SMART IRB EXCHANGE

SYSTEM USER MANUAL

June 2017

VERSION 2

WELCOME

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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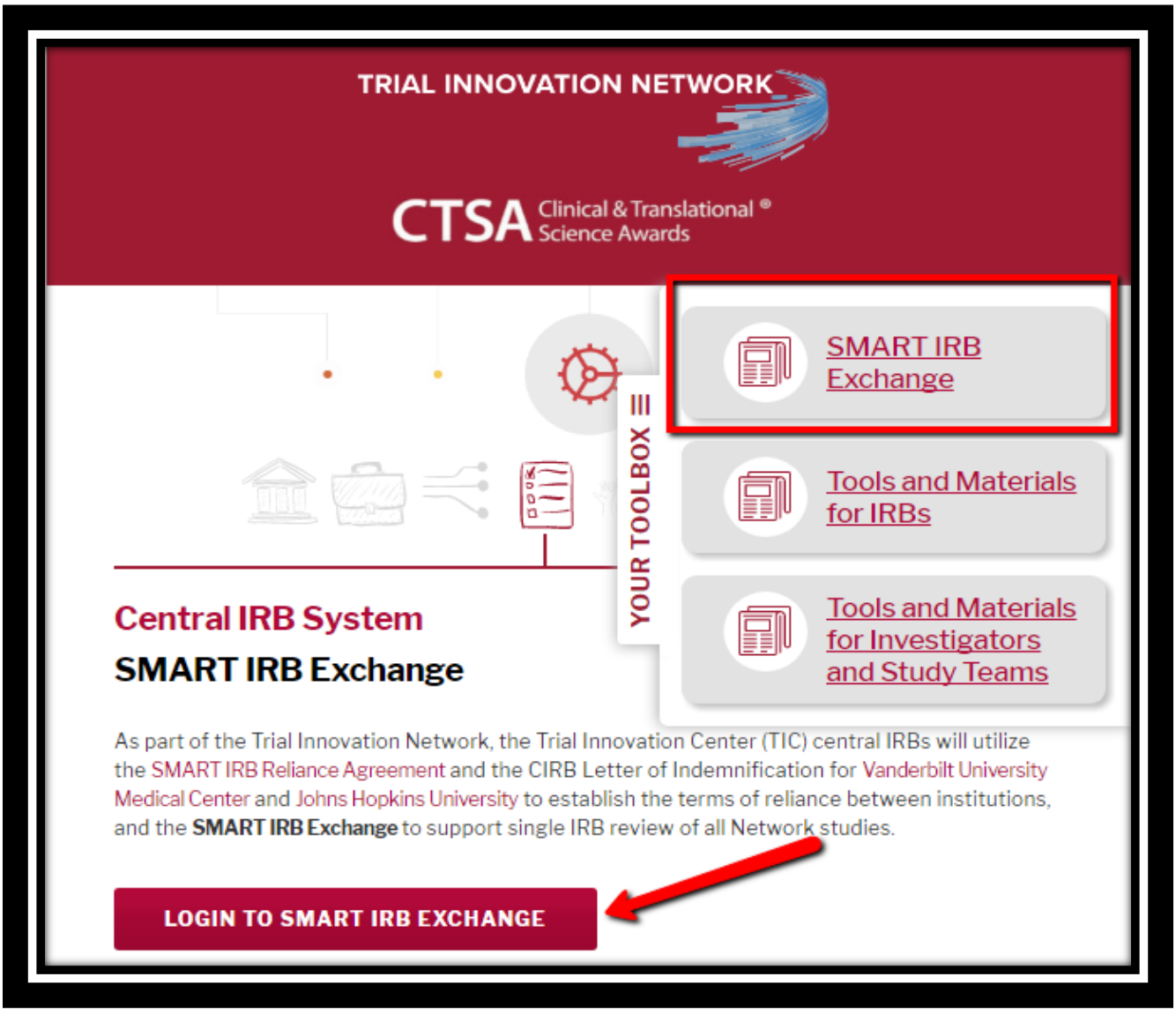
SECTION A: GETTING STARTED

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.**

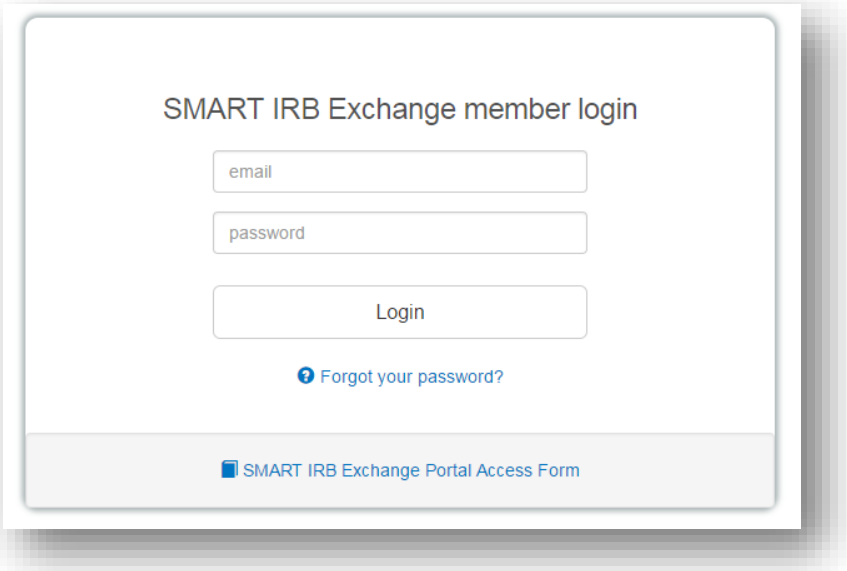


1.1. TECHINICAL REQUIREMENTS

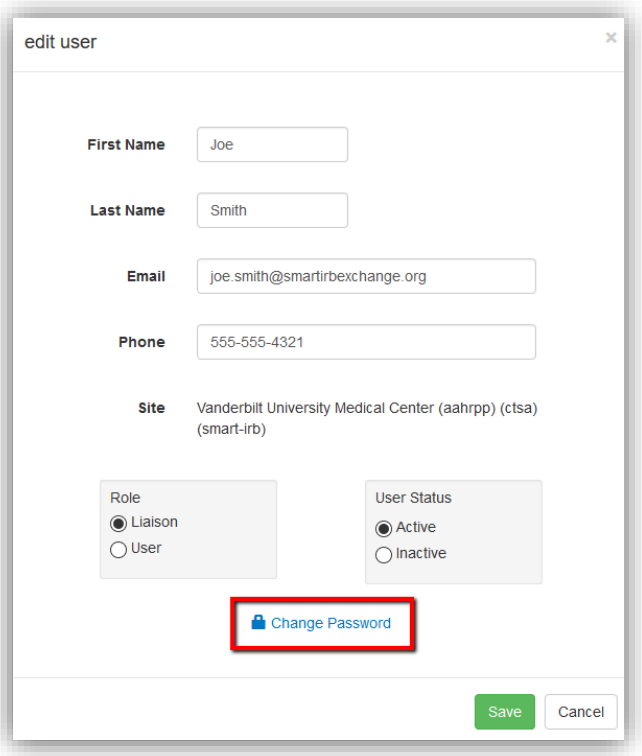
SMART IRB Exchange has very few technical requirements. The system is compatible with current versions of all major browsers (Internet Explorer 11, Apple Safari, Mozilla Firefox, and Google Chrome).

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.



3. CHANGE YOUR PASSWORD



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

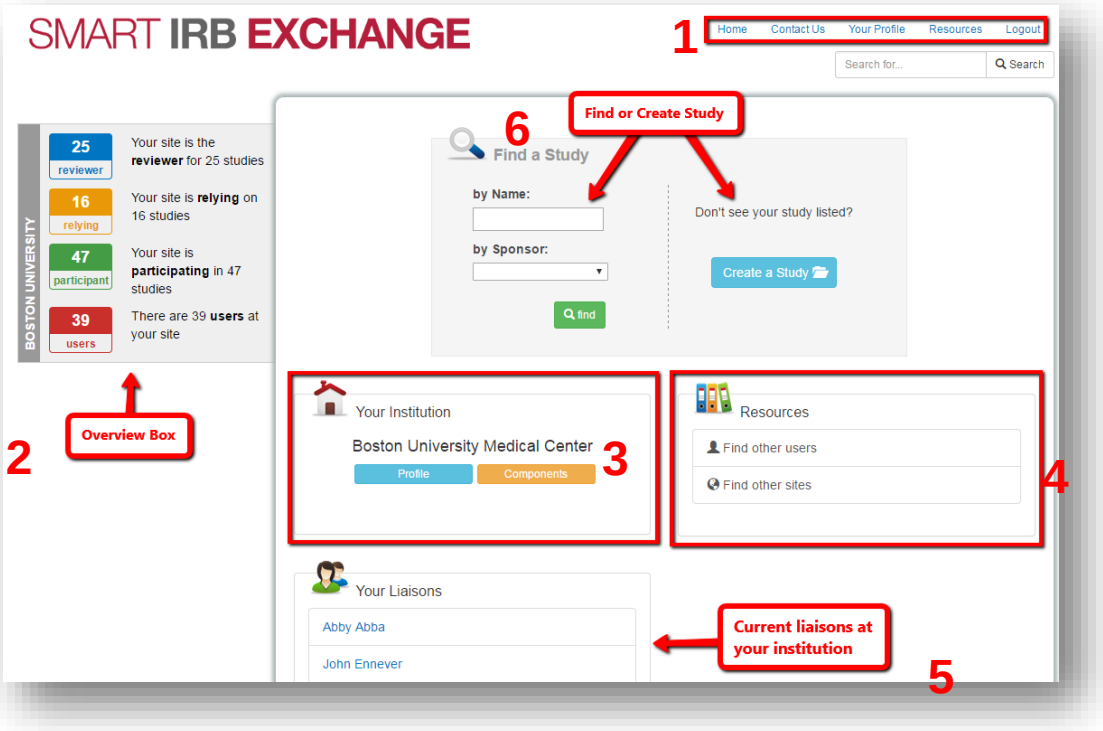
FROM YOUR PROFILE, UPDATE YOUR NAME, EMAIL ADDRESS, AND PHONE NUMBER. THIS INFORMATION CAN BE EDITED OR UPDATED AT ANY TIME.

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 .

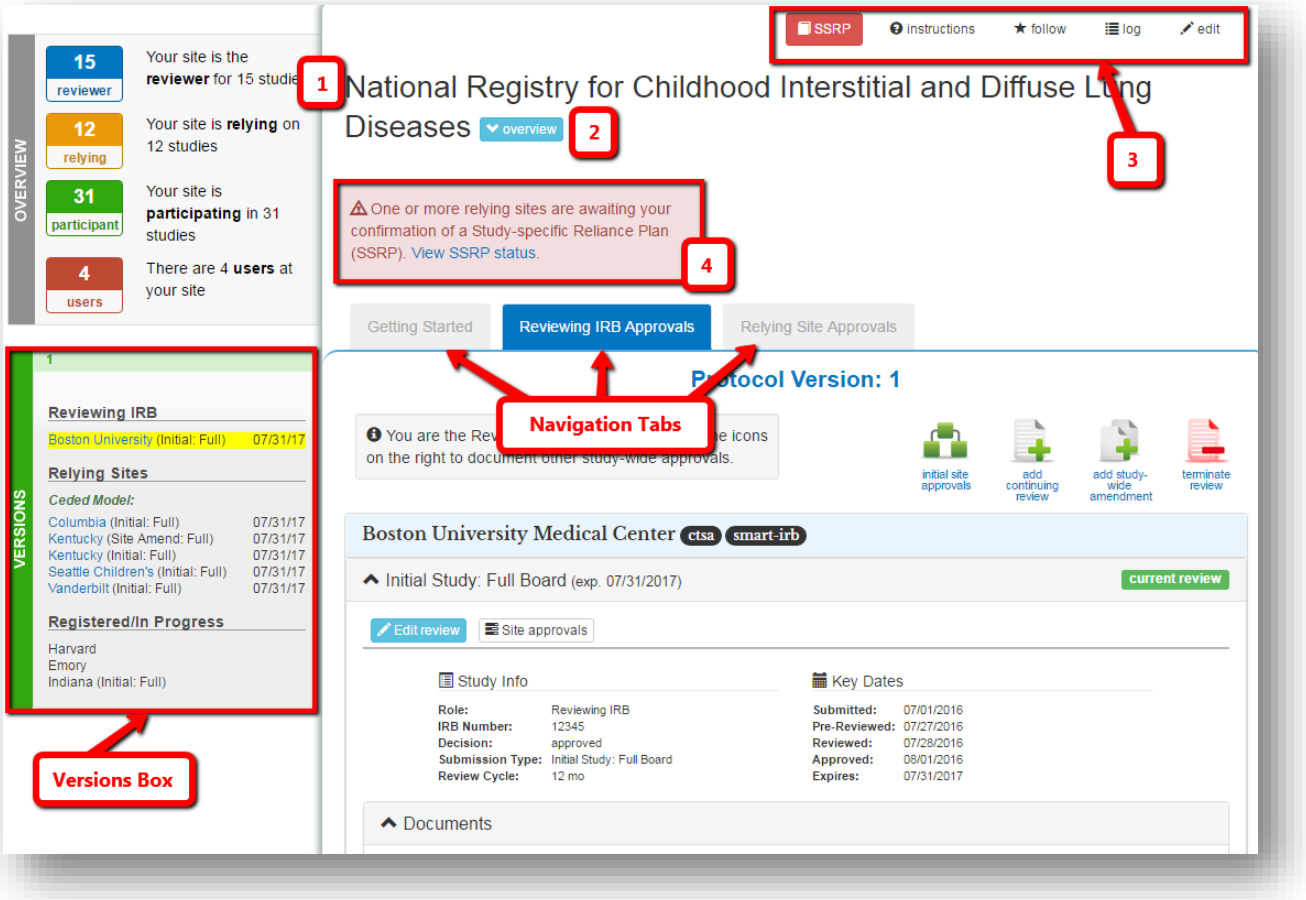
4 Under **Resources,** use **Find other sites** view the institutional profiles and list of FWA components of other SMART IRB Exchange institutions. Use **Find other sites** to view other users at your institution, as well as to identify an SMART IRB Exchange liaisons at another SMART IRB Exchange institution. 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 study page is organized by the following features: **Study Information**, **Navigation Tabs**, and **Versions Box**

2.1. STUDY INFORMATION

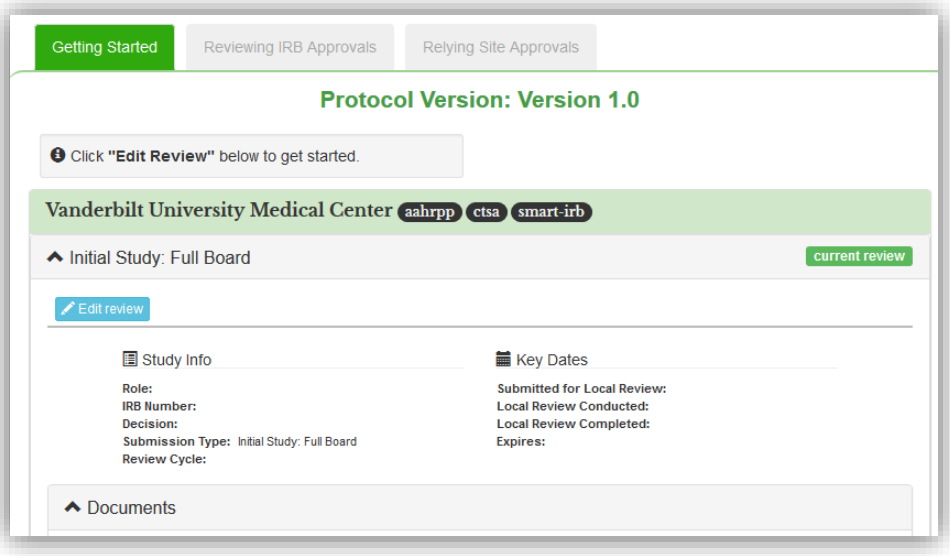
The study information section includes:

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.

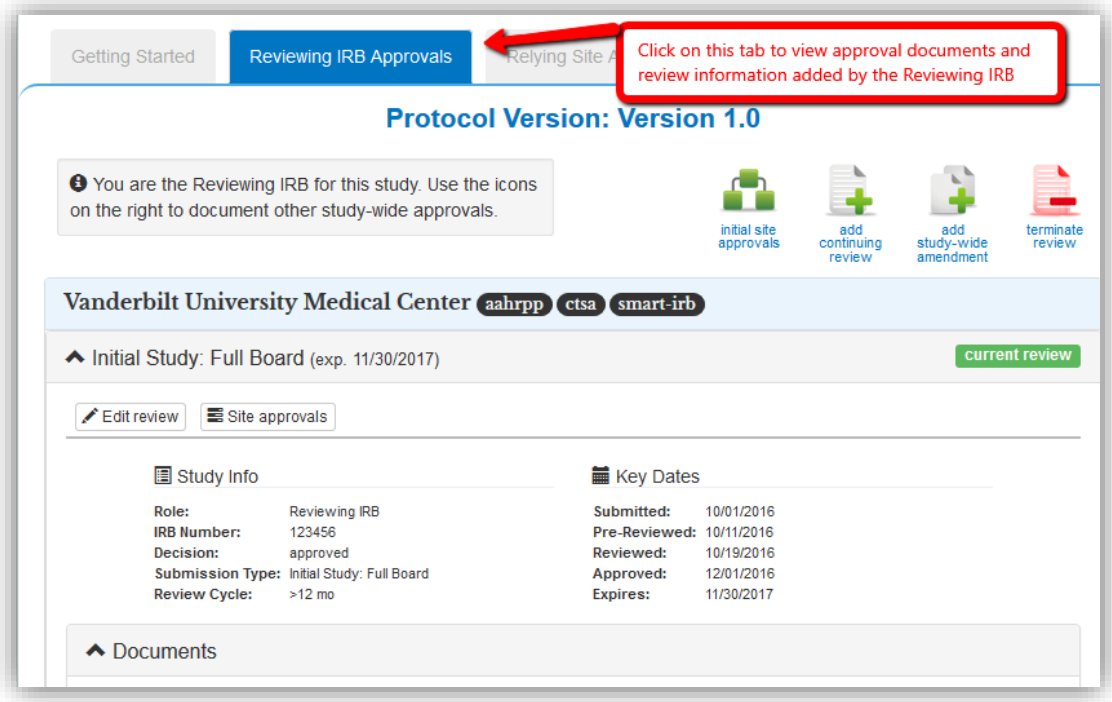
2.2. NAVIGATION TABS

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

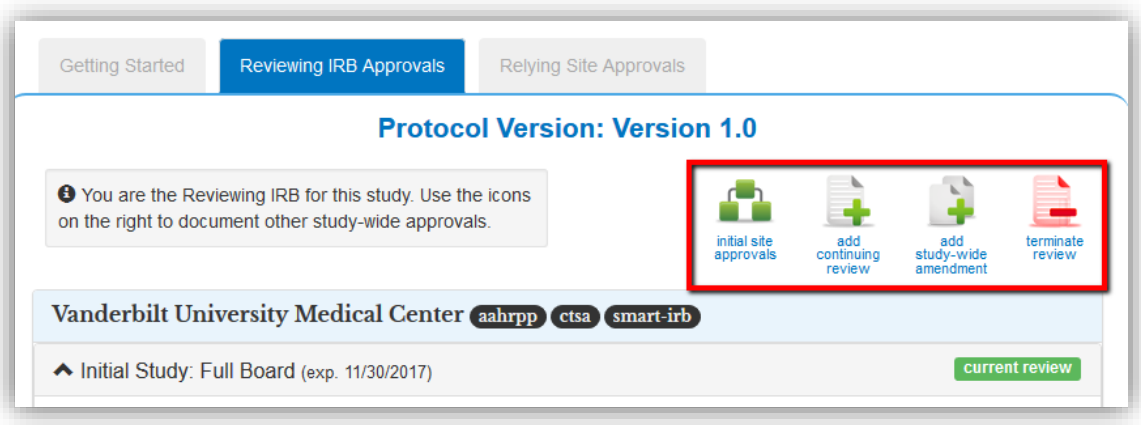
1. **Getting Started Tab**: Sites appear on this tab after registering for a study and until they have entered the required reliance information (including Study-Specific Reliance Plan (SSRP) selections) and completed all the steps needed to become a Reviewing IRB or Relying Site.



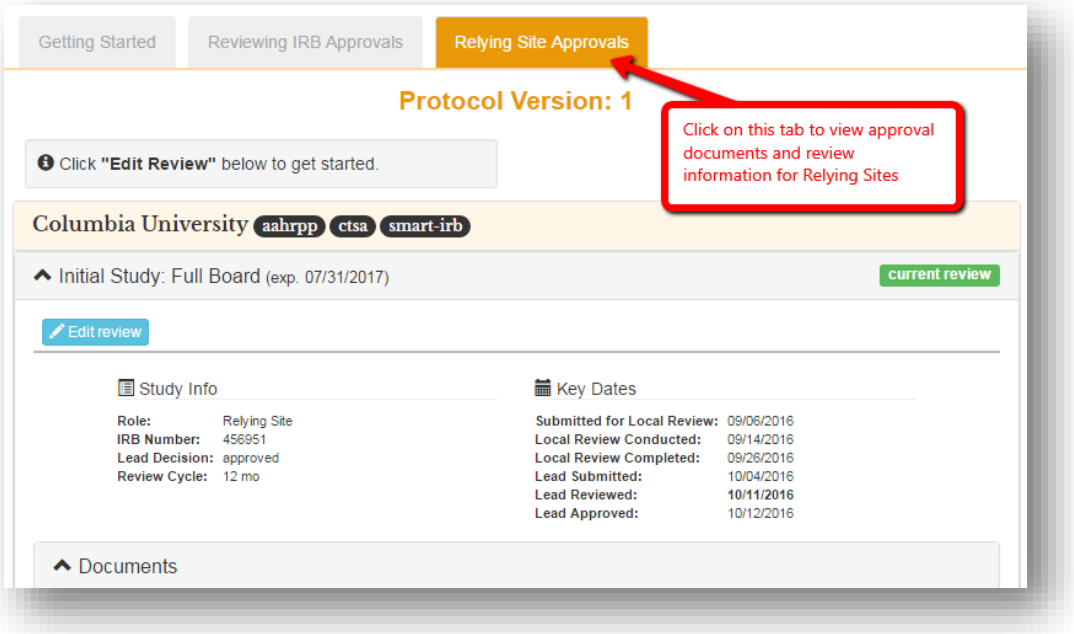
2. **Reviewing IRB Approvals Tab**: The site designated as the Reviewing IRB for a study will appear on this tab after entering preliminary study information and confirming their SSRP.



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.

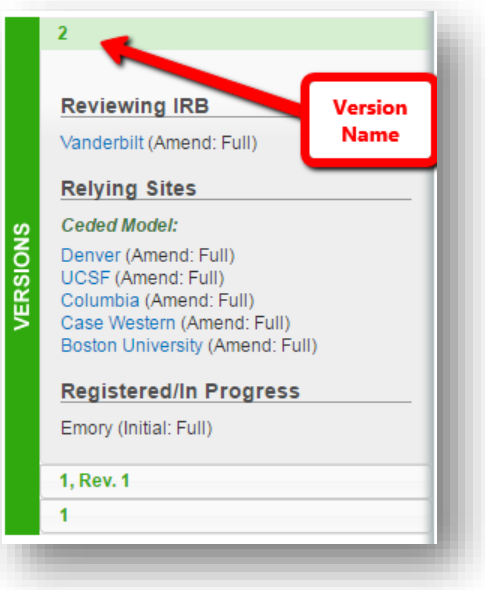


NOTE: ON BOTH **THE REVIEWING IRB APPROVALS** AND **RELYING SITE APPROVALS TAB,** CURRENT ("ACTIVE") SITE REVIEW INFORMATION IS AUTO-EXPANDED FOR EASY REFERENCING. ARCHIVED REVIEWS ARE ALWAYS AUTO-COLLAPSED

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:

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

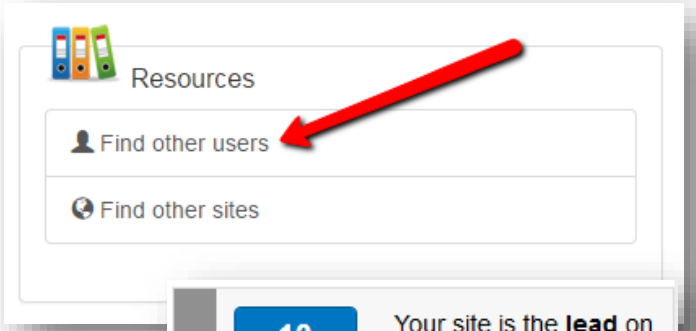
SECTION C: USER ROLES AND ACCESS

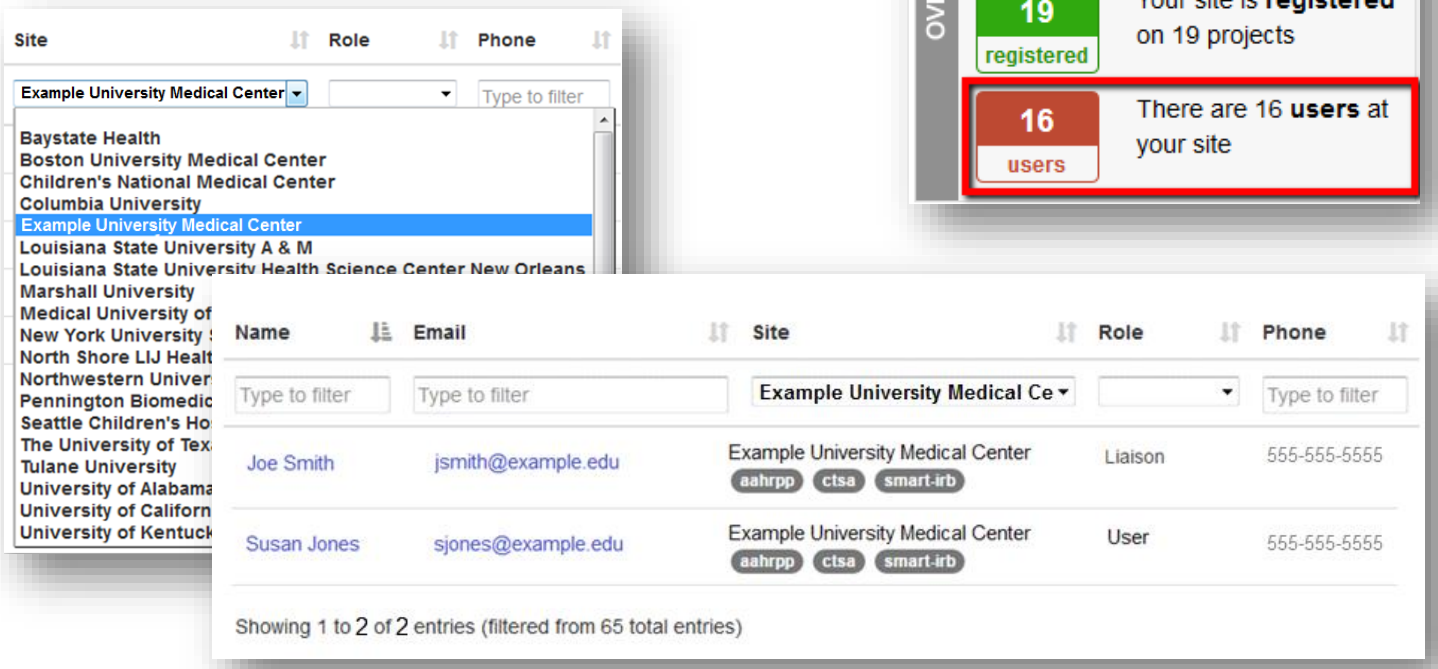
1. FIND USERS

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 INSITUTION NAME AND SEARCH FOR USERS AT THAT SITE.





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

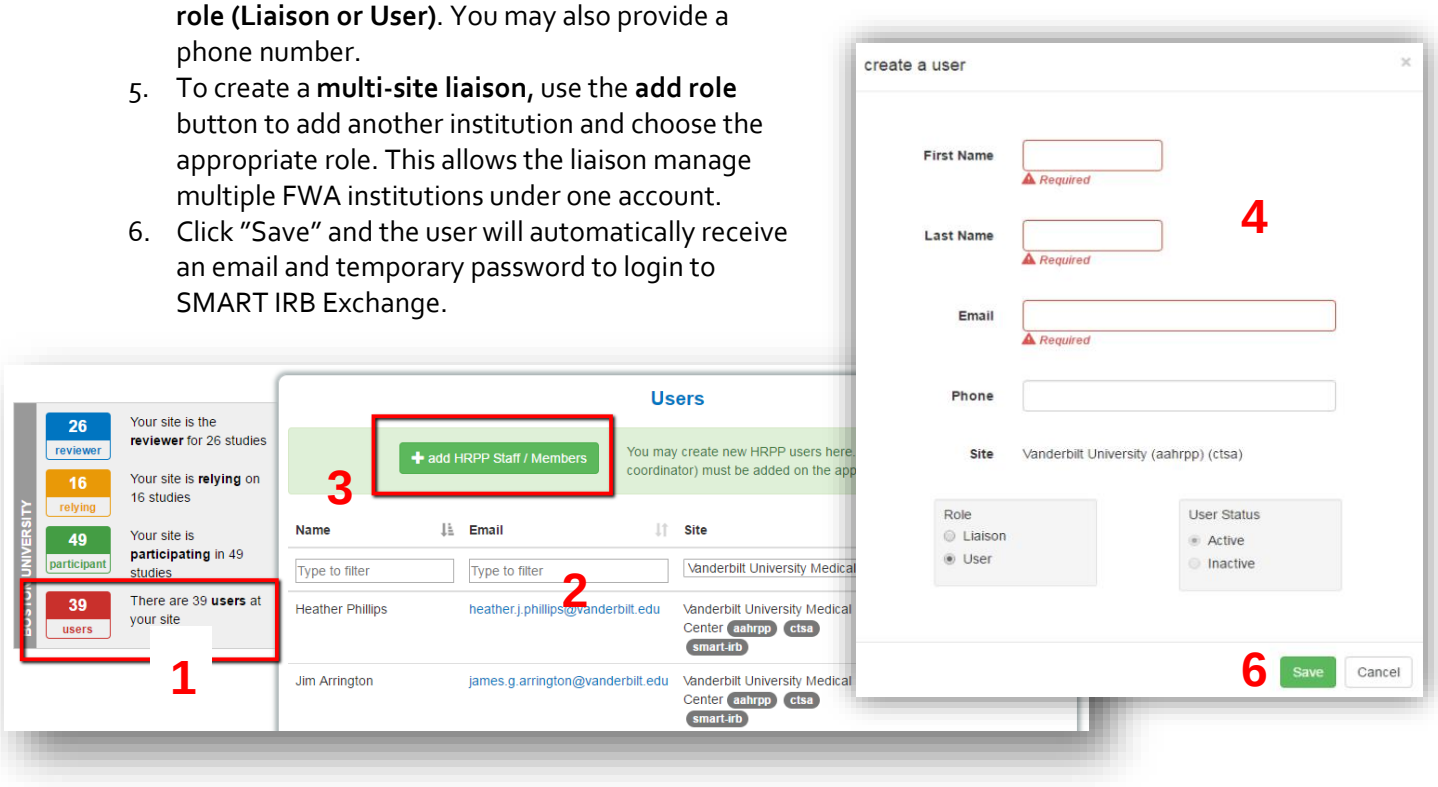
SMART IRB Exchange Liaisons have the ability to set up two roles for IRB staff and members: "Liaisons" and "Users".

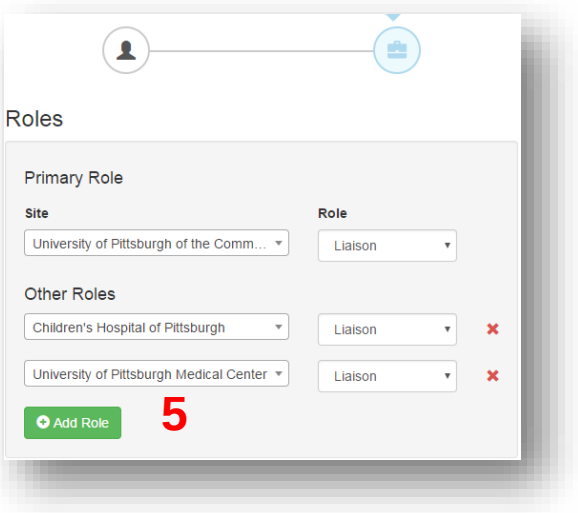
- **LIAISONS** have more permissions than "Users". Liaisons have the ability to add new users, edit the Institutional Profile, create new studies, register for studies already created in the Exchange, and accept/confirm the Study-Specific Reliance Plan (SSRP).
    - **Multi-Site Liaisons** are affiliated 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.





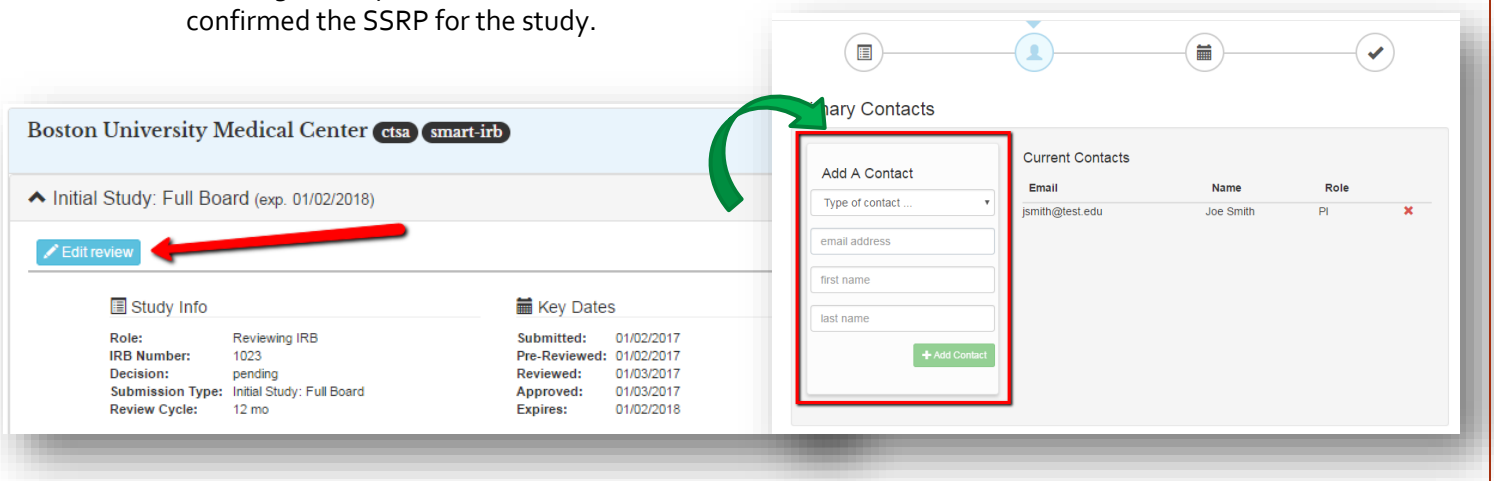
2.2. STUDY PERSONNEL

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.



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

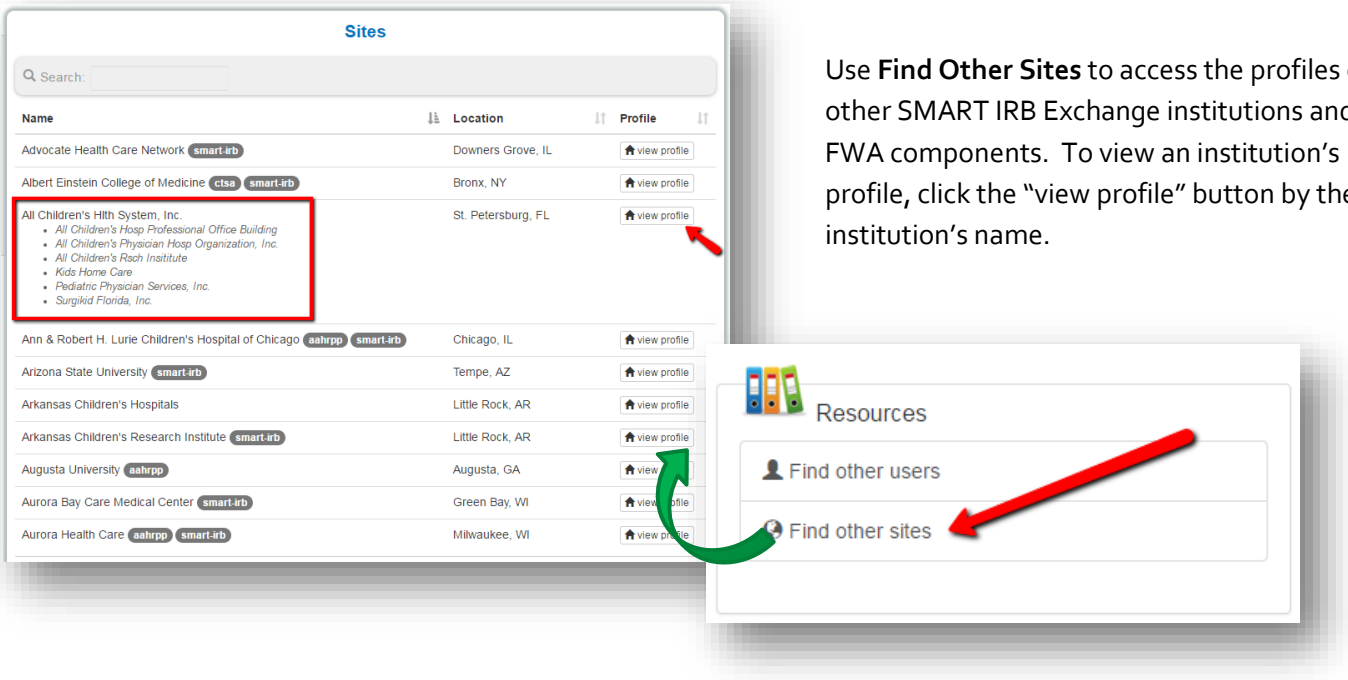
SECTION D: THE INSTITUTIONAL PROFILE

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.

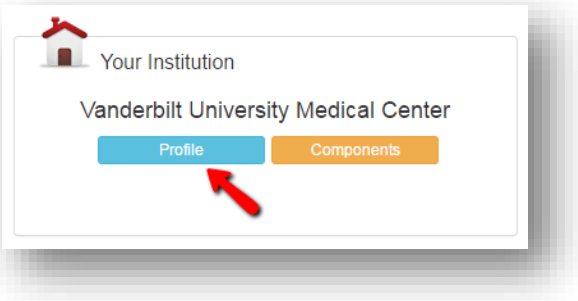
1. VIEW PROFILES



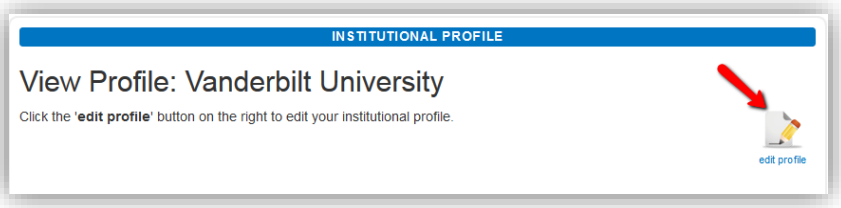
Use **Find Other Sites** to access the profiles of other SMART IRB Exchange institutions and their FWA components. To view an institution's profile, click the "view profile" button by the institution's name.

2. EDIT YOUR PROFILE

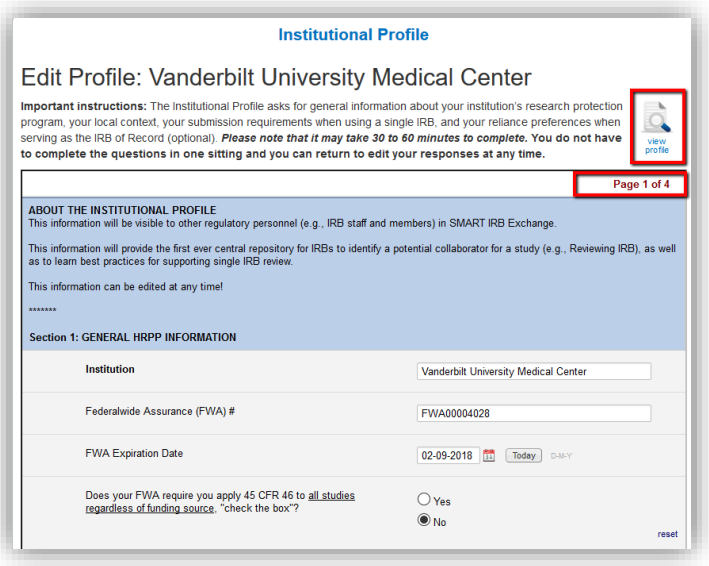
To edit your Institutional Profile, click the Profile button on the home page.



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

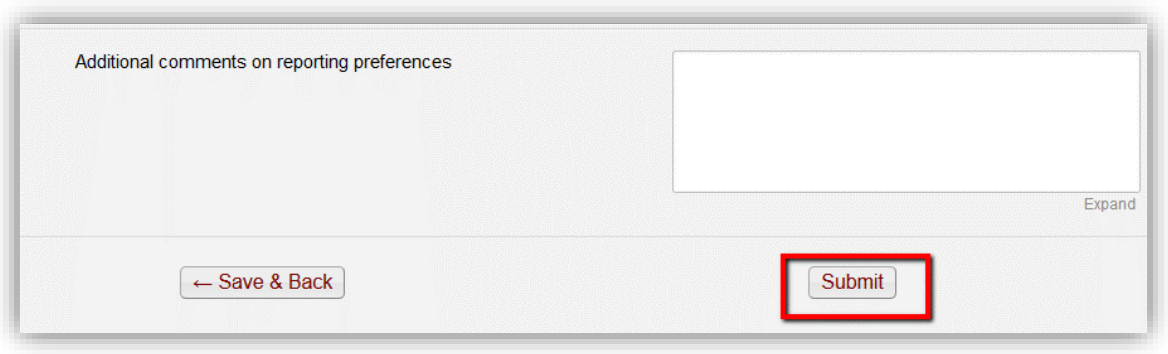


A new page will open with a survey and instructions about the Institutional Profile.



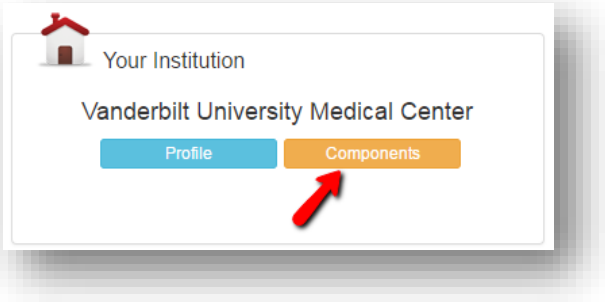
To navigate while editing, use the navigation buttons at the bottom of the edit profile screen.

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

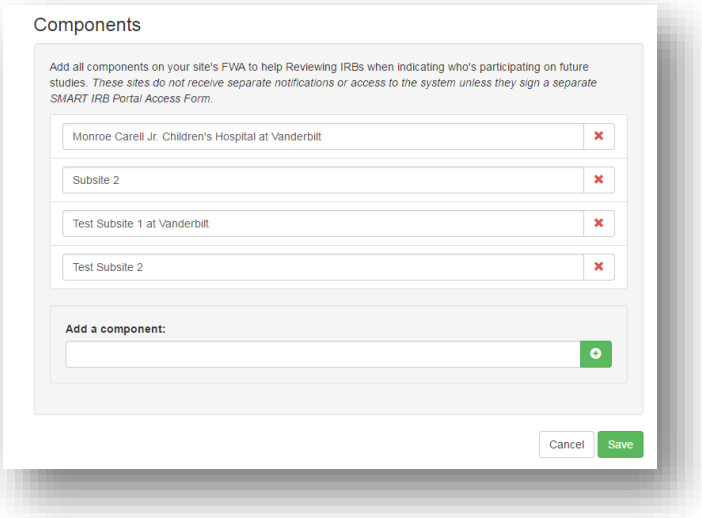


3. EDIT YOUR FWA COMPONENTS

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



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



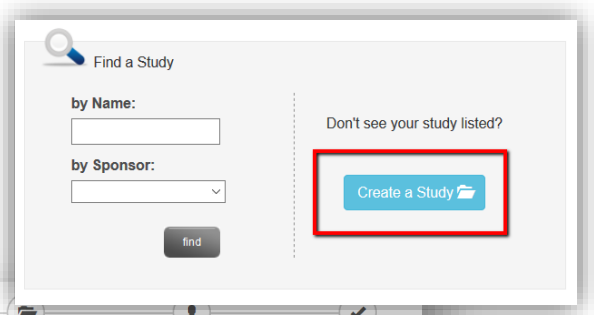
SECTION E: PARTICIPATING AS A REVEIWING IRB

1. CREATE A STUDY

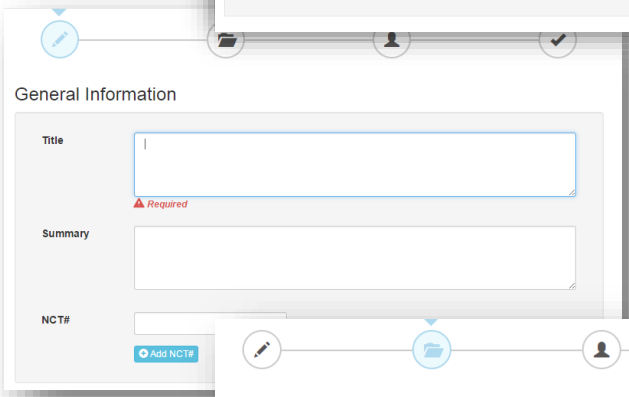
The first step is as the Reviewing IRB participating in a multi-site study that is not listed in the SMART IRB Exchange system, is to add the study as a new project.

To create a study:

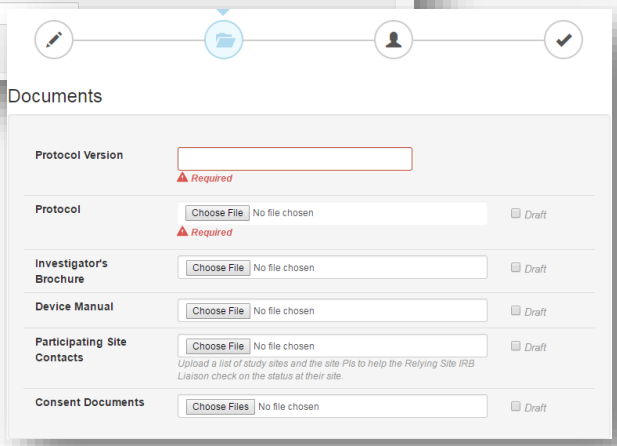
1) Click on the "Create a Study" button on the Dashboard



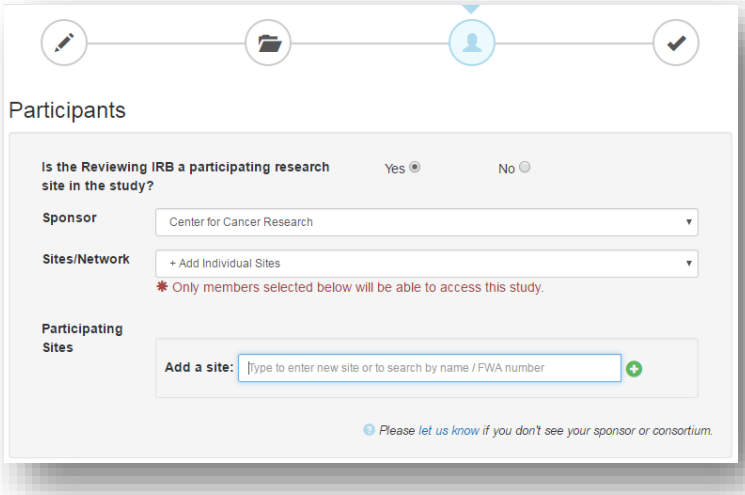
2) Enter General Information:
   a. Title of Study
   b. Summary
   c. NCT#(s)



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



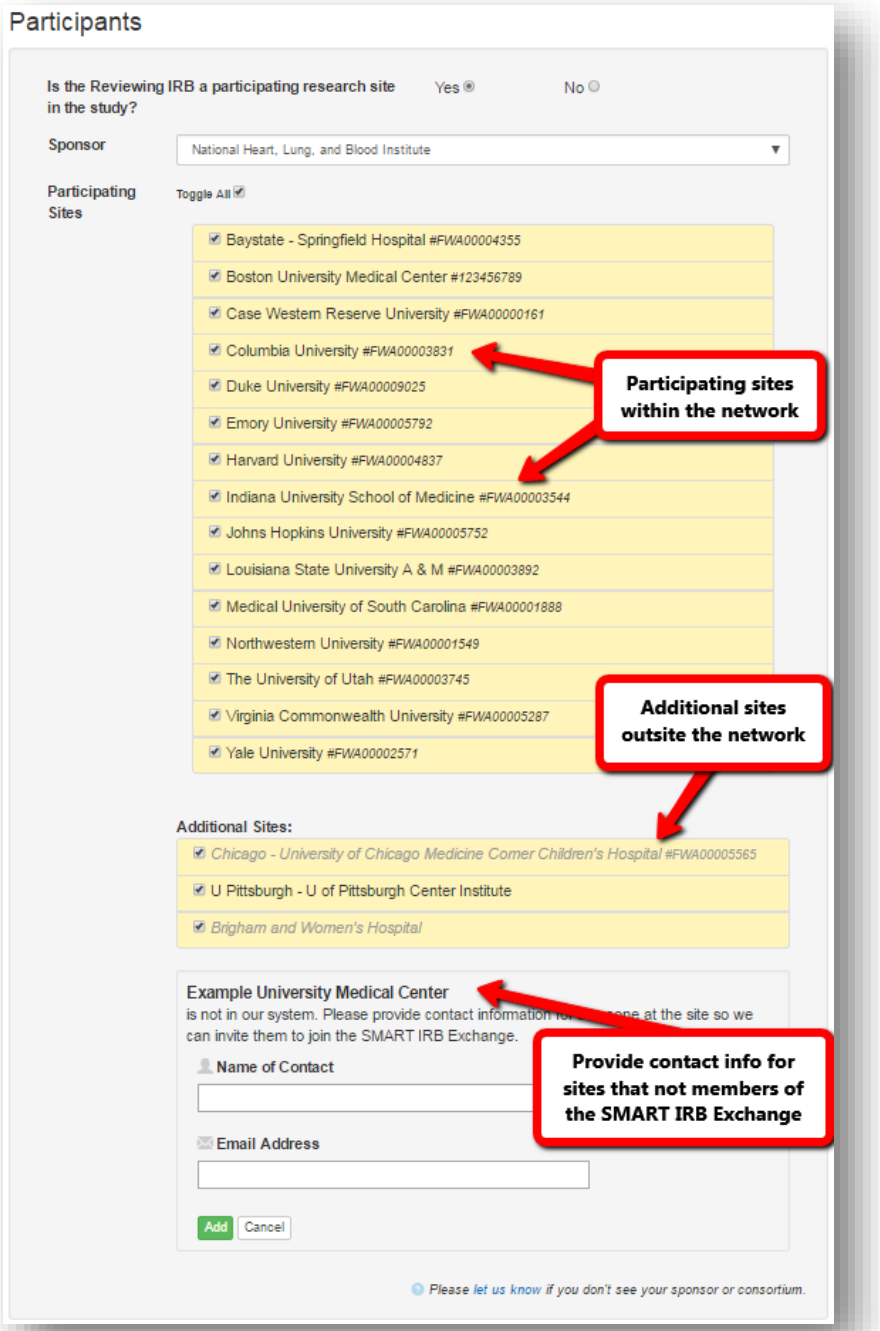
4) List Participants
   a. Indicate if the Reviewing IRB is also participating in the study
   b. Choose a Sponsor
   c. Choose your Participating Sites or Network.



   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.

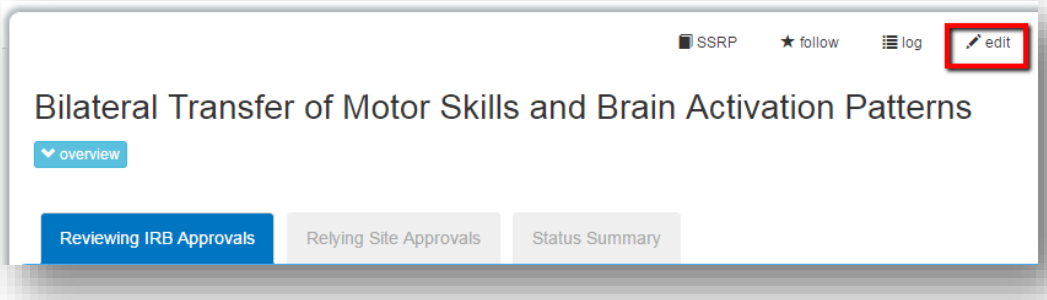
ii. Select "+Add Individual Sites" to create a list participating sites. You can search the database of SMART IRB Exchange members by name of FWA number using the **Add a Site** bar. Click on the site name to add it to the study.

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.



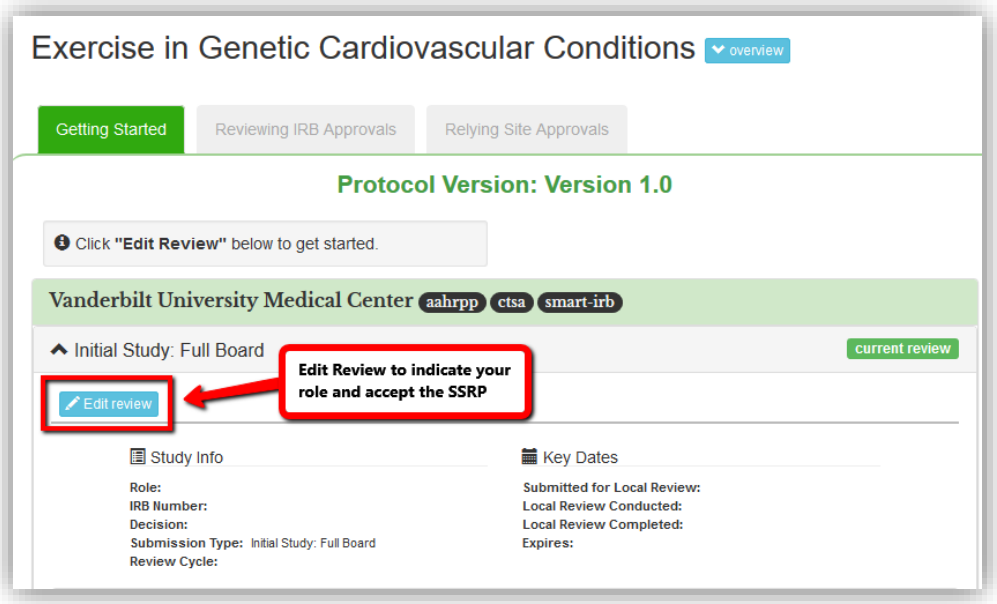
NOTE: STUDIES THAT ARE AFFILIATED WITH A NETWORK OR HAVE A PRE-SPECIFIED LIST OF PARTICIPATING SITES ARE ONLY ACCESSIBLE TO THE INSTITUTIONS LISTED AS PARTICIPATING SITES. STUDIES WITH NO AFFILIATION ARE ACCESSIBLE TO ANY INSTITUTION IN SMART IRB EXCHANGE.

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 tops right corner of the study page.



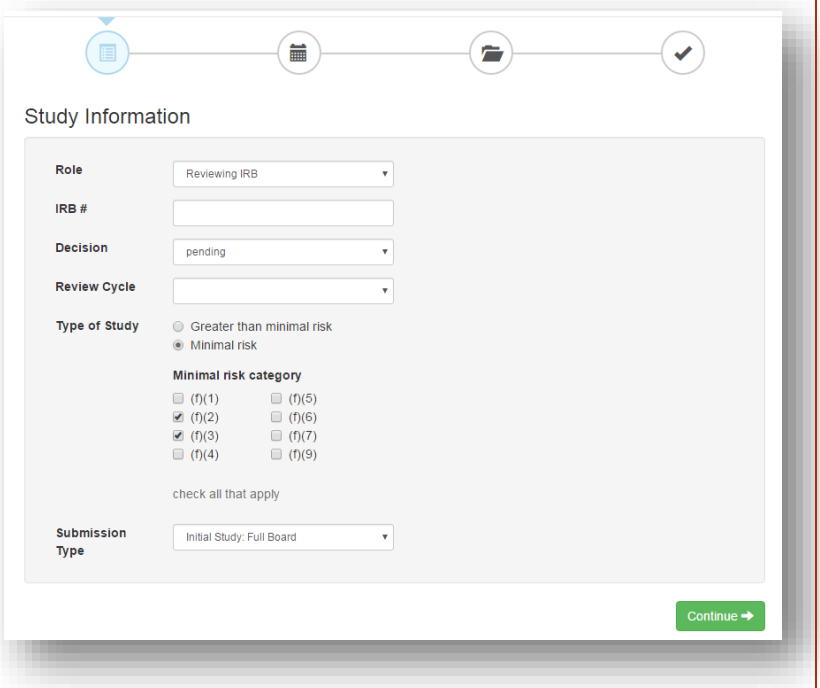
1.1. EDIT YOUR REVIEW

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?

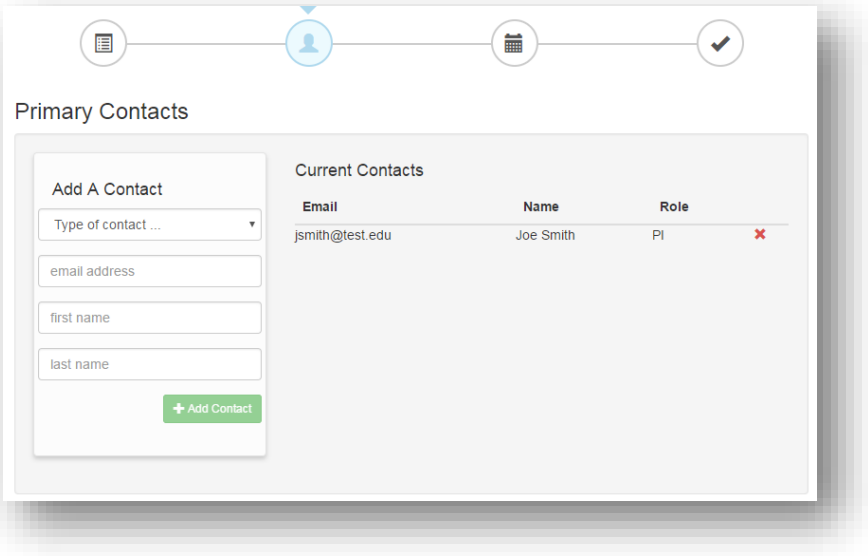


QUICK TIP

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.)

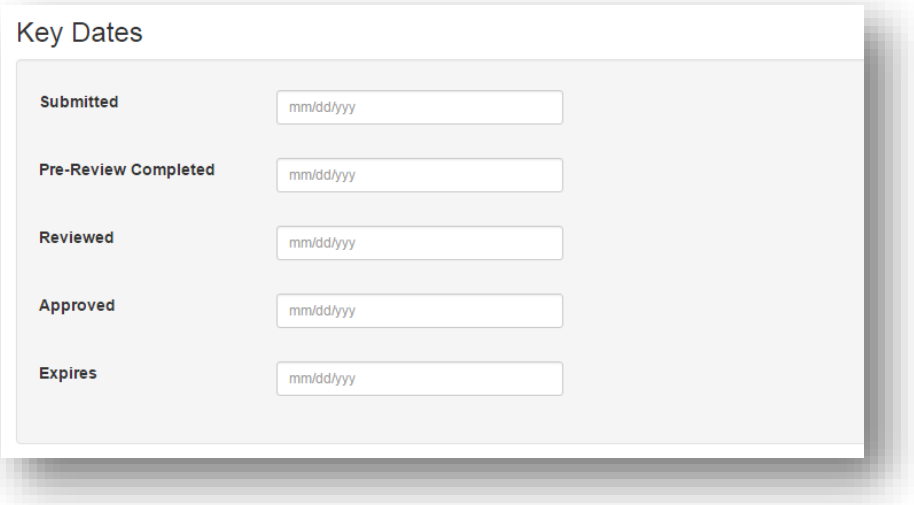
1.1.2. ADD LOCAL STUDY PERSONNEL

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..



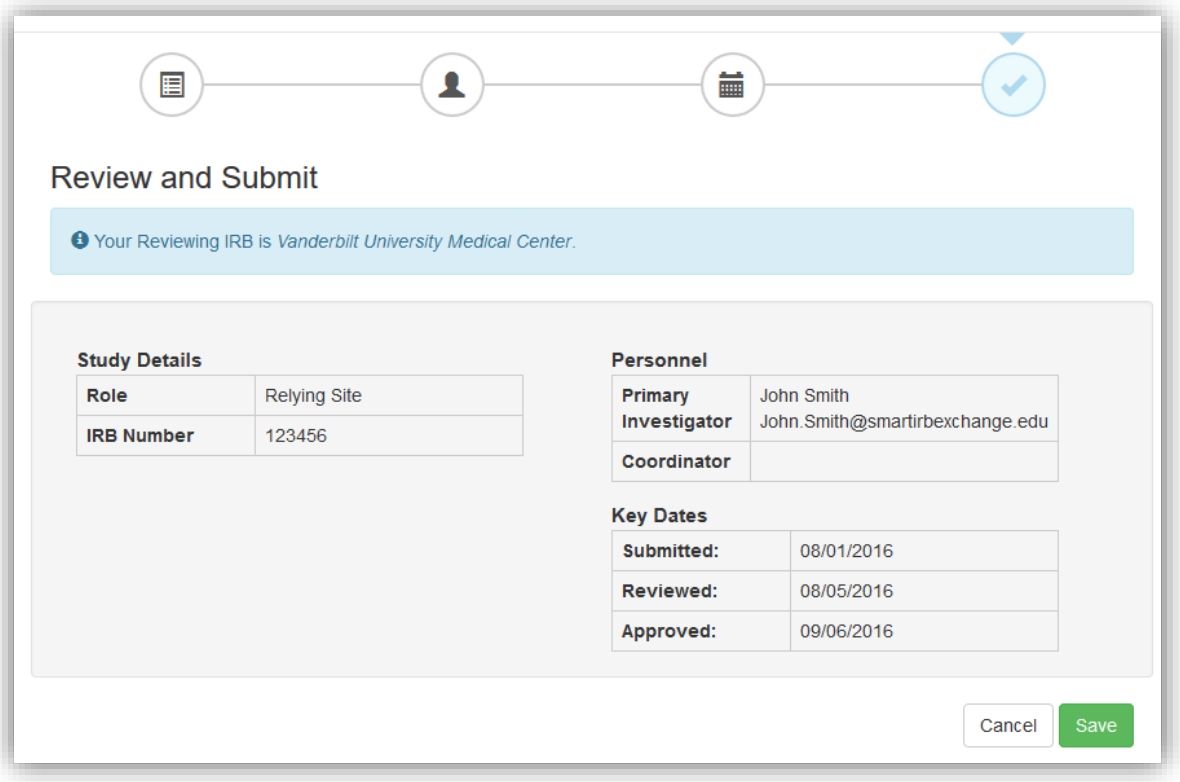
1.1.3. ENTER KEY DATES

- **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")



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.



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:

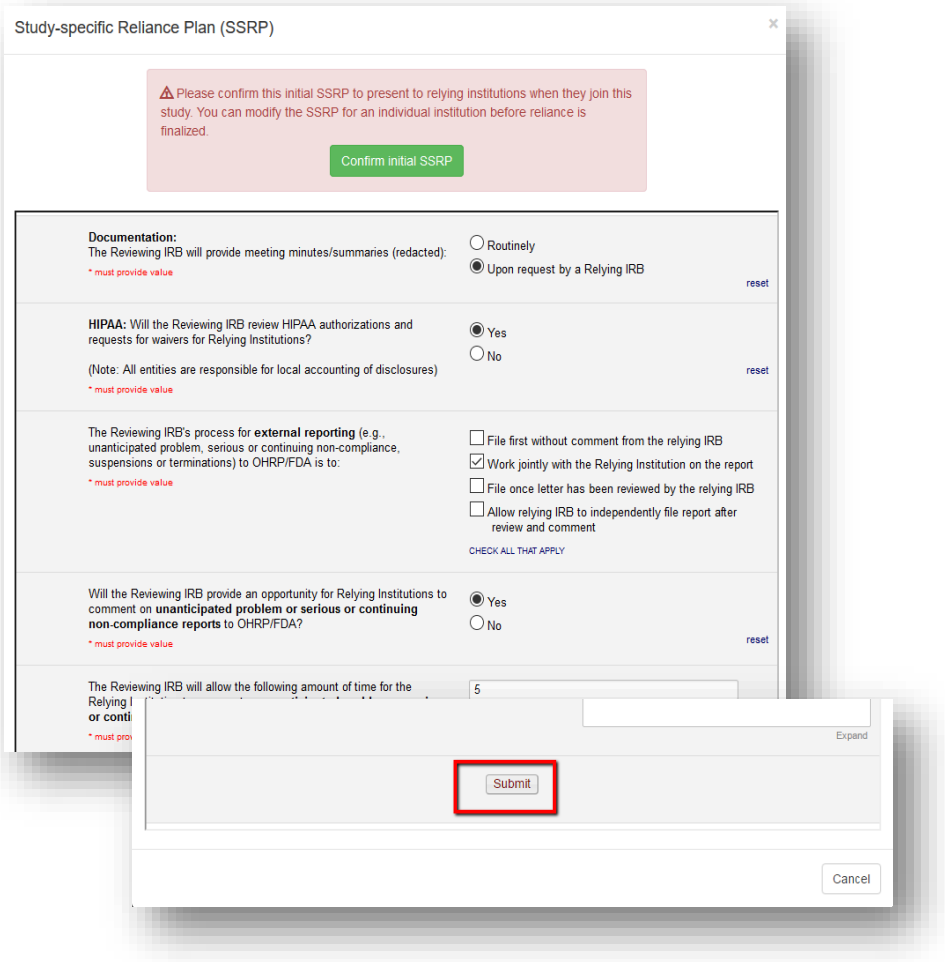
- **Providing documentation**: When will the Reviewing IRB share their minutes (routinely or as requested)?
- **Reviewing for HIPAA**: Will the Reviewing IRB review authorizations and waiver requests for Relying Sites?
- **Reporting**: What is the Reviewing IRB's preferred process for external reporting?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

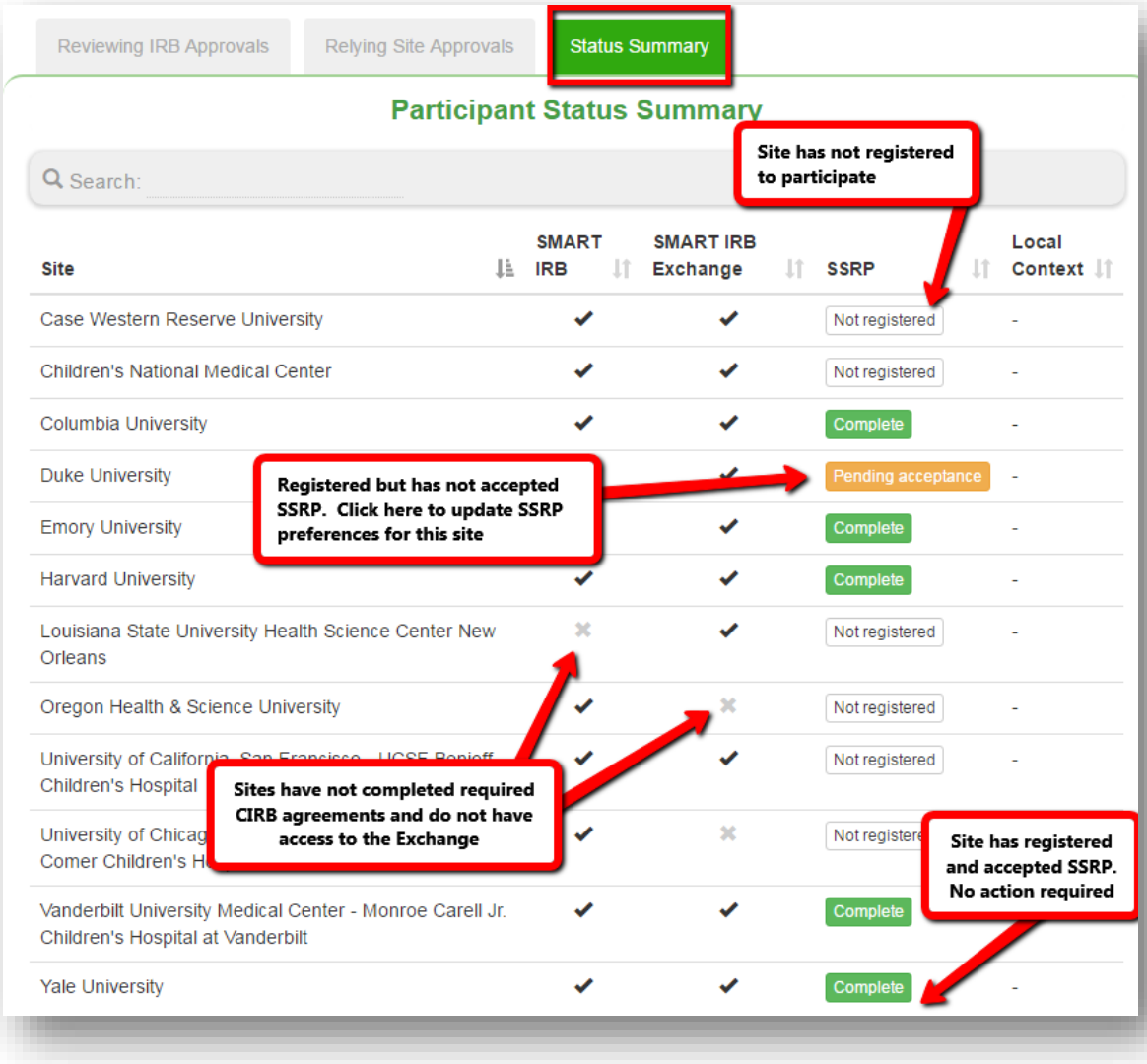


2) Once you confirm the SSRP, an email notification will be to all listed participating sites informing them of the new study and inviting them to participate.
3) In order to indicate their decision to cede review to you, relying sites must review and accept your SSRP. Once a Relying Site accepts your 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

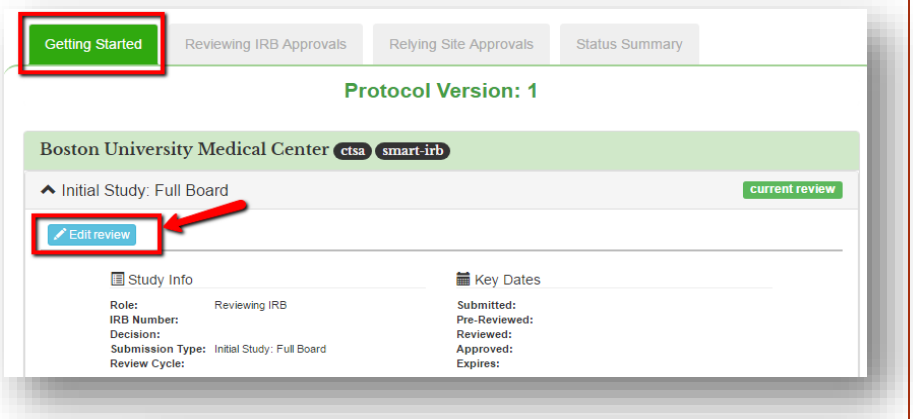
To see the list of all Relying Sites and track their Study Start-up and SSRP status, click on the **Status Summary** tab.

- **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.



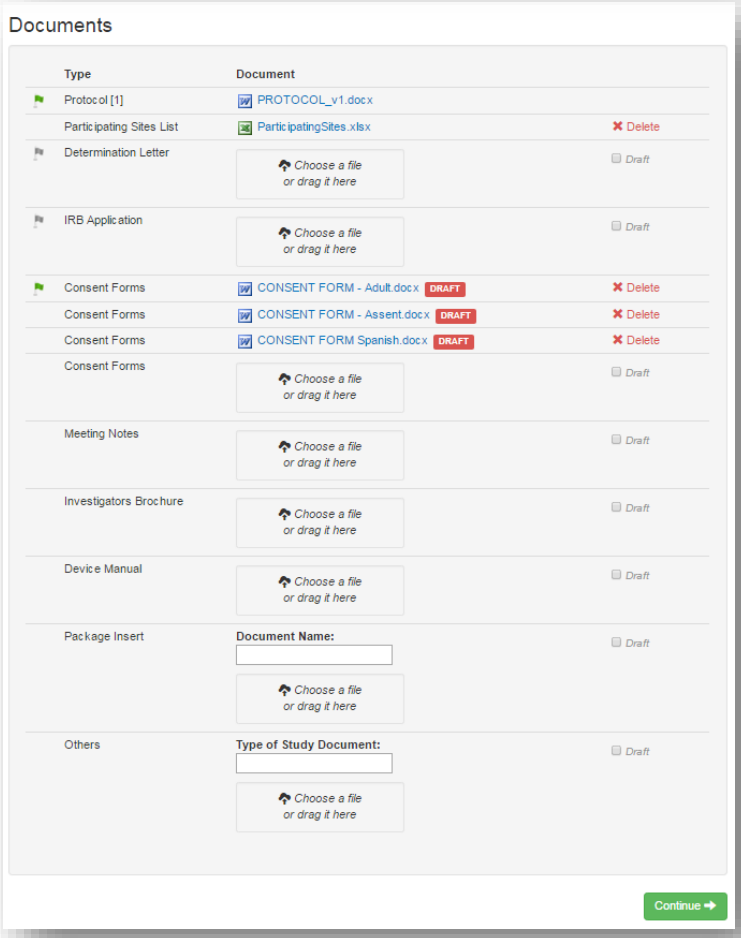
4. ADD AN INITIAL STUDY APPROVAL FOR YOUR SITE

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.

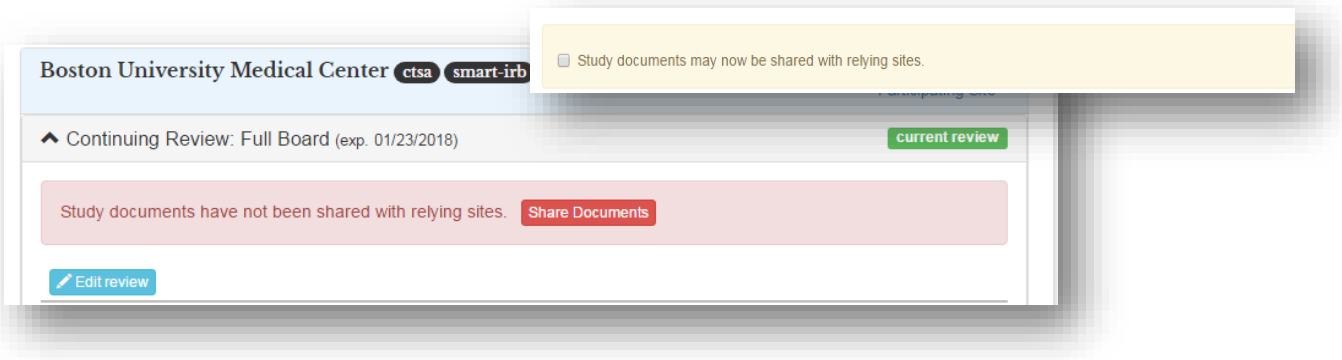
2) Update the Review Dates. See Section E.1.1.3



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.

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.

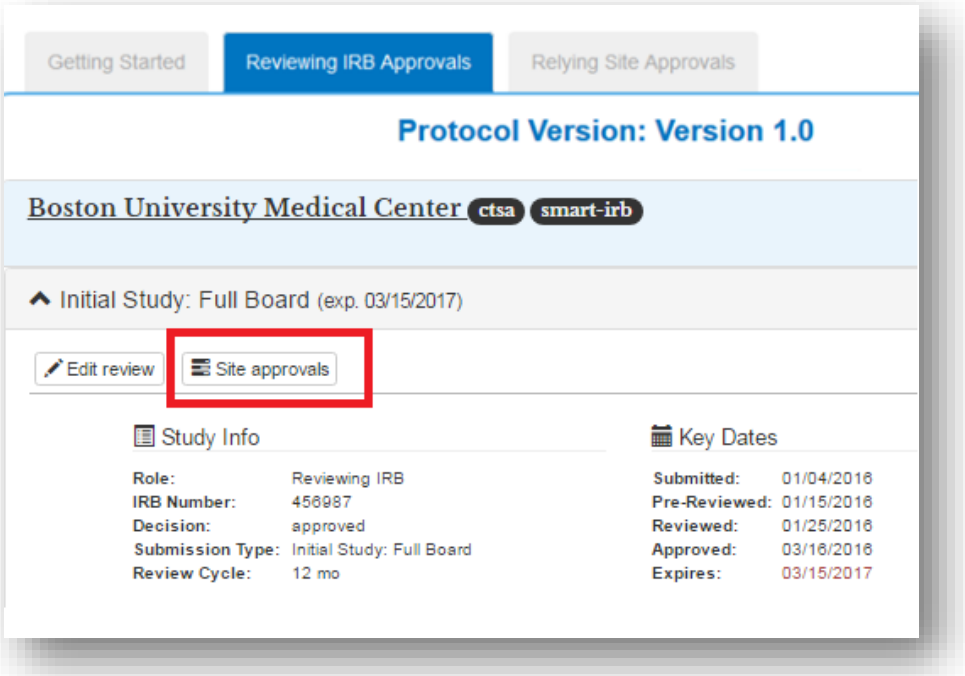


5. ADD A STUDY APPROVAL FOR A RELYING SITE

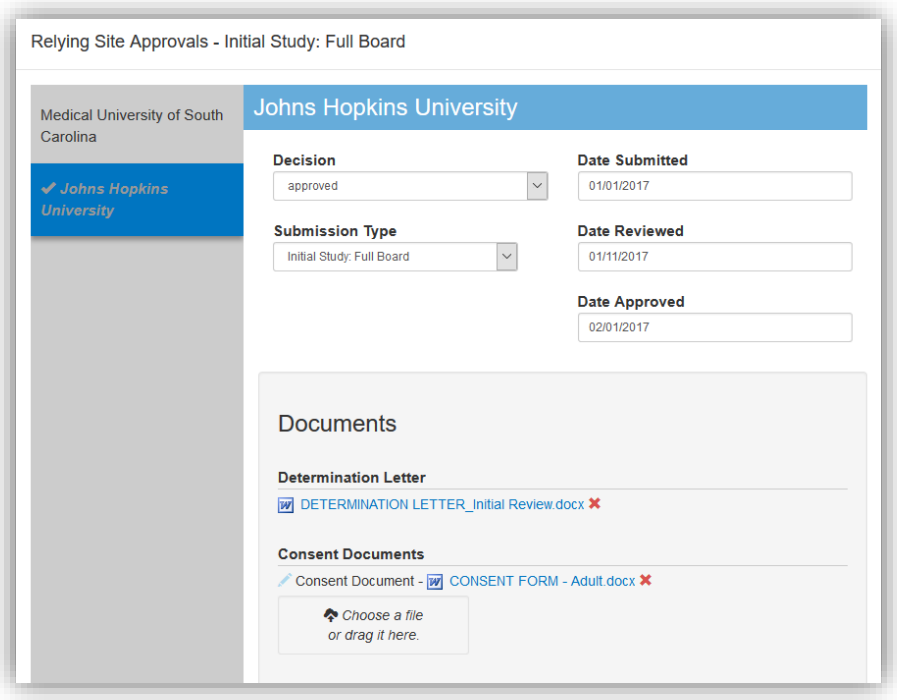
Once you have uploaded your initial approval, you can add approvals for Relying Sites who chose to cede review.

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.

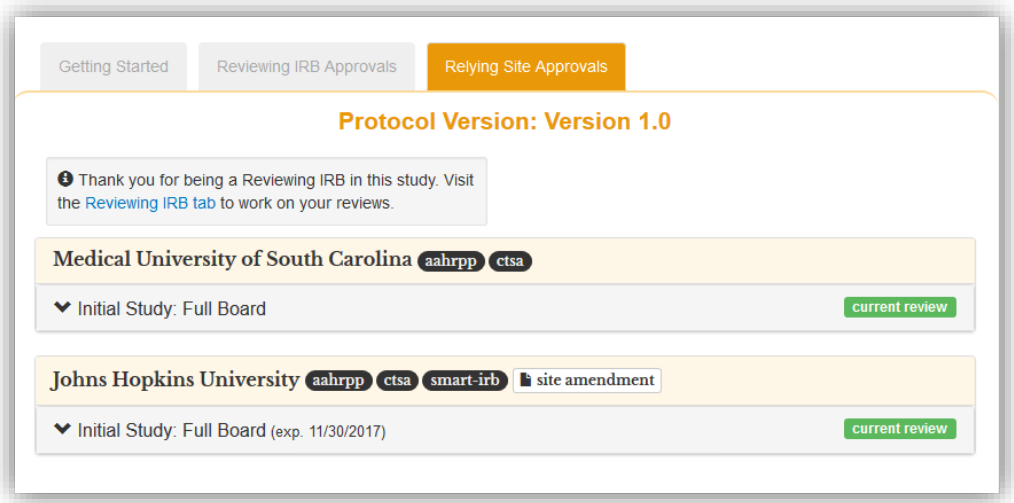


2) A pop-up will appear with a list of Relying Sites who have chosen to cede review. For each site, you will:
    a. Choose a review decision: Approved or Pending
    b. Enter the approval dates: Submitted, Reviewed, Approved
    c. Upload approvals documents specific to the Relying Site:
        i.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



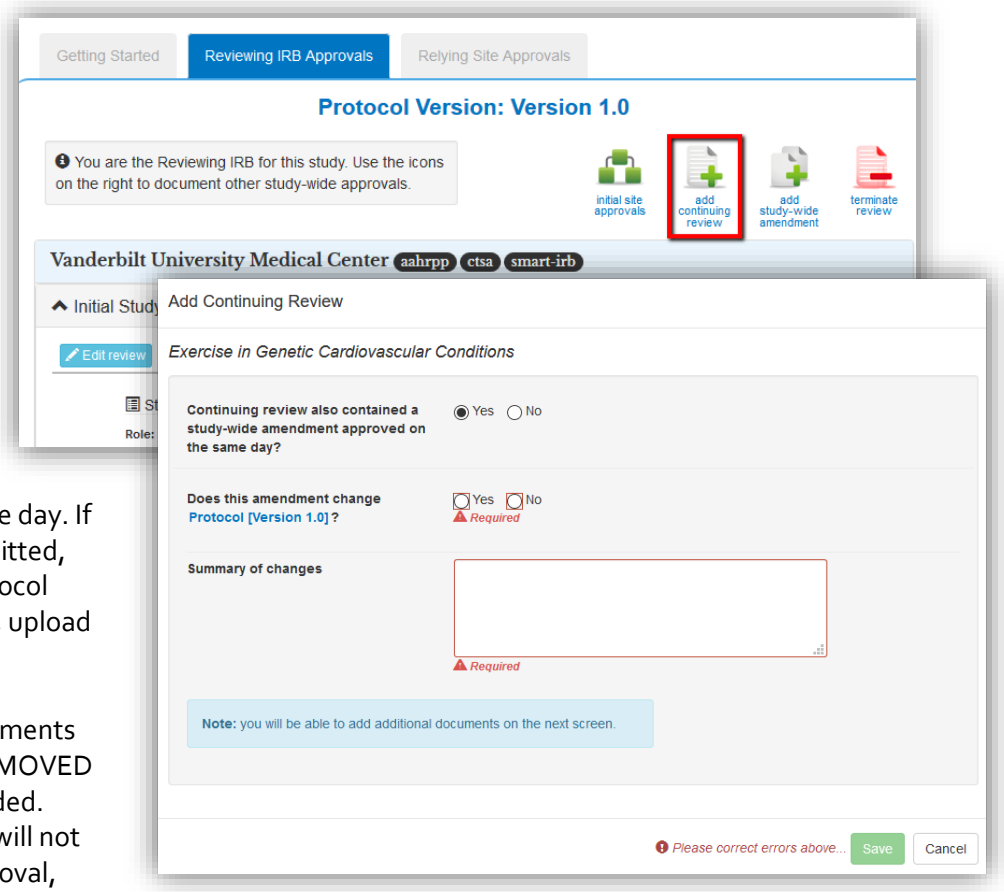
3) You must set the Decision to "**approved**" for a Relying Site in order upload approval documents for that site.

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.
    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.



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.

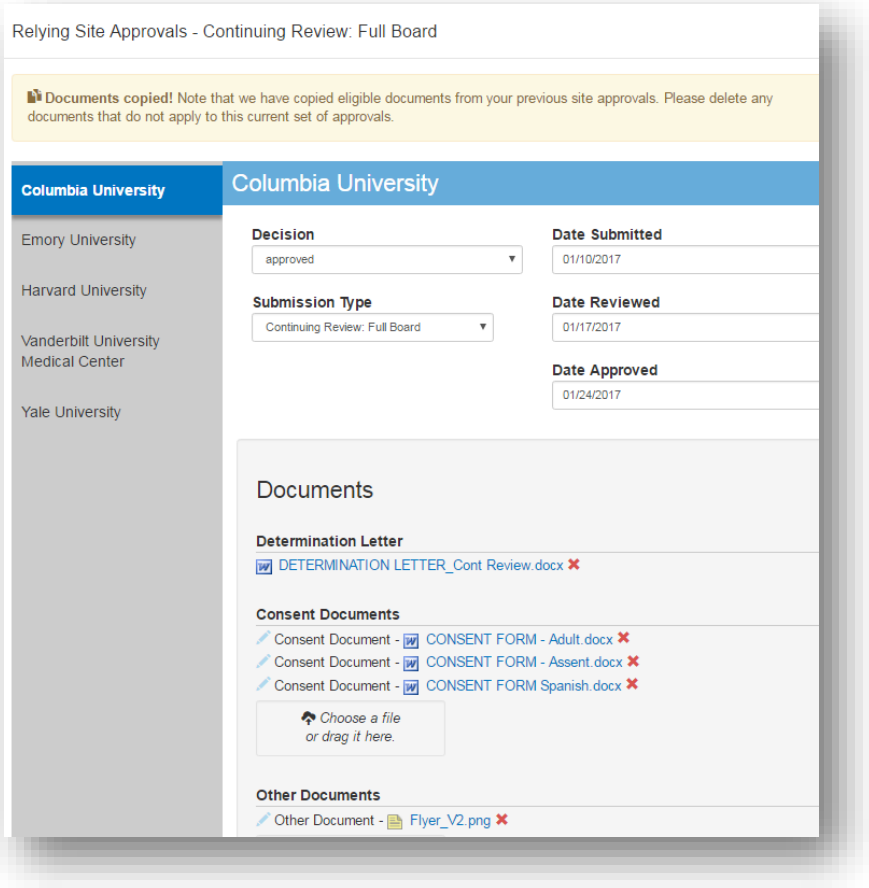
3) Indicate what, if any documents CHANGED or CAN BE REMOVED from those initially uploaded. Any documents checked will not be added to the new approval, but will remain accessible via the version to which they were originally uploaded.

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)

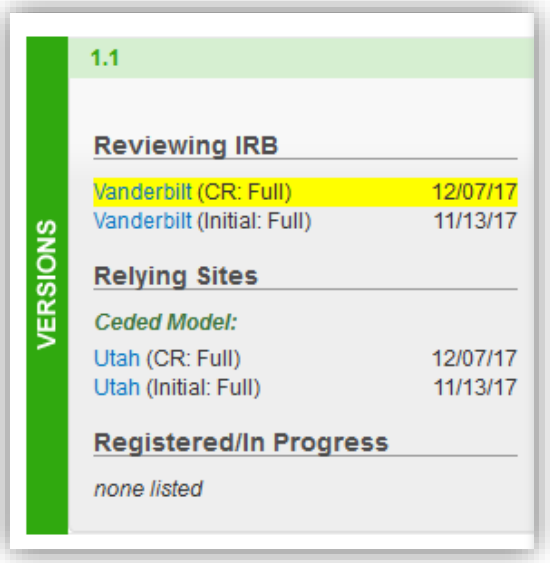
6) Once you upload this approval, a pop-up will appear with a list of Relying Sites. For each site, you will document continuing review approval information and upload new approval doucments for each site as you did for the initial study review. You can also access this by click th site approvals button 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)



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 change 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.



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:

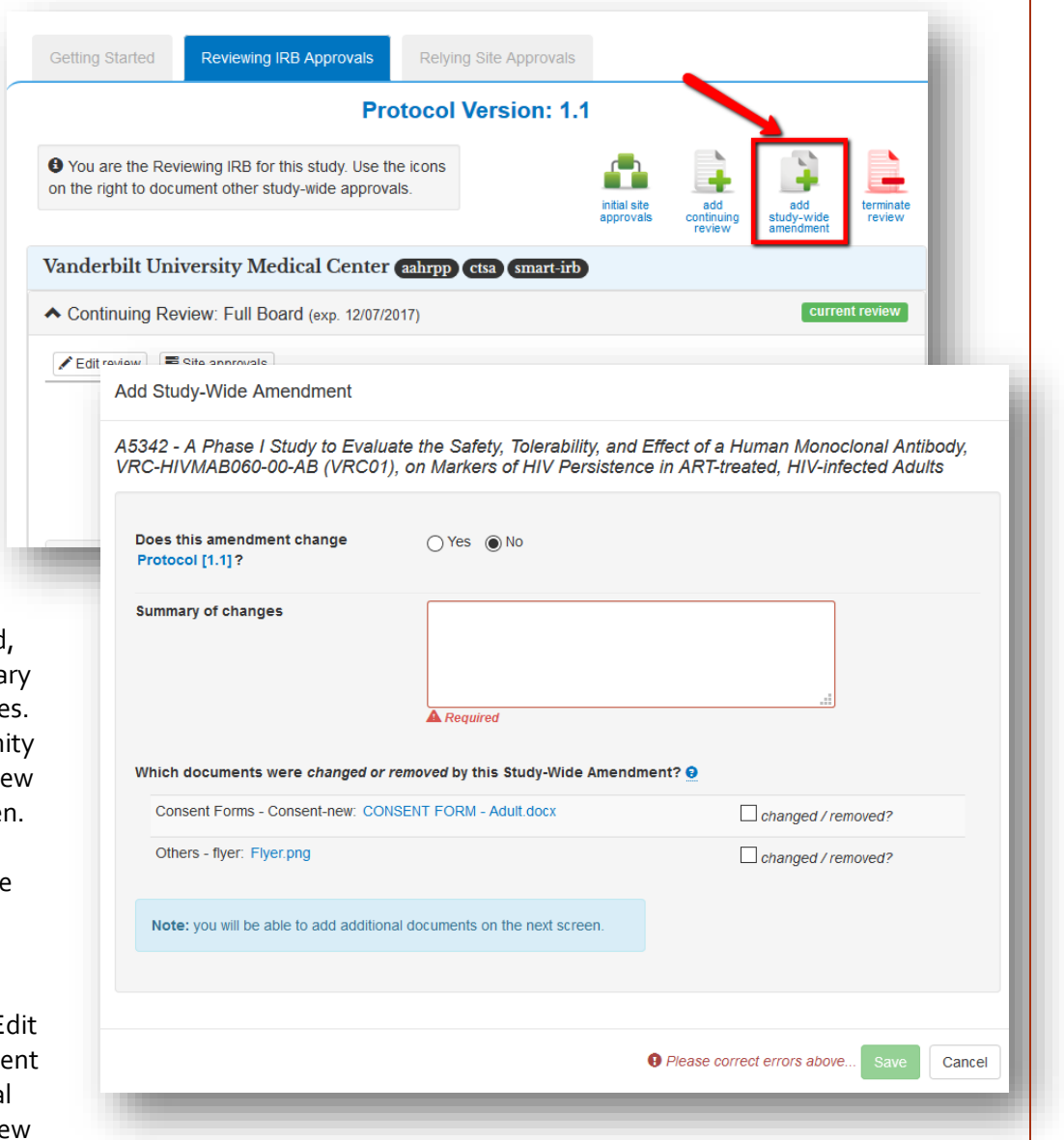
1) Click on the "**Add Study-wide Amendment**" icon at the top of the project page. An "**add amendment**" pop-up will appear asking whether the protocol has changed.

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.

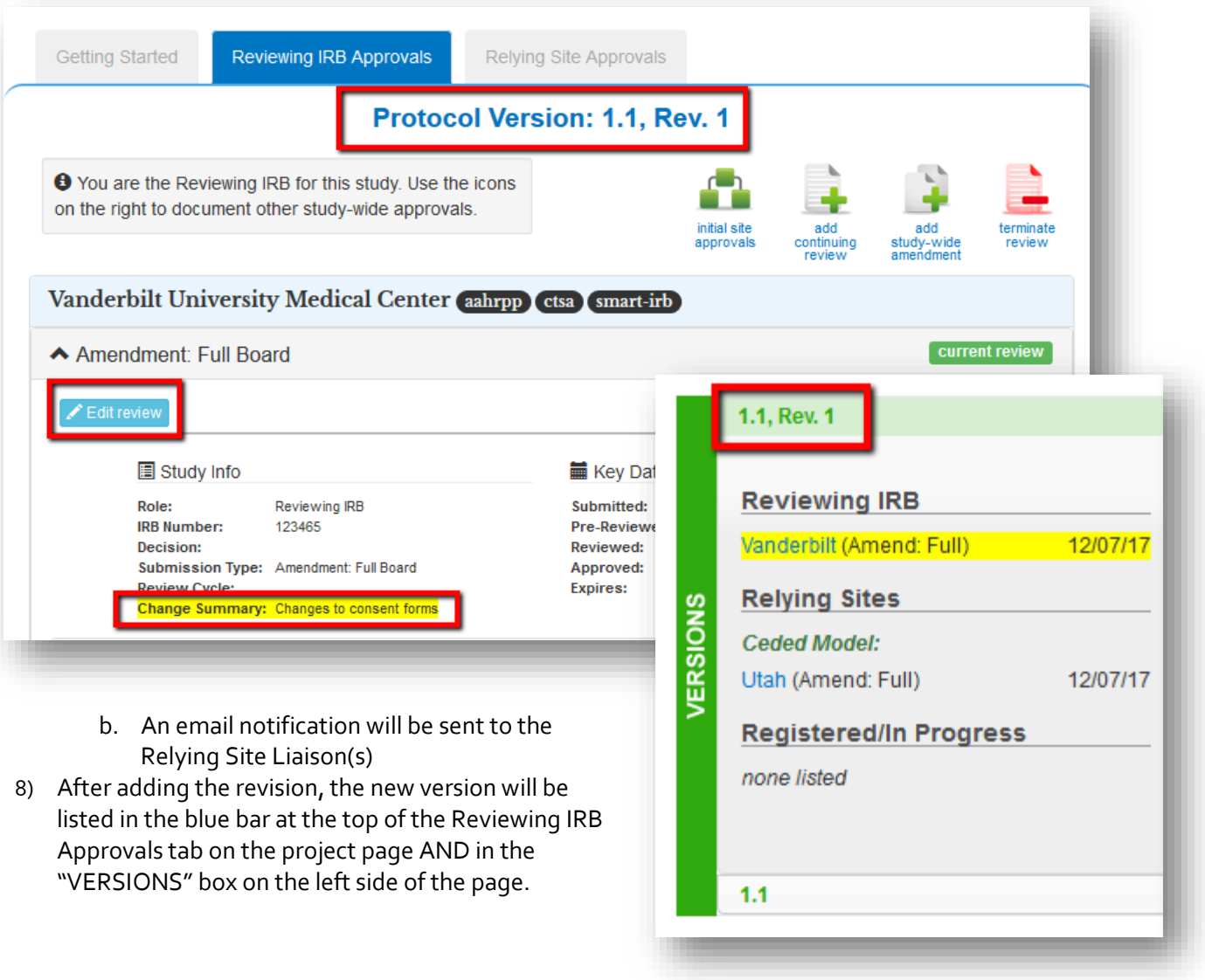
5) On the Reviewing IRB Approvals tab, click the "Edit Review" button to document your amendment approval information and upload new approval documents as you did for the initial study review. See Section E 4.



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 doucments for each site as you did for the initial study review. You can also access this by click th 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:

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

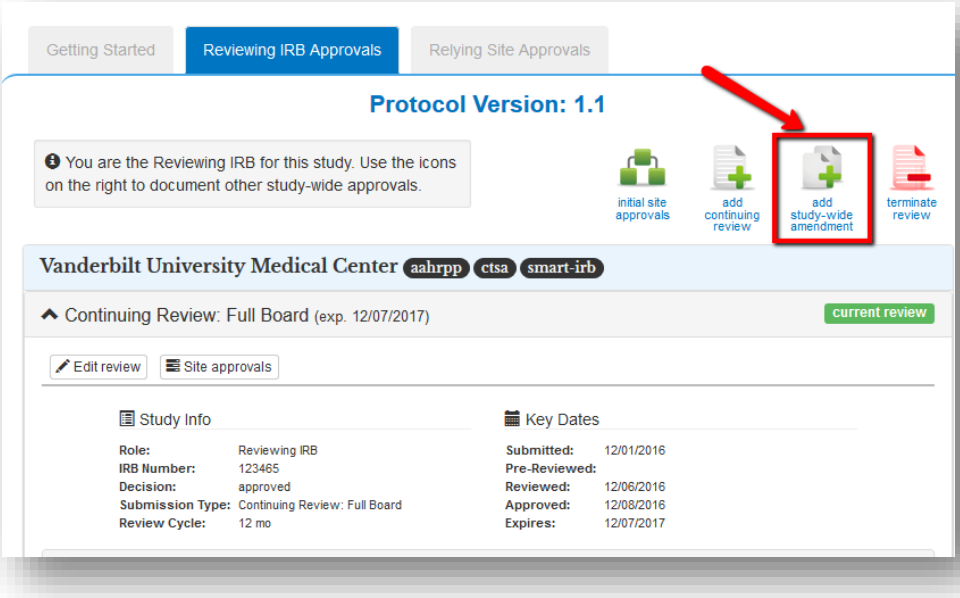


b. An email notification will be sent to the Relying Site Liaison(s)

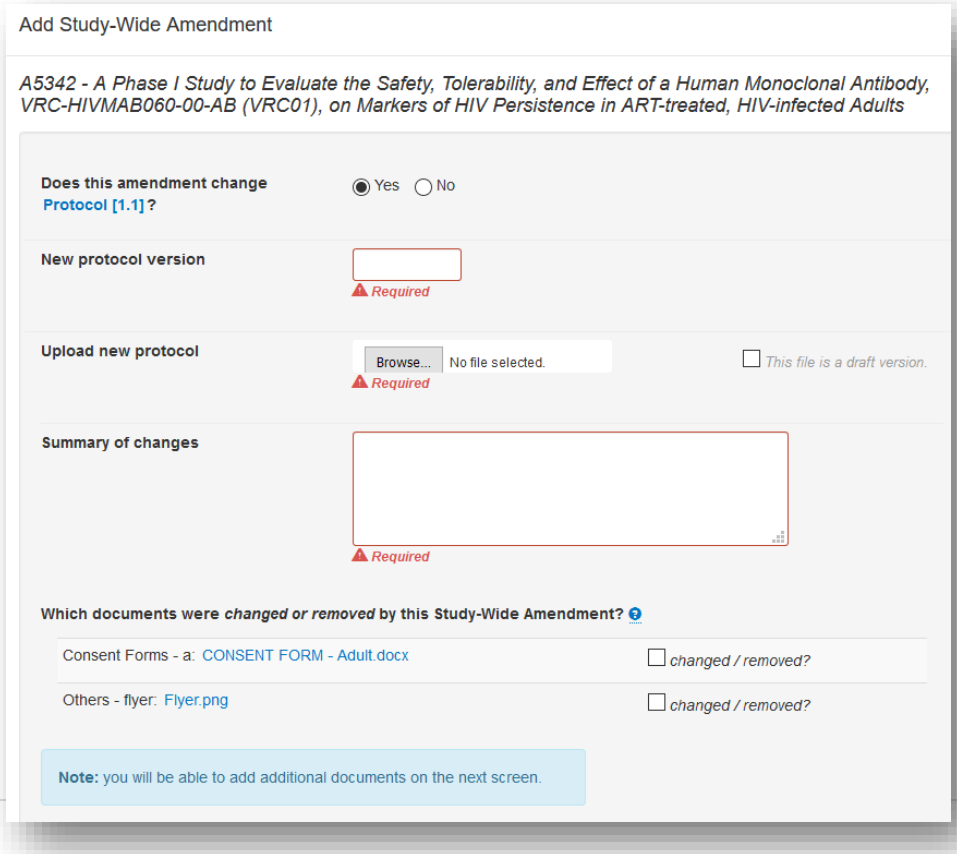
8) After adding the revision, the new version will be listed in the blue bar at the top of the Reviewing IRB Approvals tab on the project page AND in the "VERSIONS" box on the left side of the page.

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 .



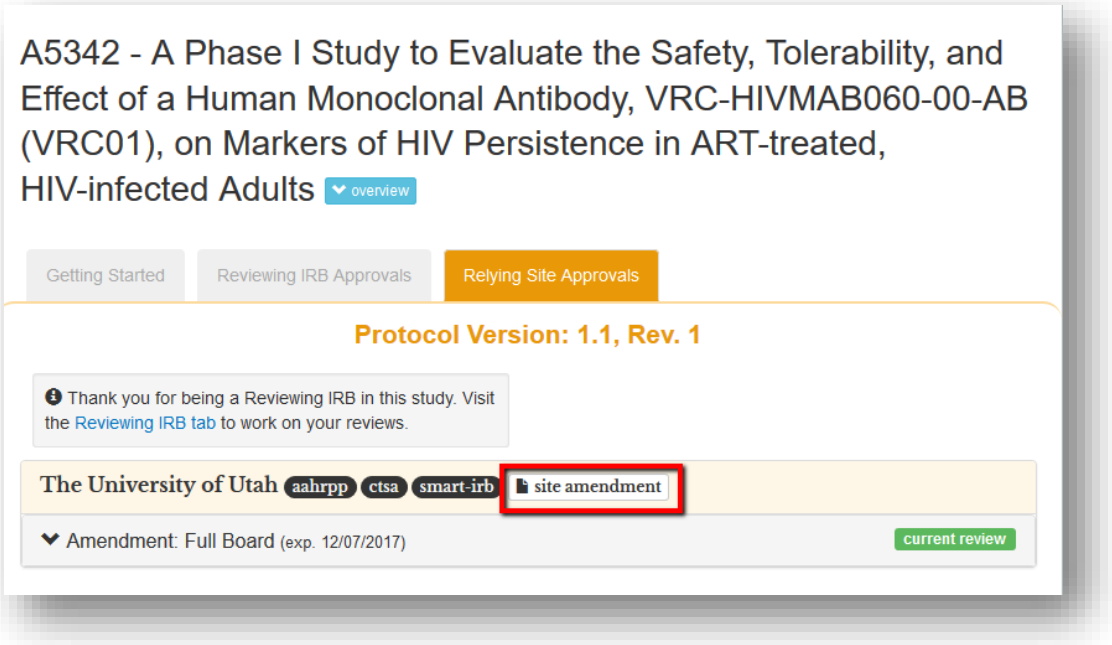
1) Follow the steps in Section E.7 above, with the exception of answering "Yes" to the question about whether the amendment changes the protocol.
2) An upload button will appear. Upload and name the new version of the protocol.



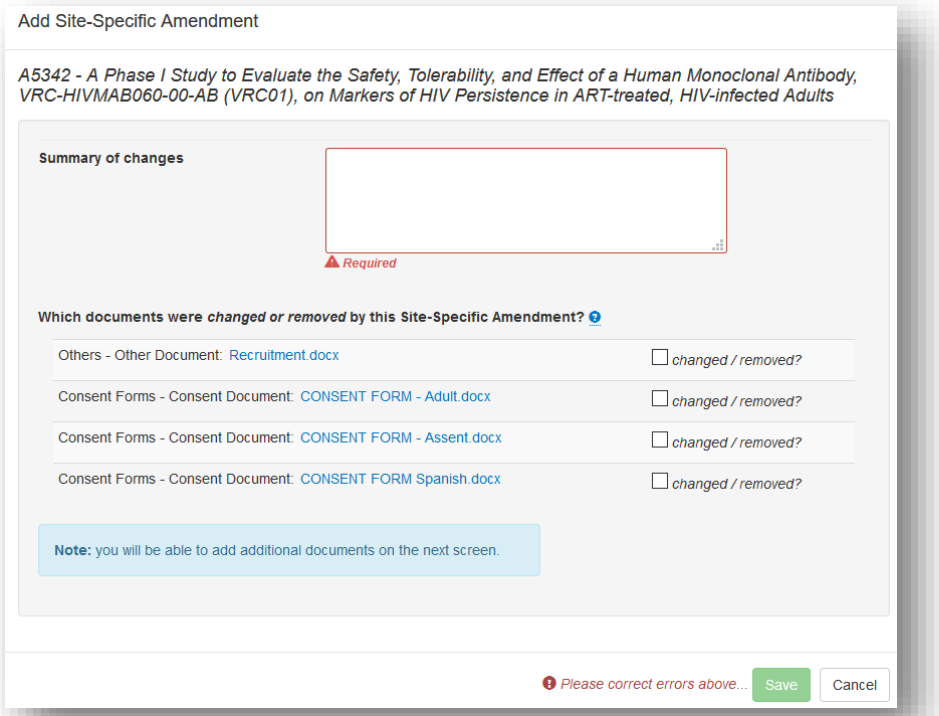
9. ADD A SITE-SPECIFIC AMENDMENT

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.

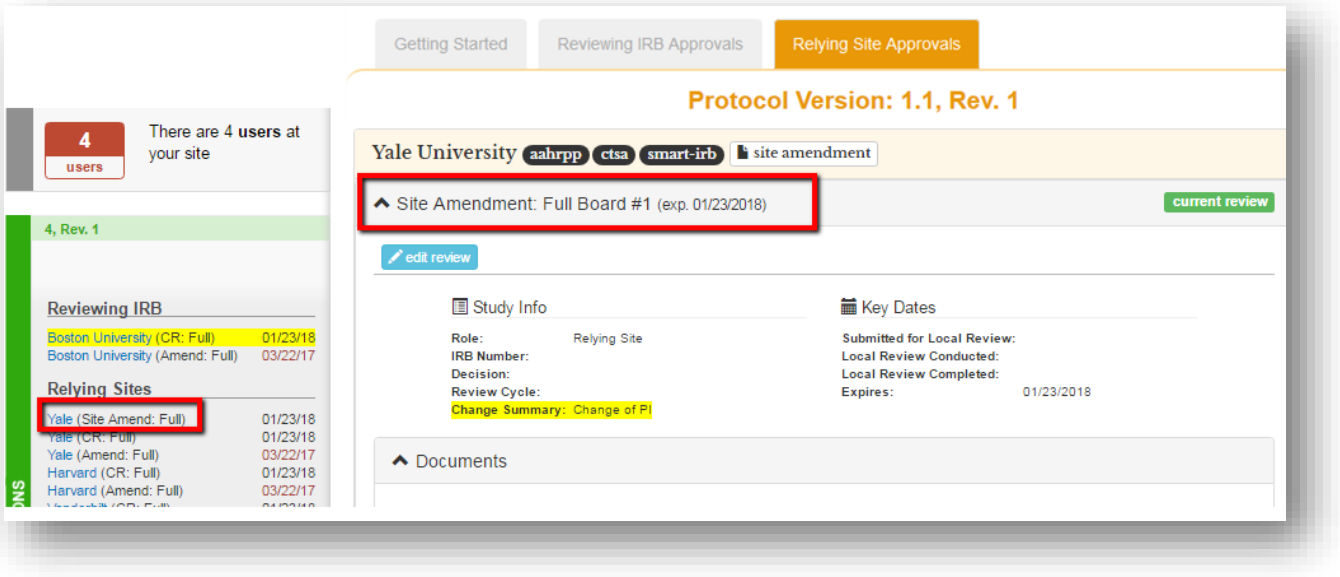


4) On the Relying Site Approvals tab, click on the "edit review" button to enter information about the site-specific approval and upload new approval documents as you did for the initial study review. See Section E.4.

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.

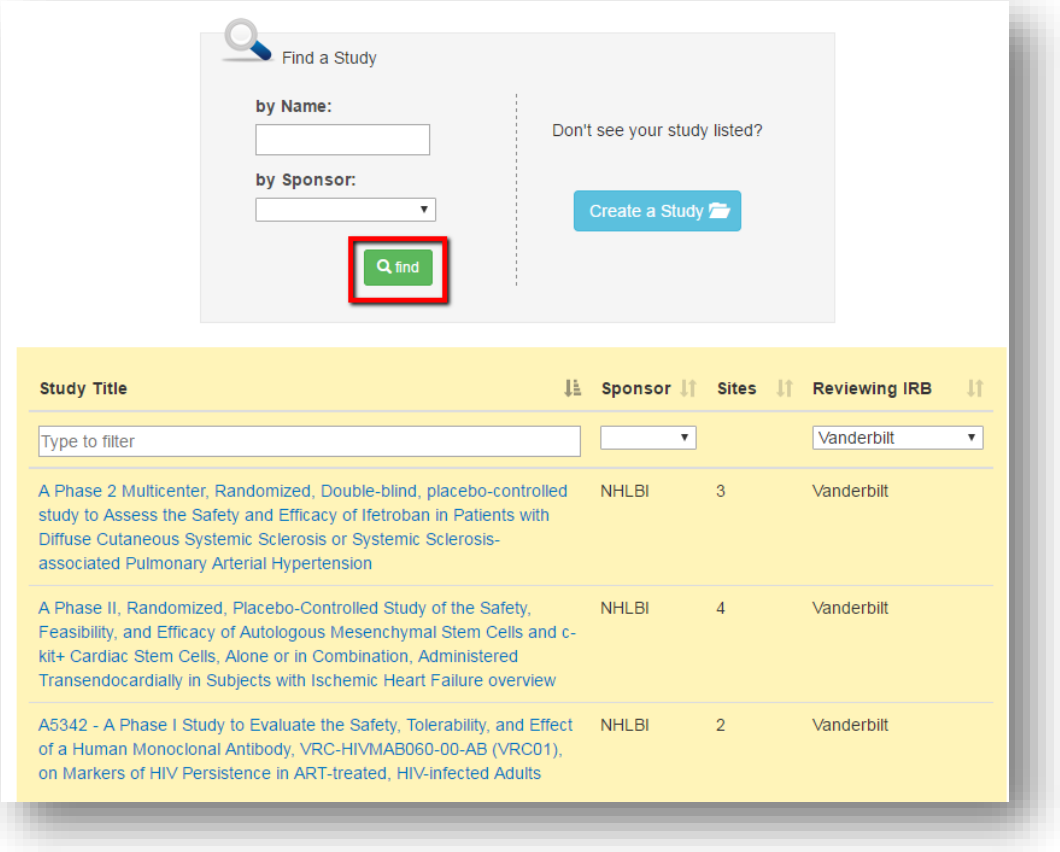
7) After adding the site-specific amendment, the amendment will be listed in the site's review information on Relying Site Approvals tab on the project page AND in the "VERSIONS" box on the left side of the page.



SECTION F: PARTICIPATING AS A RELYING SITE

1. FIND A STUDY AND REGISTER TO PARTICIPATE

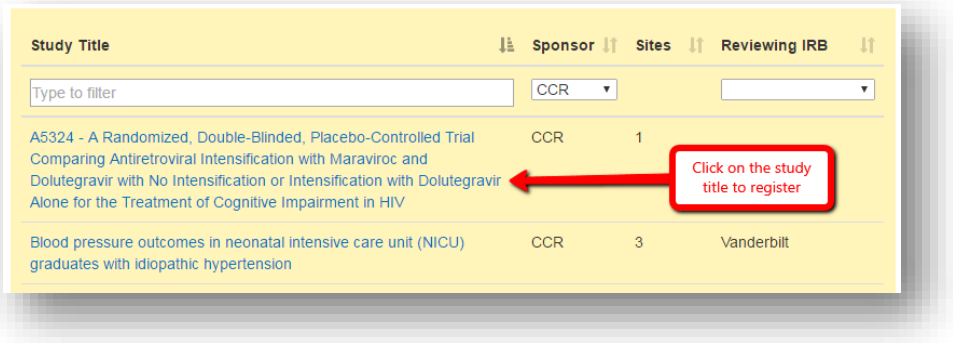
To find out if a study is in SMART IRB Exchange, use the "Find a Study" search at the top of the Dashboard. You can view the entire SMART IRB Exchange database of studies by leaving the name and sponsor fields blank and clicking "find".



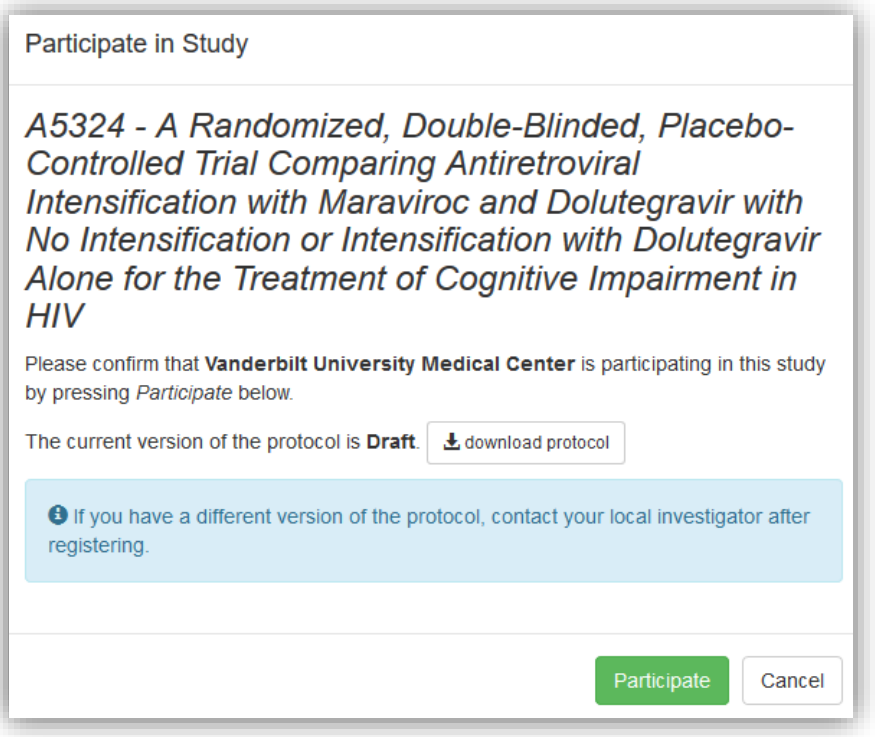
QUICK TIP

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.

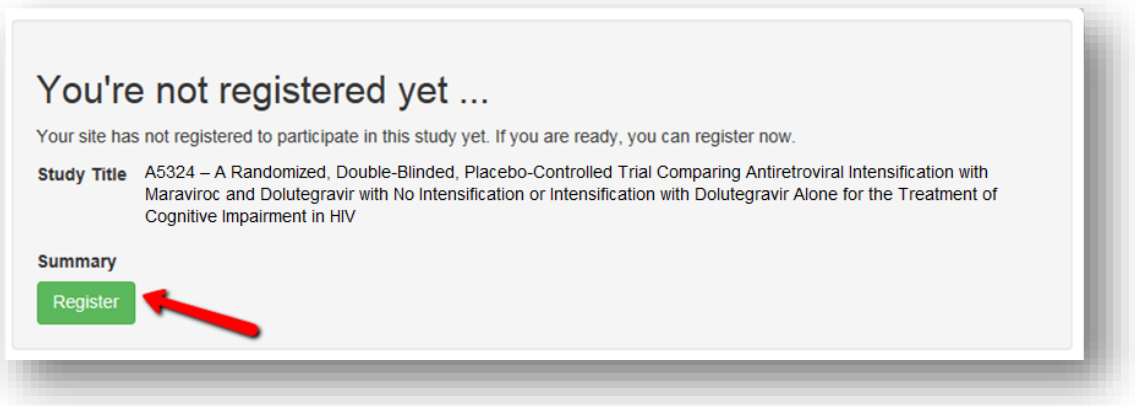


The "Participate in Study" window will pop up and you will be asked to verify that your site is participating in the study. You can also download the most recent version of the study protocol to confirm that it is the correct study. Click "Participate" to verify that you are a study site and to be directed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



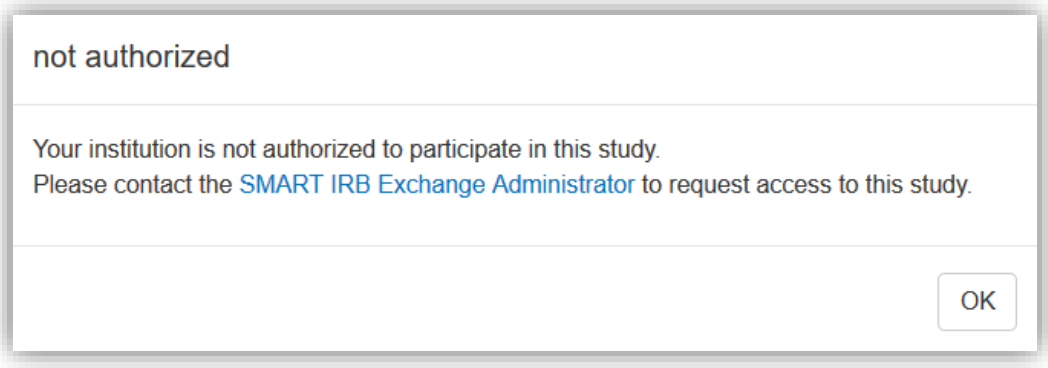
For studies that are affiliated with a network, access is restricted to sites that 1) belong to a specific consortium or network and 2) are listed as participating in the study. If the Reviewing IRB identifies your site as a study site, you will receive an email notification with a link to register for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

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



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.



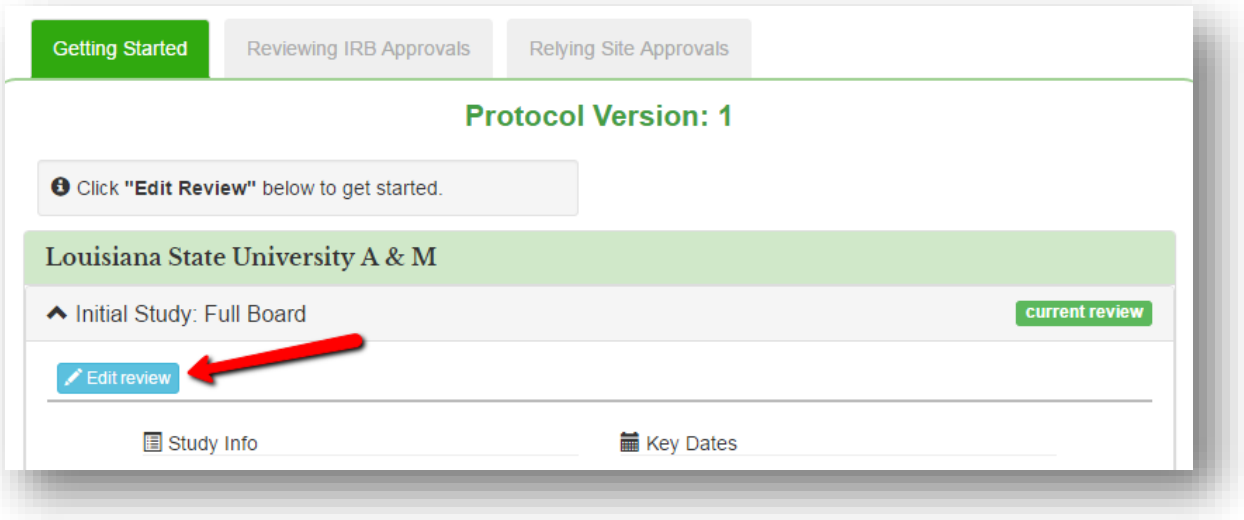
Studies that are not affiliated with a consortium and do not have a pre-specified list of participating sites are accessible to any institution in SMART IRB Exchange.

QUICK TIP

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

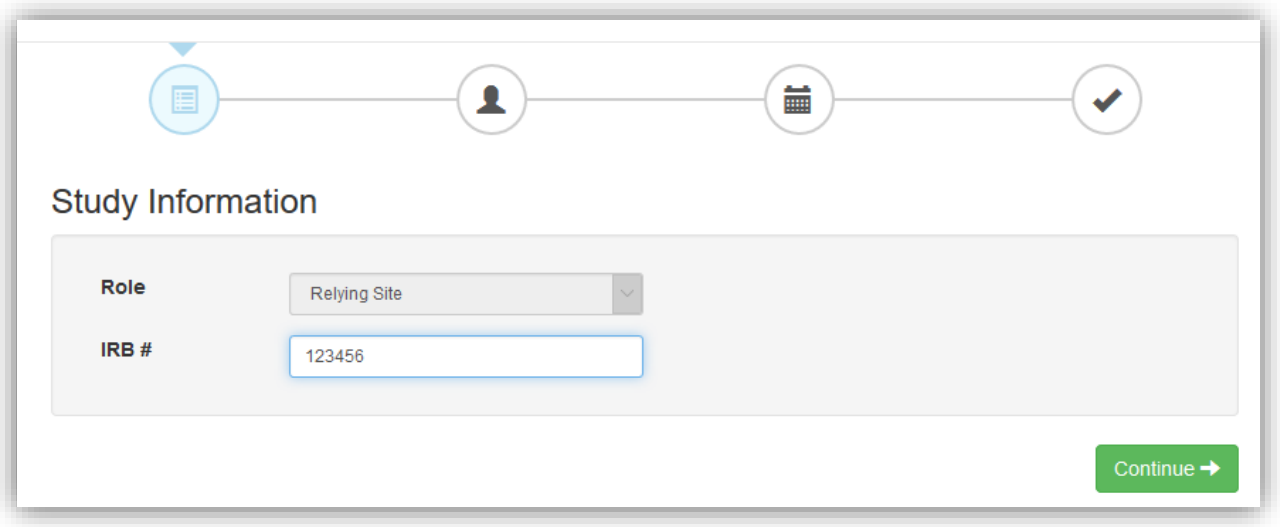
1.1. EDIT YOUR REVIEW

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.



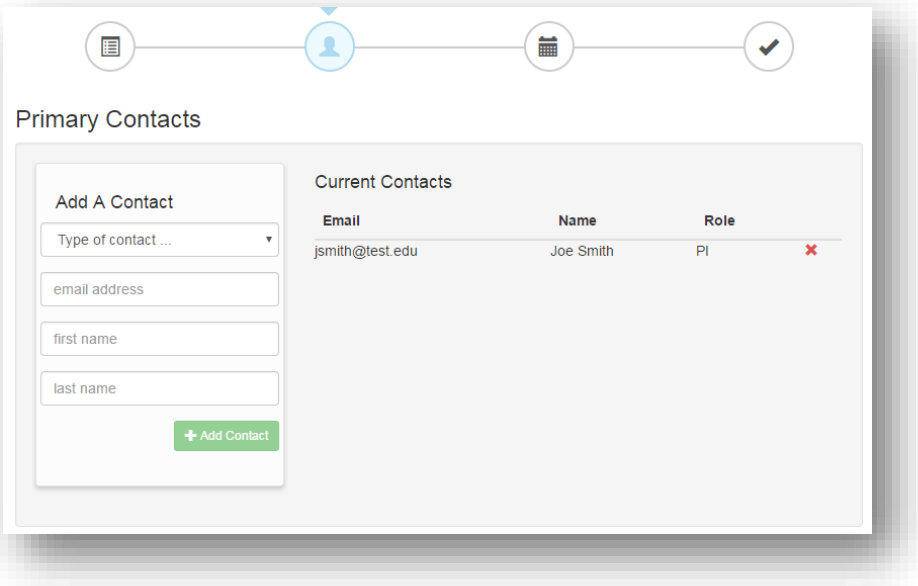
1.1.1. ENTER YOUR STUDY INFORMATION

- **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?



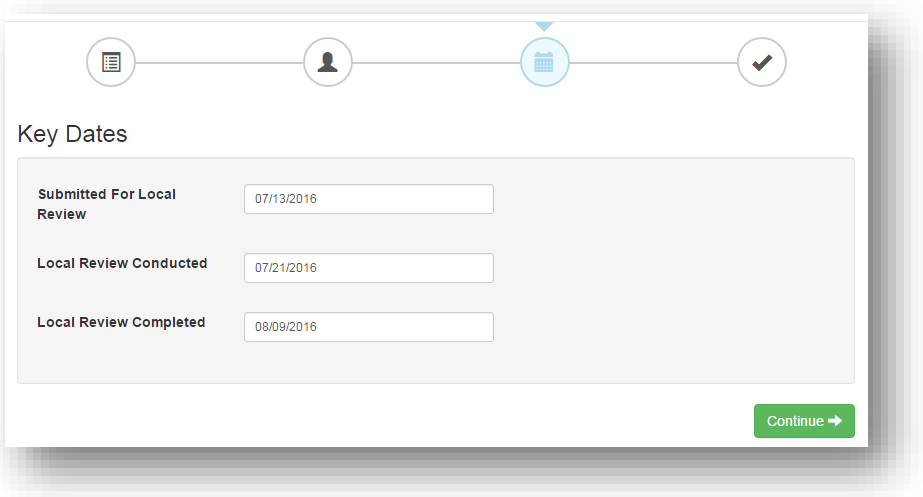
1.1.2. ADD LOCAL STUDY PERSONNEL

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..



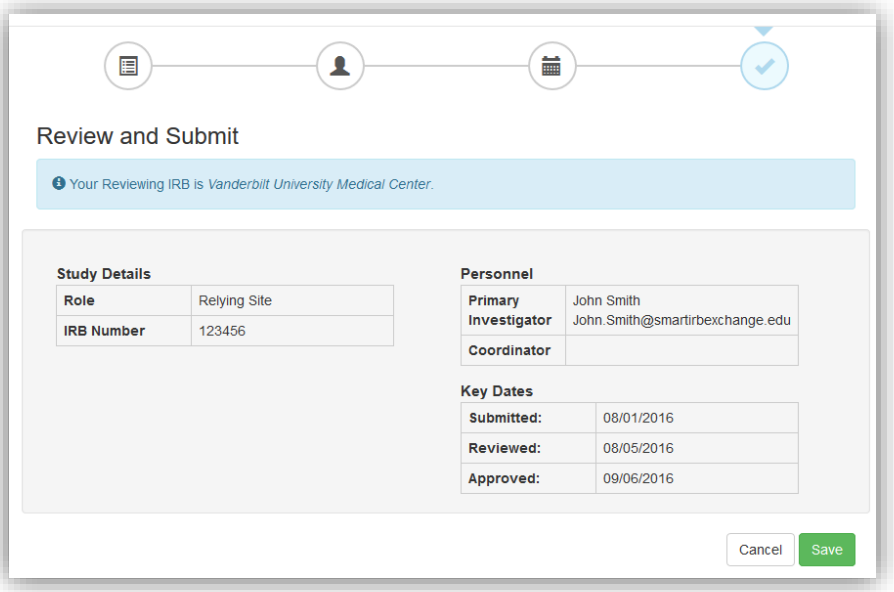
1.1.3. ENTER KEY DATES

- **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?



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.



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)

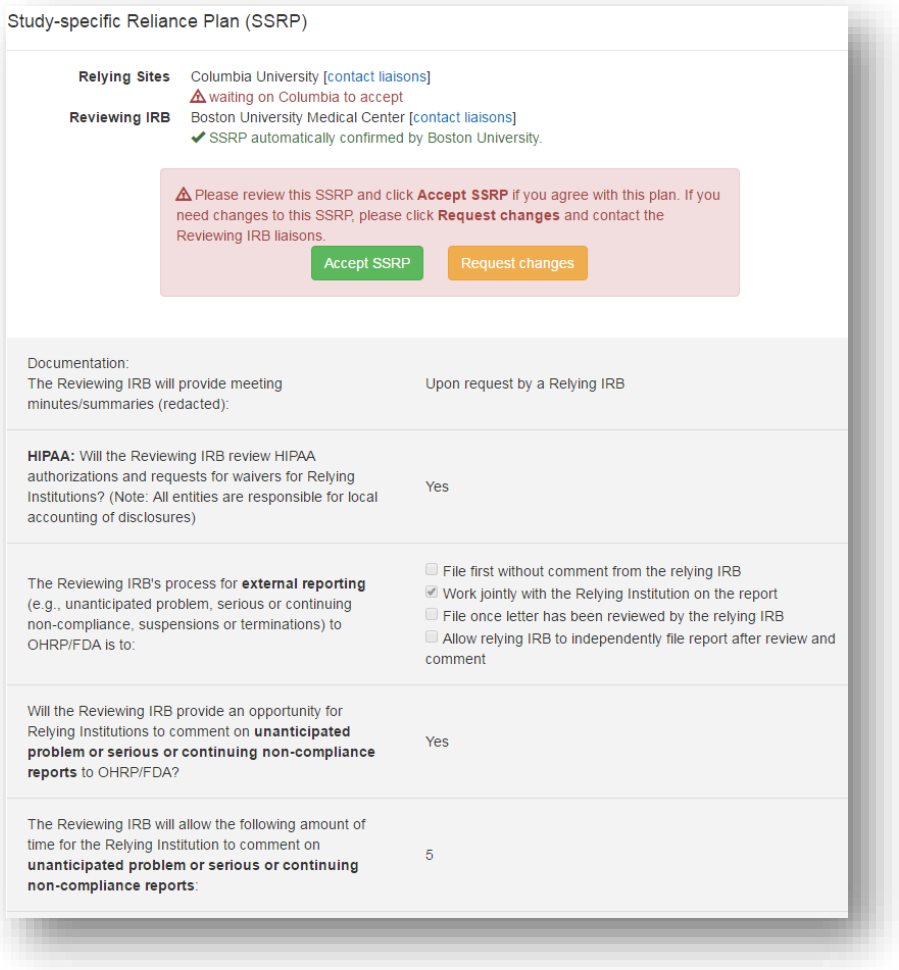
The next step to ceding review to the Reviewing IRB is to complete the Study-Specific Reliance Plan (SSRP). As described in the SMART IRB Exchange Operator Appendix, the SSRP is a set of study-specific reliance preferences between the Reviewing IRB and each of the Relying Sites regarding the following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

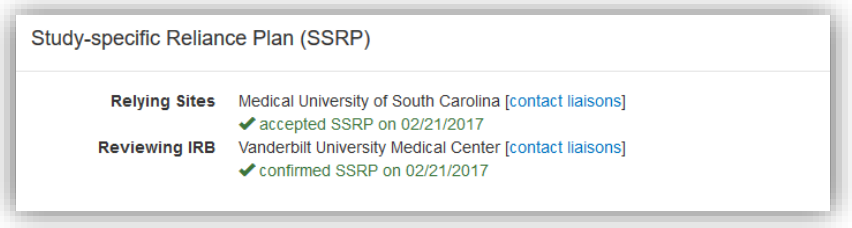
The Reviewing IRB has the final say on the SSRP for each study. In order to rely on the Reviewing IRB, you and the Reviewing IRB must agree on an SSRP. You can request changes to the SSRP initially proposed by the Reviewing IRB. The Reviewing IRB can update the SSRP to reflect any changes requested after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

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

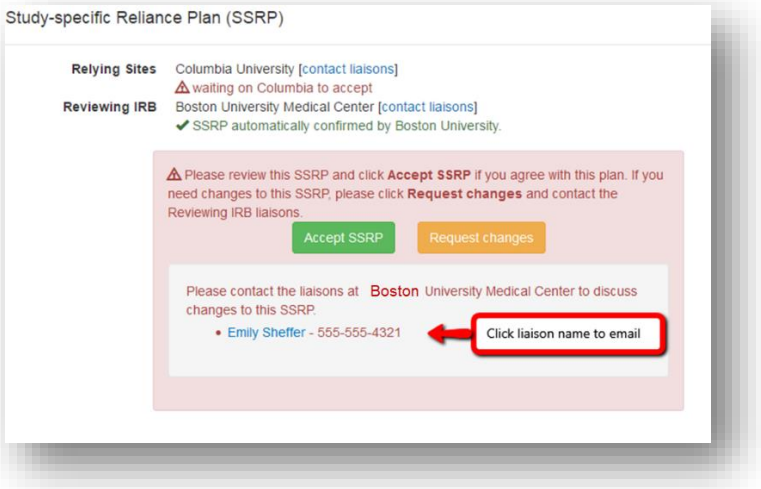
1) After you complete the required information for your site review (see above), the SSRP window will pop up showing the Reviewing IRB proposed Study-Specific Reliance Plan for your site. Review the SSRP and determine whether you wish to "accept" or "request changes".



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.

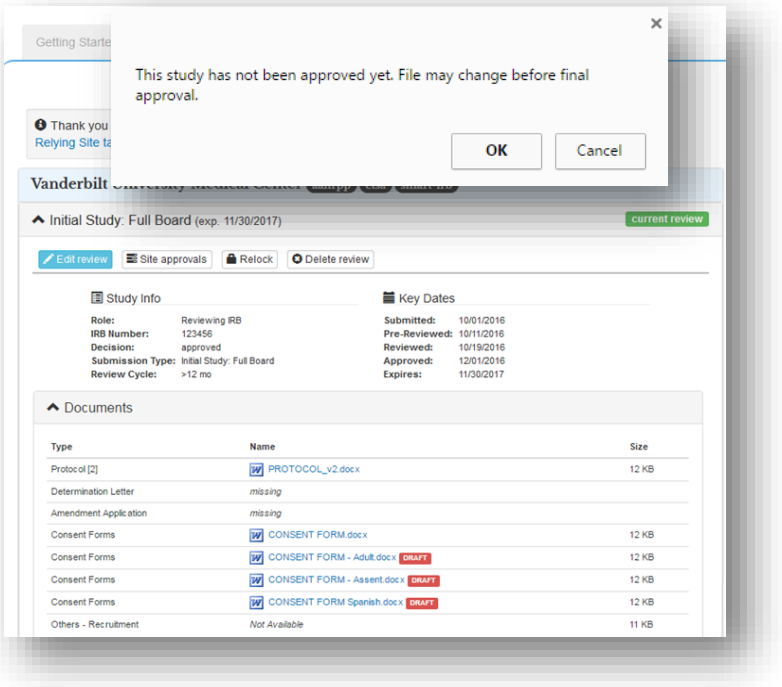


4) If the Reviewing IRB agrees to make the changes you have discussed, you will receive an email notification when the Reviewing has modified the SSRP for your site. In addition, you will see a red notification message on the project page alerting you to accept the Reviewing IRB's SSRP.

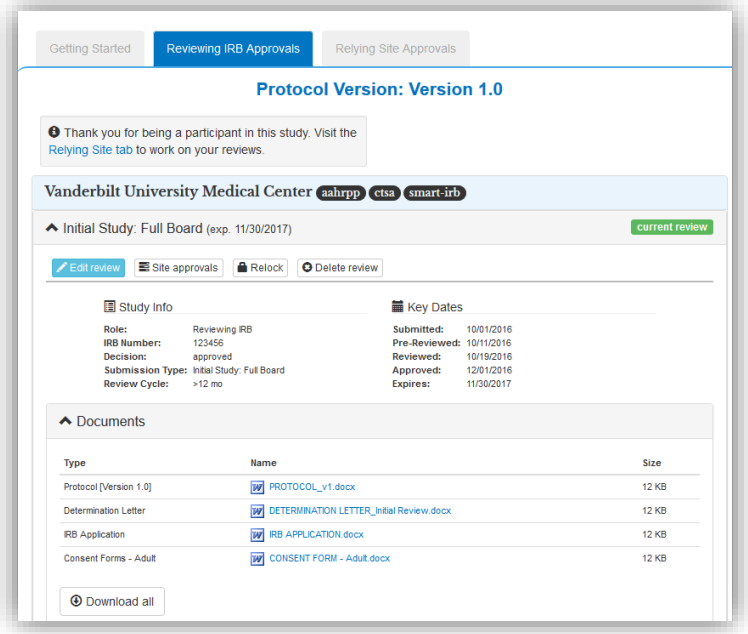
5) Once you accept the SSRP, your site name will appear under "Relying Sites" in the Versions box on the left of the project page.

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.



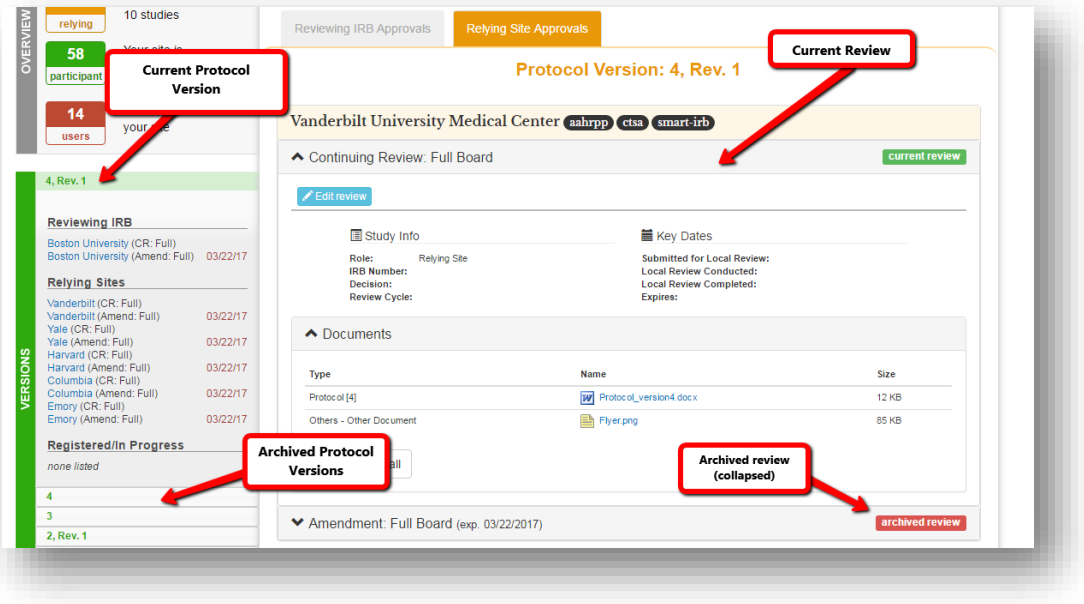
After their initial study approval, you can view and download the Reviewing's IRB approved documents on the same tab.



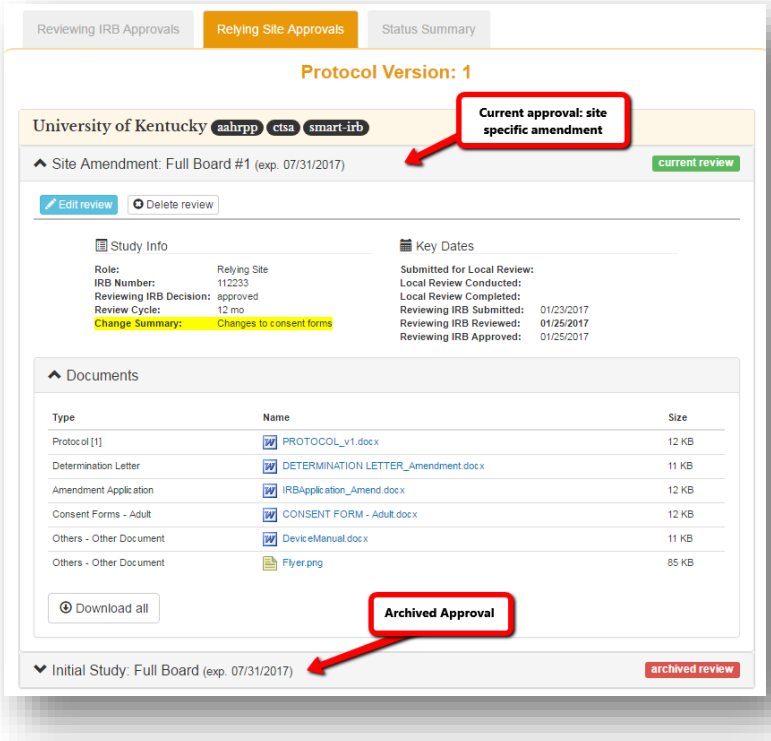
4. VIEW APPROVAL DOCUMENTS FOR YOUR SITE

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.



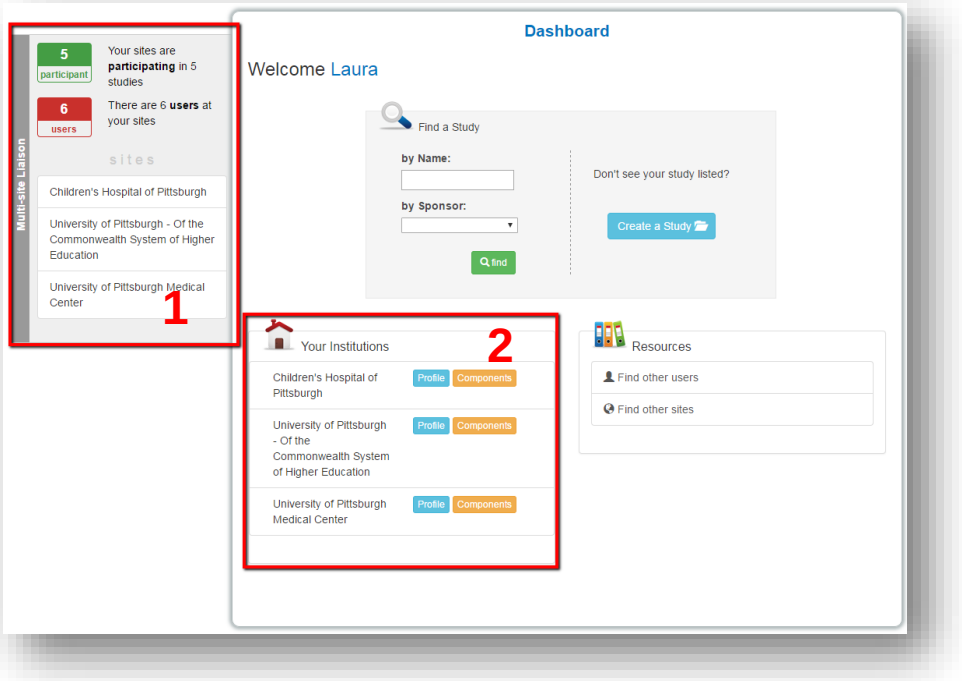
Example 2: This screenshot displays two review approvals: an initial review approval (collapsed from view) and a site-specific amendment approval. Site-specific amendment approvals are amendments/revisions specific to one site. Site-specific amendment approvals are auto-numbered and can only be added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

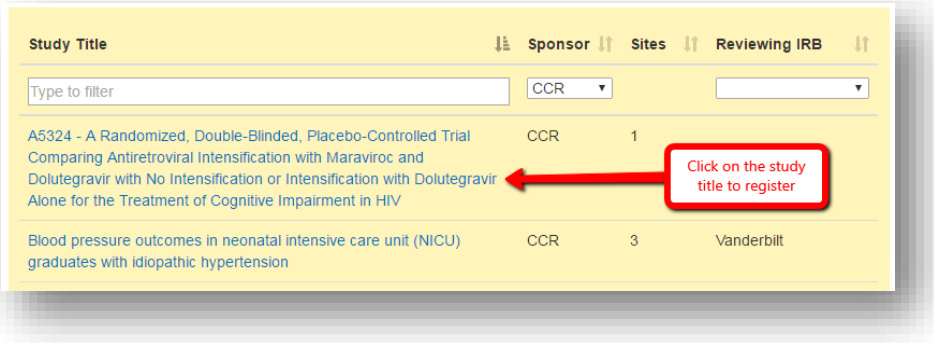


1 Use the **Overview** box located on the left side of the screen, for quick access to a list of all the studies which your FWA institutions are taking part in.

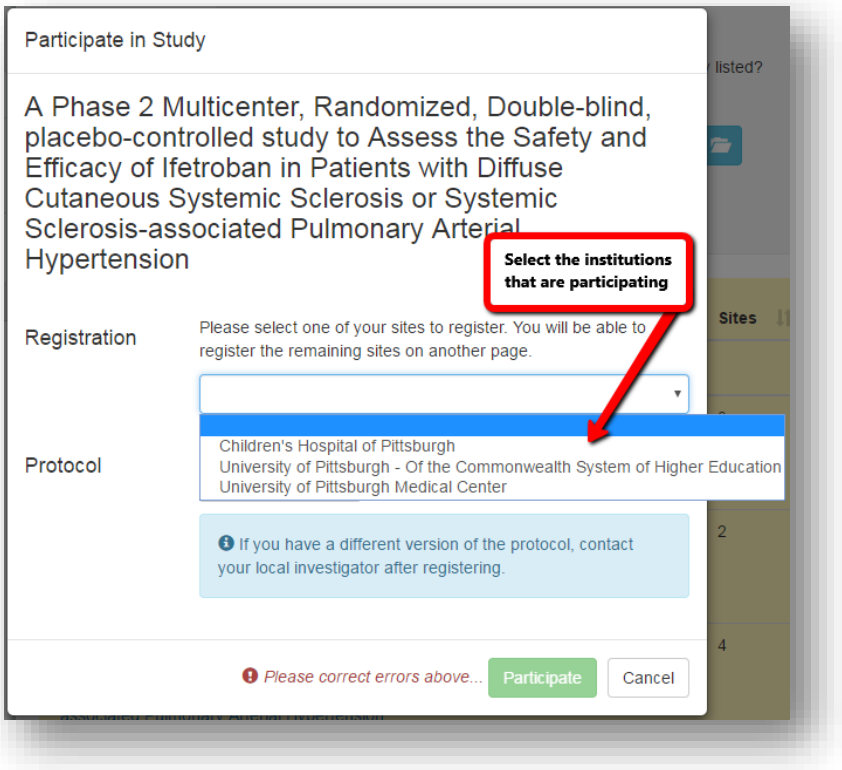
2 A list of all sites you are affiliated with is found under **Your Institutions.** Click on **Profile** to view and edit an institutional profile and **Components** to manage all components on anr institution's FWA. More information about how to do this is in **The Institutional Profile** (Section D).

5.2. REGISTERING TO PARTICIPATE IN A STUDY

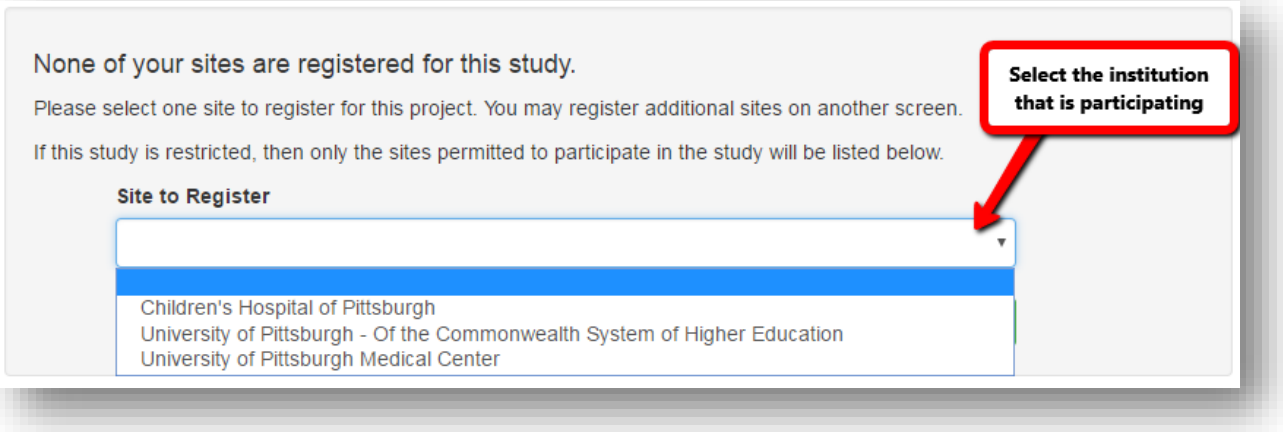
1.) To register, search for the study and click on the title in the search results.



2.) The "Participate in Study" window will pop up. Choose which of your FWA institutions is participating in the study. If more that 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.



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.

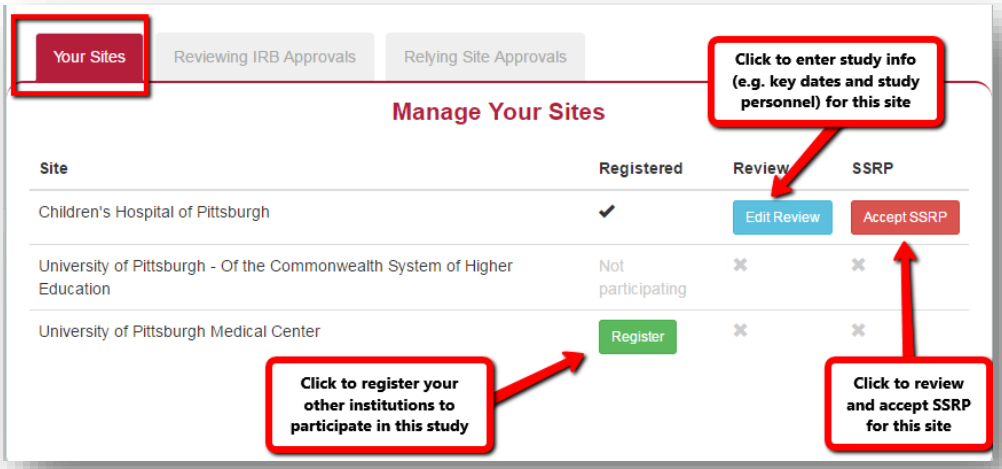


5.3. MANAGING YOUR SITES

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.

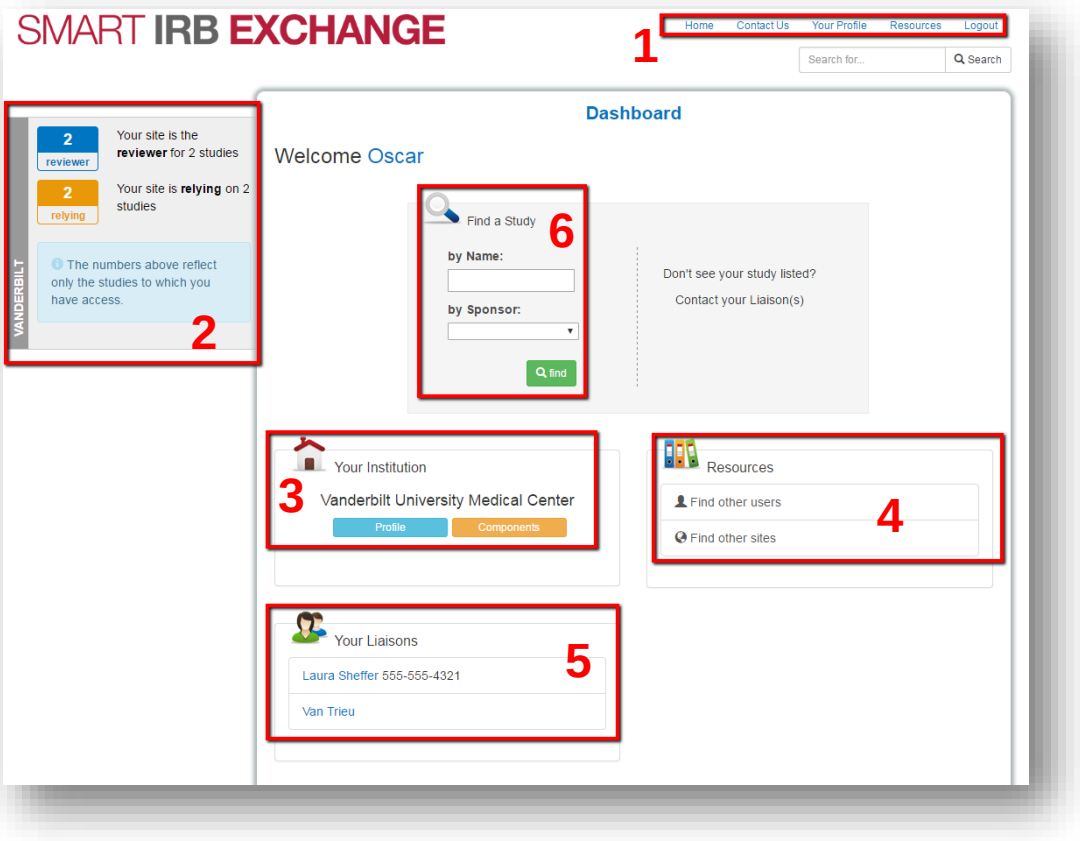
NOTE: Institutions that are not participating in for a given study are greyed out



SECTION G: USING THE SMART IRB EXCHANGE AS A STUDY TEAM MEMBER

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

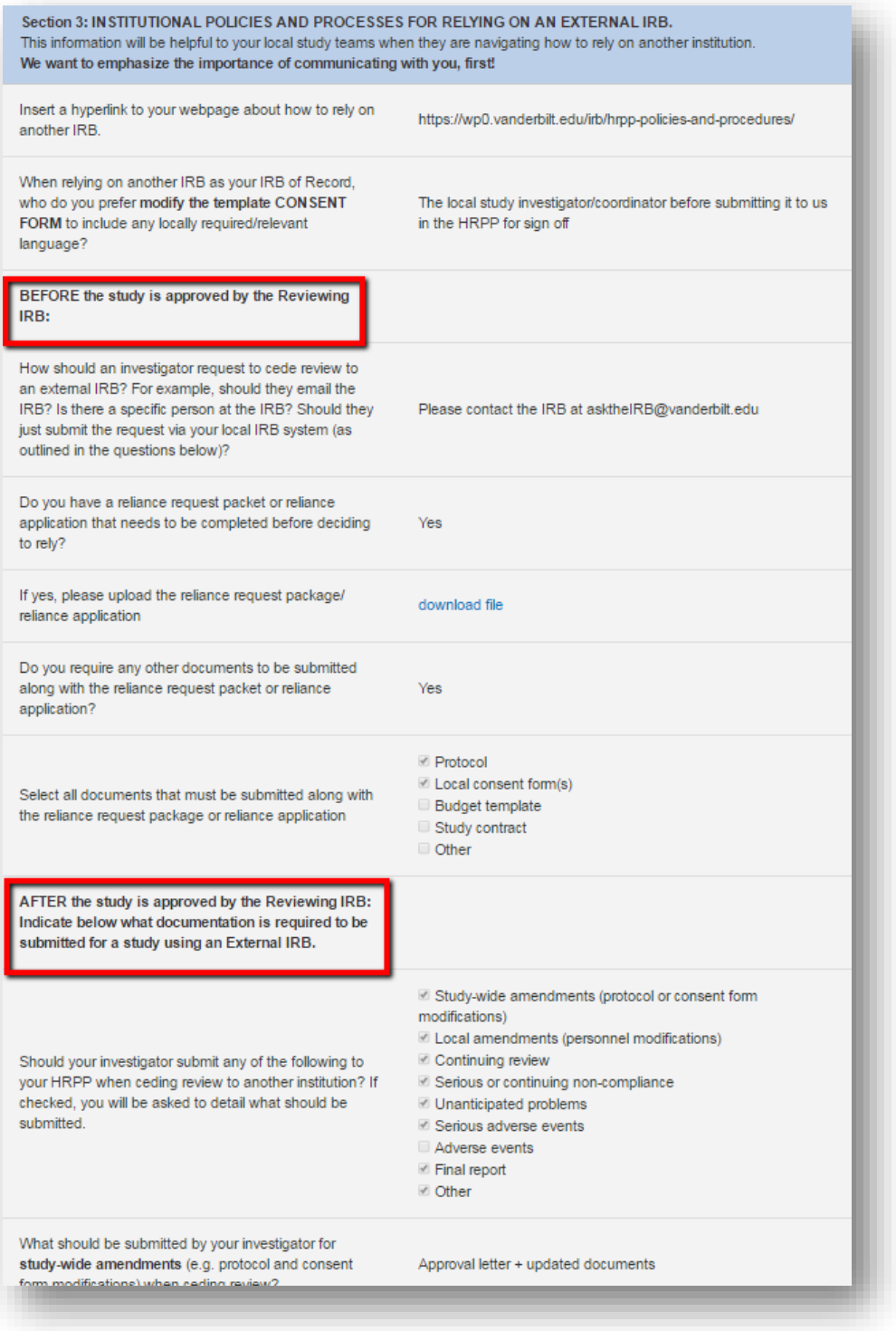
2.1. LEARN ABOUT YOUR LOCAL CONTEXT

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?	☑ By judicial petition with age limitations ☑ By judicial petition ☑ By married ☐ By joining the armed forces ☐ Temporarily while in policy custody to consent to medical treatment ☐ After giving birth ☑ 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.	☑ Cancer ☑ Hepatitis A ☑ Hepatitis B ☑ Hepatitis C ☑ HIV ☑ All communicable disease ☐ 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 processed 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.

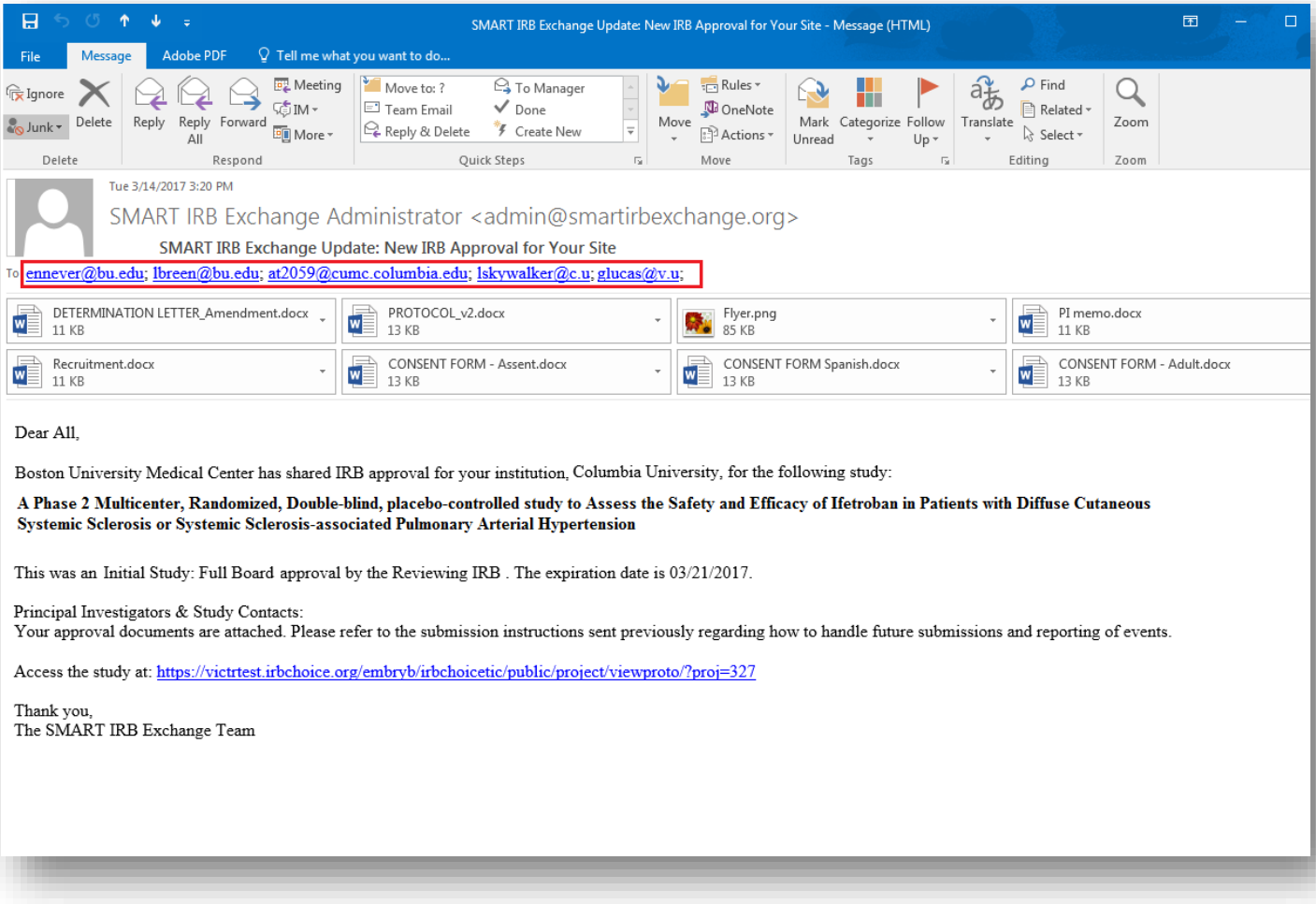


Section 3: INSTITUTIONAL POLICIES AND PROCESSES FOR RELYING ON AN EXTERNAL IRB. This information will be helpful to your local study teams when they are navigating how to rely on another institution. **We want to emphasize the importance of communicating with you, first!**	
Insert a hyperlink to your 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 askthelRB@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	☑ Protocol ☑ Local consent form(s) ☐ Budget template ☐ Study contract ☐ 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.	☑ Study-wide amendments (protocol or consent form modifications) ☑ Local amendments (personnel modifications) ☑ Continuing review ☑ Serious or continuing non-compliance ☑ Unanticipated problems ☑ Serious adverse events ☐ Adverse events ☑ Final report ☑ 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

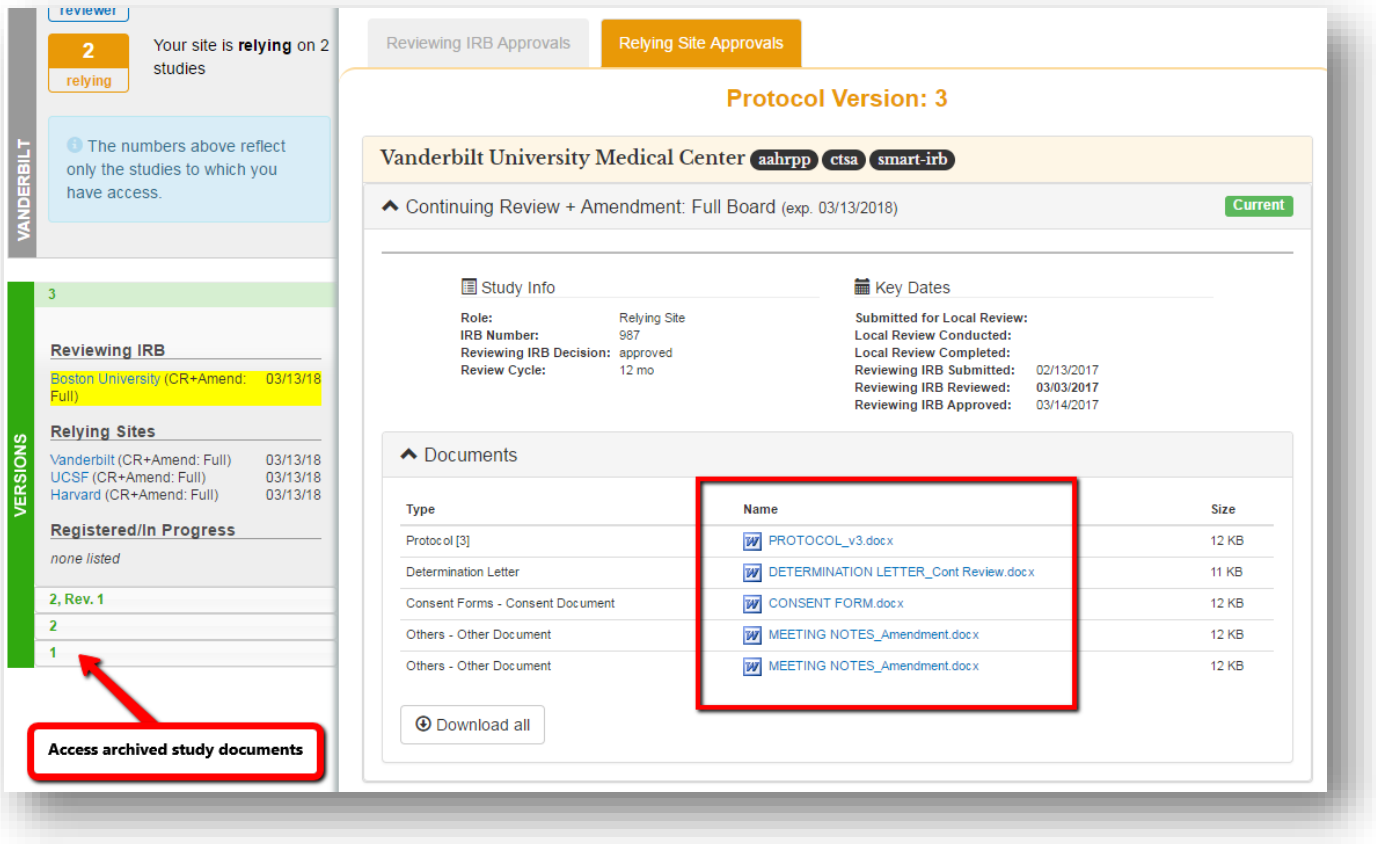
3.1. EMAIL NOTIFIICATIONS

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)



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.



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.