save the Template** button to save changes and close the edit panel.



The template remains in the list on the main **Setup Consent Template** page, and is made available to users for selection when an Informed Consent is added to a study.

Delete Consent Template

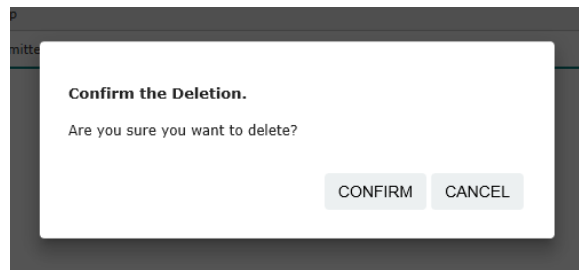
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Template** link (shown below).



The **Setup Consent Template** page opens (shown below).



Select the checkbox(es) in the far left column for the template(s) to be deleted and click the **Delete Selected Template(s)** button. A confirmation popup displays.

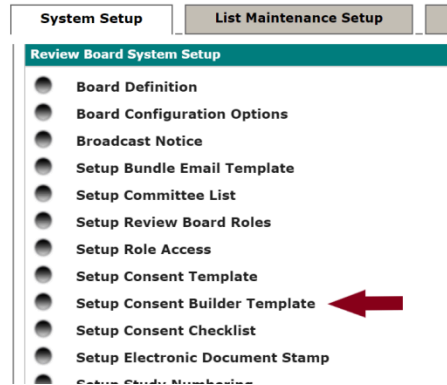


Click the **CANCEL** button to return to the **Setup Consent Template** page without deleting the selected template(s).

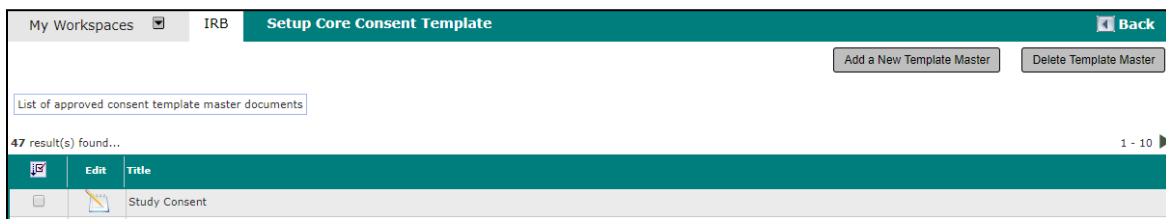
Click the **CONFIRM** button to confirm the deletion and return to the **Setup Consent Template** page.

Setup Consent Builder Template

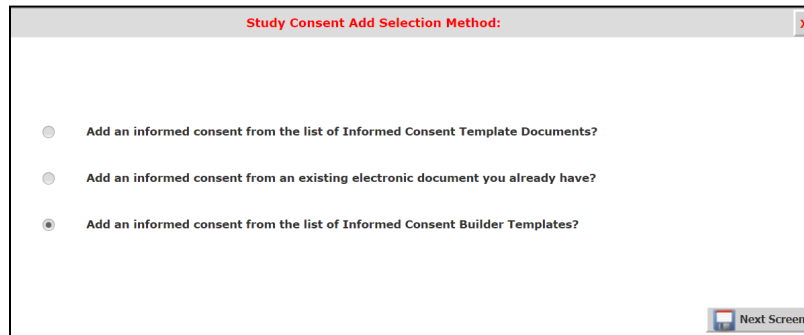
A Consent Builder Template is a document designed to step users through the process of customizing the consent form. Consent templates are configured on the **Setup Consent Template** page, which is accessed via IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Builder Template** link (shown below).



Previously configured Consent Builder templates are listed on the **Setup Core Consent Template** page.

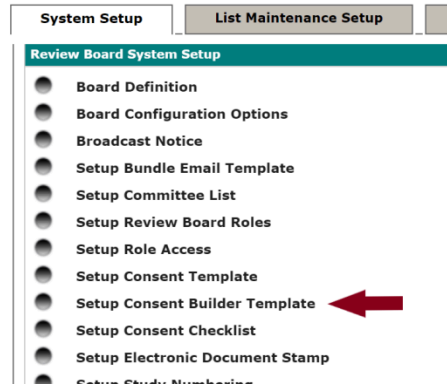


Any templates configured on the **Setup Core Consent Template** page are made available to users when an Informed Consent is added to a study, as shown below.

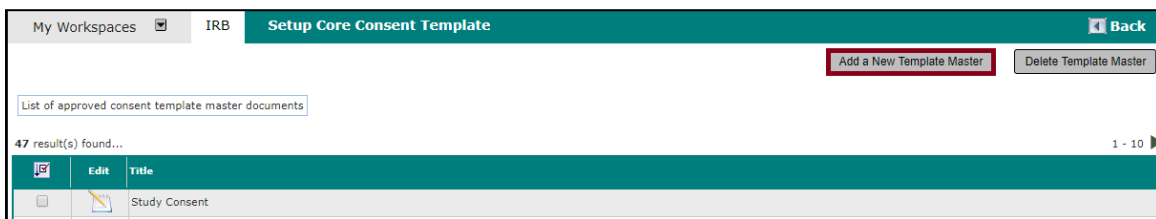


Add Consent Builder Template

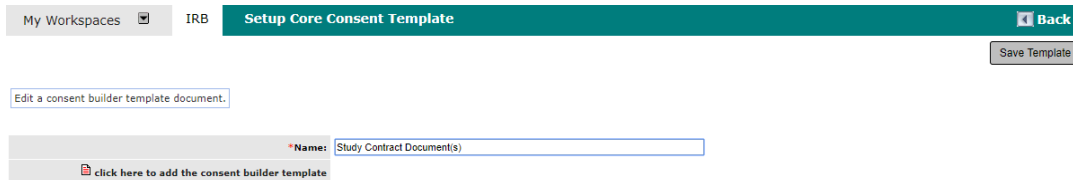
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Builder Template** link (shown below).



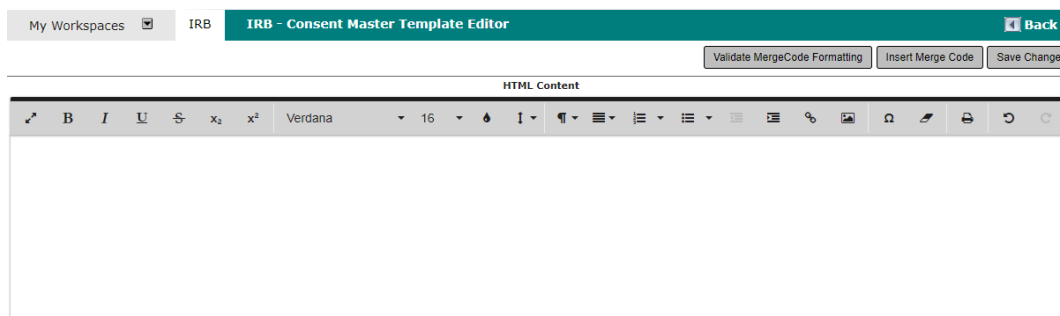
The **Setup Core Consent Template** page opens (shown below).



Click the **Add a New Template Master** button (red box in screenshot above). The **Edit a consent builder template document** panel opens, as shown below.

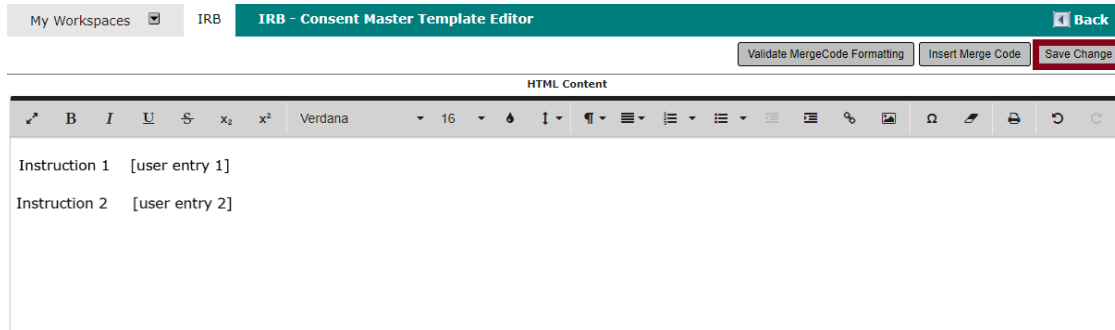


Enter a **Name** for the template and click the **Click here to add the consent builder template** link to proceed. The **IRB – Consent Master Template Editor** page opens, as shown below.

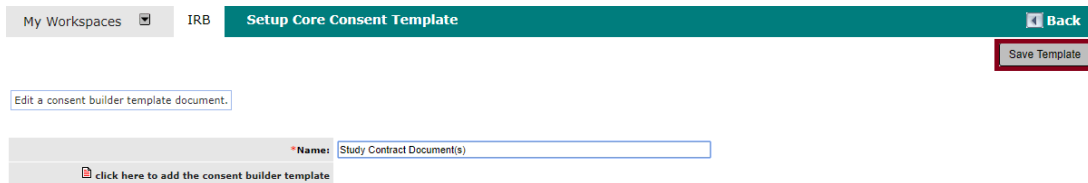


Enter desired text and Merge Codes in the text editor, and apply any desired formatting. *See the Using Merge Codes in Document Templates section of this manual for more information about working with Merge Codes.*

Recall that this type of template is intended to step the user through the process of customizing the Consent form, and should include instructions to the user.



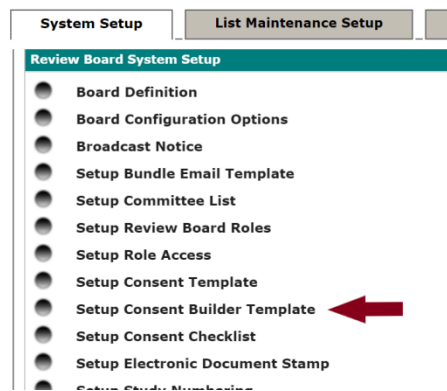
When template content is complete, click the **Save Change** button (red box in screenshot above) to save the contents of the text editor and close it. Click the **Save Template** button in the **Edit a consent builder template document** panel (shown below).



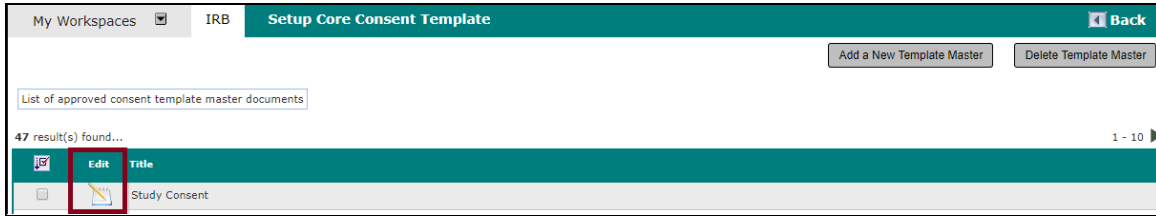
The template is added to the list on the **Setup Core Consent Template** page.

Edit Consent Builder Template

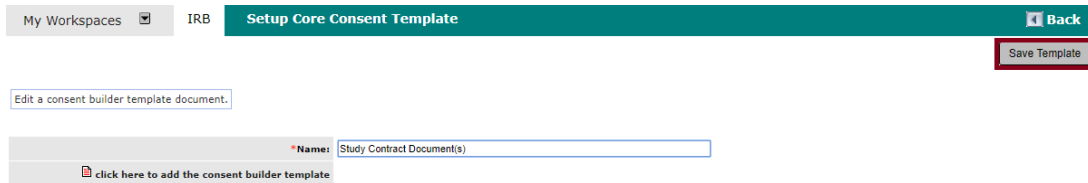
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Builder Template** link (shown below).



The **Setup Core Consent Template** page opens (shown below).



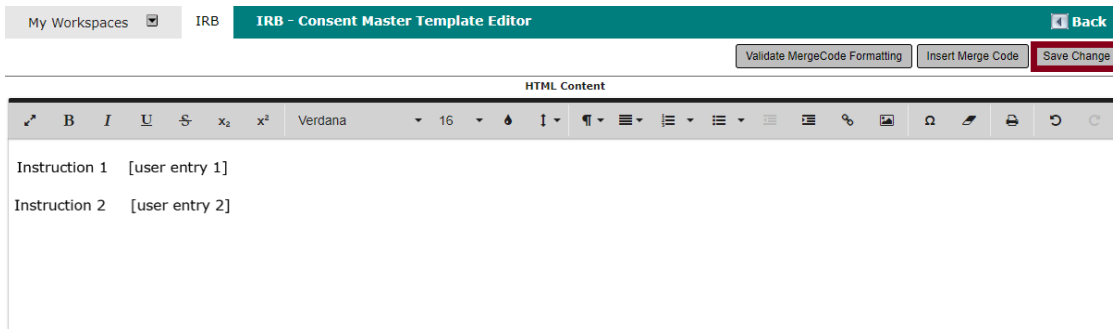
Click the applicable icon in the **Edit** column (red box in screenshot above) to open the corresponding template for revision. The **Edit a consent builder template document** panel opens, as shown below.



Make desired changes to the template **Name**.

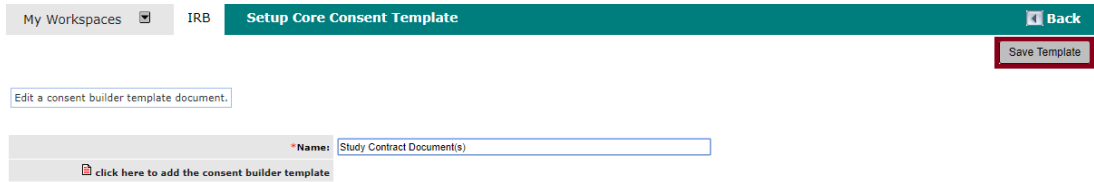
If no further changes are needed click the **Save Template** button (red box in screenshot above) to save changes and close the edit panel. The template name is revised on the **Setup Core Consent Template** list page.

To revise the contents of the template, click the **Click here to add the consent builder template** link. The template is opened in the **IRB – Consent Master Template Editor** page opens, as shown below.



Make desired changes to the text and Merge Codes in the text editor, and apply any desired formatting. *See the Using Merge Codes in Document Templates section of this manual for more information about working with Merge Codes.*

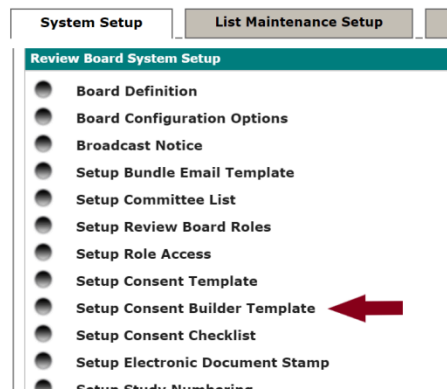
When template changes are complete, click the **Save Change** button (red box in screenshot above) to save the contents of the text editor and close it. Click the **Save Template** button in the **Edit a consent builder template document** panel (shown below).



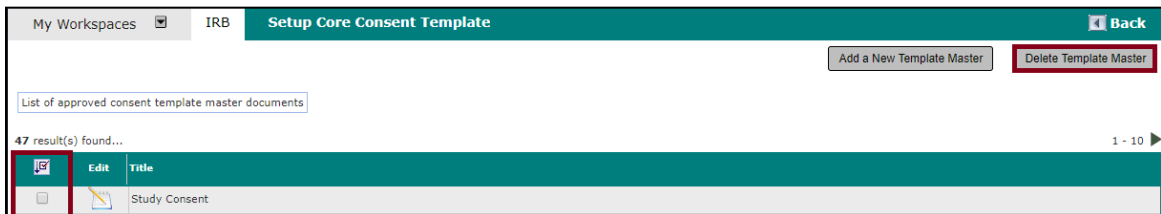
The template is revised in the list on the **Setup Core Consent Template** page.

Delete Consent Builder Template

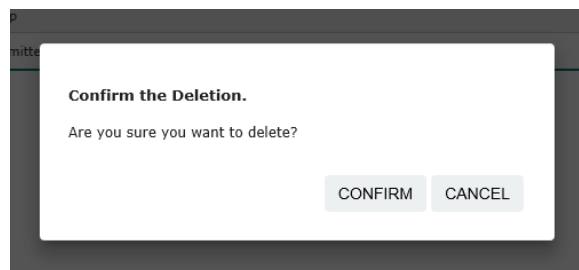
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Consent Builder Template** link (shown below).



The **Setup Core Consent Template** page opens (shown below).



Select the checkbox(es) in the far left column for the template(s) to be deleted and click the **Delete Selected Template(s)** button. A confirmation popup displays.



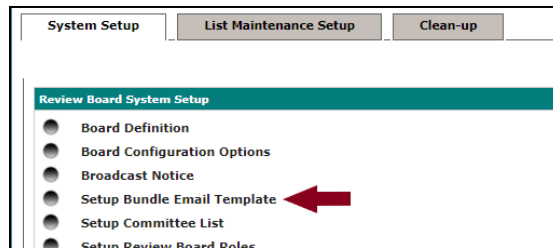
Click the **CANCEL** button to return to the **Setup Core Consent Template** page without deleting the selected template(s).

Click the **CONFIRM** button to confirm the deletion and return to the **Setup Core Consent Template** page.

Setup Bundle Email Template

Where the property `rb.use_bundle_stipulation` is set to “Yes” (accessed via IRB Assistant > Review Board Administration > Board Configuration Options > Recommendations and Stipulations link), documents selected in the Submission Complete tab of a completed submission are bundled with an electronic cover letter for routing to selected recipients.

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Bundle Email Template** link to configure the electronic cover letter.



The **RB Bundle Template** page opens. Notice that by default, once the applicable property is set to “Yes” an unconfigured “RB Bundle Document Template” is created, with **Title** and **Send E-Mail Notification** fields set to “Not Defined”.

My Workspaces		IRB		RB Bundle Template		Back
Edit	Type	Title	Send E-mail Notification	Action		
	RB Bundle Template	Not Defined	Not Defined	Add Notification		

Note that only one RB Bundle Template can be configured at any time, and once configured, that template is applied to all applicable email bundles.

Click the **Add Notification** button. The **Edit RB Bundle Template** page opens, as shown below.

Complete the page fields as follows.

E-mail Subject —subject line of the email bundle cover letter

Send E-mail Notification — select “Yes” to enable document bundling with the configured cover letter; select “No” to save the configured cover letter to the system without enabling document bundling

Recipient(s) — click the word **Recipient(s)** to add iRIS™ users to the distribution list

***Recipient(s):**

As shown below, the **Search User Directory** page opens.

Click in the **by Department** field to open a dropdown list of departments, then click a department in the list to add this criterion to the search. *Note that it is not possible to search by department alone, full or partial **Last Name** / **First Name** entries are also required.*

Enter a full or partial **Last Name** and/or **First Name** to search by name. As shown below, the **Last Name** field offers a dynamic picklist feature that populates as the **Last Name** is typed into the field.

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

As demonstrated below, clicking on a name shown in the dynamic **Last Name** picklist immediately populates search results with details for that name, it is not necessary to click the **Find** button.

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Duvrong, Rapitha R		rduv@nhvc.com

When all search criteria are entered, if results are not yet populated click the **Find** button.

As indicated below, the results section of the page offers two methods for adding users to the distribution list.

Directory Browse/Find: Last Name: duvrong (You may enter a partial name to search) First Name: by Department: All Departments Find Save Selected User(s)

Check for Multiple	Select User	Training	User Name	Department	Email
<input type="checkbox"/>	<input checked="" type="checkbox"/>		Duvrong, Rapitha R		rduv@nhvc.com

To add multiple users from a results list with multiple entries, select the **Check for Multiple** checkbox at far left (blue arrow) for each user to be added, then click the **Save Selected User(s)** button at the upper right (blue box).

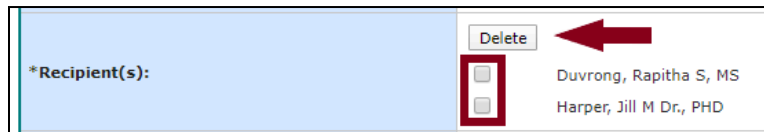
To add a single user from the results list, click the green checkmark for the applicable user (red arrow).

When the applicable user(s) is(are) selected from the **Search User Directory** page, that page closes and the name(s) is(are) added to the **Recipient(s)** list as shown below. To add more iRIS™ users to the list, click the word **Recipient(s)** again and repeat the user lookup/add process.

*Recipient(s): Delete

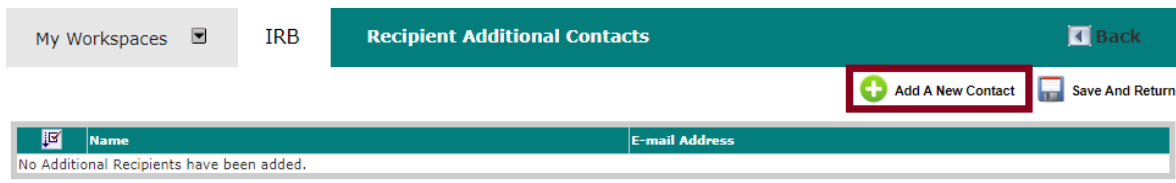
- Duvrong, Rapitha S, MS
- Harper, Jill M Dr., PHD

If any **Recipient(s)** were added in error select the checkbox to the left of the applicable name and click the **Delete** button to delete it, as shown below.

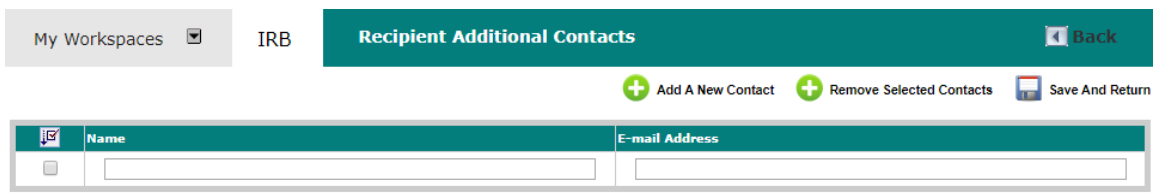


Additional recipient(s) — click the words “**Additional recipient(s)**” to add people who do not have an iRIS™ account to the distribution list

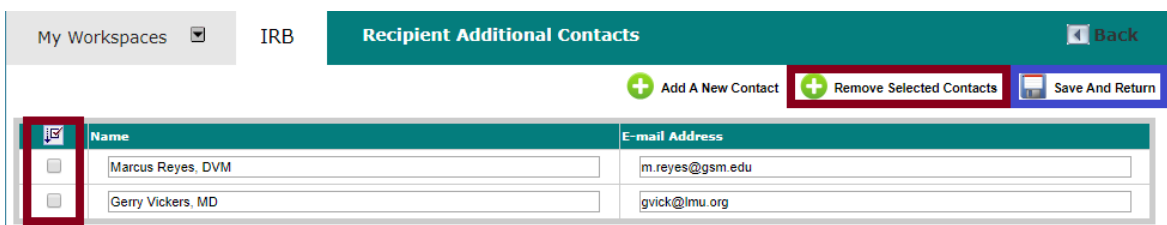
The **Recipient Additional Contacts** page opens, as shown below.



Click the **Add A New Contact** link to add a blank row to the Additional Recipients table, as shown below.



Enter the contact **Name** and **E-mail Address**. Click the **Add a New Contact** button again and enter **Name/E-mail Address** details for every non-iRIS™ user to be added to the distribution list, as shown below.



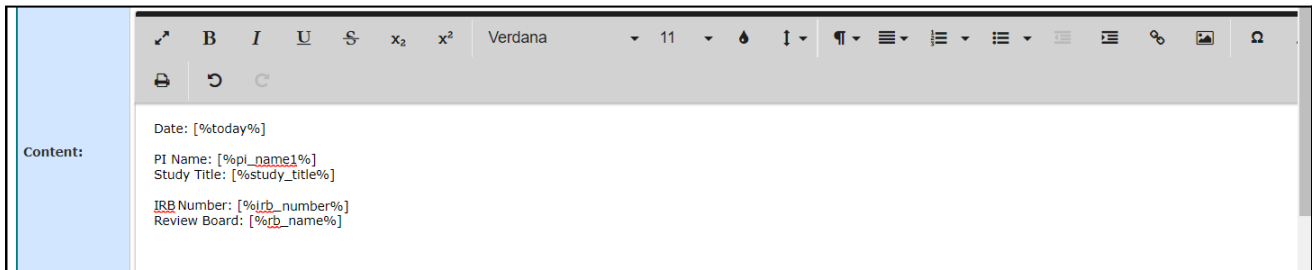
If any rows are added in error, select the checkbox in the far-left column for the applicable name and click the **Remove Selected Contacts** button (red boxes in screenshot above).

When all desired contacts are entered click the **Save And Return** button (blue box in screenshot above) to close the **Recipient Additional Contacts** page and add the listed contacts to the distribution list on the **Edit RB Bundle Template** page, as shown below.

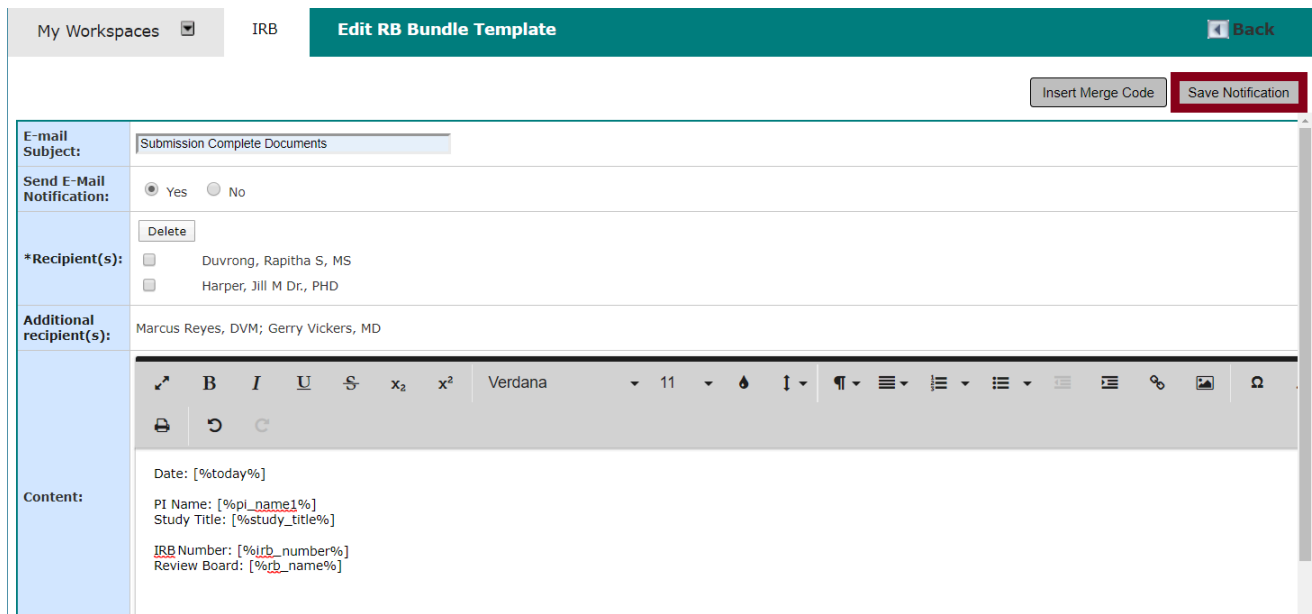
Additional recipient(s):	Marcus Reyes, DVM; Gerry Vickers, MD
---------------------------------	--------------------------------------

If any **Additional recipient(s)** are added in error, click the words **Additional recipient(s)** again to reopen the Recipient Additional Contacts form and delete the applicable contact(s).

Content — enter desired text and Merge Codes (see Using Merge Codes in Document Templates subsection of this manual for more information about working with Merge Codes) for the bundle cover letter; use the provided toolbar to format the text as desired



An example of a fully configured template is shown below. Click the **Save Notification** button to save the template and close the **Edit RB Bundle Template** page.



As shown below, the template is now configured on the **RB Bundle Template** page.

My Workspaces	IRB	RB Bundle Template			Back
Edit	Type	Title	Send E-mail Notification	Action	
	Bundle Email Template	Submission Complete Documents	Yes		

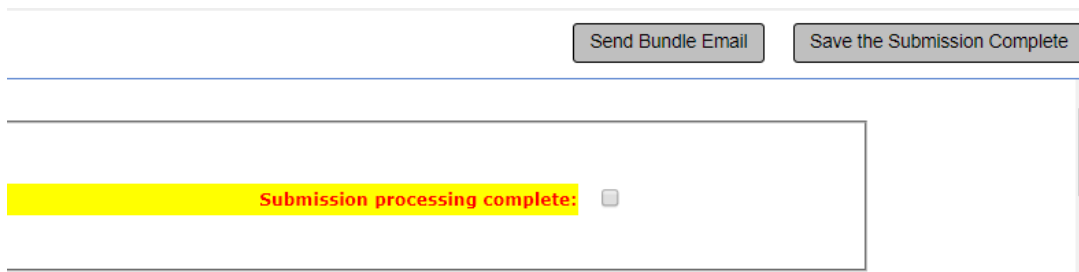
Notice that an **Edit** icon (red box in the screenshot above) is now available and the Add Notification button is now replaced with a **Delete Notification** button (blue box in the screenshot above), indicating that only one version of the template can be configured at any time.

Click the icon in the **Edit** column to reopen the template for revision in the **Edit RB Bundle Template** page.

Click the **Delete Notification** button to delete the configured template and disable document bundling with a configured cover letter.

*CAUTION: this action cannot be undone. If it later becomes necessary to resume document bundling the **RB Bundle Template** must be reconfigured according to the directions in this section.*

With the configured template in place, when a submission is completed and saved the option to **Send Bundle Email** is made available via a button, as shown below.



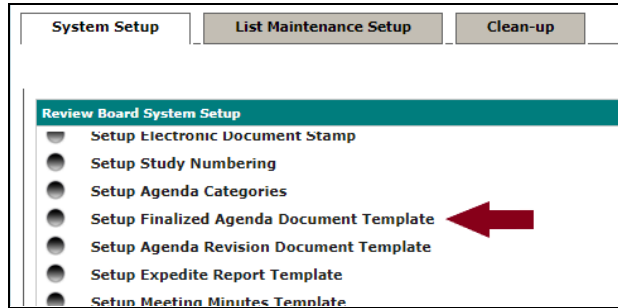
Clicking the **Send Bundle Email** button creates an email cover letter with all text, recipients and Merge Code data items as configured in the template. All configured items can be revised in this email cover letter prior to sending.

When the bundle email is sent, all documents selected in the Submission Complete tab of the applicable submission are bundled and sent to the specified recipients.

Setup Finalized Agenda Document Template

The iRIS™ system provides the ability to configure finalized meeting agenda templates that include commonly used boilerplate text and can automatically pull a variety of system data into the agenda when it is generated.

This functionality is provided on the **Finalized Agenda Templates** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Finalized Agenda Document Template** link.



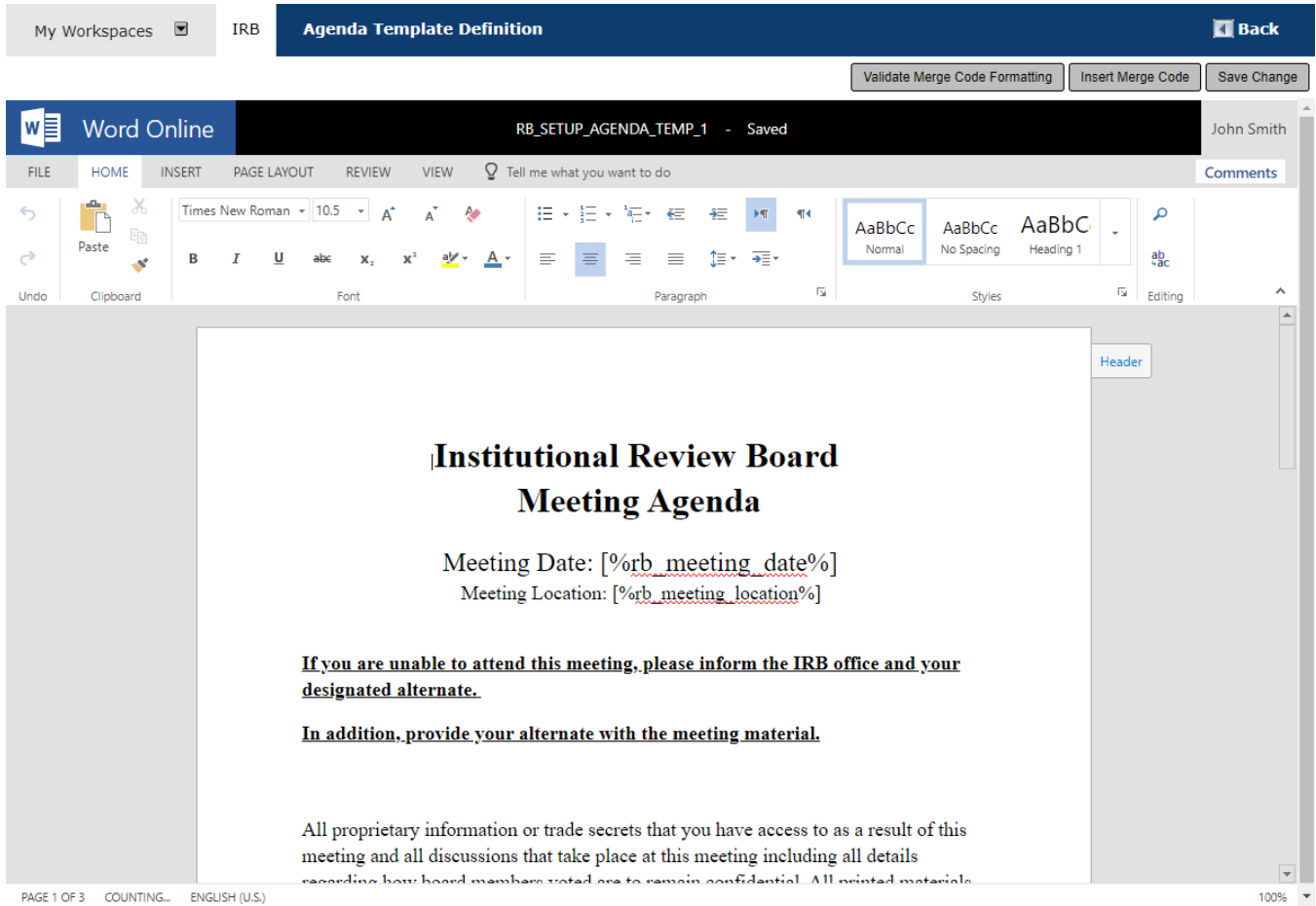
The **Finalized Agenda Templates** page opens, as shown below. Notice the two instruction items and the corresponding buttons for each.

My Workspaces ▾ IRB **Finalized Agenda Templates** [Back](#)

1. Setup the Agenda Template Master which describes the layout of the minutes document
 Agenda Template Master [Setup Agenda Template](#)
2. Setup the Agenda Template Section which will merge the data from each Agenda submission

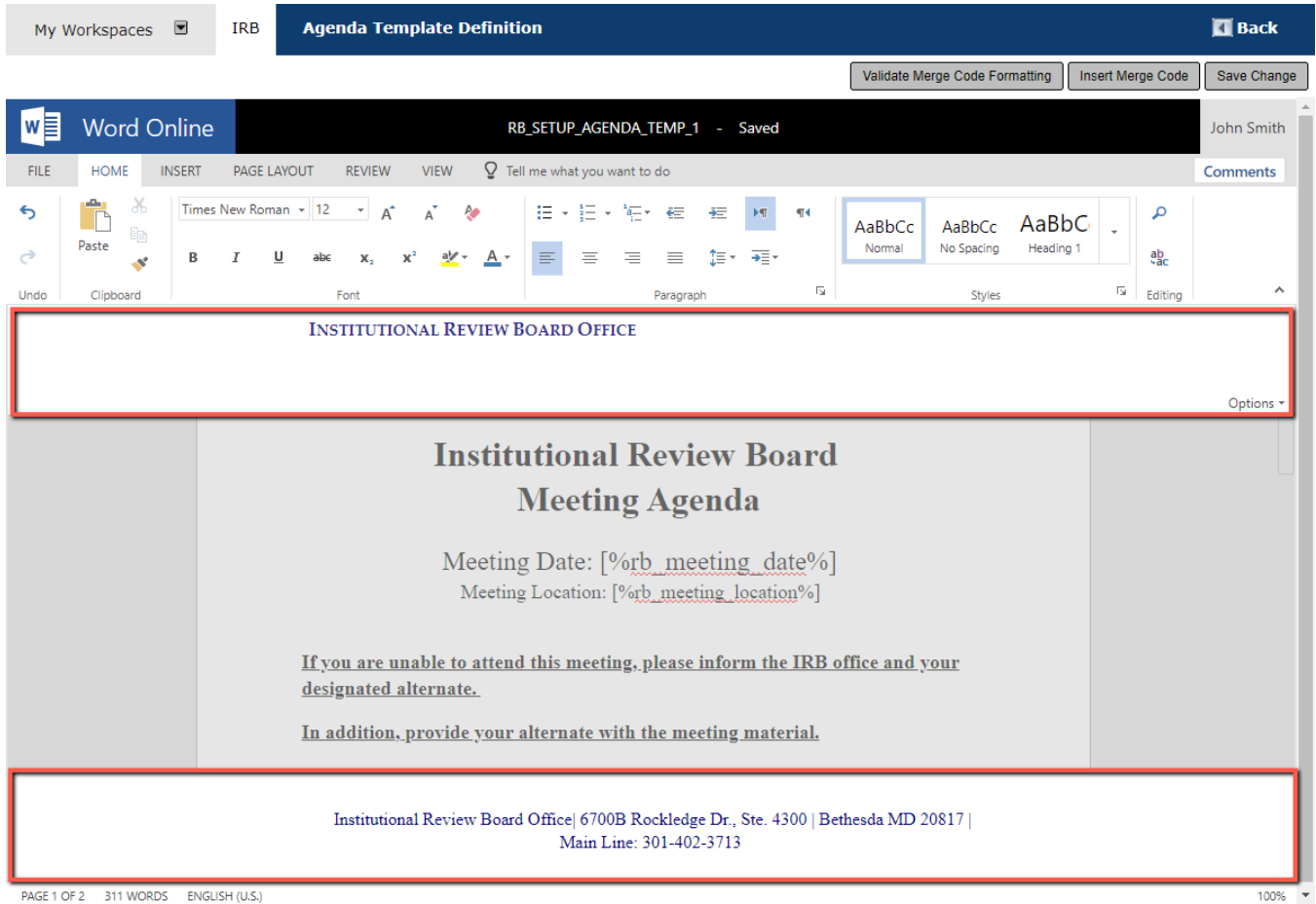
Submission Type	Edit Template
Initial Reviews	Setup Section Information
Continuing Reviews	Setup Section Information
Expedited Submissions	Setup Section Information
Amendment Submissions	Setup Section Information
Administrative Action	Setup Section Information

As indicated in the instructions, the first step is setting up the Agenda Template Master. Click the **Setup Agenda Template** button to begin. The **Agenda Template Definition** page opens in Word Online, as shown below.



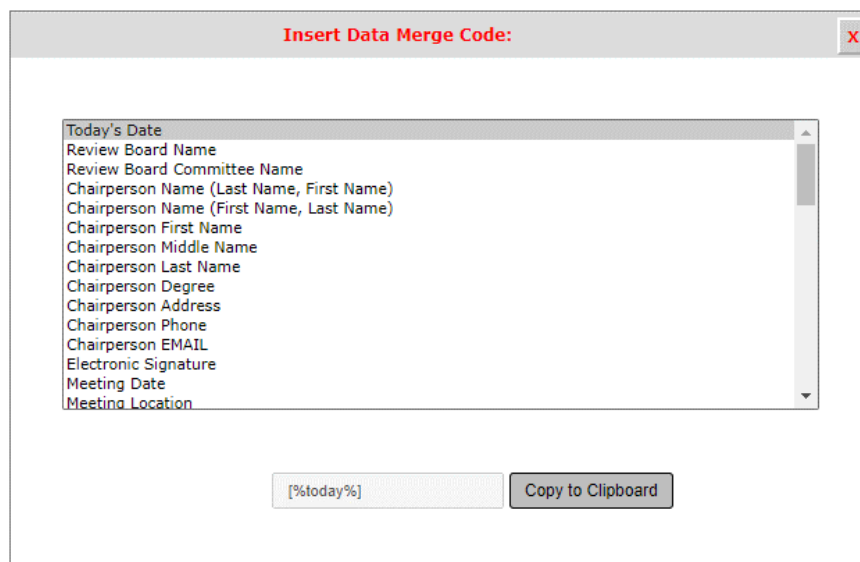
Enter desired boilerplate text, including Headers and Footers using the Word Online tools show in the screenshot above.

Click on the Header or Footer tab to edit the Header and Footer content as shown below.



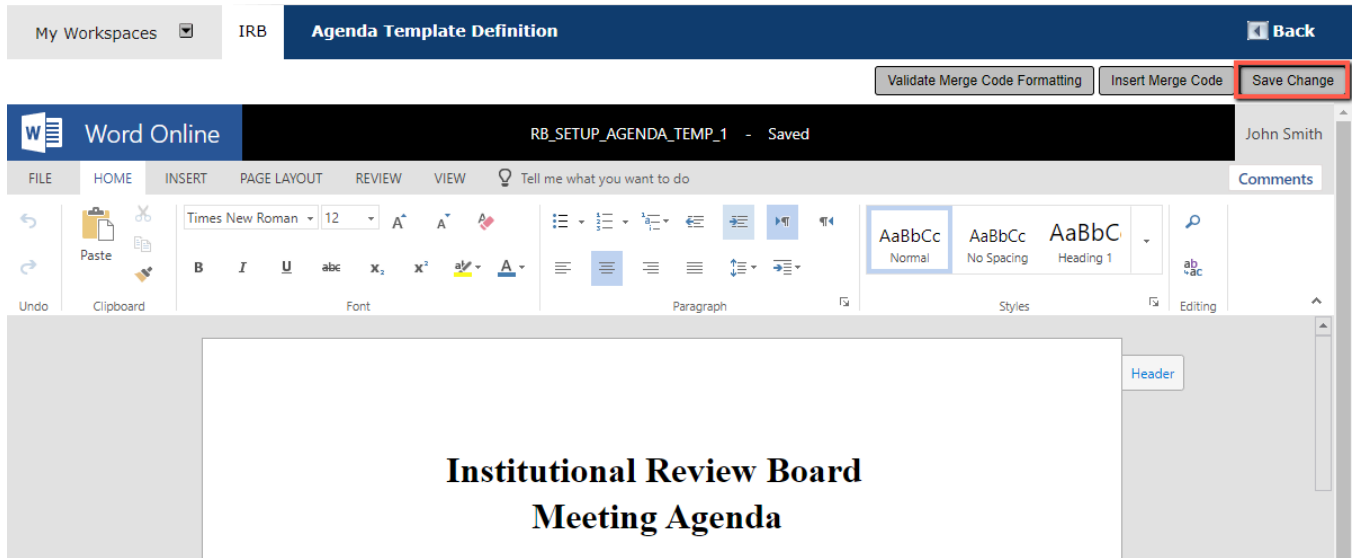
Click on the regular template area to return to exit the Header and Footer.

To add a merge code, click on Insert Merge Code to open the selection window as shown below.



Once you click on the desired merge code, click on Copy to Clipboard and paste the merge code in the desired location.

Recall that this template serves as the basis for all finalized agenda documents, and therefore it should include all items considered standard and necessary to any finalized agenda. An example of a completed finalized agenda template is shown below.

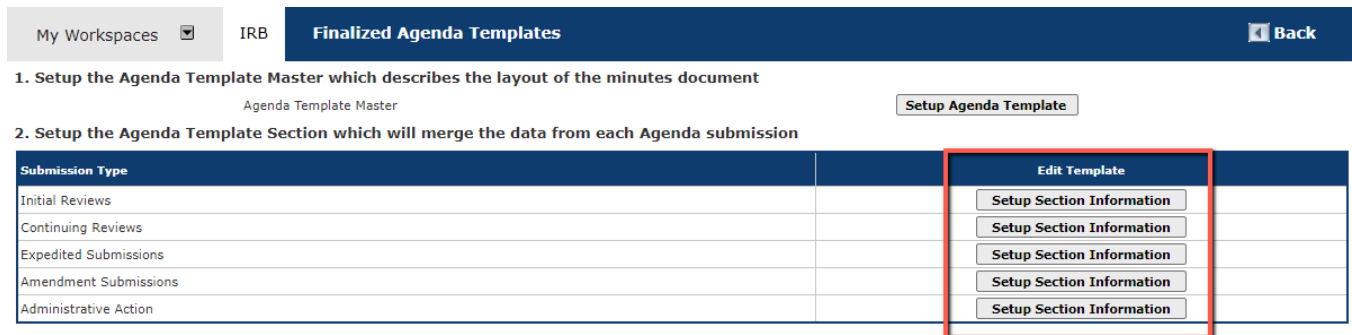


When template content is complete, click the **Save Change** button to close the page and save the template.

Back on the **Finalized Agenda Templates** page, any previously configured, custom agenda category sections are listed in the lower section of the screen. Each section can be configured to specify what information is to be displayed for each submission in the agenda template master.

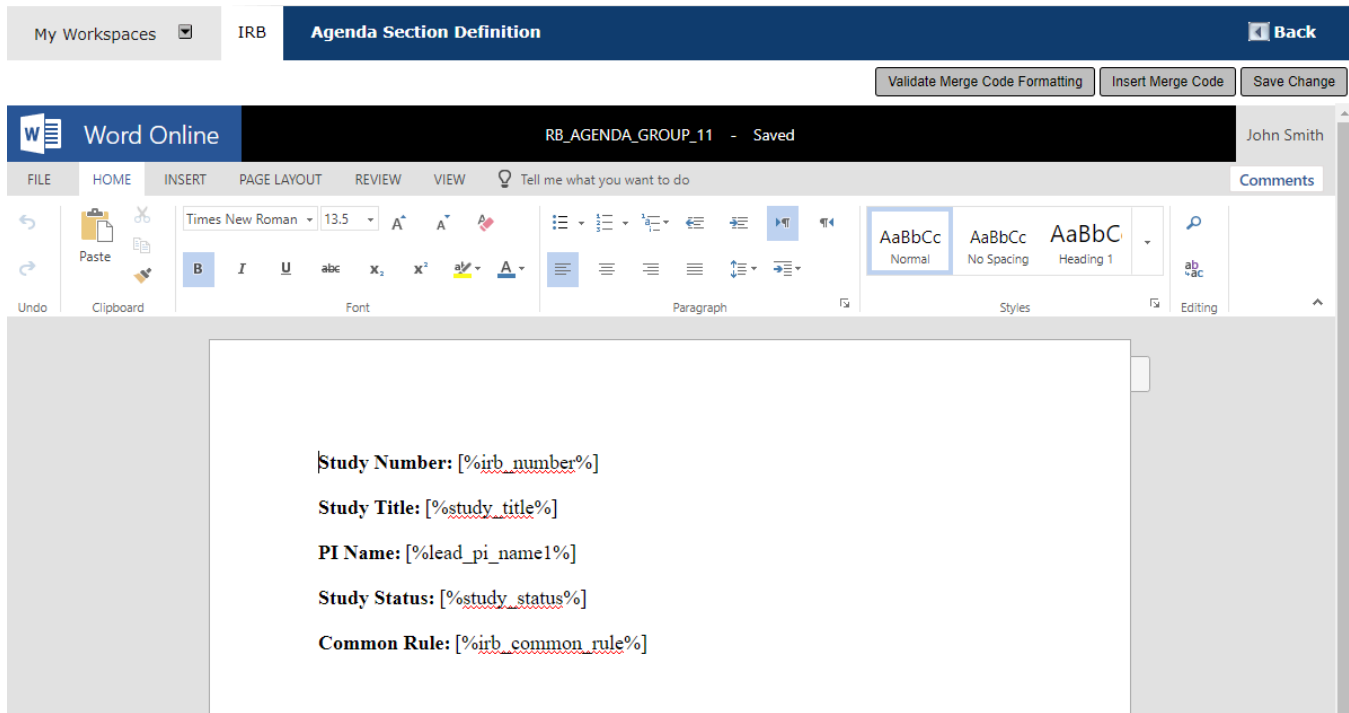
Note that custom agenda category configuration includes a study/protocol/project selection component that automatically limits review items pulled into the meeting to those matching specific criteria. Adding a custom category to the agenda does not pull all animal study/protocol/project items into the meeting.

See the *Setup Agenda Categories* section of this manual for more information about configuration of custom agenda categories.



Again, recall that the template serves as the basis for *all* finalized agenda documents; custom agenda categories should only be added to the template if those categories are applicable to most meeting agendas.

Click the **Setup Section Information** button for any agenda category to be added to the finalized agenda template. The **Agenda Section Definition** page opens, as shown below.



The boilerplate text and Merge Codes entered here depend on the purpose of the agenda category. In this example the category is intended to add animal issue reporting to the meeting, so its content is focused on changes in animal life status and population counts.

When section definition content is complete, click the **Save Change** button to close the page and save the section definition.

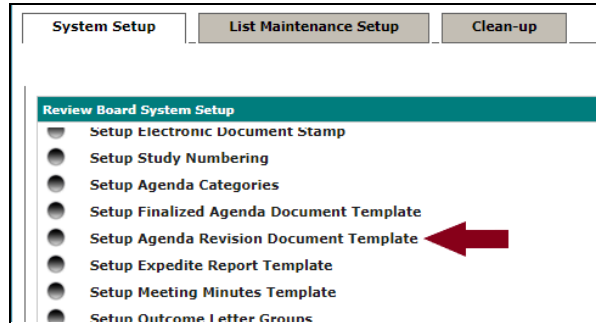
Going forward, each IRB Meeting Agenda generated for a specific meeting date will consist of one document that includes both the Agenda Template Master and any custom sections configured as above.

See the Meetings manual for more information about meeting management functionality in iRIS™.

Setup Agenda Revision Document Template

The Revision Agenda Template is used to generate an addendum when a new submission is placed on the agenda *after* the initial Agenda is published for a given meeting date.

This functionality is provided on the **Finalized Agenda Templates** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Agenda Revision Document Template** link.



The **Setup Board Agenda Revision Templates** page opens, as shown below.

My Workspaces ▾ IRB **Setup Board Agenda Revision Templates** ⏪ Back

1. Setup the Revision Template Master which describes the layout of the minutes document
 Revision Template Master Setup Revision Template
2. Setup the Revision Template Section which will merge the data from each Revision submission

Submission Type	Edit Template
Initial Reviews	Setup Section Information
Continuing Reviews	Setup Section Information
Expedited Submissions	Setup Section Information
Amendment Submissions	Setup Section Information
Administrative Action	Setup Section Information

Notice that this page is nearly identical to the Finalized Agenda Templates page, with the exception that where the Finalized Agenda Templates page is used to configure the Agenda Template Master, this page is used to configure the Revision Template Master.

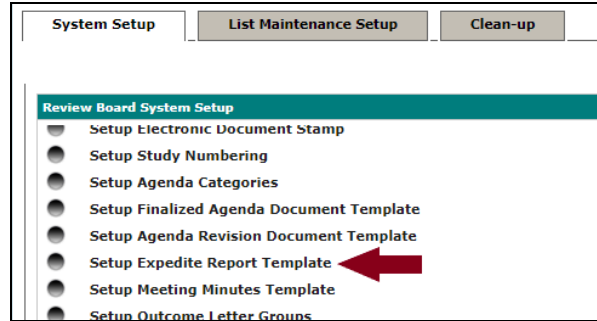
Where this feature is in use it is often necessary for the institution to configure applicable agenda categories to capture the most common agenda revision scenarios and related, pertinent data. See the Setup Agenda Categories section of this manual for more information about configuration of custom agenda categories.

The process of configuring the Revision Template Master is the same as that for configuration of the Agenda Template Master. See the Setup Finalized Agenda Document Template section of this manual for details of template configuration.

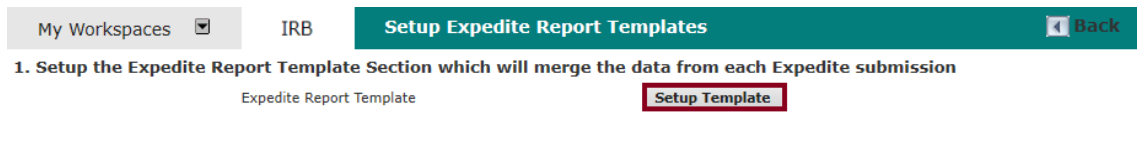
Setup Expedite Report Template

Where the property `rb.use_meeting` is set to “Yes” (accessed via IRB Assistant > Review Board Administration > System Setup tab > Board Configuration Options > Meeting Settings link), it is possible to generate a summary of expedited reports for attachment to a meeting date.

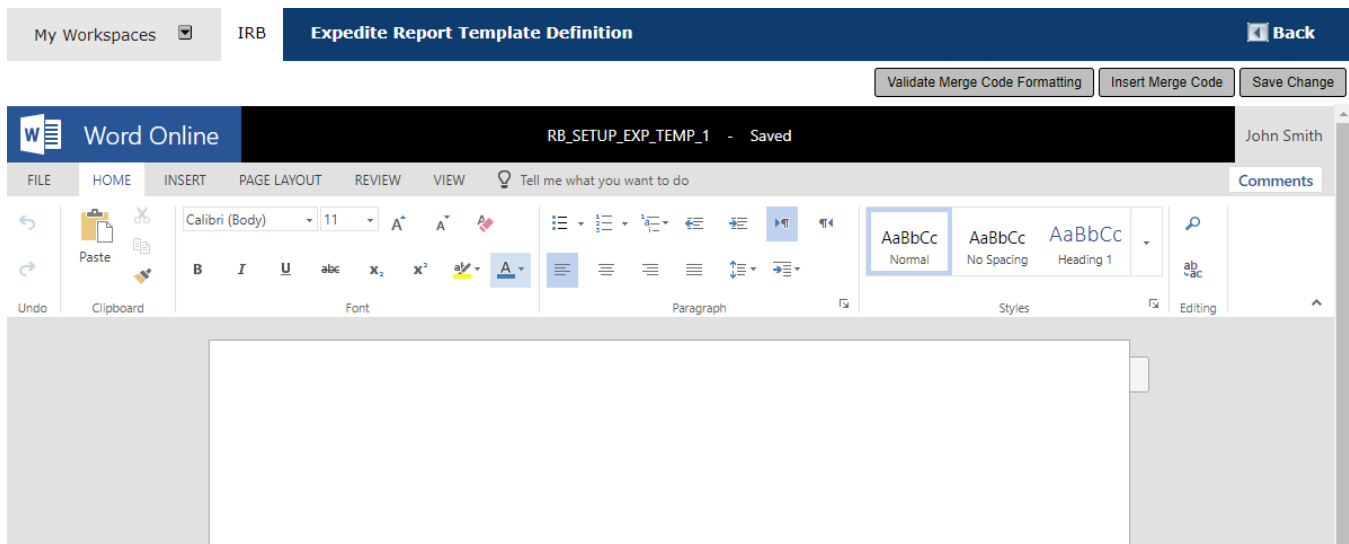
This functionality is provided on the **Setup Expedite Report Templates** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Expedite Report Template** link.



The **Setup Expedite Report Templates** page opens, as shown below.



Click the **Setup Template** button. The **Expedite Report Template Definition** text editor page opens, as shown below.



Enter desired boilerplate text and Merge Codes and apply formatting as desired using the provided Word Online toolbar.

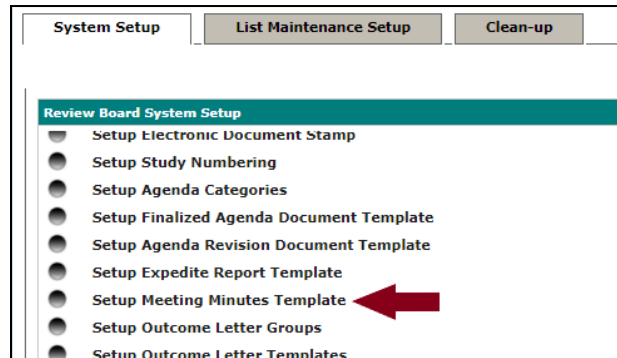
When template content is complete, click the **Save Change** button to close the page and save the template.

See the Meetings manual for more information about generation of the expedited report as it relates to meeting functionality in iRIS™.

Setup Meeting Minutes Template

The Meeting Minutes Template is used to generate a standardized minutes document for a given meeting date.

This functionality is provided on the **Setup Board Minute Templates** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Meeting Minutes Template** link.



The **Setup Board Minute Templates** page opens, as shown below.

My Workspaces ▾ IRB **Setup Board Minute Templates** [Back](#)

1. Setup the Minutes Template Master which describes the layout of the minutes document
 Minutes Template Master [Setup Minutes Template](#)
2. Setup the Minutes Template Section which will merge the data from each Agenda submission

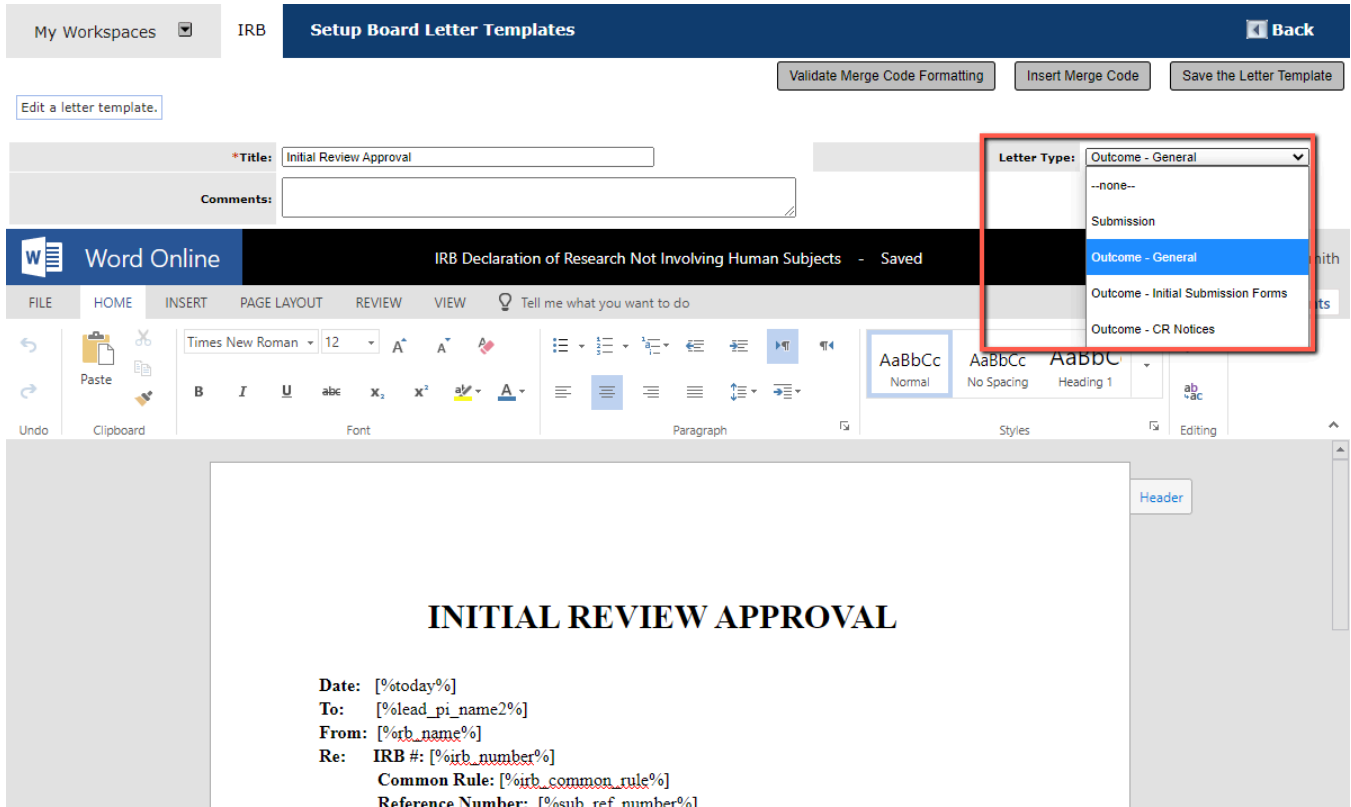
Submission Type	Edit Template
Initial Reviews	Setup Section Information
Continuing Reviews	Setup Section Information
Expedited Submissions	Setup Section Information
Amendment Submissions	Setup Section Information
Administrative Action	Setup Section Information

Notice that this page is nearly identical to the Finalized Agenda Templates page, with the exception that where the Finalized Agenda Templates page is used to configure the Agenda Template Master, this page is used to configure the Minutes Template Master.

The process of configuring the Minutes Template Master is the same as that for configuration of the Agenda Template Master. See the Setup Finalized Agenda Document Template section of this manual for details of template configuration.

Setup Outcome Letter Groups

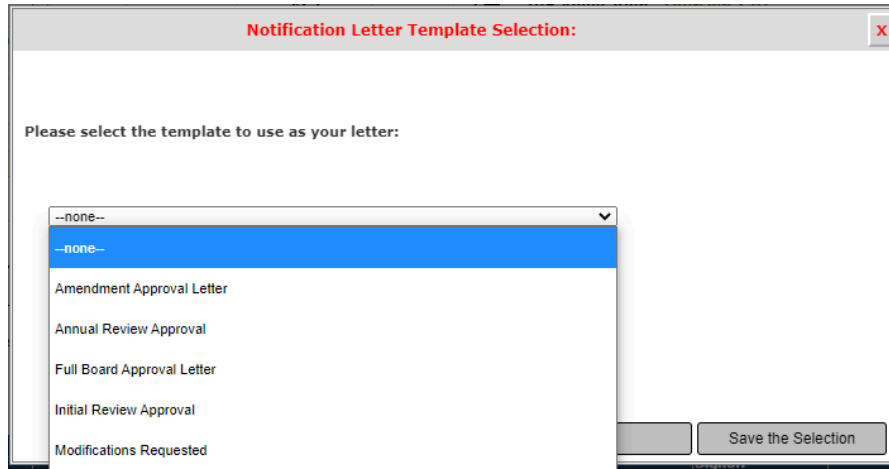
The iRIS™ system allows for collecting sets of review board forms into custom configured **Letter Type** groups for assignment to different board review types. As shown below, the **Letter Types** list on the add/edit panel of the **Setup Board Letter Templates** page (see the Setup Outcome Letter Templates section of this manual) includes two default entries:



- **Outcome - General:** letter templates of this type appear as options available for selection on the Outcome Letter tab of submission processing screens

Note: filters assigned to custom outcome letter groups determine those groups’ availability in the dropdown list on the Outcome Letter tab, but the Outcome – General Group always available. For example, a letter associated to a group called “Outcome – Full Renewal Approval” that has a filter assigning that group to the Full Renewal Submission type would only be available for a Full Renewal Submission type, this letter would not be available for any other submission type.

- **Submission:** letter templates of this type appear as options available for selection on the Submission Received Notification Letter tab of submission processing screens (IACUC example shown below)



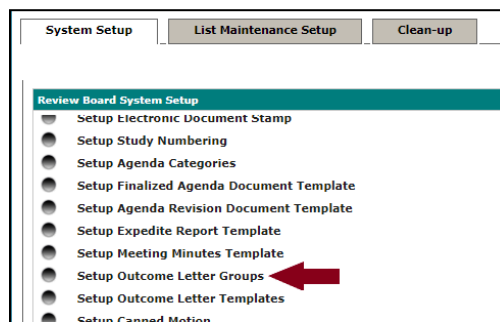
Custom configured **Letter Type** groups are added to the **Letter Type** dropdown list on the **Setup Board Letter Templates** page (shown in the first screenshot above) and are optionally made available on the Outcome Letter tab of submission processing screens according to rules established at the time a **Letter Type** group is created or revised (see Add Outcome Letter Group and Edit Outcome Letter Group subsections of this manual, below).

Letter Type groups are configured on the **Setup Board Letter Group List** page, shown below.



Add Outcome Letter Group

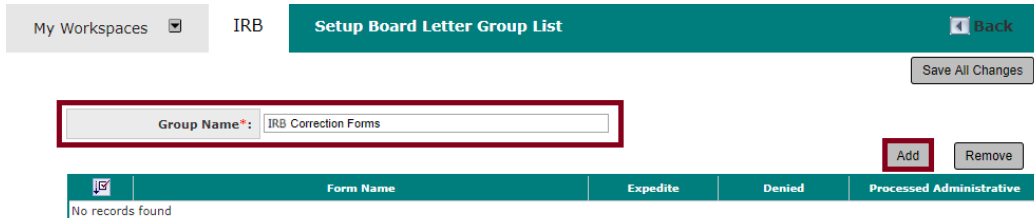
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Groups** link.



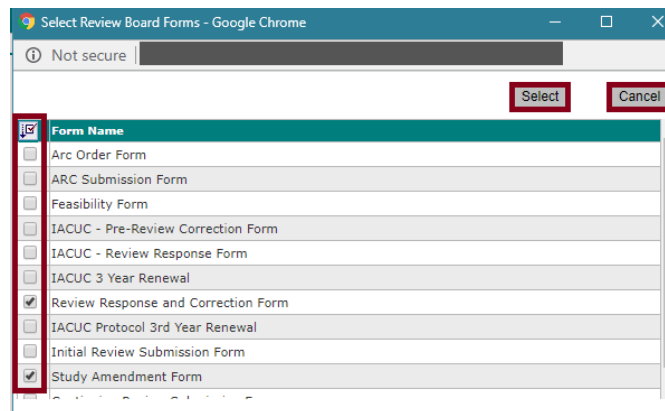
The **Setup Board Letter Group List** page opens. Click the **Add Group** button.



An add panel is opened for creation of the group. Enter the desired **Group Name**, as shown below, then click the **Add** button at right.



A popup opens for selection of review board forms to be included in the group. *Note that because forms are custom configured for each institution, the list of forms shown here will vary.*



Click the **Cancel** button to close the popup without adding any forms to the group.

Select the checkbox(es) in the far-left column for all forms to be included in the group, then click the **Select** button to add them to the group and close the popup. As shown below, the selected forms are added to the list of forms on the add panel.

My Workspaces ▾ IRB **Setup Board Letter Group List** Back

Group Name*: IRB Correction Forms Add Remove

<input type="checkbox"/>	Form Name	Expedite	Denied	Processed Administrative
<input type="checkbox"/>	Pre-Review Correction Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Review Response and Correction Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Study Amendment Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Save All Changes

If any forms were selected from the popup list in error, select the checkbox(es) for any forms to be removed from the group and click the **Remove** button.

My Workspaces ▾ IRB **Setup Board Letter Group List** Back

Group Name*: IRB Correction Forms Add Remove

<input type="checkbox"/>	Form Name	Expedite	Denied	Processed Administrative
<input type="checkbox"/>	Pre-Review Correction Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Review Response and Correction Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Study Amendment Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Save All Changes

Select or de-select the applicable checkboxes to make each form listed available/unavailable as part of the group according to board review type when the group is selected in the **Notification Letter** dropdown list in the **Outcome Letter** section of submission processing screens (shown below).

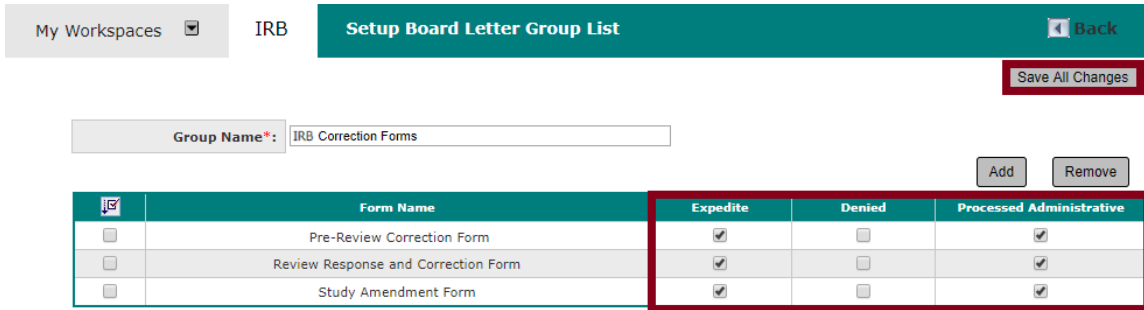
Outcome Letter ⓘ

Notification Letter: --none-- ▾

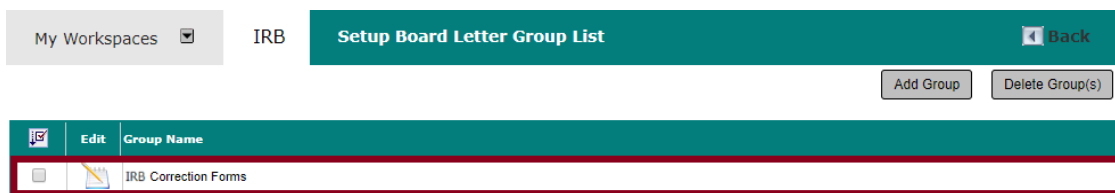
Delete/Void	Send	Edit/View	Title	Signature Required	Status	Route Signoff	Copy
No Letters have been created for this submission.							

Note that all forms in the group are made available to the Full Board Review type by default.

An example of the fully configured group is shown in the screenshot below.



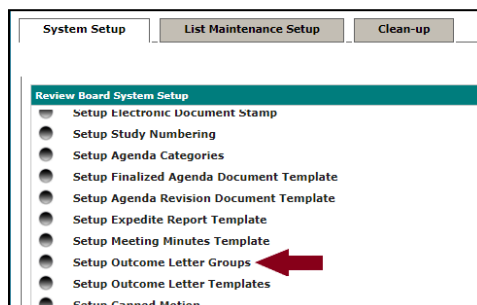
Click the **Save All Changes** button to save the new group. As shown below, the group is added on the **Setup Board Letter Group List** page.



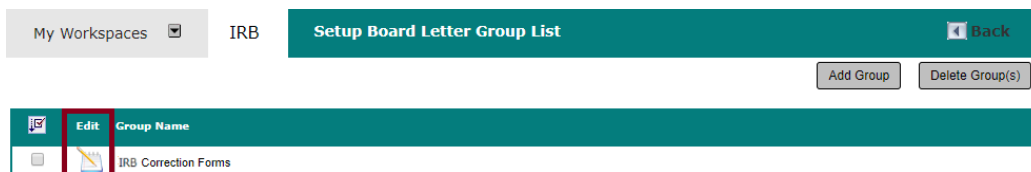
The new **Letter Type** group is also added to the **Letter Type** dropdown list on the **Setup Board Letter Templates** page and is made available on the Outcome Letter tab of submission processing screens for **Expedite**, **Exempt** and **Process Administratively** board review types.

Edit Outcome Letter Group

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Groups** link.



The **Setup Board Letter Group List** page opens. Click icon in the **Edit** column for the applicable group.



The group is opened for editing. Make any desired changes to the **Group Name**.

My Workspaces ▾ IRB **Setup Board Letter Group List** Back

Save All Changes

Group Name*: IRB Correction Forms

Add Remove

<input checked="" type="checkbox"/>	Form Name	Expedite	Denied	Processed Administrative
<input type="checkbox"/>	Pre-Review Correction Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Review Response and Correction Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Study Amendment Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

To remove forms from the group, select the applicable checkbox(es) in the far-left column and click the **Remove** button.

My Workspaces ▾ IRB **Setup Board Letter Group List** Back

Save All Changes

Group Name*: IRB Correction Forms

Add Remove

<input checked="" type="checkbox"/>	Form Name	Expedite	Denied	Processed Administrative
<input type="checkbox"/>	Pre-Review Correction Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Review Response and Correction Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Study Amendment Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Select or de-select the applicable checkboxes to make each form listed available/unavailable as part of the group according to board review type when the group is selected in the **Notification Letter** dropdown list in the **Outcome Letter** section of submission processing screens (shown below).

Outcome Letter ⓘ

Notification Letter: --none-- ▾

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

Note that all forms in the group are made available to the Full Board Review type by default.

In the example screenshot below, checkboxes for the **Expedite** board review type are de-selected. Applying this change means that the forms shown will not be included in the IRB Correction Forms group when it is selected from the **Notification Letter** dropdown list (see screenshot above) for submissions assigned to the **Exempt** board review type.

My Workspaces ▾ IRB **Setup Board Letter Group List** Back

Save All Changes

Group Name*: IRB Correction Forms

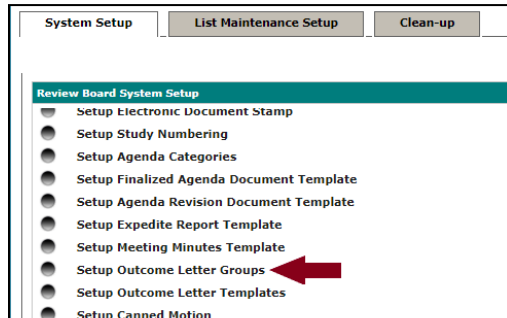
Add Remove

<input checked="" type="checkbox"/>	Form Name	Expedite	Denied	Processed Administrative
<input type="checkbox"/>	Pre-Review Correction Form	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Review Response and Correction Form	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Study Amendment Form	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

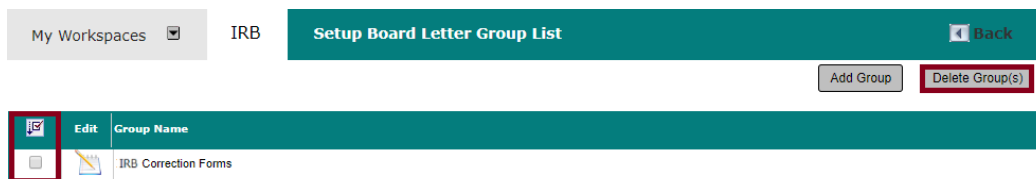
Click the **Save All Changes** button to save changes and close the edit panel.

Delete Outcome Letter Group

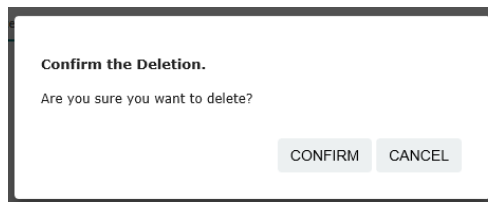
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Groups** link.



The **Setup Board Letter Group List** page opens. Select the checkbox(es) for the group(s) to be deleted and click the **Delete Group(s)** button.



A confirmation popup displays.



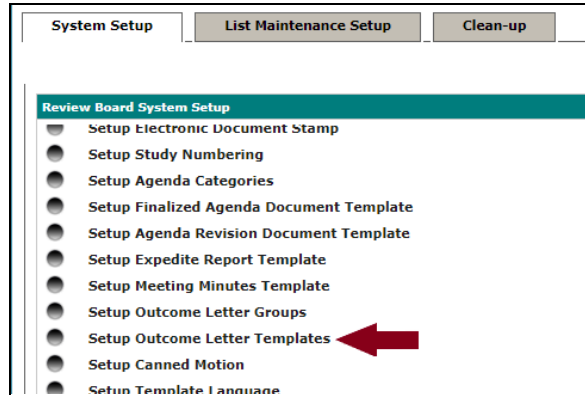
Click the **CANCEL** button to return to the **Setup Board Letter Group List** page without deleting the selected template(s).

Click the **CONFIRM** button to confirm the deletion and return to the **Setup Board Letter Group List** page.

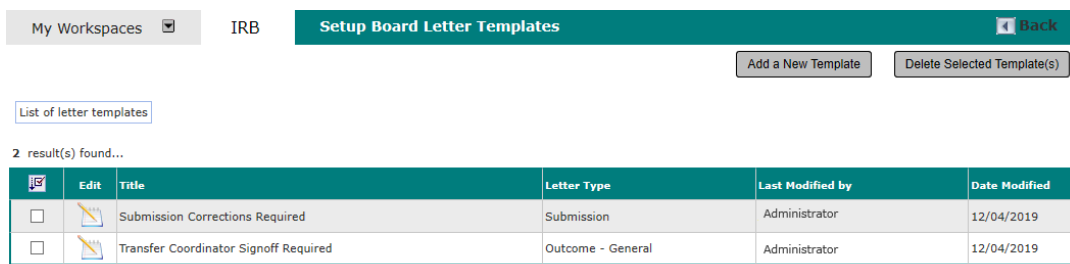
Setup Outcome Letter Templates

The iRIS™ system provides the ability to configure standardized outcome letter templates that include commonly used boilerplate text and can automatically pull a variety of system data into the letters when they are generated.

This functionality is provided on the **Setup Board Letter Templates** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Templates** link.

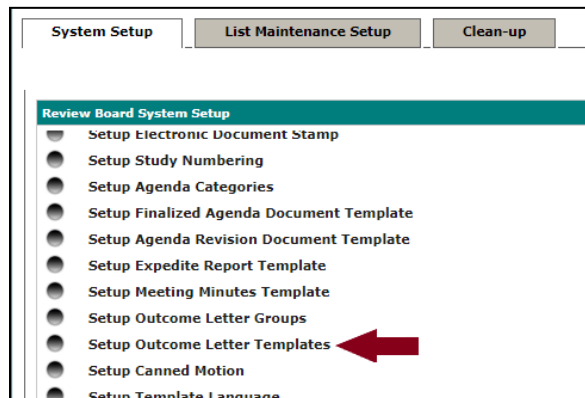


The **Setup Board Letter Templates** page opens, as shown below.

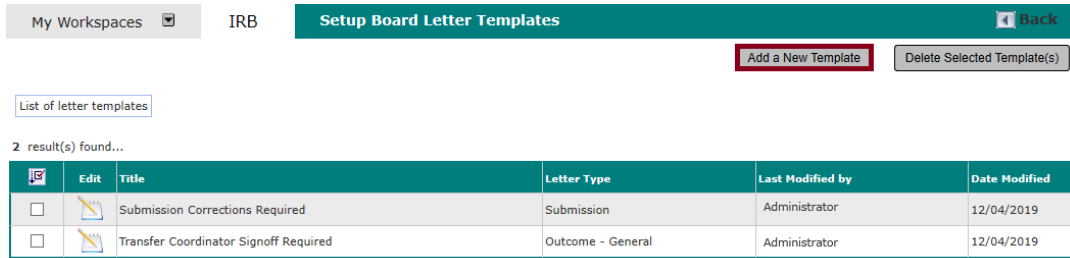


Add Outcome Letter Template

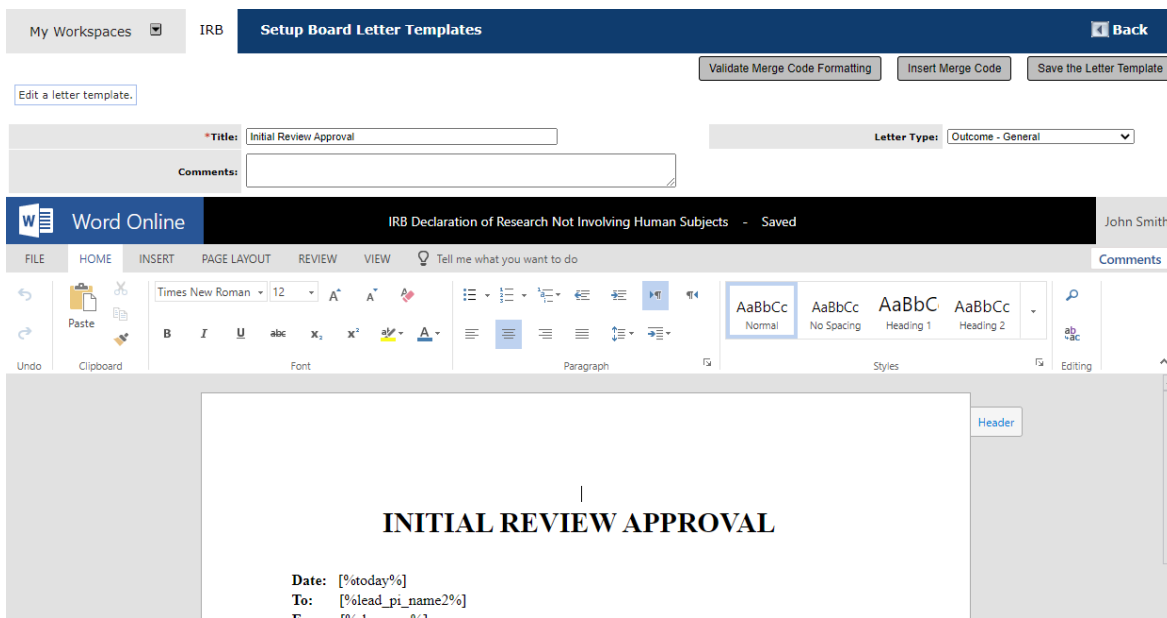
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Templates** link.



The **Setup Board Letter Templates** page opens, as shown below.

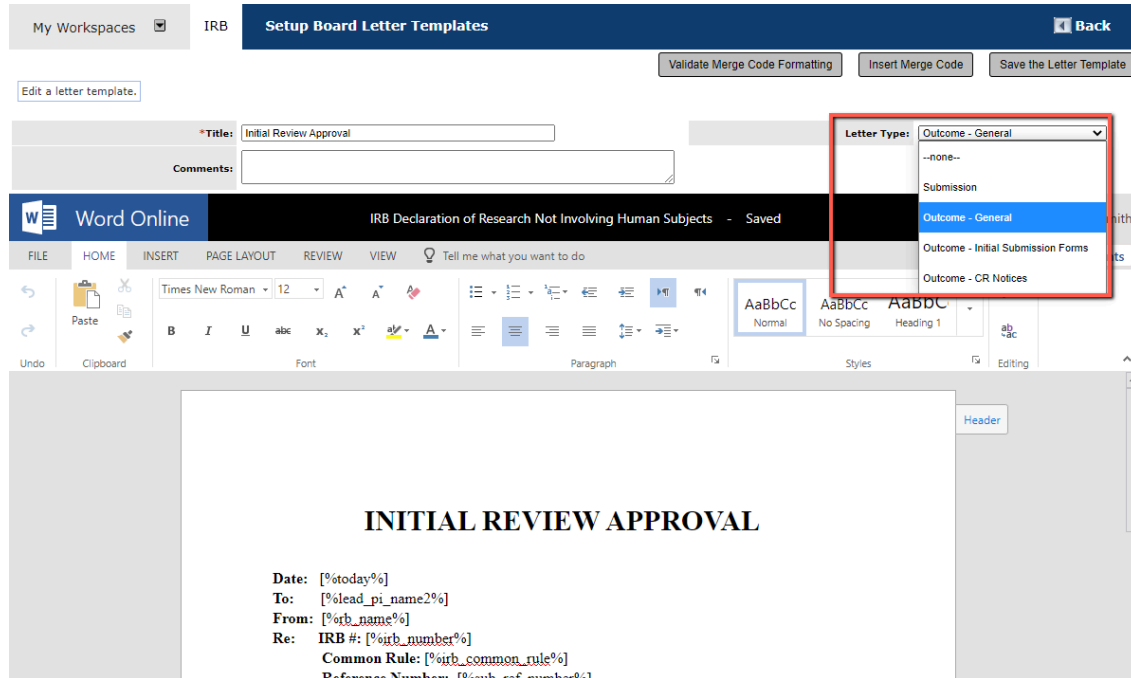


Click the **Add a New Template** button. As shown below, the **Add a letter template** panel opens for creation of the new letter.



Enter the desired **Title** and **Comments**, then click in the **Letter Type** field and click to select an item in the dropdown list. As shown below, the list includes two default entries:

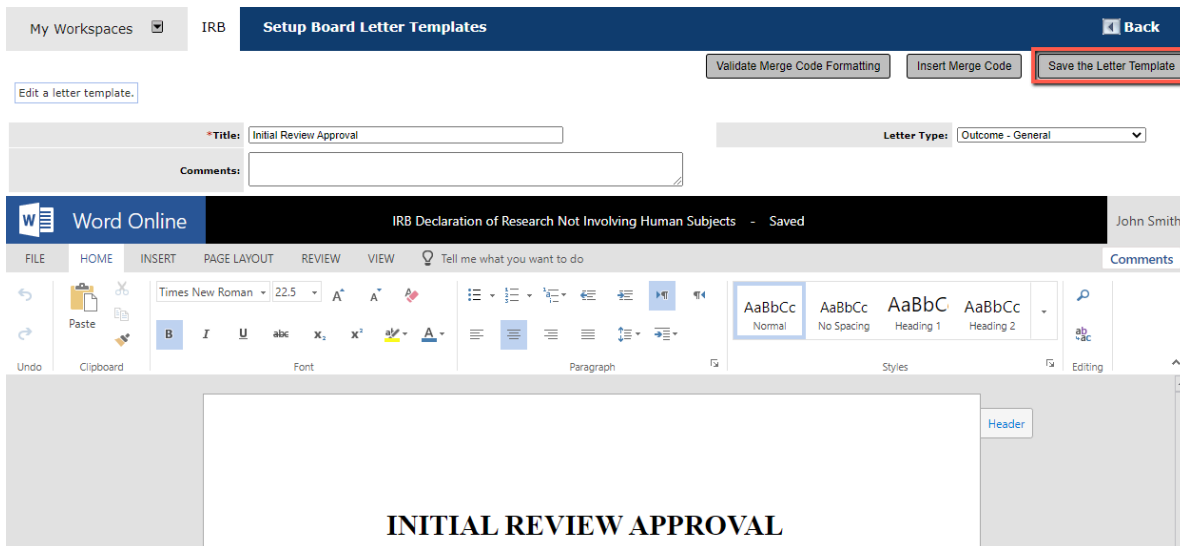
- **Outcome - General:** letter templates of this type appear as options available for selection on the Outcome Letter tab of submission processing screens
- **Submission:** letter templates of this type appear as options available for selection on the Submission Received Notification Letter tab of submission processing screens



Note that any letter types configured via the Setup Outcome Letter Groups function are added to the **Letter Type** dropdown list. When a custom configured letter type is selected, the associated letter template's inclusion as an option available for selection on the Outcome Letter tab of submission processing screens is dictated by rules established when the Letter Group is created. See the Setup Outcome Letter Groups section of this manual for more information about configuring Letter Groups.

Enter desired text and Merge Codes in the main text editor window. See the Using Merge Codes in Document Templates section of this manual for more information about working with Merge Codes.

Apply any desired formatting, then click the **Save the Letter Template** button.

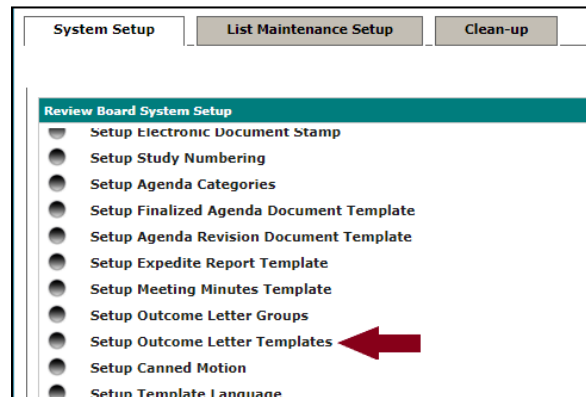


The template is added on the **Setup Board Letter Templates** page.

	Edit	Title	Letter Type	Last Modified by	Date Modified
<input type="checkbox"/>		Approved With No Conditions	Outcome - General	Administrator	12/04/2019
<input type="checkbox"/>		Submission Corrections Required	Submission	Administrator	12/04/2019
<input type="checkbox"/>		Transfer Coordinator Signoff Required	Outcome - General	Administrator	12/04/2019

Edit Outcome Letter Template

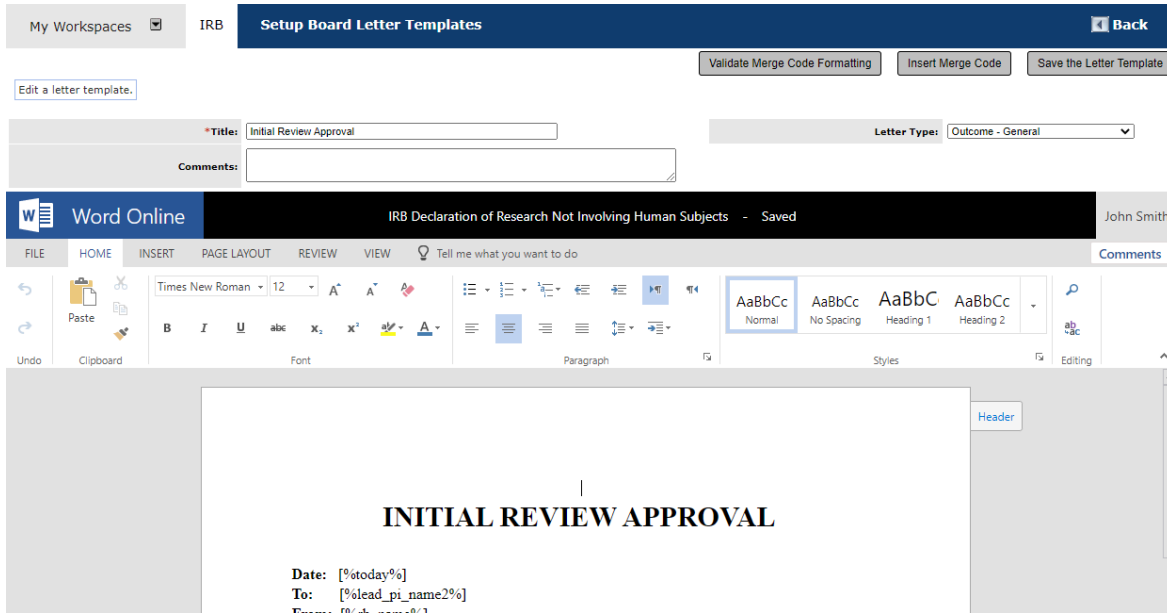
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Templates** link.



The **Setup Board Letter Templates** page opens, as shown below. Click the icon in the **Edit** column for the applicable template.

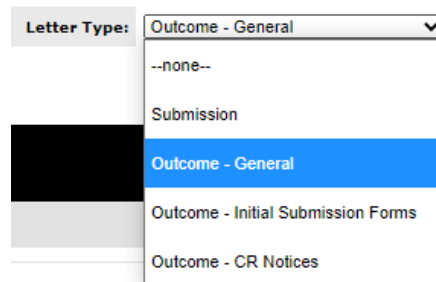
	Edit	Title	Letter Type	Last Modified by	Date Modified
<input type="checkbox"/>		Approved With No Conditions	Outcome - General	Administrator	12/04/2019
<input type="checkbox"/>		Submission Corrections Required	Submission	Administrator	12/04/2019
<input type="checkbox"/>		Transfer Coordinator Signoff Required	Outcome - General	Administrator	12/04/2019

As shown below, the template is opened for editing in an **Edit a letter template** panel.



Make desired changes to the **Title**, **Comments** and **Letter Type** fields. The **Letter Type** list includes two default entries:

- **Outcome - General**: letter templates of this type appear as options available for selection on the Outcome Letter tab of submission processing screens
- **Submission**: letter templates of this type appear as options available for selection on the Submission Received Notification Letter tab of submission processing screens



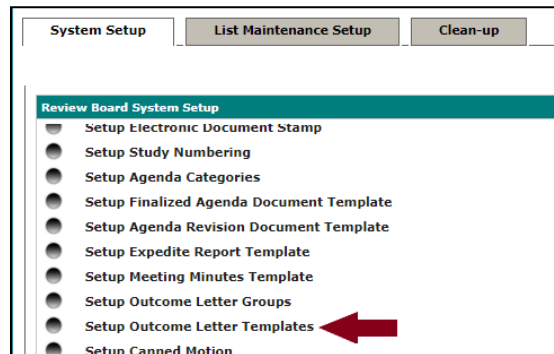
*Note that any letter types configured via the Setup Outcome Letter Groups function are added to the **Letter Type** dropdown list. When a custom configured letter type is selected, the associated letter template’s inclusion as an option available for selection on the Outcome Letter tab of submission processing screens is dictated by rules established when the Letter Group is created. See the Setup Outcome Letter Groups section of this manual for more information about configuring Letter Groups.*

The two tabs in the lower part of the edit panel offer two different methods for revising the template’s content. As shown below, the **HTML Content** tab (red arrow and box) allows for direct editing in the text editor window.

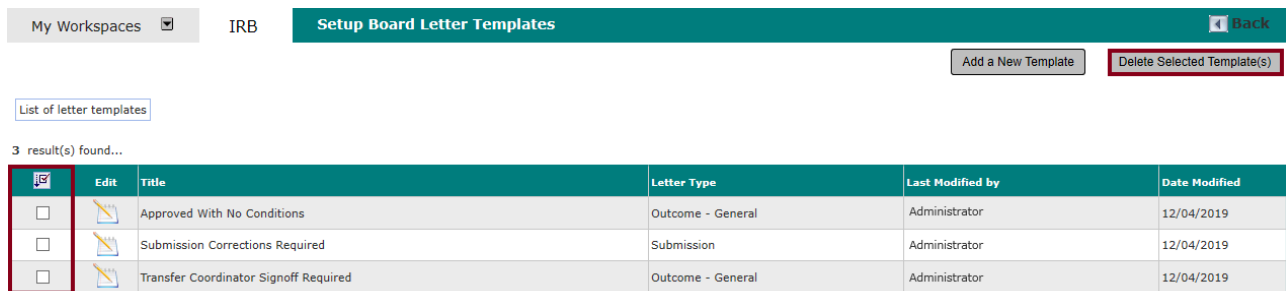
When all desired revisions are complete using the **HTML Content** tab, click the **Save the Letter Template** button to save changes and close the edit panel.

Delete Outcome Letter Template

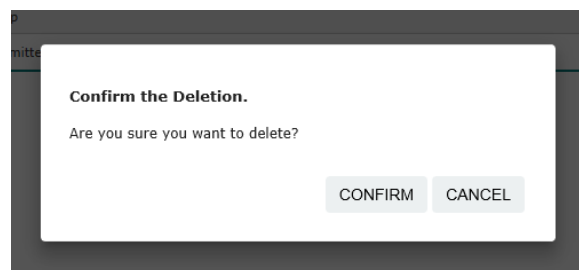
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Outcome Letter Templates** link.



The **Setup Board Letter Templates** page opens, as shown below. Select the checkbox(es) in the far-left column for the template(s) to be deleted, then click the **Delete Selected Template(s)** button.



A confirmation popup displays.



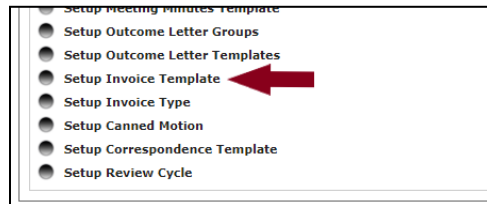
Click the **CANCEL** button to return to the **Setup Board Letter Templates** page without deleting the selected template(s).

Click the **CONFIRM** button to confirm the deletion and return to the **Setup Board Letter Templates** page.

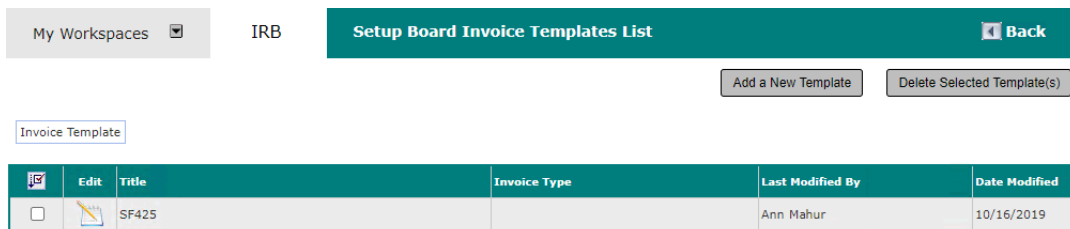
Setup Invoice Template

The iRIS™ system provides the ability to configure standardized invoice templates that include commonly used boilerplate text and can automatically pull a variety of system data into the letters when they are generated.

This functionality is provided on the **Setup Board Invoice Templates List** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Template** link.

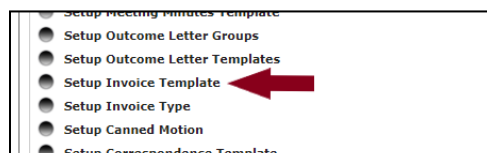


The **Setup Board Invoice Templates List** page opens, as shown below.

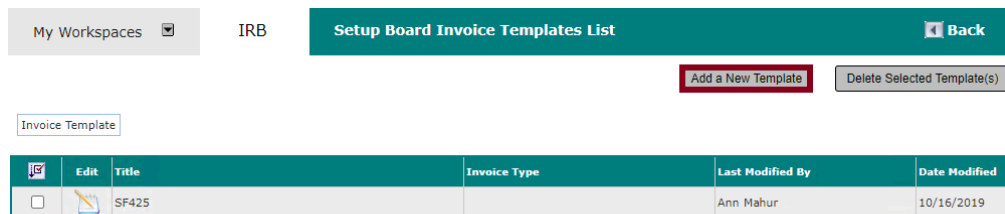


Add Invoice Template

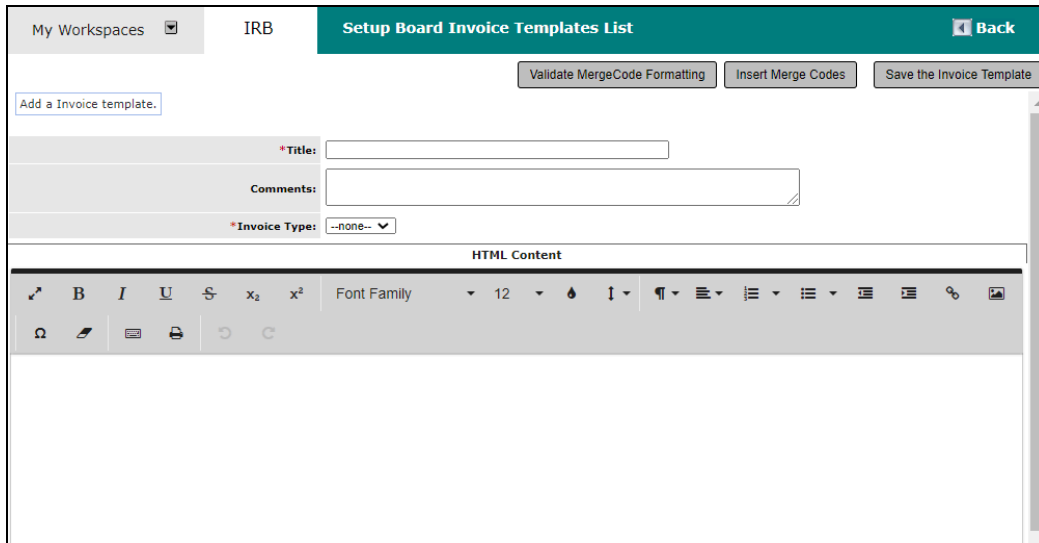
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Template** link.



The **Setup Board Invoice Templates List** page opens, as shown below.



Click the **Add a New Template** button. As shown below, the **Add a Invoice template** panel opens for creation of the new invoice.

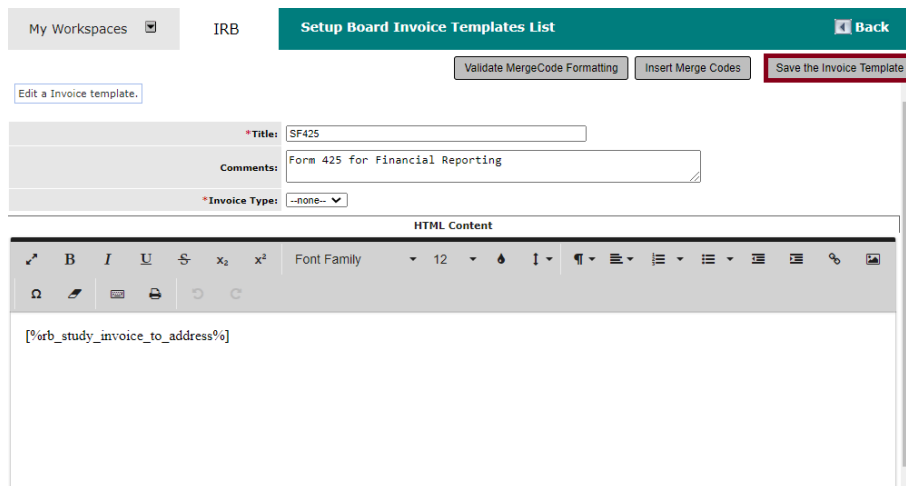


Enter the desired **Title** and **Comments**, then click in the **Invoice Type** field and click to select an item in the dropdown list.

*Note that any invoice types configured via the Setup Invoice Type function are added to the **Invoice Type** dropdown list. See the Setup Invoice Type section of this manual for more information about configuring Invoice Types.*

Enter desired text and Merge Codes in the main text editor window, and apply any desired formatting. See the *Using Merge Codes in Document Templates* section of this manual for more information about working with Merge Codes.

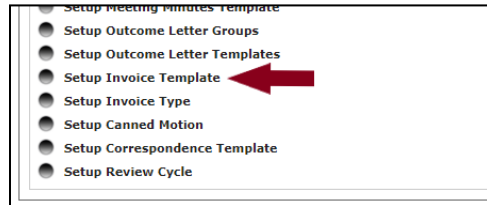
When all fields and text editor content are complete, click the **Save the Invoice Template** button.



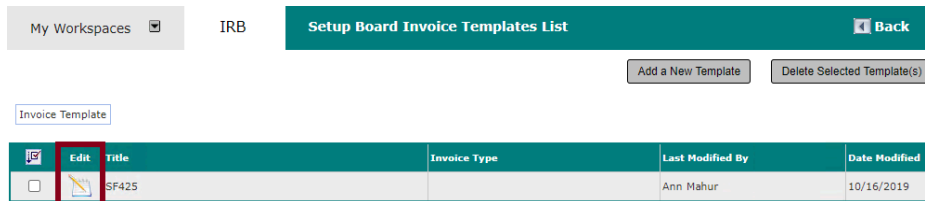
The template is added on the **Setup Board Invoice Templates List** page.

Edit Invoice Template

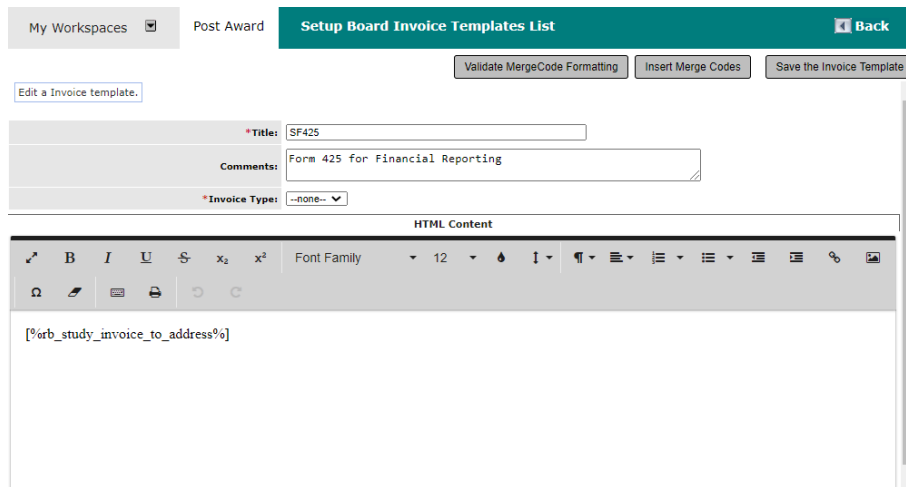
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Template** link.



The **Setup Board Invoice Templates List** page opens, as shown below.



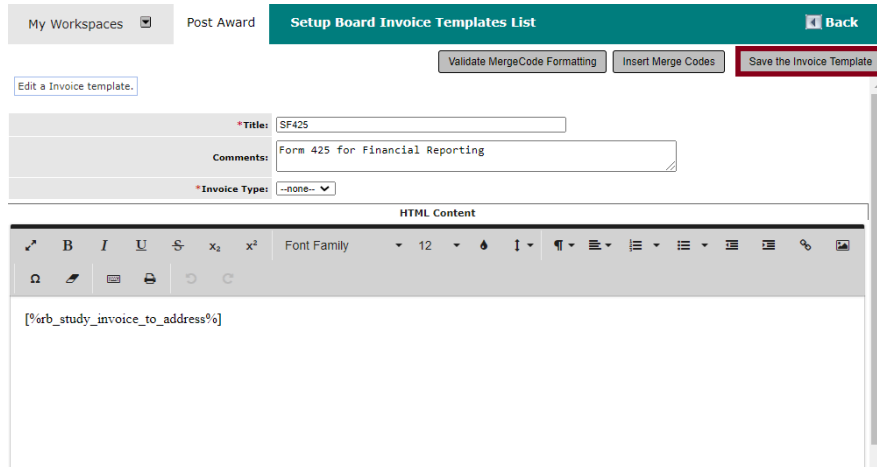
Click the icon in the **Edit** column for the applicable invoice template. As shown below, the template is opened for revision in an **Edit a Invoice template** panel.



Make desired changes to the **Title**, **Comments** and **Invoice Type** fields.

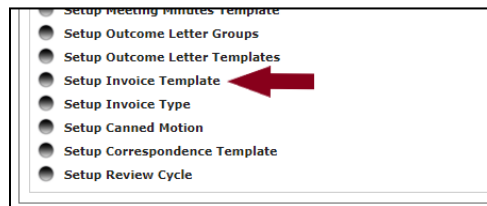
*Note that any invoice types configured via the Setup Invoice Type function are added to the **Invoice Type** dropdown list. See the Setup Invoice Type section of this manual for more information about configuring Invoice Types.*

Click the **Save the Invoice Template** button to save changes and close the edit panel.

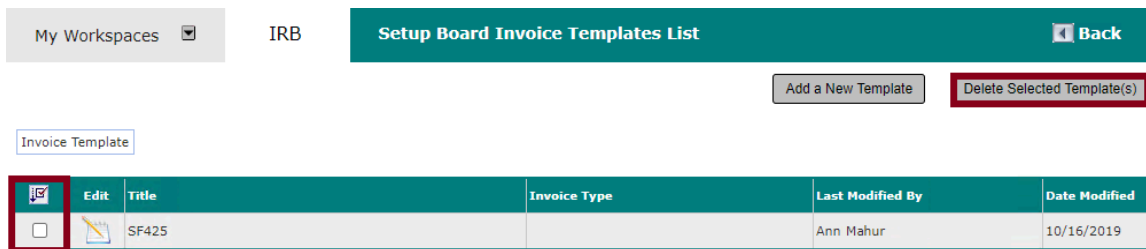


Delete Invoice Template

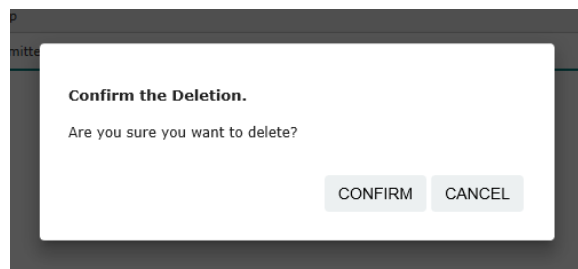
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Template** link.



The **Setup Board Invoice Templates List** page opens, as shown below. Select the checkbox(es) in the far-left column for the template(s) to be deleted, then click the **Delete Selected Template(s)** button.



A confirmation popup displays.



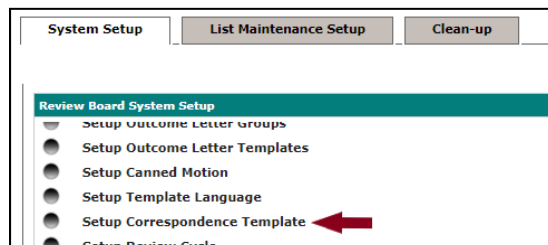
Click the **CANCEL** button to return to the **Setup Board Invoice Templates List** page without deleting the selected template(s).

Click the **CONFIRM** button to confirm the deletion and return to the **Setup Board Invoice Templates List** page.

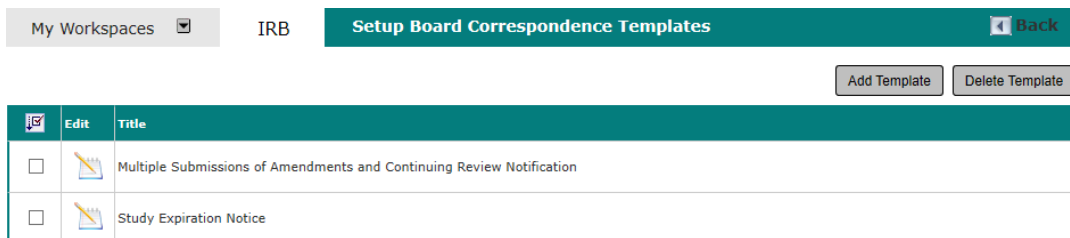
Setup Correspondence Templates

The iRIS™ system provides the ability to configure standardized correspondence templates that include commonly used boilerplate text and can automatically pull a variety of system data into the correspondence when it is generated.

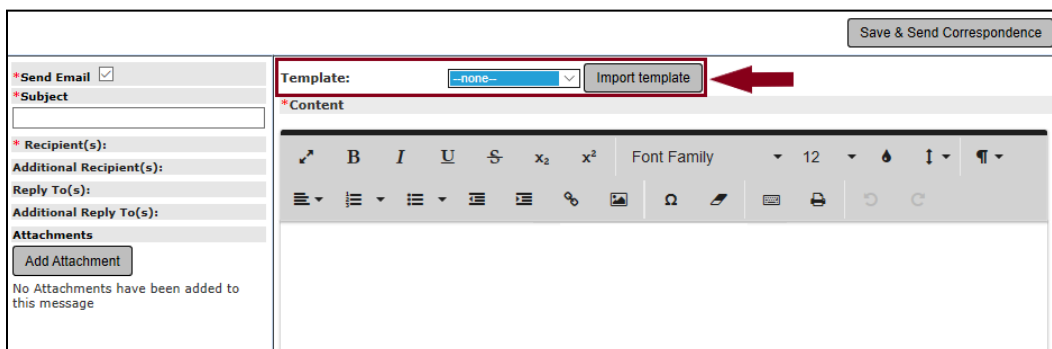
This functionality is provided on the **Setup Board Correspondence Templates** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Correspondence Template** link.



The **Setup Board Correspondence Templates** page opens, as shown below.



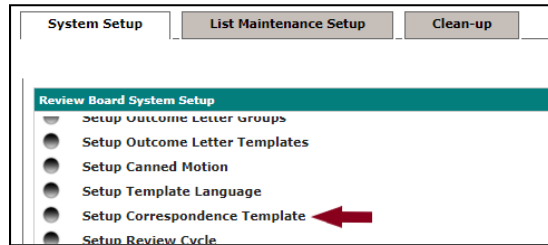
Correspondence templates can be employed when creating a correspondence record within the submission processing screens. Configured templates are made available via a **Template** dropdown picklist above the embedded rich text editor.



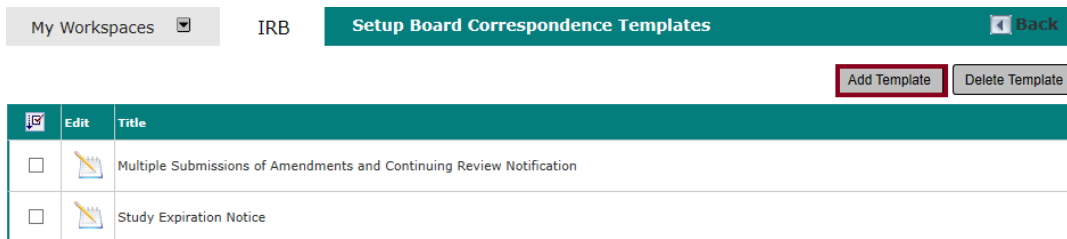
The desired template is selected in the list and when the **Import template** button is clicked, the template’s content is pulled into the text editor.

Add Correspondence Template

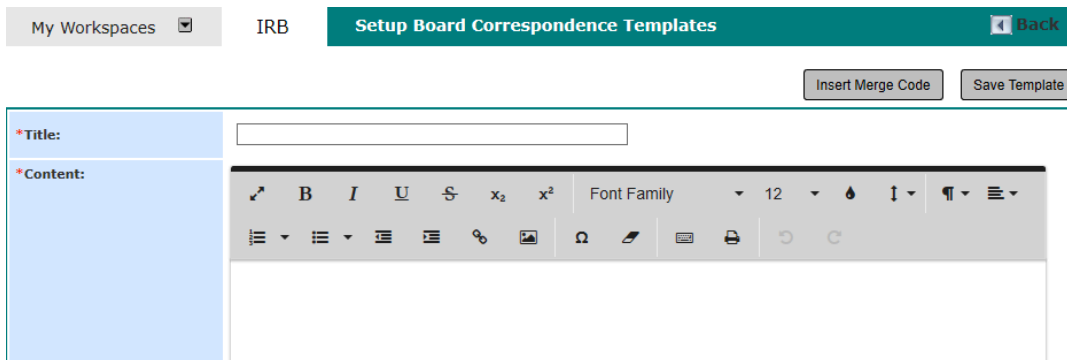
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Correspondence Template** link.



The **Setup Board Correspondence Templates** page opens, as shown below.



Click the **Add Template** button. As shown below, an add panel opens for creation of the correspondence.



Enter desired text and Merge Codes in the main text editor window. *See the Using Merge Codes in Document Templates section of this manual for more information about working with Merge Codes.*

My Workspaces ▾ IRB **Setup Board Correspondence Templates** ◀ Back

Insert Merge Code **Save Template**

***Title:**

***Content:**

Verdana 11

[%today%]

Dear [%pi_fname%] [%pi_lname%]:

To fulfill the terms of the FederalWide Assurance our Institution and the DHHS Office for Human Research Protections (OHRP), the IRB requires that investigators and their research staff complete a course in the protection of human research subjects every 3 years.

Your certification in research education expired on [Insert Expiration Date]

Because you are the principal investigator for this study and because your research education certification has expired:

1. Accrual of subjects into this study is suspended immediately.
2. You and your co-investigators and research staff may follow subjects already enrolled for safety, but no new subjects may be enrolled and the data already collected may not be analyzed.
3. If this is a chart review or database study, you must not collect data on new subjects and you must stop analyzing data that you have already collected.
4. The status of the study referenced above has been changed to "Temporarily Closed to Accrual – Administratively Inactivated."
5. The IRB will not review any new protocol that you submit to the IRB as a principal investigator.
6. The IRB will not approve your participation as a co-investigator in any new research protocol
7. The IRB will not renew approval of your participation in any studies that are due for continuing review.

When the IRB has received a copy of your certificate documenting completion of the education requirement, you will be notified in writing that you may resume accrual of new subjects to this study or resume data collection and analysis for a chart review/database study and the study status will be returned to "Open" status.

You may not enroll new subjects until you have been informed in writing by the IRB that you have approval to do so.

Options for renewal of research education:

Apply any desired formatting, then click the **Save Template** button. The template is added on the **Setup Board Correspondence Templates** page.

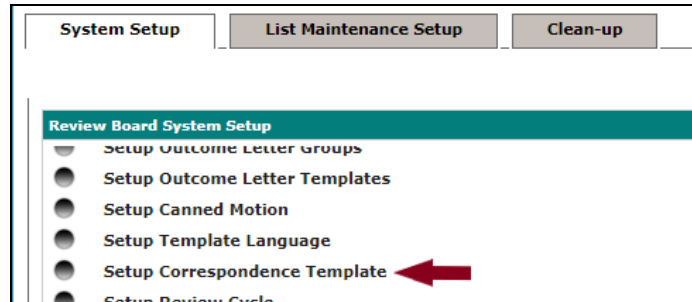
My Workspaces ▾ IRB **Setup Board Correspondence Templates** ◀ Back

Add Template Delete Template

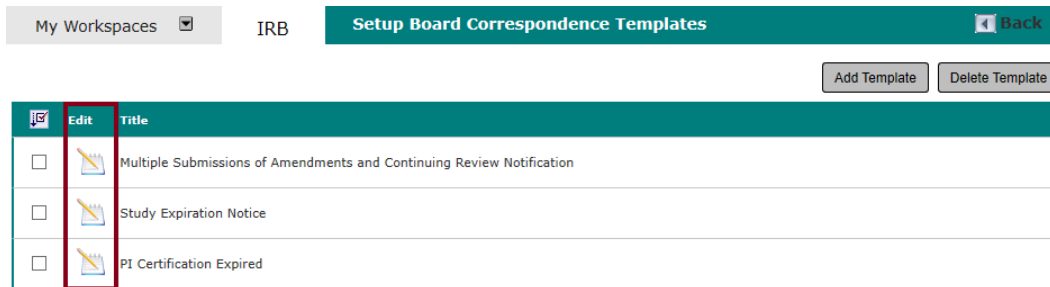
<input checked="" type="checkbox"/>	Edit	Title
<input type="checkbox"/>		Multiple Submissions of Amendments and Continuing Review Notification
<input type="checkbox"/>		Study Expiration Notice
<input type="checkbox"/>		PI Certification Expired

Edit Correspondence Template

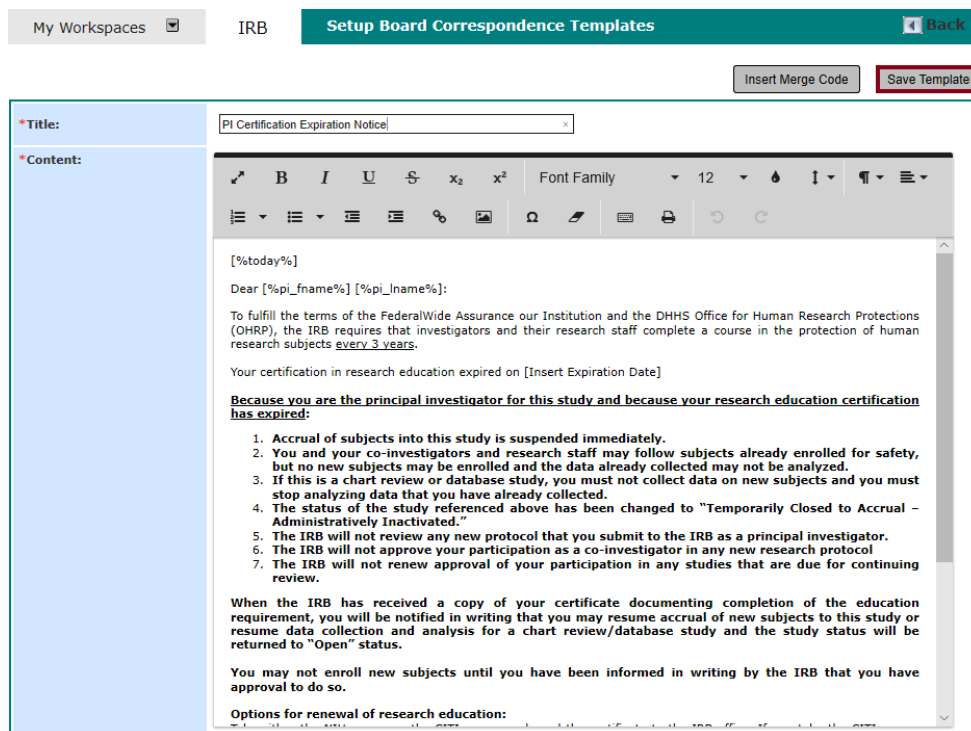
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Correspondence Template** link.



The **Setup Board Correspondence Templates** page opens, as shown below.

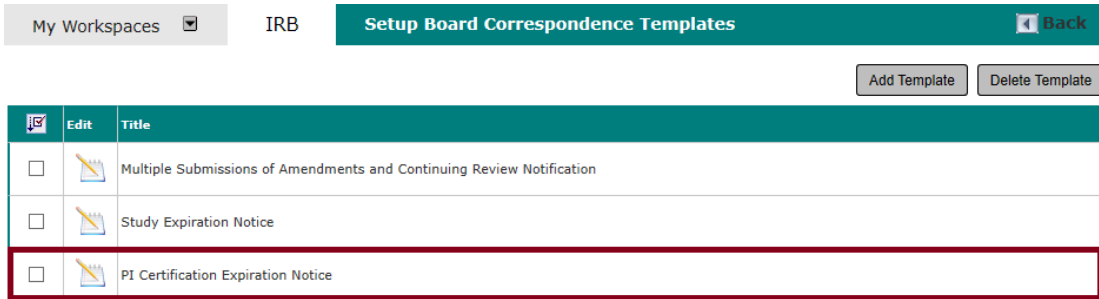


Click the icon in the **Edit** column for the applicable item. As shown below, the correspondence is opened in an edit panel. Make desired changes in the **Title** and **Content** fields.



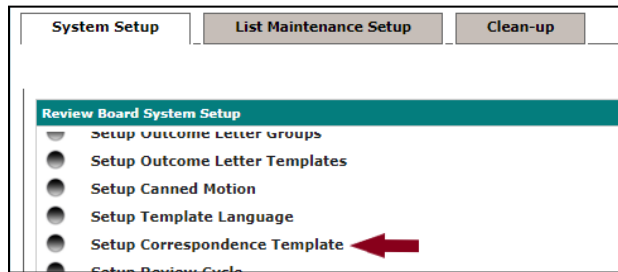
See the *Using Merge Codes in Document Templates* section of this manual for more information about working with Merge Codes.

When all desired changes are complete, click the **Save Template** button. The template is revised on the **Setup Board Correspondence Templates** page.

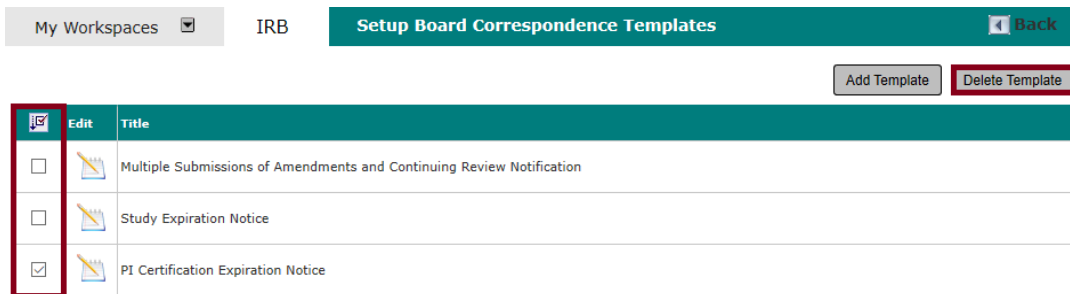


Delete Correspondence Template

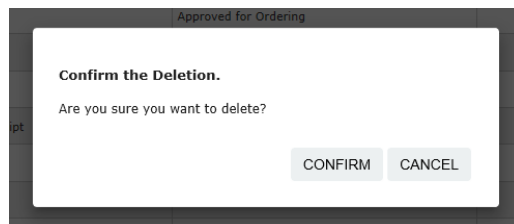
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Correspondence Template** link.



The **Setup Board Correspondence Templates** page opens. Select the checkbox(es) in the far-left column for the template(s) to be deleted, then click the **Delete Template** button.

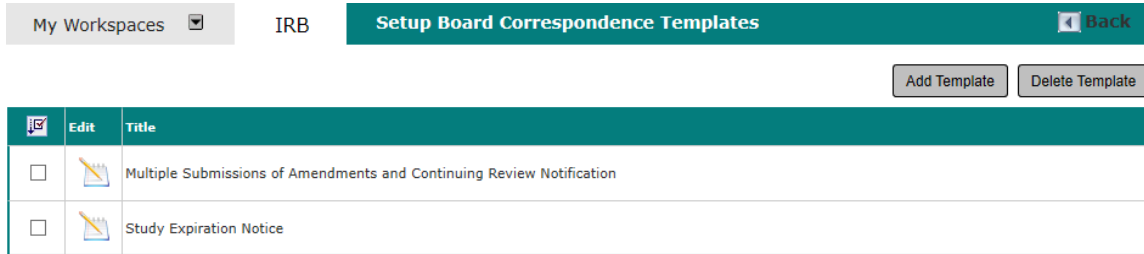


A confirmation popup window displays.



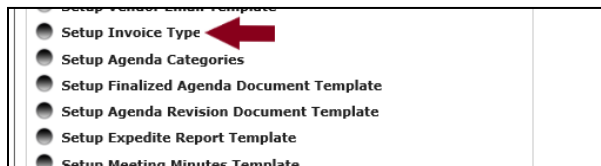
Click **CANCEL** to return to the **Setup Board Correspondence Templates** page without deleting the template(s).

Click **CONFIRM** to delete the item(s) and return to the **Setup Board Correspondence Templates** page. The template(s) is(are) deleted.

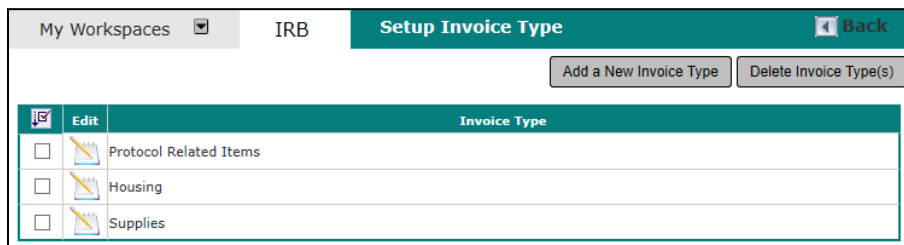


Setup Invoice Type

Invoice Types are configured on the **Setup Invoice Type** page. To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Type** link.

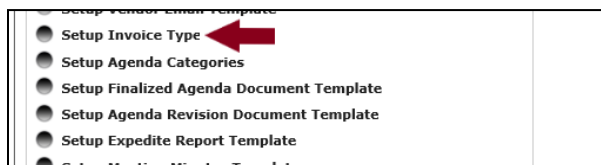


The **Setup Invoice Type** page opens.

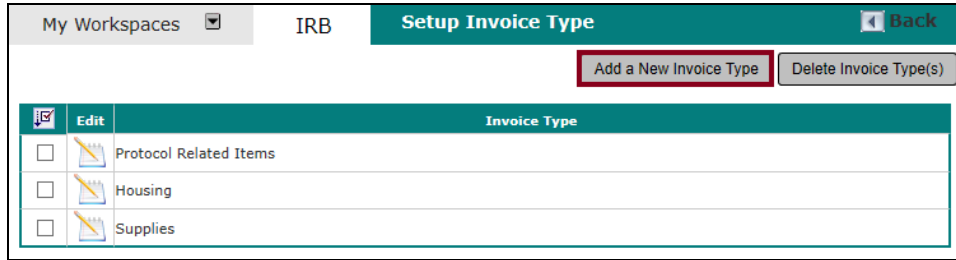


Add Invoice Type

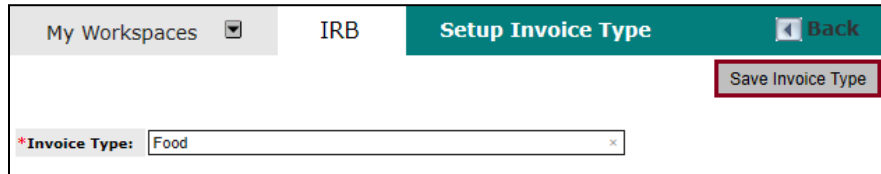
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Type** link.



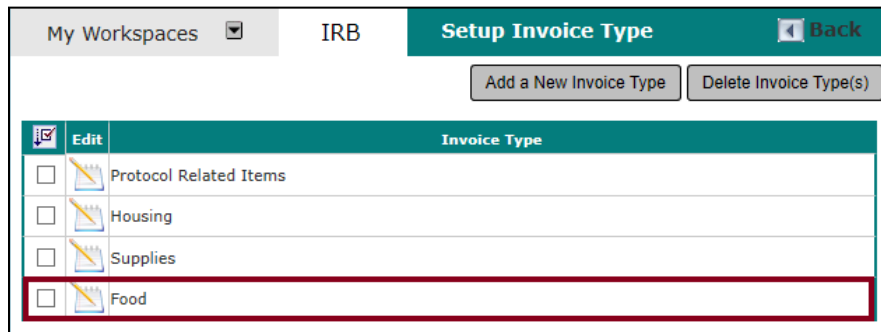
The **Setup Invoice Type** page opens. Click the **Add a New Invoice Type** button.



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

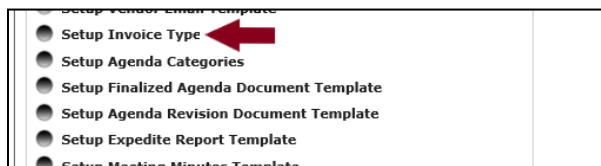


Enter an **Invoice Type** and click the **Save Invoice Type** button to save the record. The record is added on the **Setup Invoice Type** page.

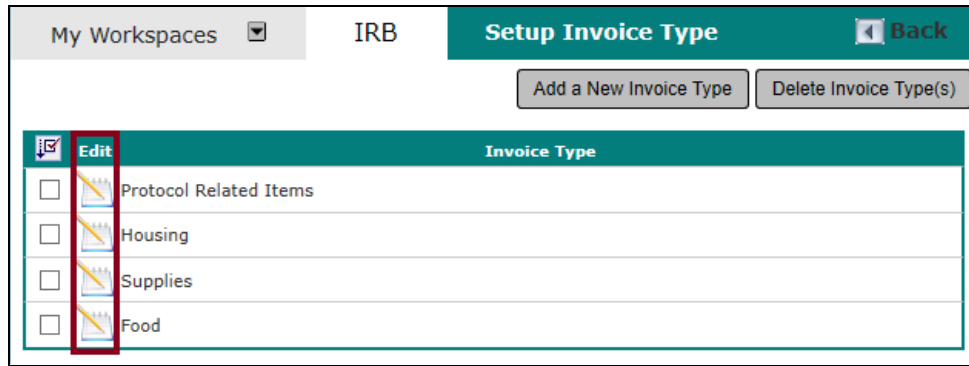


Edit Invoice Type

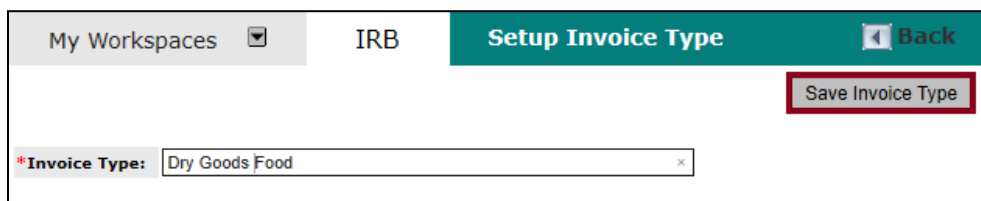
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Type** link.



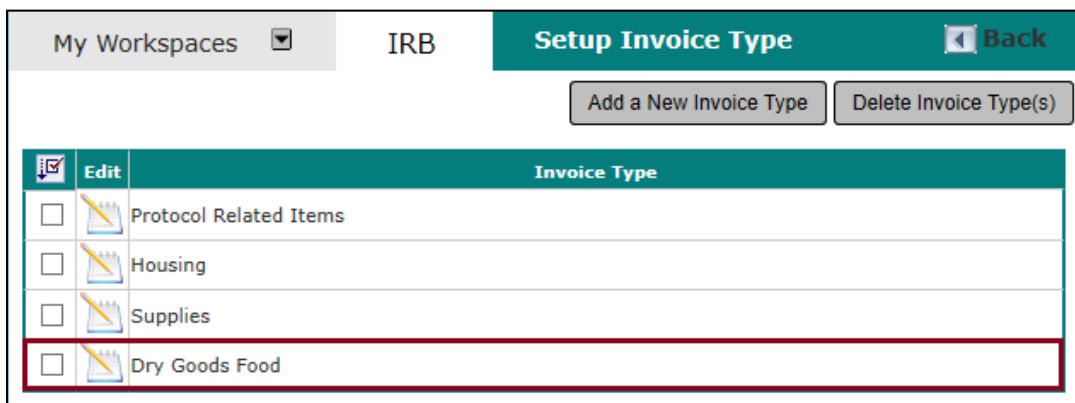
The **Setup Invoice Type** page opens. Click the icon in the **Edit** column for the applicable record.



The record is opened in an edit panel.

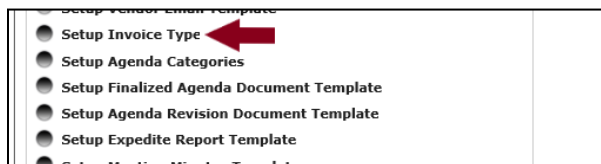


Make desired changes to the **Invoice Type** and click the **Save Invoice Type** button to save the record. The record is revised on the **Setup Invoice Type** page.

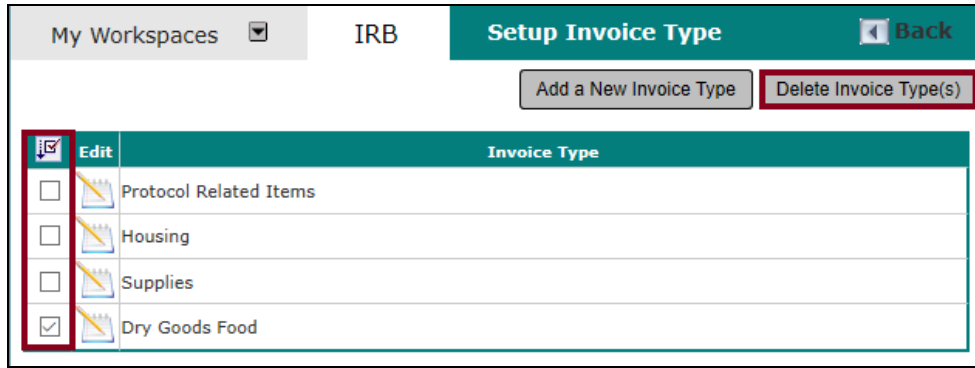


Delete Invoice Type

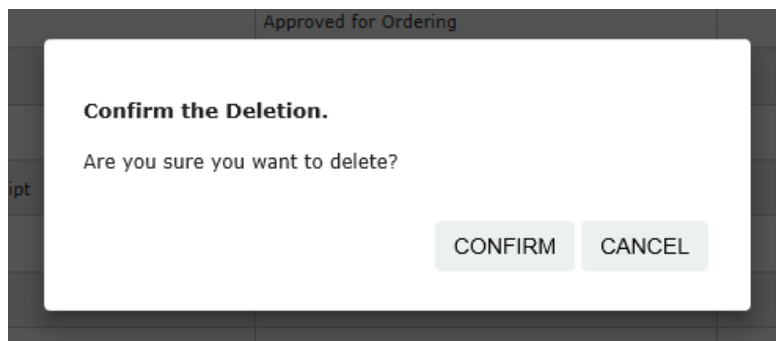
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Invoice Type** link.



The **Setup Invoice Type** page opens. Select the checkbox(es) in the far-left column for the record(s) to be deleted, then click the **Delete Invoice Type(s)** button.

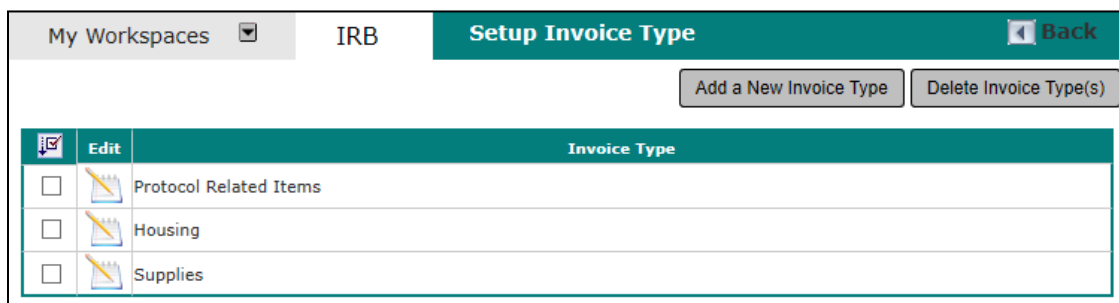


A confirmation popup displays.



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

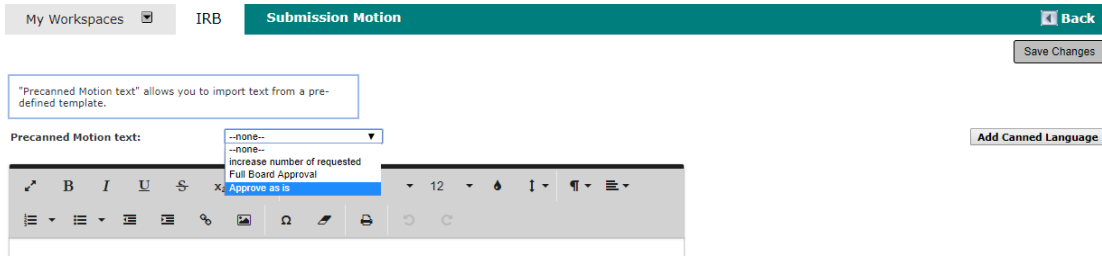
Click **CONFIRM** to delete the record and close the popup. The **Invoice Type** is deleted on the **Setup Invoice Type** page.



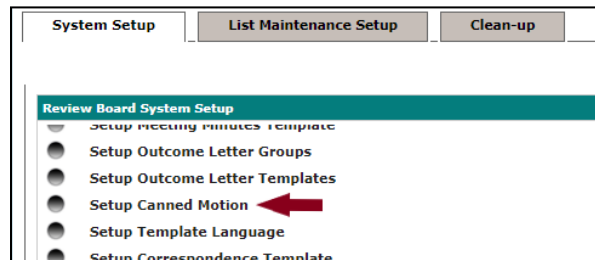
Setup Canned Motion

The iRIS™ system provides the ability for institutions to configure a list of predefined (“canned”) motions for use in review board meetings. There is no limit to the number of canned motions that can be configured in this list.

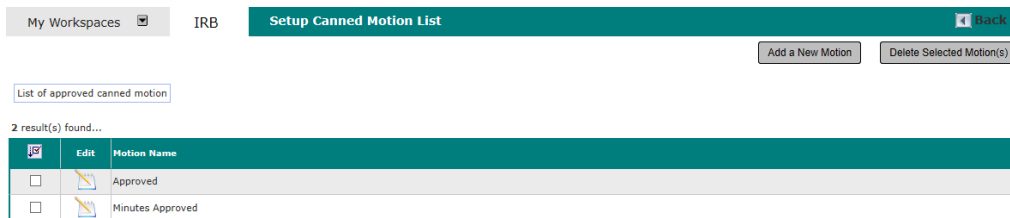
Any configured canned motion is added to the **Precanned Motion text** dropdown list on the **Submission Motion** page of the Vote tab in Submission processing screens.



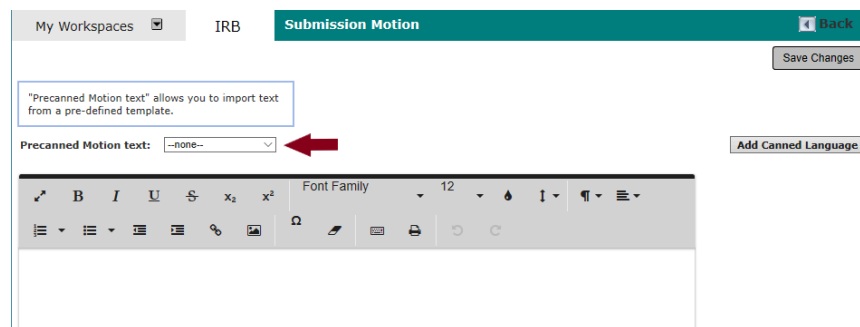
To access the configuration list, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Canned Motion** link.



The **Setup Canned Motion List** page opens.

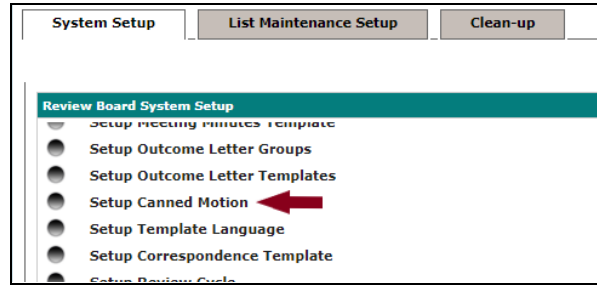


Any canned motion configured here is added to the **Precanned Motion text** dropdown list on the Vote tab of Submission processing screens.

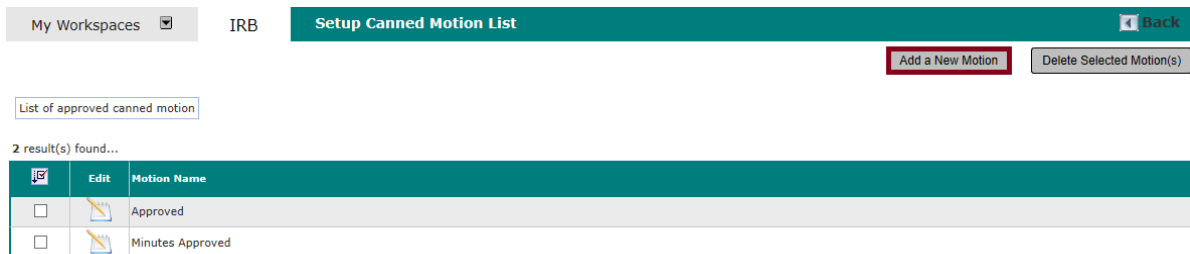


Add Canned Motion

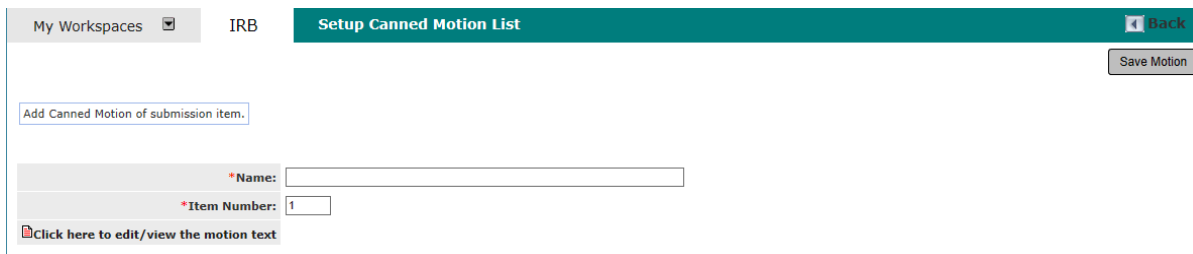
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Canned Motion** link.



The **Setup Canned Motion List** page opens.

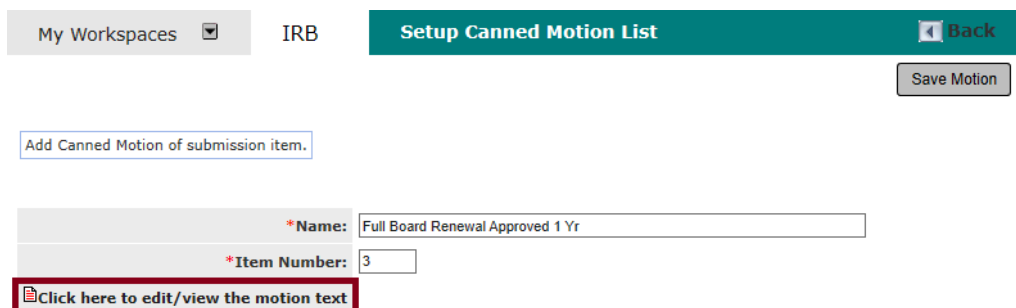


As shown below, an **Add Canned Motion of submission item** panel opens for configuration of the motion.

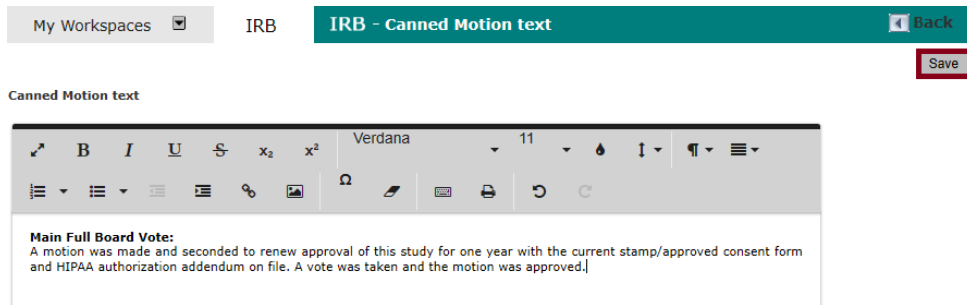


Enter the desired **Name** and **Item Number**. **Item Number** dictates the order in which canned motions appear on the **Setup Canned Motion List** page and in the Precanned Motion text dropdown list on the Vote tab of Submission processing screens.

Click the **Click here to edit/view the motion text** link to enter desired motion text.

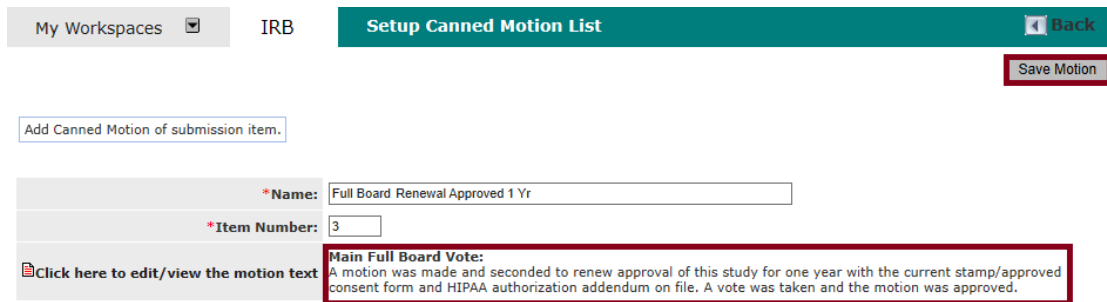


As shown below, a **Canned Motion text** page with a text editor for creation and formatting of the motion text opens.

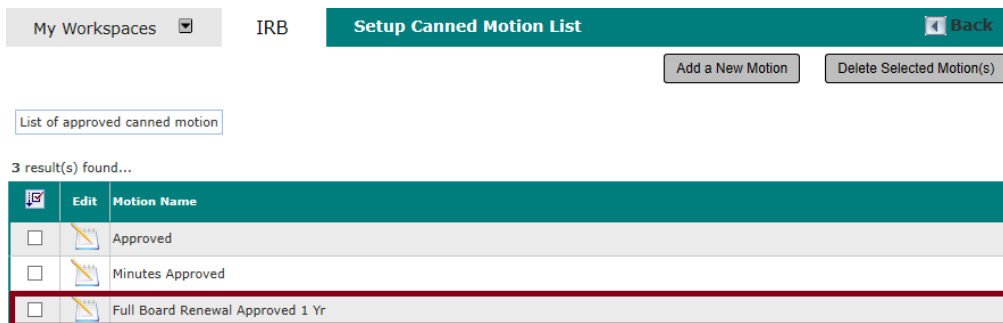


Enter desired motion text and apply any desired formatting, as shown above, then click the **Save** button.

As shown below, the text is added to the **Add Canned Motion of submission item** panel. Click the **Save Motion** button.

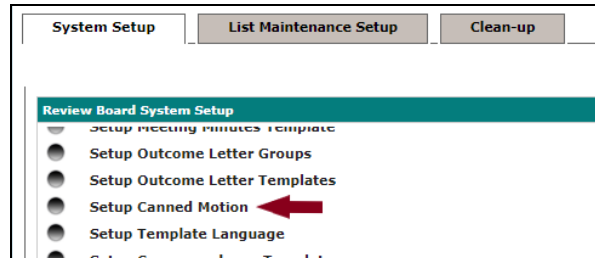


As shown below, the motion is added on the **Setup Canned Motion List** page.

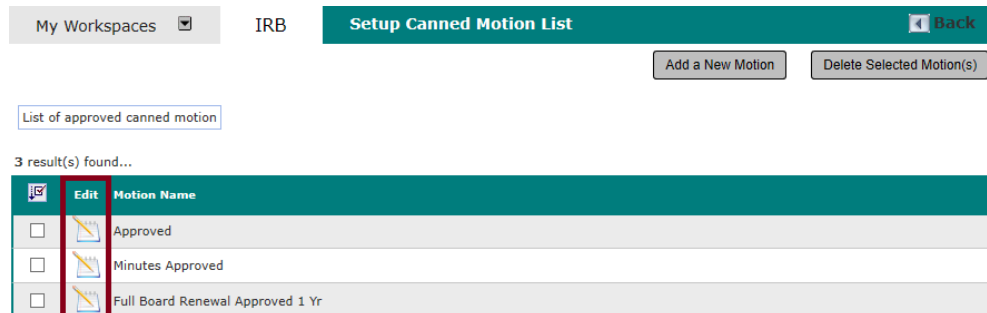


Edit Canned Motion

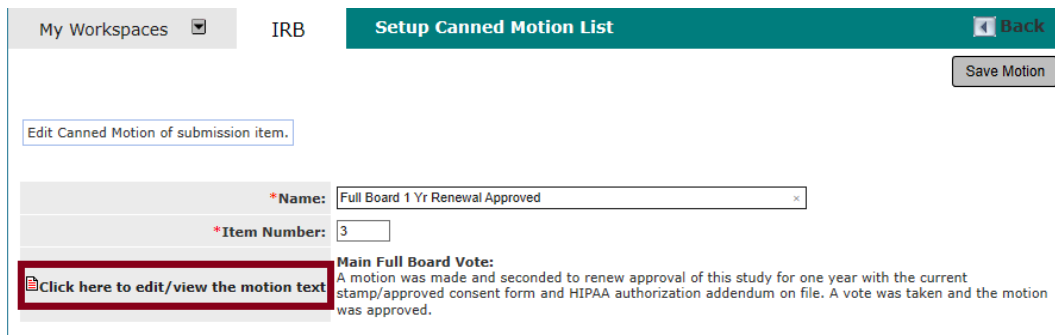
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Canned Motion** link.



The **Setup Canned Motion List** page opens. Click the icon in the **Edit** column for the applicable motion.

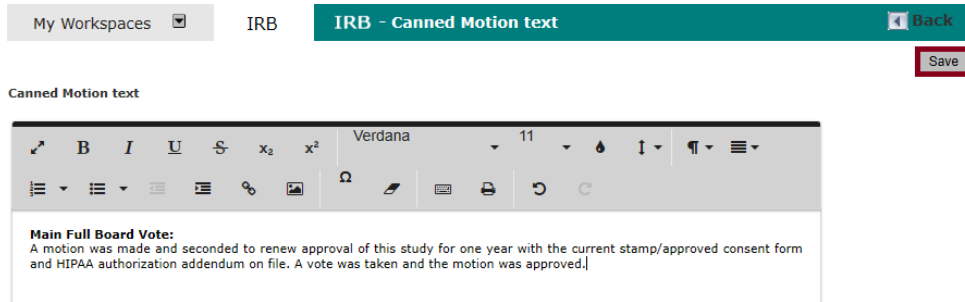


As shown below, an **Edit Canned Motion of submission item** panel opens for configuration of the motion.

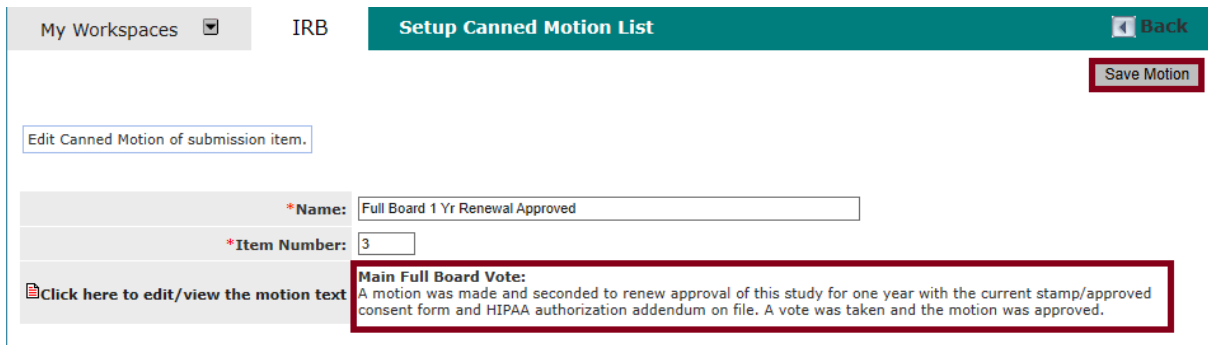


Revise the **Name** and **Item Number** fields as desired. **Item Number** dictates the order in which canned motions appear on the Setup Canned Motion List page and in the Precanned Motion text dropdown list on the Vote tab of Submission processing screens.

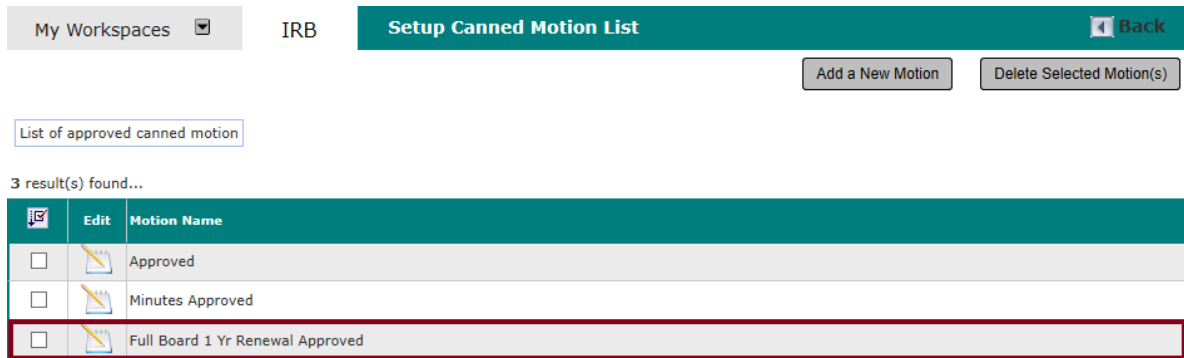
Click the **Click here to edit/view the motion text** link to revise the motion text. As shown below, the motion is opened in a **Canned Motion text** page with a text editor for revision and formatting of the motion text.



When changes are complete click the **Save** button. As shown below, the text is added to the Edit Canned Motion of submission item panel. Click the **Save Motion** button.

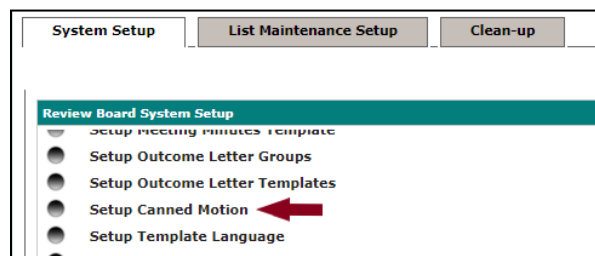


As shown below, the motion is revised on the **Setup Canned Motion List** page.

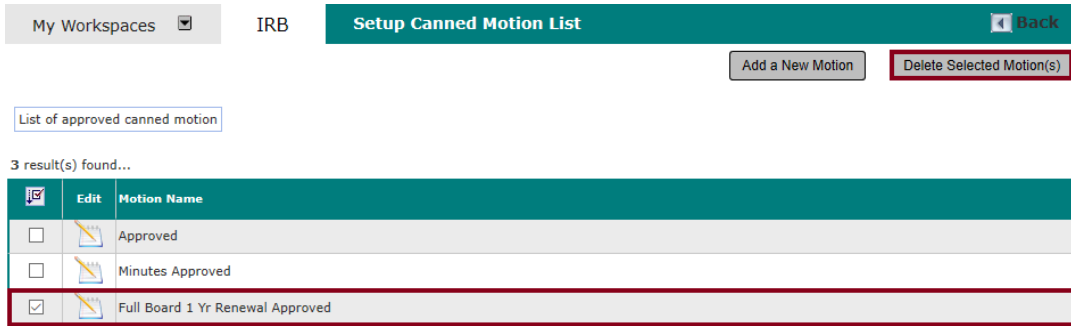


Delete Canned Motion

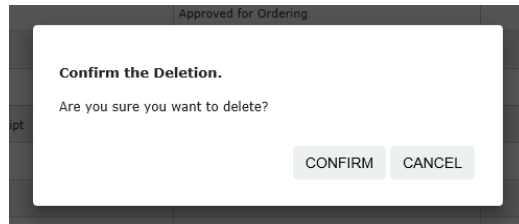
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Canned Motion** link.



The **Setup Canned Motion List** page opens. Select the checkbox(es) in the far-left column for the motion(s) to be deleted, then click the **Delete Selected Motion(s)** button.

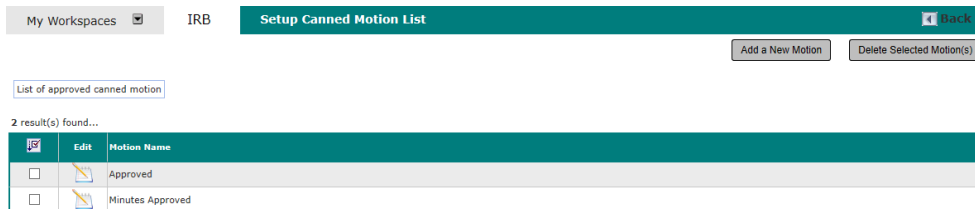


A confirmation popup window displays.



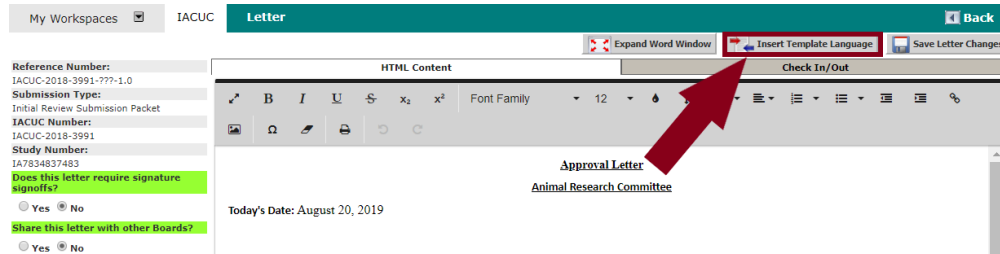
Click **CANCEL** to return to the **Setup Canned Motion List** page without deleting the motion(s).

Click **CONFIRM** to delete the motion(s) and return to the **Setup Canned Motion List** page. The motion(s) is(are) deleted.

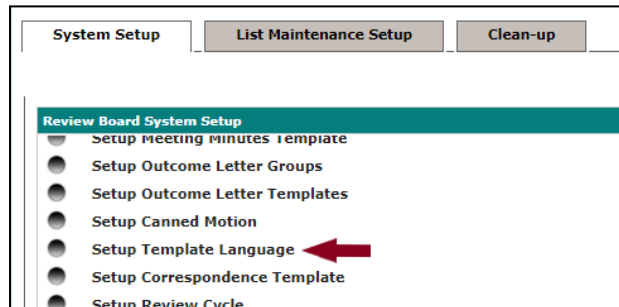


Setup Template Language

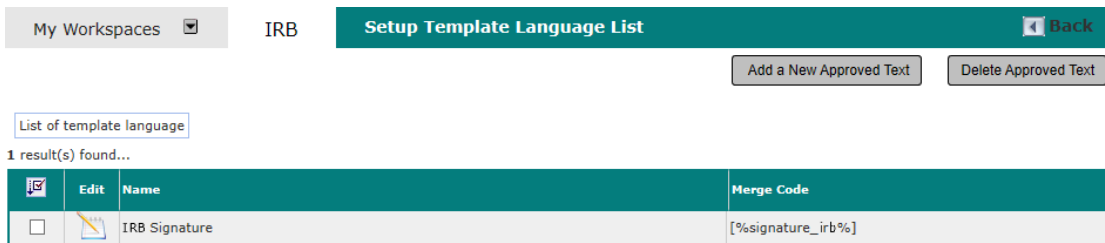
The iRIS™ system provides the ability for institutions to configure a list of predefined (“canned”) text blocks for insertion in Minutes, Agendas, and Outcome Letter documents via an **Insert Template Language** button, as shown in the IACUC example below.



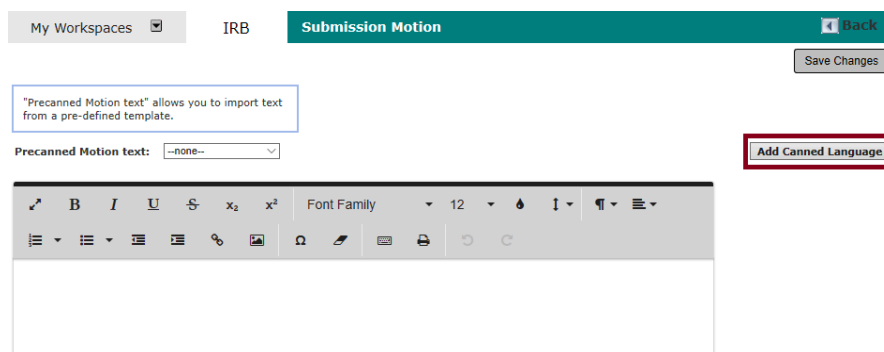
To access the configuration list, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Template Language** link.



The **Setup Template Language List** page opens.



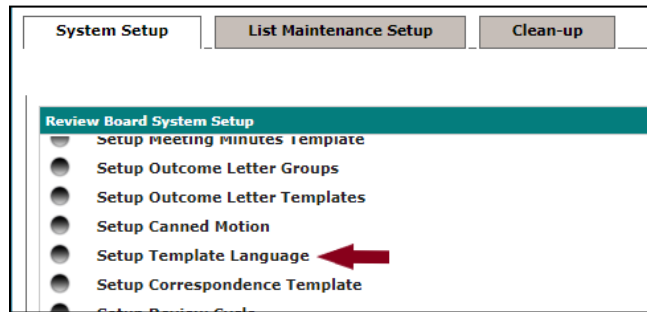
Any block of template language configured here is saved as a Merge Code and made available for insertion in Minutes, Agendas, and Outcome Letters via an **Add Canned Language** button on the applicable processing pages.



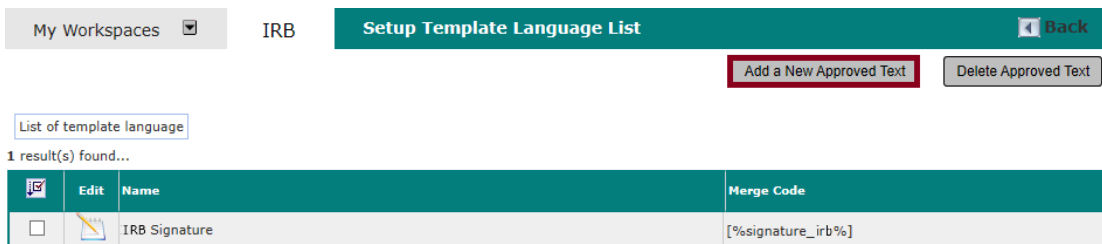
See the *Using Merge Codes in Document Templates* section of this manual for more information about working with Merge Codes.

Add Template Language

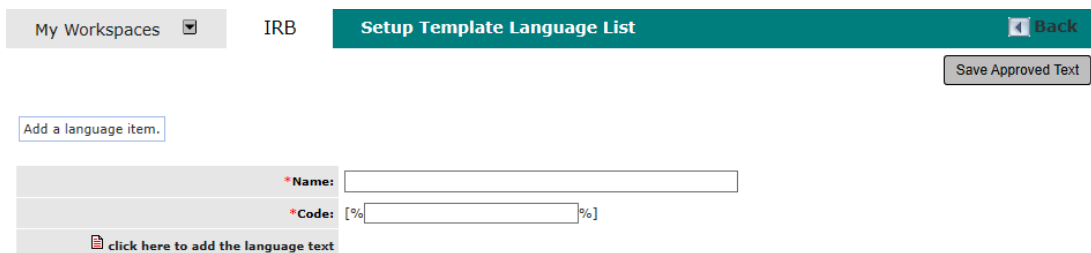
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Template Language** link.



The **Setup Template Language List** page opens. Click the **Add a New Approved Text** button.

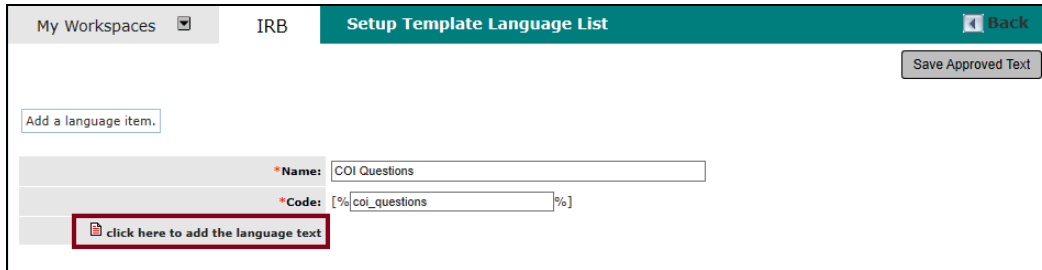


As shown below, an **Add a language item** panel opens for configuration of the text block.

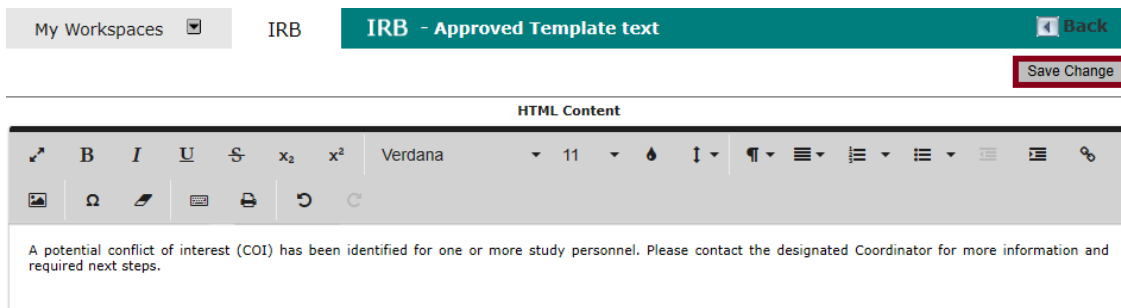


Enter a descriptive **Name** and the desired Merge **Code** to be assigned to the block of text. *Note that the code must include underscores where spaces occur between words, and cannot include any special characters (e.g., &, #, etc.).*

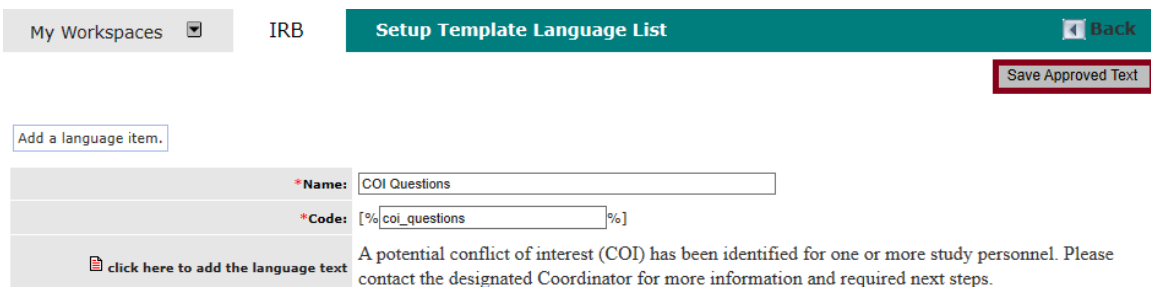
In the example below, a **Name** and **Code** are entered. Click the **click here to add the language text** link.



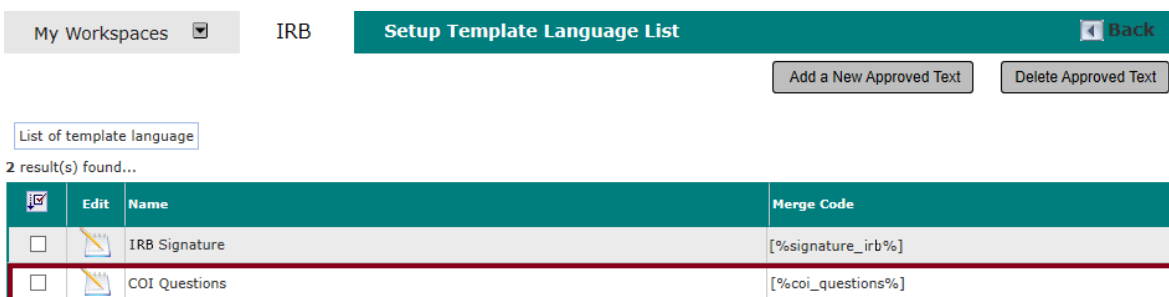
The **Approved Template text** page opens with a text editor for entry and formatting of the text block. Notice that no Insert Merge Code button is available on this page. This is because the text block entered here will itself be saved as a Merge Code, and Merge Codes cannot be nested within text blocks.



In the example shown above the desired text is entered. Click the **Save Change** button. The text block is added to the **Add a language item** panel.

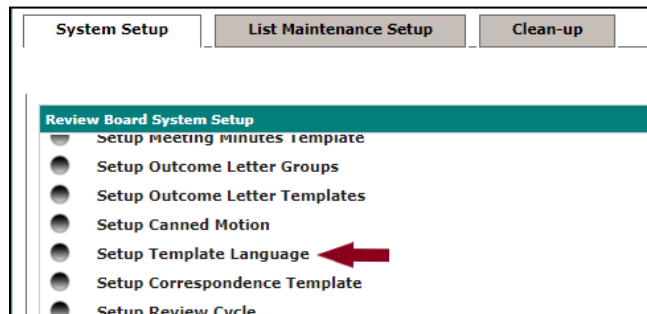


Click the **Save Approved Text** button. As shown below, the item is added on the **Setup Template Language List** page.

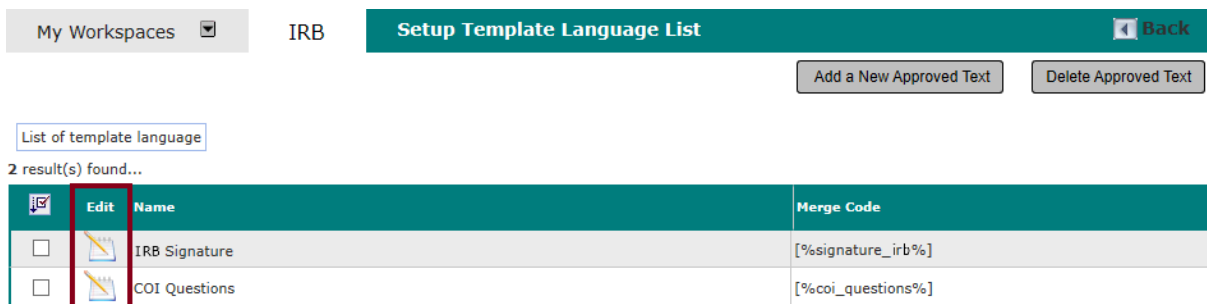


Edit Template Language

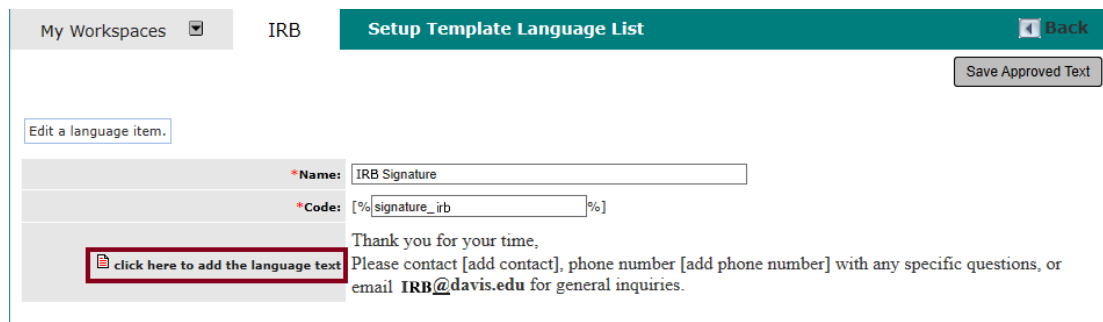
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Template Language** link.



The **Setup Template Language List** page opens. Click the icon in the **Edit** column for the applicable item.

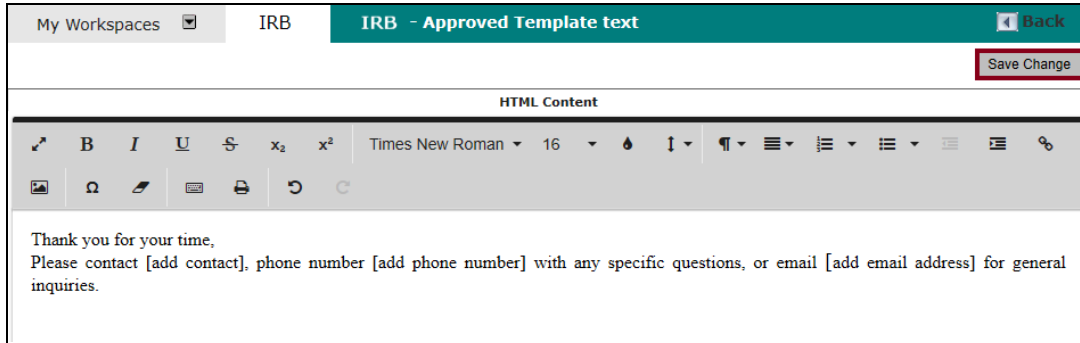


As shown below, an **Edit a language item** panel opens for revision of the text block.



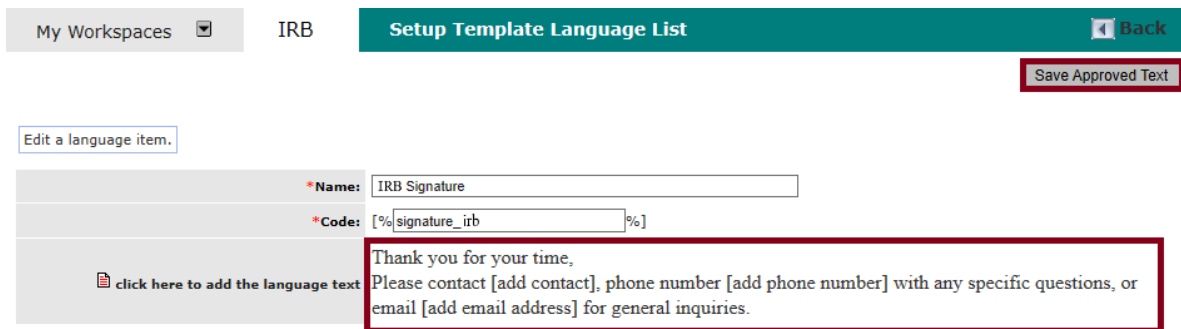
Make desired changes to the **Name** and Merge **Code** fields. *Note that the code must include underscores where spaces occur between words, and cannot include any special characters (e.g., &, #, etc.).*

Click the **click here to add the language text** link to edit the text block. As shown below, the text block is opened for editing in the **Approved Template text** page.

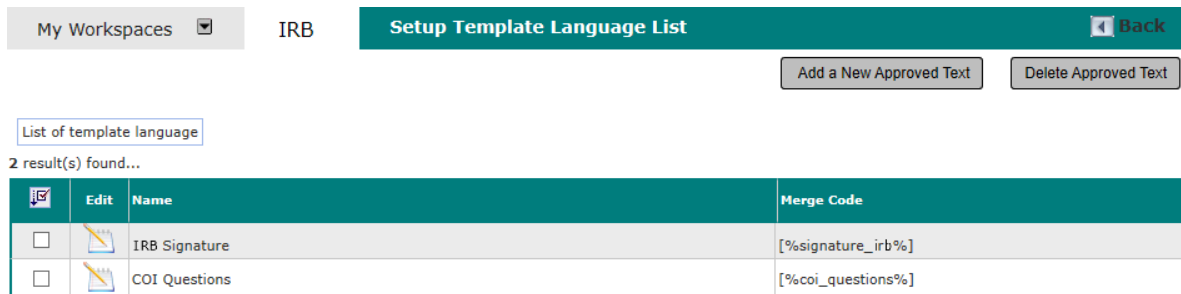


Notice that no Insert Merge Code button is available on this page. This is because the text block entered here will itself be saved as a Merge Code, and Merge Codes cannot be nested within text blocks.

Make desired changes to the text block, then click the **Save Change** button. As shown below, the text is added to the **Edit a language item** panel. Click the **Save Approved Text** button.

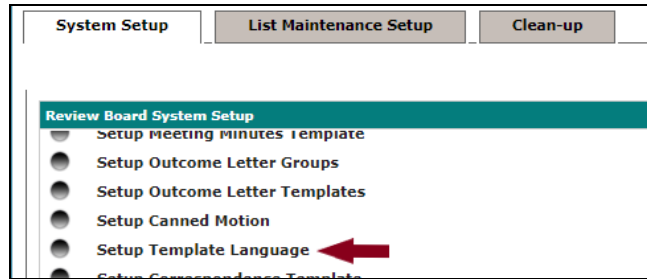


The edit panel closes, and the item is revised.

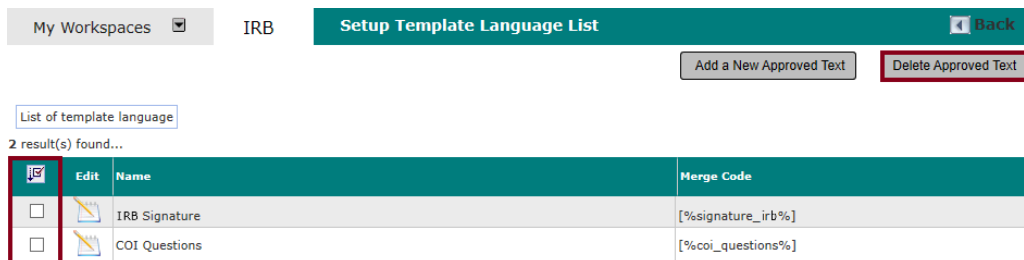


Delete Template Language

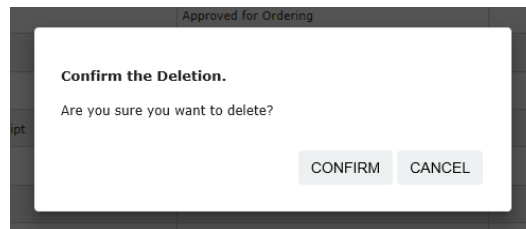
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Template Language** link.



The **Setup Template Language List** page opens. Select the checkbox(es) in the far-left column for the item(s) to be deleted, then click the **Delete Approved Text** button.

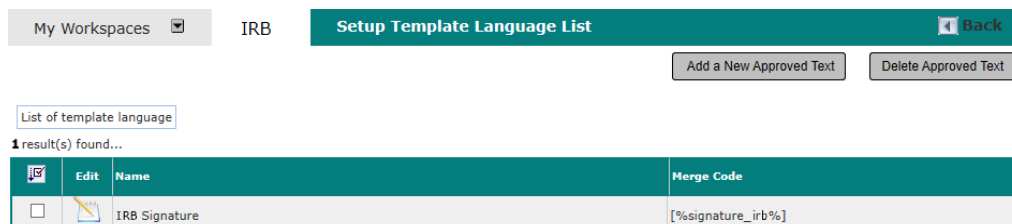


A confirmation popup window displays.



Click **CANCEL** to return to the **Setup Template Language List** page without deleting the item(s).

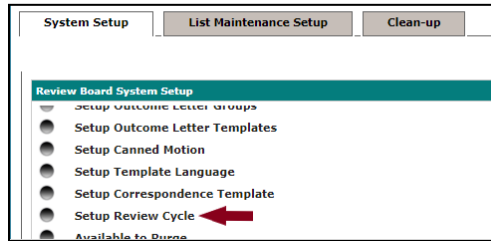
Click **CONFIRM** to delete the item(s) and return to the **Setup Template Language List** page. The item(s) is(are) deleted.



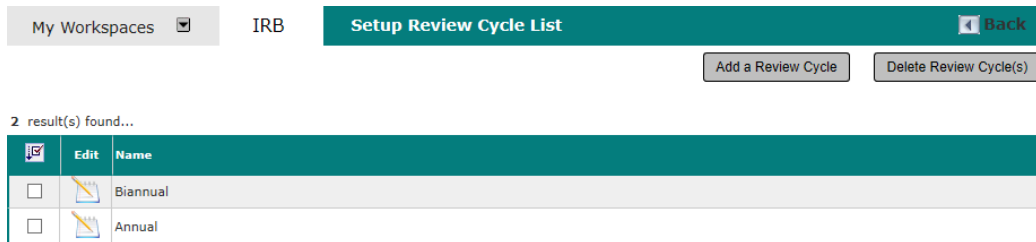
Setup Review Cycle

The iRIS™ system provides the ability to configure standardized review cycle terms for use in submission processing date calculations.

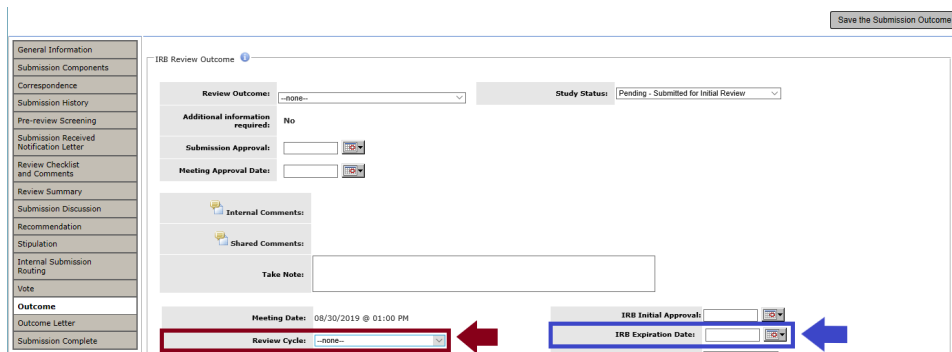
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Cycle** link.



The **Setup Review Cycle List** page opens, as shown below.



Review cycles configured here populate the **Review Cycle** dropdown picklist on the **Outcome** tab of submission processing screens (red box and arrow in screenshot below).

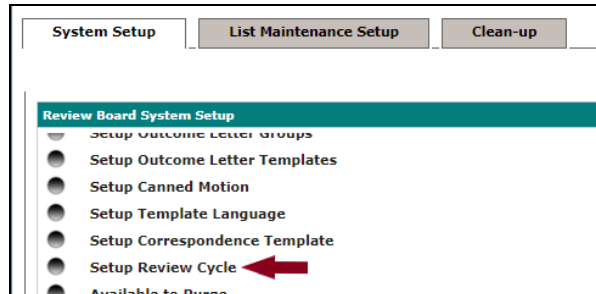


When an item is selected from the **Review Cycle** picklist on an approved submission, the **IRB Expiration Date** field automatically calculates the corresponding expiration date (blue box and arrow in screenshot above) based on the Submission Approval date.

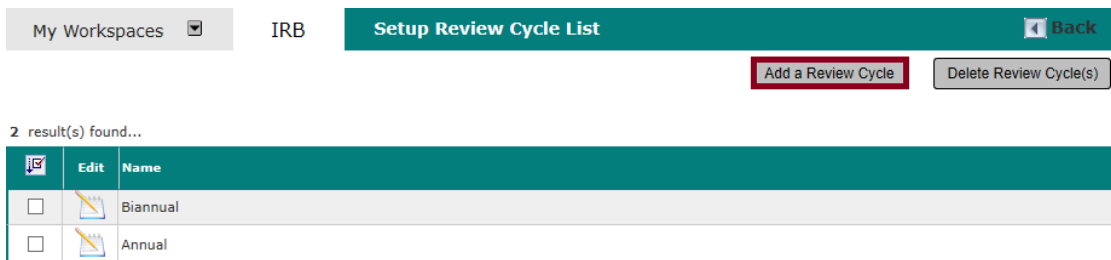
*Note that where the **Review Cycle** field is left blank the user designates an expiration date using the calendar widget provided for the expiration date field.*

Add Review Cycle

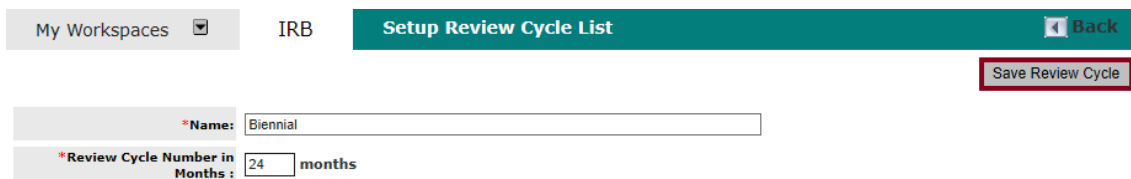
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Cycle** link.



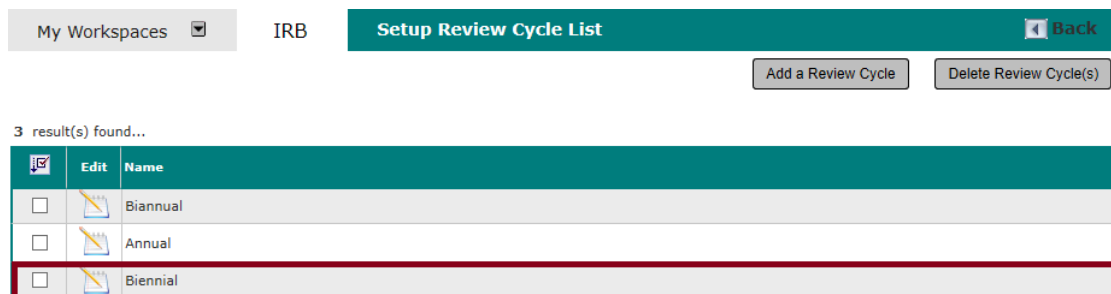
The **Setup Review Cycle List** page opens, as shown below. Click the **Add a Review Cycle** button.



An add panel is opened for creation of the new review cycle. Enter a descriptive **Name**, then enter the number of months for the cycle in the **Review Cycle Number in Months** field. An example of the filled panel is shown below.

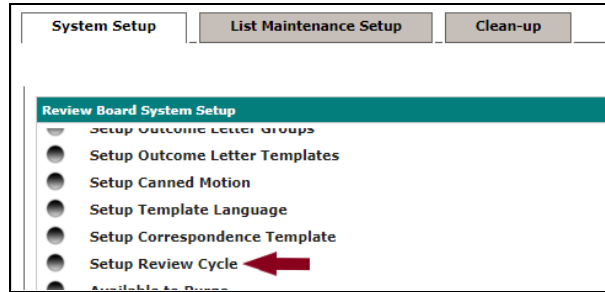


Click the **Save Review Cycle** button to save the new review cycle and close the add panel. As shown below, the new review cycle is added on the **Setup Review Cycle List** page.

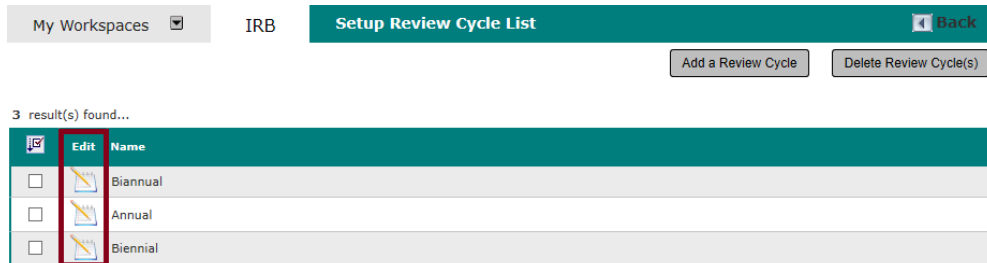


Edit Review Cycle

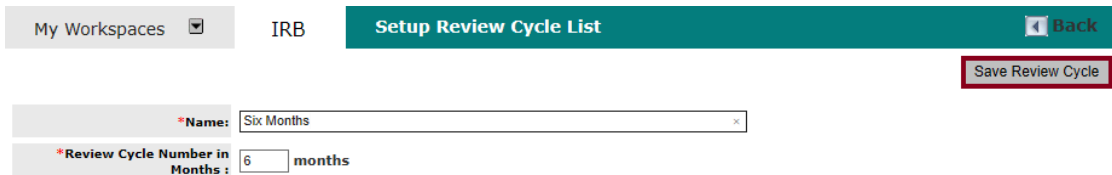
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Cycle** link.



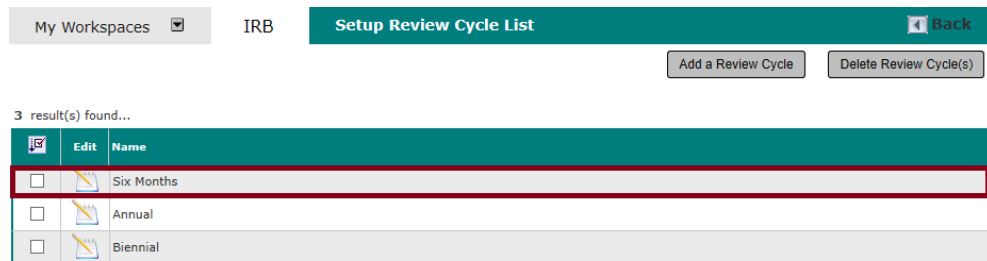
The **Setup Review Cycle List** page opens, as shown below. Click the icon in the **Edit** column for the applicable review cycle.



The selected review cycle is opened in an edit panel. Make desired changes to the **Name** and **Review Cycle Number in Months** fields, then click the **Save Review Cycle** button to save changes and close the edit panel.

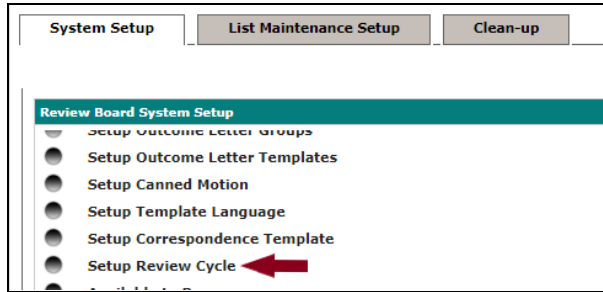


The review cycle is revised on the **Setup Review Cycle List** page.

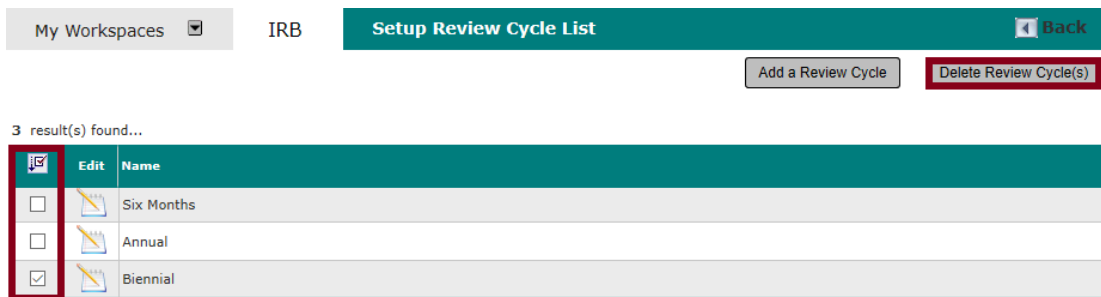


Delete Review Cycle

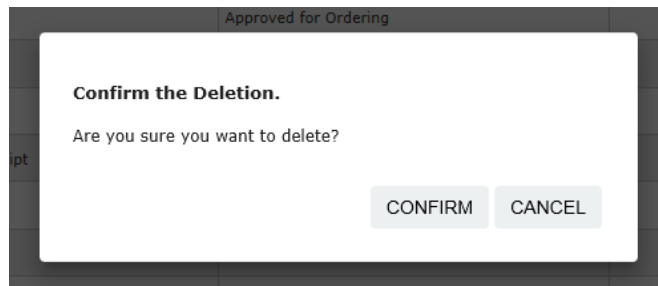
Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Review Cycle** link.



The **Setup Review Cycle List** page opens, as shown below. Select the checkbox(es) in the far-left column for the review cycle(s) to be deleted, then click the **Delete Review Cycle(s)** button.

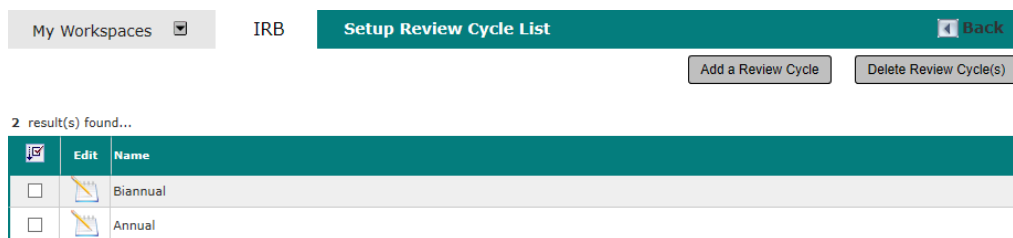


A confirmation popup window displays.



Click **CANCEL** to return to the **Setup Review Cycle List** page without deleting the selected review cycle(s).

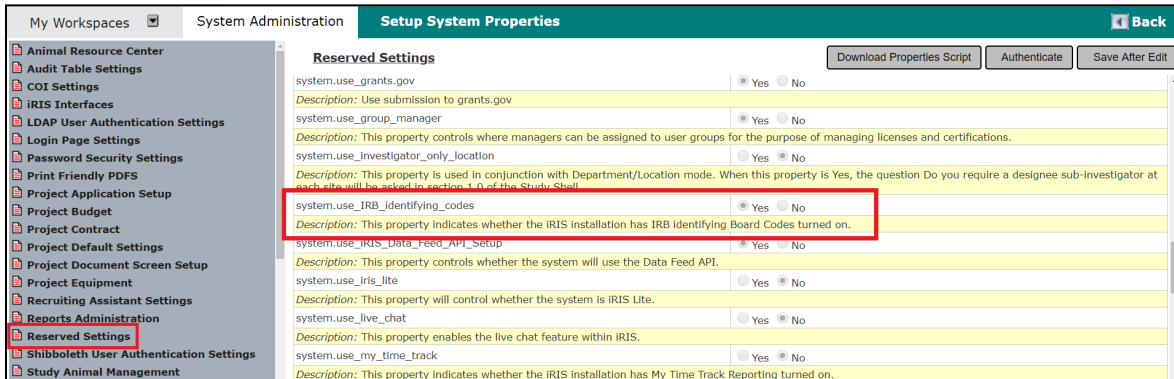
Click **CONFIRM** to delete the item(s) and return to the **Setup Review Cycle List** page. The review cycle(s) is(are) deleted.



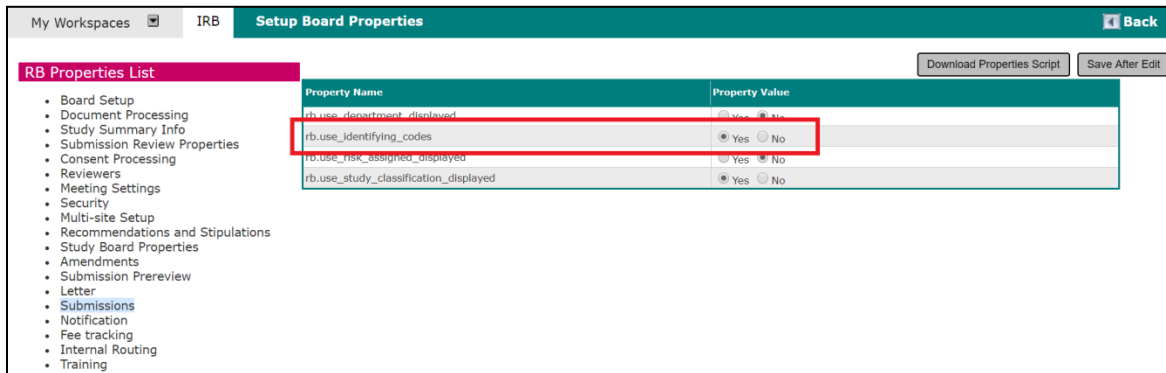
Setup Submission Codes

An add-on feature is available to enable System Administrators to organize IRB study submissions by color code. The property `system.use_IRB_identifying_codes`, under System Administration > System Configuration > Reserved Settings, toggles this feature on or off.

NOTE: This is a reserved setting; please inquire with your iMedRIS contact for assistance.

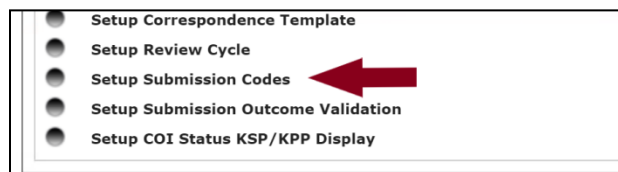


When the property is set to “Yes” the color code option is turned on and a `rb.use_identifying_codes` property becomes available in Review Board Administration under Board Configuration Options > Submissions.



When the `rb.use_identifying_codes` property is set to “No”, the user cannot configure study codes in the system.

When set to “Yes”, the property displays a new column for codes to be configured in the board submissions area, Analyst Dashboard, and the General Information tab on the board in the submissions processing page. In addition, a new **Setup Submission Codes** link is added to the Board Administration page for Review Board members with access to set up submission codes.



Here the Administrator can edit the desired label for the column where the code(s) appear in the Submissions list and Analyst Dashboard, as well as in the General Information tab for the applicable board in submissions processing.

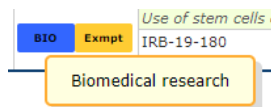
The **Predefined Name** shown on the new label is **CPT Code**. The user can change it by entering a desired name in the **Alternate Name** field and clicking the **Save Label** button.

The new properties turn on color coding for labels in a new **CPT Code** column next to the **Study Classification** column in the Submissions dashboard. The column name is taken from the system label, either the **Predefined UI Label** of “CPT Code” or the custom name entered by the user in the **Alternate UI Label** field. In the example shown below, an **Alternate UI Label** of **Codes** (second column from the right) has been entered.

Open	Codes	IRB Number	Ref Number	Type	2019 Common Rule?	Date Board Received	IRB Expiration Date	Principal Investigator	Assigned Analyst
	B10 Exmpt	IRB-19-180	001318	Unanticipated Events Form	No	07/12/2021 12:49:34 PM PDT	07/29/2021	Investigator, John	

The new column populates with configured codes (e.g., label, color, and logic).

When the user hovers over a color code label, a tooltip description displays (shown below).



Where configured, color codes also appear in submission processing queue pages (shown below).

My Workspaces | IRB Number: **IRB-19-180** | IRB | **Unanticipated Events Form** | Back

Protocol Items | Miscellaneous | Submission Forms

Ref Number: **001318** | IRB Expiration Date: 07/29/2021 | Common Rule: Common Rule - Effective 1991 | Study Title: Use of stem cells on subjects currently being treated for Diabetes Type 2

Study Status: **Open**

Submission Details | Submission Component(s) | Pre-review Screening | Submission Correspondence

Submission Review Status

Submission Received	Analyst Assigned	Analyst Checklist Completed	Review Process Assigned	Reviewer(s) Assigned	All Reviewer(s) Complete	Submission Items Reviewed/Approved	Submission Outcome Assigned	Response Letter Generated	Submission Completed
---------------------	------------------	-----------------------------	-------------------------	----------------------	--------------------------	------------------------------------	-----------------------------	---------------------------	----------------------

General Information

Study Alias: USCSD -13323

Codes: **BIO** Exmpt

Edit the Master Lay Summary

Edit the submission summary

Internal Comments:

Archive Reference Num: 001318

Setup Submission Outcome Validation

It is possible to apply automated, custom validation checks prior to applying a submission outcome, in order to enforce institution policies and practices. For example, prior to applying an “Approved” outcome a validation check can be run against the Study Status field on the submission form to verify the study is in an “Active” status, and if it is not, return an error message to the user instead of an outcome.

- Setup Correspondence Template
- Setup Review Cycle
- Setup Submission Codes
- Setup Submission Outcome Validation 
- Setup COI Status KSP/KPP Display

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Submission Outcome Validation** link to access the **Setup Review Board Submission Outcome Validations** page (shown below).

My Workspaces | IRB Board | **Setup Review Board Submission Outcome Validations** | Back

Save Validation Order | Add Validation

Define the Validation Rules for the Submission Outcome Tab

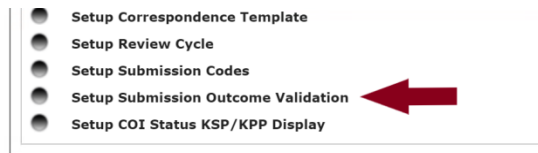
Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Expiration Date - QSF Jacob	Error
		20	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		30	Review Cycle	Add Review Cycle Please

All configured outcome validations are listed here.

Note that because the validation rules work in much the same manner as a database query, some familiarity with Structured Query Language (SQL) is required to build effective validation rules.

Add Submission Outcome Validation

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Submission Outcome Validation** link.



All configured outcome validations are listed here. Notice the **Order** column (see screenshot below).

My Workspaces ▾ IRB Board **Setup Review Board Submission Outcome Validations** Back

Save Validation Order Add Validation

Define the Validation Rules for the Submission Outcome Tab

Remove	Edit	Order	Name of Validation Rule	Error Message
		<input type="text" value="10"/>	Active Study Status - QSF Jacob	Active Status Required. Please review and modify Protocol status.
		<input type="text" value="20"/>	Expiration Date - QSF Jacob	Error
		<input type="text" value="30"/>	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		<input type="text" value="40"/>	Review Cycle	Add Review Cycle Please

The **Order** column value dictates the order in which the validation rules are applied to the submission. The rules are applied in ascending order beginning with **Order** value “10”. The rules can be re-ordered at any time by editing the values in the **Order** column and clicking the **Save Validation Order** button (see screenshot above), or by editing the individual records to apply a new **Order** value. See the *Edit Submission Outcome Validation* section of this manual for more information about editing validation rule records.

If a new rule with a duplicate **Order** value is created, or if the **Order** value of an existing rule is revised such that a duplicate **Order** value is created, the newly created or revised rule retains the entered **Order** value and all **Order** values for preexisting, higher order rules are automatically incremented upward. For example, given the screenshot below, if a new rule is created with **Order** value “10” the “Expiration Date – QSF Jacob” rule **Order** value changes to “20”, the “IRB of Record and Outcome” rule **Order** value changes to “30”, and the “Review Cycle” rule **Order** value changes to “40”.

My Workspaces ▾ IRB Board **Setup Review Board Submission Outcome Validations** Back

Save Validation Order Add Validation

Define the Validation Rules for the Submission Outcome Tab

Remove	Edit	Order	Name of Validation Rule	Error Message
		<input type="text" value="10"/>	Expiration Date - QSF Jacob	Error
		<input type="text" value="20"/>	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		<input type="text" value="30"/>	Review Cycle	Add Review Cycle Please

Note that because the validation rules work in much the same manner as a database query, some familiarity with Structured Query Language (SQL) is required to build effective validation rules.

Click the **Add Validation** button (shown in screenshot above). The **Add Outcome Validation** popup opens, as shown below.

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association	--none--
	--none--		
	Value		

Notice that the **Order** field (upper right in screenshot above) defaults to the next available **Order** number, in ascending order, which in this case is “40”. Because this rule is intended to be evaluated first however, its **Order** number is changed to “10”. When the record is saved this rule retains the Order value of “10” and the Order value of all three preexisting rules is incremented upward.

In the screenshot below, the **Order** value is changed to “10”. Complete the remaining fields as follows.

Validation Name — enter the name of the rule

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association	--none--
	--none--		
	Value		

This validation is associated which submission form — click in the field to open a list of forms currently configured in the system (see screenshot above); scroll to the form containing the data value to be validated and click to select that form

Validation Field Association — click this button (see screenshot below) to select the specific field to be validated in the selected form

As shown below, the **Review Board Outcome Field Selection** popup opens. Scroll to the applicable field and click to select it, then click the **Save** button at the bottom right of the popup to save the selection and close the popup.

Edit Error Message — click this button (see screenshot below) to create a custom error message for display to the user when the submission fails this validation check

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association	--none--

As shown below, the **Enter the Error Message for this Validation** popup opens. Enter the error message text and format it as desired, then click the **Apply** button at the lower right to save the message.

Active Status Required. Please review and modify Protocol status.

Tool Tip — enter any desired Tool Tip (mouseover) text, as shown below

Add Outcome Validation

*Validation Name: Active Study Status - QSF Jacob *Order: 10

*This validation is associated which submission form: Quick Submission Form (Jacob)

*Validation Field Association: Study Status

*Edit Error Message: Active Status Required. Please review and modify Protocol status.

Tool Tip: ***** This Submission Form Requires an Active protocol

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association	--none--

Buttons: Add a new Rule, Cancel, Save

What to Validate — click in the field to open a drop down pick list, as shown below; click in the list to select “Applic. Form all columns”, “Current Form all columns”, “Submission attributes” or “Submission Outcome selection”

Add Outcome Validation

*Validation Name: Active Study Status - QSF Jacob *Order: 10

*This validation is associated which submission form: Quick Submission Form (Jacob)

*Validation Field Association: Study Status

*Edit Error Message: Active Status Required. Please review and modify Protocol status.

Tool Tip: ***** This Submission Form Requires an Active protocol

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association	--none--

Buttons: Add a new Rule, Cancel, Save

Validation Field Association — click this button to select the specific field to be validated from the item specified in the **What to Validate** field

Add Outcome Validation

***Validation Name:** ***Order:**

***This validation is associated which submission form:**

***Validation Field Association:**

***Edit Error Message:**

Tool Tip:

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association	--none--
	--none--		
	Value		

As shown below, the **Review Board Outcome Field Selection** popup opens. Scroll to the applicable field and click to select it, then click the **Save** button at the bottom right of the popup to save the selection and close the popup.

Review Board Outcome Field Selection

Select	Outcome Field
General IRB Outcome Details	
<input type="radio"/>	Review Outcome
<input checked="" type="radio"/>	Study Status
<input type="radio"/>	Committee Name
<input type="radio"/>	Additional Information Required
<input type="radio"/>	Submission Approval
<input type="radio"/>	Follow-up Due
<input type="radio"/>	Meeting Date
<input type="radio"/>	IRB of Record
<input type="radio"/>	Use Review Notification to KSP
<input type="radio"/>	Please Select the Type of Review Notification that Must be Sent
<input type="radio"/>	IRB Initial Approval
<input type="radio"/>	Review Cycle
<input type="radio"/>	IRB Expiration Date
<input type="radio"/>	Days Prior to IRB Expiration

As shown below, the selected field populates in the **Data Value** column.

Join by, if any — select the desired join type (see screenshot below) to add a further validation rule to this record; *note that because the validation rules work in much the same manner as a database query, some familiarity with Structured Query Language (SQL) is required to build effective validation rules and this is especially true with compound rules*

In this example there is no join because only one field validation is required.

Comparator — in the **What to Validate** column (see screenshot below), click in the comparator field to open a pick list of options, and click the desired comparator to select it

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association Study Status	--none--

Comparison Ttype — in the **What to Validate** column (see screenshot below), beneath the comparator field, click in the comparison type field to open it and click to select either “Value” or “Submission Outcome selection”

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	*Validation Field Association Study Status	--none--

Note that because “Submission Outcome selection” is already selected in the first **What to Validate** field, it wouldn’t make sense to make the same selection for comparison type because that would result in the “Submission Outcome selection” being compared to itself.

Comparison Value — when “Value” is selected for comparison type, this field populates with a drop down list of possible values configured in the system for the selected field (see screenshot below); when “Submission Outcome selection” is selected for comparison type, this field populates with a list of Submission Outcome types configured in the system; click the desired value to select it

The screenshot shows the 'Add Outcome Validation' dialog box. The 'Validation Name' is 'Active Study Status - QSF Jacob' and the 'Order' is 10. The 'Validation Field Association' is 'Study Status' and the error message is 'Active Status Required. Please review and modify Protocol status.' The 'Tool Tip' is '***** This Submission Form Requires'. The 'What to Validate' table has one row with 'Submission Outcome selection' selected. The 'Data Value' dropdown is open, showing a list of submission outcomes. 'Active' is selected. The 'Join by, if any' dropdown is set to '--none--'. Buttons for 'Cancel' and 'Save' are at the bottom right.

When all fields are complete click the **Save** button (see screenshot below) to close the popup and create the record.

This screenshot shows the same 'Add Outcome Validation' dialog box, but now the 'Data Value' field is populated with 'Active'. The 'Save' button is highlighted with a red border, indicating it is the next step to complete the record creation. All other fields remain the same as in the previous screenshot.

The new rule is added on the **Setup Review Board Submission Outcome Validations** page, as shown below. Notice that because the new rule was created with an **Order** value of “10”, the three preexisting rules’ **Order** values are incremented upward.

Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Active Study Status - QSF Jacob	Active Status Required. Please review and modify Protocol status.
		20	Expiration Date - QSF Jacob	Error
		30	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		40	Review Cycle	Add Review Cycle Please

Edit Submission Outcome Validation

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Submission Outcome Validation** link.



All configured outcome validations are listed here. Notice the **Order** column (see screenshot below).

Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Active Study Status - QSF Jacob	Active Status Required. Please review and modify Protocol status.
		20	Expiration Date - QSF Jacob	Error
		30	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		40	Review Cycle	Add Review Cycle Please

The **Order** column value dictates the order in which the validation rules are applied to the submission. The rules are applied in ascending order beginning with **Order** value “10”. The rules can be re-ordered at any time by editing the values in the **Order** column and clicking the **Save Validation Order** button (see screenshot above), or by editing the individual records to apply a new **Order** value.

Click the applicable icon in the **Edit** column to open the corresponding rule for editing.

Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Active Study Status - QSF Jacob	Active Status Required. Please review and modify Protocol status.
		20	Expiration Date - QSF Jacob	Error
		30	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		40	Review Cycle	Add Review Cycle Please

The **Edit Outcome Validation** popup opens, as shown below.

Make desired changes to the fields on the popup, which are as follows.

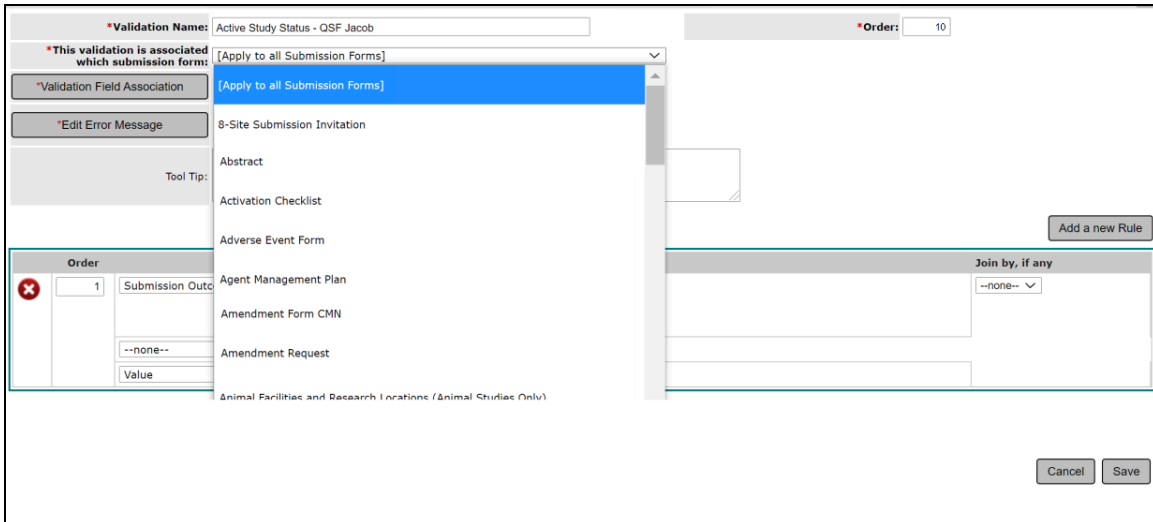
Order — priority order in which this rule will be applied to the submission; rules are applied in ascending order beginning with **Order** value “10”

If the **Order** value of an existing rule is revised such that a duplicate **Order** value is created, the revised rule retains the entered **Order** value and all **Order** values for preexisting, higher order rules are automatically incremented upward.

Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Expiration Date - QSF Jacob	Error
		20	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		30	Review Cycle	Add Review Cycle Please

For example, given the screenshot above, if the “Review Cycle” rule **Order** value is changed from “30” to “10” the “Expiration Date – QSF Jacob” rule **Order** value changes to “20”, the “IRB of Record and Outcome” rule **Order** value changes to “30”, and the “Review Cycle” rule is moved to the top of the list with an **Order** value of “10”.

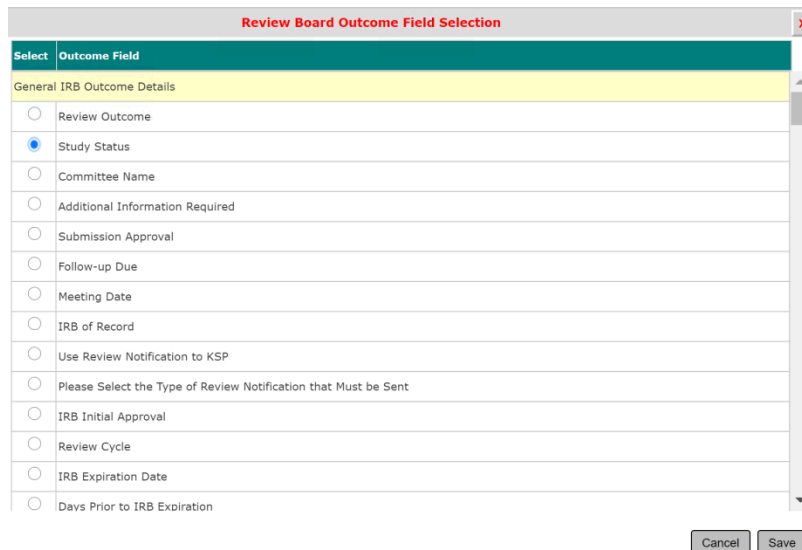
Validation Name — name of the rule



This validation is associated which submission form — click in the field to open a list of forms currently configured in the system (see screenshot above); scroll to the form containing the data value to be validated and click to select that form

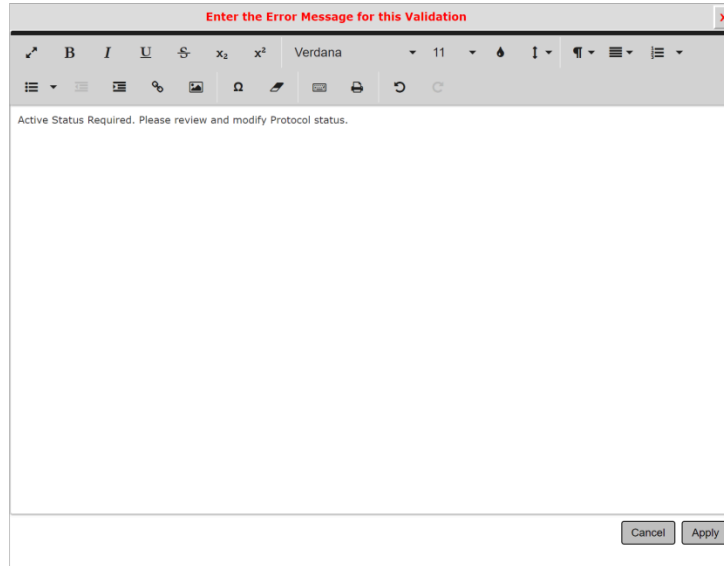
Validation Field Association — click this button to select the specific field to be validated in the selected form

As shown below, the **Review Board Outcome Field Selection** popup opens. Scroll to the applicable field and click to select it, then click the **Save** button at the bottom right of the popup to save the selection and close the popup.



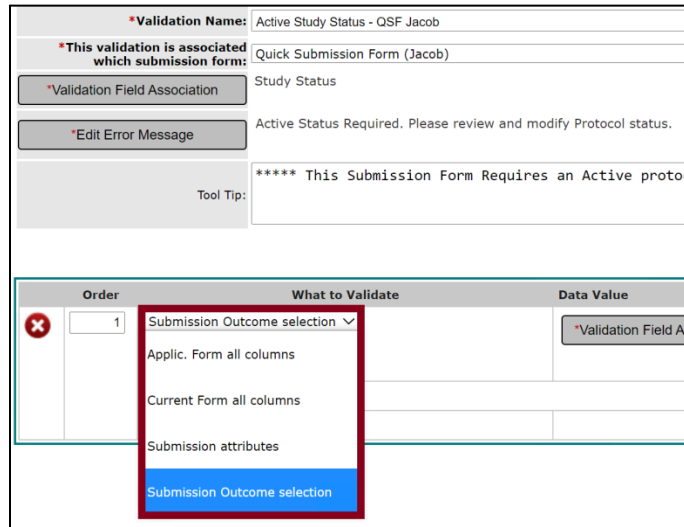
Edit Error Message — click this button to create a custom error message for display to the user when the submission fails this validation check

As shown below, the **Enter the Error Message for this Validation** popup opens. Revise the error message text and format it as desired, then click the **Apply** button at the lower right to save the message.



Tool Tip — Tool Tip (mouseover) text

What to Validate — click in the field to open a drop down pick list, as shown below; click in the list to select “Applic. Form all columns”, “Current Form all columns”, “Submission attributes” or “Submission Outcome selection”



Validation Field Association — click this button (shown below) to select the specific field to be validated from the item specified in the **What to Validate** field

*Validation Name: Active Study Status - QSF Jacob

*This validation is associated which submission form: Quick Submission Form (Jacob)

*Validation Field Association: Study Status

*Edit Error Message: Active Status Required. Please review and modify Protocol status.

Tool Tip: ***** This Submission Form Requires an Active protocol

Order	What to Validate	Data Value
1	Submission Outcome selection	*Validation Field Association

As shown below, the **Review Board Outcome Field Selection** popup opens. Scroll to the applicable field and click to select it, then click the **Save** button at the bottom right of the popup to save the selection and close the popup.

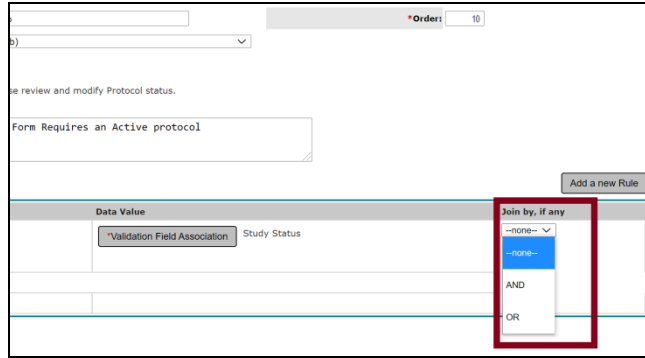
Review Board Outcome Field Selection

Select	Outcome Field
General IRB Outcome Details	
<input type="radio"/>	Review Outcome
<input checked="" type="radio"/>	Study Status
<input type="radio"/>	Committee Name
<input type="radio"/>	Additional Information Required
<input type="radio"/>	Submission Approval
<input type="radio"/>	Follow-up Due
<input type="radio"/>	Meeting Date
<input type="radio"/>	IRB of Record
<input type="radio"/>	Use Review Notification to KSP
<input type="radio"/>	Please Select the Type of Review Notification that Must be Sent
<input type="radio"/>	IRB Initial Approval
<input type="radio"/>	Review Cycle
<input type="radio"/>	IRB Expiration Date
<input type="radio"/>	Days Prior to IRB Expiration

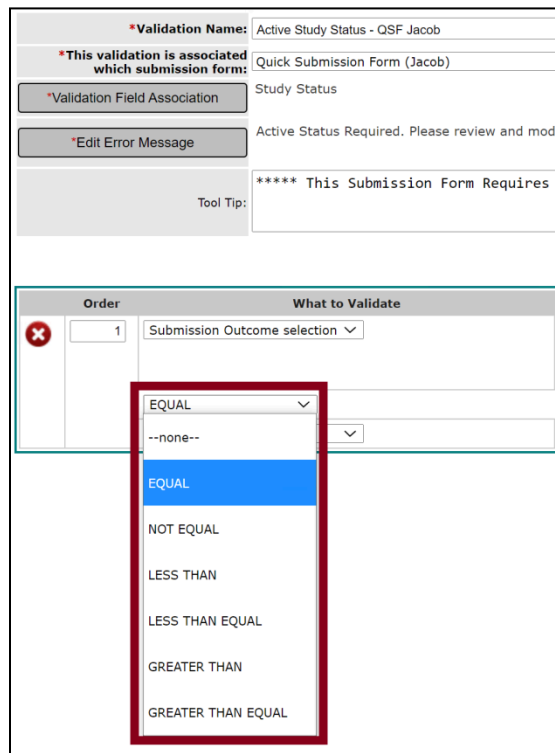
Cancel Save

Join by, if any — select the desired join type (see screenshot below) to add a further validation rule to this record; *note that because the validation rules work in much the same manner as a database query, some familiarity with Structured Query Language (SQL) is required to build effective validation rules and this is especially true with compound rules*

In this example there is no join because only one field validation is required.



Comparator — in the **What to Validate** column (see screenshot below), click in the comparator field to open a pick list of options, and click the desired comparator to select it



Comparison Type — in the **What to Validate** column (see screenshot below), beneath the comparator field, click in the comparison type field to open it and click to select either “Value” or “Submission Outcome selection”

Note that because “Submission Outcome selection” is already selected in the first **What to Validate** field, it wouldn’t make sense to make the same selection for comparison type because that would result in the “Submission Outcome selection” being compared to itself.

Comparison Value — when “Value” is selected for comparison type, this field populates with a drop down list of possible values configured in the system for the selected field (see screenshot below); when “Submission Outcome selection” is selected for comparison type, this field populates with a list of Submission Outcome types configured in the system; click the desired value to select it

When all fields are complete click the **Save** button (see screenshot below) to close the popup and save changes.

Add Outcome Validation
X

***Validation Name:** ***Order:**

***This validation is associated which submission form:**

***Validation Field Association:**

***Edit Error Message:**

Tool Tip:

Add a new Rule

Order	What to Validate	Data Value	Join by, if any
1	Submission Outcome selection	<input type="text" value="Validation Field Association"/> Study Status	--none--
	EQUAL	Value	Active

Cancel Save

The rule is revised and its location in the list is changed as necessary to correct any **Order** value changes.

My Workspaces
IRB Board

Setup Review Board Submission Outcome Validations
Back

Save Validation Order Add Validation

Define the Validation Rules for the Submission Outcome Tab

Remove	Edit	Order	Name of Validation Rule	Error Message
X		<input type="text" value="10"/>	Active Study Status - QSF Jacob	Active Status Required. Please review and modify Protocol status.
X		<input type="text" value="20"/>	Expiration Date - QSF Jacob	Error
X		<input type="text" value="30"/>	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
X		<input type="text" value="40"/>	Review Cycle	Add Review Cycle Please

Delete Submission Outcome Validation

Navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup Submission Outcome Validation** link.

- Setup Correspondence Template
- Setup Review Cycle
- Setup Submission Codes
- Setup Submission Outcome Validation** ←
- Setup COI Status KSP/KPP Display

The **Setup Review Board Submission Outcome Validations** page opens, as shown below. All configured outcome validations are listed here.

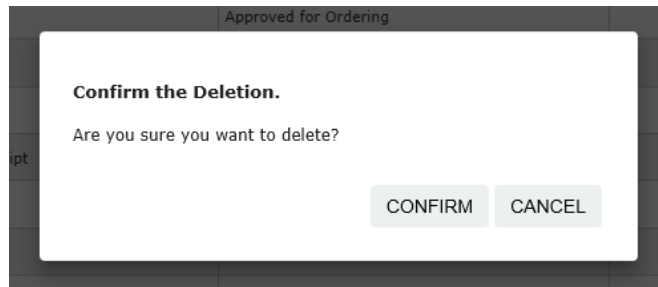
My Workspaces ▾ IRB Board **Setup Review Board Submission Outcome Validations** Back

Save Validation Order Add Validation

Define the Validation Rules for the Submission Outcome Tab

Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Active Study Status - QSF Jacob	Active Status Required. Please review and modify Protocol status.
		20	Expiration Date - QSF Jacob	Error
		30	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		40	Review Cycle	Add Review Cycle Please

Click the applicable icon(s) in the **Remove** column to delete the corresponding rule(s). A confirmation popup window displays.



Click **CANCEL** to return to the **Setup Review Board Submission Outcome Validations** page without deleting the selected rule(s).

Click **CONFIRM** to delete the item(s) and return to the **Setup Review Board Submission Outcome Validations** page. The rule(s) is(are) deleted, and **Order** values on the page are automatically updated.

My Workspaces ▾ IRB Board **Setup Review Board Submission Outcome Validations** Back

Save Validation Order Add Validation

Define the Validation Rules for the Submission Outcome Tab

Remove	Edit	Order	Name of Validation Rule	Error Message
		10	Expiration Date - QSF Jacob	Error
		20	IRB of Record and Outcome	This Protocol MUST be IRB of Record to approve.
		30	Review Cycle	Add Review Cycle Please

For example, given the screenshot above, if the “Expiration Date – QSF Jacob” rule is deleted, the “IRB of Record and Outcome” rule is moved to the top of the list with its **Order** value changed to “10”, and the “Review Cycle” rule is moved to the second position in the list with an **Order** value of “20”.

Setup COI Status KSP / KPP Display

The **COI Status** panel is where details of Key Study Personnel (KSP) Conflicts of Interest (COI) are displayed. This panel appears on the Submission Details tab when viewing the submission, and on the COI Status page. For this functionality and link to be present, rb.show_coi_status_table must be set to yes in the Review Board Configuration [Board Setup](#) area.

The contents of the panel are configured on the **Setup COI Status KSP Display** page (shown below).

My Workspaces ▾ IRB Board **Setup COI Status KSP Display** Back

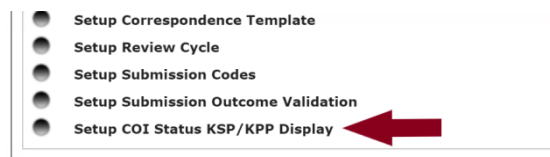
Reset Columns Save Columns

COI Status ⓘ

User Name	Role	Date Added to Study	Annual COI Due Date	Last Submitted COI Form	Date Submitted	Show Form	Total Matches	View Conflict Matches
Joe Investigator	Principal Investigator	07/30/2020	02/13/2020	DAnnual COI Form	07/29/2020 4:23:02 PM PDT	Show Form	1	[-]

Match Object Number	Object Outcome	Reported Interest Third Party	Reported Interest Type	Reporting Action	Date Submitted	Ref Number	Management Plan
008187	In Progress	[9305] Local Government	SFI - Publicly Traded Entity	Individual Annual Reporting Form	07/29/2020 4:23:01 PM PDT	026234	Show Plan

To access the page, navigate to IRB Assistant > Review Board Administration > [System Setup tab] > **Setup COI Status KSP/KPP Display** link.



All items shown appear in the **COI Status** panel by default, in the locations shown.

My Workspaces ▾ IRB Board **Setup COI Status KSP Display** Back

Reset Columns Save Columns

COI Status ⓘ

User Name	Role	Date Added to Study	Annual COI Due Date	Last Submitted COI Form	Date Submitted	Show Form	Total Matches	View Conflict Matches
Joe Investigator	Principal Investigator	07/30/2020	02/13/2020	DAnnual COI Form	07/29/2020 4:23:02 PM PDT	Show Form	1	[-]

Match Object Number	Object Outcome	Reported Interest Third Party	Reported Interest Type	Reporting Action	Date Submitted	Ref Number	Management Plan
008187	In Progress	[9305] Local Government	SFI - Publicly Traded Entity	Individual Annual Reporting Form	07/29/2020 4:23:01 PM PDT	026234	Show Plan

To remove an item from the panel, click the corresponding Delete icon (red circle with a white X in the center).

Note that the plus sign/minus sign (expand/compress) icon in the **View Conflict Matches** column, and therefore the expanded view presented to users in the sub-table (shown in screenshot above), only populate in the panel when the **View Conflict Matches** box is present. If this item is deleted from the display, users cannot expand the view for conflict match details.

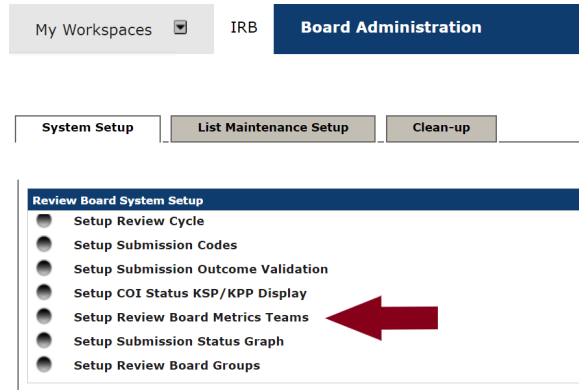
When the **Show Plan** button item is deleted, the user can see that a plan is in place but cannot view the specific plan.

If an item is removed in error, click the **Reset Columns** button to reset the panel to its default view.

When desired changes are complete click the **Save Columns** button. Changes can be confirmed in the COI Status panel in the **General Information** tab of the Submissions area, or on the COI Status page.

Setup Review Board Metrics Teams

Metrics for IRB teams can be tracked in the iRIS™ system. Teams are configured on the **Setup Review Board Metrics Teams** page. To access the page, navigate to IRB > Review Board Administration > **Setup Review Board Metrics Teams** link.



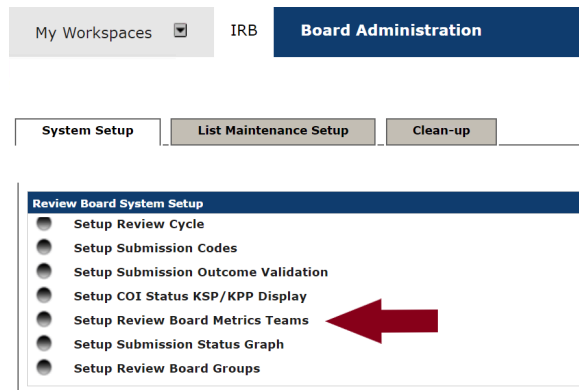
Click the link to open the **Setup Review Board Metrics Teams** page, shown below.



All previously configured metrics teams are listed on the page.

Add Review Board Metrics Team

Navigate to IRB > Review Board Administration > **Setup Review Board Metrics Teams** link.



Click the link to open the **Setup Review Board Metrics Teams** page, shown below.

My Workspaces ▾ IRB Setup Review Board Metrics Teams Back

Add Team

2 result(s) found...

Remove	Edit	Team Name	Team Leader	Analysts
<input type="checkbox"/>	<input type="checkbox"/>	Team 1	Reviewer, Luke, Ph.D, Analyst, John, Carmichael, Bob	Smith, John, Coordinator, Jane
<input type="checkbox"/>	<input type="checkbox"/>	Team 2	Administrator	Smith, John

Click the **Add Team** button at the upper right of the page. The **Add/Edit a Team** popup opens, as shown below.

Add/Edit a Team
X

Save

***Team Name:**

***Team Leader(s):** Add Delete

***Personnel Analyst(s):** Add Delete

Enter the desired **Team Name**.

Click the **Add** button in the **Team Leader(s)** section to add the **Team Leader(s)**.

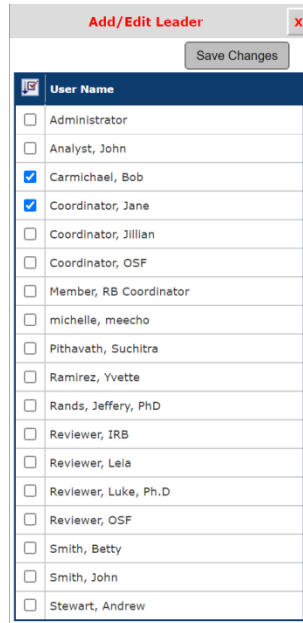
As shown below, the **Add/Edit Leader** popup opens for selection of the **Team Leader(s)**. This popup contains the names of all eligible board members.

Add/Edit Leader
X

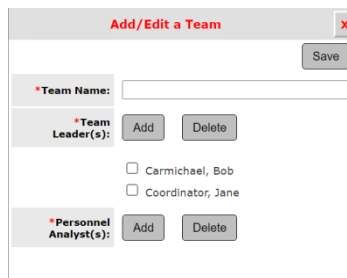
Save Changes

<input type="checkbox"/>	User Name
<input type="checkbox"/>	Administrator
<input type="checkbox"/>	Analyst, John
<input type="checkbox"/>	Carmichael, Bob
<input type="checkbox"/>	Coordinator, Jane
<input type="checkbox"/>	Coordinator, Jillian
<input type="checkbox"/>	Coordinator, OSF
<input type="checkbox"/>	Member, RB Coordinator
<input type="checkbox"/>	michelle, meecho
<input type="checkbox"/>	Pithavath, Suchitra
<input type="checkbox"/>	Ramirez, Yvette
<input type="checkbox"/>	Rands, Jeffery, PhD
<input type="checkbox"/>	Reviewer, IRB
<input type="checkbox"/>	Reviewer, Lela
<input type="checkbox"/>	Reviewer, Luke, Ph.D
<input type="checkbox"/>	Reviewer, OSF
<input type="checkbox"/>	Smith, Betty
<input type="checkbox"/>	Smith, John
<input type="checkbox"/>	Stewart, Andrew

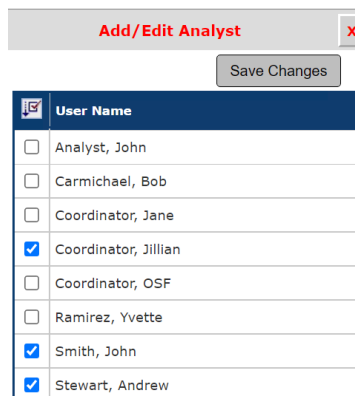
Click to select the checkbox(es) of the desired team Leader(s). Note that multiple selections are possible, as shown in the example below.



Click the **Save Changes** button to save the selected Leader(s) to the team and close the popup. As shown below, the selected Leader(s) is/are added on the **Add/Edit a Team** popup.



Click the **Add** button in the **Personnel Analyst(s)** section. As shown below, the **Add/Edit Analyst** popup opens for selection of the Analyst(s). This popup contains the names of all eligible board members who are assigned to an Analyst role in the system.



Click to select the checkbox(es) of the desired metrics team Analyst(s). Note that multiple selections are possible, as shown in the example above.

Click the **Save Changes** button to save the selected Analyst(s) to the team and close the popup. As shown below, the selected Analyst(s) is/are added on the **Add/Edit a Team** popup.

The screenshot shows a window titled "Add/Edit a Team" with a close button (X) in the top right corner. Below the title bar is a "Save" button. The main content area contains the following elements:

- *Team Name:** A text input field containing "Team 3".
- *Team Leader(s):** A section with an "Add" button and a "Delete" button. Below these are two unchecked checkboxes:
 - Carmichael, Bob
 - Coordinator, Jane
- *Personnel Analyst(s):** A section with an "Add" button and a "Delete" button. Below these are three unchecked checkboxes:
 - Coordinator, Jillian
 - Smith, John
 - Stewart, Andrew

If any personnel are added to the team in error, click to select the checkbox(es) of personnel to be deleted and click the applicable **Delete** button (in the **Team Leader(s)** or **Personnel Analyst(s)** section) to delete personnel from the team, as shown in the example below.

This screenshot shows the same "Add/Edit a Team" window. The "Delete" button in the "Personnel Analyst(s)" section is highlighted with a red border. The checkboxes for "Smith, John" and "Coordinator, Jillian" are now checked, while "Stewart, Andrew" remains unchecked. The "Team Leader(s)" section now only shows "Coordinator, Jane" and "Carmichael, Bob", with "Coordinator, Jillian" missing. The "Save" button is still present at the top right.

A confirmation popup displays. Note that this same confirmation popup displays when deleting either **Team Leader(s)** or **Personnel Analyst(s)** personnel.

The confirmation popup is a simple dialog box with the text "Are sure you want to remove this personnel(s)?" centered at the top. At the bottom, there are two buttons: "CONFIRM" on the left and "CANCEL" on the right.

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

Click **CONFIRM** to delete the selected personnel from the team and close the confirmation popup.

Click the **Save** button to save the team configuration and close the popup. As shown below, the new team is added on the **Setup Review Board Metrics Teams** page.

Remove	Edit	Team Name	Team Leader	Analysts
		Team 1	Reviewer, Luke, Ph.D, Analyst, John, Carmichael, Bob	Smith, John, Coordinator, Jane
		Team 2	Administrator	Smith, John
		Team 3	Coordinator, Jane, Carmichael, Bob	Smith, John, Coordinator, Jillian, Stewart, Andrew

Edit Review Board Metrics Team

Navigate to IRB > Review Board Administration > **Setup Review Board Metrics Teams** link.

My Workspaces ▾ IRB **Board Administration**

System Setup | List Maintenance Setup | Clean-up

Review Board System Setup

- Setup Review Cycle
- Setup Submission Codes
- Setup Submission Outcome Validation
- Setup COI Status KSP/KPP Display
- **Setup Review Board Metrics Teams** ←
- Setup Submission Status Graph
- Setup Review Board Groups

Click the link to open the **Setup Review Board Metrics Teams** page, shown below.

Remove	Edit	Team Name	Team Leader	Analysts
		Team 1	Reviewer, Luke, Ph.D, Analyst, John, Carmichael, Bob	Smith, John, Coordinator, Jane
		Team 2	Administrator	Smith, John
		Team 3	Coordinator, Jane, Carmichael, Bob	Smith, John, Coordinator, Jillian, Stewart, Andrew

Click the icon in the **Edit** column for the applicable team. The team record is opened for revision in the **Add/Edit a Team** popup, as shown below.

Make desired changes to the **Team Name**.

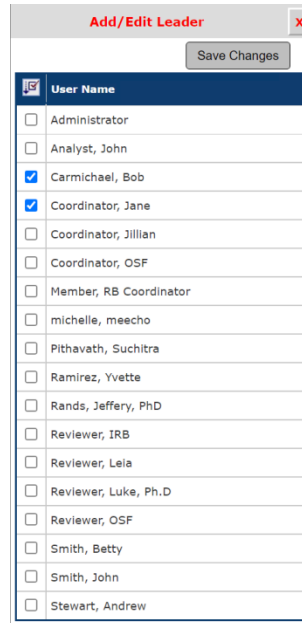
Use the **Add** and **Delete** buttons in the **Team Leader(s)** and **Personnel Analyst(s)** sections to add or delete personnel from the team.

In the example above, two of the three Analysts are selected for deletion. When the user clicks the **Delete** button, a confirmation popup displays. Note that this same confirmation popup displays when the user attempts to delete **Team Leader(s)** personnel.

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

Click **CONFIRM** to delete the selected personnel from the team and close the popup. As shown below, the selected personnel are deleted on the **Add/Edit a Team** popup. This popup remains open for the user's convenience, so that additional changes can be made to the team if desired.

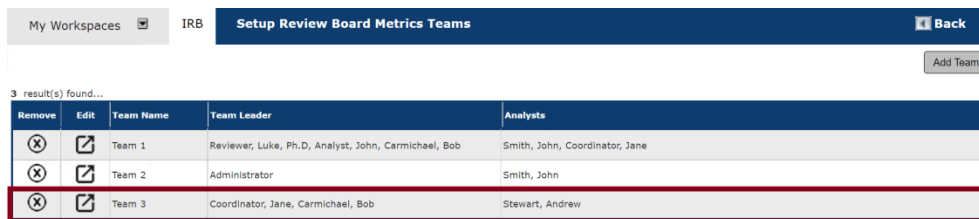
To add personnel to the team, click the **Add** button in the applicable section (**Team Leader(s)** or **Personnel Analyst(s)**). In the example below the **Add** button for **Team Leader(s)** was clicked, opening the **Add/Edit Leader** page.



The names of personnel currently assigned as **Team Leader(s)** are selected (checkmarks in blue boxes in screenshot above). Clicking the **Add** button in the **Personnel Analyst(s)** section opens the **Add/Edit Analyst** popup.

Click to select the checkboxes of any personnel to be added to the applicable list (Leader or Personnel Analyst) and click the **Save Changes** button to close the popup. Any personnel selected are shown in the applicable list on the **Add/Edit a Team** popup.

When desired changes are complete click the **Save** button to save changes and close the **Add/Edit a Team** popup. As shown in the screenshot below, the record is revised on the **Setup Review Board Metrics Teams** page.



Delete Review Board Metrics Team

Navigate to IRB > Review Board Administration > **Setup Review Board Metrics Teams** link.

My Workspaces ▾ IRB **Board Administration**

System Setup | **List Maintenance Setup** | Clean-up

Review Board System Setup

- Setup Review Cycle
- Setup Submission Codes
- Setup Submission Outcome Validation
- Setup COI Status KSP/KPP Display
- **Setup Review Board Metrics Teams** ←
- Setup Submission Status Graph
- Setup Review Board Groups

Click the link to open the **Setup Review Board Metrics Teams** page, shown below.

My Workspaces ▾ IRB **Setup Review Board Metrics Teams** [Back](#)

[Add Team](#)

3 result(s) found...

Remove	Edit	Team Name	Team Leader	Analysts
<input type="checkbox"/>	<input type="checkbox"/>	Team 1	Reviewer, Luke, Ph.D, Analyst, John, Carmichael, Bob	Smith, John, Coordinator, Jane
<input type="checkbox"/>	<input type="checkbox"/>	Team 2	Administrator	Smith, John
<input type="checkbox"/>	<input type="checkbox"/>	Team 3	Coordinator, Jane, Carmichael, Bob	Smith, John, Coordinator, Jillian, Stewart, Andrew

Click the icon in the **Remove** column for the team to be deleted. The confirmation popup shown below displays.

Are you sure you want to remove this metrics team?

[CONFIRM](#) [CANCEL](#)

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

Click **CONFIRM** to delete the selected team and close the popup. As shown below, the selected team is deleted on the **Setup Review Board Metrics Teams** page.

My Workspaces ▾ IRB **Setup Review Board Metrics Teams** [Back](#)

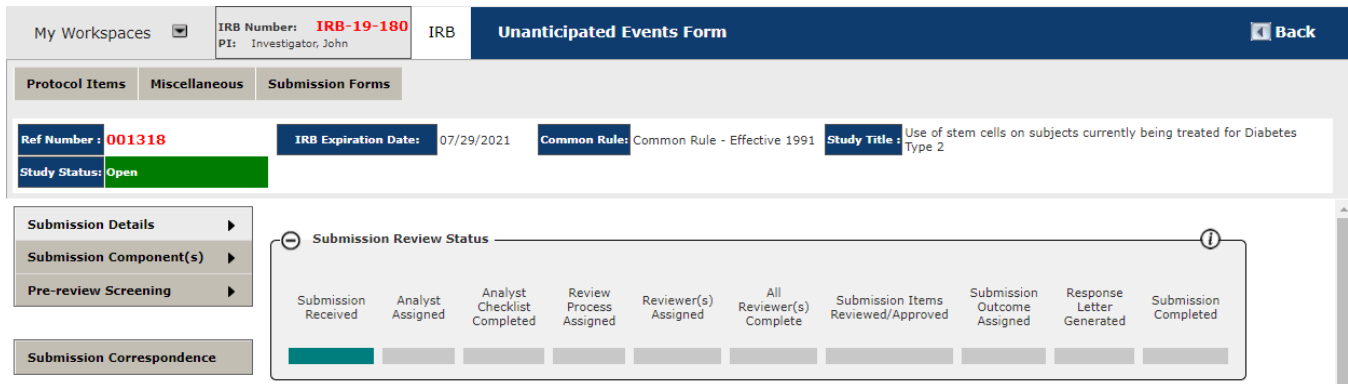
[Add Team](#)

2 result(s) found...

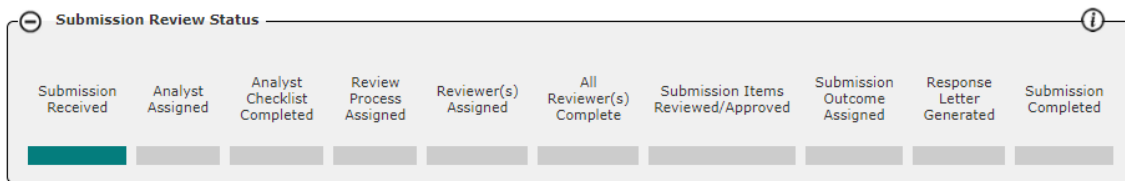
Remove	Edit	Team Name	Team Leader	Analysts
<input type="checkbox"/>	<input type="checkbox"/>	Team 1	Reviewer, Luke, Ph.D, Analyst, John, Carmichael, Bob	Smith, John, Coordinator, Jane
<input type="checkbox"/>	<input type="checkbox"/>	Team 2	Administrator	Smith, John

Setup Submission Status Graph

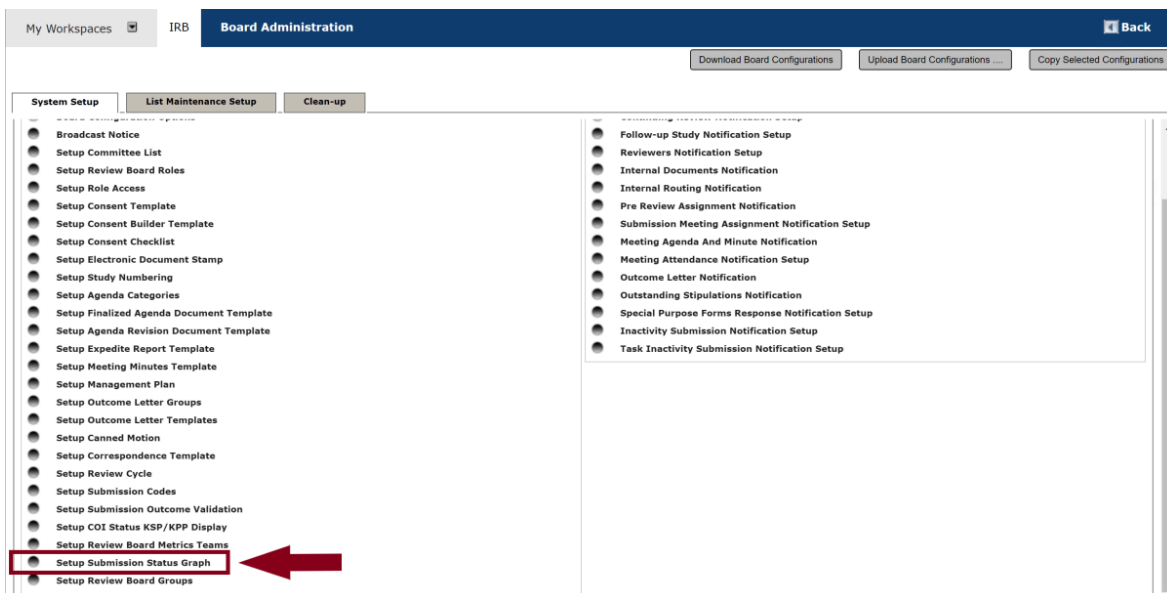
As shown below, a new **Submission Status** graphic has been added to the top of each of the tabs in submission processing to give the user an at-a-glance view of the status of the submission at this specific board.



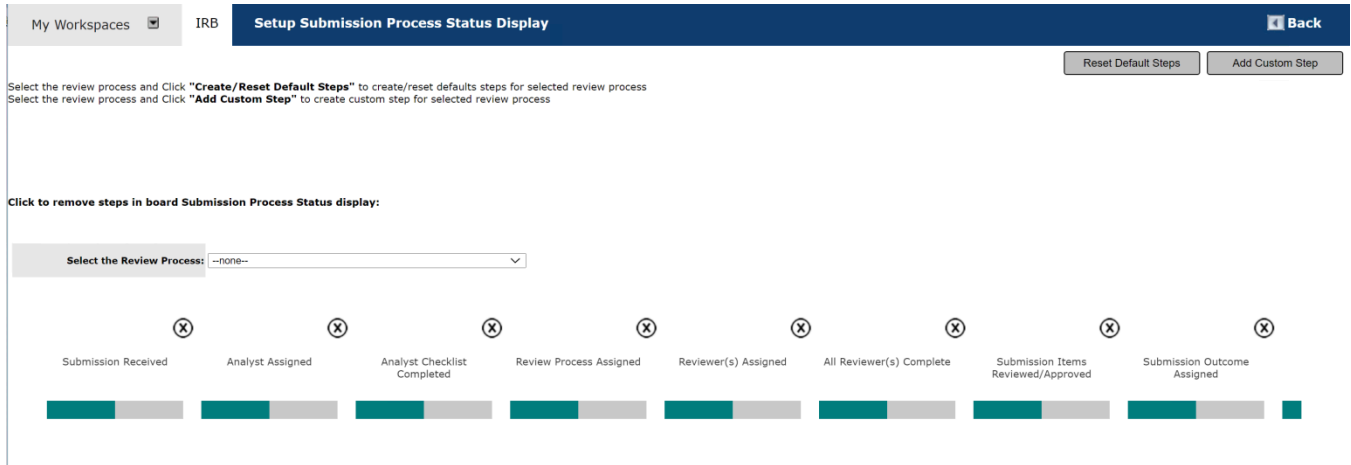
Incomplete steps are shown in gray, completed steps are shown in the color designated in the system. If a user bypasses a step by completing the next step, the bar for the bypassed step remains gray, indicating incomplete.



This graphic is configured under Review Board Administration, via the **Setup Submission Status Graph** link (shown below).



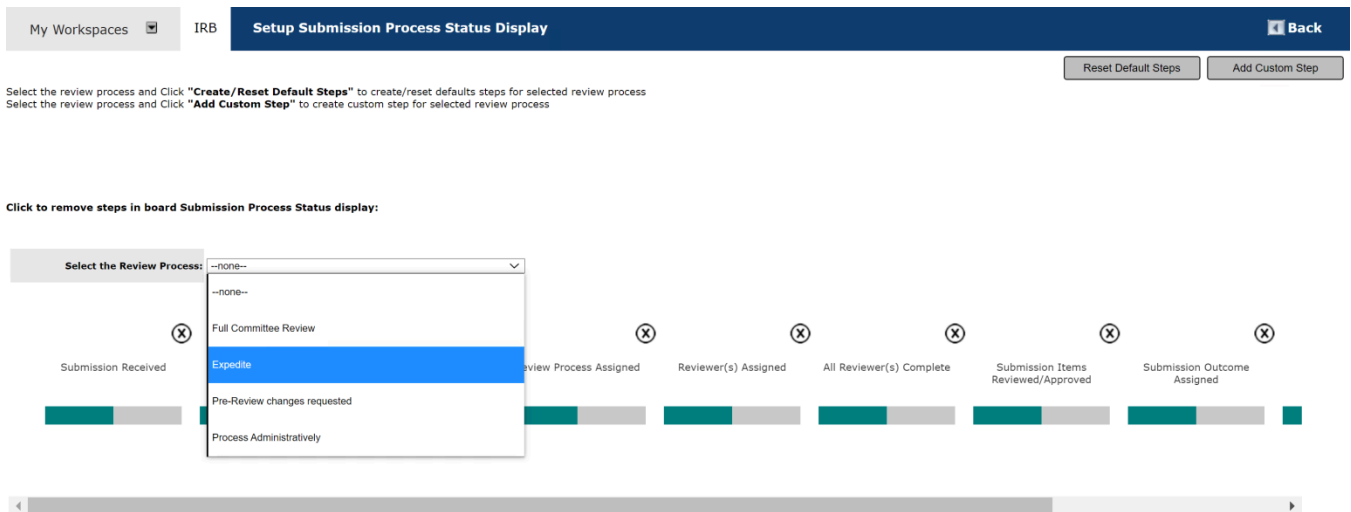
Click the link to open the **Setup Submission Processing Status Display** page, shown below.



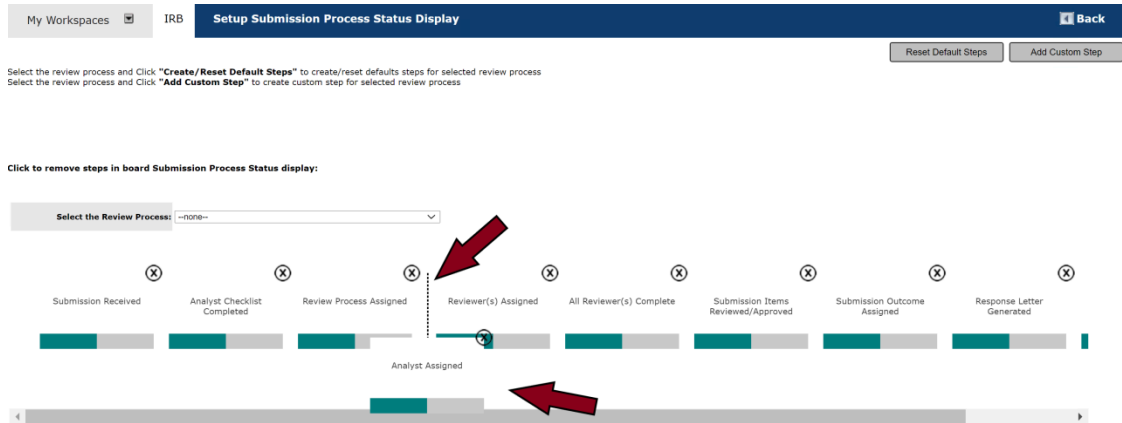
Instructions are provided to the user at the upper left of the page. The first step is to **Select the Review Process**, then click:

Reset Default Steps — to populate the default steps for the selected process in default order

Add Custom Step — to add a custom step



As demonstrated below, once a review process is selected, the **Reset Default Steps** button is clicked and steps are populated in default order, the order of steps can be rearranged via drag and drop with the mouse. In the example screenshot below, the **Analyst Assigned** step has been dragged away from its original location to the right of Submission Received. The dotted line indicates where the step can be placed by releasing the mouse with the step at that location.



Steps can be removed by clicking the delete icon  at the upper right hand corner of the step.

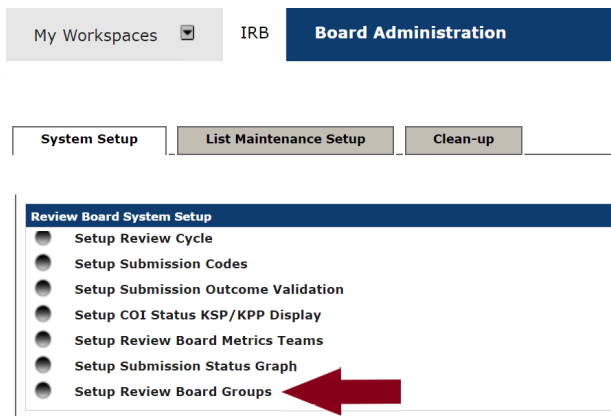
To discard changes and start over, click the **Reset Default Steps** button.

The **Add a Custom Step** button can be used to add custom steps but must be set up by iMedRIS personnel. Please contact Customer Service or your Project Manager for more information.

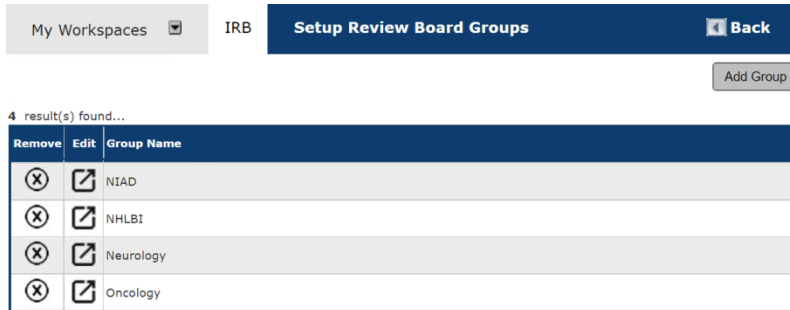
Setup Review Board Groups

Review board groups can be configured in the system to facilitate easier tracking and coordination of related study and/or submissions activity across groups of review board users.

Review board groups are configured on the Setup Review Board Groups page. To access the page, navigate to IRB > Review Board Administration > **Setup Review Board Groups** link.



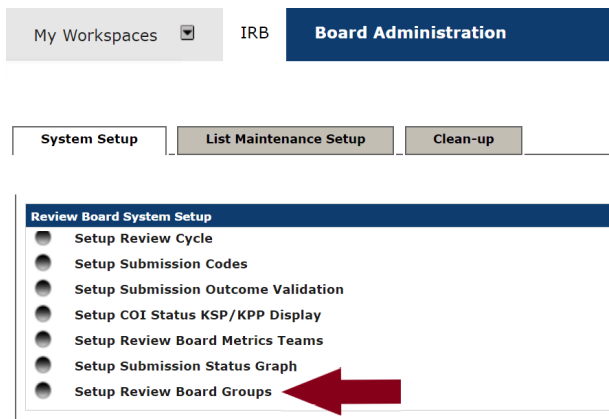
Click the link to open the **Setup Review Board Groups** page, shown below.



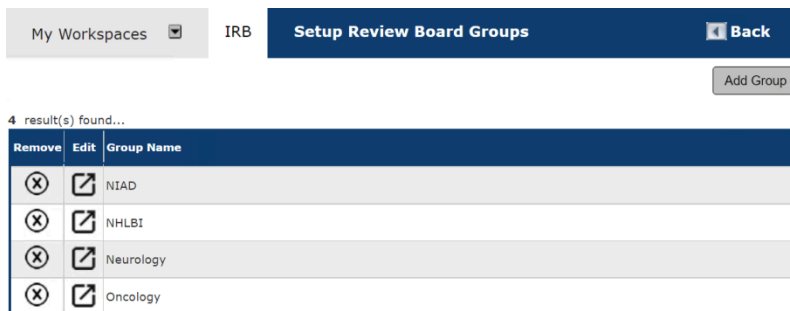
All previously configured review board groups are listed on the page.

Add Review Board Group

Navigate to IRB > Review Board Administration > **Setup Review Board Groups** link.



Click the link to open the **Setup Review Board Groups** page, shown below.



Click the **Add Group** button. The **Add/Edit a Group** popup opens, as shown below.

Enter the desired **Group Name**.

Click the **Add** button in the **Group Member(s)** section to assign personnel to the group. As shown below, the **Add/Edit Member** popup opens. This popup contains the names of all eligible board members in the system. A search filter is included at the top, for use in cases where the popup’s list of personnel is very long.

<input checked="" type="checkbox"/>	User Name	Specialty
<input type="checkbox"/>	Administrator	
<input type="checkbox"/>	Analyst, John	
<input type="checkbox"/>	Carmichael, Bob	Pediatric Oncology
<input type="checkbox"/>	Coordinator, Jane	
<input type="checkbox"/>	Coordinator, Jillian	
<input type="checkbox"/>	Coordinator, OSF	
<input type="checkbox"/>	Member, RB Coordinator	
<input type="checkbox"/>	michelle, meecho	
<input type="checkbox"/>	Pithavath, Suchitra	
<input type="checkbox"/>	Ramirez, Yvette	
<input type="checkbox"/>	Rands, Jeffery, PhD	
<input type="checkbox"/>	Reviewer, Luke, Ph.D	
<input type="checkbox"/>	Reviewer, IRB	
<input type="checkbox"/>	Reviewer, Leia	
<input type="checkbox"/>	Reviewer, OSF	
<input type="checkbox"/>	Smith, John	Anesthesiology
<input type="checkbox"/>	Smith, Betty	
<input type="checkbox"/>	Stewart, Andrew	

A sort tool is provided in the header of the far left, select column. Click the icon to toggle the list sort between ascending and descending alphabetical order, by last name.

Click to select the checkboxes of personnel to be added to the group. In the example below three names are selected.

<input checked="" type="checkbox"/>	User Name	Specialty
<input type="checkbox"/>	Administrator	
<input type="checkbox"/>	Analyst, John	
<input checked="" type="checkbox"/>	Carmichael, Bob	Pediatric Oncology
<input type="checkbox"/>	Coordinator, Jane	
<input type="checkbox"/>	Coordinator, Jillian	
<input type="checkbox"/>	Coordinator, OSF	
<input type="checkbox"/>	Member, RB Coordinator	
<input type="checkbox"/>	Michelle, meecho	
<input type="checkbox"/>	Pithavath, Suchitra	
<input type="checkbox"/>	Ramirez, Yvette	
<input type="checkbox"/>	Rands, Jeffery, PhD	
<input type="checkbox"/>	Reviewer, Luke, Ph.D	
<input checked="" type="checkbox"/>	Reviewer, IRB	
<input checked="" type="checkbox"/>	Reviewer, Leia	
<input type="checkbox"/>	Reviewer, OSF	
<input type="checkbox"/>	Smith, John	Anesthesiology
<input type="checkbox"/>	Smith, Betty	
<input type="checkbox"/>	Stewart, Andrew	

Click the **Save Changes** button to add the selected personnel to the group and close the popup.

If any personnel are added to the group in error, click to select the checkbox(es) of personnel to be deleted and click the **Delete** button. As shown below, a confirmation popup displays.

Are sure you want to remove this personnel(s)?

CONFIRM CANCEL

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

Click **CONFIRM** to delete the selected personnel from the group and close the confirmation popup.

X
Save

***Group Name:**

***Group Member(s):** Add Delete

- Carmichael, Bob
- Reviewer, IRB
- Reviewer, Leia

Back on the **Add/Edit a Group** popup, click the **Save** button. As shown below, the new group is added on the **Setup Review Board Groups** page.

My Workspaces ▾
IRB
Setup Review Board Groups
Back

Add Group

5 result(s) found...

Remove	Edit	Group Name
<input checked="" type="checkbox"/>	<input type="checkbox"/>	NIAD
<input checked="" type="checkbox"/>	<input type="checkbox"/>	NHLBI
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Neurology
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Oncology
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Peds

User can also be added to or removed from a group from **Grant User Access & Define Roles** for a review board, as shown below.

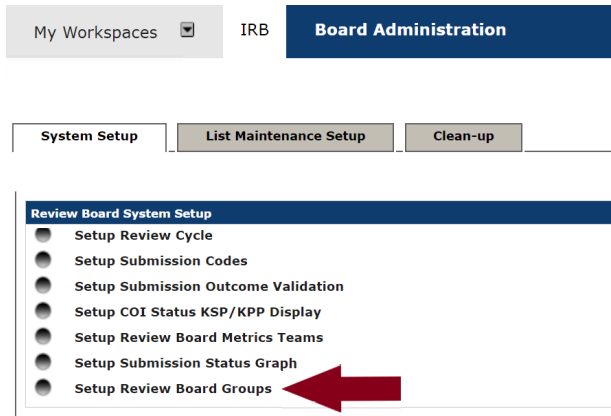
My Workspaces ▾
IRB
Grant User Access & Define Roles
Back

Save Member Info

<p>Name: Carmichael, Bob</p> <p>Highest Degree Earned:</p> <p>Specialty: Add Remove</p> <p><input type="checkbox"/> Pediatric Oncology</p> <p>Relationship to the Institution: <input type="radio"/> Affiliated <input type="radio"/> Non-Affiliated</p> <p>Affiliations: Add Remove</p> <p>Representational Capacity: <input type="radio"/> Scientist <input type="radio"/> Non-Scientist</p> <p>Representative of Specific Entity: Add Remove</p> <div style="border: 2px solid red; padding: 5px; margin-top: 5px;"> <p>Group: Add Remove</p> <ul style="list-style-type: none"> <input type="checkbox"/> NIAD <input type="checkbox"/> Oncology <input type="checkbox"/> Pediatrics </div> <p style="text-align: center; background-color: #004a87; color: white; padding: 2px;">Address:</p> <p>Primary Number:</p> <p>Cell Number:</p> <p>Pager Number:</p> <p>Fax Number:</p> <p>Primary Email:</p>	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Grant IRB Administrative Rights <input type="checkbox"/> Grant IRB Junior Administrative Rights <input type="checkbox"/> Grant IRB Limited Administrative Rights <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr style="background-color: #004a87; color: white;"> <th style="width: 15%;">Committee Access</th> <th style="width: 35%;">Committee Name</th> <th style="width: 15%;">Voting Member</th> <th style="width: 35%;">Experienced Member</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Committee 1</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <p>Roles</p> <ul style="list-style-type: none"> <input type="radio"/> Board Member <input checked="" type="radio"/> Coordinator <input type="radio"/> Chairperson <input type="radio"/> Data Entry Member <input type="radio"/> Non-Voting Member <input type="radio"/> Vice-Chairperson <input type="radio"/> Expediting Board Member <input type="radio"/> Administrative Assistant <input type="radio"/> Ex-Officio Member <input type="radio"/> Consultant/Ad Hoc Reviewer <input type="radio"/> Alternate Member <ul style="list-style-type: none"> <input type="checkbox"/> Administrator <input type="checkbox"/> Member, RB Coordinator <input type="checkbox"/> michelle, meecho <input type="checkbox"/> Pithavath, Suchitra <input type="checkbox"/> Rands, Jeffery, PhD <input type="checkbox"/> Reviewer, IRB <input type="checkbox"/> Reviewer, Luke, Ph.D <input type="checkbox"/> Reviewer, Leia <input type="checkbox"/> Reviewer, OSF <input type="checkbox"/> Smith, Betty <input type="checkbox"/> Stewart, Andrew 	Committee Access	Committee Name	Voting Member	Experienced Member	<input checked="" type="checkbox"/>	Committee 1	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Committee Access	Committee Name	Voting Member	Experienced Member						
<input checked="" type="checkbox"/>	Committee 1	<input checked="" type="checkbox"/>	<input type="checkbox"/>						

Edit Review Board Group

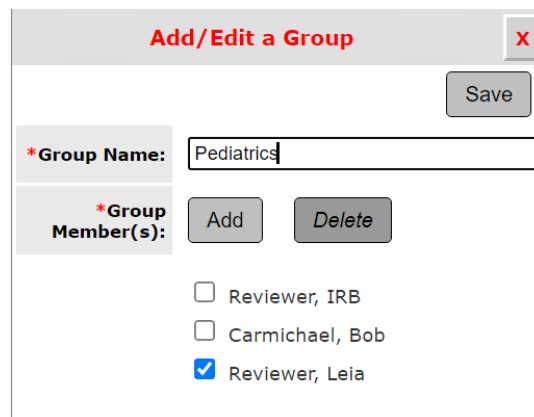
Navigate to IRB > Review Board Administration > **Setup Review Board Groups** link.



Click the link to open the **Setup Review Board Groups** page, shown below.

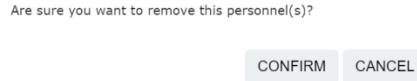


Click the icon in the **Edit** column for the applicable group. The group record is opened for revision in the **Add/Edit a Group** popup, as shown below.



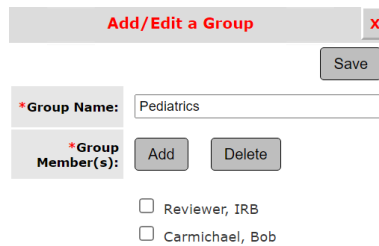
Make desired changes to the **Group Name**.

Use the **Add** and **Delete** buttons to remove members from, or add members to, the group. In the example above, one of the three group members are selected for deletion. When the user clicks the **Delete** button, a confirmation popup displays.



Click **CANCEL** to close the popup without deleting the personnel from the group.

Click **CONFIRM** to delete the selected personnel from the group and close the popup. As shown below, the selected personnel are deleted on the **Add/Edit a Group** popup. This popup remains open for the user’s convenience, so that additional changes can be made to the group if desired.



To add personnel to the group, click the **Add** button. As shown below, the **Add/Edit Member** popup opens with currently assigned group member names selected (blue check marked boxes in the far-left column). This popup contains the names of all eligible board members in the system. A search filter is included at the top, for use in cases where the popup’s list of personnel is very long.

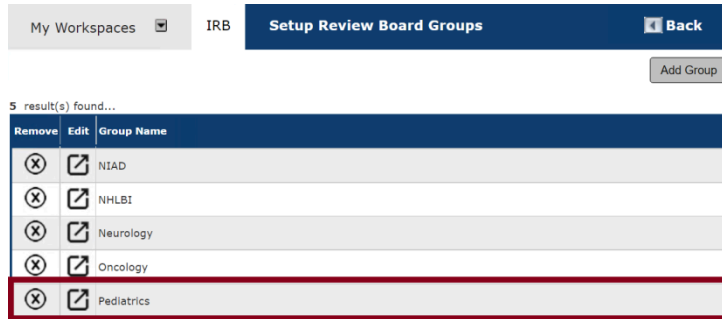
<input checked="" type="checkbox"/>	User Name	Specialty
<input type="checkbox"/>	Administrator	
<input type="checkbox"/>	Analyst, John	
<input checked="" type="checkbox"/>	Carmichael, Bob	Pediatric Oncology
<input type="checkbox"/>	Coordinator, Jane	
<input type="checkbox"/>	Coordinator, Jillian	
<input type="checkbox"/>	Coordinator, OSF	
<input type="checkbox"/>	Member, RB Coordinator	
<input type="checkbox"/>	Michelle, meecho	
<input type="checkbox"/>	Pithavath, Suchitra	
<input type="checkbox"/>	Ramirez, Yvette	
<input type="checkbox"/>	Rands, Jeffery, PhD	
<input type="checkbox"/>	Reviewer, Luke, Ph.D	
<input checked="" type="checkbox"/>	Reviewer, IRB	
<input type="checkbox"/>	Reviewer, Lela	
<input type="checkbox"/>	Reviewer, OSF	
<input type="checkbox"/>	Smith, John	Anesthesiology
<input type="checkbox"/>	Smith, Betty	
<input type="checkbox"/>	Stewart, Andrew	

Personnel currently assigned to the group are selected (checkmarks in blue boxes in screenshot above).

Click to select the checkboxes of any personnel to be added to the group and click the **Save Changes** button to close the **Add/Edit Member** popup. Any personnel added are shown in the group list on the **Add/Edit a Group** popup.

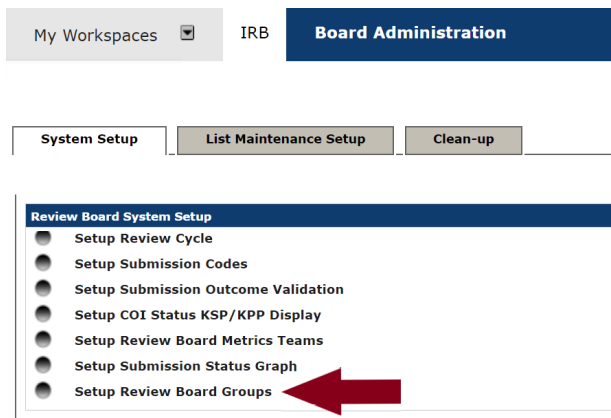
When desired changes are complete, click the **Save** button on the **Add/Edit a Group** popup.

As shown below, the Group is revised in the **Setup Review Board Groups** page.

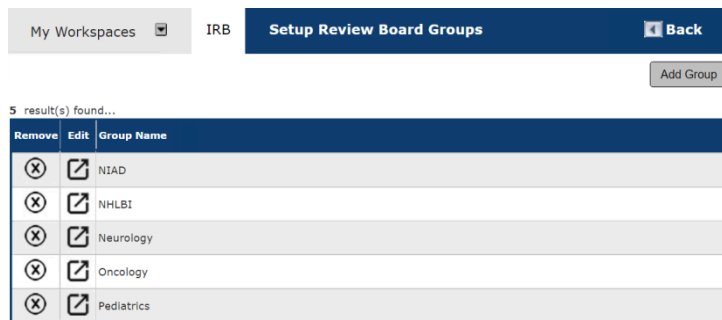


Delete Review Board Group

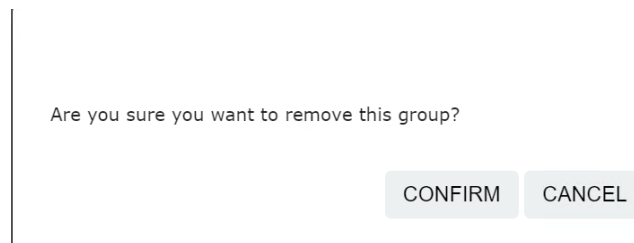
Navigate to IRB > Review Board Administration > **Setup Review Board Groups** link.



Click the link to open the **Setup Review Board Groups** page, shown below.

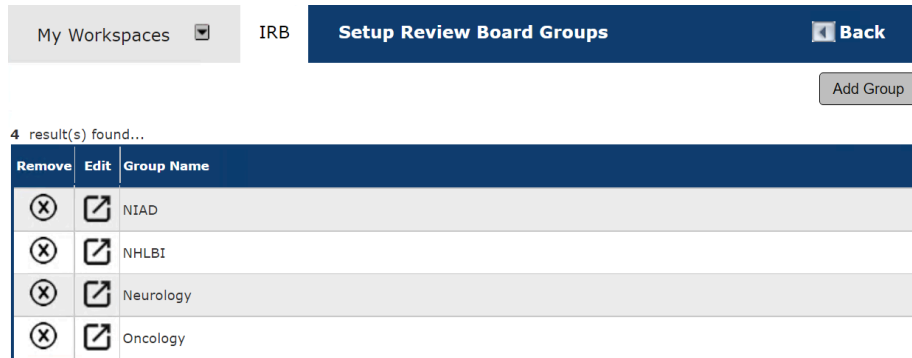


Click the icon in the **Remove** column for the group to be deleted. The confirmation popup shown below displays.



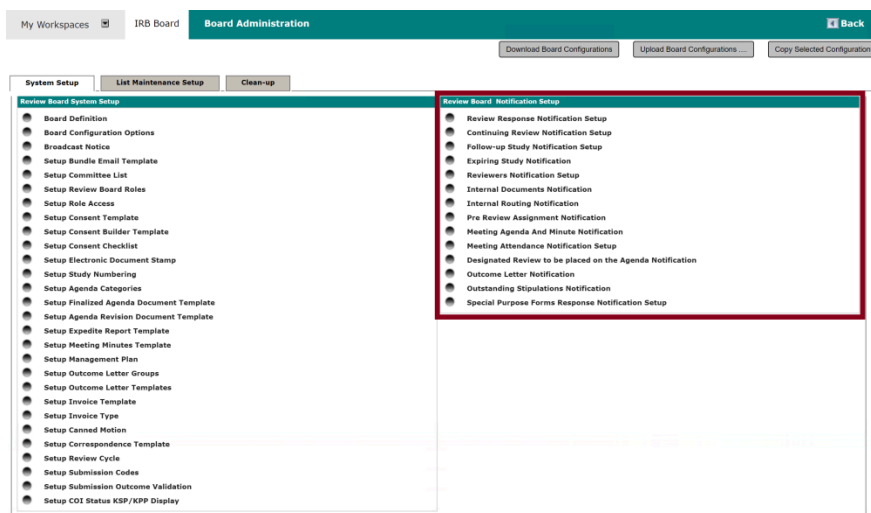
Click **CANCEL** to close the popup without deleting the group.

Click **CONFIRM** to delete the selected group and close the popup. As shown below, the selected group is deleted on the **Setup Review Board Groups** page.



Review Board Notification Setup

The **Review Board Notification Setup** panel, accessed via IRB Assistant > Review Board Administration > [System Setup tab], provides links for configuration of various standardized notification types to be sent to applicable study personnel and board members.



Notifications configured here are automatically sent to applicable personnel when study tasks (e.g., review, signoff, set meeting availability, etc.) are assigned, completed, or overdue.

See the RBA Notifications manual for details of RBA notification configuration and management.

List Maintenance Setup Tab

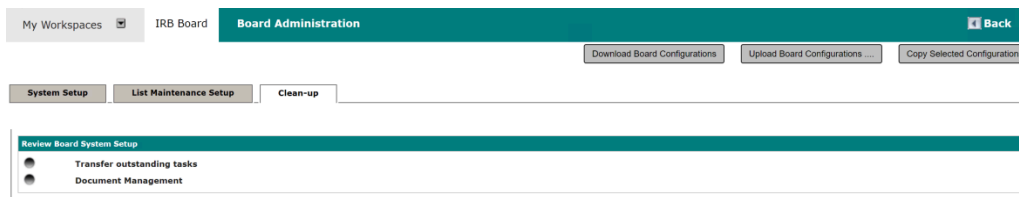
The iRIS™ system provides numerous picklists on system pages and forms. Some of these lists exist to save users the time and inconvenience of manually typing in frequently used data items. Other lists exist to enforce data validation requirements.

In the IRB Assistant module, system lists are accessed via IRB Assistant > Review Board Administration > **List Maintenance Setup** tab.

See the IRB Assistant – List Maintenance manual for details of list configuration processes and settings.

Clean-up Tab

The **Clean-up** tab under IRB Assistant > Review Board Administration provides access to pages that allow the system administrator to transfer tasks among staff members and unlock orders for editing.

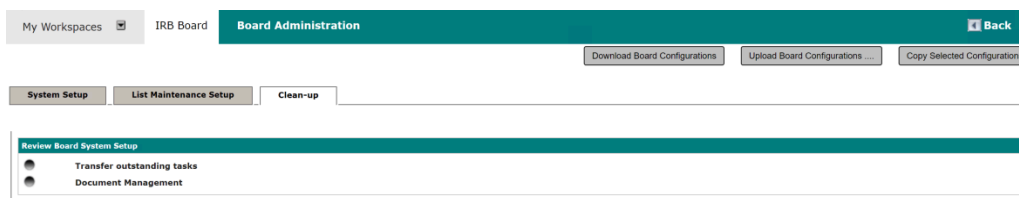


Transfer outstanding tasks

When a Coordinator leaves the institution, tasks assigned to that user must be reassigned to a different user in order to avoid any breaks in study processing continuity.

IMPORTANT: the iRIS™ user profile for the Coordinator whose tasks are being reassigned must still exist in the system, and that user must be designated as a Coordinator.

This process is completed on the **Transfer RB Tasks** page. To access the page, navigate to IRB Assistant > Review Board Administration > Clean-up tab > **Transfer outstanding tasks** link.



The **Transfer RB Tasks** page opens, as shown below.

Here, the System Administrator or designee can look up a Coordinator name, view tasks assigned to that Coordinator, and reassign them individually or in a group to one or more other, active Coordinators in the system.

Click in the **Select the user that tasks are currently assigned to** field to open a dropdown list of users assigned to the role of Coordinator.

Click an item in the list to select the name of the Coordinator whose tasks are to be reassigned.

As shown below, all tasks currently assigned to the selected Coordinator populate in the **Study Title/ Task type** list.

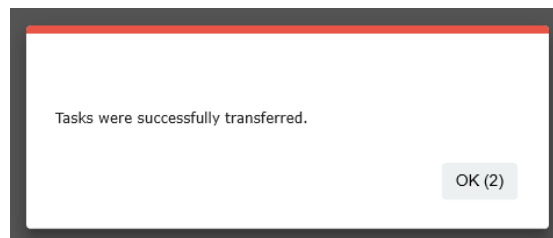
Select the checkbox(es) for the task(s) to be reassigned to a different Coordinator.

Note that in the example above all tasks are selected, but individual tasks can also be reassigned to different Coordinators by selecting a single task and repeating the process of reassignment multiple times.

Click in the **Select the user who will accepts these tasks** field to open a dropdown list of users currently assigned to the role of Coordinator.

Click an item in the list to select the name of the Coordinator to whom the selected task(s) is(are) to be reassigned, then click the **Transfer task to new user** button.

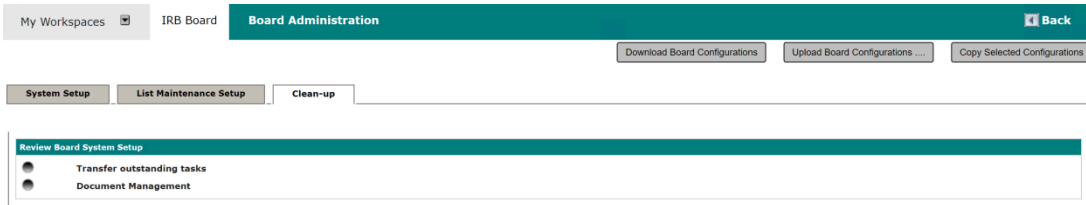
A confirmation popup briefly displays, then closes automatically when its countdown timer expires.



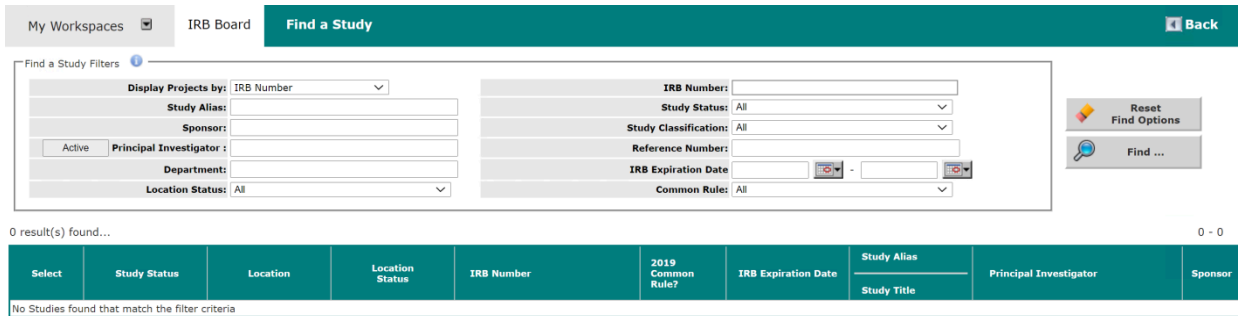
The reassigned tasks now appear in the Workspace(s) of the new assignee(s).

Document Management

Study document version merge functionality is provided via IRB Assistant > Review Board Administration > Clean-up tab > **Document Management** link.



The link opens the **Find A Study** page, as shown below.



Enter / select desired search criteria in the **Find a Study Filters** section (described below), and click the **Find** button to execute the search. Click the **Reset Find Options** button to reset all filter fields.

The **Display Projects by** dropdown allows for selection by number type (e.g., study/protocol number, IRB number).

Text entry fields are provided to search by full or partial **Study Number/Alias**, **Sponsor** name, **Department**, **IRB Number** or **Reference** number.

The **Principal Investigator** (PI) field can be used to search by full or partial PI name and includes a button to toggle the search between **Active** or **Inactive** PIs. As shown below, the button is toggled to **Active** by default.

Click the **Active** button to toggle it to **Inactive**, as shown below.



*Note that it is not possible to search by both **Active** and **Inactive** PIs simultaneously.*

The **Location Status** dropdown allows for selection by **Location Status**. *Note that Location Status is configured by the institution under System Administration > Setup Locations Status.*

The **Study Status** dropdown provides a pick list to filter the search by study status. Click an item in the list to select it.

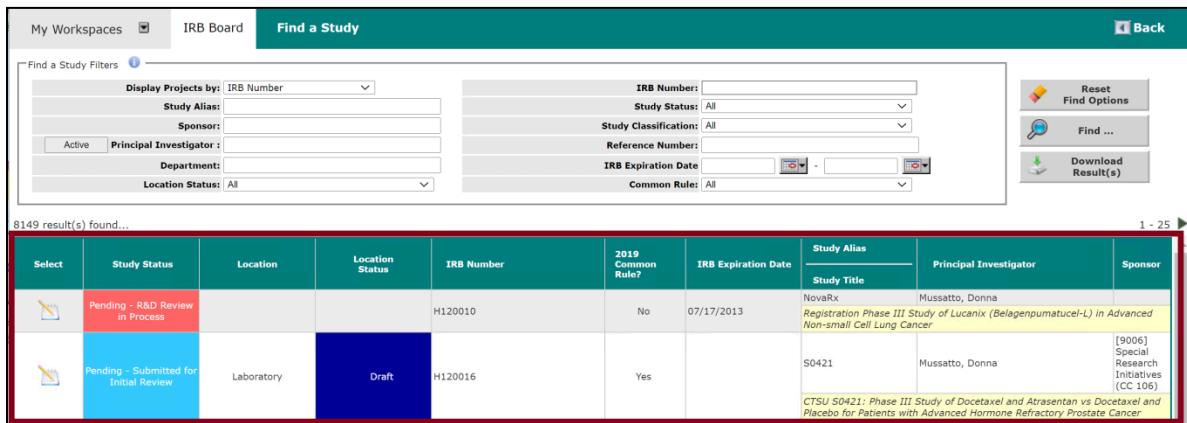
The **Study Classification** dropdown provides a pick list to filter the search by study classification. Click an item in the list to select it.

Calendar widgets are provided for searching by **IRB Expiration Date** range. Available date range options are as follows:

- to limit the search to studies whose **IRB Expiration Date** occurs on or *after* a specific date, click the left-hand calendar widget and select the desired start date; leave the right-hand date field blank
- to limit the search to studies whose **IRB Expiration Date** occurs on or *before* a specific date, click the right-hand calendar widget and select the desired end date; leave the left-hand date field blank
- to limit the search to studies whose **IRB Expiration Date** occurs *between* two specific dates, select the desired start date using the left-hand calendar widget and the end date using the right-hand calendar widget

Find a Study Results Section

As shown in the screenshot below, after search criteria and filters are applied and the **Find** button is clicked, results are displayed in the lower part of the **Find a Study** page.



Columns in the results section of the page are:

- Select** – click the icon in this column to open the **Document Management** page and proceed with merging document versions (see the Merging Document Versions subsection of this manual)
- Study Status** – current study status (e.g. Open, Pending, Draft, Completed)
- Location** – current study location
- Location Status** – status of the study at the specified location
- IRB Number** – IRB number assigned to the study, if any

2019 Common Rule? – whether or not the study is subject to the 2019 Common Rule; see the Common Rule Display section of this manual for more information

IRB Expiration Date – IRB expiration date, if any

Note that the title and contents of the **IRB Number** and **IRB Expiration Date** columns are dictated by the **Display Projects** by filter setting in the upper part of the **Find a Study** page, shown below.

Study Alias [or Number] – Nickname/Number given to the study in the Study Application

Study Title – Study Title entered in the Study Application

Principal Investigator – name of the Principal Investigator on the study

Sponsor –name of the Sponsor on the study

Merging Document Versions

When the desired study is listed in the results section of the Find a Study page, click the applicable icon in the Select column.

Select	Study Status	IACUC Number	IACUC Expiration Date	Alias	Principal Investigator	Sponsor
			IACUC Full Renewal Expiration	Study Title		
	Active	A12-020	07/25/2013	VA Merit: Arrestin Regulation of CRF1 Signaling	Hauger, Richard L	
<i>Arrestin Regulation of CRF1 Signaling: Mechanisms for Stress Resilience and PTSD</i>						

The selected study is opened in the **Document Management** page.

My Workspaces ▾ IRB Document Management ← Back

Study Status: Active **Study Title :** Arrestin Regulation of CRF1 Signaling: Mechanisms for Stress Resilience and PTSD

Please follow the next steps:
 -Select a root document.
 -Select the documents that you want to associate.
 -Review your selections.
 -Apply changes.

Associate Study Documents or Consents

Select Category: All **Title:** _____
Version #: _____ . 0 **Document Outcome:** All
Approval Date: _____ between _____ **Expiration Date:** _____ between _____
Document Type: Documents Consents

Select Root Document	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File
+	1.0 07/26/2012	12-020 Figure 1 ACORP Diagram				 32.44 KB
+	1.0 11/13/2012	test *Revision modified by the IRB - VA				 12.68 KB

All version 1.0 study documents associated with the selected study are listed in a Root Documents table. Click the icon in the **Select Root Document** column for the applicable document.

All versions of the selected document populate, and the **Select Root Document** column is replaced with a **Select Document** column containing select checkboxes. **Prepare Changes**, **Select a Different Root Document** and **Filter Documents** buttons populate in the upper right corner above the table.

Select Document	Version	Title/ Category	Document Outcome	Approval Date	Expiration Date	File
Selected Root Document	1.0 07/26/2012	12-020 Figure 1 ACORP Diagram				 32.44 KB
<input checked="" type="checkbox"/>	1.1 07/26/2012	12-020 Figure 1 ACORP Diagram				 12.46 KB
<input checked="" type="checkbox"/>	1.2 07/26/2012	12-020 Figure 1 ACORP Diagram				 12.46 KB

Click the **Select a Different Root Document** button to revert to the prior version of the Root Document table, where a different root document can be selected.

Select the checkbox(es) for all document versions to be merged with the root (version 1.0) document and click the **Prepare Changes** button.

Select Document	Version	Title/Category	Document Outcome	Approval Date	Expiration Date	File
Selected Root Document	1.0 07/26/2012	12-020 Figure 1 ACORP Diagram				32.44 KB
<input checked="" type="checkbox"/>	1.1 07/26/2012	12-020 Figure 1 ACORP Diagram				12.46 KB
<input checked="" type="checkbox"/>	1.2 07/26/2012	12-020 Figure 1 ACORP Diagram				12.46 KB

The selected documents are opened in a **Prepare Changes** popup window. If multiple versions of the same root document are chosen from the Root Documents table, all versions of that document are selected by default in the popup.

Prepare Changes				
<input checked="" type="checkbox"/>	Document Title	Current Version	Proposed Version	Category
<input checked="" type="checkbox"/>	12-020 Figure 1	1.0		ACORP Diagram
<input checked="" type="checkbox"/>	12-020 Figure 1	1.1	1. <input type="text" value="1"/>	ACORP Diagram
<input checked="" type="checkbox"/>	12-020 Figure 1	1.2	1. <input type="text" value="2"/>	ACORP Diagram
<input checked="" type="checkbox"/>	12-020 Figure 1	1.3	1. <input type="text" value="3"/>	ACORP Diagram
<input type="checkbox"/>	ACORP Diagram	1.1	1. <input type="text" value="4"/>	
<input type="checkbox"/>	ACORP Diagram	1.2	1. <input type="text" value="5"/>	

Columns in the popup are:

- **Document Title:** original name of the document, editable
- **Current Version:** current version of the document
- **Proposed Version:** suggested version of the document following the merge, editable
- **Category:** category to which the root document is assigned, editable

Any versions of the root document that were not chosen from the Root Document table also appear in the popup but are not selected by default. Click the applicable blank box(es) in the far-left column to select the additional document version(s) to be merged, as shown in the screenshot below.

Prepare Changes				
<input checked="" type="checkbox"/>	Document Title	Current Version	Proposed Version	Category
<input checked="" type="checkbox"/>	12-020 Figure 1	1.0		ACORP Diagram
<input checked="" type="checkbox"/>	12-020 Figure 1	1.1	1. <input type="text" value="1"/>	ACORP Diagram
<input checked="" type="checkbox"/>	12-020 Figure 1	1.2	1. <input type="text" value="2"/>	ACORP Diagram
<input checked="" type="checkbox"/>	12-020 Figure 1	1.3	1. <input type="text" value="3"/>	ACORP Diagram
<input checked="" type="checkbox"/>	ACORP Diagram	1.1	1. <input type="text" value="4"/>	
<input checked="" type="checkbox"/>	ACORP Diagram	1.2	1. <input type="text" value="5"/>	

Note that the documents to be merged can have different **Document Titles**.

Click the **Merge Documents** button. The **Prepare Changes** popup is updated with proposed merged document version details.

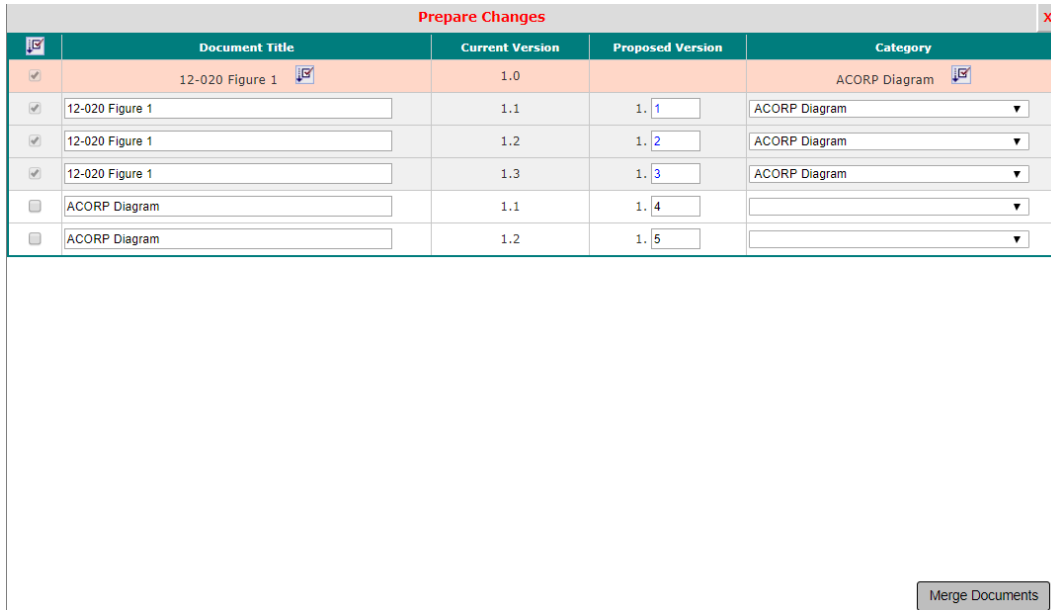
Prepare Changes						
	Version	Title/Category	Document Outcome	Approval Date	Expiration Date	File
	1.2 10/10/2012	12-020 Figure 1 ACORP Diagram				 12.46 KB
	1.1 02/21/2013	12-020 Figure 1 ACORP Diagram				 13.91 KB
	1.0 09/28/2012	12-020 Figure 1 ACORP Diagram				 13.91 KB

Note that in the example shown above only the top three document versions were selected.

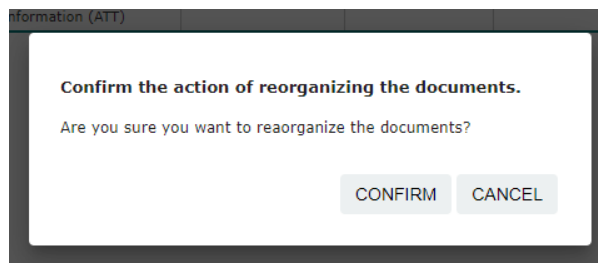
Click the icon in the **View History** column to preview document version history as it will appear after the merge is complete.

Click any document icon in the **File** column to open that version of the document in a separate, read-only window.

Click the **Cancel** button to cancel the merge and return to the pre-merge version of the **Prepare Changes** popup, as shown below.



Click the **Confirm** button to complete the merge. A confirmation popup appears.



Click **CANCEL** to close the confirmation popup and return to the **Prepare Changes** popup.

Click **CONFIRM** to complete the merge. The selected versions are merged and a “Documents have been reorganized” countdown popup briefly appears. The countdown popup closes, and an updated version of the Root Documents table is loaded.