

SMART IRB EXCHANGE

SYSTEM USER MANUAL

June 2017

VERSION 2

Dear SMART IRB Exchange User,

Welcome! We are excited that your institution has decided to join the SMART IRB Exchange Network. We are hopeful that this national IRB reliance platform will help promote consistency and compliance, reduce duplication of effort in the IRB review, facilitate IRB cooperation, as well as provide shared access to data amongst participating sites for multi-site studies – all of which has great potential to improve quality, participant safety, and timeliness of results.

This system manual is to help **SMART IRB Exchange users** become familiar with the SMART IRB Exchange System. We encourage you to report any problems, difficulties, and suggestions to us at admin@smartirbexchange.org.

Sincerely,
The SMART IRB Exchange Team

SMART IRB EXCHANGE

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1. THE SMART IRB EXCHANGE WEBSITE

The **SMART IRB Exchange website** is located at <https://trialinnovationnetwork.org/elements/central-irb/>.

The webpage has links to information about submitting a network proposal to the Trial Innovation Network, “Tools and Materials for IRBs” and “Tools and Materials for Investigators and Study Teams”, including the use of the SMART IRB Exchange. This page includes a link to the **SMART IRB Reliance Agreement**, **SMART IRB Exchange Portal Access Form**, to **Login to SMART IRB Exchange**, and to contact **Trial Innovation Center personnel**.

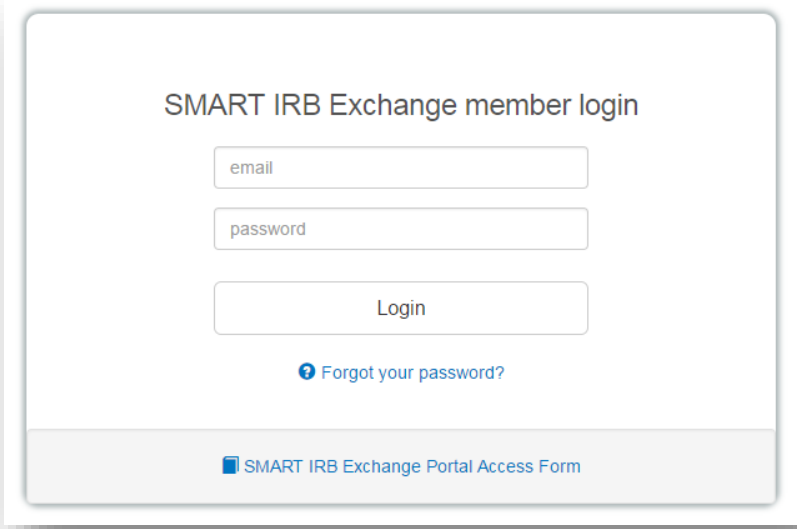


1.1. TECHNICAL REQUIREMENTS

SMART IRB Exchange has very few technical requirements. The system is compatible with current versions of all major browsers (Internet Explorer 11, Apple Safari, Mozilla Firefox, and Google Chrome).

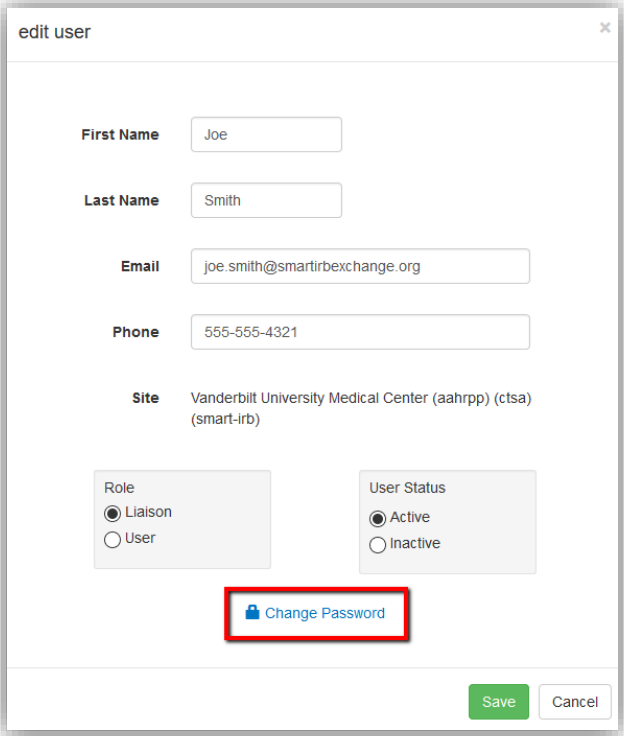
2. LOG IN

All SMART IRB Exchange users are sent an email with a temporary password to use to login for the first time. Follow the link to <https://sirb.trialinnovationnetwork.org> and login with the email address where the email was received and the temporary password.



The image shows a login form titled "SMART IRB Exchange member login". It contains two input fields: "email" and "password". Below these fields is a "Login" button. Underneath the "Login" button is a link that says "Forgot your password?". At the bottom of the form is a link that says "SMART IRB Exchange Portal Access Form".

3. CHANGE YOUR PASSWORD



The image shows a form titled "edit user". It contains several input fields: "First Name" (Joe), "Last Name" (Smith), "Email" (joe.smith@smartirbexchange.org), and "Phone" (555-555-4321). Below these fields is a "Site" dropdown menu with the selected option "Vanderbilt University Medical Center (aahrpp) (ctsa) (smart-irb)". There are two sections for user settings: "Role" with radio buttons for "Liaison" (selected) and "User", and "User Status" with radio buttons for "Active" (selected) and "Inactive". At the bottom of the form is a "Change Password" button, which is highlighted with a red box. There are also "Save" and "Cancel" buttons at the bottom right.

Set up a permanent password by clicking "Your Profile" at the top right corner of the Dashboard and then click "Change Password".

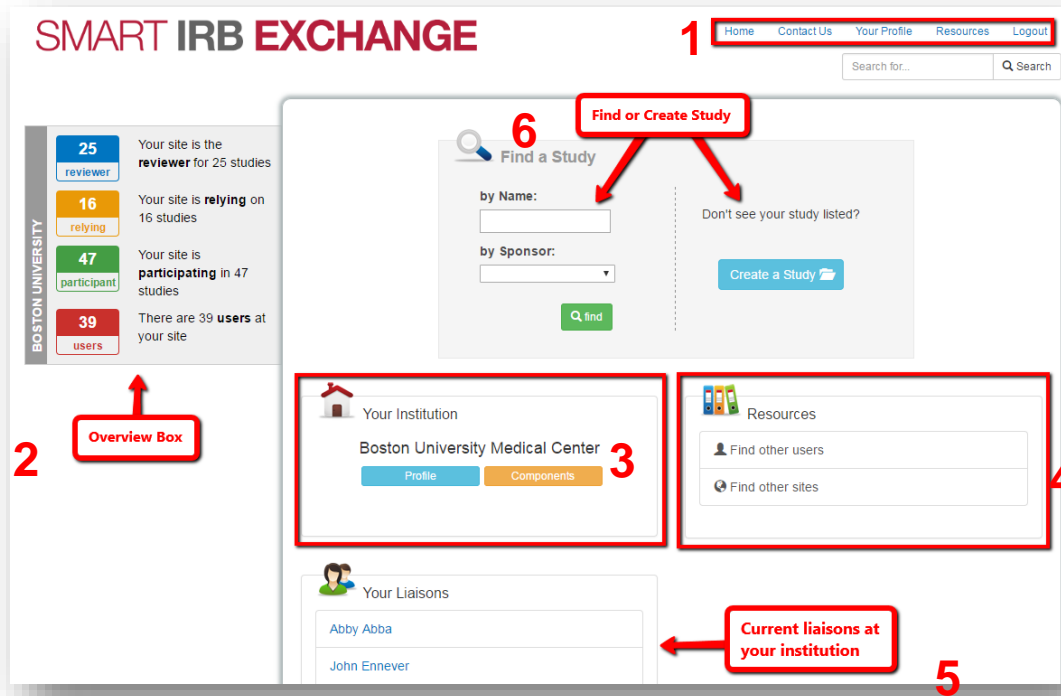
FROM YOUR PROFILE, UPDATE YOUR NAME, EMAIL ADDRESS, AND PHONE NUMBER. THIS INFORMATION CAN BE EDITED OR UPDATED AT ANY TIME.

When all updates have been made, click "Save".

SECTION B: SMART IRB EXCHANGE AT-A-GLANCE

1. DASHBOARD

After logging in, you are taken directly to your “**Dashboard**”. The Dashboard is tailored to you and provides information about your site’s use of SMART IRB Exchange.



- 1** In the top right corner are quick links, which are visible from any page of SMART IRB Exchange, that provide quick access to edit your profile, contact us, view resources, return to the Dashboard and log out of SMART IRB Exchange.
- 2** Also visible at all times, use the **Overview** box located on the left side of the screen, for quick access to a list of SMART IRB Exchange users at your institution and the studies which your institution is taking part in either as a Reviewing IRB or as a relying site.
- 3** Use **Profile** to view and edit your institutional profile and **Components** to manage all components on your institution’s FWA. More information about how to do this is in [Section D: The Institutional Profile](#) .
- 4** Under **Resources**, use **Find other sites** view the institutional profiles and list of FWA components of other SMART IRB Exchange institutions. Use **Find other sites** to view other users at your institution, as well as to identify an SMART IRB Exchange liaisons at another SMART IRB Exchange institution. More information about how to use this section is in [Section D: The Institutional Profile](#) and [Section C: User Roles and Access](#)
- 5** Use **Your Liaison** to make sure your site liaisons are properly identified.
- 6** Use **Find a Study** to search for studies in the Exchange and create new studies. More information about how to use this section is in [Section E.1: Create a Study](#) and [Section F.1: Find A Study](#).

2. STUDY PAGE OVERVIEW

Each study in SMART IRB Exchange has a page to organize the information about the study.

The screenshot displays the study page for "National Registry for Childhood Interstitial and Diffuse Lung Diseases". The page is organized into several sections:

- Overview:** A sidebar on the left shows site statistics: 15 reviewers, 12 relying sites, 31 participants, and 4 users.
- Study Title:** "National Registry for Childhood Interstitial and Diffuse Lung Diseases" with an "overview" icon.
- Announcement Box:** A red box highlights a warning: "One or more relying sites are awaiting your confirmation of a Study-specific Reliance Plan (SSRP). View SSRP status."
- Navigation Tabs:** Three tabs are visible: "Getting Started", "Reviewing IRB Approvals" (active), and "Relying Site Approvals".
- Protocol Version:** "Protocol Version: 1" is displayed.
- Action Icons:** Four icons for "initial site approvals", "add continuing review", "add study-wide amendment", and "terminate review".
- Study Information:** A section for "Boston University Medical Center" showing "Initial Study: Full Board (exp. 07/31/2017)" with a "current review" status.
- Study Info and Key Dates:** A table providing details such as Role (Reviewing IRB), IRB Number (12345), Decision (approved), Submission Type (Initial Study: Full Board), Review Cycle (12 mo), Submitted (07/01/2016), Pre-Reviewed (07/27/2016), Reviewed (07/28/2016), Approved (08/01/2016), and Expires (07/31/2017).
- Versions Box:** A sidebar on the left lists "Reviewing IRB" (Boston University), "Relying Sites" (Columbia, Kentucky, Seattle Children's, Vanderbilt), and "Registered/In Progress" (Harvard, Emory, Indiana).

The study page is organized by the following features: **Study Information**, **Navigation Tabs**, and **Versions Box**

2.1. STUDY INFORMATION

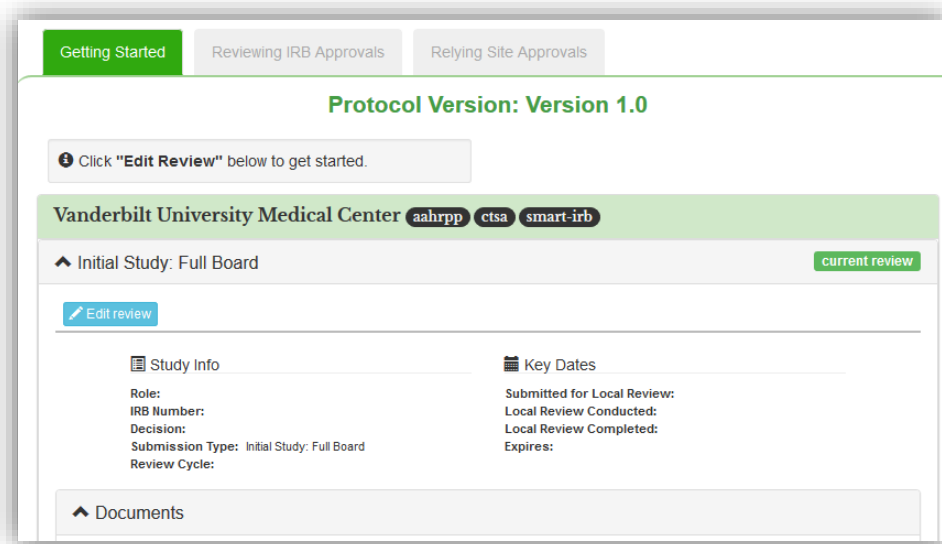
The study information section includes:

1. **Study Title:** title of study/project
2. **Study Overview:** click the blue "overview" icon to expand and view details of a study (i.e., Consortium, Study Summary, Type of Study, Sponsor)
3. **Study-level Action Icons:** use these buttons to complete study level actions, such as,
 - a) Complete the Study-Specific Reliance Plan (SSRP). See [Section E.2](#)
 - b) View the Access Log to see the most recent activity
 - c) Edit study information; more information in [Section E.1](#)
4. **Study Announcement Box:** reference the announcement box for active items to complete before adding or relying on a review.

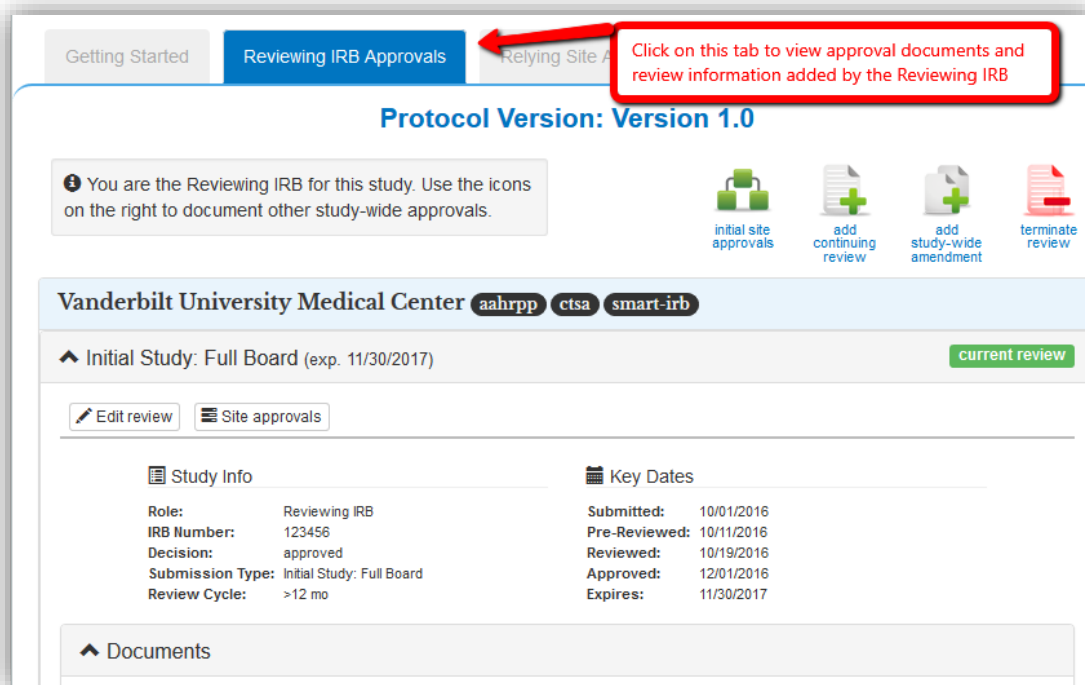
2.2. NAVIGATION TABS

The navigation tabs provide an easy way to reference various site approvals:

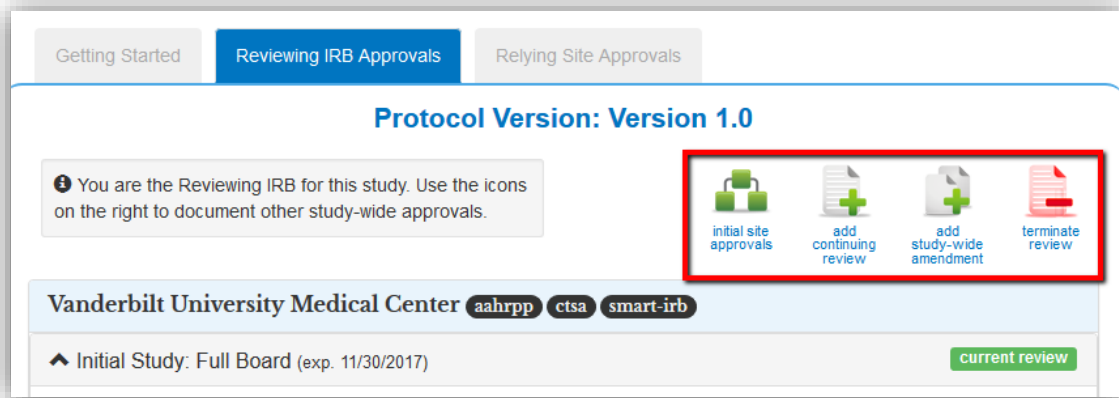
1. **Getting Started Tab:** Sites appear on this tab after registering for a study and until they have entered the required reliance information (including Study-Specific Reliance Plan (SSRP) selections) and completed all the steps needed to become a Reviewing IRB or Relying Site.



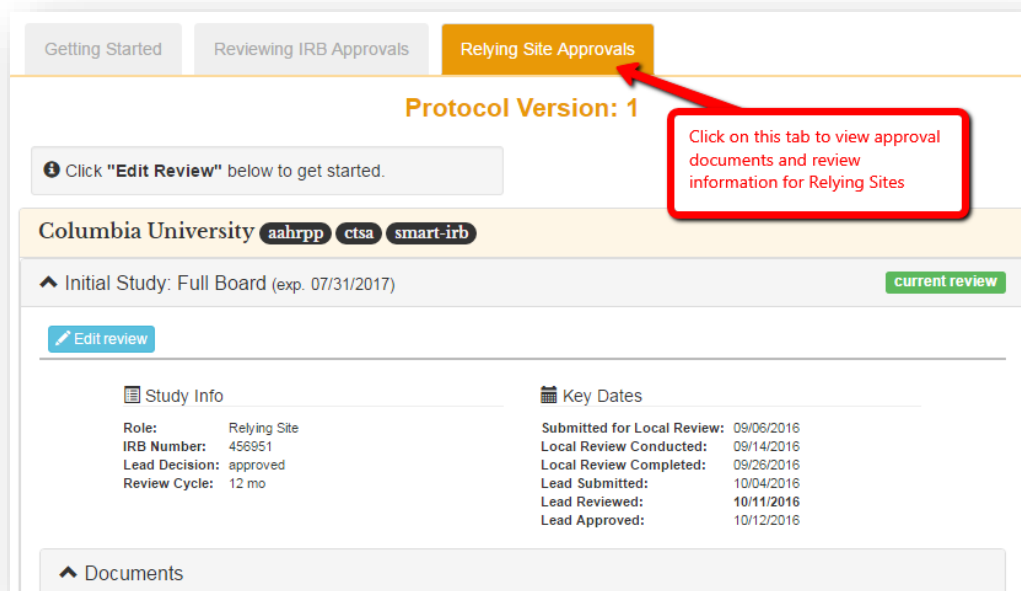
2. **Reviewing IRB Approvals Tab:** The site designated as the Reviewing IRB for a study will appear on this tab after entering preliminary study information and confirming their SSRP.



The Reviewing IRB tab also has **review-level icons** that the Reviewing IRB can use to view initial site approvals, add an amendment or continuing review, or terminate a review. See [Section B.3](#) for more information on action icons.



3. **Relying Site Approvals Tab:** Relying sites will appear on this tab after entering all required approval and study personnel information and accepting the Reviewing IRB's SSRP.



NOTE: ON BOTH THE REVIEWING IRB APPROVALS AND RELYING SITE APPROVALS TAB, CURRENT ("ACTIVE") SITE REVIEW INFORMATION IS AUTO-EXPANDED FOR EASY REFERENCING. ARCHIVED REVIEWS ARE ALWAYS AUTO-COLLAPSED

2.3. VERSIONS BOX



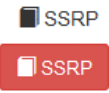

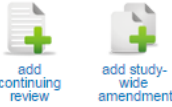

The Versions box on the project page tiers review information based on the study protocol version, amendment changes, and any revisions (non-protocol changes to the study). The protocol version is displayed in the version box as the version name. Amendments that do not change the protocol version (revisions) are listed with a Rev. ending, as shown below. All Revisions are auto-numbered. When a site is registered for a study, they appear as “Registered/In Progress” in the green Versions Box.

After a site becomes a Reviewing or Relying Site, they appear as either the “Reviewing IRB” or the “Relying Site” in the Versions Box.



3. ACTION ICONS

The action icons allow you to perform various functions within the SMART IRB Exchange project page:

	<p>View when the project was accessed or documents were downloaded by any other system user. The log can be exported to Excel.</p>
	<p><i>Reviewing IRB Only:</i> Edit the general information about the project including the study title, summary information, sponsor, and NCT #.</p>
	<p>View or finalize the status of your Study-Specific Reliance The icon is red when action is required.</p>
	<p><i>Reviewing IRB Only:</i> Add initial site approvals for Relying Sites. See Section E.5.</p>
	<p><i>Reviewing IRB only:</i> Add ongoing study approvals. See Section E.6, Section E.7, and Section E.8.</p>
	<p><i>Reviewing IRB only:</i> Document study termination.</p>

SECTION C: USER ROLES AND ACCESS

1. FIND USERS

If you are interested in collaborating or contacting a PI or an IRB contact at another institution, there are two ways to find contact information:

- 1) Click on the **Find Other Users** in the **Resources** box on the Dashboard. Use the site filter on the Users page to search for users outside your institution.
- 2) Click on the **Users** icon in the Overview box. Use the site filter on the Users page to search for users outside your institution.

NOTE: IF THE SITE FILTER IS PREFILLED FOR YOUR INSTITUTION, USE THE DROPDOWN MENU TO CHOOSE A DIFFERENT INSTITUTION NAME AND SEARCH FOR USERS AT THAT SITE.

Resources

- Find other users
- Find other sites

OVERVIEW

- 13** lead: Your site is the **lead** on 13 projects
- 6** relying: Your site is **relying** on 6 projects
- 19** registered: Your site is **registered** on 19 projects
- 16** users: There are 16 **users** at your site

Site: Example University Medical Center

Role: [] Phone: []

Type to filter

- Baystate Health
- Boston University Medical Center
- Children's National Medical Center
- Columbia University
- Example University Medical Center
- Louisiana State University A & M
- Louisiana State University Health Science Center New Orleans
- Marshall University
- Medical University of
- New York University
- North Shore LIJ Health
- Northwestern University
- Pennington Biomedical
- Seattle Children's Hospital
- The University of Texas
- Tulane University
- University of Alabama
- University of California
- University of Kentucky

Name	Email	Site	Role	Phone
Joe Smith	jsmith@example.edu	Example University Medical Center	Liaison	555-555-5555
Susan Jones	sjones@example.edu	Example University Medical Center	User	555-555-5555

Showing 1 to 2 of 2 entries (filtered from 65 total entries)

2. ADD NEW USERS

The SMART IRB Exchange system provides access for two types of users in the system: **IRB/ HRPP staff and members** and **Study Personnel**. You must be a liaison to create a new user.

2.1. IRB/HRPP MEMBERS AND STAFF

SMART IRB Exchange Liaisons have the ability to set up two roles for IRB staff and members: "Liaisons" and "Users".

- **LIAISONS** have more permissions than "Users". Liaisons have the ability to add new users, edit the Institutional Profile, create new studies, register for studies already created in the Exchange, and accept/confirm the Study-Specific Reliance Plan (SSRP).
 - **Multi-Site Liaisons** are affiliated with multiple FWA institutions and can perform liaison functions for all these institutions. (See [Section F.5](#))
- **USERS** have the ability to monitor and update studies that have been created in the Exchange and accept/confirm the Study-Specific Reliance Plan (SSRP). Users do **NOT** have the ability to create or register for studies or add new Exchange liaisons or users. IRBs with small staff may or may not opt to have "users".

To add IRB Staff and Members:

1. Click on the **Users** icon in the **Overview** section of the SMART IRB Exchange Dashboard. A list of users at the site will be visible.
2. You can search by name or email to make sure the contact you wish to add is not already in the system. A filter is provided to make searching for a user quick and easy. The filter will accept partial entries in both fields.
3. Click "**add HRPP Staff/ Members**" in the upper right corner to add a new user.
4. Enter the user's **first name**, **last name**, **email address**, and select the appropriate **institution** and **role (Liaison or User)**. You may also provide a phone number.
5. To create a **multi-site liaison**, use the **add role** button to add another institution and choose the appropriate role. This allows the liaison manage multiple FWA institutions under one account.
6. Click "Save" and the user will automatically receive an email and temporary password to login to SMART IRB Exchange.

The image shows two screenshots from the SMART IRB Exchange system. The left screenshot is the 'Users' overview page, featuring a sidebar with site statistics (26 reviewers, 16 relying studies, 49 participating studies, 39 users) and a main table of users. A green button labeled '+ add HRPP Staff / Members' is highlighted with a red box and the number 3. The table has columns for Name, Email, and Site. The right screenshot is the 'create a user' form, which includes input fields for First Name, Last Name, Email, and Phone, each with a 'Required' warning. It also has radio buttons for Role (Liaison, User) and User Status (Active, Inactive), and 'Save' and 'Cancel' buttons. Red numbers 1 through 6 are overlaid on the image to correspond to the numbered steps in the text.

Roles

Primary Role

Site: University of Pittsburgh of the Comm... Role: Liaison

Other Roles

Children's Hospital of Pittsburgh Liaison ✖

University of Pittsburgh Medical Center Liaison ✖

+ Add Role **5**

2.2. STUDY PERSONNEL

Study Personnel (PIs and Coordinators) have restricted access on a study-by-study basis. They have view-only access to Institutional Profiles and user contact information. They receive **email notifications** whenever the Reviewing IRB uploads new approval documents for their study and can download these study documents for their site. They do **NOT** have the ability to create or edit content.

SMART IRB Exchange Liaisons can add PIs and Coordinators to each study during the study setup process.

To add study personnel:

1. Go to the appropriate study page and click on the **Edit Review** button.
2. On the Primary Contact tab, select the **type of contact** you wish to add (PI or Coordinator).
3. Type the **email address** of the contact you wish to add to search the database for existing study contacts at your site. Click on the email address to add it.
4. For new study contacts, enter the **first and last name**. For existing study contacts, these fields will be auto-populated.
5. Click **Add Contact** to add the contact. You must add at least one PI to each study. All personnel listed here will receive email notifications of any new approvals the Reviewing IRB uploads for your site.
6. The study contact will automatically receive an email and temporary password to login to SMART IRB Exchange once you have reviewed and confirmed the SSRP for the study.

Boston University Medical Center **ctsa** **smart-irb**

Initial Study: Full Board (exp. 01/02/2018)

Edit review

Study Info

Role: Reviewing IRB
IRB Number: 1023
Decision: pending
Submission Type: Initial Study: Full Board
Review Cycle: 12 mo

Key Dates

Submitted: 01/02/2017
Pre-Reviewed: 01/02/2017
Reviewed: 01/03/2017
Approved: 01/03/2017
Expires: 01/02/2018

Primary Contacts

Add A Contact

Type of contact ...
email address
first name
last name
+ Add Contact

Current Contacts

Email	Name	Role
jsmith@test.edu	Joe Smith	PI ✖

2.3. ROLES AND PERMISSIONS

The table below summarizes the permissions for each role in the SMART IRB Exchange.

Permissions	Liaison	User	Study Personnel
Create a new study	X		
As Reviewing, edit an existing study	X	X	
Register for an existing project	X		
Add HRPP/IRB members (Liaisons + Users)	X		
Add new Study Personnel (PI + Coordinator)	X	X	
Find other users	X	X	X
Edit Institutional Profile	X		
View Institutional Profile	X	X	X
Accept/Confirm Study-Specific Reliance Plan	X	X	
As Reviewing, upload approvals for my site	X	X	
As Reviewing, upload approvals for relying sites	X	X	
View + download study approval documents	X	X	X

SECTION D: THE INSTITUTIONAL PROFILE

The SMART IRB Exchange Institutional Profile is designed to capture information about each member institution's IRB and their processes and considerations when using reliance. This information is available to other Exchange members in hopes of providing a centralized repository for identifying potential collaborators (e.g., Reviewing IRBs), as well as to learn best practices for supporting single IRB review. The Institutional Profile is site-specific and can be edited at anytime.

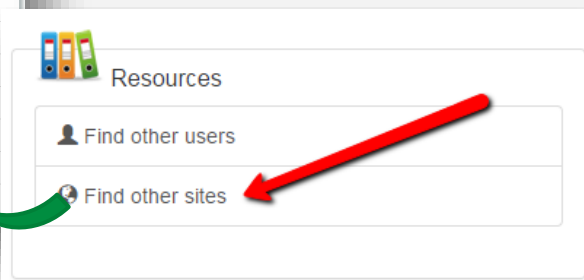
It contains four sections:

- Section 1 General HRPP Information
 - Give us general information about your IRB/HRPP (e.g., FWA #, IRB Registry #s, AAHRPP status, checking the box status, etc.)
- Section 2: Local Context
 - Provide an overview of the local context requirements such as state and local laws that must be considered at your institution (e.g., age of majority, state/local laws or policies affecting consent, etc.)
- Section 3: Institutional Policies and Processes for Relying on an External IRB
 - Capture your institution's/HRPP's submission requirements and processes for local investigators when you are ceding review. This information will be helpful to your local study teams when they are navigating how to rely on another institution.
- Section 4: Reliance Preferences when serving as the IRB of Record
 - Enter your general preferences for handling HIPAA, external reporting, and auditing when you serve as the IRB of record for a study. This section forms the basis for the Study-specific Reliance Plan between your IRB and relying sites.

1. VIEW PROFILES

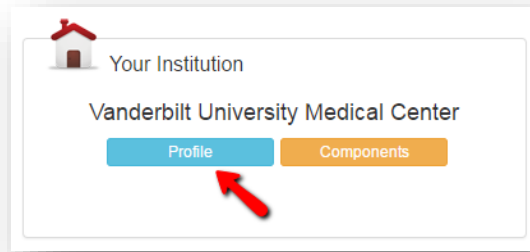
Name	Location	Profile
Advocate Health Care Network <small>smart-irb</small>	Downers Grove, IL	view profile
Albert Einstein College of Medicine <small>ctsa smart-irb</small>	Bronx, NY	view profile
All Children's Hlth System, Inc. <ul style="list-style-type: none">• All Children's Hosp Professional Office Building• All Children's Physician Hosp Organization, Inc.• All Children's Rsch Institute• Kids Home Care• Pediatric Physician Services, Inc.• Surgikid Florida, Inc.	St. Petersburg, FL	view profile
Ann & Robert H. Lurie Children's Hospital of Chicago <small>aahrpp smart-irb</small>	Chicago, IL	view profile
Arizona State University <small>smart-irb</small>	Tempe, AZ	view profile
Arkansas Children's Hospitals	Little Rock, AR	view profile
Arkansas Children's Research Institute <small>smart-irb</small>	Little Rock, AR	view profile
Augusta University <small>aahrpp</small>	Augusta, GA	view profile
Aurora Bay Care Medical Center <small>smart-irb</small>	Green Bay, WI	view profile
Aurora Health Care <small>aahrpp smart-irb</small>	Milwaukee, WI	view profile

Use **Find Other Sites** to access the profiles of other SMART IRB Exchange institutions and their FWA components. To view an institution's profile, click the "view profile" button by the institution's name.

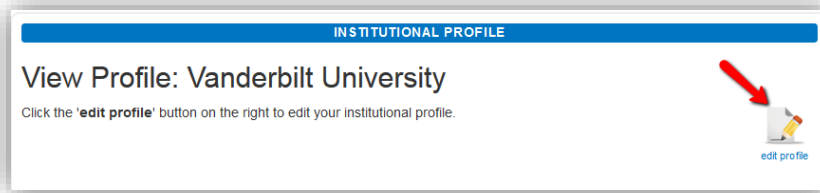


2. EDIT YOUR PROFILE

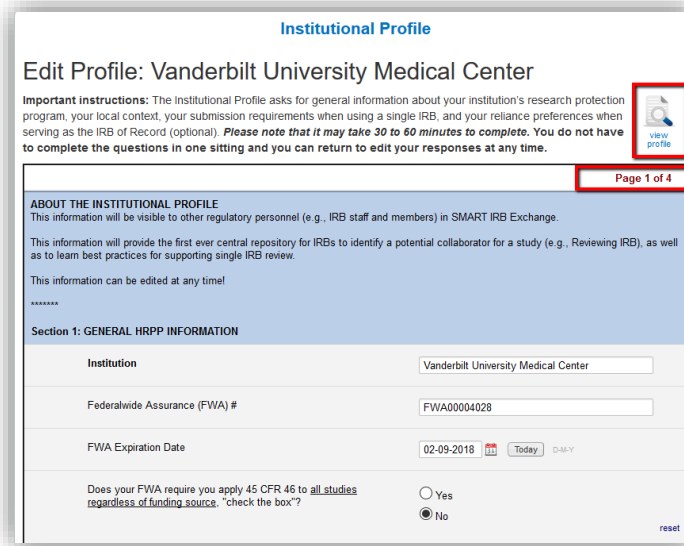
To edit your Institutional Profile, click the Profile button on the home page.



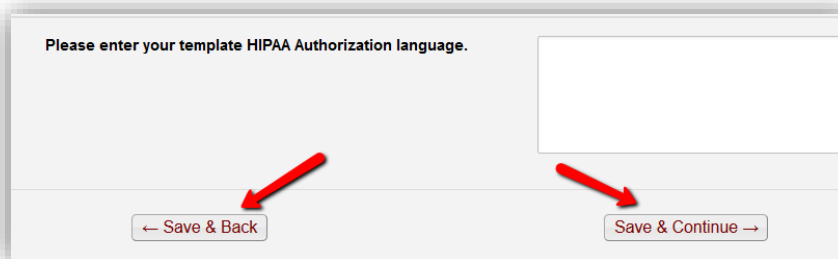
Next click the "edit profile" icon in the top right corner.



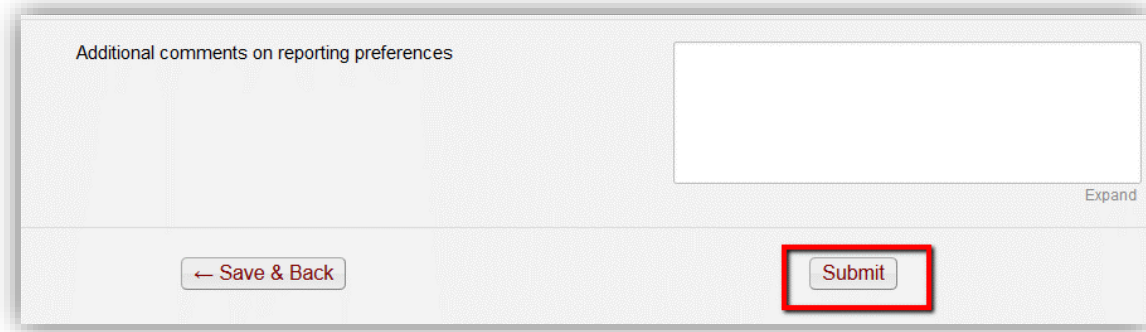
A new page will open with a survey and instructions about the Institutional Profile.

A screenshot of a survey page titled "Edit Profile: Vanderbilt University Medical Center". At the top, it says "Important instructions: The Institutional Profile asks for general information about your institution's research protection program, your local context, your submission requirements when using a single IRB, and your reliance preferences when serving as the IRB of Record (optional). Please note that it may take 30 to 60 minutes to complete. You do not have to complete the questions in one sitting and you can return to edit your responses at any time." Below this, there is a "view profile" icon in a red box. The page is labeled "Page 1 of 4". The main content area is titled "Section 1: GENERAL HRPP INFORMATION" and contains several form fields: "Institution" (Vanderbilt University Medical Center), "Federalwide Assurance (FWA) #" (FWA00004028), "FWA Expiration Date" (02-09-2018), and a question "Does your FWA require you apply 45 CFR 46 to all studies regardless of funding source, 'check the box'?" with radio buttons for "Yes" and "No". A "reset" button is at the bottom right.

To navigate while editing, use the navigation buttons at the bottom of the edit profile screen.

A screenshot of the bottom navigation area of the edit profile screen. It contains two buttons: "← Save & Back" and "Save & Continue →". Red arrows point to each button.

The Institutional Profile automatically saves when you navigate using the icons at the bottom of the screen. Once finished editing, click the submit button.



Additional comments on reporting preferences

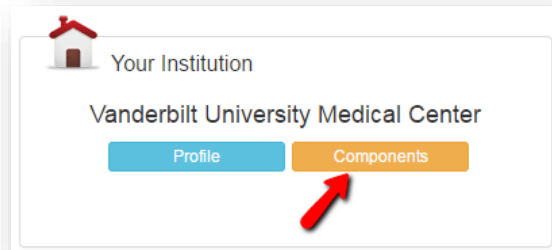
Expand

← Save & Back

Submit

3. EDIT YOUR FWA COMPONENTS

To edit your FWA components, click the Components button on the home page.

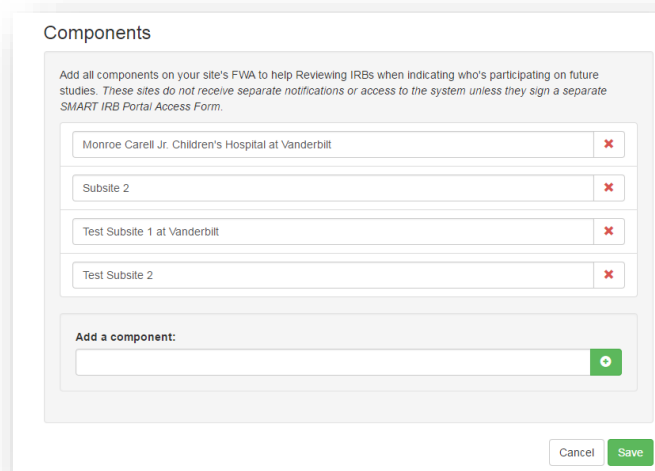


Your Institution

Vanderbilt University Medical Center

Profile Components

Use the **Add a component** to add any institutions that listed on your FWA. These sites will be listed in our database so that Reviewing IRBs can find your affiliate institutions when creating a study. Components do not receive separate email notifications or access to the system.



Components

Add all components on your site's FWA to help Reviewing IRBs when indicating who's participating on future studies. *These sites do not receive separate notifications or access to the system unless they sign a separate SMART IRB Portal Access Form.*

Monroe Carell Jr. Children's Hospital at Vanderbilt

Subsite 2

Test Subsite 1 at Vanderbilt

Test Subsite 2

Add a component:

Cancel Save

SECTION E: PARTICIPATING AS A REVIEWING IRB

1. CREATE A STUDY

The first step is as the Reviewing IRB participating in a multi-site study that is not listed in the SMART IRB Exchange system, is to add the study as a new project.

To create a study:

- 1) Click on the "Create a Study" button on the Dashboard
- 2) Enter General Information:
 - a. Title of Study
 - b. Summary
 - c. NCT#(s)
- 3) Upload Documents (You can upload draft versions which can be changed later)
 - a. Protocol, note version
 - b. Investigator's Brochure
 - c. Device Manual
 - d. Participating Site Contacts
 - e. Consent Documents
- 4) List Participants
 - a. Indicate if the Reviewing IRB is also participating in the study
 - b. Choose a Sponsor
 - c. Choose your Participating Sites or Network.
 - i. If your study belongs to a consortium/network, select the appropriate network and indicate which members of the network are participating in the study.

The image displays four overlapping screenshots of the SMART IRB system interface, illustrating the steps to create a study:

- Find a Study:** A search interface with fields for "by Name:" and "by Sponsor:", a "find" button, and a "Create a Study" button highlighted with a red box. A message "Don't see your study listed?" is also present.
- General Information:** A form with fields for "Title", "Summary", and "NCT#". The "Title" field is marked as "Required".
- Documents:** A form with fields for "Protocol Version", "Protocol", "Investigator's Brochure", "Device Manual", "Participating Site Contacts", and "Consent Documents". Each field has a "Choose File" button and a "Draft" checkbox. The "Protocol" field is marked as "Required".
- Participants:** A form with a question "Is the Reviewing IRB a participating research site in the study?" (Yes/No), a "Sponsor" dropdown menu (set to "Center for Cancer Research"), a "Sites/Network" dropdown menu (+ Add Individual Sites), and a "Participating Sites" section with an "Add a site:" input field. A note states: "* Only members selected below will be able to access this study." A footer note says: "Please let us know if you don't see your sponsor or consortium."

- ii. Select “+Add Individual Sites” to create a list of participating sites. You can search the database of SMART IRB Exchange members by name of FWA number using the **Add a Site** bar. Click on the site name to add it to the study.
- iii. If you cannot find a participating site in the Exchange, type the site name in the **Add a Site** field and click the green plus sign to provide their contact information. The SMART IRB Exchange team will contact the institution and invite them to join the Exchange.

NOTE: STUDIES THAT ARE AFFILIATED WITH A NETWORK OR HAVE A PRE-SPECIFIED LIST OF PARTICIPATING SITES ARE ONLY ACCESSIBLE TO THE INSTITUTIONS LISTED AS PARTICIPATING SITES. STUDIES WITH NO AFFILIATION ARE ACCESSIBLE TO ANY INSTITUTION IN SMART IRB EXCHANGE.

Participants

Is the Reviewing IRB a participating research site in the study? Yes No

Sponsor: National Heart, Lung, and Blood Institute

Participating Sites: Toggle All

- Baystate - Springfield Hospital #FWA00004355
- Boston University Medical Center #123456789
- Case Western Reserve University #FWA00000161
- Columbia University #FWA00003831
- Duke University #FWA00009025
- Emory University #FWA00005792
- Harvard University #FWA00004837
- Indiana University School of Medicine #FWA00003544
- Johns Hopkins University #FWA00005752
- Louisiana State University A & M #FWA00003892
- Medical University of South Carolina #FWA00001888
- Northwestern University #FWA00001549
- The University of Utah #FWA00003745
- Virginia Commonwealth University #FWA00005287
- Yale University #FWA00002571

Participating sites within the network

Additional sites outside the network

Additional Sites:

- Chicago - University of Chicago Medicine Comer Children's Hospital #FWA00005565
- U Pittsburgh - U of Pittsburgh Center Institute
- Brigham and Women's Hospital

Example University Medical Center
is not in our system. Please provide contact information for someone at the site so we can invite them to join the SMART IRB Exchange.

Name of Contact:

Email Address:

Please let us know if you don't see your sponsor or consortium.

- 5) Review and submit the study by clicking “save” You can return to edit your study details and add new participating sites after the initial set up by clicking the edit button on the top right corner of the study page.

SSRP follow log **edit**

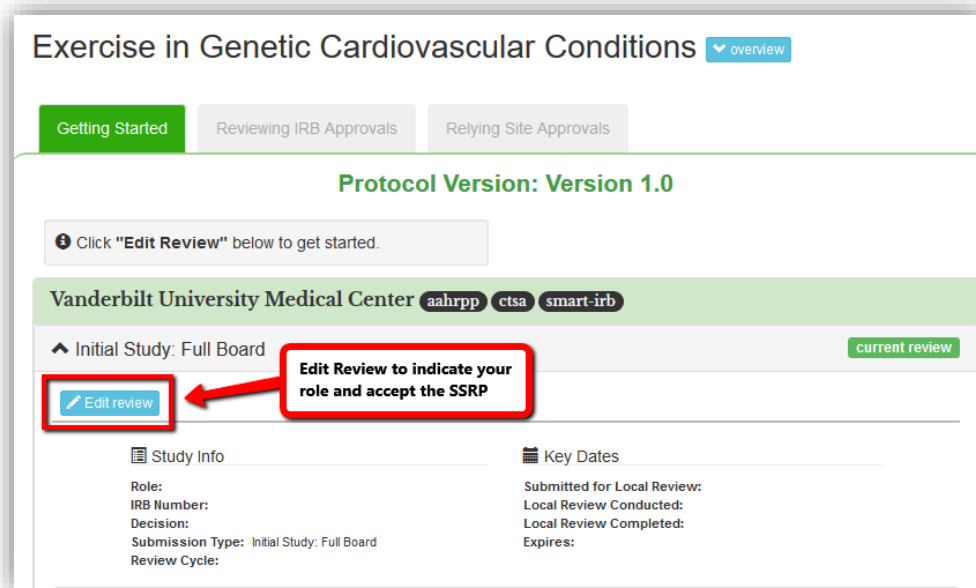
Bilateral Transfer of Motor Skills and Brain Activation Patterns

[overview](#)

Reviewing IRB Approvals Relying Site Approvals Status Summary

1.1. EDIT YOUR REVIEW

After creating a new project, your site will appear on the Getting Started tab of the project. Click the blue **"Edit Review"** button to indicate your role and provide study information basic study information. To finalize your role as the Reviewing IRB you must also complete a **Study-Specific Reliance Plan (SSRP)** for this study.



1.1.1. ENTER YOUR STUDY INFORMATION

- **Role:** will your institution be the **Reviewing IRB** or **Relying Site** for this study?
- **IRB Number:** what is the number used at your institution to track the study?
- **Decision:** is the study **Approved** or **Pending** approval at your institution?
- **Review Cycle:** what review cycle was selected for the study? *3, 6, 9, 12 or >12 months*
- **Type of Study:** Greater than minimal risk or Minimal risk
- **Submission Type:** is this a **full board** or **expedited** review?



NOTE: YOU DO NOT HAVE TO HAVE IRB APPROVAL BEFORE INDICATING YOU WILL BE THE REVIEWING IRB IN SMART IRB EXCHANGE. IN FACT, YOU ARE ENCOURAGED TO INDICATE YOUR ROLE AS THE REVIEWING IRB AS EARLY IN THE PROCESS AS POSSIBLE TO FACILITATE EFFICIENCY IN THE RELIANCE PROCESS (E.G., INVESTIGATOR AWARENESS AND BETTER STUDY COORDINATION.)

1.1.2. ADD LOCAL STUDY PERSONNEL

After selecting a role, liaisons are asked to enter the contact information of local study personnel. This information is used to alert the investigator that their IRB will be a Reviewing IRB for a study, as well as provide the investigator with information on how their responsibilities will change because their IRB is the Reviewing IRB. For example, the investigator may have to submit on behalf of Relying Sites or serve as a liaison between their IRB and Relying Site investigators. Personnel listed here will receive email notifications of any new approvals documents the Reviewing IRB uploads for their site. Search the database for existing investigators or enter contact information for new investigators. This will create an account with which they can log in to the Exchange, view Institutional Profiles, user contact information and download their study documents..

Email	Name	Role
jsmith@test.edu	Joe Smith	PI

1.1.3. ENTER KEY DATES

- **Submitted:** when was the study first submitted to your IRB for review?
- **Pre-Review Completed:** when was the pre-review completed?
- **Reviewed:** when was the review for the study conducted by your IRB?
- **Approved:** when was the study approved?
- **Expires:** when does the study expire? (pre-populated for studies with Decision status: "Approved")

Submitted	mm/dd/yyyy
Pre-Review Completed	mm/dd/yyyy
Reviewed	mm/dd/yyyy
Approved	mm/dd/yyyy
Expires	mm/dd/yyyy

1.1.4. REVIEW AND SUBMIT

Review your study information and click "Save" when you are ready to submit. Any sections that are missing required fields will be highlighted red.

Review and Submit

Your Reviewing IRB is *Vanderbilt University Medical Center*.

Study Details	
Role	Relying Site
IRB Number	123456

Personnel	
Primary Investigator	John Smith John.Smith@smartirbexchange.edu
Coordinator	

Key Dates	
Submitted:	08/01/2016
Reviewed:	08/05/2016
Approved:	09/06/2016

Cancel Save

NOTE: You do not have to complete all sections in order to cede review. After study personnel information is entered, the Relying Site is ready to confirming the Study-Specific Reliance Plan and cede review to the Reviewing IRB.

2. CONFIRM YOUR STUDY-SPECIFIC RELIANCE PLAN (SSRP)

The next step to serving as the IRB of Record for other sites is to complete the Study-Specific Reliance Plan (SSRP). As described in the SMART IRB Exchange Portal Access Form, the SSRP is a set of study-specific reliance preferences between the Reviewing IRB and each of the Relying Sites regarding the following information:

- **Providing documentation:** When will the Reviewing IRB share their minutes (routinely or as requested)?
- **Reviewing for HIPAA:** Will the Reviewing IRB review authorizations and waiver requests for Relying Sites?
- **Reporting:** What is the Reviewing IRB's preferred process for external reporting?
- **Auditing:** What is the Reviewing IRB's preferred process for auditing?

The Reviewing IRB has the final say on the SSRP for each study. In order to serve as the Reviewing IRB, the Reviewing IRB must agree on an SSRP with each relying site. Relying Sites can request changes to the SSRP initially proposed by the Reviewing IRB. The Reviewing IRB may update the SSRP to reflect any changes requested after they have been discussed with the Relying Site by phone or email.

STEPS TO COMPLETING THE STUDY-SPECIFIC RELIANCE PLAN (SSRP) FOR A STUDY

After completing the site review, you will be prompted to complete the SSRP. The SSRP is based on your responses to section 4 of your institutional profile. If you have completed an SSRP for a previous study, the original responses will be copied over and you will be allowed to edit.

- 1) Review your SSRP selections. If change any responses, click the "Submit" button at the bottom of the page to update the SSRP for the study. Once you are satisfied with the responses, click the "Confirm Initial SSRP" button to share your preferences with Relying Sites.

Study-specific Reliance Plan (SSRP)

⚠ Please confirm this initial SSRP to present to relying institutions when they join this study. You can modify the SSRP for an individual institution before reliance is finalized.

Confirm initial SSRP

Documentation:
The Reviewing IRB will provide meeting minutes/summaries (redacted):
* must provide value

Routinely
 Upon request by a Relying IRB

HIPAA: Will the Reviewing IRB review HIPAA authorizations and requests for waivers for Relying Institutions?
(Note: All entities are responsible for local accounting of disclosures)
* must provide value

Yes
 No

The Reviewing IRB's process for **external reporting** (e.g., unanticipated problem, serious or continuing non-compliance, suspensions or terminations) to OHRP/FDA is to:

* must provide value

File first without comment from the relying IRB
 Work jointly with the Relying Institution on the report
 File once letter has been reviewed by the relying IRB
 Allow relying IRB to independently file report after review and comment

CHECK ALL THAT APPLY

Will the Reviewing IRB provide an opportunity for Relying Institutions to comment on **unanticipated problem or serious or continuing non-compliance reports** to OHRP/FDA?
* must provide value

Yes
 No

The Reviewing IRB will allow the following amount of time for the Relying I or conti
* must provide value

5

Submit

Expand

Cancel

- 2) Once you confirm the SSRP, an email notification will be to all listed participating sites informing them of the new study and inviting them to participate.
- 3) In order to indicate their decision to cede review to you, relying sites must review and accept your SSRP. Once a Relying Site accepts your SSRP, an email notification is sent to you and the Relying Site liaison noting their acceptance. This email will also have the official documentation of reliance letter.

3. TRACK STATUS OF PARTICIPATING SITES

To see the list of all Relying Sites and track their Study Start-up and SSRP status, click on the **Status Summary** tab.

- **NO ACTION REQUIRED WHEN THE SSRP STATUS IS:**

- **Complete:** the Relying Site has accepted your SSRP and you, as the Reviewing IRB, have confirmed you act as their IRB of Record.

- **ACTION IS REQUIRED WHEN THE SSRP STATUS IS:**

- **Pending acceptance:** the Relying Site has not yet accepted your SSRP or they may have emailed you to request you make changes to your initially proposed SSRP for their site. Click on the status icon to update the SSRP for the corresponding site only.

The screenshot shows a web interface with three tabs: "Reviewing IRB Approvals", "Relying Site Approvals", and "Status Summary" (highlighted in green). Below the tabs is a search bar and a table titled "Participant Status Summary". The table has columns for "Site", "SMART IRB", "SMART IRB Exchange", "SSRP", and "Local Context". The "SSRP" column contains status icons: "Not registered", "Complete", and "Pending acceptance". Red callout boxes with arrows point to specific rows, explaining the status: "Site has not registered to participate" points to Case Western Reserve University; "Registered but has not accepted SSRP. Click here to update SSRP preferences for this site" points to Duke University; "Sites have not completed required CIRB agreements and do not have access to the Exchange" points to Oregon Health & Science University and University of Chicago Comer Children's Hospital; "Site has registered and accepted SSRP. No action required" points to Yale University.

Site	SMART IRB	SMART IRB Exchange	SSRP	Local Context
Case Western Reserve University	✓	✓	Not registered	-
Children's National Medical Center	✓	✓	Not registered	-
Columbia University	✓	✓	Complete	-
Duke University	✓	✓	Pending acceptance	-
Emory University	✓	✓	Complete	-
Harvard University	✓	✓	Complete	-
Louisiana State University Health Science Center New Orleans	✗	✓	Not registered	-
Oregon Health & Science University	✓	✗	Not registered	-
University of California - San Francisco - UCSF Benioff Children's Hospital	✓	✓	Not registered	-
University of Chicago Comer Children's Hospital	✓	✗	Not registered	-
Vanderbilt University Medical Center - Monroe Carell Jr. Children's Hospital at Vanderbilt	✓	✓	Complete	-
Yale University	✓	✓	Complete	-

4. ADD AN INITIAL STUDY APPROVAL FOR YOUR SITE

The Reviewing IRB can upload approval documents for the lead site once the initial review is complete. To upload initial study approval for your site, complete the following steps:

- 1) On the Getting Started tab, click the blue “Edit Review” button and complete the study information. Once the decision field is set to “Approved”, all required fields will be highlighted red.

Getting Started | Reviewing IRB Approvals | Relying Site Approvals | Status Summary

Protocol Version: 1

Boston University Medical Center **ctsa** **smart-irb**

Initial Study: Full Board current review

Edit review

Study Info | Key Dates

Role: Reviewing IRB | Submitted: | Pre-Reviewed: | Reviewed: | Approved: | Expires:

IRB Number: |

Decision: |

Submission Type: Initial Study: Full Board |

Review Cycle: |

- 2) Update the Review Dates. See [Section E.1.1.3](#)
- 3) Upload the approved study documents (consent forms, investigator brochures, device manuals, package inserts etc.) that you have for this review. Drag and drop files from a file folder or click the “drag n’ drop” box to upload documents. If you have draft documents already in the system, you must either accept them or delete and replace them with the final version. A document name is required for documents uploaded under the “Others” category (e.g., recruitment materials). These documents will be visible to all relying sites once they register to participate. Choose as a document name that allows relying sites to easily identify files when downloading. Required documents are indicated with a flag.

Documents

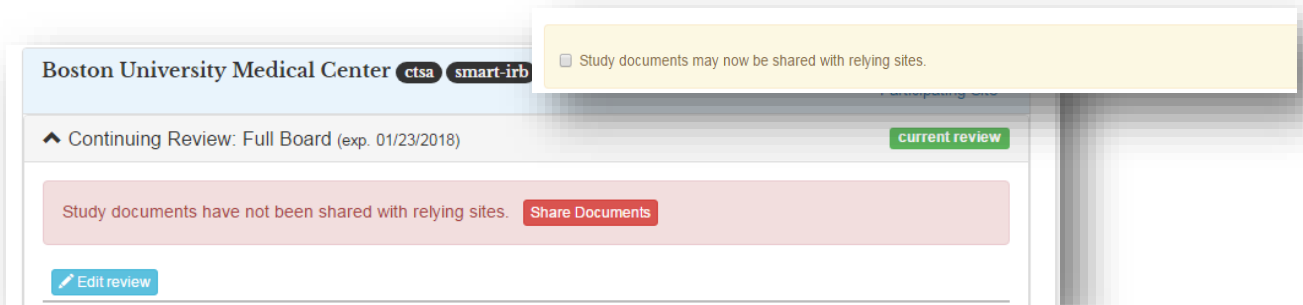
Type	Document	
Protocol [1]	PROTOCOL_v1.docx	
Participating Sites List	ParticipatingSites.xlsx	Delete
Determination Letter	Choose a file or drag it here	Draft
IRB Application	Choose a file or drag it here	Draft
Consent Forms	CONSENT FORM - Adult.docx	DRAFT Delete
Consent Forms	CONSENT FORM - Assent.docx	DRAFT Delete
Consent Forms	CONSENT FORM Spanish.docx	DRAFT Delete
Consent Forms	Choose a file or drag it here	Draft
Meeting Notes	Choose a file or drag it here	Draft
Investigators Brochure	Choose a file or drag it here	Draft
Device Manual	Choose a file or drag it here	Draft
Package Insert	Document Name: Choose a file or drag it here	Draft
Others	Type of Study Document: Choose a file or drag it here	Draft

Continue →



NOTE: THE SMART IRB EXCHANGE SYSTEM ALLOWS UPLOADS OF MULTIPLE DOCUMENTS OF THE SAME TYPE AT ONCE. FOR EXAMPLE, DRAG AND DROP ALL CONSENT FORMS IN THE CONSENT FORMS DRAG’N’DROP BOX TO CREATE MULTIPLE ENTRIES. THIS ALSO WORKS FOR INVESTIGATORS BROCHURES, DEVICE MANUALS, PACKAGE INSERTS, AND ANY OTHER ADDITIONAL DOCUMENTS. TO REMOVE ANY DOCUMENT, CLICK THE RED “DELETE” BUTTON.

- 4) When all the review information is complete and all required documents are uploaded, click the checkbox "Study documents may now be shared with relying sites" to share your documents. This sends an email notification to all participating sites informing them that the lead site has been approved. You will not be able to check this box until all the required fields are complete, in addition to having completed your initial SSRP for the study. You can also do this by clicking the "Share Documents" button on the Reviewing IRB tab.

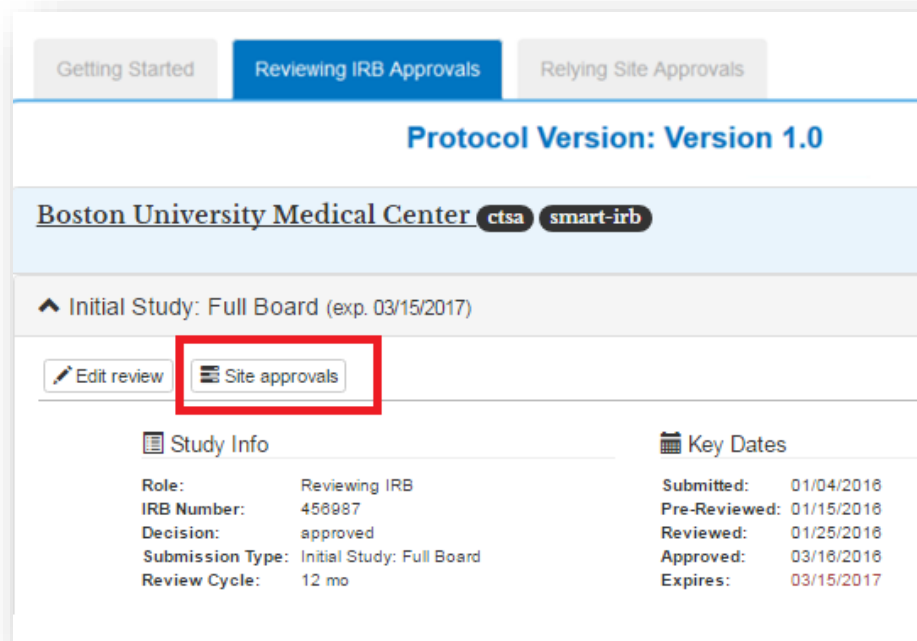


5. ADD A STUDY APPROVAL FOR A RELYING SITE

Once you have uploaded your initial approval, you can add approvals for Relying Sites who chose to cede review.

To upload Relying Site approvals:

- 1) Click on the "Site approvals" icon on the Reviewing IRB Approvals tab. You can upload approvals for more than one Relying Site, at once.



- 2) A pop-up will appear with a list of Relying Sites who have chosen to cede review. For each site, you will:
 - a. Choose a review decision: Approved or Pending
 - b. Enter the approval dates: Submitted, Reviewed, Approved
 - c. Upload approvals documents specific to the Relying Site:
 - i. Determination Letter (required)
 - ii. Consent Documents (required; multiple uploads allowed)
 - iii. Other Documents (optional; multiple uploads allowed)

3) You must set the Decision to **“approved”** for a Relying Site in order upload approval documents for that site.

4) Once you upload and save an approval for a Relying Site, the following happens:

- a. The Relying Site Approval documents and information will be added to the Relying Site Approvals tab for that site.

Relying Site Approvals - Initial Study: Full Board

Medical University of South Carolina | Johns Hopkins University

Decision: approved | Date Submitted: 01/01/2017

Submission Type: Initial Study, Full Board | Date Reviewed: 01/11/2017

Date Approved: 02/01/2017

Documents

Determination Letter

DETERMINATION LETTER_Initial Review.docx

Consent Documents

Consent Document - CONSENT FORM - Adult.docx

Choose a file or drag it here.

- b. An email notification will be sent to the Relying Site Liaison(s), Investigator and Study Coordinator (as entered by the Relying Site Liaison) indicating your IRB has approved the study for the Relying Site. Your approval letter, site-specific consent form and other study approved documents will be attached to the email.

Getting Started | Reviewing IRB Approvals | Relying Site Approvals

Protocol Version: Version 1.0

Thank you for being a Reviewing IRB in this study. Visit the [Reviewing IRB tab](#) to work on your reviews.

Medical University of South Carolina (aahrpp) (ctsa)

Initial Study: Full Board (current review)

Johns Hopkins University (aahrpp) (ctsa) (smart-irb) (site amendment)

Initial Study: Full Board (exp. 11/30/2017) (current review)

5) To add approvals for other sites, click the site name on the side bar and repeat the steps above.

6. ADD A CONTINUING REVIEW APPROVAL

- 1) Click the **“Add Continuing Review”** icon at the top of the Reviewing IRB Approvals tab. An **“Add Continuing Review”** box will open.
- 2) In the Continuing Review window, indicate whether a study-wide amendment was approved on the same day. If an amendment was submitted, indicate whether the protocol version changed and if so, upload the new protocol.
- 3) Indicate what, if any documents **CHANGED** or **CAN BE REMOVED** from those initially uploaded. Any documents checked will not be added to the new approval, but will remain accessible via the version to which they were originally uploaded.
- 4) Click **“Save”** to create the new continuing review.
- 5) On the Reviewing IRB Approvals tab, click the **“Edit Review”** button to document your continuing review approval information and upload new approval documents as you did for the initial study review. ([Section E.4](#))
- 6) Once you upload this approval, a pop-up will appear with a list of Relying Sites. For each site, you will document continuing review approval information and upload new approval documents for each site as you did for the initial study review. You can also access this by clicking the site approvals button on the Reviewing IRB tab. See [Section E.5](#).
- 7) When you set the Decision to **“approved”** for a Relying Site, you can upload approval documents for that site. Once you upload and save an approval for a Relying Site, the following happens:
 - a. The Relying Site Approval documents and information will be added to the Relying Site Approvals tab for that site.
 - b. An email notification will be sent to the Relying Site Liaison(s)

The screenshot displays the 'Reviewing IRB Approvals' tab in a web application. At the top, there are three tabs: 'Getting Started', 'Reviewing IRB Approvals' (selected), and 'Relying Site Approvals'. Below the tabs, the text 'Protocol Version: Version 1.0' is visible. A message box states: 'You are the Reviewing IRB for this study. Use the icons on the right to document other study-wide approvals.' To the right of this message are four icons: 'initial site approvals', 'add continuing review' (highlighted with a red box), 'add study-wide amendment', and 'terminate review'. Below the icons, the text 'Vanderbilt University Medical Center' is followed by three buttons: 'aahrpp', 'ctsa', and 'smart-irb'. The main content area shows a form titled 'Add Continuing Review' for the study 'Exercise in Genetic Cardiovascular Conditions'. The form includes a question: 'Continuing review also contained a study-wide amendment approved on the same day?' with radio buttons for 'Yes' (selected) and 'No'. Below this is another question: 'Does this amendment change Protocol [Version 1.0]?' with radio buttons for 'Yes' and 'No', and a red 'Required' label. A text area for 'Summary of changes' is also present, with a red 'Required' label. A blue note box says: 'Note: you will be able to add additional documents on the next screen.' At the bottom right, there is a red error message: 'Please correct errors above...' and two buttons: 'Save' and 'Cancel'.

Relying Site Approvals - Continuing Review: Full Board

Documents copied! Note that we have copied eligible documents from your previous site approvals. Please delete any documents that do not apply to this current set of approvals.

Columbia University	Columbia University	
Emory University	Decision approved	Date Submitted 01/10/2017
Harvard University	Submission Type Continuing Review: Full Board	Date Reviewed 01/17/2017
Vanderbilt University Medical Center		Date Approved 01/24/2017
Yale University		

Documents

Determination Letter

DETERMINATION LETTER_Cont Review.docx ✖

Consent Documents

Consent Document - CONSENT FORM - Adult.docx ✖

Consent Document - CONSENT FORM - Assent.docx ✖

Consent Document - CONSENT FORM Spanish.docx ✖

Choose a file or drag it here.

Other Documents

Other Document - Flyer_V2.png ✖

- 8) On the versions box on the study page, you will have two versions listed in the versions box (as shown): one for the initial review uploaded and another for the continuing review. The protocol number will carry forward as it can only be changed with an amendment or if you are uploading a Continuing Review + Amendment.

NOTE: TO VIEW (ONLY) SITE APPROVALS FOR ARCHIVED REVIEWS, CLICK ON THE SITE APPROVALS BUTTON LOCATED ON BENEATH THE ARCHIVED APPROVAL.

1.1	
VERSIONS	Reviewing IRB
	Vanderbilt (CR: Full) 12/07/17
	Vanderbilt (Initial: Full) 11/13/17
	Relying Sites
	<i>Ceded Model:</i>
	Utah (CR: Full) 12/07/17
	Utah (Initial: Full) 11/13/17
	Registered/In Progress
	none listed

7. ADD A REVISION (NON-PROTOCOL CHANGES)

The SMART IRB Exchange system also allows Reviewing IRBs to add revisions, study-wide amendment changes that do not affect or change the protocol. To add a revision for a study in SMART IRB Exchange:

1) Click on the “**Add Study-wide Amendment**” icon at the top of the project page. An “add amendment” pop-up will appear asking whether the protocol has changed.

2) Click “no” to indicate that the amendment does not change the most current version of the protocol.

3) Indicate the documents that changed and/or should be removed, and include a brief summary of the amendment changes. You will have an opportunity to upload and name the new versions on the next screen.

4) Click “**save**” to confirm the new amendment.

5) On the Reviewing IRB Approvals tab, click the “Edit Review” button to document your amendment approval information and upload new approval documents as you did for the initial study review. See [Section E 4](#).

6) Once you upload this approval, a pop-up will appear with a list of Relying Sites. For each site, you will document amendment approval information and upload new approval documents for each site as you did for the initial study review. You can also access this by clicking the site approvals button on the Reviewing IRB tab. See previous [Section E.5](#).

7) When you set the Decision to “**approved**” for a Relying Site, you can upload approval documents for that site. Once you upload and save an approval for a Relying Site, the following happens:

The screenshot displays the SMART IRB Exchange interface. At the top, there are tabs for 'Getting Started', 'Reviewing IRB Approvals' (which is active), and 'Relying Site Approvals'. Below the tabs, the 'Protocol Version: 1.1' is shown. A red arrow points to the 'add study-wide amendment' icon, which is highlighted with a red box. Below this, there are icons for 'initial site approvals', 'add continuing review', 'add study-wide amendment', and 'terminate review'. The main content area shows 'Vanderbilt University Medical Center' with logos for 'aahrpp', 'ctsa', and 'smart-irb'. Below that, it says 'Continuing Review: Full Board (exp. 12/07/2017)' and 'current review'. A pop-up form titled 'Add Study-Wide Amendment' is overlaid on the screen. The form contains the following fields and options:

- Does this amendment change Protocol [1.1]? Yes No
- Summary of changes: A text area with a red border and a 'Required' warning icon.
- Which documents were changed or removed by this Study-Wide Amendment? Consent Forms - Consent-new: CONSENT FORM - Adult.docx changed / removed?
- Others - flyer: Flyer.png changed / removed?
- Note: you will be able to add additional documents on the next screen.
- Buttons: Save (green), Cancel (grey), and a warning message: Please correct errors above...

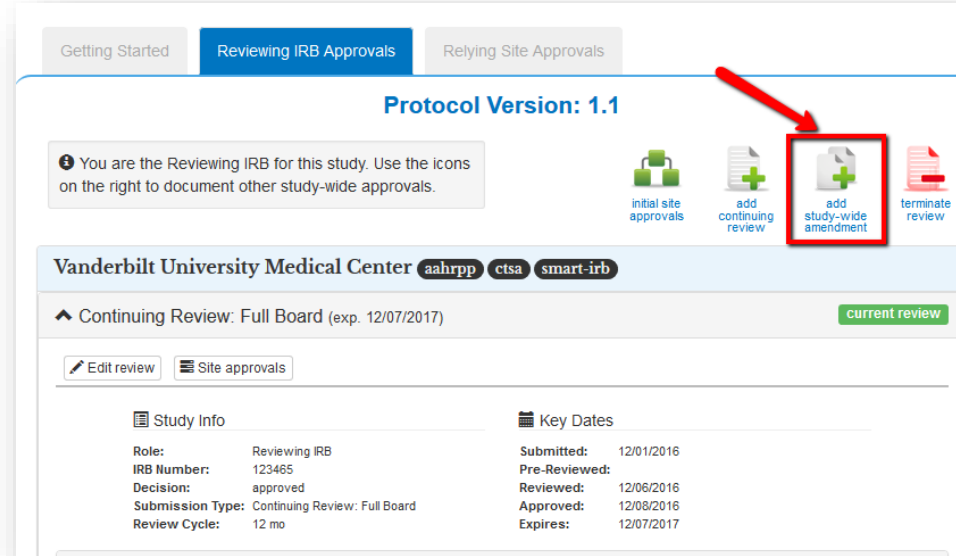
- a. The Relying Site Approval documents and information will be added to the Relying Site Approvals tab for that site.

The screenshot displays the 'Reviewing IRB Approvals' tab. At the top, a blue bar indicates 'Protocol Version: 1.1, Rev. 1'. Below this, a message states: 'You are the Reviewing IRB for this study. Use the icons on the right to document other study-wide approvals.' Four icons are provided: 'initial site approvals', 'add continuing review', 'add study-wide amendment', and 'terminate review'. The main content area shows 'Vanderbilt University Medical Center' with filters for 'aahrpp', 'ctsa', and 'smart-irb'. Under 'Amendment: Full Board', there is a 'current review' button and an 'Edit review' button. The 'Study Info' section includes: Role: Reviewing IRB, IRB Number: 123465, Decision: (blank), Submission Type: Amendment: Full Board, Review Cycle: (blank), and Change Summary: Changes to consent forms. The 'Key Data' section includes Submitted, Pre-Review, Reviewed, Approved, and Expires. A 'VERSIONS' sidebar on the right lists: 1.1, Rev. 1 (highlighted), Reviewing IRB, Vanderbilt (Amend: Full) 12/07/17, Relying Sites, Ceded Model: Utah (Amend: Full) 12/07/17, Registered/In Progress, none listed, and 1.1.

- b. An email notification will be sent to the Relying Site Liaison(s)
- 8) After adding the revision, the new version will be listed in the blue bar at the top of the Reviewing IRB Approvals tab on the project page AND in the "VERSIONS" box on the left side of the page.

8. ADD A STUDY-WIDE AMENDMENT

To add a study-wide amendment that changes the protocol in SMART IRB Exchange, Click on the “Add Study-wide Amendment” icon at the top of the project page .



- 1) Follow the steps in [Section E.7](#) above, with the exception of answering “Yes” to the question about whether the amendment changes the protocol.
- 2) An upload button will appear. Upload and name the new version of the protocol.

Add Study-Wide Amendment

A5342 - A Phase I Study to Evaluate the Safety, Tolerability, and Effect of a Human Monoclonal Antibody, VRC-HIVMAB060-00-AB (VRC01), on Markers of HIV Persistence in ART-treated, HIV-infected Adults

Does this amendment change Protocol [1.1]? Yes No

New protocol version **Required**

Upload new protocol No file selected. This file is a draft version. **Required**

Summary of changes **Required**

Which documents were changed or removed by this Study-Wide Amendment? ⓘ

Consent Forms - a: [CONSENT FORM - Adult.docx](#) changed / removed?

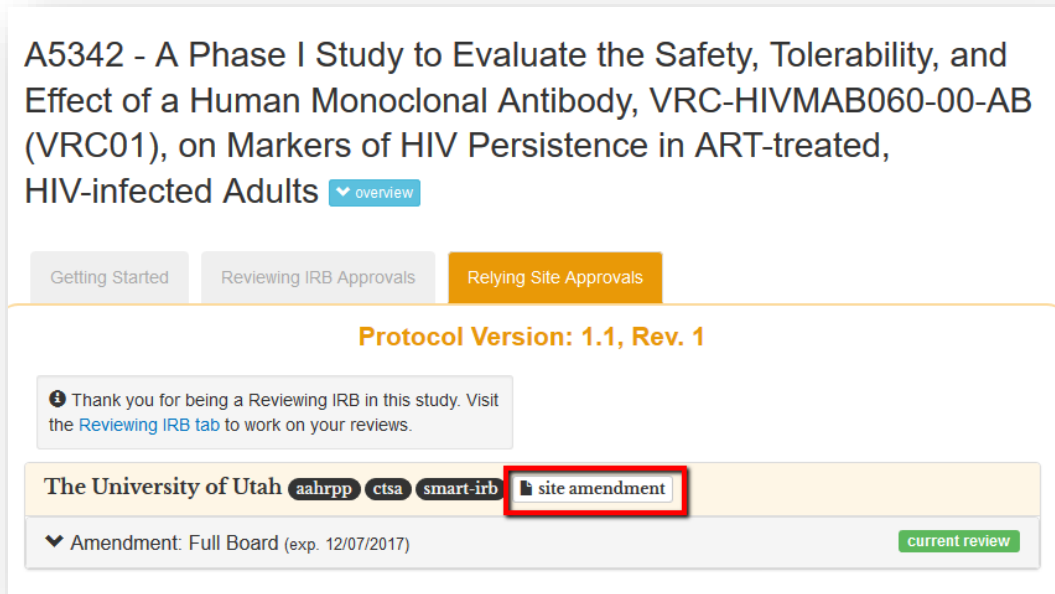
Others - flyer: [Flyer.png](#) changed / removed?

Note: you will be able to add additional documents on the next screen.

9. ADD A SITE-SPECIFIC AMENDMENT

To add a site-specific amendment for a relying site,

- 1) Click on the Relying Site Approvals tab
- 2) Find the site for which you need to document approval and click on the “**site amendment**” button beside the Relying Site’s name.



- 3) An “**add site-specific amendment**” pop-up will appear. Indicate if documents changed and/or should be removed, include a brief summary of the amendment changes, and click “**Save**”. You will have an opportunity to upload and name the new versions on the next screen.
- 4) On the Relying Site Approvals tab, click on the “**edit review**” button to enter information about the site-specific approval and upload new approval documents as you did for the initial study review. See [Section E.4](#).

The screenshot shows the 'Add Site-Specific Amendment' form for the same study. It includes a 'Summary of changes' text area with a 'Required' warning. Below is a section titled 'Which documents were changed or removed by this Site-Specific Amendment?' with a list of documents and checkboxes for 'changed / removed?':

Document	changed / removed?
Others - Other Document: Recruitment.docx	<input type="checkbox"/>
Consent Forms - Consent Document: CONSENT FORM - Adult.docx	<input type="checkbox"/>
Consent Forms - Consent Document: CONSENT FORM - Assent.docx	<input type="checkbox"/>
Consent Forms - Consent Document: CONSENT FORM Spanish.docx	<input type="checkbox"/>

A note states: 'Note: you will be able to add additional documents on the next screen.' At the bottom, there is a 'Please correct errors above...' message, a 'Save' button, and a 'Cancel' button.

- 5) Set the Reviewing Decision field to **“approved”** for a Relying Site, enter approval information and key dates, and upload approval documents for that site.
- 6) Click **“save”** to save your changes.
- 7) After adding the site-specific amendment, the amendment will be listed in the site’s review information on Relying Site Approvals tab on the project page AND in the **“VERSIONS”** box on the left side of the page.

The screenshot displays the 'Relying Site Approvals' interface. At the top, there are navigation tabs: 'Getting Started', 'Reviewing IRB Approvals', and 'Relying Site Approvals'. Below the tabs, the page title is 'Protocol Version: 1.1, Rev. 1'. The main content area is for 'Yale University' and includes a search bar with filters for 'aahrpp', 'ctsa', 'smart-irb', and 'site amendment'. A red box highlights the entry 'Site Amendment: Full Board #1 (exp. 01/23/2018)' with a 'current review' status. Below this, there is an 'edit review' button. The interface is divided into two columns: 'Study Info' and 'Key Dates'. The 'Study Info' column lists 'Role: Relying Site', 'IRB Number:', 'Decision:', 'Review Cycle:', and 'Change Summary: Change of PI'. The 'Key Dates' column lists 'Submitted for Local Review:', 'Local Review Conducted:', 'Local Review Completed:', and 'Expires: 01/23/2018'. At the bottom, there is a 'Documents' section. On the left side, there is a sidebar with a '4 users' notification and a 'Relying Sites' table. The table lists various sites and their review dates, with 'Yale (Site Amend: Full)' highlighted in a red box.

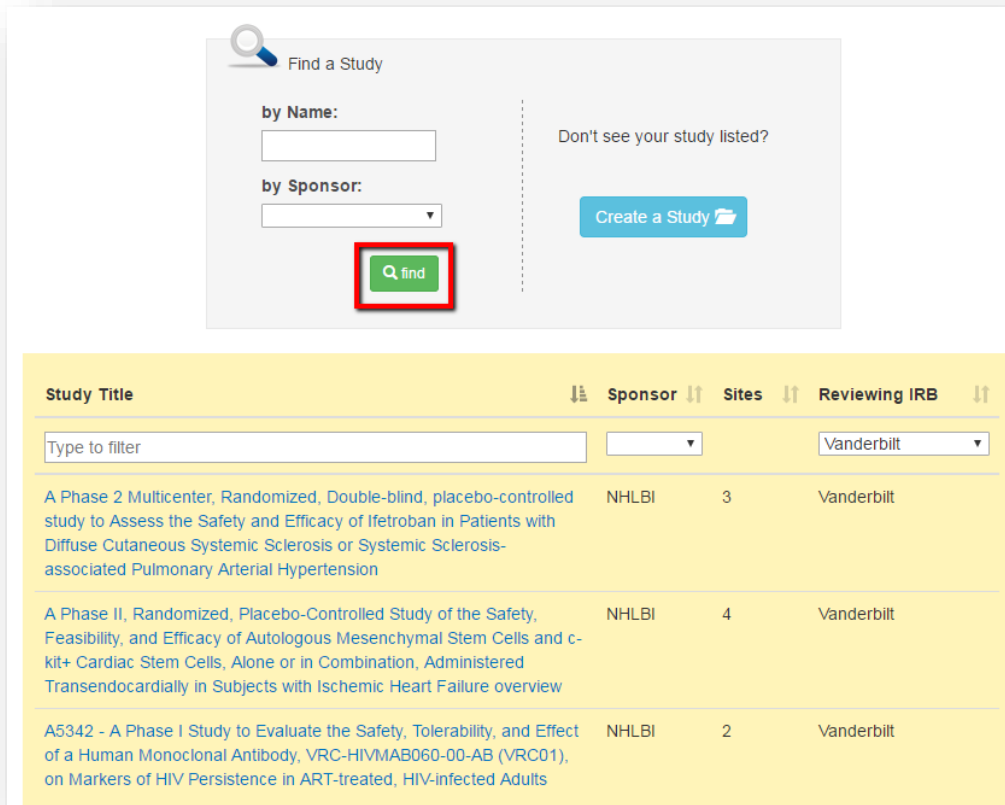
Reviewing IRB	Date
Boston University (CR: Full)	01/23/18
Boston University (Amend: Full)	03/22/17

Relying Sites	Date
Yale (Site Amend: Full)	01/23/18
Yale (CR: Full)	01/23/18
Yale (Amend: Full)	03/22/17
Harvard (CR: Full)	01/23/18
Harvard (Amend: Full)	03/22/17

SECTION F: PARTICIPATING AS A RELYING SITE

1. FIND A STUDY AND REGISTER TO PARTICIPATE

To find out if a study is in SMART IRB Exchange, use the “Find a Study” search at the top of the Dashboard. You can view the entire SMART IRB Exchange database of studies by leaving the name and sponsor fields blank and clicking “find”.



Find a Study

by Name:

by Sponsor:


Don't see your study listed?

Study Title	Sponsor	Sites	Reviewing IRB
<input type="text" value="Type to filter"/>	<input type="text" value="Vanderbilt"/>		
A Phase 2 Multicenter, Randomized, Double-blind, placebo-controlled study to Assess the Safety and Efficacy of Ifetroban in Patients with Diffuse Cutaneous Systemic Sclerosis or Systemic Sclerosis-associated Pulmonary Arterial Hypertension	NHLBI	3	Vanderbilt
A Phase II, Randomized, Placebo-Controlled Study of the Safety, Feasibility, and Efficacy of Autologous Mesenchymal Stem Cells and c-kit+ Cardiac Stem Cells, Alone or in Combination, Administered Transendocardially in Subjects with Ischemic Heart Failure overview	NHLBI	4	Vanderbilt
A5342 - A Phase I Study to Evaluate the Safety, Tolerability, and Effect of a Human Monoclonal Antibody, VRC-HIVMAB060-00-AB (VRC01), on Markers of HIV Persistence in ART-treated, HIV-infected Adults	NHLBI	2	Vanderbilt



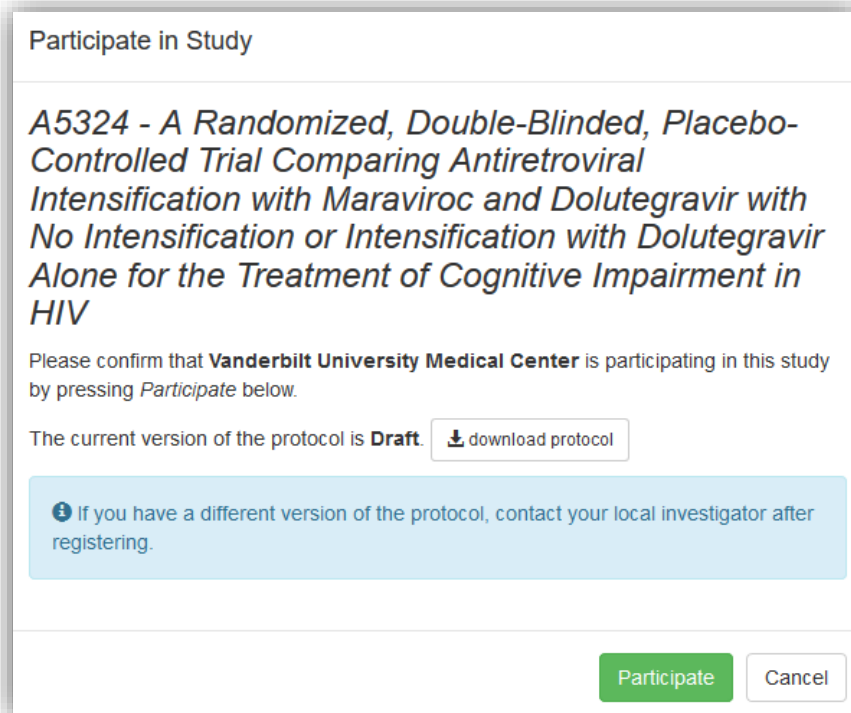
NOTE: SEARCH FOR SPECIFIC STUDIES BY ENTERING A *FULL* OR *PARTIAL NAME* OF THE STUDY, OR BY *SELECTING A SPONSOR* OR *REVIEWING IRB*.

Only SMART IRB Exchange Liaisons can register their site with a study in the system. To register, search for the study and click on the title in the search results.



Study Title	Sponsor	Sites	Reviewing IRB
<input type="text" value="Type to filter"/>	<input type="text" value="CCR"/>		
A5324 - A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV	CCR	1	
Blood pressure outcomes in neonatal intensive care unit (NICU) graduates with idiopathic hypertension	CCR	3	Vanderbilt

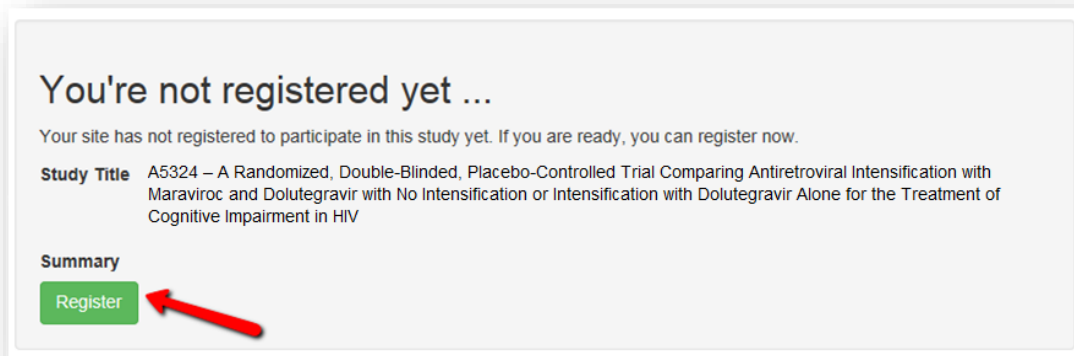
The "Participate in Study" window will pop up and you will be asked to verify that your site is participating in the study. You can also download the most recent version of the study protocol to confirm that it is the correct study. Click "Participate" to verify that you are a study site and to be directed to the study page.



The screenshot shows a dialog box titled "Participate in Study". The main heading is "A5324 - A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV". Below this, it asks the user to confirm that "Vanderbilt University Medical Center" is participating by clicking "Participate". A "download protocol" button is available, and the current version is noted as "Draft". A light blue information box states: "If you have a different version of the protocol, contact your local investigator after registering." At the bottom right, there are "Participate" and "Cancel" buttons.

For studies that are affiliated with a network, access is restricted to sites that 1) belong to a specific consortium or network and 2) are listed as participating in the study. If the Reviewing IRB identifies your site as a study site, you will receive an email notification with a link to register for the study. Click the link to go directly to the study registration page.

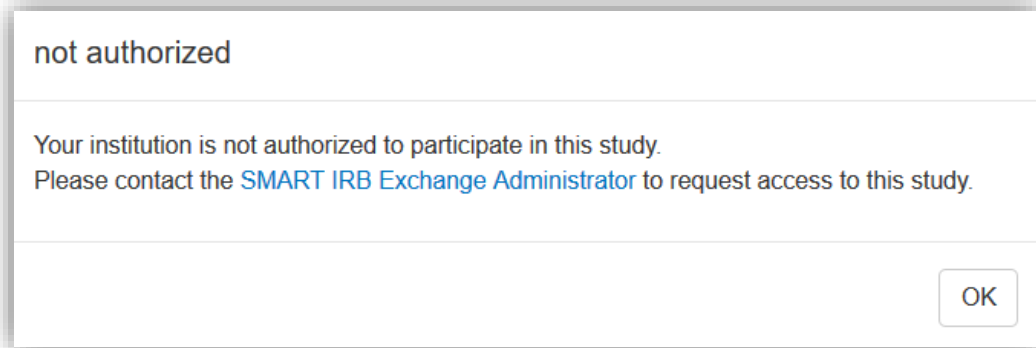
Click on the "Register" button to register for the study.



The screenshot shows a dialog box titled "You're not registered yet ...". It informs the user that their site has not registered and offers to register now. The "Study Title" is "A5324 – A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV". Under the "Summary" section, there is a green "Register" button, which is highlighted by a red arrow.

You can also register for such studies by clicking on the title in the search results. If your site meets both criteria listed above, the Participate in Study window will pop up and you can click the "Participate" button to verify that your site is participating in the study.

If your site is not listed as a participating site on a study you wish to participate in, contact the SMART IRB Exchange Administrator to request access. SMART IRB Exchange Administrator will verify membership inclusion with the consortium contact before institutions are added.



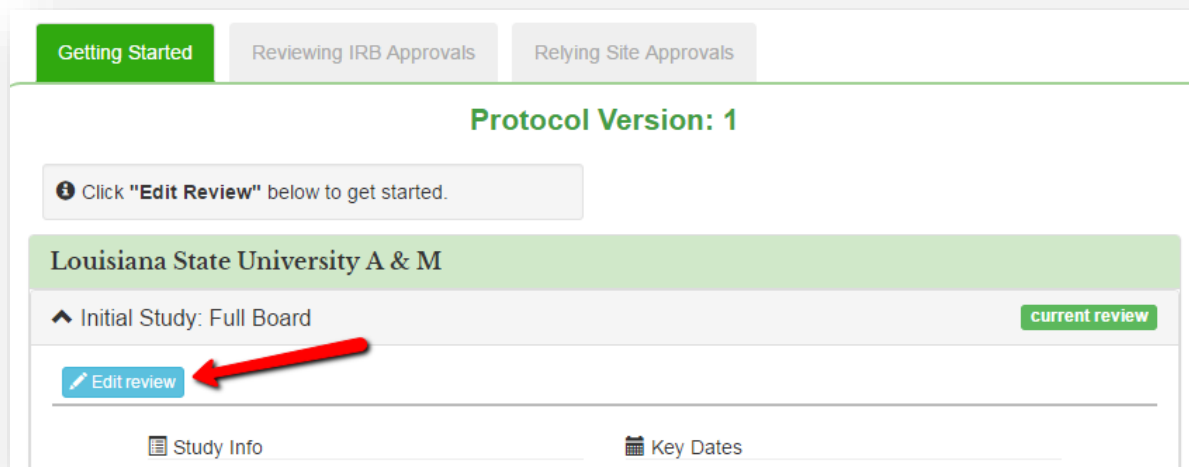
Studies that are not affiliated with a consortium and do not have a pre-specified list of participating sites are accessible to any institution in SMART IRB Exchange.



NOTE: If you would like to add a consortium/ network to SMART IRB Exchange, please contact the SMART IRB Exchange Administrator at ADMIN@SMARTIRBEXCHANGE.ORG

1.1.1. EDIT YOUR REVIEW

After registering for a study, click the "Edit review" button on the Getting Started Tab to indicate **Study Information, Primary Contacts, and Key Dates** as shown below.



1.1.1. ENTER YOUR STUDY INFORMATION

- **Role:** will your institution be the **Reviewing IRB** or **Relying Site** for this study? (For Consortium-specific studies, the roles will default to Relying Site.)
- **IRB Number:** what is the number used at your institution to track the study?

Study Information

Role Relying Site

IRB # 123456

Continue →

1.1.2. ADD LOCAL STUDY PERSONNEL

The next step is to enter the contact information of local study personnel. Personnel listed here will receive email notifications of any new approvals and documents the Reviewing IRB uploads for your site. Select the **type of contact** you wish to add (PI or Coordinator) and enter their email address to search the database for existing investigators. For new contacts, enter the **email, first and last name**. This will create an account with which the study personnel can log in to the Exchange, view Institutional Profiles, user contact information and download their study documents..

Primary Contacts

Add A Contact

Type of contact ...

email address

first name

last name

+ Add Contact

Current Contacts

Email	Name	Role	
jsmith@test.edu	Joe Smith	PI	✖

1.1.3. ENTER KEY DATES

- **Submitted for Local Review:** when was the study first submitted to your IRB for local context review?
- **Local Review Conducted:** when was the local context review for the study conducted by your IRB?
- **Local Review Completed:** when was the local context review for the study completed by your IRB?

Key Dates

Submitted For Local Review	07/13/2016
Local Review Conducted	07/21/2016
Local Review Completed	08/09/2016

Continue →

1.1.4. REVIEW AND SUBMIT

Review your study information and click “Save” when you are ready to submit. Any sections that are missing required fields will be highlighted red.

Review and Submit

Your Reviewing IRB is Vanderbilt University Medical Center.

Study Details		Personnel	
Role	Relying Site	Primary Investigator	John Smith
IRB Number	123456	Investigator	John.Smith@smartirbexchange.edu
		Coordinator	
		Key Dates	
		Submitted:	08/01/2016
		Reviewed:	08/05/2016
		Approved:	09/06/2016

Cancel Save

NOTE: You do not have to complete all sections in order to cede review. After study personnel information is entered, the Relying Site is ready to review and accept the Study-Specific Reliance Plan and cede review to the Reviewing IRB.

2. REVIEW AND ACCEPT YOUR STUDY-SPECIFIC RELIANCE PLAN (SSRP)

The next step to ceding review to the Reviewing IRB is to complete the Study-Specific Reliance Plan (SSRP). As described in the SMART IRB Exchange Operator Appendix, the SSRP is a set of study-specific reliance preferences between the Reviewing IRB and each of the Relying Sites regarding the following information:

- **Providing documentation:** E.g., When will the Reviewing IRB share their minutes (routinely or as requested)?
- **Reviewing for HIPAA:** E.g., Will the Reviewing IRB review authorizations and waiver requests for Relying Sites?
- **Reporting:** E.g., What is the Reviewing IRB's preferred process for external reporting?
- **Auditing:** E.g., What is the Reviewing IRB's preferred process for auditing?

The Reviewing IRB has the final say on the SSRP for each study. In order to rely on the Reviewing IRB, you and the Reviewing IRB must agree on an SSRP. You can request changes to the SSRP initially proposed by the Reviewing IRB. The Reviewing IRB can update the SSRP to reflect any changes requested after they have been discussed with the Relying Site by phone or email.

STEPS TO COMPLETING THE STUDY-SPECIFIC RELIANCE PLAN (SSRP) FOR A STUDY

- 1) After you complete the required information for your site review (see above), the SSRP window will pop up showing the Reviewing IRB proposed Study-Specific Reliance Plan for your site. Review the SSRP and determine whether you wish to "accept" or "request changes".

Study-specific Reliance Plan (SSRP)

Relying Sites Columbia University [[contact liaisons](#)]
⚠️ waiting on Columbia to accept

Reviewing IRB Boston University Medical Center [[contact liaisons](#)]
✔️ SSRP automatically confirmed by Boston University.

⚠️ Please review this SSRP and click **Accept SSRP** if you agree with this plan. If you need changes to this SSRP, please click **Request changes** and contact the Reviewing IRB liaisons.

Accept SSRP **Request changes**

Documentation:
The Reviewing IRB will provide meeting minutes/summaries (redacted): Upon request by a Relying IRB

HIPAA: Will the Reviewing IRB review HIPAA authorizations and requests for waivers for Relying Institutions? (Note: All entities are responsible for local accounting of disclosures) Yes

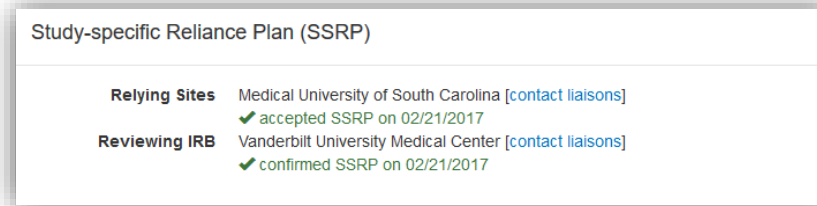
The Reviewing IRB's process for **external reporting** (e.g., unanticipated problem, serious or continuing non-compliance, suspensions or terminations) to OHRP/FDA is to:

- File first without comment from the relying IRB
- Work jointly with the Relying Institution on the report
- File once letter has been reviewed by the relying IRB
- Allow relying IRB to independently file report after review and comment

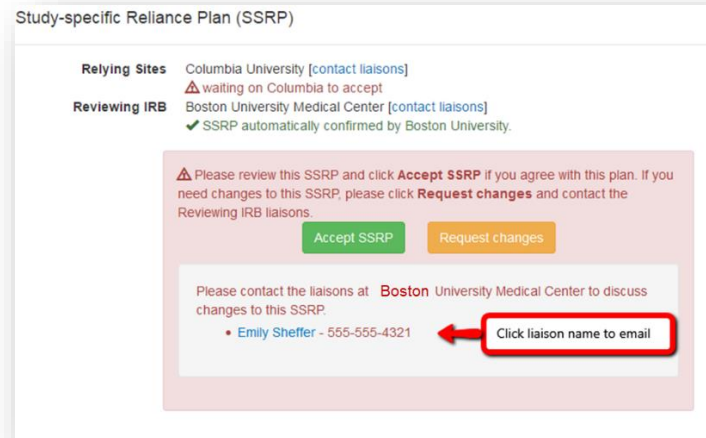
Will the Reviewing IRB provide an opportunity for Relying Institutions to comment on **unanticipated problem or serious or continuing non-compliance reports** to OHRP/FDA? Yes

The Reviewing IRB will allow the following amount of time for the Relying Institution to comment on **unanticipated problem or serious or continuing non-compliance reports**: 5

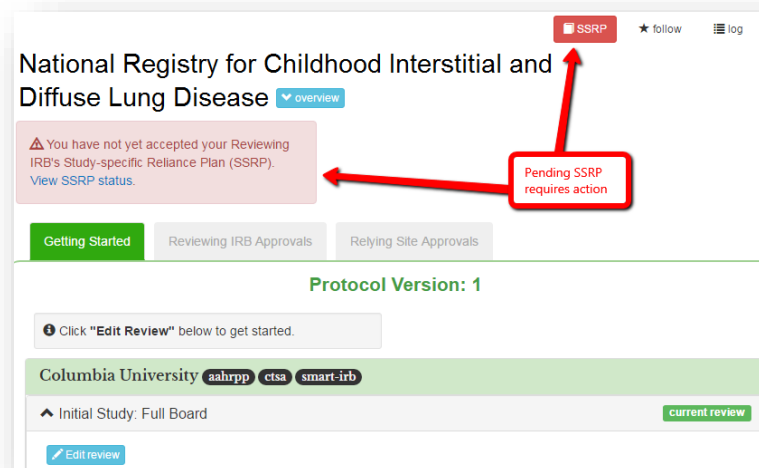
- 2) **Accept SSRP:** Click "Accept SSRP" if you accept the proposed SSRP. You (and the Reviewing IRB liaison) will receive an email noting your acceptance. This email will also have your official documentation of reliance letter.



- 3) **Request Changes:** If you wish to request changes, click "request changes" to show the contact information (phone and email) for the Reviewing IRB's Liaison. You must contact them to discuss the desired changes.



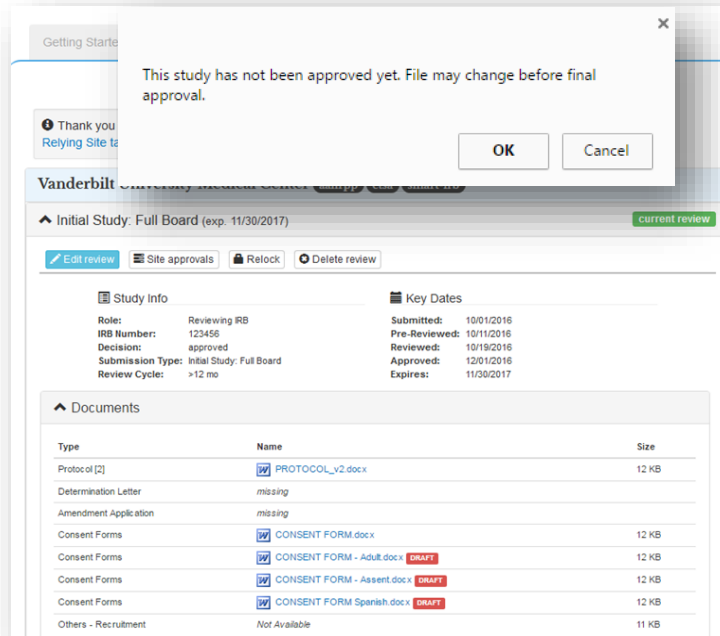
- 4) If the Reviewing IRB agrees to make the changes you have discussed, you will receive an email notification when the Reviewing has modified the SSRP for your site. In addition, you will see a red notification message on the project page alerting you to accept the Reviewing IRB's SSRP.



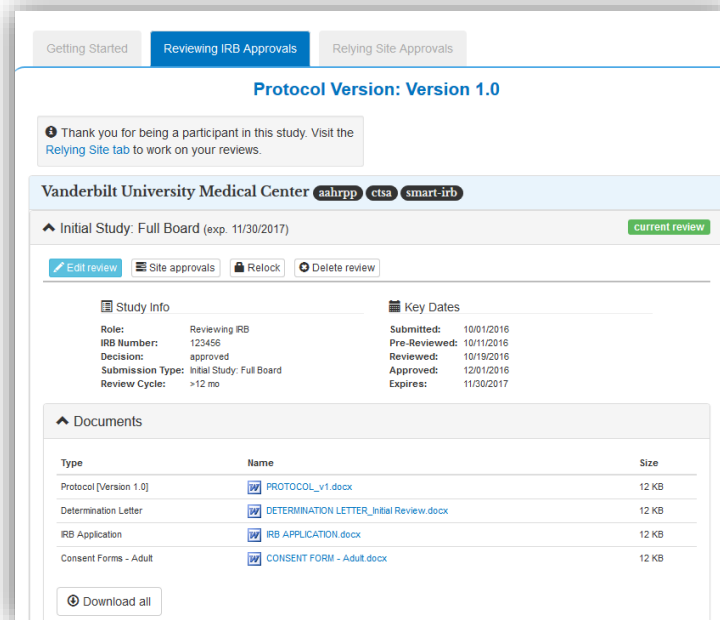
- 5) Once you accept the SSRP, your site name will appear under "Relying Sites" in the Versions box on the left of the project page.

3. VIEW APPROVAL DOCUMENTS FOR THE LEAD SITE

Once you are registered to participate in a study, you can view documents pertaining to the Reviewing IRB has uploaded on the Reviewing IRB Approvals tab. Prior to the initial approval, you may view any draft documents the Reviewing IRB has uploaded. You will receive a warning if you download documents that have not yet been approved.



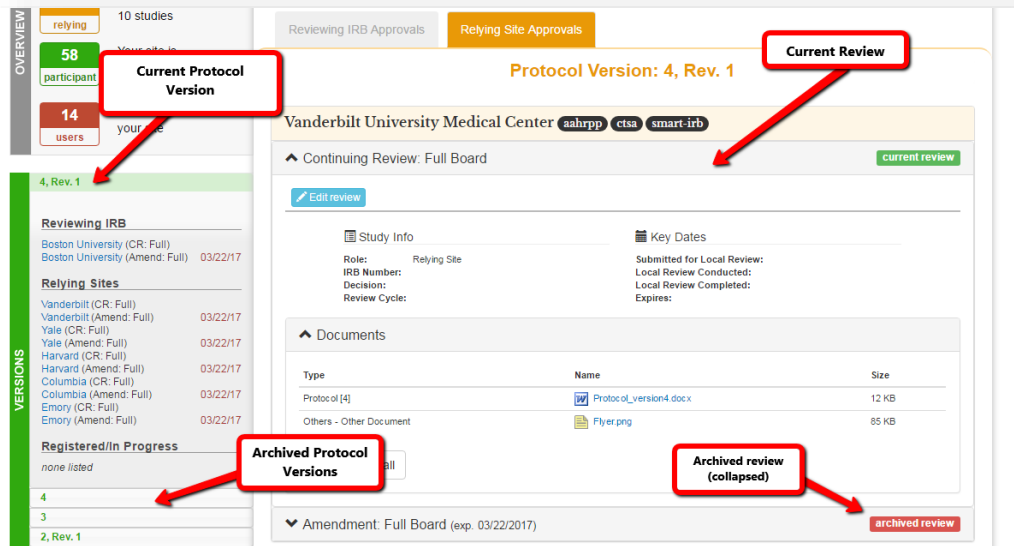
After their initial study approval, you can view and download the Reviewing's IRB approved documents on the same tab.



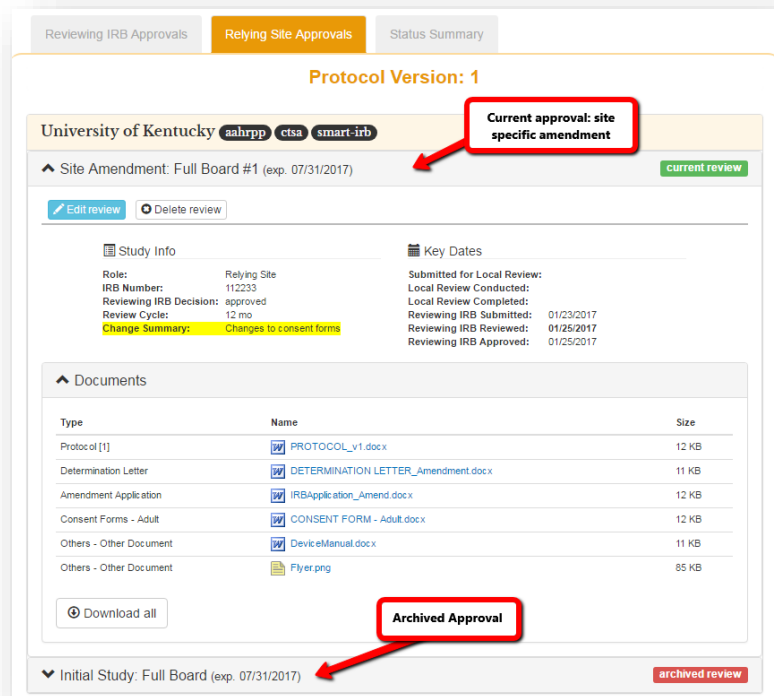
4. VIEW APPROVAL DOCUMENTS FOR YOUR SITE

After the Reviewing IRB uploads an approval for your site, your site-specific approval documents will show at the top of the Relying Site Approvals page, where you can access and download the documents.

Example 1: The screenshot below displays several review approvals: the initial review approval and old versions of the protocol (archived & collapsed from view), an amendment review approval of the current version of the protocol (archived & collapsed from view), and a continuing review approval.



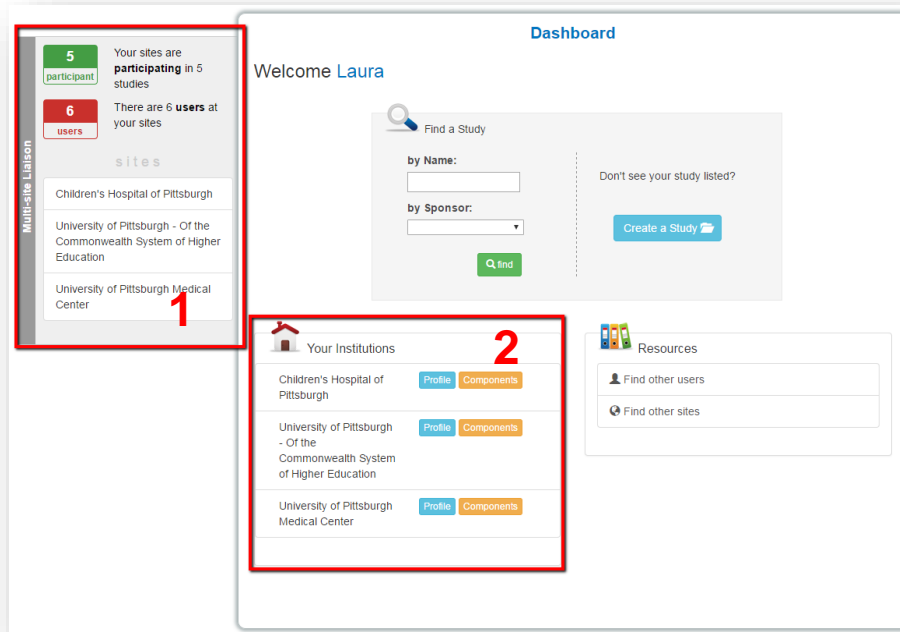
Example 2: This screenshot displays two review approvals: an initial review approval (collapsed from view) and a site-specific amendment approval. Site-specific amendment approvals are amendments/revisions specific to one site. Site-specific amendment approvals are auto-numbered and can only be added by Reviewing IRBs.



5. RELYING AS A MULTI-SITE LIAISON

5.1. MULTI-SITE LIAISON DASHBOARD

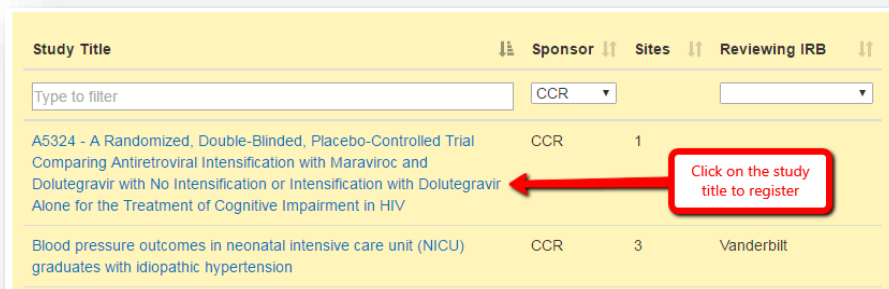
Multi-site liaisons are affiliates with multiple FWA institutions and can participate and cede review for these institutions under one account. The Multi-site Liaison Dashboard is tailored to provide information about all institutions the liaison is affiliated with.



- 1 Use the **Overview** box located on the left side of the screen, for quick access to a list of all the studies which your FWA institutions are taking part in.
- 2 A list of all sites you are affiliated with is found under **Your Institutions**. Click on **Profile** to view and edit an institutional profile and **Components** to manage all components on an institution's FWA. More information about how to do this is in **The Institutional Profile** ([Section D](#)).

5.2. REGISTERING TO PARTICIPATE IN A STUDY

- 1.) To register, search for the study and click on the title in the search results.



- 2.) The "Participate in Study" window will pop up. Choose which of your FWA institutions is participating in the study. If more than one of your institutions is participating, select one. You will be allowed to register the remaining sites later. Click "Participate" to register for the study.

Participate in Study

A Phase 2 Multicenter, Randomized, Double-blind, placebo-controlled study to Assess the Safety and Efficacy of Ifetroban in Patients with Diffuse Cutaneous Systemic Sclerosis or Systemic Sclerosis-associated Pulmonary Arterial Hypertension

Registration Please select one of your sites to register. You will be able to register the remaining sites on another page.

Protocol If you have a different version of the protocol, contact your local investigator after registering.

Please correct errors above... Participate Cancel

- 3.) If the Reviewing IRB identifies your site as a study site, you will receive an email notification with a link to register for the study. You can click the link to go directly to the study registration page. Select which of your FWA institutions is participating in the study from the drop down and click on the "Register" button to register for the study.

None of your sites are registered for this study.

Please select one site to register for this project. You may register additional sites on another screen.

If this study is restricted, then only the sites permitted to participate in the study will be listed below.

Site to Register

Children's Hospital of Pittsburgh
University of Pittsburgh - Of the Commonwealth System of Higher Education
University of Pittsburgh Medical Center

Select the institution that is participating

5.3. MANAGING YOUR SITES

After registering for a study you will have access to the **Your Sites** tab where you can view and manage all your FWA institutions that are participating in the study. Click **Edit Review** to enter general study information and add study personnel for the appropriate site. Next, click **Accept SSRP** to view the Reviewing IRB's study specific reliance plan for that site. You can accept the SSRP or Request changes. (See [Section F.2](#))

To register the remaining institutions, click the **Register** button next to the appropriate site name to register to that site to participate in the study. Click the corresponding Edit Review and Accept SSRP buttons to complete the process of ceding review for that site.

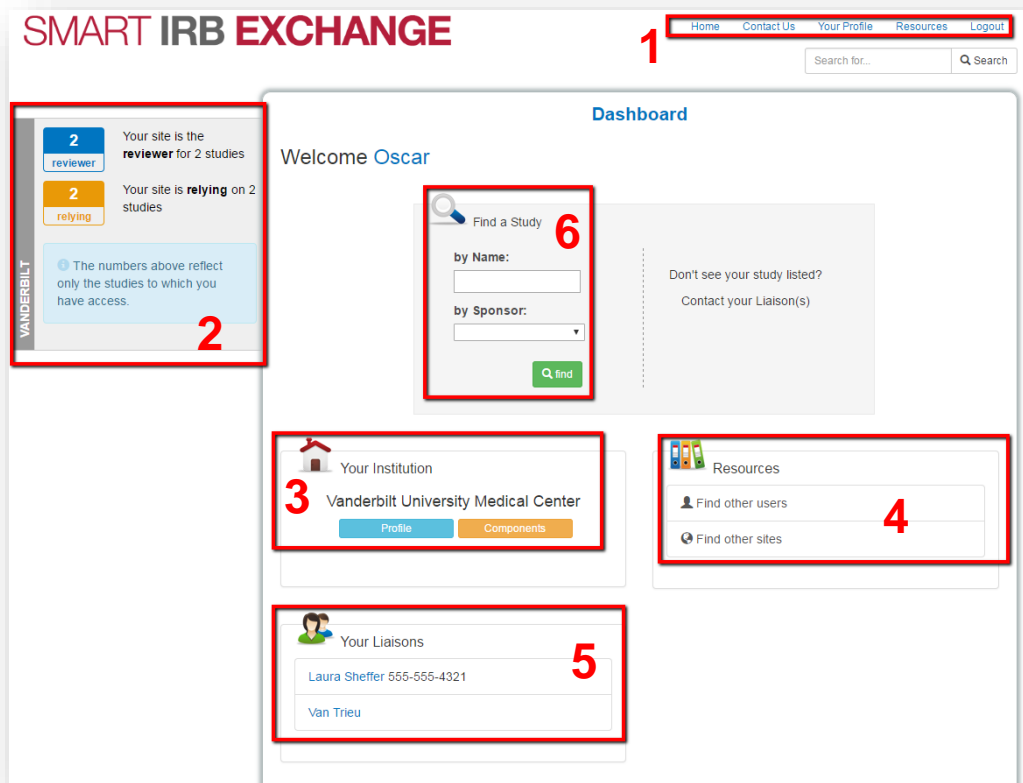
NOTE: Institutions that are not participating in for a given study are greyed out

The screenshot shows the 'Manage Your Sites' interface with three tabs: 'Your Sites', 'Reviewing IRB Approvals', and 'Relying Site Approvals'. The 'Your Sites' tab is active. Below the tabs is a table with columns for 'Site', 'Registered', 'Review', and 'SSRP'. Three rows of sites are listed. Callouts with red arrows point to specific buttons: 'Click to enter study info (e.g. key dates and study personnel) for this site' points to the 'Edit Review' button; 'Click to register your other institutions to participate in this study' points to the 'Register' button; and 'Click to review and accept SSRP for this site' points to the 'Accept SSRP' button.

Site	Registered	Review	SSRP
Children's Hospital of Pittsburgh	✓	Edit Review	Accept SSRP
University of Pittsburgh - Of the Commonwealth System of Higher Education	Not participating	✗	✗
University of Pittsburgh Medical Center	Register	✗	✗

1. STUDY PERSONNEL DASHBOARD

The Study Team Dashboard is tailored to you and provides information about your use of SMART IRB Exchange.



1 In the top right corner are quick links, which are visible from any page of SMART IRB Exchange, that provide quick access to edit your profile, contact us, view resources, return to the Dashboard and log out of SMART IRB Exchange.

2 Also visible at all times, use the **Overview** box located on the left side of the screen, for quick access to a list of all the studies that you are taking part in as an investigator at either the reviewing institution or the relying site.

3 Use **Profile** to view your institution's profile which contains information about your IRB and their processes and considerations when using reliance. It has four sections that capture **General HRPP Information, Local Context, Institutional Policies and Processes** for Relying on an External IRB, and **Reliance Preferences** when serving as the IRB of Record. Use **Components** to see all components on your institution's FWA.).

4 Under **Resources**, use **Find other sites** view the institutional profiles and list of FWA components of other SMART IRB Exchange institutions. Use **Find other sites** to view other users at your institution, as well as to identify users at other SMART IRB Exchange institution.

5 Use **Your Liaison** to identify your site liaisons.

6 Use **Find a Study** to search for studies in the Exchange.

2. LEARN ABOUT YOUR IRB

2.1. LEARN ABOUT YOUR LOCAL CONTEXT

Use **Section 2** of your Institutional Profile to get an overview of your local context requirements such as state and local laws that must be considered at your institution (e.g., age of majority, state/local laws or policies affecting consent, etc. is site-specific and can be edited at anytime.

Section 2: LOCAL CONTEXT	
In what state is your institution located?	TN
Age of majority in your state?	18
How does a minor become emancipated in your state?	<input checked="" type="checkbox"/> By judicial petition with age limitations <input checked="" type="checkbox"/> By judicial petition <input checked="" type="checkbox"/> By married <input type="checkbox"/> By joining the armed forces <input type="checkbox"/> Temporarily while in policy custody to consent to medical treatment <input type="checkbox"/> After giving birth <input checked="" type="checkbox"/> Other
Please describe how a minor becomes emancipated in your state.	See attached Department of Health definition of emancipated minor
What circumstances affect age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment	Only adults 18 year or older and emancipated minors can consent.
Do you have any state or local laws or institutional policies that require record keeping for longer than federal law requires under the Privacy Rule or Common Rule?	No
Please indicate the diseases below that require mandatory reporting to health authorities in your state. Please do not include all diseases; only list those diseases for which there would likely be a reason for testing in a research setting.	<input checked="" type="checkbox"/> Cancer <input checked="" type="checkbox"/> Hepatitis A <input checked="" type="checkbox"/> Hepatitis B <input checked="" type="checkbox"/> Hepatitis C <input checked="" type="checkbox"/> HIV <input checked="" type="checkbox"/> All communicable disease <input type="checkbox"/> Other (upload or describe below)
Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?	Yes

2.2. LEARN ABOUT YOUR LOCAL SUBMISSION REQUIREMENTS

Use **Section 3** learn about your institutional policies and processes for when you are ceding review to an External IRB. This section will list your HRPP's submission requirements and processes before the study is approved, after the study has been approved and for ongoing reviews. This can be very helpful when navigating how to rely on another institution.

Section 3: INSTITUTIONAL POLICIES AND PROCESSES FOR RELYING ON AN EXTERNAL IRB.	
This information will be helpful to your local study teams when they are navigating how to rely on another institution. We want to emphasize the importance of communicating with you, first!	
Insert a hyperlink to your webpage about how to rely on another IRB.	https://wp0.vanderbilt.edu/irb/hrpp-policies-and-procedures/
When relying on another IRB as your IRB of Record, who do you prefer modify the template CONSENT FORM to include any locally required/relevant language?	The local study investigator/coordinator before submitting it to us in the HRPP for sign off
BEFORE the study is approved by the Reviewing IRB:	
How should an investigator request to cede review to an external IRB? For example, should they email the IRB? Is there a specific person at the IRB? Should they just submit the request via your local IRB system (as outlined in the questions below)?	Please contact the IRB at asktheIRB@vanderbilt.edu
Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?	Yes
If yes, please upload the reliance request package/ reliance application	download file
Do you require any other documents to be submitted along with the reliance request packet or reliance application?	Yes
Select all documents that must be submitted along with the reliance request package or reliance application	<input checked="" type="checkbox"/> Protocol <input checked="" type="checkbox"/> Local consent form(s) <input type="checkbox"/> Budget template <input type="checkbox"/> Study contract <input type="checkbox"/> Other
AFTER the study is approved by the Reviewing IRB: Indicate below what documentation is required to be submitted for a study using an External IRB.	
Should your investigator submit any of the following to your HRPP when ceding review to another institution? If checked, you will be asked to detail what should be submitted.	<input checked="" type="checkbox"/> Study-wide amendments (protocol or consent form modifications) <input checked="" type="checkbox"/> Local amendments (personnel modifications) <input checked="" type="checkbox"/> Continuing review <input checked="" type="checkbox"/> Serious or continuing non-compliance <input checked="" type="checkbox"/> Unanticipated problems <input checked="" type="checkbox"/> Serious adverse events <input type="checkbox"/> Adverse events <input checked="" type="checkbox"/> Final report <input checked="" type="checkbox"/> Other
What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?	Approval letter + updated documents

3. MANAGE STUDIES USING RELIANCE

3.1. EMAIL NOTIFIICATIONS

The SMART IRB Exchange automatically notifies study personnel when they are added to a study. These personnel receive email notifications of all IRB approvals and documents that the Reviewing IRB uploads for their site as well as for expiring reviews. All approval documents are attached in the email and can also be accessed on the study page. (See section G for more details on Notifications)

SMART IRB Exchange Update: New IRB Approval for Your Site - Message (HTML)

Tue 3/14/2017 3:20 PM

SMART IRB Exchange Administrator <admin@smartirbexchange.org>

SMART IRB Exchange Update: New IRB Approval for Your Site

To: ennever@bu.edu; lgreen@bu.edu; at2059@cumc.columbia.edu; lskvwalker@c.u; glucas@v.u;

Attachments:

- DETERMINATION LETTER_Amendment.docx 11 KB
- Recruitment.docx 11 KB
- PROTOCOL_v2.docx 13 KB
- CONSENT FORM - Assent.docx 13 KB
- Flyer.png 85 KB
- CONSENT FORM Spanish.docx 13 KB
- PI memo.docx 11 KB
- CONSENT FORM - Adult.docx 13 KB

Dear All,

Boston University Medical Center has shared IRB approval for your institution, Columbia University, for the following study:

A Phase 2 Multicenter, Randomized, Double-blind, placebo-controlled study to Assess the Safety and Efficacy of Ifetroban in Patients with Diffuse Cutaneous Systemic Sclerosis or Systemic Sclerosis-associated Pulmonary Arterial Hypertension

This was an Initial Study: Full Board approval by the Reviewing IRB . The expiration date is 03/21/2017.

Principal Investigators & Study Contacts:
Your approval documents are attached. Please refer to the submission instructions sent previously regarding how to handle future submissions and reporting of events.

Access the study at: <https://victtest.irbchoice.org/embryb/irbchoicetic/public/project/viewproto/?proj=327>

Thank you,
The SMART IRB Exchange Team

3.2. DOCUMENT MANAGEMENT WITH VERSION CONTROL

Use the Relying Site Approvals tab to view all IRB approved documents for your site over the lifetime of a study. Click on the protocol version number in the version box to access archived reviews. Click the document titles to download individually or use **Download All** to create a zip folder of all the documents associated with a review. You can also download general study documents (e.g. protocol, investigator’s brochure, device manual, etc.) on the Reviewing IRB tab.

The screenshot displays the 'Relying Site Approvals' interface. On the left, a sidebar shows the 'VERSIONS' section with a list of versions: 3 (highlighted), 2, Rev. 1, 2, and 1. A red arrow points from a box labeled 'Access archived study documents' to version 1. The main content area shows 'Protocol Version: 3' and a list of documents. A red box highlights the document list table.

Access archived study documents

Type	Name	Size
Protocol [3]	PROTOCOL_v3.docx	12 KB
Determination Letter	DETERMINATION LETTER_Cont Review.docx	11 KB
Consent Forms - Consent Document	CONSENT FORM.docx	12 KB
Others - Other Document	MEETING NOTES_Amendment.docx	12 KB
Others - Other Document	MEETING NOTES_Amendment.docx	12 KB

SECTION H: NOTIFICATIONS

Category	Email Title	To Whom	Occurrence	Why
User Account	Your SMART IRB Exchange user account has been created	New User	Occurs when a liaison or site admin adds a new user	Allows users to create a password and login to SMART IRB Exchange.
Study Creation	SMART IRB Exchange study at your site.	Liaisons at Participating Sites listed on study page	Occurs after the Reviewing IRB creates the study and completes the SSRP	Informs participating sites of studies their investigator is participating in using the SMART IRB Exchange.
Study Creation	Your Study is in SMART IRB Exchange.	Study Personnel at Participating Sites	Occurs after the Relying site accepts the SSRP	Informs participating sites study personnel of studies they are participating in using the SMART IRB Exchange.
Study Registration	SMART IRB Exchange: New site	Reviewing IRB liaison	Occurs after a relying sites registers to participate in a study	Informs Reviewing IRB of sites signing on to studies
Study-Specific Reliance Plan	SMART IRB Exchange Notification of Reliance	Reviewing IRB Liaisons, Relying Site liaisons and Relying Site study personnel	Occurs after relying site accepts the Reviewing IRB's SSRP	Serves at the official documentation of reliance
Approval Uploaded	SMART IRB Exchange Update: Lead Site Granted Approval	All Liaisons at Participating Sites listed on study page and Relying Site study personnel for registered sites	Occurs when Reviewing IRB uploads the initial study approval for the lead site	Informs all participating sites that Lead IRB has uploaded the initial approval for the lead site and provides steps for how complete the reliance process if still pending.
Approval Uploaded	SMART IRB Exchange Update: New IRB Approval for Your Site	Relying Site liaison, Relying Site study personnel and Reviewing IRB liaison	Occurs when Reviewing IRB uploads a new relying site approval for a study	Informs all participating sites that Lead IRB has uploaded a new approval for their site
Approval Expiration	SMART IRB Exchange Approval will expire on MM/DD/YYYY	Lead IRB Liaisons and study teams	Occurs at 90, 60, 30, 14, and 7 days from the expiration or until approval is uploaded.	Reminds Lead IRB to upload a new approval in to SMART IRB Exchange before the current approval expires.
Approval Expiration	SMART IRB Exchange Approval will expire on MM/DD/YYYY	Relying Site(s) Liaisons and study teams	Occurs at 90, 60, 30, 14, and 7 days from the expiration or until Relying Site documents reliance on new approval.	Reminds Relying Site to complete any local submission requirements before approval expires.