



iRIS

Powered by iMedRIS

**MULTI-SITE
MANUAL**

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Introduction

The concept behind the “Multi-Site” module is that an institution can invite other institutions, departments in their own institution to participate in their research project. When the Multi-Site property is enabled within iRIS, it allows an institution to create a project and have other people working on different aspects of that same project.

The property which enables Multi-Site, is activated by a representative at iMedRIS after the Multi-Site module is purchased.

Key Concepts

There are some key concepts that need to be understood when using the Multi-Site module.

Concept 1. There are two different types of Multi-Site models. This is the most important concept to understand as using one of the models alters major functionality systemwide throughout iRIS.

1. **Independent Model:** This model takes away the ability to search for users throughout iRIS. All look ups are replaced with single text fields, and users can only be added to a study if their First Name, Last Name, and Email Address are known to the individual that is filling out the application.



2. **Institutional Model:** In this model all users throughout an institution are all searchable and can be looked up and added to a study.

The figure displays two side-by-side screenshots of the 'Assign key study personnel(KSP) access to the study' interface. The left screenshot, labeled 'Independent Model', shows a form with sections for adding a Principal Investigator, additional investigators, research support staff, and study contacts. Each section contains a table with 'Remove', 'First Name', 'Last Name', and 'Email Address' columns. A callout box states: 'Clicking on any of the "Add User" buttons will create another row of single text fields in the respected table.' The right screenshot, labeled 'Institutional Model', shows a similar form but with a search dropdown and an 'Add User' button. A callout box states: 'Clicking on the "Add User" button will prompt an ajax window to appear, which will allow an institution wide user'. A central diamond labeled 'KEY DIFFERENCE' and 'Study Shell section 3.' points to the 'Add User' buttons on both screens.

Figure SEQ Figure * ARABIC 1

Figure 1 compares two Study Shell section 3 screens. The screen on the left is the screen for the Independent model and the screen on the right is the Institutional model screen. Notice that the main difference is that the screen on the left (Independent model) has single text boxes. When the “Add User” button is clicked, rows of single text boxes are added for the respected question so that the desired user’s first name, last name, and email address can be manually added. When the “Add User” button is clicked on the screen on the right (Institutional model), a search ajax window is prompted and all personnel in the given institution are searchable.

Note: Most institutions will fall under the Institutional Model unless the institution is a central IRB.

Concept 2. *There are two ways to become a Multi-Site.*

1. When a Multi-Site project is initiated, it starts off with the Core application, and invitations to participate on the study are sent to other institutions from the Initial Review form. The Core submits the form to the IRB, and the IRB reviews the Core package. In parallel to this process, the invited Sites receive their invitations and fill out their Site-specific application and submit the application to the review board. The submitted Site application is tied under the umbrella of the Core study.
2. Another way to become a Multi-Site is by starting off with a single site submission. If it is later decided that other sites must participate on the study; a data value can be added to a form which once approved by the board, can convert the single site into a Multi-Site study.

NOTE: *You can never have a Multi-Site application and go back to a single site. The only possible way for that to happen is if all the sites on a multi-site application close.*

Core Level Roles

- Project Manager
**The "Initiator" of the project; they do not conduct the research themselves, they have the sites go out and do the research.*
- Lead Investigator

Site Level Roles

- Site Investigators
**Sites will always have Site Investigators*

Concept 3. *There are three differentiating icons that are used to identify a single study, Site, and Core.*

This is a fundamental concept in Multi-Site because it allows for anyone looking at the application to know what is being viewed.

- 1) Looking at a regular application; single study will display a regular study icon, which is currently used throughout the system.
- 2) If it is a Site application or form, then there is a three-document stack that gets placed in the "Open" column for that application.
- 3) A Core application will have a "C" placed on top of the three-document stack. This is very important especially for a board member who is reviewing the submission.

Open	IRB Number	Ref Number	Type
			Regular application.
			Only the site application.
			Core application.

Figure SEQ Figure * ARABIC 2

Multi-Site Setup for System Administrators

Multi-Site System Properties

There are five Multi-Site properties that allow users to view and conduct various actions. A quick overview of these five properties will be provided in this section.

The following chart will list the Multi-Site properties and give a brief description as to what they dictate within the system:

Property	Dictated Action
<code>system.allow_multisite_external_invite</code>	Sending External Invites
<code>system.use_multisite_contact_invite_ack</code>	Invite Response Screen
<code>system.use_multisite_independent_model</code>	Using the Independent Model
<code>system.use_multisite_lead_investigator</code>	Having a Lead Investigator
<code>system.use_multisite_project_manager</code>	Having a Project Manager

Users with System Administration access can navigate to *System Administration > System Configuration > System Multi-Site* to edit the Multi-Site properties.

The screenshot shows the 'System Multisite' configuration page in the iRIS System Administration interface. The page is titled 'System Multisite' and contains a table with five rows, each representing a system property. The table has two columns: 'Name' and 'Value'. The properties are:

Name	Value
<code>system.allow_multisite_external_invite</code>	<input checked="" type="radio"/> Yes <input type="radio"/> No <i>Description: This property determines whether external sites will be allow to send multisite invitations.</i>
<code>system.use_multisite_contact_invite_ack</code>	<input checked="" type="radio"/> Yes <input type="radio"/> No <i>Description: This property determines whether site contacts have an acceptance screen for multisite invitations.</i>
<code>system.use_multisite_independent_model</code>	<input type="radio"/> Yes <input checked="" type="radio"/> No <i>Description: This property determines whether the system multi-site performs to the independent IRB requirements.</i>
<code>system.use_multisite_lead_investigator</code>	<input checked="" type="radio"/> Yes <input type="radio"/> No <i>Description: This property determines whether the system uses the Lead Investigator on the Core study.</i>
<code>system.use_multisite_project_manager</code>	<input type="radio"/> Yes <input checked="" type="radio"/> No <i>Description: This property determines whether the system uses the Project Manager on the Core study.</i>

A blue callout box at the bottom of the screenshot states: "Clicking on the 'System Multisite' link within System Administration > System Configuration, will display five system properties."

External Invites Property

Figure SEQ Figure * ARABIC 3

The property `system.allow_multisite_external_invite` dictates if external institutions can be invited to participate on a study. When this property is set to "Yes" institutions that are not already in the system can be invited, and when this property is set to "No" only institutions within the system can be invited to participate on a study.

This block shows a partial view of the iRIS System Administration interface, specifically the 'System Multisite' configuration page. The page title is 'System Multisite' and it includes a 'Download Properties Script' button. The interface also shows navigation elements like 'Calendar', 'Help', and 'My Profile'.

Property set to "Yes"

In the Initial Review Submission form, when contacts that must be invited to the study are not already in the system, the name of the institution can be typed in the field under the "Institution Name". Once the system cannot find the institution, a dropdown message will appear.

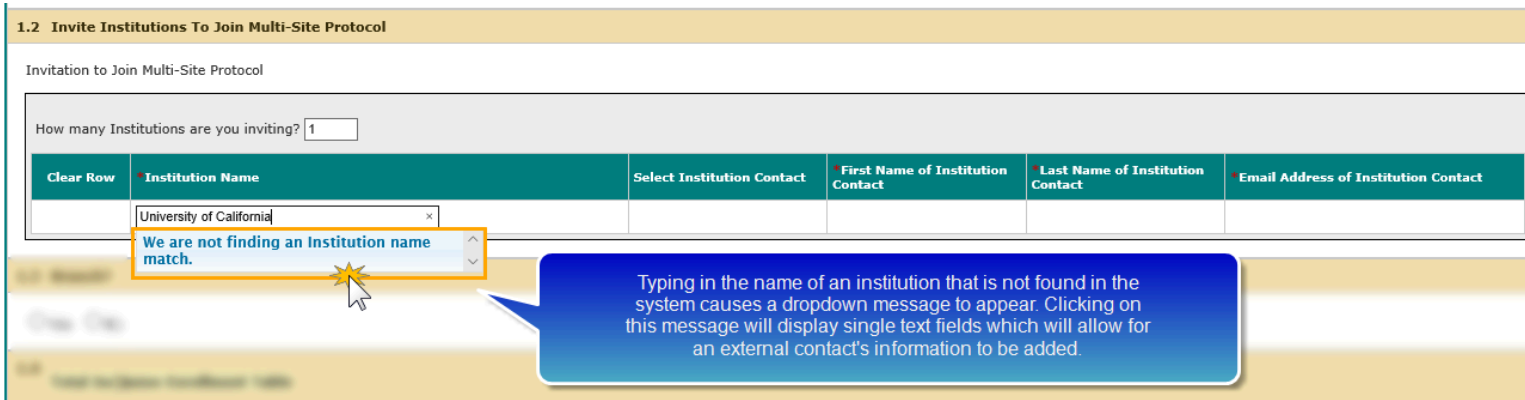


Figure SEQ Figure * ARABIC 5

Clicking on the dropdown message will display three single text fields under the "First Name of Institution Contact", "Last Name of Institution Contact" and "Email Address of Institution Contact" columns, shown in the image below.

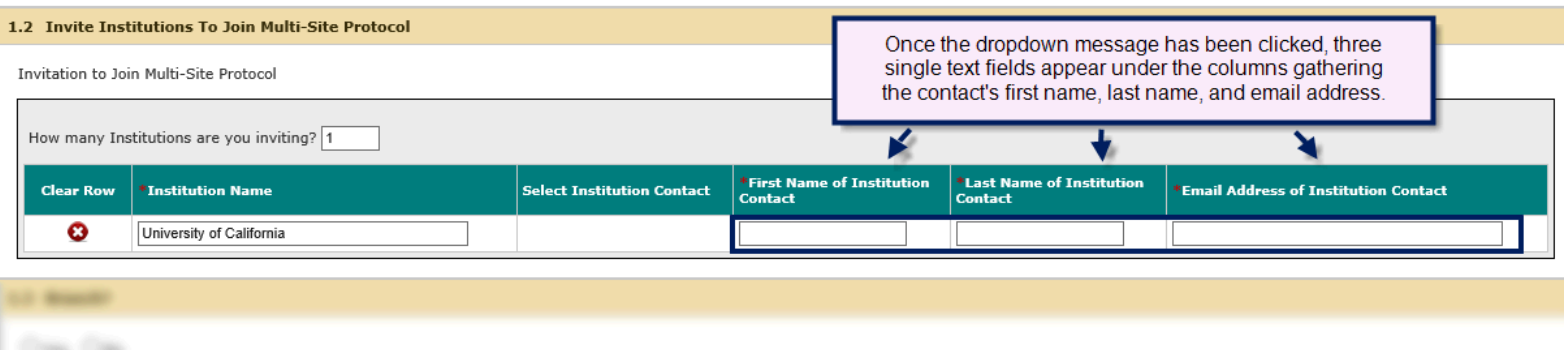
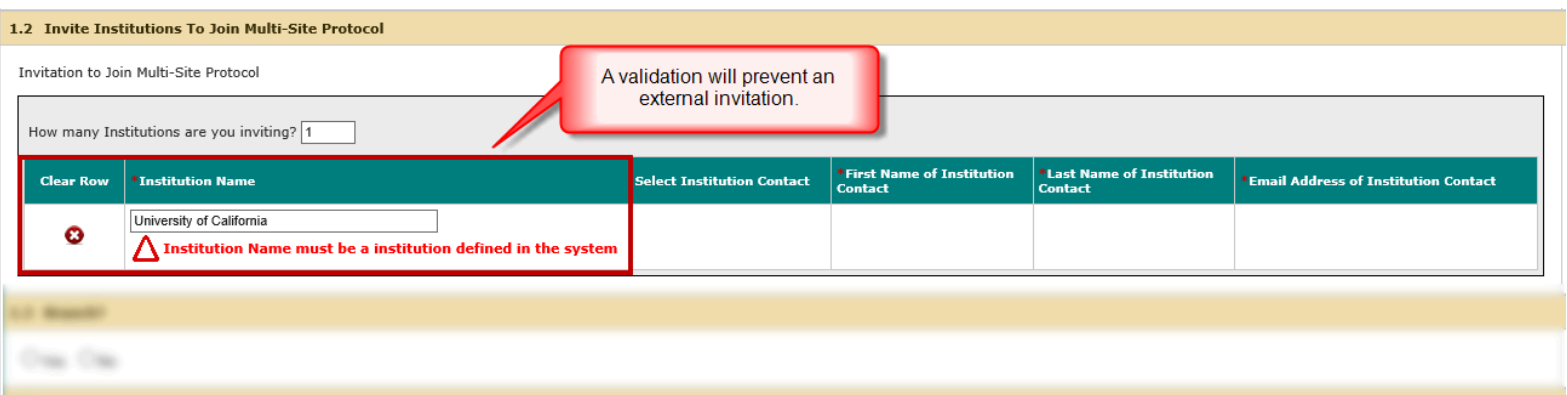


Figure SEQ Figure * ARABIC 6

Property set to "No"

When the property is set to "No" and the name of an institution is typed that is not in the system, a validation message will appear, and the institution's contact will not be able to be added to the study.



The image above displays the error message stating that the institution is not defined in the system.

Invite Response Screen Property

The property `system.use_multisite_contact_invite_ack` dictates whether the screen with invite responses is displayed.

Calendar Help My Profile

Setup System Properties

System Multisite Download Properties Script

Name	Value
system.use_multisite_contact_invite_ack	<input checked="" type="radio"/> Yes <input type="radio"/> No
<i>Description: This property determines whether site contacts have an acceptance screen for multisite invitations.</i>	
system.use_multisite_institution_invite	Yes No
<i>Description: This property determines whether the system will use partners in the independent IRB environment.</i>	
system.use_multisite_invite_invite	Yes No
<i>Description: This property determines whether the system uses the user knowledge in the Core Study.</i>	
system.use_multisite_invite_invite	Yes No
<i>Description: This property determines whether the system uses the Project Manager in the Core Study.</i>	

Figure SEQ Figure \^*ARABIC 8

When this property is set to "Yes" four invite responses are displayed, and when this property is set to "No", the Site application is launched immediately after the invite is opened.

Figure 9 displays the screen that is presented to the recipient of the invitation when they open the invitation.

iRIS by iMedRIS Integrated Research Information System

My Workspaces IRB Number: IRB-18-2454 Alias: Lead PI: Study Assistant

Site Contact acknowledgement to participate in a multi-site study

Independent Model Property

The property `system.use_multisite_independent_model` is the most important Multi-Site property.

This property dictates whether an open or closed system is being used. When this property is set to "Yes" no look ups will be displayed throughout iRIS. This means that all areas and modules an institution has will not have the ability to search for users within their institution.

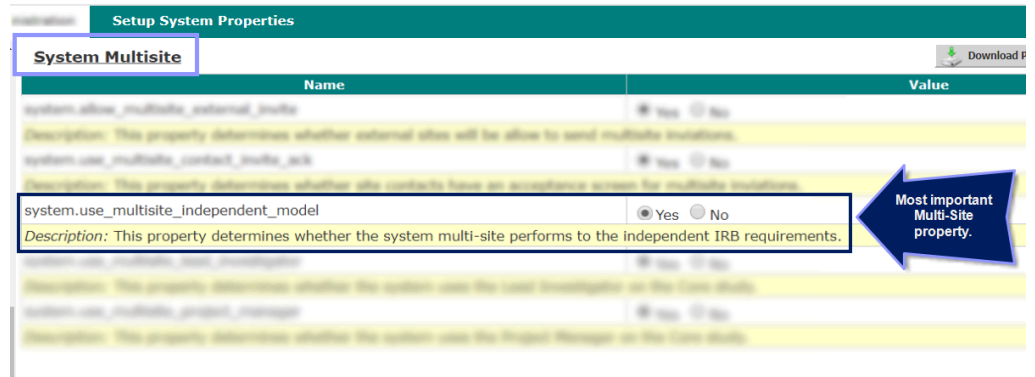


Figure SEQ Figure * ARABIC 10

This is a major system wide action and it turns all areas within iRIS that have the capability to search users into single text boxes, as shown in Figures 1 and 11.

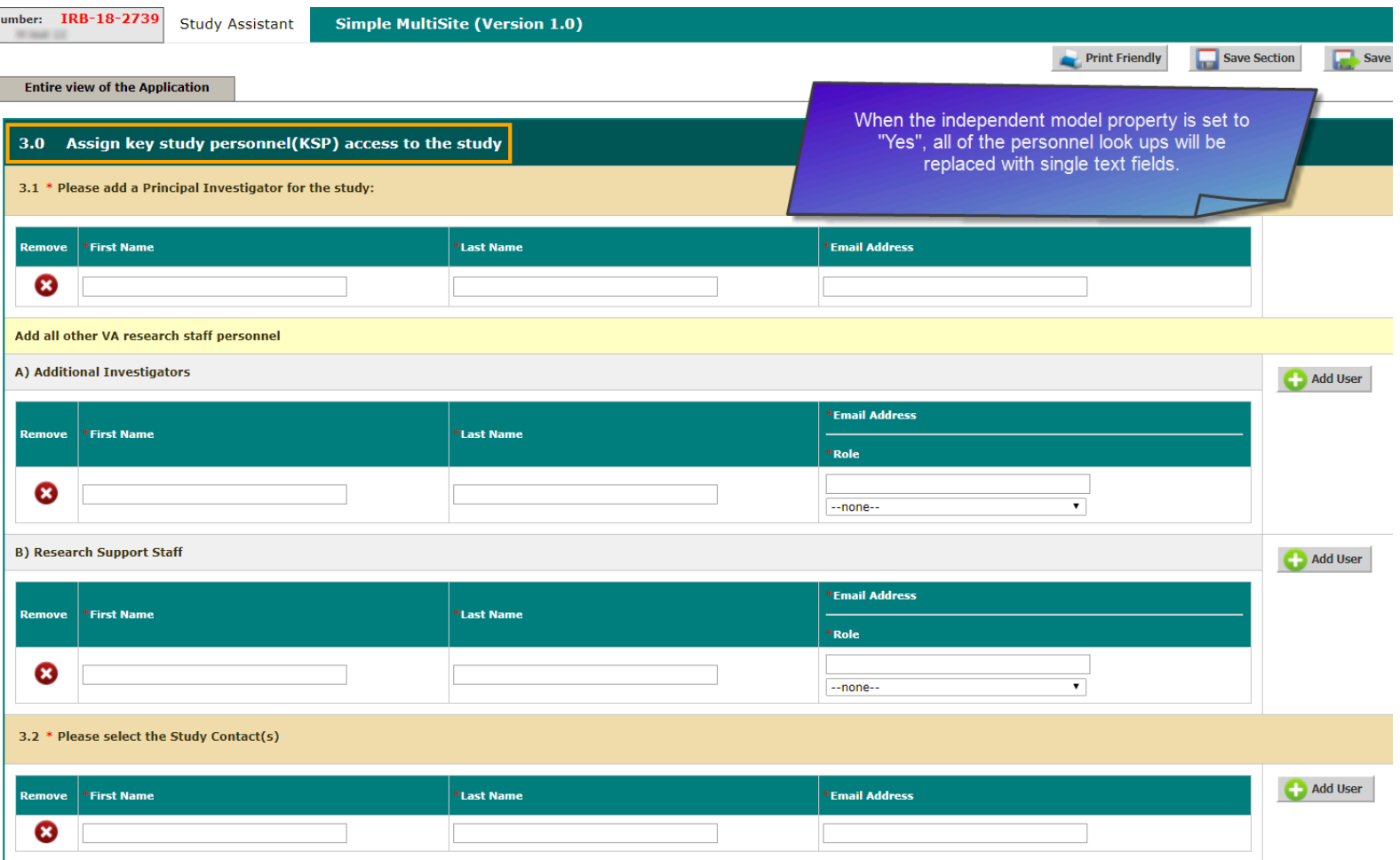


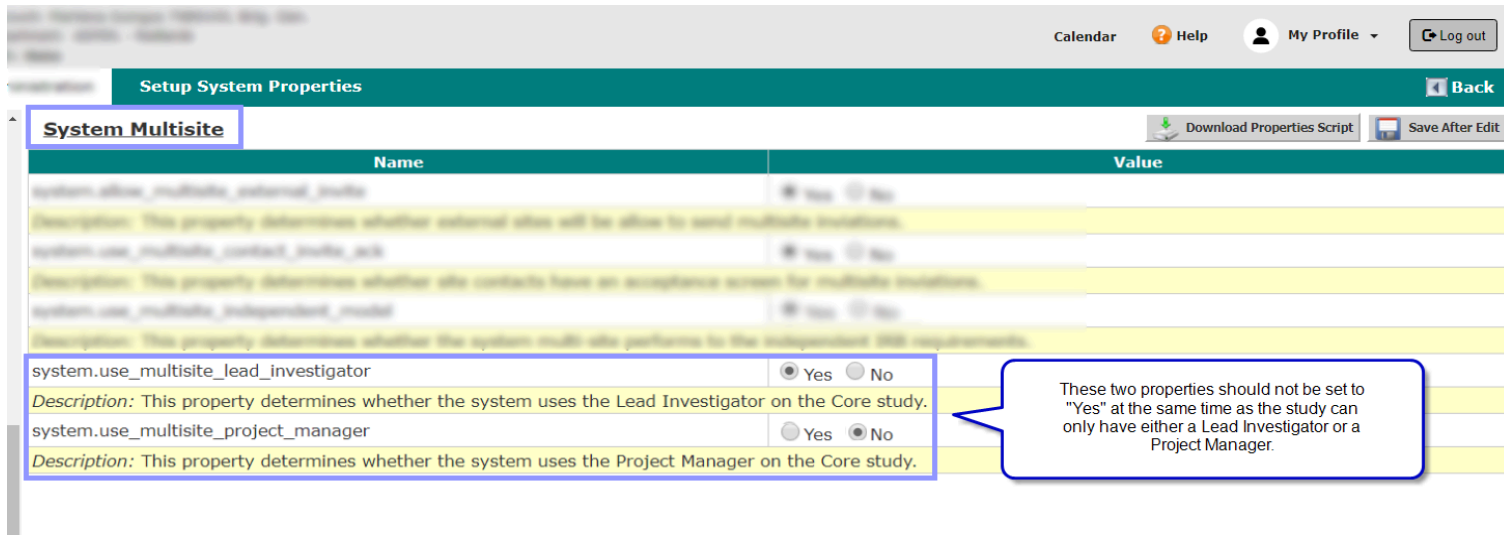
Figure SEQ Figure * ARABIC 11

Lead Investigator and Project Manager Properties

The following properties control whether an institution will have a Lead Investigator or a Project Manager:

- *system.use_multisite_lead_investigator*
- *system.use_multisite_project_manager*

As a study can only have either a Lead Investigator or a Project Manager, these properties must not be set to “Yes” at the same time. When the property *system.use_multisite_lead_investigator* is set to “Yes”, there will be a Lead Investigator on the study, and if the property *system.use_multisite_project_manager* is set to “Yes” then a Project Manager will be on the study.



Multi-Site Process [Study Side]

This section will provide a walkthrough of the Multi-Site process from the study side. The process for both Institutional and Independent models is very similar with only one difference. As discussed in the Key Concepts section, the varying factor between the two is the ability to search for all users and adding to them to a study, verses replacing all user searches with single text fields.

Institutional Model

- The property *system.use_multisite_independent_model* must be set to “No”.

In this walkthrough, the Multi-Site properties will be set in the way a standard Multi-Site would be setup (same as [Figure 3](#)):

Property	Dictated Action
<i>system.allow_multisite_external_invite</i>	Yes
<i>system.use_multisite_contact_invite_ack</i>	Yes
<i>system.use_multisite_independent_model</i>	No
<i>system.use_multisite_lead_investigator</i>	Yes
<i>system.use_multisite_project_manager</i>	No

Step 1: Create a New Study

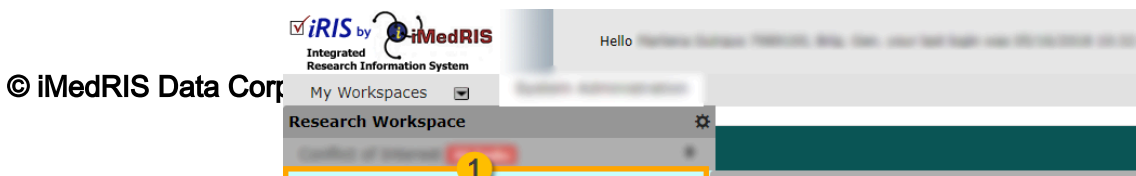


Figure SEQ Figure * ARABIC 13

Step 2: Select a Study Application

The screenshot shows the iRIS by iMedRIS interface. The top navigation bar includes the logo, 'Path: Home', and a 'Calendar' icon. Below this, a breadcrumb trail shows 'Study Assistant' and 'Select New Study Application Form'. Two buttons are visible: 'Cancel and Return' and 'Start selected Application'. A table titled 'Please select a New Study Application from the list below:' contains the following data:

Form Name	Form Description
<input type="radio"/> Study Application - 1234	
<input type="radio"/> Study Application - 5678	
<input type="radio"/> Study Application - 9012	
<input type="radio"/> Study Application - 3456	
<input type="radio"/> Study Application - 7890	
<input checked="" type="radio"/> Study Application	
<input type="radio"/> Study Application - 1111	
<input type="radio"/> Study Application - 2222	

A blue dashed arrow points from the selected 'Study Application' row to the 'Start selected Application' button. A starburst callout box contains the text: 'Step 2: Select a study application, then click on the "Start Selected Application" button.'

Figure SEQ Figure * ARABIC 14

Step 3:
Section
1 of the

study must contain the following Multi-Site question, answering "Yes" to this question triggers the Multi-Site icons.

Pathway: Study Assistant > Add New Study > Application > General Information > 'Is this a multi-site study?'

The screenshot shows the iRIS by iMedRIS Study Assistant interface. The top navigation bar includes 'My Workspaces', 'Study Assistant', and 'Simple Simple (Version 1.0)'. The left sidebar shows 'Section view of Application' with '1.0 General Information' selected. The main content area is titled 'Entire view of the Application' and contains a form with several questions. A blue arrow points to the question: 'Is this a multi-site study (i.e. Each site has their own Principal Investigator)?' with radio buttons for 'Yes' and 'No'. Below this question are two more questions: 'Will this study require feasibility?' and 'Is this study going to be conducted in multiple locations?'. The 'Yes' radio button for the first question is selected.

Figure SEQ Figure *ARABIC 15

Step 4: Finish filling out the rest of the application. Immediately after the last section of the application, a user (from the core study) is directed to the Initial Review Submission form. In section 1.2, the user can invite their sites.

Step 5: In section 1.2 institutions can be invited to join the study.

Section view of the Form | Entire view of the Form

1.0 Submission Packet to the Review Board

1.2 Invite Institutions To Join Multi-Site Protocol

Invitation to Join Multi-Site Protocol

How many Institutions are you inviting?

Clear Row	Institution Name	Select Institution Contact	First Name of Institution Contact	Last Name of Institution Contact	Email Address of Institution Contact
No Institutions have been added to this Study					

1.3 Branch?
 Yes No

1.4 Total Inclusion Enrollment Table

Figure SEQ Figure * ARABIC 16

Step 6: After entering the number of Institutions invited, a table will appear with the number of rows corresponding with the number of invited you selected. As users type in the single text field under the Institution Name column, iRIS will search through the institutions already existing in the system and prefill the name of the institution.

1.2 Invite Institutions To Join Multi-Site Protocol

Invitation to Join Multi-Site Protocol

How many Institutions are you inviting?

Clear Row	Institution Name	Select Institution Contact	First Name of Institution Contact	Last Name of Institution Contact	Email Address of Institution Contact
1	W				
2	Wally World				

Figure SEQ Figure * ARABIC 17

Step 7: When an institution is added, an orange icon will appear in the “Select Institution Contact” column.

1.2 Invite Institutions To Join Multi-Site Protocol

Invitation to Join Multi-Site Protocol

How many Institutions are you inviting?

Clear Row	Institution Name	Select Institution Contact	First Name of Institution Contact	Last Name of Institution Contact	Email Address of Institution Contact
✖	Wally World		<input type="text"/>	<input type="text"/>	<input type="text"/>

Figure SEQ Figure * ARABIC 18

Step 8: Clicking on the orange icon shown in the image above will prompt an ajax window to appear. Here a user search can be conducted and the different people with accounts created within the system for that added institution will be displayed, in accordance to the filters used.

KB-18-2704 Study Assistant Initial Review Submission Form - (Version 1.0)

Search User:

Last Name: First Name:

by Area: Find User/Search Directory

by Location:

by Department:

Select	Name	Department	Email
	Makwana, Sameer	Redlands	smakwana@iMedRIS.com
	Maldonado, Yadira	Research	
	Mamo, Laura	Research	mann@aol.com
	Mandloi, Akshay, M.S.	Healthcare Sys	amandloi@imedris.com
	Mann, Clark	Redlands	lcmann@aol.com
	Mann, Super	Redlands	ismann@aol.com
	Mann, Willie	Redlands	lwmann@aol.com
	Mano, Quintino	Research	
	Manso, Ana Maria	Research	
	Manswer, May A	Research	
	Marks, Jenny Lynn	Research	
	Marler, Matthew Robert	Research	

Click to add.

This "Search User" ajax window is prompted when the orange button is clicked. After finding the desired user, the icon placed in the "Select" column for that user must be clicked. Once the select icon is clicked, the user will be added to the table.

Figure SEQ Figure * ARABIC 19

Step 9: Once the desired user is found, the icon for that user placed in the "Select" column must be clicked in order for that user to be added to the "Join Multi-Site Protocol" table.

1.2 Invite Institutions To Join Multi-Site Protocol

Invitation to Join Multi-Site Protocol

How many Institutions are you inviting?

Clear Row	Institution Name	Select Institution Contact	First Name of Institution Contact	Last Name of Institution Contact	Email Address of Institution Contact
	Wally World		<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>				

Once the institution name is added, this orange icon will appear in the cell for that institution under the "Select Institution Contact" column.

Figure SEQ Figure * ARABIC 20

Step 10: Complete and Signoff. The form will follow its workflow, and invitations will be sent out to the added users from the selected institutions. Upon signoff, if the users that need to sign off don't have an account in the system, there should be a new status in the Workflow-Submission Tracking which states "Waiting for all user accounts to be created". If the users already have accounts, this status would not appear.

Note: A user must have an email address associated to their account in order for them to be added to the invitation list. If the user does not have an email address, a validation will prevent them from being added to the list.

1.2 Invite Institutions To Join Multi-Site Protocol

Invitation to Join Multi-Site Protocol

How many Institutions are you inviting?

Clear Row	Institution Name	Select Institution Contact	*First Name of Institution Contact	*Last Name of Institution Contact	*Email Address of Institution Contact
	Wally World		<input type="text" value="Sarah"/>	<input type="text" value="Maggs"/>	<input type="text"/> Email cannot be empty

Callout: User cannot be added as there is no email address for the user in the system.

Figure SEQ Figure * ARABIC 21

The user can add their email address by going to My Account and inserting their email address in the email address field, or a user with System Administration can go to User Accounts > Search user > Click on the user's name > Add email address.

1.2 Invite Institutions To Join Multi-Site Protocol

Invitation to Join Multi-Site Protocol

How many Institutions are you inviting?

Clear Row	Institution Name	Select Institution Contact	*First Name of Institution Contact	*Last Name of Institution Contact	*Email Address of Institution Contact
	Wally World		<input type="text" value="Sarah"/>	<input type="text" value="Maggs"/>	<input type="text" value="smaggs@uworld.com"/>

Callout: User can now be added.

Figure SEQ Figure * ARABIC 22

- **Note:** As the system.allow_multisite_external_invite is set to "Yes", invitations to institutions that are not found within the system can also be sent. If this property is set to "No" then the only institutions that can be invited to participate are institutions that are already in the system.

Independent Model (Central IRB)

The property: `system.use_multisite_independent_model` is set to “Yes”.

The only difference between the Institutional Multi-Site process and Independent Multi-Site process is the Study Shell section 3 search capability. In the Independent model process all of the user searches are turned off and replaced with single text fields. In this model, if a user must be added to a study, their first name, last name, and email address must be known by the person adding the user to the application.

For images see Figures 1 and 11.

Site Invitations

Invitations are sent out to Site Contacts that were added on the Initial Review Submission form. This section will go through the various responses, and the process for each response.

- Note: The Site invitation responses only appear if the property: `system.use_multisite_contact_invite_ack` is set to “Yes”. If the property is set to “No” once the “Open” icon is clicked on an invite, the Site application will automatically be launched.

Site invitations are sent when all of the users that are supposed to sign off on the submission sign off on it, and in the case of the external invite property being set to “Yes”; all of the invited users have accounts created for them in the system. After all of the users sign off on the Core application, the Core application is sent to the IRB submissions queue for review.

If an invited user views their invitation **before** the board has approved the submission, they will not be able to see any of the submissions forms that belong to the study, shown in Figure 28. If the invited user views their invitation **after** the board has approved the submission, they will then see all of the submission forms that belong to the study they are being invited to participate in, shown in Figure 25.

Site Invitation Process

The user(s) invited to partake in the study will find a new task under *Study Assistant > Tasks*. This task will read ‘Multi-Site Study – Site Contact Invitation to Participate’. This is the invitation to participate on a Multi-Site study.

When the “Multi-Site Study – Site Contact Invitation to Participate” link is clicked, the page will automatically scroll to down to show “All

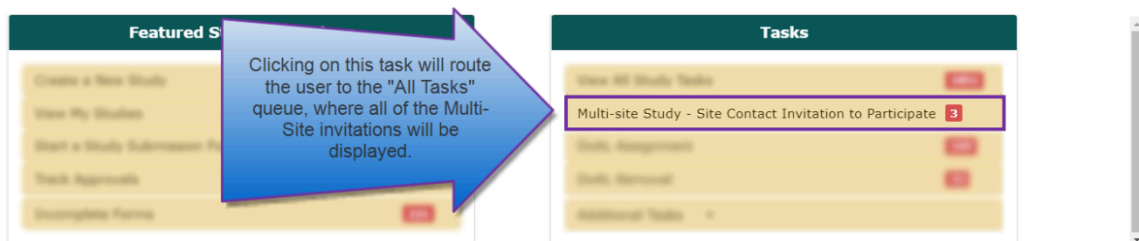
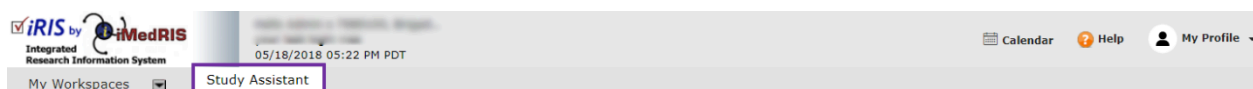


Figure SEQ Figure 1* ARABIC 23

Tasks” queue, which will contain all of the Multi-Site invitations awaiting a response from the logged in user.

Click to open	Task Type	Received	Study Status	Study Title	Principal Investigator	Review Board	RB Number	RB Expiration
	Multi-site Study - Site Contact Invitation to Participate	03/02/2018 11:02 AM PST	Approved	Test #6604		IRB	IRB-18-2454	06/01/2018
	Multi-site Study - Site Contact Invitation to Participate	11/08/2017 08:34 AM PST	Approved	test for site investigator		IRB	<Not Assigned>	<Not Assigned>
	Multi-site Study - Site Contact Invitation to Participate	11/07/2017 09:12 AM PST	Pending - Submitted for Initial Review	MS "upload CSV" data value		IRB	<Not Assigned>	<Not Assigned>

Figure SEQ Figure 1* ARABIC 24

When the open icon shown above is clicked, the invite will be displayed. Four responses to the invitation are available within the invitation:

These four responses will be discussed in detail in the coming sections. The four responses are as follows:

- 1) Accept – Start the site application now
- 2) Accept- Wait for the Site Investigator to accept
- 3) Forward- Defer to another Site Contact
- 4) Deny- Our site does not wish to participate

Include in PDF Packet	Submission Component Name - Version
<input type="checkbox"/>	EIRB Protocol Template - (Version 1.0)

Figure SEQ Figure 1* ARABIC 25

Accept – Start the Site Application Now

The invitation is received by the Site Contact. If the Site Contact chooses the option: ‘Accept – Start the site application now’ they will be taken directly to the Site-specific application.

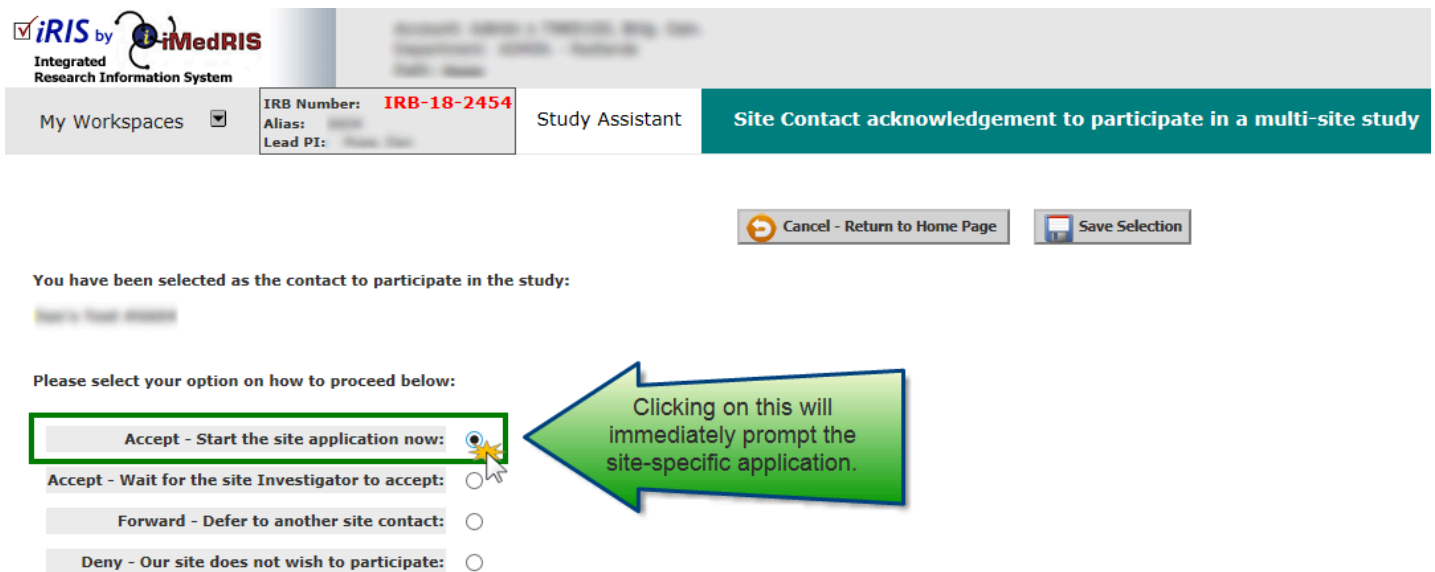


Figure SEQ Figure * ARABIC 26

At the end of the application, the Site Contact will sign off on the submission, and the form will then be routed to the IRB submissions queue.

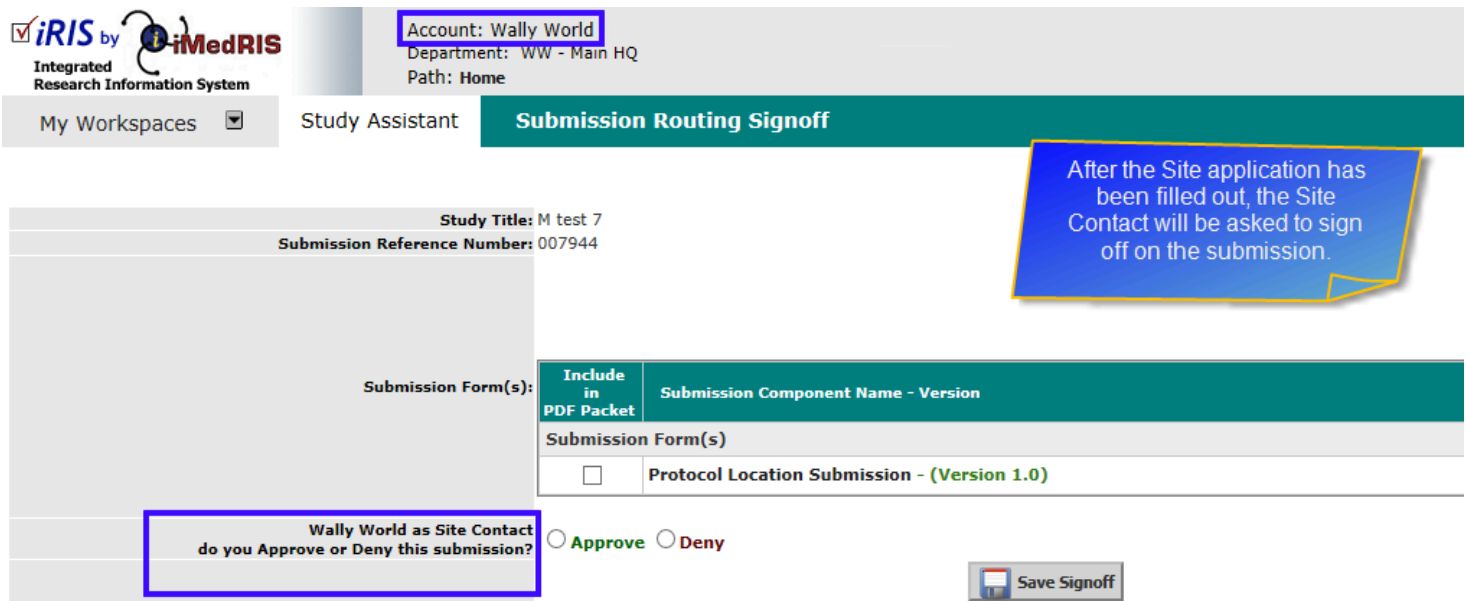


Figure SEQ Figure * ARABIC 27

This concludes the process of the “Accept- Start the site application now” response.

Accept – Wait for the Site Investigator to Accept

If the Site Contact views the invitation and chooses the response ‘Accept – Wait for the Site Investigator to accept’ a popup box to choose the PI for the site to invite populates, as shown in Figure 28.

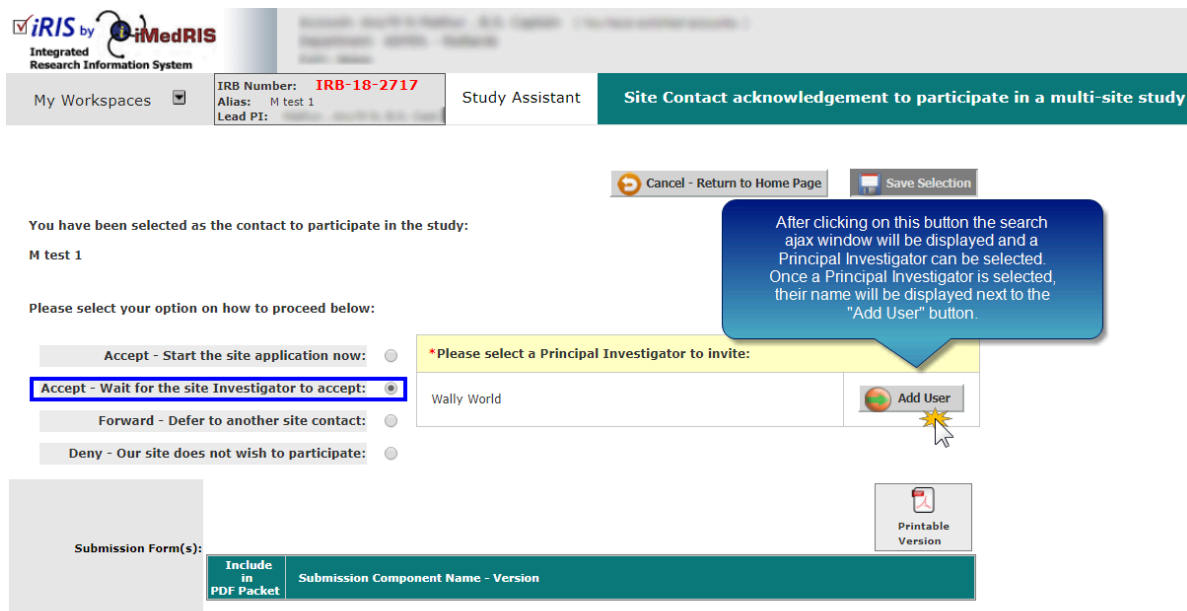


Figure SEQ Figure * ARABIC 28

After the invitation is sent, Site Contact who had originally received the invitation still has the “Site Contact Invitation” placed in their queue. This invitation will only be removed when the Site Investigator they have invited responds to the invitation.

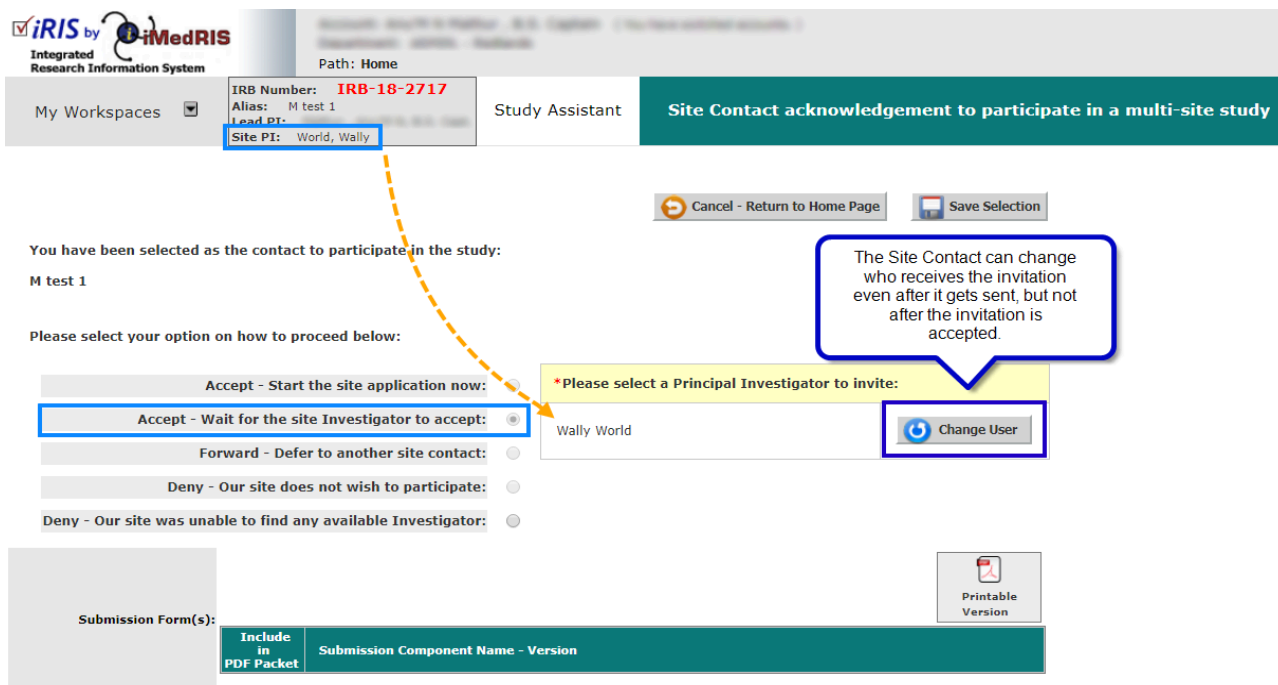


Figure SEQ Figure * ARABIC 29

Before the Site Investigator responds to the invitation, the Site Contact has the ability to open the invitation again and change the user that was invited, shown in Figure 29.

In Figure 29, as the user “Wally World” has been selected as the Site Investigator by the Site Contact, Wally World has received the invitation but has not replied. Therefore, the Site Contact can still open the invitation and has the option to use the “Change User” button to invite a different Site Investigator.

When a Site Investigator is invited, they receive a home screen task under:

Pathway: Study Assistant > Tasks

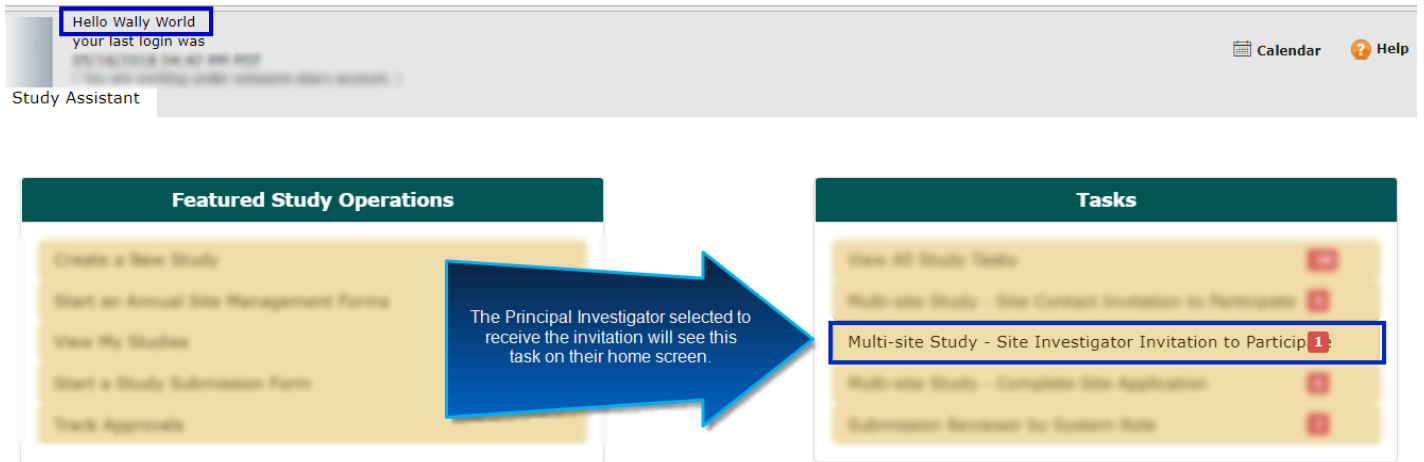


Figure SEQ Figure * ARABIC 30

When the home screen task is selected, the page scrolls down and automatically takes the user to the Approval/Denial page. If approved they are taken directly to the site-specific application.

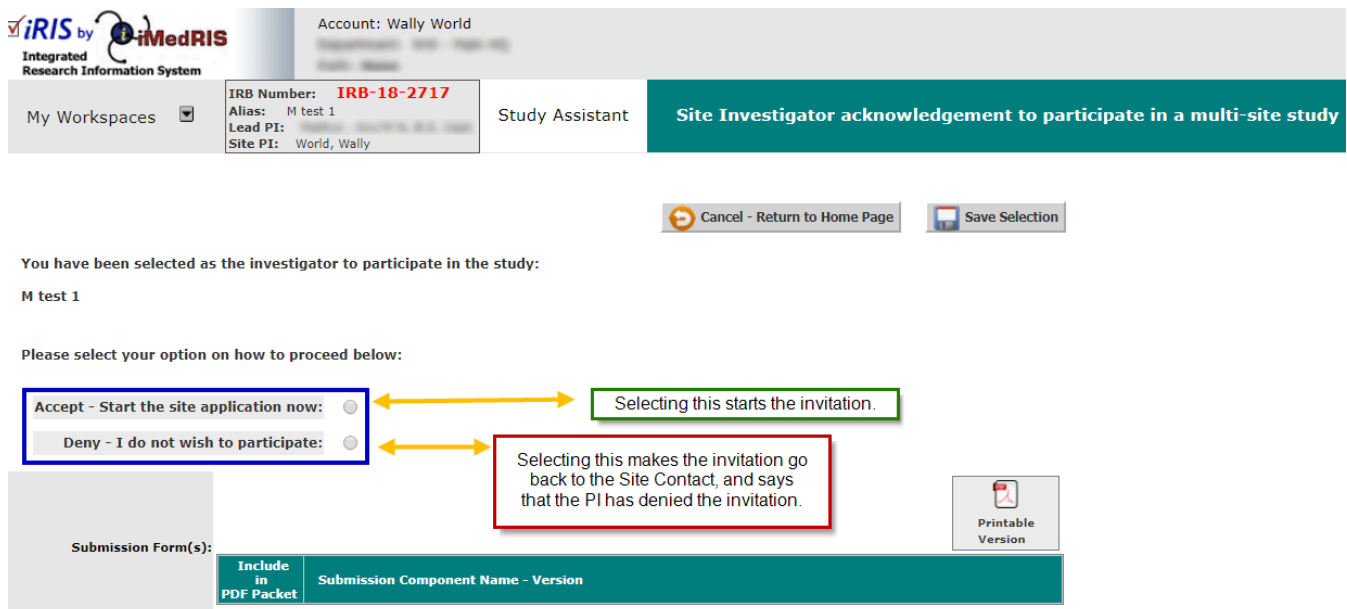


Figure SEQ Figure * ARABIC 31

However, if the Site Investigator selected by the Site Contact denies the invitation, the Site Contact can then invite another Site Investigator. This process has take place twice in Figure 32.

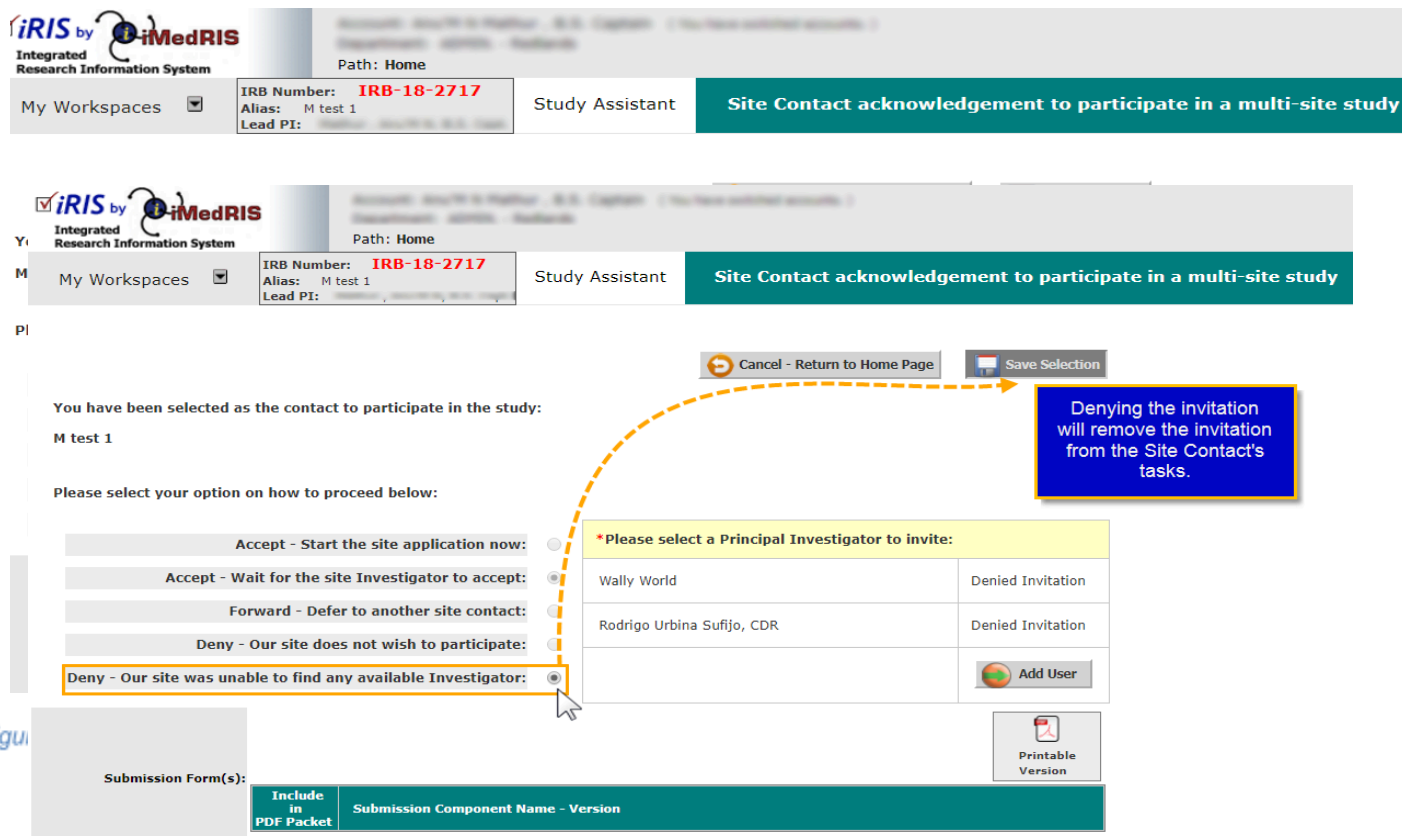
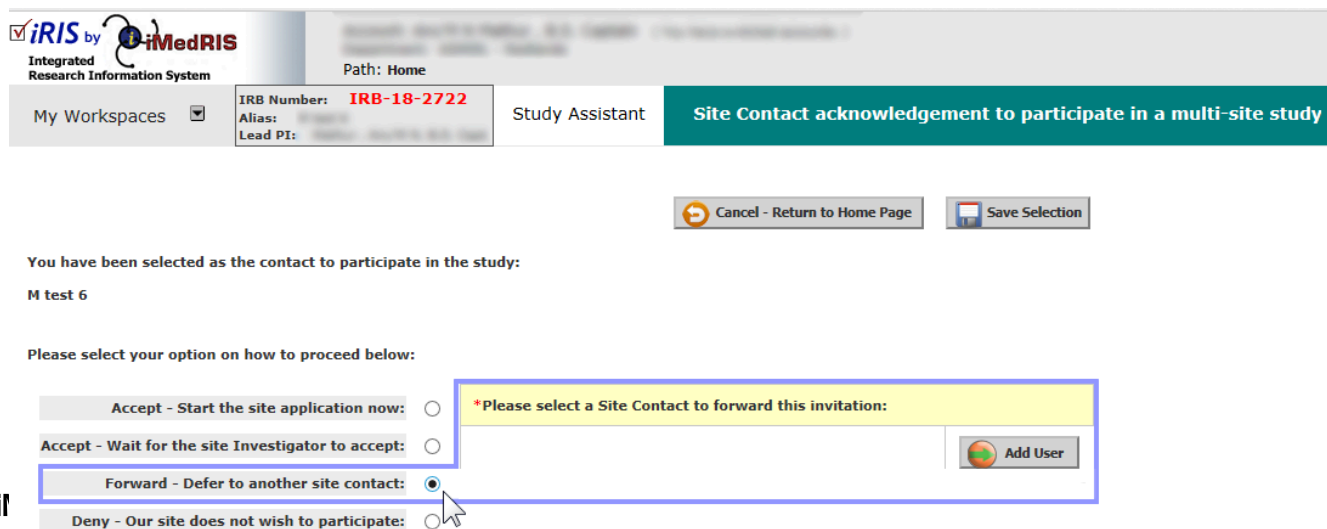


Figure SEQ Figure * ARABIC 33

When this happens, the Site Contact can keep inviting other Site Investigators, by clicking on the “Add User” button which will get displayed when a Site Investigator denies the invitation. The only other option the Site Contact has at this stage is just denying the invitation by selecting the option “Deny – Our site was unable to find any available Investigator”. This response is the only response that is not in read-only mode. This is shown in Figure 33.

Forward – Defer to Another Site Contact

When selecting the option ‘Forward – Defer to another site contact’ a popup box to choose the Site Contact to forward to should populate. Shown below:



By selecting this option, the current user who is the Site Contact is choosing to not take part in the study and is also giving up the ability to select a Site Investigator.

Deny – Our Site Does Not Wish to Participate

Deny – Our site does not wish to participate.

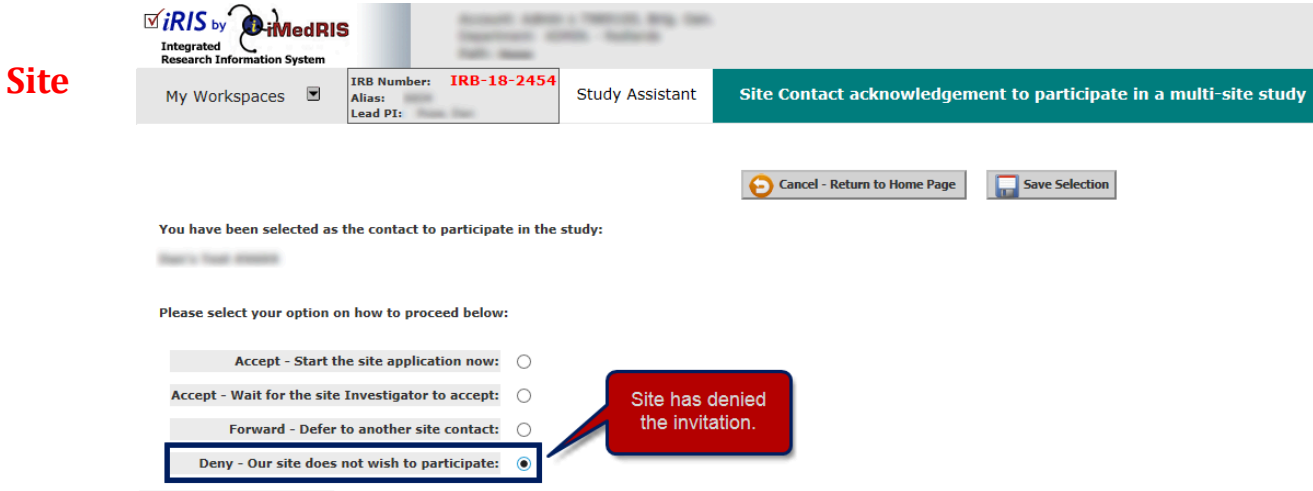


Figure SEQ Figure * ARABIC 35

Access

Request and User Accounts

Site Access Request

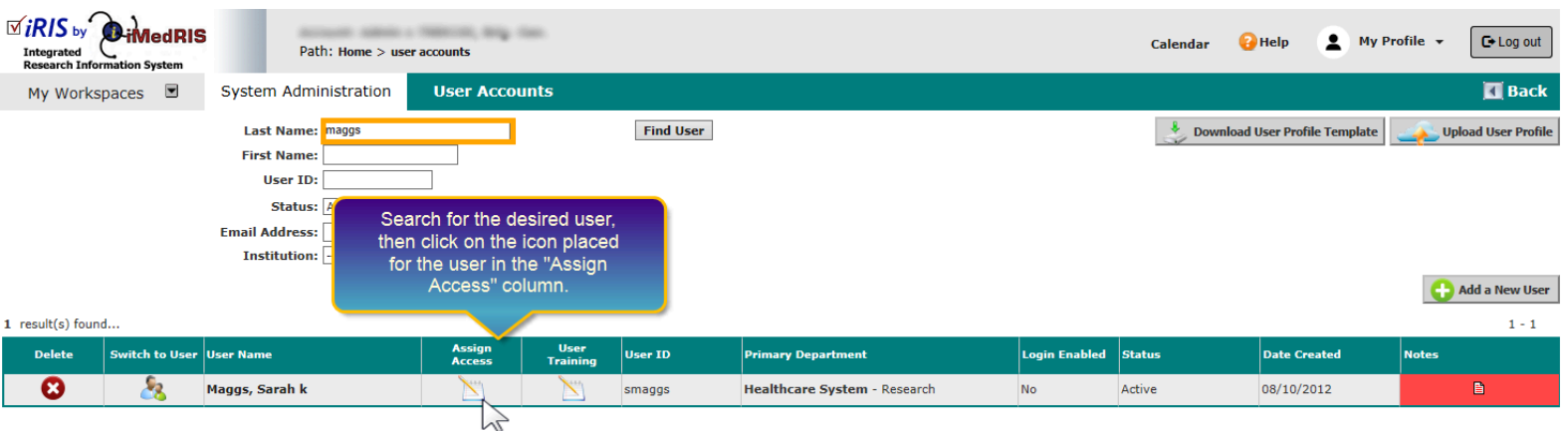
System Administrator can create a user ID and fill in information for those invited to be on site application. Once saved, a notification will go out to the person to let them know they have an account and to start their site application.

??

User Accounts

When Multi-Site is enabled in a system, three new roles a displayed on the Assign System Access and Roles screen.

Pathway: System Administration > User Accounts > Assign Access



Account: [Name] [Email]
Path: Home > user accounts

My Workspaces [v] System Administration **Assign System Access and Roles for Ack, Abby**

Full System Administrator: []
System Administrator 1: []
Admin: []
Recruiting Role: []
Recruiting Department Researcher Role: []
Recruiting Role Designer: []

Treatment Administrator: []
Treatment Role: []
CRF Form Designer: []
Department/Site Administrator: []
Global Study Access: []
Global Subject Access: []
Information Security Officer: []
Privacy Officer: []
AMP Screener: []
ACIP Screener: []

Institution Signatory Contact:
Institution Principal Investigator:
Institution Research Staff:

When Multi-Site is enabled, these three new roles will be displayed within System Administration > User Accounts > Assign Access.

The following are the three added roles for Multi-Site, when these are checked, the system uses this as an additional filter when allowing users to add people to different roles:

- 1) **Institution Signatory Contact:** When this role is assigned to a user, the system will pull this user in the search for when a Site Contact must be added.
- 2) **Institution Principal Investigator:** When this role is assigned to a user, the system will pull this user in the search for when a Principal Investigator must be added.
- 3) **Institution Research Staff:** When this role is assigned to a user, the system will pull this user in the search for when a Researcher must be added.

Site Management Tab [Core Application]

On the Study Summary screen of the Core application, a “Site Management” tab is available next to the Study Management tab.

This tab is only available on Core studies. Clicking on the “Site Management” tab prompts the “Site Management” screen. Through this screen the Core study can view some information on the Site studies. The kind of information that the Core has access to will be discussed in this section.

Integrated Research Information System
Path: Home

My Workspaces [v] Alias: [Name] [Email] Lead PI: [Name] [Email] Study Assistant Submissions

Study Status: Approved

Submissions Study Management **Site Management** Subject Management

The Study Summary screen of a Core application, contains a “Site Management” tab. When this tab is clicked, another screen which displays all of the sites for this study will be prompted.

Note: Sites will only be able to see their own work and will not be able to see the work of any other Site. Only the Core is privy to the Site Management tab and Site information.

An important concept to understand is that the "Site Management" tab is role access based. This means that the Principal Investigator or anyone who must have access to the "Site Management" tab on the Core side must be granted access to the tab.

Open	Site Invite Details	Site Status	Institution/Site	Site Principal Investigator	Site Contact	Expiration Date
		Pending - Submitted for Initial Review				
		Pending - Acceptance to Participate				

Clicking on this icon will prompt an ajax window to appear. This ajax window will display the invite details.

Clicking on the Open icon will prompt the Site's Study Summary screen.

The Core can open the Study Summary screen of any of the Site's listed on the Site Management screen. The Core can see what forms Sites have filled out and their progress, track where the invitation is, and the status of the site. Even though the Core can see what forms and applications Sites are working on, the Core cannot edit or submit forms on behalf of the Site.

When the Core clicks on the 'Open' icon for a Site, the Core will be able to view all of the sites contents and forms pertaining to the study will be shown, however the Core cannot modify any form.

Site : Administration

Study Title: test for site investigator

Protocol Items

- Core Forms & Documents
- Informed Consent
- Other Study Documents
- Contract Documents
- Application for Continuing Review / Renewal
- Ashley's First Form
- Branching and Validation Form
- Branching Test Sub Form

Submissions History

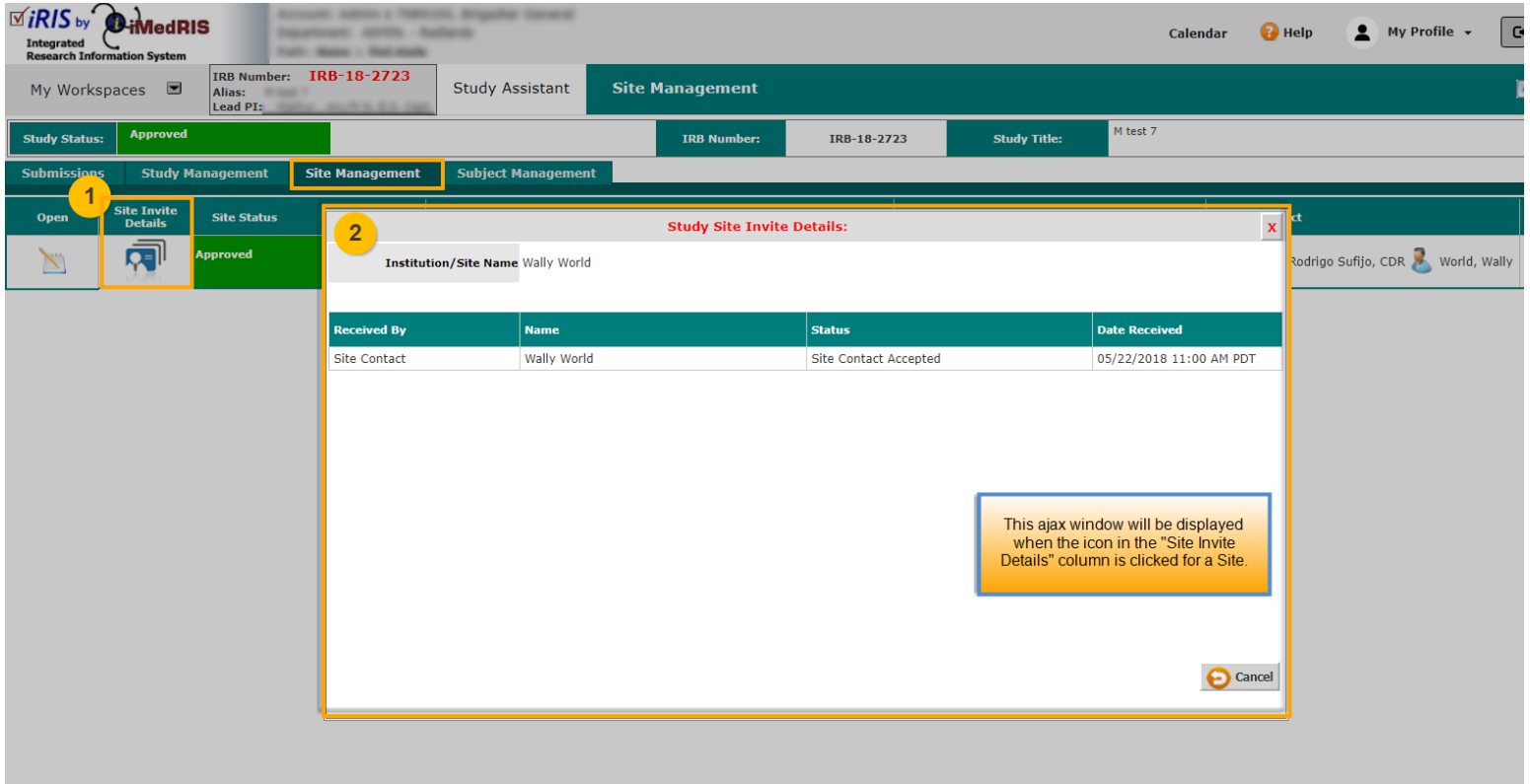
Study Correspondence

Outstanding Submission(s)

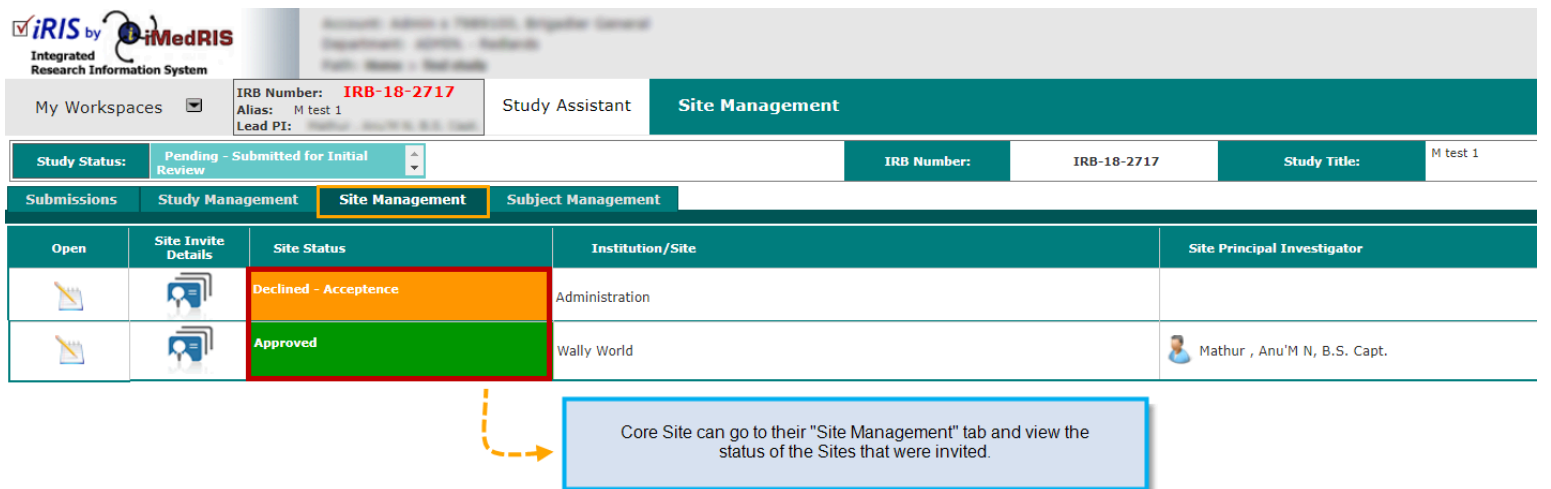
Ref Number	Request Type
There are no outstanding submissions.	

The name of the Site will be displayed on the Study Summary screen for the site.

Clicking on the "Site Invite Details" icon will prompt an ajax window to appear. This ajax window will display the invitation details for that Site and will allow for the Core to see the status of the invitation, along with the roles and names of the personnel that are in possession of the invitation. The "Study Site Invite Details" ajax window is shown in Figure ____.



As seen in the image below, the Core can see the status of all of the Sites that they have invited.



Form Details

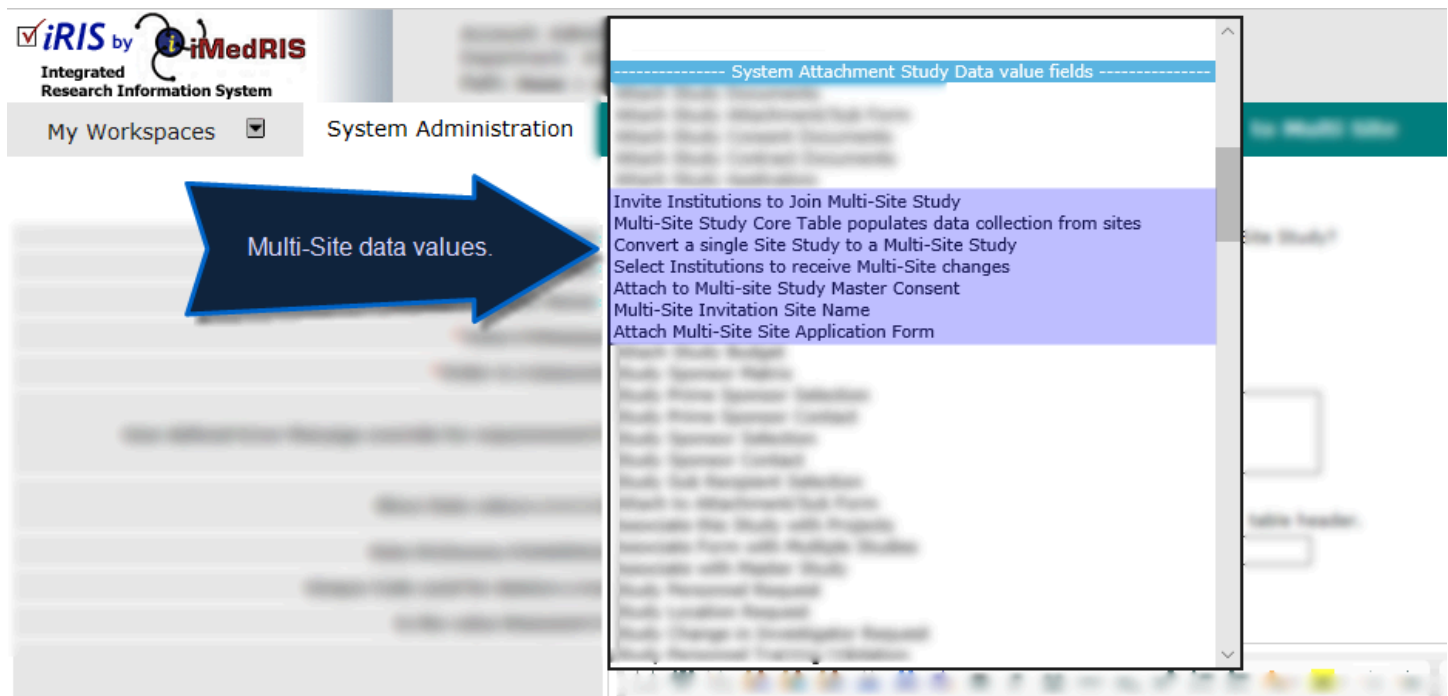
Data Values

This section will discuss the seven Multi-Site data values within iRIS. These data values can be added to forms by users with System Administrator role access by navigating to:

Pathway: *System Administration > System Forms Designer*

The following seven data values are related to Multi-Site:

1. Invite Institutions to Join Multi-Site Study
2. Multi-Site Study Core Table Populates Data Collection from Sites
3. Convert a Single Site Study to a Multi-Site Study
4. Select Institutions to Receive Multi-Site Changes
5. Attach to Multi-Site Study Master Consent
6. Multi-Site Invitation Site Name
7. Attach Multi-Site Site Application Form



Invite Institutions to Join Multi-Site Study

Adding the data value: Invite Institutions to Join Multi-Site Study to a form adds a section on the Core application which allows the Core to invite sites to join their study.

As seen in [Figures 16-18](#).

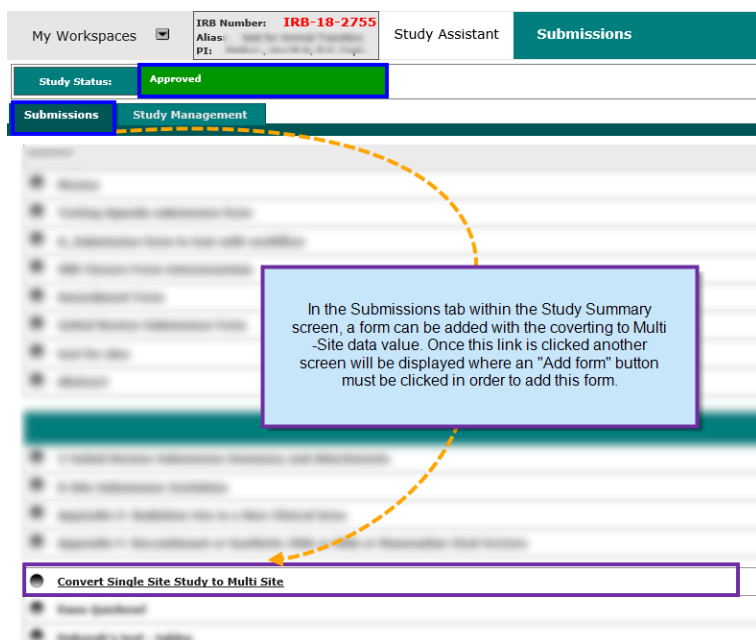
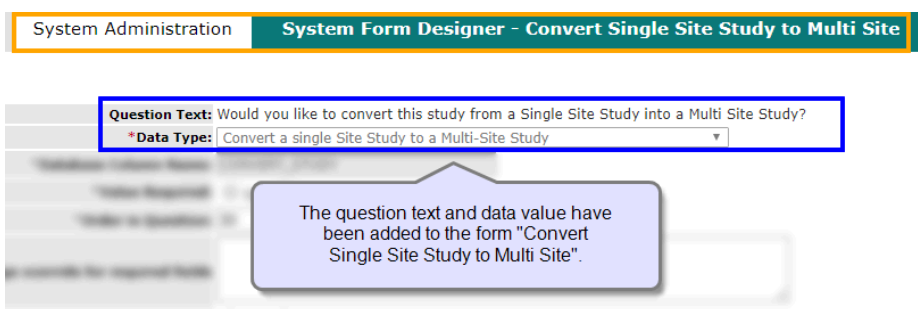
Multi-Site Study Core Table Populates Data Collection from Sites

- **Key:** The Site needs to be approved.

This value is used when closing a study or doing a continuing review for the core. On the Core's side, it will have a list of all the sites on the Study and the Core will be able to select the ones they want. From there, the Core sends the form to the site; the sites get a notification and when opened it populates with information from the dynamic table that the user defined in the Forms Designer. Each site represents one row on the dynamic table, site fills in information and sends back to core. The table is then automatically populated with sites information on the core side. (see [here](#) for example)

Convert a Single Site Study to a Multi-Site Study

Step 1: This will be done by a user with *System Administration* access within System Administration > System Form Designer. The data value "Covert a Single Site Study to a Multi-Site Study" must be added onto a form.



This data value adds a "Yes/No" question to the form. The question asks if the user wishes to convert the study into a Multi-Site study. If a "Yes" selection is made, and the board approves this form, then the Site will convert from a single site to a Multi-Site.

Step 2: On the study side navigating to the Study Summary screen and viewing forms under the Submission tab- the form containing the data value added in the previous step will be available for selection.

Step 3: The form will contain a "Yes/No" question invoked by the data value entered in System Form Design. If a "Yes" selection is made to this question and the form is approved by the board, then the study will be converted from a single study to a Multi-Site study.

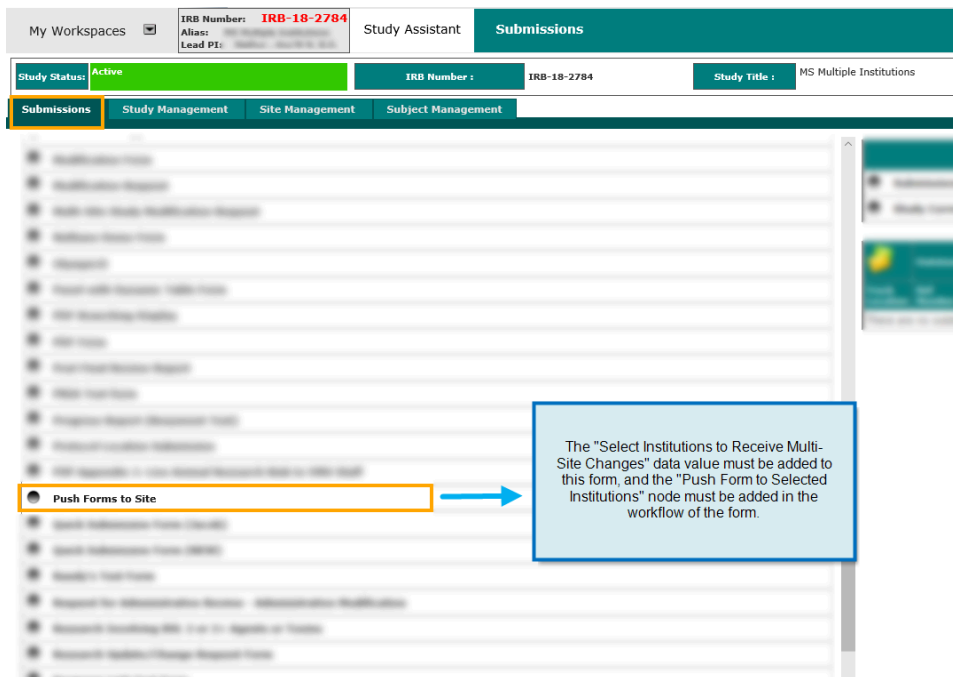
Select Institutions to Receive Multi-Site Changes

Add to push form. Lets you select the institution you want to send the form to.

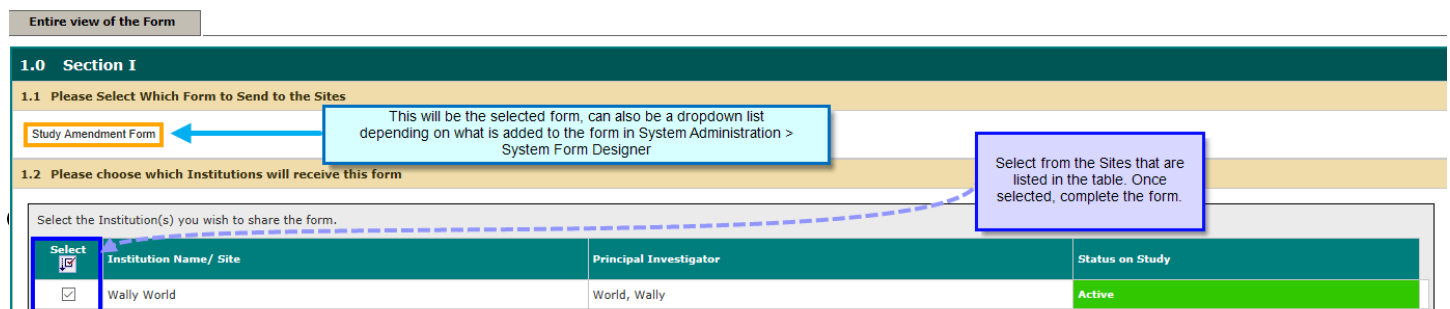
Step 1: The data value "Select Institutions to Receive Multi-Site Changes" must be added onto a form. This will be done by a user with *System Administration* access within System Administration > System Form Designer.

Step 2: The "Push Form to Selected Institutions" node must be added to the workflow of the same form. This will be done by a user with *System Administration* access within System Administration > System Form Designer > click on the Workflow button.

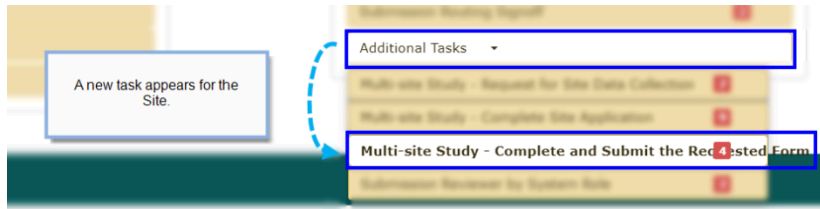
Step 3: When the Core goes into their Study Summary screen, the Submission tab will display the Push form (the role access must allow the form to be displayed in this section).



Step 4: When



Step 5: After the form is signed off on, the workflow node kicks in and the form that the Core wanted the Site(s) to fill out gets sent to the Site(s).



Step 6: Clicking on the task scrolls the user down to the “Multi-Site- Complete and Submit the Requested Form” queue.

Task List: Multi-site Study - Complete and Submit the Requested Form

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

Click to open	Task Type	Received	Study Status	Study Title	Principal Investigator	Review Board	RB Number	RB Expiration
	Multi-site Study - Complete and Submit the Requested Form	05/30/2018 09:42 AM PDT	Active	MS Multiple Institutions	Wally World, Wally	1) IRB 2) IRB	1) IRB-18-2784 2) IRB-18-2784-1	1) <Not Assigned> 2) <Not Assigned>

Step 7: After the task is opened, Figure ___ will be displayed. The Site will be able to fill out the form that was pushed by the Core by clicking on the “Click here to start this form” button.

Account: Wally World

Calendar Help My Profile

IRB Numbers: IRB-18-2784
 Alias: Core's PI
 Lead PI: World, Wally
 Site PI: World, Wally

Study Assistant

Print Friendly Save Section

Entire view of the Form

1.0 Protocol Changes

1.1 Populate Data Collection

Please choose Institutions to Populate Tables with

Select the Institution(s) you wish to share the form.

Select	Institution Name/ Site	Principal Investigator	Status on Study
<input checked="" type="checkbox"/>	Wally World	World, Wally	Active
<input type="checkbox"/>	Administration		Active

1.2 Attach Site App

This is the form that is being pushed and was selected by the Core.

After the form is filled out by the Site, it will continue to follow its workflow.

The "Select Institutions to Receive Multi-Site Changes" data value must be added to this form, and the "Push Form to Selected Institutions" node must be added in the workflow of the form.

Attach to Multi-Site Study Master Consent

This data value must be added to the Initial Review Submission form. When the Master Consent form is approved by the board

This data value works with the "Push form to Site" workflow node.

Once the institution is chosen, the workflow node kicks in and sends the form to the selected institution.

Then go to the User—Switch accounts who received it, a task must be sent to the recipient called "Multi-Site Complete & Submit the Requested form".

Section view of the Form

1.0 Submission Packet to the Review Board

12.0 Master Consent

12.1 Master Consent

Select or Revise Existing **+ Add a New Consent**

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
✖	1.0	Master Consent Test	Study Consent Category I	English				38.63 KB

Clicking on this button will display an ajax window which will allow the user to add a Consent form.

The Site can then

Account: Wally World (You have switched accounts.)
Department: WW - Main HQ
Path: Home

IRB Number: **IRB-18-2763**
Alias:
Lead PI:
Study Assistant

Protocol Location Submission - (Version 1.0)

Print Friendly Refresh Constant Fields Save

Section view of the Form Entire view of the Form

1.0 Signatory Institution Information
2.0 Location Site Application

2.0 Location Site Application

2.1 Please Describe your role on the study

Click here to access the text editor.

2.2 Please Upload any Study Documents here:

Add a New Document

Detach	Version	Title
No Document(s) have been attached to this form.		

2.3 Please Attach your Informed Consent Here:

Add a New Consent

Detach	Version	Sponsor Version	Title
No Consent(s) have been attached to this form.			

Study Consent Add Selection Method:

Add a new informed consent from the Master Informed Consent?
 Add an informed consent from an existing electronic document you already have?

Next Screen

Clicking on the "Add a New Consent" button will prompt an ajax window to appear. This ajax window will allow the Site to add the Master Consent document.

63 Study Assistant Protocol Location Submission - (Version 1.0)

Print Friendly Refresh Constant Fields Save

2.0 Location Site Application

your role on the study

the text editor.

y Study Documents here:

ment

Title
e been attached to this form.

ar Informed Consent Here:

ent

Sponsor Version	Title
een attached to this form.	

Study Consent Add from Master:

* Please select the Consent Version: --none--
Master Consent Test (English)

Generate Consent from the Master

After the "Next Screen" button is clicked, this ajax window will appear. Select a Consent from the dropdown list.

Study Assistant Protocol Location Submission - (Version 1.0)

Print Friendly Refresh Constant Fields

4 Select Existing or Create Revised Study Consent

Select Category: --none-- Title: _____

Version #: _____ Search level: Top All

Version Date: _____ between _____ Expiration Date: _____ between _____

Consent Outcome: --none--

1 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Title	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
				1.0	05/25/2018	1	Master Consent Test Study Consent Category	English				 18.98 KB	

After the "Generate Consent from the Master" button is clicked the Consent form is added and this ajax appears and can be crossed out. Revisions to the consent can also be made here.

Multi-Site Invitation Site Name

When this data value is added to a form, it will display the name of the Site that is viewing the form to be displayed on the form. This is an informational data value.

Attach Multi-Site Site Application Form

This data value allows you to attach the Site application to another submission form.

Edit/Save Form Details:

- Include for Multi-Site institutions: In the Study Management area, when a user opens a study they can see the forms. Using this field, you can say whether or not a form is included.
 - No Site Usage: For the core
 - Site Only Usage: Only for the Sites on the Study
 - None: Both

- Initial Review Form: Use Routing Signoff Sheet:
 - In the Open Case (Schulman, Principal IRB) Should be 'No' to be able to build signoffs into the workflow.

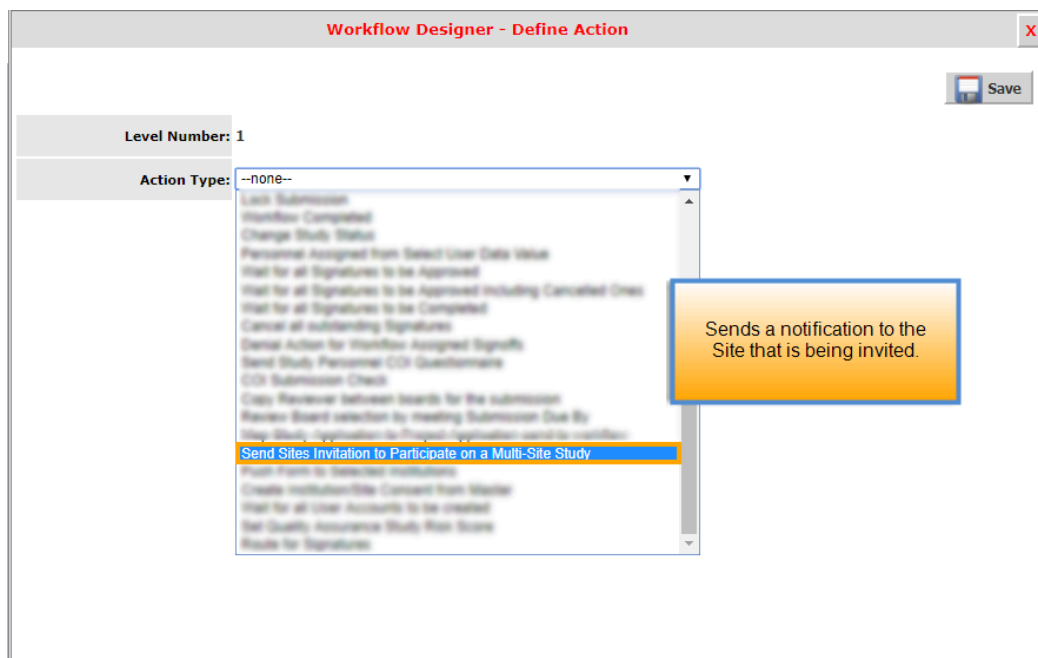
Workflow Designer

Similar to the Forms Designer, actions were added to the Workflow Designer for Multi-Site. The following four actions are related to Multi-Site and will be explained in this section: Send Sites Invitation to Participate on a Multi-Site Study, Push Form to Selected Institutions, Create Institution/Site Consent from Master, and Wait for User Accounts to be Created.

Pathway: System Administration > Workflow Designer > Initial Review Form > Click on the desired level > Click on the "Define Action" button

Send Sites Invitation to Participate on a Multi-Site Study

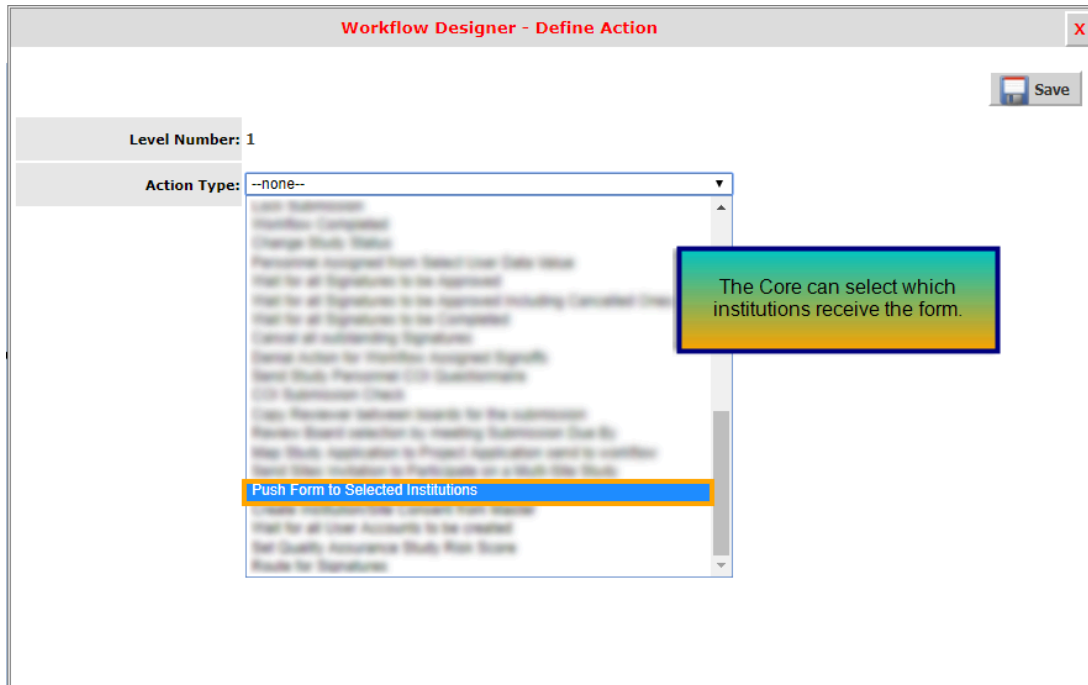
When this node is hit in the workflow, the form with the data value "Invite Institutions to Join Multi-Site Study" will be used to send out the notifications. This starts off with a notification and then launches the Site Initiation Form if they accept the invitation.



Push Form to Selected Institutions

When this action is used, it gives the Core the ability to send out the form to a specific institution, or to all of the institutions.

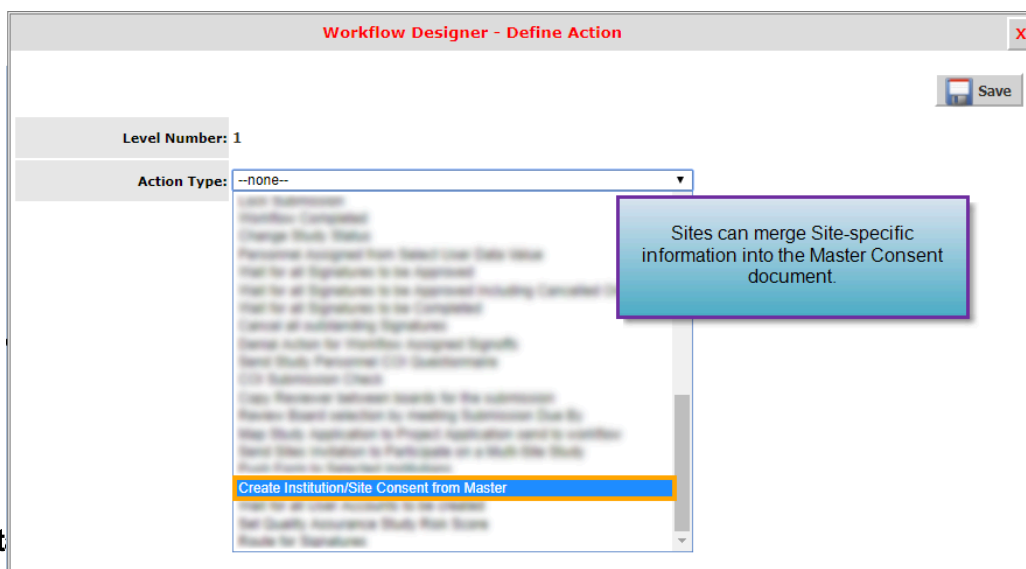
The Core selects form and who should get the form. The form then gets pushed to



Create Institution/Site Consent from Master

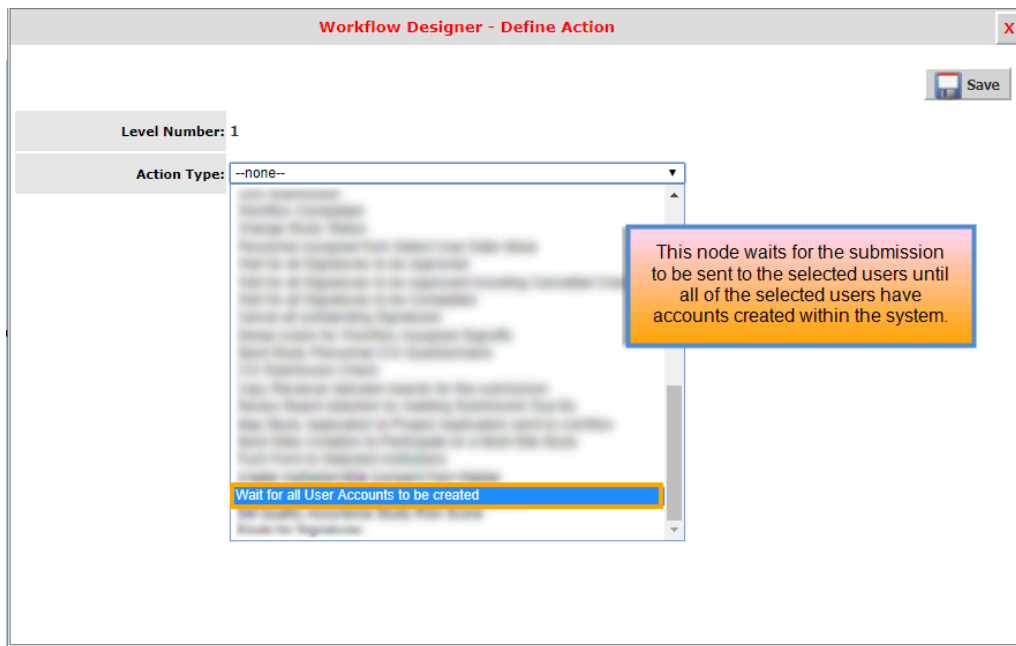
Allows the Site to take the Master Consent and add it as a regular consent to their application. The system duplicated the Master consent and bundles it up with the Site application.

- **Rundown:** The Master Consent document gets submitted to the IRB and approved. Merge codes are inserted in to the document for each site, then the Site invitations are sent, the system then takes the Master Consent document and automatically merge in the Site's site-specific information into that document (Site specific information does not update the Master because the Master is its own thing).



Wait for User Accounts to be Created

This node is a stop node, which prevents any invitations to be sent out until all of the requested account have been created.



Multi-Site Process [Board Side]

IRB Submissions

Pathway: IRB Assistant > Submission

For the most part, studies are processed like any other submission. Some differences:

- Sites will inherit some of the properties within the Outcome tab (Review Cycle and IRB Expiration) directly from the Core Protocol. This allows sites to be synchronized to the Core Protocol. This is controlled by a property.
- The system knows you've created virtual space underneath the Core Protocol (Study Shell) you have other ones that are related as subsets of that and are all managed under that same container of a study.