



STUDY ASSISTANT

Adding a New Study & Submitting to the Review Board

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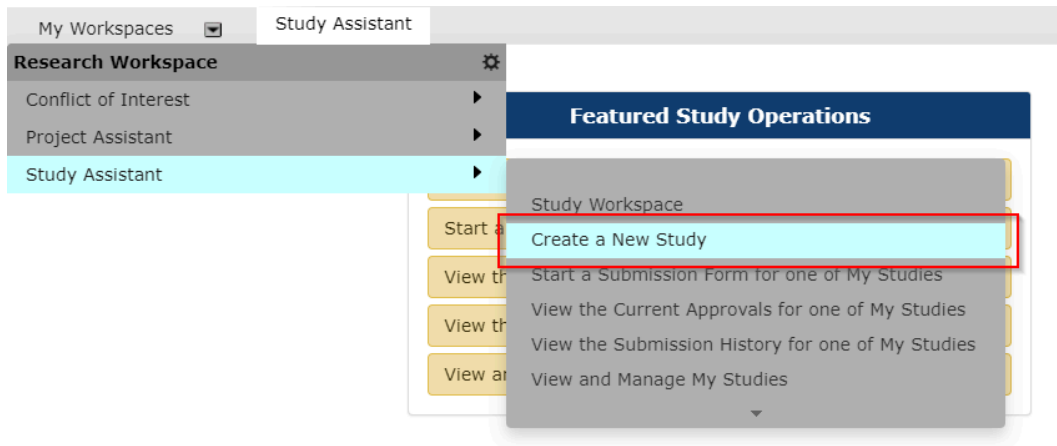
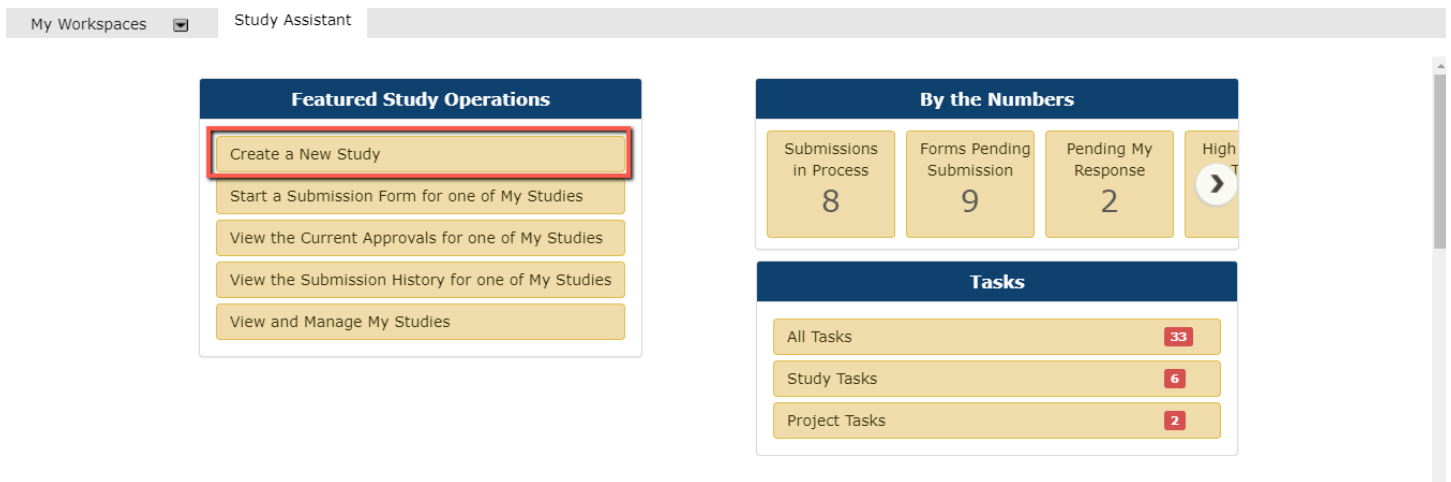
Add a New Study

Introduction

This manual outlines the process of creating a study in iRIS™ and submitting that study to a review board. This process includes creating an initial application, completing a submission form, and addressing any responses or corrections requested by the review board.

Add a Study

To begin, click the **Create a New Study** button in the “Featured Study Operations” panel of Study Assistant Workspace or via the “My Workspaces” drop-down navigation menu.



Selecting an Application

Clicking **Create a New Study** redirects the user to the application selection page below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

My Workspaces ▾ Study Assistant **Select New Study Application Form** [Back](#)

[Cancel and Return](#) [Start selected Application](#)

Please select a New Study Application from the list below:

Form Name	Form Description
<input type="radio"/> IRB Application	Please use this application for use of Human Subjects in research.
<input type="radio"/> IBC APPLICATION (BIO-SAFETY)	Please use this application for your Bio-safety Committee
<input type="radio"/> IACUC APPLICATION (ANIMALS)	Please use this application for your Animal Research
<input type="radio"/> Simple MultiSite	Simple MultiSite
<input type="radio"/> Aplicacion de IACUC	Usar esta aplicacion para coleccionar informacion sobre es estudio de animal.
<input type="radio"/> Rocky Mountain Application	

*Note: If your system only contains one Study Application Form, clicking **Create a New Study** will bypass the above screen and take the user directly into the first section of the form.*

The number and nature of applications that display on this application selection page is dependent on the modules being used by your institution. The form names and descriptions are configurable by your institution and may not look like the examples shown in this document.

To continue creating a new study, select the desired application from the screen above and then click the **Start selected Application** button. If you do not need to create a new study at this time, click the **Cancel and Return** button to return to the Study Assistant Workspace.

My Workspaces ▾ Study Assistant **Select New Study Application Form** [Back](#)

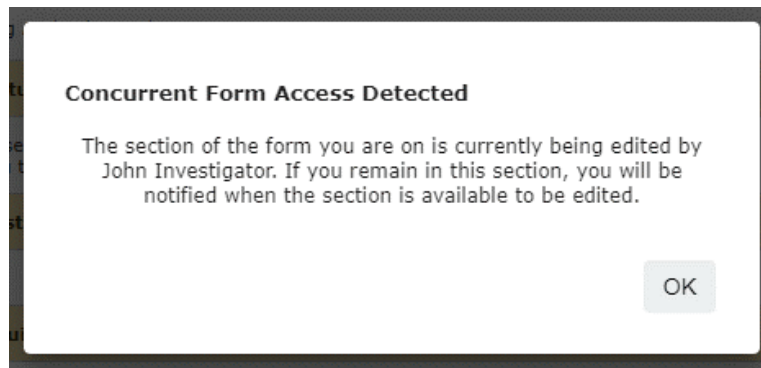
[Cancel and Return](#) [Start selected Application](#)

Please select a New Study Application from the list below:

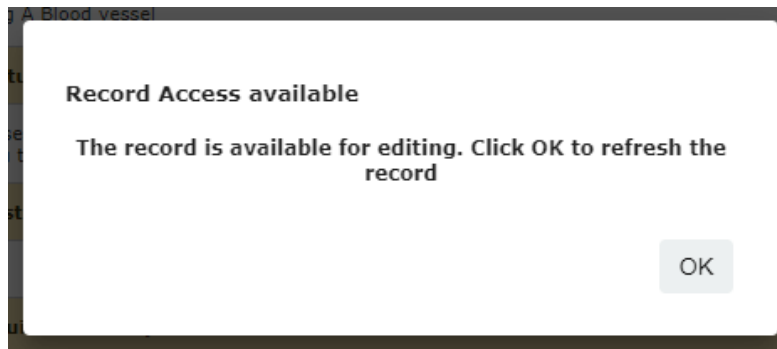
Form Name	Form Description
<input checked="" type="radio"/> IRB Application	Please use this application for use of Human Subjects in research.
<input type="radio"/> IBC APPLICATION (BIO-SAFETY)	Please use this application for your Bio-safety Committee
<input type="radio"/> IACUC APPLICATION (ANIMALS)	Please use this application for your Animal Research
<input type="radio"/> Simple MultiSite	Simple MultiSite
<input type="radio"/> Aplicacion de IACUC	Usar esta aplicacion para coleccionar informacion sobre es estudio de animal.
<input type="radio"/> OSF Health Care Research Application	

Multiple Users Accessing Forms Simultaneously

In the event that two users are accessing the same section of a form, the user that accessed the section first will have the ability to edit that section of the form. The second user will receive the following message and the form will load in read-only mode.



Once the first user has left the section, the second user will receive the following message informing them that the other user has left the section. The user will only receive this message if they are still accessing that section of the form.



The Study Shell

Once an application form is selected and **Start selected Application** is clicked, the user will be taken into form's "Study Shell".

In iRIS™, the Study Shell comprises the first three sections of every study application form. These sections allow the user to define the general identifiers for the study and assign Key Study Personnel. The Study Shell is the only area of study application forms that is not configurable and is universal for all forms of that type in the system.

1.0 General Information

The first section of the Study Shell is General Information. All newly created application forms will open to this section by default.

My Workspaces ▾ Study Assistant IRB Application (Version 1.0) Back

Section view of Application Entire view of the Application

1.0 General Information

1.0 General Information

* Please enter the full title of your study::

* Please enter the Study Number you would like to use to reference the study:

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

Yes No

Does this study require feasibility review?

Yes No

Is this Study using Animal Research?

Yes No

Here the user may define the full title of the new study as well a study number identifier. Both of these fields are required and must be completed before the user can continue through the Study Shell.

If the Subject Management module is activated, the following additional question will appear at the end of the General Information section.

Is this Study using Subject Management?

Yes No

Answering “Yes” to this question enables the use of Subject Management functionality for this study once it is approved by the appropriate review board.

Once all required fields have been completed, the user may click the **Save and Continue to the Next Section** button in the upper right corner of the screen as shown below.

The screenshot shows the 'IRB Application (Version 1.0)' interface. At the top, there are navigation elements: 'My Workspaces' with a dropdown arrow, 'Study Assistant', and a 'Back' button. Below this, there are two tabs: 'Section view of Application' and 'Entire view of the Application'. The 'Section view of Application' tab is active, showing a sidebar with '1.0 General Information' selected. The main content area is titled '1.0 General Information' and contains several form sections:

- A yellow header bar with the text: '* Please enter the full title of your study::'
- A text input field containing 'Malaria in Juveniles', which is highlighted with a red box.
- A yellow header bar with the text: '* Please enter the Study Number you would like to use to reference the study:'
- A text input field containing 'M10630', which is highlighted with a red box.
- A small note below the study number field: 'This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.'
- A yellow header bar with the text: 'Is this a multi-site study (i.e. Each site has their own Principal Investigator)?'
- Radio buttons for 'Yes' and 'No', with 'No' selected.
- A yellow header bar with the text: 'Does this study require feasibility review?'
- Radio buttons for 'Yes' and 'No', with 'No' selected.
- A yellow header bar with the text: 'Is this Study using Animal Research?'
- Radio buttons for 'Yes' and 'No', with 'No' selected.
- A yellow header bar with the text: 'Is this Study using Subject Management?'
- Radio buttons for 'Yes' and 'No', with 'No' selected.

At the top right of the form area, there are two buttons: 'Save Section' and 'Save and Continue to Next Section'. The 'Save and Continue to Next Section' button is highlighted with a red box.

This will save the information entered on the General Information page and take the user to the next section, which in this case is the second section of the Study Shell: **Add Department(s)**.

Clicking **Save Section** instead will still save the General Information data and refresh the page, but not redirect the user to the next section.

2.0 Add Department(s)

The second section of the Study Shell enables the user to associate the study with one or more departments defined in the system. Note that Department Administrators will be able to pull data from the study into certain reports based on the Department(s) chosen in this section.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

The screenshot shows the 'IRB Application (Version 1.0)' interface. At the top, there is a navigation bar with 'My Workspaces', 'IRB Number: IRB-21-419', 'Study Assistant', and 'IRB Application (Version 1.0)'. Below this are buttons for 'Print Friendly', 'Assign User(s) to Sections', 'Save Section', and 'Save and Continue to Next Section'. The main content area is titled '2.0 Add departments' and contains a section '2.1 List departments associated with this study:'. A table lists departments with columns for 'Is Primary?' and 'Department Name'. The first entry is 'GHW - 7543 - General Hospital' with the 'Is Primary?' radio button selected. To the right of the table are 'Add Department' and 'Remove Department' buttons. The 'Add Department' button is highlighted with a red box.

By default, the system will pull in the form author's primary department as the potential primary department for the study. This can be changed using the **Add Department** and **Remove Department** buttons.

Adding Departments

Departments may be added to the study by clicking the **Add Department** button.

This screenshot is identical to the one above, showing the 'IRB Application (Version 1.0)' interface. The 'Add Department' button in the '2.1 List departments associated with this study:' section is highlighted with a red box.

This will open the following window.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Adding Department - Search Window
X

Select the Department(s) that you would like to filter by, then click Save.
 You may also filter these results by searching for Institution Name, Department name, Department Code or School Code on the inputs below.
Any Departments already added will not appear here.

Institution Name

School Code

Department Name

Dept Code

11 result(s) found... 1 - 10 ▶

Select	Institution	Department Name	School Code	Department Code
<input type="checkbox"/>	General Chicago Hospital	IBC	N/A	123
<input type="checkbox"/>	General Chicago Hospital	Office of Human Protection		
<input type="checkbox"/>	General Hospital Grants Office	Grants Office		
<input type="checkbox"/>	General Hospital Parnassis	Pediatric		
<input type="checkbox"/>	General University of Hoth	Study Team		
<input type="checkbox"/>	General University of Redlands	Oncology		001
<input type="checkbox"/>	General University of Redlands	Pediatric		
<input type="checkbox"/>	Hurricane Children's Research Hospital	Pediatric		
<input type="checkbox"/>	Jupiter Research Institute	Veterinary		
<input type="checkbox"/>	Miami Research Institute	Research Staff		800

Cancel
Save

The table in the window above lists all departments defined in the system. Four filters and a **Search** button are provided above the department table to aid in the search process.

One or more of these departments may be added to the study by checking the appropriate “Select” checkboxes and clicking the **Save** button in the bottom right corner.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Adding Department - Search Window

Select the Department(s) that you would like to filter by, then click Save.
You may also filter these results by searching for Institution Name, Department name, Department Code or School Code on the inputs below.
Any Departments already added will not appear here.

Institution Name Department Name
 School Code Dept Code Search

11 result(s) found... 1 - 10 ▶

Select	Institution	Department Name	School Code	Department Code
<input type="checkbox"/>	General Chicago Hospital	IBC	N/A	123
<input type="checkbox"/>	General Chicago Hospital	Office of Human Protection		
<input type="checkbox"/>	General Hospital Grants Office	Grants Office		
<input checked="" type="checkbox"/>	General Hospital Parnassis	Pediatric		
<input type="checkbox"/>	General University of Hoth	Study Team		
<input type="checkbox"/>	General University of Redlands	Oncology		001
<input type="checkbox"/>	General University of Redlands	Pediatric		
<input type="checkbox"/>	Hurricane Children's Research Hospital	Pediatric		
<input type="checkbox"/>	Jupiter Research Institute	Veterinary		
<input type="checkbox"/>	Miami Research Institute	Research Staff		800

This will add the select department(s) to the study application form as shown below.

My Workspaces ▾ IRB Number: **IRB-21-419** Study Assistant IRB Application (Version 1.0)

Section view of Application

1.0 General Information

2.0 **Setup Department(s) Access**

2.0 Add departments

2.1 List departments associated with this study:

	Is Primary?	Department Name	
<input type="checkbox"/>	<input checked="" type="radio"/>	GHW - 7543 - General Hospital	<input type="button" value="Add Department"/> <input type="button" value="Remove Department"/>
<input type="checkbox"/>	<input type="radio"/>	GHP - Pediatric	

Setting a Primary Department

By default, the initial department is set as the study's primary. This is easily modified by clicking the desired department's **Is Primary?** radio button and saving the section.

Removing Departments

A department may be removed from the study by selecting the department’s checkbox and clicking the **Remove Department** button as shown in the screenshot below.

The screenshot shows the 'IRB Application (Version 1.0)' interface. The left sidebar has '2.0 Setup Department(s) Access' selected. The main content area is titled '2.0 Add departments' and contains a table '2.1 List departments associated with this study:'. The table has columns 'Is Primary?' and 'Department Name'. The first row is 'GHW - 7543 - General Hospital' with a selected radio button. The second row is 'GHP - Pediatric' with an unselected radio button. A red box highlights the 'Remove Department' button to the right of the table.

Is Primary?	Department Name
<input checked="" type="radio"/>	GHW - 7543 - General Hospital
<input type="radio"/>	GHP - Pediatric

Clicking **Remove Department** prompts the user with the confirmation message shown below.

A modal dialog box with the title 'Confirm the Deletion of Department(s)'. The text inside asks 'Are you sure you want to delete?'. At the bottom right, there are two buttons: 'CONFIRM' and 'CANCEL'.

Confirming this message refreshes the form page with the selected departments removed.

The screenshot shows the same interface as before, but the table '2.1 List departments associated with this study:' now only contains one row: 'GHW - 7543 - General Hospital' with a selected radio button. The 'Remove Department' button is still present.

Is Primary?	Department Name
<input checked="" type="radio"/>	GHW - 7543 - General Hospital

After the desired changes to the study departments have been made, click the **Save and Continue to the Next Section** button to continue to the last section of the Study Shell.

3.0 Key Study Personnel (KSP) Assignment

The third section of the Study Shell involves the assignment of Key Study Personnel (KSP). Each question on this page represents a role that is available to add to this study. When adding KSP, a user will assign them one of these available roles.

Depending on your system configuration you may see different role requirements than the example below.

Print Friendly Assign User(s) to Sections Save Section Save and Continue to Next Section

Section view of Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 Grant Key Personnel access to the study

Entire view of the Application

3.0 Assign key study personnel (KSP) access to the study

Click Here to Setup Study Personnel

3.1 * Please add a Principal Investigator for the study:

Name	Role	Responsibility	Training Record
No Principal Investigator has been added			

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Name	Role	Responsibility	Training Record
No Additional Investigators have been added			

B) Research Support Staff

Name	Role	Responsibility	Training Record
No Research Support Staff have been added			

3.3 * Please add a Study Contact:

Name	Role	Responsibility	Training Record
No Study Contact have been added			

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Department Approval(s):

Name	Role	Responsibility	Training Record

Role Descriptions

Some of the roles available in this section include the following:

Principal Investigator – All studies in iRIS™ must be assigned a Principal Investigator (PI). Without a PI, the third section of the Study Shell cannot be completed and the study will remain in Draft mode. Note that there may only be one PI per study. If additional PIs exist, add them to the “Additional Investigators” section.

Additional Investigators – Any non-PI investigators. There is no limit to the number of Additional Investigators that can be added to a study. Each user in this section is given a specific study role.

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Research Support Staff – Any non-investigator study personnel. There is no limit to the number of Research Support Staff that can be added to a study. Each user in this section is given a specific study role.

Contact – User(s) on the study who will receive study related notifications from the system, such as Continuing Review notifications, Submission Correction notifications, Review Response notifications, etc. The Principal Investigator defaults as the study contact, but this is editable. Any number of contacts be defined for a given study.

Department Administrator – If a study requires department approval before being submitted to a review board, a Department Administrator (DA) may be added. This administrator will appear in the form’s submission routing configuration, giving users the ability to send the application to the DA before being approved by a review board. More details on this process are given later in this document. Any number of DAs may be defined for a given study. Users added as DAs will populate in the “Designated Department Approval(s)” section of the Study Shell section 3.0.

Adding Key Study Personnel (KSP)

To add a user to the study, first click the **Click Here to Setup Study Personnel** button next to the section title. The following pop-up window will appear.

Setup Study Personnel

User Search by Study

Last Name: First Name:

User Search by Study: All Departments

Select	Training?	Name	Department	Email
No results found				

Selected Study Personnel:

Principal Investigator

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Additional Investigators

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Research Support Staff

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Contact

There are two methods to add KSP using the window above: manual search and personnel pool. Both will be described below.

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Manual User Search

One approach to adding a user to a study application is to navigate to the **User Search By Study** tab (open by default) and manually search for the desired user.

A help message is displayed on the left side of the window providing further information on the functionality and purpose of this tab.

Setup Study Personnel

User Search by Study

Study Personnel Pool
Create My Personnel Pool
Update My Personnel Pool
Delete My Personnel Pool

Last Name: First Name:

User Search by Study:

Select	Training?	Name	Department	Email
No results found				

i This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

Selected Study Personnel:

Principal Investigator

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Additional Investigators

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Research Support Staff

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Contact

Three filter fields are provided to help narrow down the search results: last name, first name, and department.

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Setup Study Personnel X

User Search by Study

Study Personnel Pool

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

Last Name: First Name:

 User Search by Study: Find User/Search Directory

i This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

Select	Training?	Name	Department	Email
		Investigator, John	i General Hospital	

Selected Study Personnel:

Principal Investigator

	Name	Role	Responsibilities
	No Personnel has been selected for this group.		

Additional Investigators

	Name	Role	Responsibilities
	No Personnel has been selected for this group.		

Research Support Staff

	Name	Role	Responsibilities
	No Personnel has been selected for this group.		

Contact

	Name	Role	Responsibilities
	No Personnel has been selected for this group.		

Clear Key Study Personnel Close Setup of Study Personnel

From this search results display table the users' department, contact information, training history, and study associations may be viewed.

Once the desired user is found, they can be added to the study by clicking the icon. Clicking this icon opens the following secondary pop-up window.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Add Personnel Role

Select the Role for **John Investigator** :

Principal Investigator

Additional Investigators

Research Support Staff

Contact

Department Administrator

Select any additional responsibilities to the named user: <None added>

Notice that the available roles match those displayed in the form as the section questions.

The user can then be assigned a role on the study by clicking the desired radio button. Once a role is selected, an additional field may appear asking if the user should be added as contact.

Add Personnel Role [X]

Select the Role for **John Investigator** :

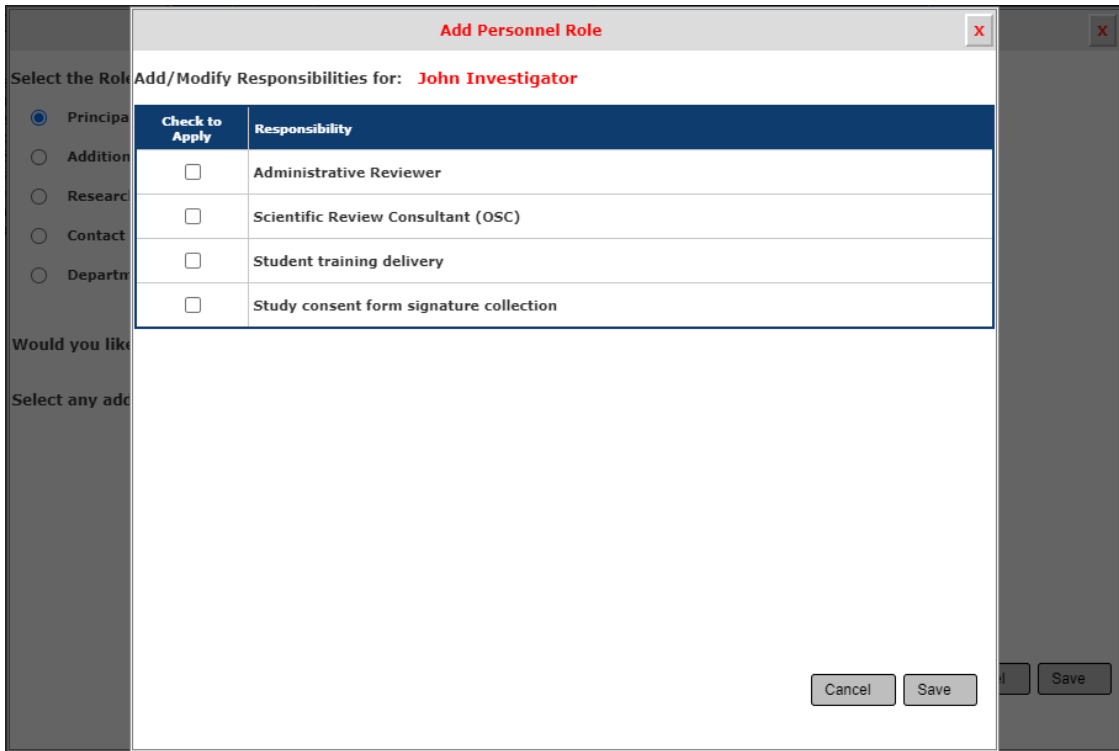
- Principal Investigator**
- Additional Investigators** --none--
- Research Support Staff** --none--
- Contact**
- Department Administrator** --none--

Would you like to include as a Contact ? Yes No

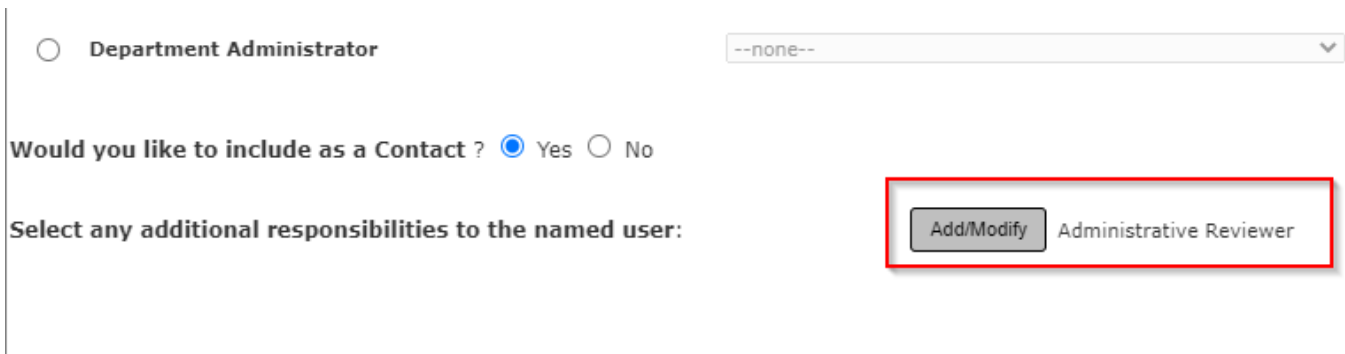
Select any additional responsibilities to the named user: <None added>

Lastly, additional responsibilities may be assigned to the user by clicking the **Add/Modify** button, which opens a third pop-up window as shown below.

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Any selected responsibilities will populate next to the **Add/Modify** button.



These role responsibilities are configured in System Administration via *System Administration* ▢ *List Configuration and Maintenance* ▢ *Define Study and Project Responsibilities*.

Each responsibility may then be assigned customized access to Study Assistant via the Study Assistant role matrix (*System Administration* ▢ *List Configuration and Maintenance* ▢ *Define Study Assistant Role Access*).

Once a role and optional responsibilities have been defined, the user can be added to the study by clicking **Save**.

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The screenshot shows a dialog box titled "Add Personnel Role" with a close button (X) in the top right corner. The main content area contains the following elements:

- A label: "Select the Role for **John Investigator** :
- Five radio button options:
 - Principal Investigator
 - Additional Investigators
 - Research Support Staff
 - Contact
 - Department Administrator
- Three dropdown menus, each containing "--none--":
 - Next to "Additional Investigators"
 - Next to "Research Support Staff"
 - Next to "Department Administrator"
- A question: "Would you like to include as a Contact ?" with radio buttons for "Yes" (selected) and "No".
- A section titled "Select any additional responsibilities to the named user:" containing an "Add/Modify" button and the text "Administrative Reviewer".
- At the bottom right, two buttons: "Cancel" and "Save". The "Save" button is highlighted with a red rectangular box.

A record of the newly added user will populate in the appropriate role table.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup Study Personnel X

User Search by Study

Study Personnel Pool

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

Last Name: First Name:

User Search by Study: Find User/Search Directory

Select	Training?	Name	Department	Email
		Investigator, John	General Hospital	

This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

Selected Study Personnel:

Principal Investigator

Name	Role	Responsibilities
Investigator, John	Principal Investigator	Administrative Reviewer

Additional Investigators

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Research Support Staff

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Contact

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Clear Key Study Personnel Close Setup of Study Personnel

Closing the **Setup Study Personnel** window shows that the user has been successfully added to the study.

Print Friendly Assign User(s) to Sections Save Section Save and Continue to Next Section

Section view of Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study

Entire view of the Application

3.0 Assign key study personnel (KSP) access to the study

[Click Here to Setup Study Personnel](#)

3.1 * Please add a Principal Investigator for the study:

Name	Role	Responsibility	Training Record
John Investigator	Principal Investigator	Administrative Reviewer Add/Modify	View Training Record

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Name	Role	Responsibility	Training Record
No Additional Investigators have been added			

B) Research Support Staff

Name	Role	Responsibility	Training Record
No Research Support Staff have been added			

3.3 * Please add a Study Contact:


Name	Role	Responsibility	Training Record
Investigator, John	Contact	Administrative Reviewer Add/Modify	View Training Record

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Department Approval(s):

Name	Role	Responsibility	Training Record

Notice that John Investigator was added both as a Principal Investigator and a Study Contact due to the fact that the **Would you like to include as a Contact?** field was set to “Yes”.

The added user can be deleted from the study by again clicking **Click Here to Setup Study Personnel** and then clicking the  icon.

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Setup Study Personnel ✕

User Search by Study

- Study Personnel Pool
- Create My Personnel Pool
- Update My Personnel Pool
- Delete My Personnel Pool

i This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

Last Name: First Name:

User Search by Study: Find User/Search Directory

Select	Training?	Name	Department	Email
No results found				

Selected Study Personnel:

Principal Investigator

	Name	Role	Responsibilities
<input checked="" type="checkbox"/>	Investigator, John	Principal Investigator	Administrative Reviewer

Additional Investigators

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Research Support Staff

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Contact

Name	Role	Responsibilities
------	------	------------------

Clear Key Study Personnel Close Setup of Study Personnel











All users may be removed from the study by clicking the **Clear Key Study Personnel** button. Note that if a Principal Investigator is removed from the study the system will require a replacement PI to be chosen before the original is deleted.

Viewing User Training Details


Clicking the  icon opens the secondary pop-up window shown below, detailing the user's training information.

Setup Study Personnel

Training Details for Investigator, John:

Training Group	Courses (Course Date - Expiration) All Courses must be green within one rule for the group to be valid	Status
Working with Mice in Research Settings	Rule 1  Animal Handlers Course (03/03/2020 -)	Active
Animal Care and Use Training (ACUT) Certificate	Rule 1  Basic Course (01/01/2020 - 06/01/2021) Rule 2  AVMA Guidelines for the Euthanasia of Animals: 2020 Edition (03/02/2020 - 07/07/2021)	Active
General Training Course	Rule 1  Human Research Subjects Training	Never Active
CITI Training		Never Active
Sponsored Projects Training courses	Rule 1  Sponsored Projects Training 101	Never Active
Good Clinical Practice (GCP)	Rule 1  GCP course (US FDA focus) Rule 2  GCP course for clinical trials involving investigational drugs (international/ICH focus) Rule 3  GCP course for clinical trials involving investigational medical devices (international focus)	Never Active
Human Subjects Research	Rule 1  Biomedical Research Investigators and Key Personnel Group Rule 2  Social Behavioral Research investigators and Key Personnel Group.	Never Active
Test IRB Group		Never Active
Continuing Review Modification Form		Never Active
IACUC Trainings		Never Active

The window above is from the point-of-view of a user with read-only access to KSP training information. Clicking **Cancel** closes the training details window.

If the user instead has read and write access to training data, clicking the  icon will redirect the user to the following page.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

My Workspaces
Study **Training record list for Investigator, John**
 Back

*** User ID:** demopi

Job Title:

Degree:

Employee ID: 020017109

Specialty:

Relationship to the Institution Affiliated Non-Affiliated

Name: John Investigator

Status: Active

Email Address: jalvarenga@imedris.com

Primary Number: 909-111-2222

Cell Number: 909-222-4444

Pager Number:

Fax Number:

Login Enabled: Yes

Mailing Address:

446 Missouri Ct

User Training Group Status
User Training Courses
Reevaluate Training Status
Add a New Training Group
Delete Training Group(s)

<input type="checkbox"/>	Edit/ View	Training Group	Courses (Course Date - Expiration) All Courses must be green within one rule for the group to be valid	Status	Override
<input type="checkbox"/>		Working with Mice in Research Settings	Rule 1 Animal Handlers Course (03/03/2020 -)	Active	No
<input type="checkbox"/>		Animal Care and Use Training (ACUT) Certificate	Rule 1 Basic Course (01/01/2020 - 06/01/2021) Rule 2 AVMA Guidelines for the Euthanasia of Animals: 2020 Edition (03/02/2020 - 07/07/2021)	Active	No
<input type="checkbox"/>		General Training Course	Rule 1 Human Research Subjects Training	Never Active	No
<input type="checkbox"/>		CITI Training		Never Active	No
<input type="checkbox"/>		Sponsored Projects Training courses	Rule 1 Sponsored Projects Training 101	Never Active	No
<input type="checkbox"/>		Good Clinical Practice (GCP)	Rule 1 GCP course (US FDA focus) Rule 2 GCP course for clinical trials involving investigational drugs (international/ICH focus) Rule 3 GCP course for clinical trials involving investigational medical devices (international focus)	Never Active	No
<input type="checkbox"/>		Human Subjects Research	Rule 1 Biomedical Research Investigators and Key Personnel Group Rule 2 Social Behavioral Research investigators and Key Personnel Group.	Never Active	No
<input type="checkbox"/>		Test IRB Group		Never Active	No
<input type="checkbox"/>		Continuing Review		Never Active	No

This screen allows the logged-in user to both view and edit the KSP's training records. Clicking the **Back** button will return the user to the section 3.0 of the application's Study Shell.

KSP training access is determined by a study role property that is configured in System Administration (*see the System Administration – List Configuration and Maintenance manual for more details*).

Viewing User Study Associations

A user's study associations may be viewed by clicking the icon in the user search display table.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup Study Personnel X

User Search by Study

Study Personnel Pool

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

Last Name: First Name:

User Search by Study: Find User/Search Directory

Select	Training?	Name	Department	Email
		Investigator, John	i	General Hospital

i This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

Selected Study Personnel:

Principal Investigator

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Additional Investigators

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Research Support Staff

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Contact

Name	Role	Responsibilities
No Personnel has been selected for this group.		

Clear Key Study Personnel
Close Setup of Study Personnel

Clicking this icon will open the following secondary pop-up window.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup Study Personnel

Investigator, John Studies:

Display Studies by : IRB Number ▾

57 result(s) found... 1 - 10 ▶

Study Alias	Study Status	IRB Number	IRB Expiration	Principal Investigator
<i>Malaria in Juveniles</i>				
MJ0630	Draft	IRB-21-481		
<i>NIH Demonstration</i>				
NIH D123	Returned for Corrections	IRB-21-468		Investigator, John
<i>Copy of Malaria in Juveniles</i>				
Malaria in Juveniles	Pending - Submitted for Initial Review	IRB-21-482		Investigator, John
<i>The Barrow 5-ALA Intraoperative Confocal Evaluation (BALANCE) trial</i>				
BALANCE Trial	Open	IRB-19-135	07/09/2021	Investigator, John
<i>Malaria in Juveniles</i>				
Malaria in Juveniles	Open	IRB-21-479	06/29/2022	Investigator, John
<i>Malaria in Juveniles</i>				
Malaria in Juveniles	Open	IRB-21-478	06/28/2022	Investigator, John
<i>Directing differentiation of human induced pluripotent stem cells by target organ co-culture</i>				
Directing differentiation of human induced pluripotent stem cells by target organ co-culture	Active	IRB-21-458	06/24/2022	Investigator, John
<i>Malaria in Juveniles</i>				
Malaria in Juveniles	Active	IRB-21-476	06/24/2022	Investigator, John
<i>Malaria in Juveniles in South Africa</i>				
Malaria in Juveniles	Active	IRB-21-477	06/24/2022	Investigator, John
<i>Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail</i>				
Serum Metal Ion Concentration after Insertion of Pediatric Flexible Nail	Active	IRB-20-336	07/14/2021	Smith, Betty

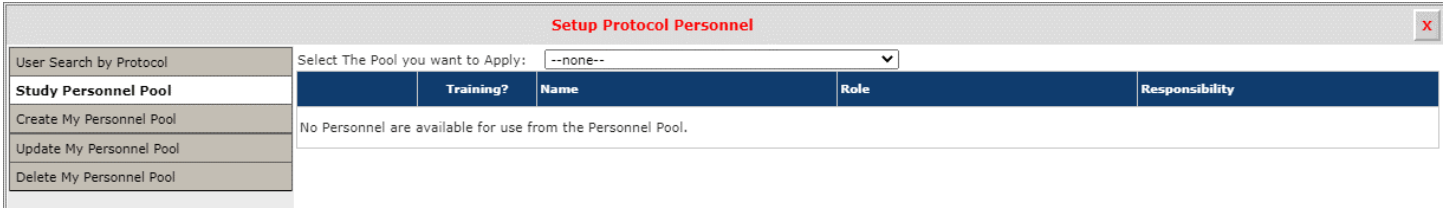
All studies that the selected user has been designated as a KSP on will populate in this display table. The format of the column's headers may be modified using the **Display Studies by** combobox.

Personnel Pools

The second method to add users to a study is to use personnel pools. A personnel pool is a pre-defined KSP configuration, composed of one or more users with pre-assigned roles. This method is especially useful for scenarios where the same personnel and roles are added to many different studies.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

To use a personnel pool, first navigate to the **Study Personnel Pool** tab as shown below.



Setup Protocol Personnel

User Search by Protocol

Select The Pool you want to Apply: --none--

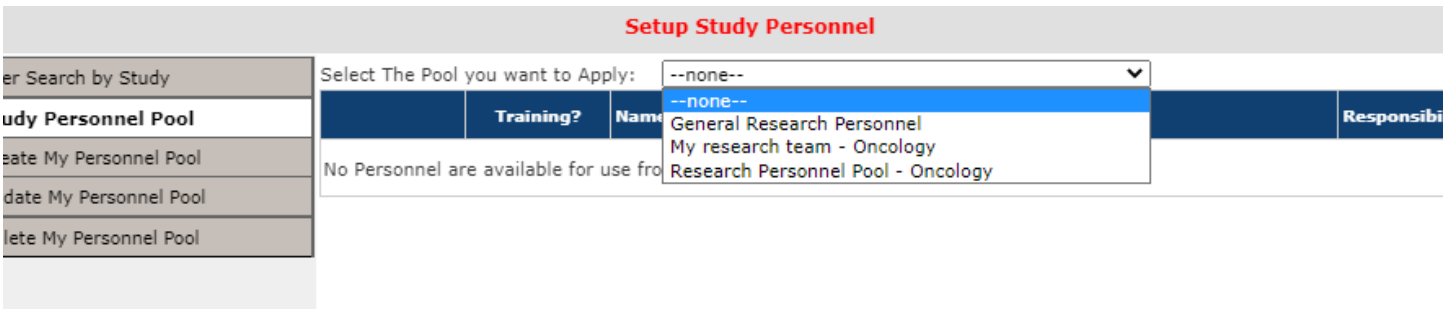
Training?	Name	Role	Responsibility
No Personnel are available for use from the Personnel Pool.			

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

Use the **Select The Pool you want to Apply** combobox to open a personnel pool. All pools that have been created by the current user will populate in this drop-down menu.



Setup Study Personnel

User Search by Study

Select The Pool you want to Apply: --none--

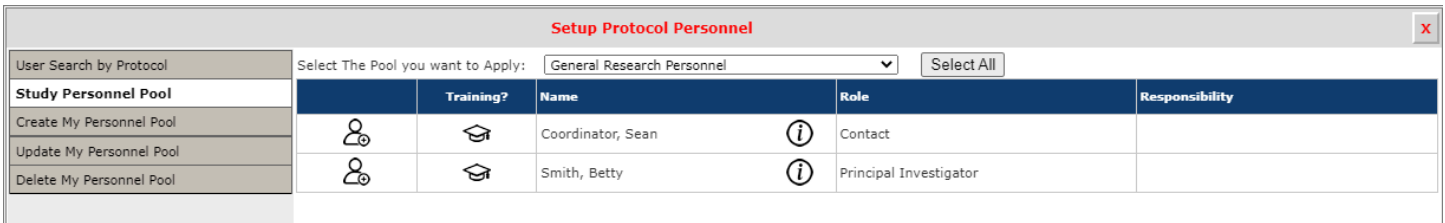
Training?	Name	Role	Responsibility
No Personnel are available for use from the Personnel Pool.			

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

Selecting a personnel pool will refresh the display table to show all users defined in that pool.



Setup Protocol Personnel

User Search by Protocol


Select The Pool you want to Apply: General Research Personnel

Training?	Name	Role	Responsibility
	Coordinator, Sean	Contact	
	Smith, Betty	Principal Investigator	

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

This “General Research Personnel” pool consists of the users Sean Coordinator (Principal Investigator) and Betty Smith (Contact). In order to add one of these users to the study, simply click the  select icon. Doing so will bypass the intermediate role configuration pop-up window and directly add the user to the study.

Creating Personnel Pools

To create a new personnel pool, navigate to the **Create My Personnel Pool** tab.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup Protocol Personnel X

User Search by Protocol

Study Personnel Pool

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

i This section is used to create a pool of personnel to reuse on future studies. In order for this menu to function the existing study must have been set-up with personnel to save into the pool.

Reference name of the Pool you are creating:

Selected Protocol Personnel:

Principal Investigator

	Name	Role	Responsibilities
(X)	Investigator, John	Principal Investigator	<None added>

Additional Investigators

	Name	Role	Responsibilities
(X)	Coordinator, Sean	Additional Principal Investigator	<None added>
(X)	Jefferson, Tom	Co-Investigator	<None added>

Research Support Staff

	Name	Role	Responsibilities
(X)	Jefferson, George	Nurse	<None added>

This page allows the user to create a new pool based on the current KSP configuration for the study. For example, in the screen above, this new pool will include John Investigator (Principal Investigator), Sean Coordinator (Additional Principal Investigator), Tom Jefferson (Co-Investigator), George Jefferson (Nurse), and any others not visible in this screenshot.

If any KSP should be excluded from the new personnel pool, they must be deleted from the study before saving this pool configuration.

Once the appropriate users have been added to the study, the new pool can be saved by entering a name for the pool and clicking the **Save** button.

Setup Protocol Personnel X

User Search by Protocol

Study Personnel Pool

Create My Personnel Pool

Update My Personnel Pool

Delete My Personnel Pool

i This section is used to create a pool of personnel to reuse on future studies. In order for this menu to function the existing study must have been set-up with personnel to save into the pool.

Reference name of the Pool you are creating:

Selected Protocol Personnel:

Principal Investigator

	Name	Role	Responsibilities
(X)	Investigator, John	Principal Investigator	<None added>

Additional Investigators

	Name	Role	Responsibilities
(X)	Coordinator, Sean	Additional Principal Investigator	<None added>
(X)	Jefferson, Tom	Co-Investigator	<None added>

Research Support Staff

	Name	Role	Responsibilities
(X)	Jefferson, George	Nurse	<None added>

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

This new “Research Personnel Pool – Oncology” pool will now populate in the **Study Personnel Pool** tab.

Updating a Personnel Pool

Navigate to the **Update My Personnel Pool** tab to update a pool.

Setup Protocol Personnel

User Search by Protocol
Study Personnel Pool
Create My Personnel Pool
Update My Personnel Pool
Delete My Personnel Pool

Select from the list of pools you are updating:

Select	Pool Reference Name
<input type="radio"/>	General Research Personnel
<input type="radio"/>	My research team - Oncology
<input type="radio"/>	Research Personnel Pool - Oncology

All pools associated to the current user will populate in this table.

Once a pool is selected, a new field will appear allowing the user to change the pool’s name.

Setup Protocol Personnel

User Search by Protocol
Study Personnel Pool
Create My Personnel Pool
Update My Personnel Pool
Delete My Personnel Pool

Select from the list of pools you are updating:

Select	Pool Reference Name
<input type="radio"/>	General Research Personnel
<input type="radio"/>	My research team - Oncology
<input checked="" type="radio"/>	Research Personnel Pool - Oncology


If you are changing the Pool name, Please modify the name:

Save

i This section is used to replace the personnel defined in the Selected Protocol Personnel (section below) to a named pool. The name of the pool can be updated to a different name.

Saving this page will update the personnel pool to display the new name. Note that update is purely aesthetic and does not modify the actual pool KSP configuration. Once a personnel pool has been defined, the users in that pool cannot be changed, only the name of the pool itself.

Deleting a Personnel Pool

Users may delete one or more of their pools by navigating to the **Delete My Personnel Pool** tab. Click the  icon to remove the pool.

Setup Protocol Personnel

User Search by Protocol
Study Personnel Pool
Create My Personnel Pool
Update My Personnel Pool
Delete My Personnel Pool

Delete from the list of pools:

Delete	Pool Reference Name
<input checked="" type="checkbox"/>	General Research Personnel
<input checked="" type="checkbox"/>	My research team - Oncology
<input checked="" type="checkbox"/>	Research Personnel Pool - Oncology

i This section allows you to delete a named pool. The pool will be removed from use.

Assign User(s) to Sections

After granting KSP access to the study, depending on the application form’s configuration, the **Assign User(s) to Sections** button may appear.

The screenshot shows the '3.0 Assign key study personnel (KSP) access to the study' screen. A red box highlights the 'Assign User(s) to Sections' button. Below the header, there is a table for assigning users to sections.

Name	Role	Responsibility	Training Record
John Investigator	Principal Investigator	Administrative Reviewer	View Training Record

Click the button to open the Define Study Access screen. Displayed here is a list of sections that have been accessed by the form author. Accompanying each section is a combobox enabling a KSP to be assigned to complete that section.

The screenshot shows the 'Define Study Access' screen. It displays a table with the following data:

Section Name	Status	Assign User to Complete Section
Initial Screening Question		--none--
Drugs and Devices		--none--
Funding		--none--

Any user that has been added to this study via the Study Shell section 3.0 will populate in these drop-down menus.

The screenshot shows the 'Define Study Access' screen with the dropdown menu for 'Initial Screening Question' open. The options are 'John Investigator' and 'George Jefferson'.

Section Name	Status	Assign User to Complete Section
Initial Screening Question		John Investigator George Jefferson
Drugs and Devices		--none--
Funding		--none--

Assign a user to a section by selecting their username in the drop-down. Once a user has been assigned to a form section, that section will appear as read-only to all other users. The assigned KSP will then receive a *Form Section Assignment* task to complete the section.

The screenshot shows the 'Define Study Access' screen with 'George Jefferson' selected in the dropdown menu for 'Initial Screening Question'.

Section Name	Status	Assign User to Complete Section
Initial Screening Question		George Jefferson
Drugs and Devices		--none--
Funding		--none--

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

In the example above, George Jefferson has been assigned to complete the “Initial Screening Question” section. Saving this assignment and navigating to the “Initial Screening Question” section will show the following screen.

My Workspaces ▾ IRB Number: **IRB-21-473** Study Assistant IRB Application (Version 1.0) Back

Section Assigned to George Jefferson

Print Friendly Assign User(s) to Sections Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 Initial Screening Question
5.0 Drugs and Devices
6.0 Funding

4.0 Initial Screening Question

4.1 * HUD DEVICE: (REQUIRED) Does this application involve a **Humanitarian Use Device (HUD)**: test

No
 Yes, and it includes a research component
 Yes, and it involves clinical care ONLY

4.2 Does this research involve Covid-19 parameters?

Will your research involve severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)?

Yes No

4.3 * TYPE OF RESEARCH: (Click the Help link for definitions and guidance): (REQUIRED)

Biomedical research
 Social, behavioral, educational, and/or public policy research
 Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social/behavioral but also involves specimen collection or blood draws to look at biological measures)

4.4 * REVIEW LEVEL: (REQUIRED) Requested review level (Click on the orange question mark to the right for definitions and guidance):

Full Committee
 Expedited
 Exempt

4.7 * **CLINICAL TRIAL**: (REQUIRED) Is this a clinical trial? According to The World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE) a **clinical trial** is:

- Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

ICMJE requires **registration** of a clinical trial in a public database (such as ClinicalTrials.gov) prior to enrollment, for eventual publication of results in member biomedical journals. Guidance: Public Law 110-85 requires that all investigators who perform an *applicable clinical trial* must ensure that the trial is registered on a government web site called ClinicalTrials.gov. The FDA requires registration for “applicable clinical trials,” defined as follows:

- For any trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small

Note that a message displaying the name of the assigned user is displayed on the upper left-hand corner of the screen. This message only displays when the assigned section is opened.

Also notice that the fields in this section are read-only. This is because the current logged-in user is still John Investigator, and this section has been assigned to George Jefferson. From George Jefferson’s point of view, he will have received a task to complete this section, as shown below.

All Tasks						
Outstanding		Completed				
All Tasks		Study Tasks				
Task List : All		Filter By : --none--				
3 result(s) found...						1 - 3
Click to open	Task Type	Date Received	Description	Priority	Complete By	
<input type="checkbox"/>	Form Section Assignment	07/20/2021 11:31 AM PDT	Study Application section assignment	No Priority	<input type="text"/> <input type="text"/>	

Opening this task takes Mr. Jefferson into the application form to complete the assigned section.

Section Assigned to George Jefferson

Print Friendly Save Section Save and Continue to Next Section

Section view of Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study
- 4.0 Initial Screening Question
- 5.0 Drugs and Devices
- 6.0 Funding

4.0 Initial Screening Question

Completed?
 Yes No

4.1 * HUD DEVICE: (REQUIRED) Does this application involve a **Humanitarian Use Device (HUD)** is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year" (21 CFR 814.3(n)). > **Humanitarian Use Device (HUD): test**

No ?

Yes, and it includes a research component

Yes, and it involves clinical care ONLY

4.2 Does this research involve Covid-19 parameters?

Will your research involve severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)? ?

Yes No

4.3 * TYPE OF RESEARCH: (Click the Help link for definitions and guidance): (REQUIRED)

Biomedical research ?

Social, behavioral, educational, and/or public policy research

Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social/behavioral but also involves specimen collection or blood draws to look at biological measures)

4.4 * REVIEW LEVEL: (REQUIRED) Requested review level (Click on the orange question mark to the right for definitions and guidance):

Notice that from George Jefferson’s point of view, the fields in this section are editable. To complete the section, Jefferson will simply select “Yes” for the **Completed?** field shown in the section header (red box in screen above). Doing so will complete the section and finalize the Form Section Assignment task.

From the form author’s point of view, once George Jefferson completes his assigned section, the status of this assignment will update to completed.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

My Workspaces ▾ IRB Number: **IRB-21-473** Study Assistant Define Study Access Back

Save Section Assignments

Section Name	Status	Assign User to Complete Section
Initial Screening Question	Completed	George Jefferson ▾
Drugs and Devices		--none-- ▾
Funding		--none-- ▾

The section itself will remain read-only, but the left-corner message will update to show that it has been completed.

My Workspaces ▾ IRB Number: **IRB-21-473** Study Assistant IRB Application (Version 1.0) Back

Section Completed by George Jefferson

Print Friendly Assign User(s) to Sections Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study
- 4.0 Initial Screening Question
- 5.0 Drugs and Devices
- 6.0 Funding

4.0 Initial Screening Question

4.1 * HUD DEVICE: (REQUIRED) Does this application involve a [Humanitarian Use Device \(HUD\)](#): test

No
 Yes, and it includes a research component
 Yes, and it involves clinical care ONLY

4.2 Does this research involve Covid-19 parameters?

Will your research involve severe acute respiratory syndrome *coronavirus 2* (SARS-CoV-2)?

Yes No

4.3 * TYPE OF RESEARCH: (Click the Help link for definitions and guidance): (REQUIRED)

Biomedical research
 Social, behavioral, educational, and/or public policy research
 Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social/behavioral but also involves specimen collection or blood draws to look at biological measures)

4.4 * REVIEW LEVEL: (REQUIRED) Requested review level (Click on the orange question mark to the right for definitions and guidance):

Custom Application Sections

The application sections following the Study Shell are customizable, based on the configuration of the Study Application Form.

To complete a section and move on, click the **Save and Continue to Next Section** button. If a required field is left blank, an error message will display.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

The screenshot shows the IRB Application (Version 1.0) interface. The top navigation bar includes "My Workspaces", "IRB Number: IRB-19-189", "PI: Smith, John", "Study Assistant", and "IRB Application (Version 1.0)". There are buttons for "Print Friendly", "Assign User(s) to Sections", "Save Section", and "Save and Continue to Next Section". The main content area is divided into "Section view of Application" and "Entire view of the Application". The "Section view of Application" shows a list of sections: 1.0 General Information, 2.0 Setup Department(s) Access, 3.0 Grant Key Personnel access to the study, and 4.0 Initial Screening Questions. The "Entire view of the Application" shows a form with a question 4.2: "TYPE OF RESEARCH: (Click the Help link for definitions and guidance)". The question has three radio button options: "Biomedical research", "Social, behavioral, educational, and/or public policy", and "Hybrid - includes aspects of BOTH types of research". A red error message is displayed: "The field above is a required field and cannot be left unselected." A modal dialog box is open in the center, titled "Error Encounter Saving the Application", with the message "An error occurred on the page. Please correct the mistake and resave the form" and an "OK (3)" button.

Correct the missing field to save and continue. Below is an example of an error message that might display within the form.

The screenshot shows a section of the IRB Application (Version 1.0) interface. The section is titled "4.6 * EXEMPT REVIEW CATEGORY: (REQUIRED)". It contains four radio button options: "Category 1: Evaluation of educational strategies, curricula and/or classroom management methods", "Category 2: Use of educational tests, surveys, interviews, or observations of public behavior", "Category 3: Use of educational tests, surveys, interviews, or observations of public behavior when the subjects are elected or appointed officials or candidates for public office, or if federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter", and "Category 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects". A red error message is displayed: "A selection is required from the above choice(s)".

Several unique data values often used in study applications to collect specific information are detailed below. These data values are added to Study Application Forms via the System Form Designer in System Administration and may or may not be present in your form.

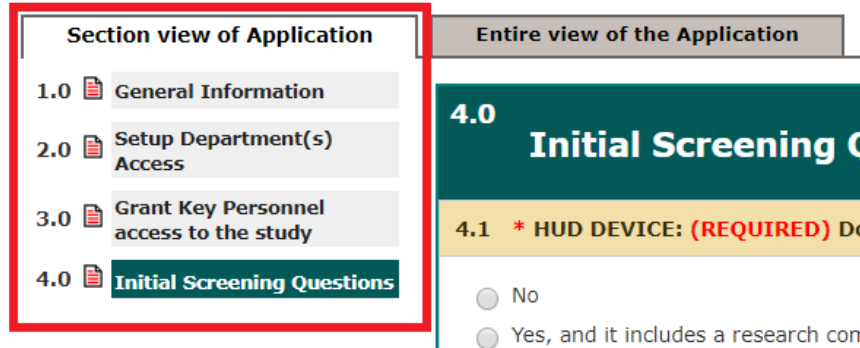
Notes Regarding Form Navigation

Back Button: When completing the Study Application, it is important to remember that if you need to return to the previous section, DO NOT hit the Back button on your Internet browser. To properly navigate to the previous section, click on the link for that section in the navigation pane.

The screenshot shows the IRB Application (Version 1.0) interface. The top navigation bar includes "My Workspaces", "IRB Number: IRB-21-473", "PI: Investigator, John", "Study", and "IRB Application (Version 1.0)". There are buttons for "Print Friendly", "Assign User(s) to Sections", "Save Section", and "Save and Continue to Next Section". The main content area is divided into "Section view of Application" and "Entire view of the Application". The "Section view of Application" shows a list of sections: 1.0 General Information, 2.0 Setup Department(s) Access, 3.0 Grant Key Personnel access to the study, and 4.0 Initial Screening Question. The "Entire view of the Application" shows a question 4.1: "HUD DEVICE: (REQUIRED) Does this application involve a Humanitarian Use Device (HUD): test". The question has a radio button option "No". A red error message is displayed: "A selection is required from the above choice(s)".

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Navigation Pane: On the left side of the screen, a navigation pane builds as you progress through the application. Click on the link of a section at any time to move to that section. The section you are currently viewing will appear green, while the other sections will appear gray.



Help Icons: Some sections may contain help icons. Click or hover your mouse over the icon to open a window or a small pop up That has been configured to provide additional information about a certain question.

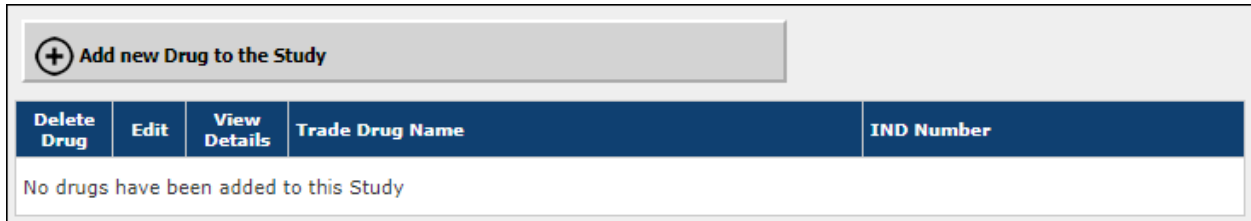
The image shows the application interface with a help window open. The top navigation bar includes "My Workspaces", "IRB Number: IRB-21-473", "PI: Investigator, John", "Study", "IRB Application (Version 1.0)", and a "Back" button. Below the navigation bar are buttons for "Print Friendly", "Assign User(s) to Sections", "Save Section", and "Save and Continue to Next Section". The main content area shows the "Section view of Application" and "Entire view of the Application" tabs. The "Section view of Application" lists sections 1.0 through 7.0, with 4.0 "Initial Screening Question" highlighted. The "Entire view of the Application" shows the question "4.0 Initial Screening Question" and sub-question "4.1 * HUD DEVICE: (REQUIRED) Does this application involve a Humanitarian Use Device (HUD): test". A help icon (question mark in a circle) is visible next to the question. A "Guidance" window is open, showing the definition of a Humanitarian Use Device (HUD) and links to "Humanitarian Use Devices" and "FDA guidance". The window has "Print" and "Close" buttons.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Study Drugs

The Study Drug data value enables users to search the iRIS™ database for a drug to add to their study. Any number of drugs may be added to a study.

To add a drug, begin by clicking on the **Add a New Drug to the Study** button in the Study Drug data value, as seen in the image below.

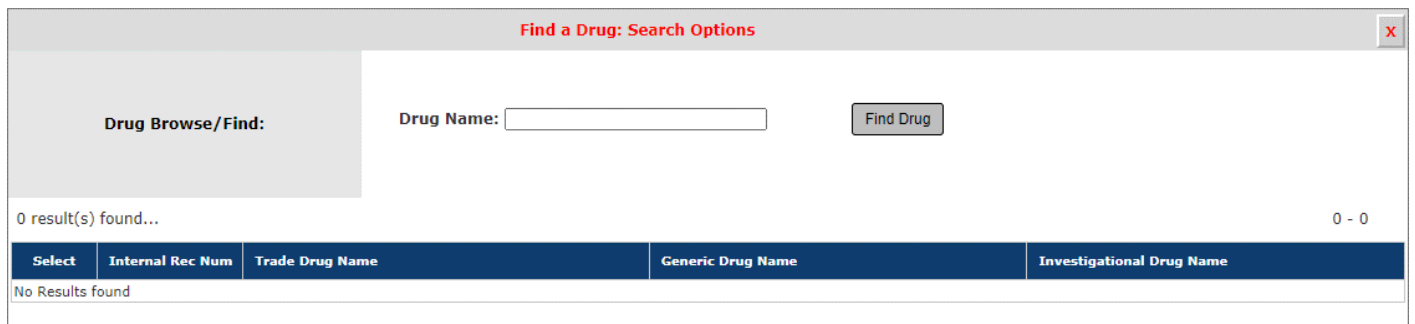


+

Add new Drug to the Study

Delete Drug	Edit	View Details	Trade Drug Name	IND Number
No drugs have been added to this Study				

The following pop-up window will open.



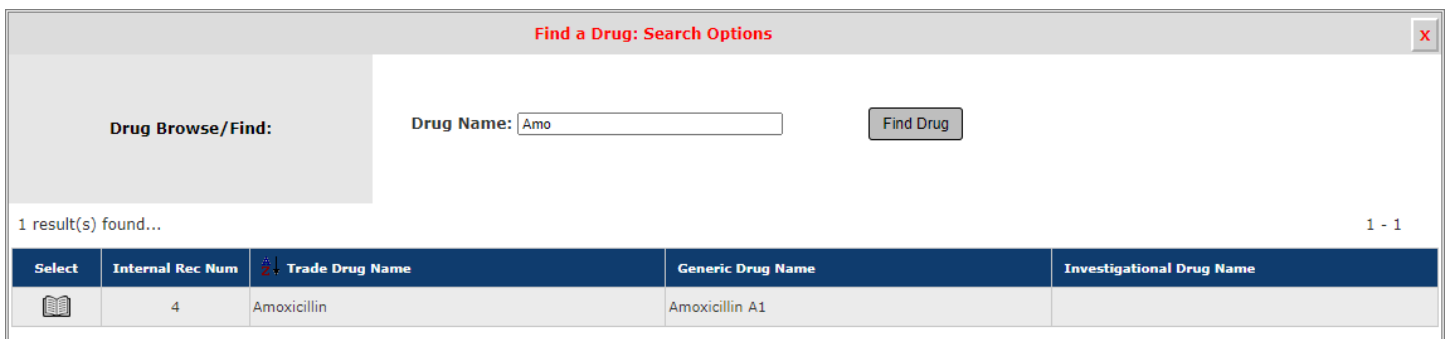
Find a Drug: Search Options

Drug Browse/Find: Drug Name: Find Drug

0 result(s) found... 0 - 0

Select	Internal Rec Num	Trade Drug Name	Generic Drug Name	Investigational Drug Name
No Results found				

Search for a drug by entering a full or partial drug name into the **Drug Name** text box and clicking the **Find Drug** button. If the text box is left blank, all drugs in the system will populate.



Find a Drug: Search Options

Drug Browse/Find: Drug Name: Amo Find Drug

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

Select	Internal Rec Num	Trade Drug Name	Generic Drug Name	Investigational Drug Name
	4	Amoxicillin	Amoxicillin A1	

Click the icon in the **Select** column to add a certain drug. If the desired drug is not populating in this table, the user may create this drug by clicking the **Add a New Drug** button. This will update the window to show the following screen, allowing the user to specify the Trade Drug Name, Generic Name and/or Investigational Drug Name. Click **Save Drug Info** to add this new drug to the system's master drug list.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

The screenshot shows a window titled "Add a New Drug" with a close button (X) in the top right corner. Below the title bar is a text input field labeled "Trade Drug Name:". To the right of the input field is a "Save Drug Info" button.

Whether adding an existing drug by clicking on the icon in the **Select** column, or adding a new drug to the master list, the user will next be taken to the Study Drug Details screen as shown below.

The screenshot shows a window titled "Study Drug Details:" with a close button (X) in the top right corner. The "Trade Drug Name" is set to "Amoxicillin". Below this is a blue header bar: "Protocol Information: Drugs and Biological Products".

The form contains several sections:

- Does your study involve INVESTIGATIONAL drugs, reagents, or chemicals?** (Left column)
- Has this study been submitted to the Institutional Biosafety Committee (IBC) review? The IRB requires documentation of IBC approval before final approval of the study can be granted.** (Right column)
 - Yes
 - No
 - N/A
- Investigational New Drug Application (IND)#** (Text input field)
- Is the drug provided free of charge?** (Right column)
 - Yes
 - No
 - N/A
- What is the cost of the investigational drug to your institution?** (Text input field)
- Manufacturer:** (Text input field)
- Form of Administration:** (Text area)
- Procedure for Minimizing Adverse Events:** (Text area)
- Is IND held by the sponsor? If Yes, provide a copy of the investigator's brochure and the sponsor's protocol in the Attachments section.** (Text area)

A "Save Drug Info" button is located at the bottom right of the form.

This screen enables the user to associate study-specific information to the added drug. The questions below the blue bar are configurable via System Form Designer and may or may not appear different in your system.

Once the fields on this screen have been completed, click **Save Drug Info** to add this drug to the study.

You will be returned to the Study Application and the drug you added will appear in the table below the **Add a New Drug to the Study** button.

+ Add new Drug to the Study				
Delete Drug	Edit	View Details	Trade Drug Name	IND Number
			Trade Drug Name: Amoxicillin	

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

You may delete the drug by clicking the icon in the **Delete Drug** column. To edit the study-specific drug information, click the icon in the **Edit** column. You can also view the study-specific details by clicking the icon in the **View Details** column, as seen in the image below.

The screenshot displays the 'Add new Drug to the Study' interface. At the top, there is a button with a plus icon and the text 'Add new Drug to the Study'. Below this is a table with four columns: 'Delete Drug', 'Edit', 'View Details', and 'Trade Drug Name'. The 'Trade Drug Name' column contains the text 'Trade Drug Name: Amoxicillin'. Below the table, there is a section titled 'Protocol Information: Drugs and Biological Products'. This section contains several questions and input fields:

- Does your study involve INVESTIGATIONAL drugs, reagents, or chemicals? (No options are visible)
- Has this study been submitted to the Institutional Biosafety Committee (IBC) review? The IRB requires documentation of IBC approval before final approval of the study can be granted. (Radio buttons for Yes, No, N/A; 'Yes' is selected)
- Investigational New Drug Application (IND)# (Text input field containing '15224-8')
- Is the drug provided free of charge? (Radio buttons for Yes, No, N/A; 'No' is selected)
- What is the cost of the investigational drug to your institution? (Text input field containing '\$17 per dose')
- Manufacturer: (Text input field containing 'Biogen')

You can add additional drugs by clicking the **Add a New Drug to the Study** button and follow the steps listed above.

Study Devices

The Study Device data value enables users to search the iRIS™ database for a device to add to their study. Any number of devices may be added a study.

Begin by clicking on the **Add a New Device to the Study** button.

The screenshot shows the 'Add a New Device to the Study' button at the top. Below it is a table with four columns: 'Delete Device', 'Edit', 'View Details', and 'Device Name'. The table is currently empty, and the text 'No devices have been added to this Study' is displayed below the table.

A popup window will open within your browser allowing you to search the system for the device you would like to add to the study. You can enter in all or part of the Device Name, Device Mode and/or Device Serial Number, or leave these fields blank and click the **Find Device** button to return all devices in the system.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Find A Device: Search Options

Device Browse/Find:

Device Name:

Device Mode:

Device Serial Number:

0 result(s) found... 0 - 0

Select	Device Name	Device Mode	Device Serial Number
No Results found			

Once your search returns results, you can select the desired device by clicking on the icon in the **Select** column.

If the desired device is not in the list, you can add a device to the system's master device list by clicking the **Add a New Device** button.

Find A Device: Search Options

Device Browse/Find:

Device Name:

Device Mode:

Device Serial Number:

4 result(s) found... 1 - 4

Select	Device Name	Device Mode	Device Serial Number
	Cardiac Stent	15L	Z54889563
	IV Autodrip for 1L Bags	Standard	89NB555-PL
	Lap Band	Gastrointestinal Lap Band	A33242
	Stent		

Doing so will update the window to show the screen below, allowing you to specify the **Device Name** (required field), **Device Mode** and **Device Serial Number**.

Add a New Device

*Device Name:

Device Mode:

Device Serial Number:

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

When finished defining the new device, click the **Save Device Info** button to add the device to the system's master list.

Whether you chose an existing device by clicking on the icon in the **Select** column, or added a new device to the master list, you will next be taken to the Study Device Details screen as shown below.

The screenshot shows a window titled "Protocol Device Details:" with a close button (X) in the top right corner. Below the title bar, there is a header "Device Name Cardiac Stent". A green bar contains the text "Protocol Information: Medical Equipment, Study Devices".

On the left side, there is a grey box with the following text:

BIOMEDICAL FULL BOARD EXPEDITED STUDIES

Study Devices

General Hospital defines a "study device" as a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

On the right side, there are several form fields:

- Manufacturer:** A text input field.
- Describe how dispensing of the study device(s) will be controlled; describe where the device(s) will be stored and how access to the device(s) will be limited to only the individuals listed as study personnel on the protocol.** A large text area.
- Regulatory Status:** A text area containing the text: "The FDA is responsible for defining the development, testing, approval, and marketing of each medical device. Except for certain low-risk devices, each new medical device must be submitted to the FDA for review and assignment of its regulatory status. For more information, see FDA Information Sheet, titled "Medical Devices."

At the bottom right of the window is a button labeled "Save Device Info".

This screen allows you to enter study-specific information for the device. You may or may not see the same information listed on this page, depending on your system configuration.

The questions below the green bar are configurable via the System Form Designer. When the fields in the above window are complete, click on the **Save Device Info** button to add the device to the study application.

+ Add a New Device to the Study			
Delete Device	Edit	View Details	Device Name
			Cardiac Stent

You can delete the device by clicking the icon in the **Delete Device** column. To edit the study-specific device information, click the icon in the **Edit** column. You can also view the study-specific details by clicking the icon in the **View Details** column.

+ Add a New Device to the Study

Delete Device	Edit	View Details	Device Name
⊗	✎	☰	Cardiac Stent

Protocol Information: Medical Equipment, Study Devices

BIOMEDICAL FULL BOARD EXPEDITED STUDIES

Study Devices

General Hospital defines a "study device" as a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

Manufacturer:

Describe how dispensing of the study device(s) will be controlled; describe where the device(s) will be stored and how access to the device(s) will be limited to only the individuals listed as study personnel on the protocol.

Regulatory Status: The FDA is responsible for defining the development, testing, approval, and marketing of each medical device. Except for certain low-risk devices, each new medical device must be submitted to the FDA for review and assignment of its regulatory status. For more information, see FDA Information Sheet, titled "Medical Devices."

You can add additional devices by clicking the **Add a New Device to the Study** button and follow the steps listed above.

Inclusion/Exclusion Criteria

The Inclusion Criteria and Exclusion Criteria data values allow inclusion/exclusion criteria to be defined for potential subjects on the study. You can add the criteria to your Study Application for board review, and later, for flagging which enrolled subjects meet each criterion.

The same process is used to add both Inclusion and Exclusion criteria. This is described below using Inclusion Criteria as an example.

Begin by clicking the **Add a New Inclusion Criteria to the Study** button in the Inclusion Criteria data value.

+ Add a New Inclusion Criteria to the Study

Delete	Edit	Order Number	Criteria
No Criteria has been added to this Study			

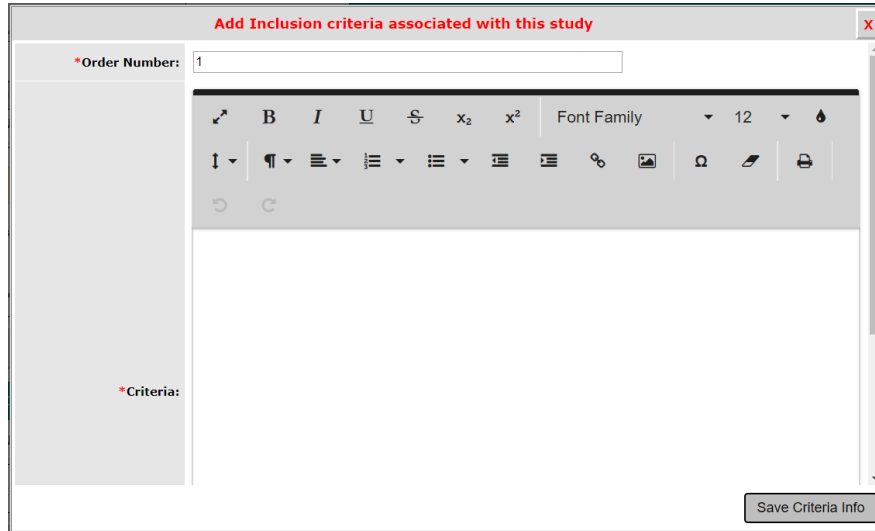
+ Add a New Exclusion Criteria to the Study

Delete	Edit	Order Number	Criteria
No Criteria has been added to this Study			



Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01



A popup window will open allowing you to specify the Order Number and the wording for the Criteria. The Order Number will default to 1.

The required Criteria field allows both copying and pasting and manually typing of the criteria description.



When finished, click the **Save Criteria Info** button. You will be returned to the Study Application and the new Inclusion Criteria will be listed in the table.

+ Add a New Inclusion Criteria to the Study			
Delete	Edit	Order Number	Criteria
		1	Must be 18-45 years of age, inclusive.


An additional Inclusion Criteria may be added as needed. Click the **Add a New Inclusion Criteria to the Study** button and repeat the steps above. Delete an Inclusion Criteria record by clicking the  icon in the Delete column. Modify existing records by clicking the  icon in the Edit column.

Sponsor

The Sponsor data value enables you to search the system for a sponsor to add to your study. Depending on your system settings, you may or may not be able to add more than one sponsor to a given study. Follow the process described below to add a sponsor record.

Begin by clicking on the **Add a New Sponsor to the Study** button.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

 **Add a New Sponsor to the Study**

Delete	Edit	View Details	Sponsor Name	Sponsor Type
No Sponsor has been added to this Study				

A popup window will open allowing you to search the system for the sponsor you would like to add. You can enter in full or partial Sponsor Names, Familiar Names and/or Legal Names, or leave these fields blank and click the **Find Sponsor** button to return all sponsors in the system.

Find a Sponsor: Search Options x

Sponsor Browse/Find:

Sponsor Name:

Familiar Name:

Legal Name:

0 result(s) found... 0 - 0

Select	Sponsor ID	Sponsor Name	Familiar Name	Legal Name
No Results found				

If the desired sponsor does not appear in the table, you can add this sponsor to the system’s master list by clicking on the **Add a New Sponsor to the Master List** button. This feature is controlled by a system property, please contact your System Administrator for more information.

Find a Sponsor: Search Options
X

Sponsor Browse/Find:

Sponsor Name:

Familiar Name:

Legal Name:

208 result(s) found... 1 - 10 ▶

Select	Sponsor ID	Sponsor Name	Familiar Name	Legal Name
⊕		3-M Pharmaceuticals	3M	3-M Pharmacueticals
⊕		A.G. Bessalear	A.G. Bessalear	A.G. Bessalear
⊕		Abbott Pharmaceutical	Abbott Pharmaceutical	Abbott Pharmaceutical

After you choose to add a new sponsor, the window will update allowing you to specify the Sponsor Abbreviation, Sponsor Name (required field), Sponsor Type (required field) and sponsor location information. When finished, click the **Save Sponsor and add to Study** button to add this new sponsor to the master list.

Add Sponsor to Master List Details:
X

Sponsor Abrv:

*Sponsor Name:

*Sponsor Type:

Street 1:

Street 2:

City:

County:

State:

Province:

Country:

Zip/Postal Code:

Whether you chose an existing sponsor by clicking on the ⊕ icon in the Select column, or added a new sponsor to the master list, you will next be taken to the Study Sponsor Details screen as shown below.

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Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Protocol Sponsor Details: X

Sponsor Name:	3-M Pharmaceuticals
Sponsor Type:	Pharmaceutical

Funding

<p style="font-size: small; margin: 0;">ALL STUDIES</p> <p style="font-size: x-small; margin: 0;">Add funding source(s) below: Federal, Sponsor, or Other. Select "Original Development by Applicant(s)" above if there is no funding for the study.</p>	<p>IF SPONSOR(s)</p> <p style="font-size: x-small; margin: 0;">Please provide contact information below for the IRB Fee billing purposes. NOTE: * Denotes mandatory field.</p> <p>Contact Name: *</p> <input style="width: 90%; border: 1px solid gray;" type="text"/> <p>Contact Title: *</p> <input style="width: 90%; border: 1px solid gray;" type="text"/> <p>Mailing Address: *</p> <input style="width: 90%; border: 1px solid gray;" type="text"/> <p>City: *</p> <input style="width: 90%; border: 1px solid gray;" type="text"/> <p>State: *</p> <input style="width: 90%; border: 1px solid gray;" type="text"/>
--	---

The questions below the green bar are configurable via the System Form Designer. Once the appropriate fields have been completed, click the **Save** button to add the sponsor to the study. If a sponsor is given a “Funding Sponsor” role and your system has access to the finance area of Subject Management, you will have the ability to generate invoices for the sponsor when certain study events and milestones are triggered.

Once added, this sponsor will populate in the Sponsor data value display table.

<input type="button" value="+ Add a New Sponsor to the Protocol"/>				
Delete	Edit	View Details	Sponsor Name	Sponsor Type
⊗	✎	⊕	3-M Pharmaceuticals	Pharmaceutical

You can delete the sponsor from the study by clicking on the icon in the Delete column. If your system is set up to allow only one sponsor per study, the button to add sponsors to the study will not appear once a sponsor has been added. If you delete the sponsor, the button will reappear, allowing you to add a different sponsor.

If your system does not restrict the number of sponsors allowed per study, you can add additional sponsors to the study by clicking on the **Add a New Sponsor to the Study** button and following the same steps as above.

You can view additional details related to the sponsor by clicking on the expand icon in the **View Details** column.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

+ Add a New Sponsor to the Protocol

Delete	Edit	View Details	Sponsor Name	Sponsor Type
⊗	✎	☰	3-M Pharmaceuticals	Pharmaceutical

Sponsor Name:	3-M Pharmaceuticals
Sponsor Type:	Pharmaceutical

Funding

<p style="text-align: center; margin: 0;">ALL STUDIES</p> <p style="font-size: small; margin: 5px 0;">Add funding source(s) below: Federal, Sponsor, or Other. Select "Original Development by Applicant(s)" above if there is no funding for the study.</p>	<p>IF SPONSOR(s)</p> <p style="font-size: small;">Please provide contact information below for the IRB Fee billing purposes. NOTE: * Denotes mandatory field.</p> <p>Contact Name: *</p> <input style="width: 90%; border: 1px solid #ccc;" type="text" value="Sean McMurray"/> <p>Contact Title: *</p> <input style="width: 90%; border: 1px solid #ccc;" type="text" value="Director"/> <p>Mailing Address: *</p>
---	--

Sponsor Contact

Once a sponsor is added to a study, you may then associate one or more contacts to this sponsor via the **Add a New Contact(s) to the Study** data value.

+ Add a New Contact(s) to the Study

Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
No Prime Recipient Contact has been added to this Study								

There is no limit to the number of contacts that can be associated to a sponsor. Clicking **Add a New Contact(s) to the Study** will open a pop-up window allowing you to search the system for existing sponsor contacts. You can enter all or partial information in any of the search fields or leave these fields blank and click the **Find Sponsor Contact** button to return all sponsor contacts associated to the sponsor you added to the study.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Find a Sponsor Contact: Search Options X

Sponsor Contact

Browse/Find:

Sponsor Name: 3-M Pharmaceuticals

Last Name:

First Name:

Division:

Find Sponsor Contact

0 result(s) found... 0 - 0

Select	Sponsor Name	Division	First Name	Last Name
No Results found				

If you cannot find the desired sponsor contact in the list, you can add a new sponsor by clicking on the **Add a new Contact to the Master List** button.

Find a Sponsor Contact: Search Options X

Sponsor Contact

Browse/Find:

Sponsor Name: 3-M Pharmaceuticals

Last Name:

First Name:

Division:

Find Sponsor Contact

Add a new Contact to the Master List

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

Select	Sponsor Name	Division	First Name	Last Name
	3-M Pharmaceuticals	Research and Funding	Sean	McMurray

After you choose to add a new contact, the window will update, allowing you to specify the Contact Category, **Division** (required field), **First Name** (required field), Middle Initial, **Last Name** (required field), and additional information for the sponsor contact. When you are finished, click the **Save Sponsor Contact Info** button.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Sponsor Contact: Details
X

Contact Category:	<input type="text" value="--none--"/>
* Division:	<input type="text"/>
* First Name:	<input type="text"/>
Middle Initial:	<input type="text"/>
* Last Name:	<input type="text"/>
Prefix:	<input type="text"/>
Suffix:	<input type="text"/>
Title:	<input type="text"/>
* Primary E-mail:	<input type="text"/>
Secondary E-mail:	<input type="text"/>
* Primary Phone:	<input type="text"/>
Secondary Phone:	<input type="text"/>
Street 1:	<input type="text"/>
Street 2:	<input type="text"/>
City:	<input type="text"/>
County/Parish:	<input type="text"/>
State:	<input type="text" value="--none--"/>
Province:	<input type="text"/>
Country:	<input type="text" value="--none--"/>

Once the contact is saved, you will be redirected back to the study application form where the sponsor contact has been added to the Contact data value display table.

Add a New Contact(s) to the Study

Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
			3-M Pharmaceuticals	Research and Funding	McMurray, Sean		951-885-6896	sean.m@3m.com

To add another contact, click on the **Add a New Sponsor Contact(s) to the Study** button again. Delete a contact from the study by clicking on the icon in the **Delete** column. Edit a contact by clicking on the icon in the **Edit** column.

You can view additional details related to the sponsor contact by clicking on the expand icon in the **View Details** column. Your system may or may not have the fields shown in the screenshot below, depending on system settings.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

+ Add a New Contact(s) to the Study

Delete	Edit	View Details	Sponsor Name	Division	Contact Name	Title	Primary Phone	Email
ⓧ	✎	☰	3-M Pharmaceuticals	Research and Funding	McMurray, Sean		951-885-6896	sean.m@3m.com
Contact Category:			Fiscal					
Contact Name:			McMurray, Sean					
Title:								
Division:			Research and Funding					
Primary Phone:			951-885-6896					
Secondary Phone:								
E-mail:			sean.m@3m.com					

Link Study to Project

The Link Study to Project data value will allow you to link your study to an existing iRIS™ project.

Search/Link Study to Projects

Remove Project	Project Status	Proposal Number	Project Title	Principal Investigator
No Projects are Linked to this Study				

Begin by clicking on the **Search/Link Study to Projects** button. The window below will display allowing you to search for your project.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Find A Project: Search Options X

Proposal Number: <input style="width: 90%;" type="text"/> Project Status: All ▼	Principal Investigator: <input style="width: 90%;" type="text"/> Study Keywords: <input style="width: 90%;" type="text"/>
--	--

0 result(s) found... 0 - 0

Link Project	Project Status	Proposal Number	Project Short Title Project Title	Principal Investigator
No Projects are linked to this Study				

Enter your search criteria and click **Find Projects**.

Find A Project: Search Options X

Proposal Number: <input style="width: 90%;" type="text" value="154"/> Project Status: Awarded ▼	Principal Investigator: <input style="width: 90%;" type="text"/> Study Keywords: <input style="width: 90%;" type="text" value="malar"/>
--	--

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

Link Project	Project Status	Proposal Number	Project Short Title Study Title	Principal Investigator
+	Awarded	PRE-19-0154	Malaria in Juveniles Malaria in Juveniles	Jeff Sykes

Click on the + icon to add the desired project to this Study Application.

Search/Link Study to Projects

Remove Project	Project Status	Proposal Number	Project Title	Principal Investigator
X	Awarded	PRE-19-0154	Malaria in Juveniles Malaria in Juveniles	946 Jeff Sykes

You can click on the X icon to remove the association to this project.

Initial Review Transition

The screenshot shows the IRB Application interface. At the top, there is a header with 'My Workspaces' and a dropdown menu. To the right, it displays 'IRB Number: IRB-21-473' and 'PI: Investigator, John'. The main title is 'Study IRB Application (Version 1.0)' with a 'Back' button. Below the header, there are four buttons: 'Print Friendly', 'Assign User(s) to Sections', 'Save Section', and 'Save and Continue to Next Section'. The main content area is divided into two tabs: 'Section view of Application' and 'Entire view of the Application'. The 'Section view of Application' tab is active, showing a list of sections from 1.0 to 15.0. Section 15.0, 'End of Study Application', is highlighted. The content of section 15.0 is displayed in a large box with a green header and yellow background. It contains the following text:

15.0 End of Study Application

15.1 End of Study Application Form To continue working on the Study Application: Click on the section you need to edit in the left-hand menu. Remember to save through the entire Study Application after making changes. If you are done working on the Study Application: Click Save and Continue. If this is a new study, you will automatically enter the Initial Review Submission Packet form, where you can attach consent forms or other study documents. Review the [Initial Review Submission Checklist](#) for a list of required attachments. Answer all questions and attach all required documents to speed up your approval.

The iMedRIS IRB wants your feedback about this new form. Please click the link to take a [brief survey](#) about the new application form.

Note: Not every Study Application will have an end like the one in the screen shown above, this is dependent on your system configuration.

Once the Study Application has been completed, the system will transition into the Initial Review Submission Form. This transition is signaled by the following pop-up window.

You have completed the Application.

The System has transitioned to the Initial Review Submission Form Real and your application has been attached.

Please complete the Initial Review Submission Form Real and attach any supporting documents with your submission.

OK

Clicking **OK** in this window will take the user into the Initial Review Submission Form as shown below. Note that this is independent of the original Study Application and does not mean that the application has reset.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

The screenshot shows the top navigation bar with "My Workspaces" (dropdown), "IRB Number: IRB-21-473" and "PI: Investigator, John", "Study Assistant", and "Initial Review Submission Form - (Version 1.0)" with a "Back" button. Below the navigation are buttons for "Print Friendly", "Refresh Constant Fields", "Save Section", and "Save and Continue to Next Section". The main content area has two tabs: "Section view of the Form" and "Entire view of the Form". On the left is a sidebar with a list of sections: "1.0 Transitioning to Initial Review Submission" (selected), "2.0 IRB - Initial Review Submission Packet", and "3.0 Application Form". The main content area displays section 1.0 with the heading "1.0 Transitioning to Initial Review Submission" and a sub-section "1.1 Please select the type of Research:". Below this are three radio button options: "Human Research", "Social Behavior Research", and "Biochemical Review". A question mark icon is visible in the right-hand column of the form.

The Initial Review form serves as the actual submission form that will be sent to the review board. The Study Application will be attached to this form, along with any informed consents and supporting study documents.

The mechanics of the Initial Review Submission Form are identical to those for the Study Application (navigating between sections, viewing tool tips, completing questions, etc.). Remember that the content and structure of this form is configurable and may not appear the same in your own Initial Review form. In the first section of this example Initial Review form a question about the type of research being conducted in this study is posed.

The second section in this example form displays some high-level study information pulled from the Study Shell of the application form.

The screenshot shows the same top navigation bar as the previous image. The main content area now displays section 2.0 with the heading "2.0 IRB - Initial Review Submission Packet". Below the heading is a "Note:" section with three bullet points: "This is the submission packet. The Study Application should be attached below under 'Study Application Form'. To access the attached 'Study Application', click on the 'Edit/View' icon next to it.", "To create and attach your consent form(s), go to section 'Consent Documents' below.", and "To upload and attach any study related document(s) that were not already attached in the Study Application, go to section 'Other Study Documents' below." Below the note is sub-section "2.1 Study Title:" with a text input field containing "Malaria in Juveniles". Below this are three more text input fields: "IRB Number:" containing "IRB-21-481", and "Principal Investigator:" containing "John Investigator".


Described below are some common data values used in Initial Review Submission forms. These may or may not appear in your specific submission form depending on your system configuration.

Lay Summary

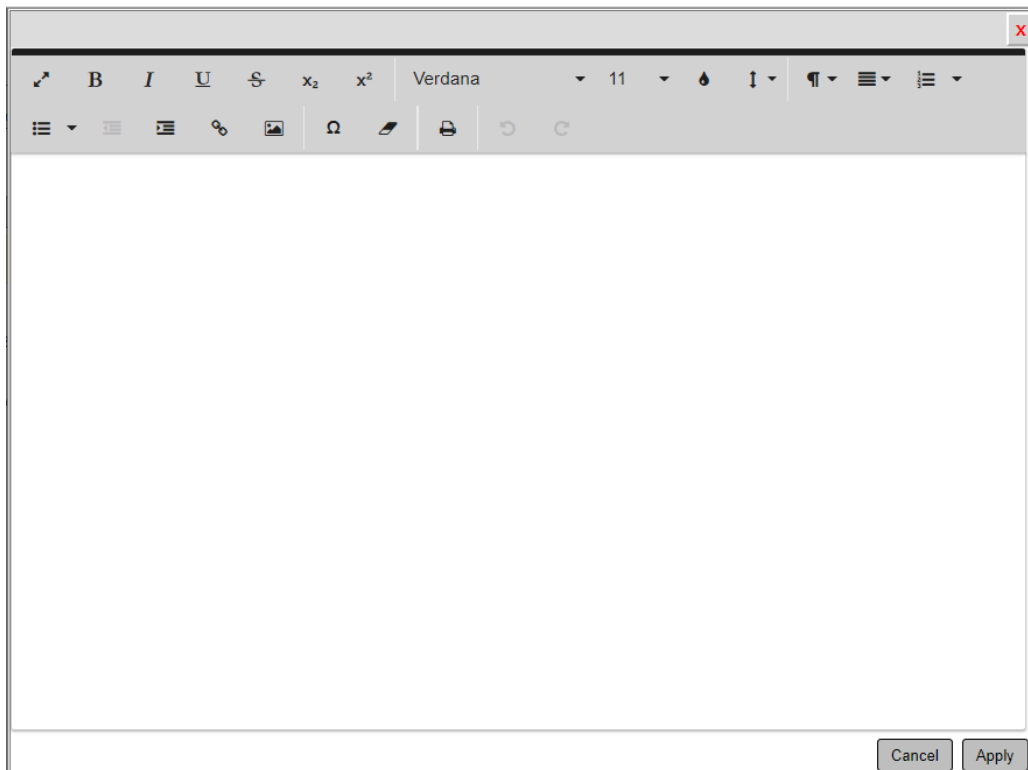
The Lay Summary data value is a required field for most Initial Review Submission form. It captures the Lay Summary and/or Master Lay Summary for your study. The text entered in this data value will be used by the review board to gain an understanding of the overall goals and structure of the study.

Click the **Click here to access the text editor** button on the Lay Summary data value to create the summary.

Master Lay Summary:


 **Click here to access the text editor.**

A small popup will display, allowing you to copy and paste or type in the text of your Lay Summary. When you are finished, click the **Apply** button.



The window will close, returning you to the Initial Review Submission packet. The newly entered Lay Summary text will populate underneath the Lay Summary section.

Master Lay Summary:

 **Click here to access the text editor.**

The purpose of the study is to see the effectiveness of different antihistamines and their side effects of drowsiness in conjunction with sleeping aids.

Application Attachment


Because the purpose of the Initial Review Submission Form is to submit the Study Application to a board for review, one of the form's section will include an Application Attachment data value.

The screenshot shows the 'Initial Review Submission Form - (Version 1.0)' interface. At the top, there are navigation elements: 'My Workspaces' with a dropdown arrow, 'IRB Number: IRB-21-473' and 'PI: Investigator, John' in a box, and a 'Study' label. A dark blue header bar contains the title 'Initial Review Submission Form - (Version 1.0)' and a 'Back' button. Below the header are five buttons: 'Print Friendly', 'Refresh Constant Fields', 'Save Section', 'Save and Continue to Next Section', and 'Validation Check/Save Form'. A sidebar on the left lists sections: '1.0 Transitioning to Initial Review Submission', '2.0 IRB - Initial Review Submission Packet', '3.0 Application Form' (highlighted), '4.0 Consent Documents', '5.0 Other Study Documents', and '6.0 Additional Special Routing'. The main content area is titled '3.0 Study Application Form' and contains section '3.1 Attach the IRB application you completed for this protocol: (For an Initial Submission the application will automatically attach for you)'. Below this is a table with columns: 'Deattach', 'Revise/Attach', 'Edit/View', and 'Title'. The table has one row with a circled 'X' in the 'Deattach' column, an icon in the 'Revise/Attach' column, an icon in the 'Edit/View' column, and the text 'IRB Application (Version 1.0)' in the 'Title' column.

For Initial Review forms, the Study Application will be pulled into this data value automatically. At this point no further actions are required, and you may continue to the next section. Later in the lifecycle of the study, if the review board has requested changes, you may have to revisit this data value to apply those changes, depending on the nature of the request.

For other types of submission forms, the Study Application is not pulled into this data value by default and instead must be added manually. In this case a **Click here to attach the application** button will appear.

2.1 Attach study application


 [Click here to attach the application.](#)


No Application has been associated with this submission.

Clicking this button will open a window listing the available Study Applications you can attach.

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Attaching Protocol Application ✕


 Select the application that you would like to attach and then click Save Attachment


Select	Show Rev.	Edit/ View	Form Name	Approved	Create a Revised Application
<input type="radio"/>			IRB Application (Version 1.0)	No	

Because this is a new study, only one Study Application is visible.

To add this application, make sure it is selected and click the **Save Attachment** button.

Attaching Study Application ✕

 Select the application that you would like to attach and then click Save Attachment

Select	Show Rev.	Edit/ View	Form Name	Approved	Create a Revised Application
<input checked="" type="radio"/>			IRB Application (Version 1.0)	No	

Informed Consent Attachments

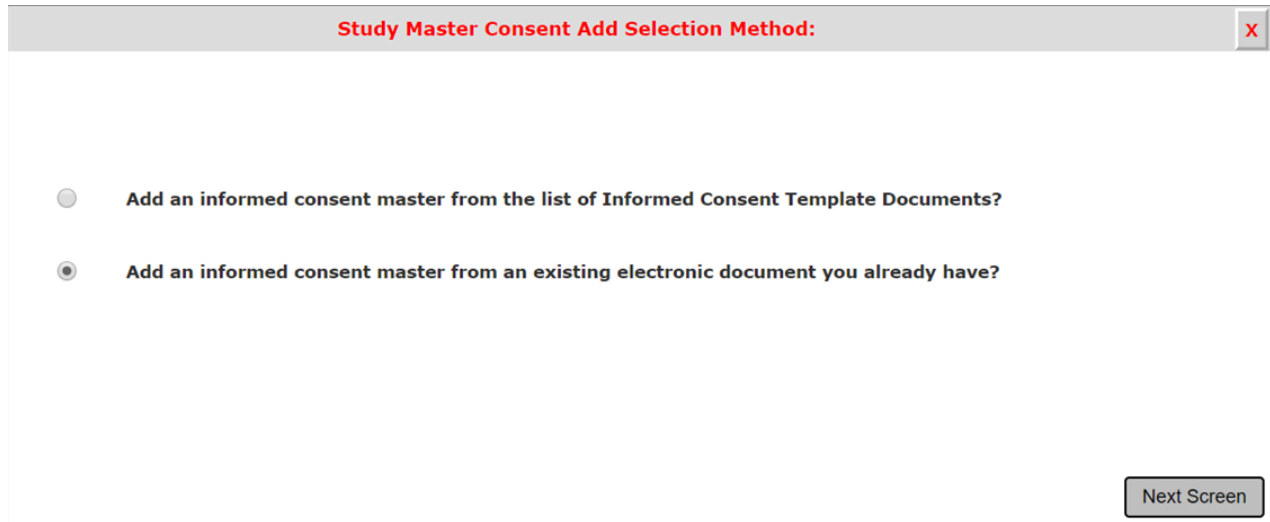
You may be directed to attach any necessary Informed Consent documents. Any consent document you upload to the Initial Review will be attached to the form and submitted for review. These documents will also be stored in the Informed Consent document library in the study record. If the review board approves the document, the approval information will update the document stored in the library. If your system is using Subject Management, you will also be able to update consent information for subjects on the study.

Add a consent to the submission by clicking the **Add a New Consent** button.



The screenshot shows a button labeled "Add a New Consent" at the top left. Below it is a table with the following columns: Detach, Version, Title, Category, Language, Expiration Date, Consent Outcome, Checked Out, and View Document. The table content is empty, with a message below it stating "No Consent(s) have been attached to this form."

A small window will open asking for input on how you will upload the Consent document.



The dialog box has a title bar that reads "Study Master Consent Add Selection Method:" and a close button (X) in the top right corner. It contains two radio button options:

- Add an informed consent master from the list of Informed Consent Template Documents?
- Add an informed consent master from an existing electronic document you already have?

A "Next Screen" button is located in the bottom right corner of the dialog box.

Depending on your system settings, you may or may not see the same options as above.

Both options are described below. Choose the appropriate action then click the **Next Screen** button.

1. Add an informed consent master from the list of Informed Consent Template Documents?

Review boards may make consent templates available for you to download, modify, and then upload to the study. If you would like to download a copy and use the review board’s consent template, choose this option.

Selecting this option will present you with the ability to select the desired template from a dropdown list. Select the template and then click the **Download Template** button.

Study Consent Add from Template: X

Instructions

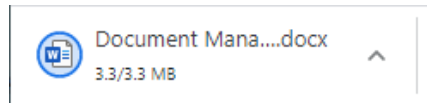
1. Download the document to your workstation by clicking the **Download** button at the top right side of the screen. Your browser will then ask if you would like to save or open the file named "ConsentDocument.rtf". Click the **Save** option. This will download the file to your workstation.
2. You can now edit this document using any standard word processing program such as MS Word and WordPerfect used on either a MAC or a standard PC. Make sure you save the document to your workstation in .rtf format.
3. Check the document into the iRIS system by clicking the **Check in Document** button. Use the **browse** button and find your document. Select your document, then select the **open** button. Select the **ok** button, then when back in the iRIS system, click the **Save Consent** link.

*** Please select the Consent Template:** Standard Consent ▼

Download Template

Depending on your Internet browser, version, and settings, you may or may not be prompted with the same file download information as below.

In this example, Google Chrome is used. The browser downloads the selected template and displays the file at the bottom of the screen.



Once the template is downloaded, you will be redirected to the **Study Consent Add** pop-up window shown below.

Study Consent Add:

* Consent Title:

* Select the consent to upload:

Please drop file/click here to upload

* Version Number: .0

* Version Date:

Category:

* Language:

Description:

Comments:

From this window you may upload the edited consent template that was downloaded in the last step. This is done with the **Select the consent to upload** field.

Once the document has been uploaded, complete the rest of the consent's required fields, and then click **Save Consent** to add the document to the submission.

2. Add an informed consent from an existing document you already have?

If you already have a consent document ready to upload, choose this option.

The **Study Consent Add** pop-up window will open.

The screenshot shows a window titled "Study Consent Add:". The window contains the following fields and controls:

- *Consent Title:** A text input field.
- *Select the consent to upload:** A dashed box containing the text "Please drop file/click here to upload".
- *Version Number:** A text input field with "1" and ".0" (partially visible).
- *Version Date:** A date input field with "07/12/2021" and a calendar icon.
- Category:** A dropdown menu with "--none--" selected.
- * Language:** A dropdown menu with "--none--" selected.
- Description:** A large text area.
- Comments:** A large text area.
- Buttons:** "Close, don't save any changes" and "Save Consent".

The fields in this window are described below:

Consent Title – This is the title of the consent you wish to upload.

Select the consent to upload – This is where you can upload your consent form. You may drag and drop your file directly into the dotted box or click the box to open a file upload window.

Version Number – Requires you to specify the version number of the new consent. This can be any character or number. Placed after the editable version number is a hard coded '0'. This is the iRIS™ version number for the consent. Any new document uploaded to the system will begin with the '0' affixed to your manually entered version number. Once a revision is made to the document, iRIS™ will change the '0' to '1'. It will continue to increment the numbers each time a revision is made.

Version Date – This is the date of the manually entered version number. This is typically the date that the Consent document was uploaded to the system.

Category – This configurable drop-down list allows you to group documents into certain categories.

Language – This configurable drop-down list allows you to select which language the consent is written in.

Description – A description of the document.

Comments – Any comments regarding the consent document you feel necessary to add for the review board.

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Enter the required information, then click the **Save Consent** button.

The Consent document will be uploaded to the study, and it will appear as attached to the Initial Review Submission Packet in the Consent Attachment section. You can remove the attached consent by clicking the icon in the **Detach** column. When you detach the Consent, you are removing it from the submission. If the record needs to be deleted, you will need to navigate to the study's "Submissions" page and open the Informed Consent library. Once a document is submitted it cannot be deleted from the study.

Once a Consent document is uploaded, an additional button will populate within the Informed Consent data value called **Select or Revise Existing**. This button is available whenever you have documents in the Informed Consent library and allows you to select from the existing Consent documents on the study. You can also make any edits to the attached Consent, if needed, by clicking this button.

Select or Revise Existing		Add a New Consent						
Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
	1.0	Standard Consent (English)	Consent	English				 2.68 MB

A new window will open, listing any existing Consent documents. Because only one record has been created for the study, only one record will display. It is already attached to the Initial Review Submission Packet, so you will not be able to re-attach it. To make changes to the document, click the icon in the **Edit** column.

Select Existing or Create Revised Protocol Consent X




Select Category: Title:

Version #: . Search level: Top All

Version Date: between Expiration Date: between

Consent Outcome:

1 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
						Category						
				1.0	06/23/2021	Standard Consent (English) Consent	English				 2.68 MB	

This triggers the Study Consent Revision window to open, shown below. From here you can make changes to the Consent details.

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Study Consent Revision:

* Consent Title: Standard Consent

Version Number: 1 .0

* Version Date: 07/26/2019

Category: ▾

* Language: English ▾

Description:

Check-out the Document to your workstation for editing: Check-out Document...

Comments:

Save Consent

You may check-out the document by clicking the **Check-out Document** button. Depending on your Internet browser, the download may require a few steps, but after it is downloaded you can edit the document outside of the iRIS™ system.

Once the document is checked out, you may return to the Study Consent Revision window. The page will indicate the document is checked out and will also give you the ability to check-in the document or undo the check-out with the **Check-in Document** and **Undo Check-out Document** buttons.

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Protocol Consent Revision

*Consent Title:

*Version Number: .

*Version Date:

Category:

*Language:

Description:

Comments:

Download Consent:

This document is currently checked out by.. **John Investigator at 06/23/2021 01:59:42 PM**

Check-in when you are done editing upload the document back into iRIS.

Revert to the document stored in iRIS.

Once you have made changes to the document in Microsoft Word, you can check it back in by navigating to the consent data value in the Initial Review form. Click **Select or Revise Existing**, as shown in the image below.

Select or Revise Existing		Add a New Consent							
Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document	
	1.1	Standard Consent (English)	Consent	English			John Investigator 06/23/2021 01:59:39 PM		

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

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Select Existing or Create Revised Protocol Consent

Select Category: --none--
 Version #: .
 Version Date: between
 Consent Outcome: --none--

Title:
 Search level: Top All
 Expiration Date: between

1 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
						Category						
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1.1	06/23/2021	Standard Consent (English) Consent	English			John Investigator 06/23/2021 01:59:42 PM	<input type="button" value="View Document"/> 2.68 MB	(Read Only)

Click the **Check-in Document** button.

Protocol Consent Revision

* Consent Title: Standard Consent (English)
 * Version Number: 1.1
 * Version Date: 06/23/2021
 Category: Consent
 * Language: English

Description:
 Comments:

Download Consent:

This document is currently checked out by.. John Investigator at 06/23/2021 01:59:42 PM

Check-in when you are done editing upload the document back into IRIS.

Revert to the document stored in IRIS.

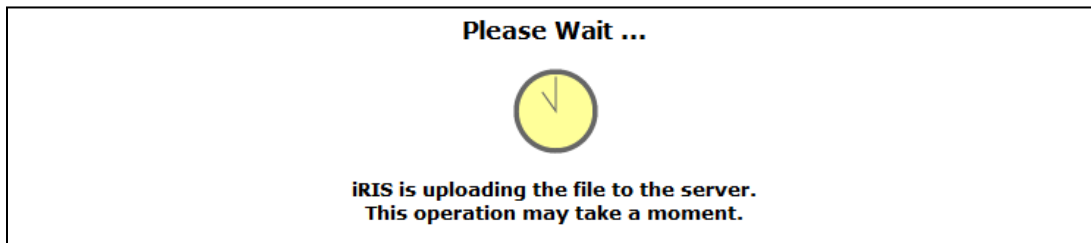
A popup window will open allowing you to browse your computer for the Consent document you would like to upload. Click the **Save selected file** button once you specify the document location. If you do not want to upload the document, click on the **Cancel** button.

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Document Location: No file chosen

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

Depending on the file size, you may see a message from the system indicating that iRIS™ is uploading the document.



You will then be returned to the Study Consent Revision window, with the document successfully checked in and associated to the study. Click the **Save Consent** button to apply the changes to the Initial Review.

Study Consent Revision: X

*Consent Title:	<input type="text" value="Standard Consent"/>
Version Number:	<input type="text" value="1"/> . <input type="text" value="0"/>
*Version Date:	<input type="text" value="07/26/2019"/> <input type="button" value="Calendar"/>
Category:	<input type="text"/>
* Language:	<input type="text" value="English"/>
Description:	<input type="text"/>
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>
Comments:	<input type="text"/>

Study Document Attachments

You may be directed to attach other supporting Study Documents. Any document you upload to the Initial Review Submission Packet will be attached to the form and will be submitted for review. The document(s) you upload will also be stored in the Other Study Document library in the study record. When the review board approves the document, the

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approval information will update the document stored in the library. From this library the document may be viewed, edited, and printed.

You can add as many documents as needed to the Document attachment data value. You can choose to add one document at a time, or if you have multiple documents, you can add them all at once using the **Add Multiple Documents** button.

Select Existing User Documents		Add a New Document			Add Multiple Documents			
Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.								

Add a New Document

To add one document to the Document attachment data value, click **Add a New Document**. This will open the following window.

***Document Title:**

***Select the document to upload:**

Please drop file/click here to upload

***Version Number:** .0

Version Date:

Category:

Description:

Comments:

The fields in this window are described as follows:

Document Title – The title you would like to display for this document. If you did not enter the Document Title prior to uploading the document, the system will automatically apply the name of the document to the Document Title field.

Select the document to upload – Attach the document by dragging and dropping to this window. You can also click within the box to upload the file manually.

Version Number - Requires you to specify the version number of the new document. This can be any character or number. Placed after the editable version number is a hard coded '0'. This is the iRIS™ version number. Any

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new document uploaded to the system will consist of the '.0' affixed to your manually entered version number. Once a revision is made to the document, iRIS™ will change the '.0' to '.1'. It will continue to increment the numbers each time a revision is made.

Version Date – This required field is the date of the manually entered version number. This is typically the date that the document was uploaded to the system. You may configure this field to auto-fill by turning on the *system.auto_fill_version_date* property.



Category – This configurable drop-down list allows you to group documents into certain categories. The categories displayed here are configurable via System Administration. This field may or may not be required based on the value of the *system.doc_category_required* property.

Description – A description of the document.

Comments – Any comments regarding the document you feel necessary to add for the review board.



Once the above required fields are completed and the document has been uploaded, click the **Save Document** button. The document will be uploaded to the study, and it will appear as attached to the Initial Review in the Other Study Documents Attachment section. You can remove the attached document by clicking the icon in the **Detach** column. When you detach a study document you are removing it from the submission. If the record needs to be deleted entirely, you will need to navigate to the study's "Submissions" page and open the Other Study Document library. Note that once a document is submitted it cannot be deleted from the study.

Once a document is uploaded, an additional button will populate in the Other Study Document data value: **Select or Revise Existing**. This button is available when you have existing documents in the Other Study Documents library and allows you to select and edit these existing documents.

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.0		Recruitment Flyer	Flyer				 1.12 KB

Add Multiple Documents

You can add multiple documents to the Document attachment field at once. Click on the **Add Multiple Documents** button.

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.0		Recruitment Flyer	Flyer				 1.12 KB

This will open a popup within the browser. Here you will be able to specify details for multiple documents at a time.

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Protocol Document Add Multiple: X

Add New Record(s)
Save Documents

* Document Title	* Version	Version Date	Sponsor Version	* Category	* File path
	.0			--none--	Choose File No file chosen
	.0			--none--	Choose File No file chosen
	.0			--none--	Choose File No file chosen
	.0			--none--	Choose File No file chosen
	.0			--none--	Choose File No file chosen

Document Title, Version, Category, and File Path are all required fields. If necessary, you can also add the **Version Date**.

If you need to add more than five documents at a time, click on the **Add New Record(s)** button and an additional five rows will populate in the window.

Protocol Document Add Multiple: X

Add New Record(s)
Save Documents

* Document Title	* Version	Version Date	Sponsor Version	* Category	* File path
Recruitment Flyer	1	06/23/2021		Flyer	Choose File Flyer.rtf
Sponsor Profile	1	06/23/2021		Other	Choose File Business Profile.docx
	.0			--none--	Choose File No file chosen
	.0			--none--	Choose File No file chosen
	.0			--none--	Choose File No file chosen

Once you enter the desired number of documents and the necessary details, click on the **Save Documents** button.



Any document you uploaded will now display in the table.

Select Existing User Documents		Select or Revise Existing		Add a New Document		Add Multiple Documents		
Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
⊗	1.0		Sponsor Profile	Other				 12.47 KB
⊗	1.0		Recruitment Flyer	Flyer				 1.12 KB
⊗	1.0		Recruitment Flyer	Flyer				 1.12 KB

The document details will display in the Other Study Documents attachment data value.

Once you upload at least one document, one more button at the top of the table is available: **Select or Revise Existing**. This will be addressed below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Select Existing User Documents		Select or Revise Existing		Add a New Document		Add Multiple Documents		
Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
	1.0		Recruitment Flyer	Flyer				 1.12 KB

Select or Revise Existing











Anytime you see this button available in the Other Study Documents attachment data value, it means that your study already has documents uploaded. Using this feature, you can select an existing document to add to the Initial Review Submission Form.

Clicking the **Select or Revise Existing** button will open the following popup window. Listed in the window will be any Other Study Documents associated to the study.


Select Existing or Create Revised Protocol Document X

Select Category: <input type="text" value="--none--"/>	Title: <input type="text"/>
Version #: <input type="text"/>	Search level: <input checked="" type="radio"/> Top <input type="radio"/> All
Version Date: <input type="text"/> between <input type="text"/>	Expiration Date: <input type="text"/> between <input type="text"/>
Document Outcome: <input type="text" value="--none--"/>	

3 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out By	View Document	Create Revision
				1.0	06/23/2021		Recruitment Flyer	Flyer				 1.12 KB	
				1.0	06/23/2021		Recruitment Flyer	Flyer				 1.12 KB	
				1.0	06/23/2021		Sponsor Profile	Other				 12.47 KB	

Attaching the Document

You can attach any document to the form by clicking on the  icon in the Select column. This will associate the document to the form.

Note: If a document is already associated to the form (as is the case in the example above), no icon will display in this column. Also, you cannot delete a document that is associated to the form. If no icon displays in the Delete column, the document needs to be removed from the submission before it can be deleted (provided the document has not been submitted for review).

Checkout the Document for Editing

You can also edit the details of the document prior to attaching the document to the form by clicking on the icon in the **Edit Details** column.

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This will open the Study Document Revision window. From here you can make any desired changes to the document details, or if you need to modify the content of the document itself, you can check out the document.

The screenshot shows a window titled "Protocol Document Revision:". The window contains the following fields and buttons:

- * Document Title:** Recruitment Flyer
- Version Number:** 1
- Version Date:** 06/23/2021
- Sponsor Version:** (empty)
- * Category:** Flyer
- Description:** (empty text area)
- Comments:** (empty text area)
- Download Document:** Download
- Check-out the Document to your workstation for editing:** Check-out Document...
- Close, don't save any changes** button
- Save Document** button
- View Document** button (with RTF icon)

If checking the document out, returning to the Study Document Revision window will give you the ability to check-in the document or undo the document check-out via the **Check-in Document** or **Undo Check-out Document** buttons.

Click the **Check-in Document** button to check back in the document after the desired changes have been made.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Protocol Document Revision:

* Document Title: Recruitment Flyer

Version Number: 1 .1

Version Date: 06/23/2021

Sponsor Version:

* Category: Flyer

Description:

Comments:

Download Document: Download

This document is currently checked out by: John Investigator at 06/23/2021

Check-in when you are done editing upload the document back into iRIS. Check-in Document...

Revert to the document stored in iRIS. Undo Check-out Document...

Close, don't save any changes Save Document

View Document

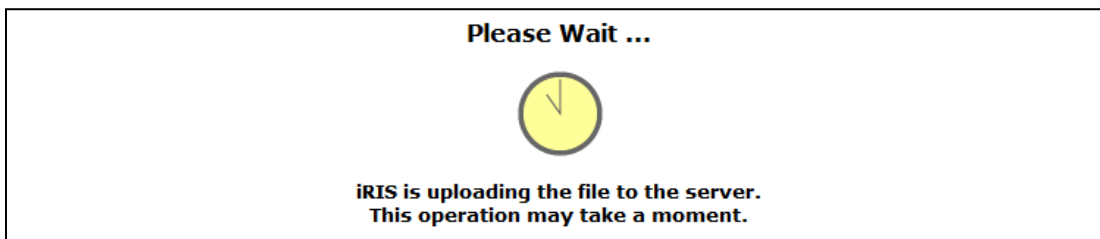
A popup window will open allowing you to browse your computer for the document you would like to upload. Click the **Save selected file** button once you specify the document location. If you do not want to upload the document, click on the **Cancel** button.

Document Location: Choose File No file chosen

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

Save selected file Cancel

Depending on the file size, you may see a message from the system indicating iRIS™ is uploading the document.



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You will then be returned to the Study Document Revision window, with the document successfully checked in and associated to the study. Click the **Save Document** button to apply the changes to the Initial Review Submission Packet.

Protocol Document Revision:

*Document Title: Recruitment Flyer

Version Number: 1 .1

Version Date: 06/23/2021

Sponsor Version:

* Category: Flyer

Description:

Comments:

Download Document: Download

Check-out the Document to your workstation for editing: Check-out Document...

Close, don't save any changes Save Document

View Document
RTF

When the document is checked out, the page will read that the document is checked out and display the name of the user and the date that the document was checked out.

Viewing the Document

To view any document prior to attaching it to a form, click on the icon in the **View the Document** column.

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Select Existing or Create Revised Protocol Document

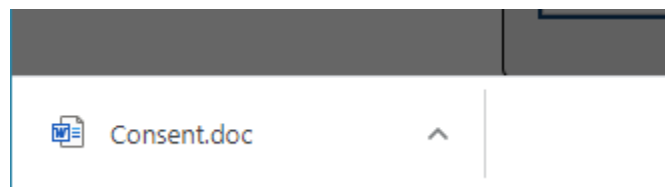
Select Category: --none--
Version #: .
Version Date: between
Document Outcome: --none--
Title:
Search level: Top All
Expiration Date: between

Add a New Document Filter Documents

3 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Title	Expiration Date	Document Outcome	Checked Out By	View Document	Create Revision
				1.1	06/23/2021		Recruitment Flyer				1.15 KB	
				1.0	06/23/2021		Recruitment Flyer				1.12 KB	
				1.0	06/23/2021		Sponsor Profile				12.47 KB	

Depending on your Internet browser settings you may need to allow the download or confirm a popup window asking if you want to Open or Save the file. In the example below, the user is using Google Chrome, and the file automatically downloads and is displayed at the bottom of the browser window.



Create Revision

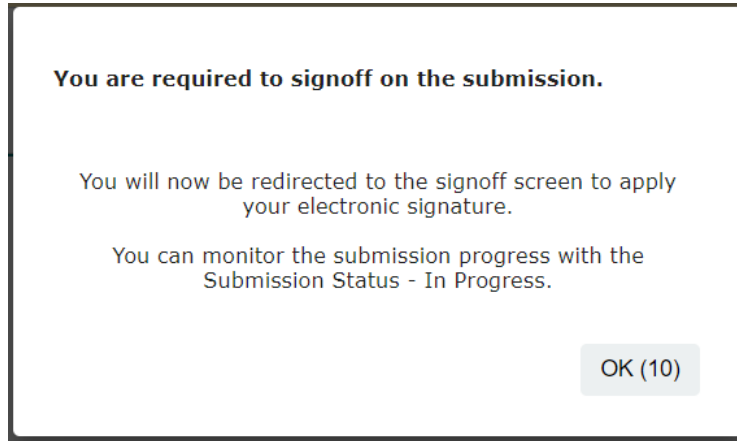
You also have the ability to revise a document. When doing so, the system will update the document to the next version number, for example changing the version number from x.0 to x.1 when you choose to create a revision of a newly added document.

Signoff and Submit

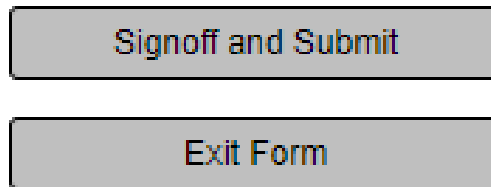
Once the Study Application is complete and the required documents are attached, the form is ready to send to the review board.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

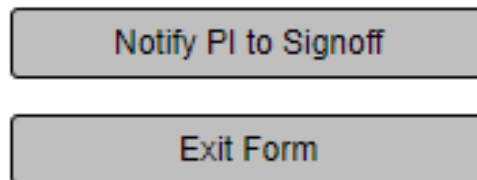
You will be presented with a section in the form notifying you that the form is complete. Depending on your role on the study, and your systems signoff requirements, you may see different buttons on this page or a different notification.



If you are on the routing list for this form, the following buttons will appear.



If you are not the Principal Investigator on this study and the form requires a PI signature, the buttons on this page will be **Notify PI to Signoff** and **Exit Form**.



If your role on the study does not allow submission of forms, when you reach this page, you will only have the **Exit Form** button option. You will exit the form, and the Principal Investigator and Study Contact will be notified that a submission is waiting to be sent.



To initiate the signoff process, click the **Signoff and Submit** or **Notify PI to signoff** button, depending on which is available to you. At this point, you may be prompted to route for additional signatures.

Setup for Submission Routing and Signoff
X

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="checkbox"/>	John Investigator	Principal Investigator
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Tom Jefferson	Co-Investigator
<input type="checkbox"/>	<input type="checkbox"/>	George Jefferson	Nurse
<input type="checkbox"/>	<input type="checkbox"/>	Nathan Mossman	Nurse
<input type="checkbox"/>	<input type="checkbox"/>	Sean Coordinator	Additional Principal Investigator

Select Additional Personnel for Submission Routing and Signoff: Add Additional Personnel to the Routing List

Include in signoff	Order	Approved	Name	Role
No additional personnel have been added to the signoff routing list.				

Cancel - Finalize later
Save - Signoff Routing List

You may choose to route for additional signatures if you need to have other study personnel review the form before it reaches the review board, or if you first need department approval.

If the Principal Investigator signature is required on this form, that user will be pre-selected in the personnel display table, and you will not be able to deselect them.

Setup for Submission Routing and Signoff X

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		John Investigator	Principal Investigator
<input checked="" type="checkbox"/>		Tom Jefferson	Co-Investigator
<input type="checkbox"/>		George Jefferson	Nurse
<input type="checkbox"/>		Nathan Mossman	Nurse
<input type="checkbox"/>		Sean Coordinator	Additional Principal Investigator

Select the name(s) of the any additional personnel you would like to include in the signoff process.






You can also add non-KSP reviewers to the signoff list by clicking the **Add Additional Personnel to the Routing List** button, as shown below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup for Submission Routing and Signoff

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		 John Investigator	Principal Investigator
<input checked="" type="checkbox"/>		 Tom Jefferson	Co-Investigator
<input type="checkbox"/>		 George Jefferson	Nurse
<input type="checkbox"/>		 Nathan Mossman	Nurse
<input type="checkbox"/>		 Sean Coordinator	Additional Principal Investigator

Select Additional Personnel for Submission Routing and Signoff:

Add Additional Personnel to the Routing List

Include in signoff	Order	Approved	Name	Role
No additional personnel have been added to the signoff routing list.				

This will open a new page allowing you to search the database for a user. Use the Last Name, First Name, Department search filters to find the user you wish to add, then click the icon in the **Select User** column.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Add Additional Key personnel to the Routing Signoff List X

Last Name: First Name:
by Department: Find User/Search Directory

Select	Name	Department	Email
No results found.			

The Additional Personnel will to be added to the signoff routing list upon clicking the "Save - Add to Routing List" button

Remove	Name	Role
No additional personnel have been added to the signoff routing list.		

Add Additional Key personnel to the Routing Signoff List X

Last Name: First Name:
by Department: Find User/Search Directory

Select	Name	Department	Email
<input checked="" type="checkbox"/>	Sykes, Jeff	General Hospital	

The user you selected will add to the signoff list as shown below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup for Submission Routing and Signoff

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input type="checkbox"/>		John Investigator	Principal Investigator
<input checked="" type="checkbox"/>		Tom Jefferson	Co-Investigator
<input type="checkbox"/>		George Jefferson	Nurse
<input type="checkbox"/>		Nathan Mossman	Nurse
<input type="checkbox"/>		Sean Coordinator	Additional Principal Investigator

Select Additional Personnel for Submission Routing and Signoff: Add Additional Personnel to the Routing List

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		Jeff Sykes	Department Chair

Cancel - Finalize later Save - Signoff Routing List

Make sure you check the checkbox next to users you want to include in the signoff process. You can also set the **Order** in which the users will receive their signoff task. iRIS™ will default each user to the order of 1, which means they will all receive their task at the same time. You can change this if one reviewer should receive the task before another.






Click the **Save – Signoff Routing List** button when you are ready to proceed.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01


Setup for Submission Routing and Signoff

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input type="checkbox"/>		 John Investigator	Principal Investigator
<input checked="" type="checkbox"/>		 Tom Jefferson	Co-Investigator
<input type="checkbox"/>		 George Jefferson	Nurse
<input type="checkbox"/>		 Nathan Mossman	Nurse
<input type="checkbox"/>		 Sean Coordinator	Additional Principal Investigator

Select Additional Personnel for Submission Routing and Signoff: Add Additional Personnel to the Routing List

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		 Jeff Sykes	<input type="text" value="Department Chair"/>

Cancel - Finalize later Save - Signoff Routing List




This will take you to a summary page, displaying all the users you selected for the signoff process.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup for Submission Routing and Signoff

i This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel - Finalize later" will close this window. The submission process is incomplete, not eligible for submission, until the routine is complete.

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		 John Investigator	Principal Investigator
		 Tom Jefferson	Co-Investigator
1		 Jeff Sykes	Department Chair

Please verify the list above represents the finalized Personnel for review and signoff? Yes No

If you need to further modify the signoff list, click the **Go back and Make changes** or **Cancel – Finalize later** buttons.




When you are ready to initiate the signoffs, ensure you have selected “Yes” next to the question, ‘Please verify the list above represents the finalized Personnel for review and signoff?’. Doing so will enable the **Save – Start Signoff Routing** button as shown below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup for Submission Routing and Signoff

i This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel - Finalize later" will close this window. The submission process is incomplete, not eligible for submission, until the routine is complete.

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		 John Investigator	Principal Investigator
		 Tom Jefferson	Co-Investigator
1		 Jeff Sykes	Department Chair

Please verify the list above represents the finalized Personnel for review and signoff? Yes No

If you choose “Yes” and click the **Save – Start Signoff Routing** button, and you are assigned to sign off on the application, you will be brought to the Signoff Page shown below.

You are required to signoff on the submission.

You will now be redirected to the signoff screen to apply your electronic signature.

You can monitor the submission progress with the Submission Status - In Progress.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

My Workspaces ▾ Study Assistant **Submission Routing Signoff** Back

Save Signoff

Study Title: COVID 19 Complications in adults 55 and older
 Submission Reference Number: 001320 Create PDF Packet

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>			
Submission Form(s)			
<input type="checkbox"/>			Initial Review Submission Form
Application			
<input type="checkbox"/>			IRB Application

John Investigator as Principal Investigator
 Do you Approve or Deny this submission? Approve Deny Comments: [Click here to add comments.](#)

This form requires your electronic signature.
 Please enter your User ID & Password: User ID: Password:

Save Signoff

View Other Comments:

Andrew Investigator Co-Investigator
 Comments:

If you choose “Yes” and click the **Save – Start Signoff Routing** button, and you are NOT assigned to sign off on the application, you will be brought to the Workflow Submission Tracking page and the users assigned to sign off will receive notifications from iRIS™ regarding their new assignments.

Pre-Submission

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
Pre-Submission Retract Submission			06/24/2021 11:07 AM PDT		0 Day(s) 4 Hour(s) 28 Minute(s)
Completed		Initial Review Submission Form is waiting to be submitted	06/24/2021 11:07 AM PDT	06/24/2021 03:35 PM PDT	Day Hour Minute 0 0 0
Completed		Submission rejected	06/24/2021 11:14 AM PDT	06/24/2021 12:22 PM PDT	Day Hour Minute 0 0 0
Completed		Initial Review Submission Form has been retracted by John Investigator	06/24/2021 12:22 PM PDT	06/24/2021 12:22 PM PDT	Day Hour Minute 0 0 0
Received	Modify Signoff Routing List	Assign Department Personnel for Signoff	06/24/2021 03:35 PM PDT	06/24/2021 03:36 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	06/24/2021 03:36 PM PDT	06/24/2021 03:36 PM PDT	Day Hour Minute 0 0 0
Received	Pending Signoff	Tom Jefferson as Co-Investigator review and apply signoff, assigned by John Investigator	06/24/2021 03:36 PM PDT		Day Hour Minute 0 0 0

A user who is assigned to sign off on the Initial Review Submission Form/Study Application will receive a notification sent to the email address defined in their user account. They will also receive a *Submission Routing Signoff* task on their homepage. This task will remain on their homepage until the user opens the task and completes the sign off.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

All Tasks **Outstanding** **Completed** ⚙️

All Tasks **Study Tasks** Task List : All Filter By : --none--

22 result(s) found... 1 - 5 ▶

<input type="checkbox"/>	Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>		Submission Routing Signoff	07/20/2021 11:58 AM PDT	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	No Priority	<input type="text"/>
<input type="checkbox"/>		Conflict of Interest Study Disclosure Questionnaire	07/19/2021 09:39 AM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	No Priority	<input type="text"/>
<input type="checkbox"/>		Conflict of Interest Study Disclosure Questionnaire	07/19/2021 08:10 AM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	Low	<input type="text"/>
<input type="checkbox"/>		Conflict of Interest Study Disclosure Questionnaire	07/19/2021 08:08 AM PDT	Notice to complete conflict of interest study disclosure questionnaire assigned to John Investigator	Medium	<input type="text"/>
<input type="checkbox"/>		Continuing Review Due	07/16/2021 03:30 AM PDT	Pending Expiration Notice for 60 Day Continuing Review Notification with the expiration date of 09/14/2021	High	<input type="text"/>

22 result(s) found... 1 - 5 ▶

When the task is opened, the Submission Routing Signoff page will display.

My Workspaces ▾ Study Assistant **Submission Routing Signoff** ⏪ Back

Study Title: COVID 19 Complications in adults 55 and older
Submission Reference Number: 001320

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>	<input type="checkbox"/>		Initial Review Submission Form
Application			
<input type="checkbox"/>	<input type="checkbox"/>		IRB Application

Submission Form(s):

John Investigator as Principal Investigator
Do you Approve or Deny this submission? Approve Deny Comments:

This form requires your electronic signature.
Please enter your User ID & Password:
User ID:
Password:

View Other Comments:

Andrew Investigator: Co-Investigator
Comments:

At the top of the page, the Study Title and Submission Reference Number are listed. iRIS™ assigns a unique reference number to each form created in the system. The Reference Number displayed here is the number assigned to the Initial Review Submission.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Also listed on this page is a link to the Submission Components. This table contains a link to the Initial Review Submission Form, the Study Application, and any Consent and Other Study Document that has been associated to the form. This is the package that is being submitted to the review board for review. Before applying your signature, you can review any of the attachments and make any necessary changes.

The screenshot shows the 'Submission Routing Signoff' page. At the top, there are navigation elements: 'My Workspaces' with a dropdown arrow, 'Study Assistant', and 'Submission Routing Signoff' with a 'Back' button. A 'Save Signoff' button is in the top right. Below the navigation, the study details are: 'Study Title: COVID 19 Complications in adults 55 and older' and 'Submission Reference Number: 001320'. A 'Create PDF Packet' button is on the right. The main content is a table with columns: 'Include in PDF Packet', 'Compare to Last Approved', 'View in Separate Window', and 'Submission Component Name'. The table lists two components: 'Initial Review Submission Form' and 'IRB Application'. The 'Initial Review Submission Form' row has a checked checkbox in the 'Include in PDF Packet' column and a document icon in the 'View in Separate Window' column. The 'IRB Application' row has an unchecked checkbox in the 'Include in PDF Packet' column and a document icon in the 'View in Separate Window' column.

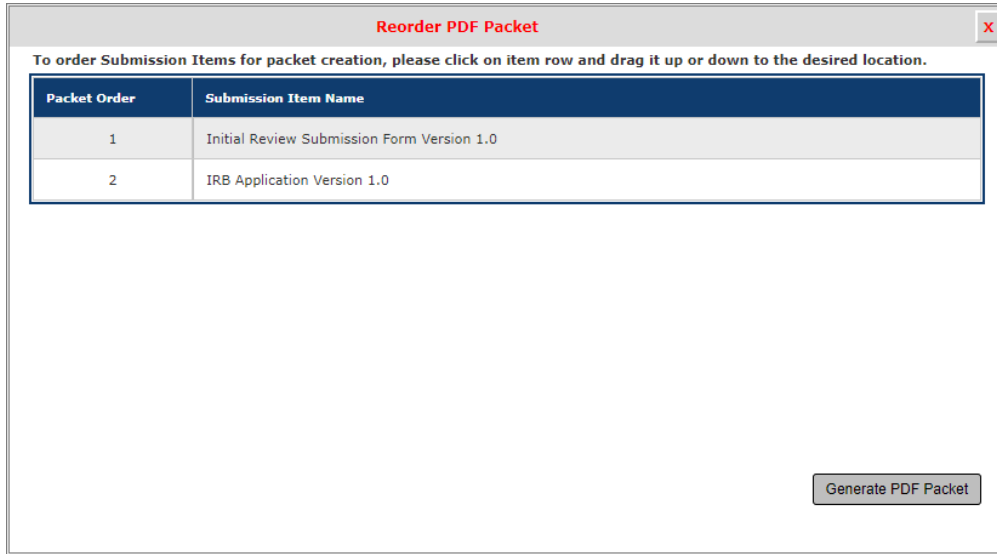
Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input checked="" type="checkbox"/>			Initial Review Submission Form
<input type="checkbox"/>			IRB Application

If configured, you will also see a customizable Attestations section that can be set to require the user to agree to conditions set forth by the review board.

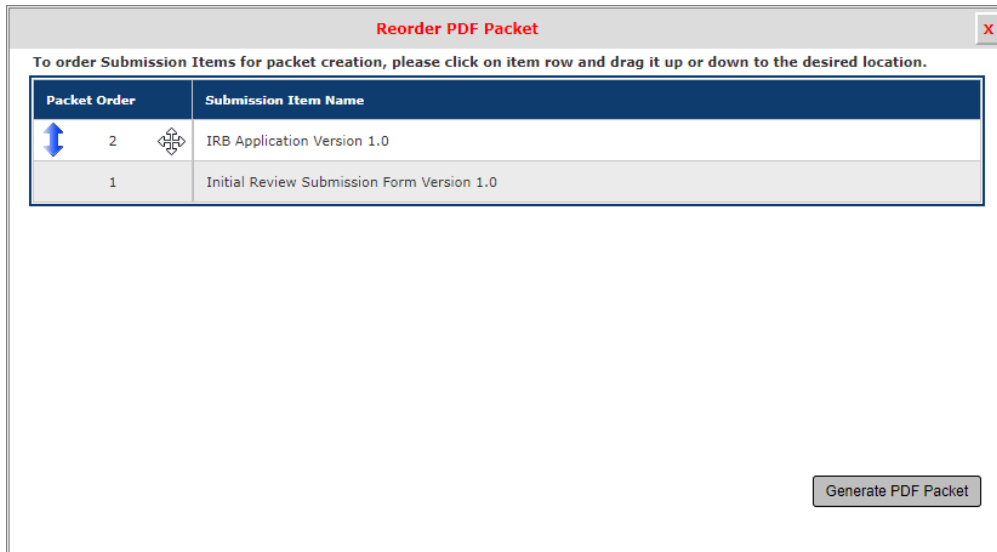
The screenshot shows the 'Submission Routing Signoff' page with the 'IRB Application' component selected. Below the table, there is a section titled 'REVIEW BOARD INVESTIGATOR AGREEMENT'. It starts with 'I certify that:' followed by a list of 11 bullet points regarding research protocols, safety, reporting, and informed consent. Below the list is a statement: 'I hereby give assurance that in conducting this research project I will comply with the statements indicated above, policies, procedures, and Regulations related to research with human subjects. I have completed required training pertaining to research with human subjects and I am familiar with the regulatory and ethical requirements necessary to conduct this project.' There are radio buttons for 'Agree' and 'Disagree'. At the bottom, there is a section for 'John Investigator as Principal Investigator Do you Approve or Deny this submission?' with 'Approve' and 'Deny' radio buttons, a 'Comments:' field with a 'Click here to add comments.' button, and a section for 'This form requires your electronic signature. Please enter your User ID & Password:' with 'User ID:' and 'Password:' input fields. A 'Save Signoff' button is in the bottom right corner.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Some of the attachments are available to print. If a document can be printed, a check box will populate next to the document in the **Include in PDF Packet** column. You can select any of these items then click the **Create PDF Packet** button at the top of the table to display the following popup.

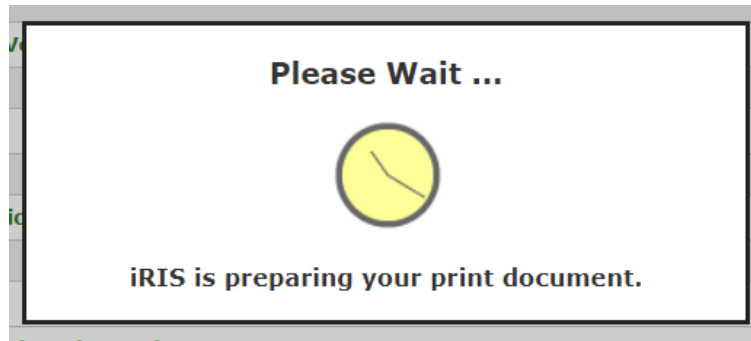


From here the user can click and drag to change the order of the items in the packet as shown below.

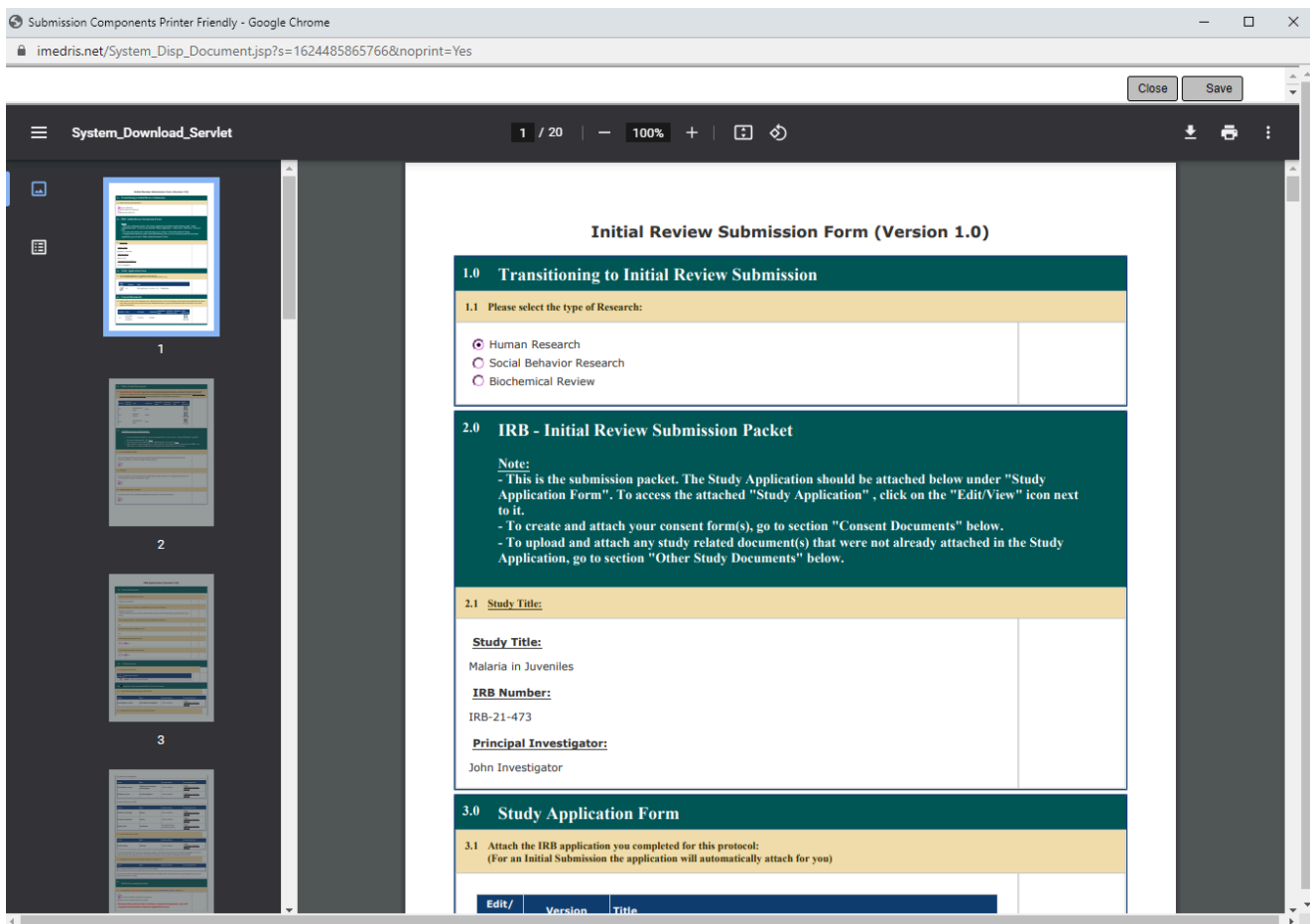


Once the order of the items is satisfactory, click the **Generate PDF Packet** button to create the PDF packet.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01



While the system prepares your documents, you may be prompted with the waiting icon above. Once the system has finished generating the PDF packet, a new browser window will open displaying this PDF.



You can save this PDF or print it. When you are finished, click the **Close** button.

Below Submission Components table you might be prompted to enter your electronic signature. You must indicate whether you **Approve** or **Deny** the submission then enter your User ID and Password then click on the **Save Signoff** button. Below the electronic signature portion of the page you will be able to see any other Key Personnel listed for signoff. If any of the additional signoffs have been completed, their approval or denial information will populate here.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

John Investigator as Principal Investigator
Do you Approve or Deny this submission? Approve Deny

Comments:

This form requires your electronic signature. Please enter your User ID & Password:

User ID: Password:

View Other Comments:

Tom Jefferson Co-Investigator
Comments:

If you select **Approve**, iRIS™ will assign the next user in the list their *Submission Signoff Routing* task and the submission will continue in the workflow. iRIS™ will then take you to the Study Assistant Workspace Study Submission Status – In Progress panel with the submission status displayed for the submission as shown below:

Protocols Submission Status - In Progress

16 result(s) found... 1 - 5 ▶

Click to open Protocol Dashboard	Reference Number	Form Name	Protocol Title	Form Author	Date Submitted	Actions
			Protocol Alias			
	IRB-21-473-NEW-1.0	Initial Review Submission Form	Malaria in Juveniles	Investigator, John	06/23/2021 02:56 PM PDT	Incomplete Tasks Open Steps to Complete
<input type="button" value="Pre-Submission"/>						
Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time	
<input type="checkbox"/>		<input type="button" value="Retract Submission"/>	06/23/2021 02:35 PM PDT		0 Day(s) 0 Hour(s) 31 Minute(s)	
Completed		Initial Review Submission Form is waiting to be submitted	06/23/2021 02:35 PM PDT	06/23/2021 02:56 PM PDT	Day Hour Minute 0 0 0	
Completed		Initial Review Submission Form has been retracted by John Investigator	06/23/2021 02:51 PM PDT	06/23/2021 02:51 PM PDT	Day Hour Minute 0 0 0	
Completed		Initial Review Submission Form has been retracted by John Investigator	06/23/2021 02:56 PM PDT	06/23/2021 02:56 PM PDT	Day Hour Minute 0 0 0	
Received	<input type="button" value="Modify Signoff Routing List"/>	Assign Department Personnel for Signoff	06/23/2021 02:56 PM PDT	06/23/2021 02:57 PM PDT	Day Hour Minute 0 0 1	
Completed	<input type="button" value="View Signoff"/>	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	06/23/2021 02:57 PM PDT	06/23/2021 03:06 PM PDT	Day Hour Minutes 0 0 9	
Received	<input type="button" value="Pending Signoff"/>	Tom Jefferson as Co-Investigator review and apply signoff, assigned by John Investigator	06/23/2021 02:57 PM PDT		Day Hour Minutes 0 0 10	

If you select **Deny**, any other signoff task will cancel, and this signoff denial will be recorded in the submission history. The Principal Investigator and Study Contact will also receive a Submission Signoff Denied task. This will allow the PI to make any needed corrections and then resubmit the application.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

<input type="checkbox"/>		<input type="checkbox"/>	Submission Signoff Denied	06/10/2021 01:15 PM PDT
--------------------------	--	--------------------------	---------------------------	-------------------------

My Workspaces System Administration **Signoff Denied** Back

Protocol Title: SKK Lumbar Disc Herniation Study
Submission Reference Number: 001218
Signoff Details:

John Smith Principal Investigator
Comments:
 Click on the hyperlink to view the submission.


If the user wants to modify the Routing Signoff List, they can click on the **Modify Signoff Routing List** button in Submission History and the following window will appear.

My Workspaces IRB Number: **IRB-21-483** Study Assistant **Workflow - Submission Tracking** Back




Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<input type="checkbox"/> Pre-Submission <input type="button" value="Retract Submission"/>			07/12/2021 03:51 PM PDT		0 Day(s) 0 Hour(s) 7 Minute(s)
Completed		Initial Review Submission Form is waiting to be submitted	07/12/2021 03:51 PM PDT	07/12/2021 03:51 PM PDT	Day Hour Minute 0 0 0
Received	<input type="button" value="Modify Signoff Routing List"/>	Assign Department Personnel for Signoff	07/12/2021 03:51 PM PDT	07/12/2021 03:52 PM PDT	Day Hour Minute 0 0 0
Received	<input type="button" value="Pending Signoff"/>	John Investigator as Principal Investigator review and apply signoff, assigned by John Investigator	07/12/2021 03:52 PM PDT		Day Hour Minutes 0 0 7
Received	<input type="button" value="Pending Signoff"/>	Andrew Investigator as Co-Investigator review and apply signoff, assigned by John Investigator	07/12/2021 03:52 PM PDT		Day Hour Minutes 0 0 7

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Setup for Submission Routing and Signoff

 This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel -

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
	Yes	 John Investigator	Principal Investigator
		 Tom Jefferson	Co-Investigator
1		 Jeff Sykes	Department Chair

Please verify the list above represents the finalized Personnel for review and signoff? Yes No

Once all assigned users have completed their sign off tasks and they have indicated approval of the submission, the form will go to the review board's submission queue for processing.

At any time during the sign off process, or while the review board is processing your submission, you can check the status of the form and where it is currently located. Open your study record in My Studies and navigate to the Submissions page. Your submission will display in the Outstanding Submission(s) queue. You can click on the icon in the **Track Location** column.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

My Workspaces IRB Number: **IRB-21-473** Study **Submissions** Back

Protocol Status: **Pending - Submitted for Initial Review** IRB Number: IRB-21-473 Protocol Title: Malaria in Juveniles

Submissions Protocol Management

Protocol Items

- Protocol Application
- Informed Consents
- Other Protocol Documents
- Contract Documents
- Reportable Event Form
- Initial Review Submission Form

Submissions History

Protocol Correspondence

Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
Waiting for signoffs	IRB-21-473-NEW-1.0	Click on the hyperlink to edit/view the submission. Initial Review Submission Form	Retract Submission

This will open the same Workflow Submission Tracking screen as that which opens after completing a signoff task. The workflow will update as the submission moves forward in its processing.

Print Friendly

Pre-Submission → IRB Completed

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
Pre-Submission			06/18/2021 05:53 PM PDT	06/18/2021 05:53 PM PDT	0 Day(s) 0 Hour(s) 0 Minute(s)
Completed		Initial Review Submission Form is waiting to be submitted	06/18/2021 05:53 PM PDT	06/18/2021 05:53 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	06/18/2021 05:53 PM PDT	06/18/2021 05:53 PM PDT	Day Hour Minute 0 0 0
Completed	View Signoff	John Investigator as Principal Investigator review and apply signoff	06/18/2021 05:53 PM PDT	06/18/2021 05:53 PM PDT	Day Hour Minute 0 0 0
IRB	View Details	Submission Components Review Process Pre-Review changes requested Review Outcome Outcome Letters	06/21/2021 06:39 AM PDT		21 Day(s) 9 Hour(s) 55 Minute(s)

The screenshot above shows that the submission successfully passed required signoffs and has been received by the IRB, who has requested pre-review changes.

If users you have assigned have not completed their signatures, the Workflow would show that they are still in process. The Principal Investigator and the Study Contact would also receive notifications from the system to alert them that a certain user has not completed signoff yet.

Responding to Corrections

The review board may return items to you for correction. When a submission is returned for corrections, the Principal Investigator and any Study Contacts listed on the study will receive a notification from iRIS™ alerting them of the request. They will also receive a task on the homepage called *Submission Correction* or, if a review board has met on your submission and returned it for corrections based on the review, the task will be called *Review Response*.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

The screenshot below shows a task for Pre-Review Changes, called a *Submission Correction*. This task will remain on your homepage until you respond to the corrections and resubmit the form to the review board. Click the icon in the **Open** column to open the Pre-Review Corrections form.

The screenshot displays the 'All Tasks' interface. At the top, there are tabs for 'All Tasks', 'Outstanding', and 'Completed'. Below this, there are sub-tabs for 'All Tasks' and 'Study Tasks'. The 'Task List' dropdown is set to 'Submission Correction' and the 'Filter By' dropdown is set to '--none--'. The interface shows '1 result(s) found...' and a table with one task. The task is highlighted with a red border.

	Click to open	Task Type	Date Received	Description	Priority	Complete By
<input type="checkbox"/>		Submission Correction	06/30/2021 01:43 PM PDT	IRB returned the submission for corrections , assigned by John Smith	> High	<input type="text" value="07/22/2021"/>

When you open the task, a Pre-Review Correction or a Review Response form will open. This form works similar to other forms in the system, where you navigate through the form using the **Save and Continue** button on the top right and the navigation pane on the left side of the page.

Responding to Stipulations

Stipulations Linked to Forms or Documents

Any stipulations added by the review board will populate within the Pre-Review Corrections form. Some stipulations may direct you to a document or form that needs to be changed.

The screenshot displays the 'Review Response Form' interface. At the top, there are tabs for 'Section view of the Form' and 'Entire view of the Form'. The main content area is titled '1.0 Review Response Form' and contains a section '1.1 Stipulations'. A warning icon indicates 'Stipulation 1 out of 1:'. The 'Description' field contains the text: 'Please attach the study lay summary in a separate document.' Below this, the 'Stipulation Type' is 'Stipulation must be addressed'. A 'Links to Components' section lists one component with the following details:

Operation	Action Status	Component Name	Action
Add New Attachment	Action Not Complete	Please add the Study Document	Add Document

Below the table, there are radio buttons for 'Do you accept this Stipulation?' with options 'N/A', 'Yes', and 'No'. A rich text editor is visible below the radio buttons, and a text area at the bottom is labeled 'Provide an explanation on how you addressed this Stipulation:'.

The **Description** at the top of the stipulation will detail what the review board is requesting for the change.

The **Stipulation Type** will display either “Stipulation must be addressed,” “Comment must be addressed,” or “Comments.”

The **Links to Components** section of the stipulation will list the details about the linked component(s).

For each linked component, as seen above, the following fields will display:

Operations – A read-only icon used to distinguish the modification request type.

Action Status – This is the current state of the requested change as it pertains to the linked component.

Component Name – The component the link is associated to.

Action –This is the available corrective action that can be taken on the component.

Add and Remove Components

The example below details a stipulation that is request changes to the submission’s attached documents.

Note: Removing a document from a submission will not delete the document. The document will still be located in the document library for the study.

In this example, the stipulation is to add a new attachment (Study Documents, Consent forms, Sub/Attachment forms) to the Initial Review form. The view of this stipulation from the study-side of the system is shown below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Stipulation 1 out of 1:

Description:
Please attach the study lay summary in a separate document.

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Add New Attachment	Action Not Complete	Please add the Study Document	Add Document

Do you accept this Stipulation?
 N/A Yes No

In order to respond to this request, click **Add Document**. This will open the following **Study Document Add** pop-up window.

Study Document Add:

*Document Title:

*Select the document to upload:

Please drop file/click here to upload

*Version Number: .0

Version Date:

Sponsor Version:

* Category:

Description:

Comments:

The requested document may be uploaded here and saved to the study by clicking **Save Document**.


After you have added the document, the status of the stipulation action will update to **Action Complete**, as shown below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Stipulation 1 out of 1:

Description:
Please attach the study lay summary in a separate document.

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Action Status	Component Name	Action
	Add New Attachment	Action Complete	 Study Document Study Lay Summary (Version 1.0)	<input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action

Do you accept this Stipulation? N/A Yes No


If you need to view or make any other changes to the document, you may open the document using the edit/view icon in the **Component Name** column.

After the stipulation action is completed, you may complete the stipulation review by selecting “Yes” or “No” for the **Do you accept this Stipulation?**. You may also add an explanation on how you addressed the stipulation.

Stipulation 1 out of 1:

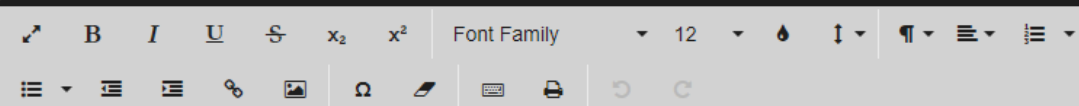
Description:
Please attach the study lay summary in a separate document.

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Action Status	Component Name	Action
	Add New Attachment	Action Complete	 Study Document Study Lay Summary (Version 1.0)	<input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action

Do you accept this Stipulation? N/A Yes No

Provide an explanation on how you addressed this Stipulation:



Revise Components – Consents and Other Study Documents

If the stipulation is requesting a change to a Consent or Other Study Document already attached to the submission, the study-side personnel will be given the ability to modify the document’s details, edit the document content, or replace with a brand-new document.

⚠ Stipulation 1 out of 1:

Description:
Please edit the title of this consent document to be more descriptive.

Stipulation Type: (Stipulation must be addressed)

<p>Links to Components (These are the items that are linked to this stipulation)</p>	Operation	Action Status	Component Name	Action
	Modify Existing Attachment	Action Not Complete	📖 Study Document Study Consent Demo Test Consent 1 (Version 1.1)	<input type="button" value="Revise Existing"/>

Do you accept this Stipulation?
 N/A Yes No

Click **Revise Existing** to create a new version of the attached document. Doing so will open the following **Study Document Revision** window, where you may modify the document details, check-out the document, and view it.

Study Document Revision:

View Document

*Document Title:	<input type="text" value="Study Consent Demo Test Consent 1"/>
Version Number:	<input type="text" value="1"/> .2
Version Date:	<input type="text" value="07/13/2021"/>
Sponsor Version:	<input type="text"/>
* Category:	Flyer
Description:	<div style="border: 1px solid gray; height: 30px;"></div>
Comments:	<div style="border: 1px solid gray; height: 30px;"></div>
Download Document:	<input type="button" value="Download"/>
Check-out the Document to your workstation for editing:	<input type="button" value="Check-out Document..."/>

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Once the details of the revised document are completed, click **Save Changes** to attach the new document version to the submission packet.

The original document and the current document will display in the **Component Name** column. The **Status** column will update to reflect the action is complete.

Stipulation 1 out of 1:

Description:
Please edit the title of this consent document to be more descriptive.

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Action Status	Component Name	Action
	Modify Existing Attachment	Action Complete	Study Document Study Consent for Subject D-56 (Version 1.2) Study Document Study Consent Demo Test Consent 1 (Version 1.1)	Compare Document Version <input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action

Revise Components – Study Application or Submission Forms

If the stipulation is requesting a revision to a Submission Form or a Study Application, the system will create a revision of that form and open the new version for you to make your changes.

For this operation you are given multiple options to respond to the request. You can choose to **Select Already prepared** or **Revise Existing**. The **Select Already prepared** action button will retrieve the study application library where you can select to attach a newer version of the application. The **Revise Existing** action button will allow you to create a new, editable, version of the application where the changes can be made.

The stipulation below requests modification to the Initial Review Submission Form.

Stipulation 1 out of 1:

Description:
Are you sure that this is a human study?

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Action Status	Component Name	Action
	Modify Existing Attachment	Action Not Complete	Initial Review Submission Form (Version 1.0) Section: Transitioning to Initial Review Submission Question: Please select the type of Research:	Revise Existing

Do you accept this Stipulation?
 N/A Yes No

Clicking **Revise Existing** creates a new, editable version of the Initial Review form, as shown below.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Section view of the Form

Entire view of the Form

- 1.0 Transitioning to Initial Review Submission
- 2.0 IRB - Initial Review Submission Packet
- 3.0 Application Form
- 4.0 Consent Documents
- 5.0 Other Study Documents
- 6.0 Additional Special Routing

1.0 Transitioning to Initial Review Submission

1.1 Please select the type of **Research**:

Modifications Required:

Are you sure that this is a Human Study?

Human Research
 IACUC Research
 Biochemical Review

After revising and completing the form, both versions will display in the **Component Name** column. You can view either item by clicking on their names. The **Status** column will update to reflect the action is complete.

⚠ Stipulation 1 out of 1:

Description:
Are you sure that this is a human study?

Stipulation Type: (Stipulation must be addressed)



Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Complete	<p> Initial Review Submission Form (Version 1.1)</p> <p> Initial Review Submission Form (Version 1.0) Section: Transitioning to Initial Review Submission Question: Please select the type of Research:</p>	<div style="background-color: #ccc; padding: 5px; display: inline-block; margin-bottom: 5px;">Compare Form Version</div> <p><input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action</p>

Links to Components
(These are the items that are linked to this stipulation)

After the stipulation action is completed, you may complete the stipulation review by selecting “Yes” or “No” for the **Do you accept this Stipulation?**. You may also add an explanation on how you addressed the stipulation.

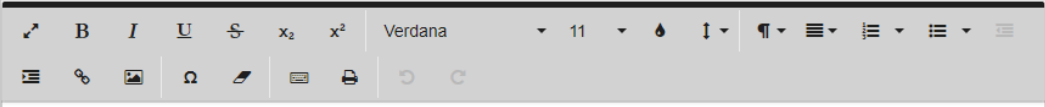
Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Complete	 Initial Review Submission Form (Version 1.1)  Initial Review Submission Form (Version 1.0) Section: Transitioning to Initial Review Submission Question: Please select the type of Research:	<input type="button" value="Compare Form Version"/> <input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action

Do you accept this Stipulation? N/A Yes No

Provide an explanation on how you addressed this Stipulation:



Submission Components

Listed below the stipulations in a *Response* or *Correction* form are the submission components.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Show submission component(s) in round: 2 Current Round		Items in Folder View		Add New Component		Compare Item(s)		Create PDF Packet	
Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	All Submission Components Previous Rounds & Currently Attached			
Submission Form(s)									
<input type="checkbox"/>	<input type="checkbox"/>					IRB - Pre-Review Correction Form - RB - (Version 1.0 (Incomplete))			
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form - (Version 1.0)			
Application									
<input type="checkbox"/>	<input type="checkbox"/>					IRB Application - (Version 1.0)			
Consent Form(s)									
Category : Consent									
<input type="checkbox"/>	<input type="checkbox"/>					Standard Consent (English) (English) - (Version 1.1)			
Document(s)									
Category : Flyer									
<input type="checkbox"/>	<input type="checkbox"/>					Recruitment Flyer - (Version 1.1)			
<input type="checkbox"/>	<input type="checkbox"/>					Recruitment Flyer - (Version 1.0)			
Category : Other									
<input type="checkbox"/>	<input type="checkbox"/>					Sponsor Profile - (Version 1.0)			

Using this table you may view, modify, and revise components attached to the current submission. This table will also update with any revisions made to components through the stipulations.

Please note you can now view submission components from previous rounds if needed by using the dropdown highlighted in red above.

If you need to make corrections or add items to the submission that were not included in the Stipulations, you could revise the Initial Review form and make any necessary changes.

Note: This functionality is only available if the property "system.use_response_wizard_window" within System Administration > System Configuration > System Signoff and Submission Settings is set to "Yes".

Click the icon located in the **Revise/Attach** column of the submission components display table.

Submission Form(s)									
<input type="checkbox"/>	<input type="checkbox"/>					IRB - Pre-Review Correction Form - RB - (Version 1.0 (Incomplete))			
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form - (Version 1.0)			
Application									
<input type="checkbox"/>	<input type="checkbox"/>					IRB Application - (Version 1.0)			
Consent Form(s)									
Category : Consent									

The following confirmation window opens.

Confirm the Revise.

Are you sure you want to revise this item from the submission? A new revision will be created as part of the submission.

You will be asked to confirm the revision. Select the **Confirm** button.

Section view of the Form

1.0 **Transitioning to Initial Review Submission**

2.0 IRB - Initial Review Submission Packet

3.0 Application Form

4.0 Consent Documents

5.0 Other Study Documents

6.0 Additional Special Routing

Entire view of the Form

1.0 Transitioning to Initial Review Submission

1.1 Please select the type of Research:

Human Research

Social Behavior Research

Biochemical Review

?

You may now edit the revised Initial Review application .

Note: Once the Initial Review has been revised, the button revise icon will disappear and the unattached icon will display.

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

Compare	Include in PDF Packet	Compare to Last Approved	View in Separate Window	Unattach	Revise/Attach	All Submission Components <small>Previous Rounds & Currently Attached</small>
Submission Form(s)						
<input type="checkbox"/>	<input type="checkbox"/>					IRB - Pre-Review Correction Form - RB - (Version 1.0)
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form - (Version 1.1)
<input type="checkbox"/>	<input type="checkbox"/>					Initial Review Submission Form - (Version 1.0)

Form Creation Restriction Property

Depending on your system’s configuration, you may or may not be able to create another submission form while another is still pending in the workflow, incomplete. This behavior is controlled by a system property. Please contact your System Administrator for more details.

If this property is on, when there is a submission form that has been started with the data value to attach a study application, users will not be able to start another submission until the first submission has completed the workflow and has been fully processed.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Deattach	Revises/Attach	Edit/View	Title
			IRB Application (Version 1.0)

Note: Users will not be able to start another submission even if there is no study application attached to the submission form. As long as the data value exists in the form, users will not be able to start a new submission form.

In the Study Management section on the study side, when the user clicks into the details of the form, in this case the Initial Submission Review Form, and the property is set to “Yes”, the option to **Add a New Application Type** or **Delete Selected Version** will not be available.

Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Last Modified By	Last Date Modified	Create a Revised Application
<input type="checkbox"/>		IRB Application (Version 1.0)	No		John Investigator	06-21-2021 08:37	John Smith	07-21-2021 13:25	

When the property is set to “No”, the buttons **Add a New Application Type** and **Delete Selected Version** will become available.

When the user clicks on the **Start a Submission Form for one of My Protocols** button or clicks on the **Forms** icon in My Studies, and the property is set to “Yes”, all submission forms with the application data value will be unavailable for use, as long as there exists an incomplete submission with that data value.

- Create a New Protocol
- Start a Submission Form for one of My Protocols**
- View the Current Approvals for one of My Studies
- View the Submission History for one of My Studies
- View and Manage My Studies

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

Submission Form List

Study Status: Active
IRB Number: IRB-21-476
Study Title: Malaria in Juveniles

Regulatory Forms

Regulatory Submission Forms	Version List	Start a new Submission	Edit Incomplete Submissions
Continuing Review Submission Form	📄	Submission Types with Applications cannot be in progress concurrently	📄 1
Study Amendment Form	📄	Submission Types with Applications cannot be in progress concurrently	
Study Closure Form	📄	📄+	
Unanticipated Events Form	📄	📄+	
Yearly Check-in Form	📄	📄+	

Cancel

Users will receive a message stating that another form cannot be created until the form referenced has completed the workflow process.

My Workspaces
IRB Number: IRB-21-476
Study Assistant
Continuing Review Submission Form
⏪ Back

Study Status: Active
IRB Number: IRB-21-476
Study Title: Malaria in Juveniles

PI: Investigator, John
IRB Expiration Date: 06/24/2022

Compare Two Versions
Delete Selected Form(s)

List of records associated with form: Continuing Review Submission Form.
To view previous versions click on the folder icon 📁.

Unable to add a new form until the following form(s) have completed board processing: Study Amendment Form (3.0)

0 result(s) found...

📄	Show Rev	Edit/View	Details	Ref Number	Sub. Rounds	Track Location	Process Submission	Submission Date	Created By	Date Created	Last Modified By	Last Date Modified
No results found.												

Return the Form to the Review Board

When you are finished modifying items and responding to stipulations, and you save and continue through the rest of the *Response* or *Correction* form until it is completed.

Study Assistant—Adding a New Study & Submitting to the Review Board iRIS™ v13.01

My Workspaces IRB Number: **IRB-21-473** PI: Investigator, John Study Pre-Review Correction Form - RB - (Version 1.0) Back

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

Review Response
1.0 Submission Form You have received this form ...
2.0 Stipulations and Comments

Form has been Completed!

Grant Key Personnel access to the study

At this point you can choose to **Exit Form** and return later to finish any additional corrections (if you do this, the Submission Correction task will stay on your homepage), or you can click the **Signoff and Submit** button to initiate the signoff. Once you complete the signoff, the Submission Correction task will be removed from your incomplete homepage tasks. The review board will receive your corrections and will further process your submission. If any additional changes are requested, the review board will return the submission for another round of changes. At that point, you would receive a new Submission Correction task and notification from the system.