IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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1.0 INTRODUCTION FOR HRPP/ IRBS

IREx is a freely available web-based portal supporting single IRB documentation & coordination:

Basic Reliance Documentation	Advanced Reliance Documentation	sIRB Coordination
•sIRB agreement completion •Study-specific reliance decisions	•Study-specific local considerations from sites •sIRB approval documents for sites	•Communicating with sites •Tracking site readiness for sIRB review •Faciliating site submissions to the sIRB •Disseminating approvals to sites

IREX IS USED BY MANY STAKEHOLDERS

Single IRBs	Lead Study Teams & Coordinating Centers	Participating Site HRPPs/IRBs	Participating Site Study Teams
capture information from site HRPPs & study teams	track site progress towards sIRB review & approval	document reliance & local considerations	communicate with the sIRB & retrieve sIRB approvals

STANDARDIZE THE RELIANCE PROCESS ACROSS SIRBS

Using IREx promotes a standardized single IRB review process for capturing reliance documentation and facilitating communication between the sIRB, study teams, and relying HRPPs, while allowing sIRBs to delegate sIRB coordination responsibilities to the Lead Study Team or Coordinating Center on a study-by-study basis.

HARMONIZE SIRB DATA COLLECTION

sIRBs can use IREx to capture local considerations from sites. This creates consistency in (a) the data collected by sIRBs and (b) provided from sites. Two types of data are collected in IREx:

The Institutional Profile (IP): All sites complete an IP upon joining IREx. The IP captures (1) general FWA/IRB information; (2) overarching local and state laws/policies affecting all research; (3) processes and requirements *when relying on an sIRB*; and (4) preferences for handling the flexible elements of reliance when *serving as the sIRB*. Tip: The IP is completed once and can be updated as the information changes.

Study-specific Local Considerations: On a study-by-study basis, participating sites must document local considerations for the sIRB. IREx can be used to capture this information, which includes consent form language and applicable state or local laws, regulations, institutional policies, standards, or other local factors, including ancillary reviews, that would affect the conduct or approval of the study at an institution.

FACILIATE SIRB COORDINATION WITH PARTICIPATING SITES

sIRB review requires additional coordination to ensure all reliance documentation is captured from sites. IREx provides dashboards and tracking mechanisms the Lead Study Teams and Coordinating Centers ("Study Managers") use to (1) communicate with sites; (2) track site readiness for sIRB review; (3) capture information for submission to the sIRB, and (4) disseminate site approvals.

SYSTEMATIZE THE COLLECTION OF SIRB METRICS

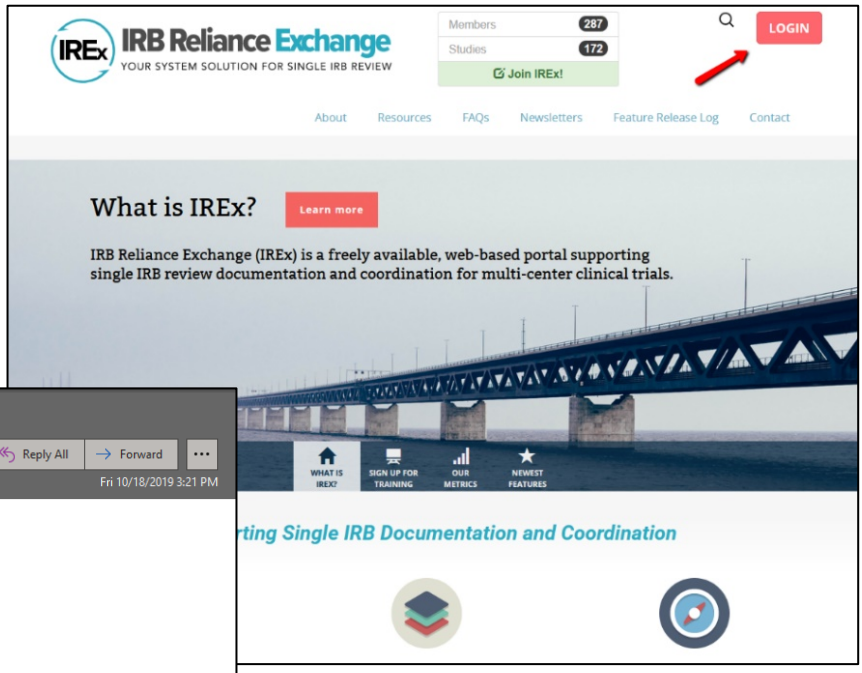
IREx captures time to approval metrics for the Lead and Relying Sites in the hopes of evaluating the success of existing national policies and informing future policy decisions. Data are captured on a site-by-site and study-by-study basis so bottlenecks can be identified and resolved.

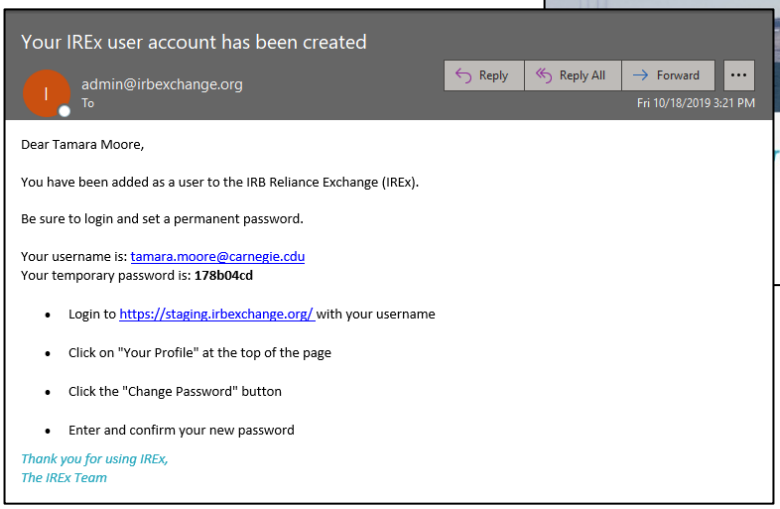
1.1 ACCESS THE IRB RELIANCE EXCHANGE (IREX)

The IREx website can be accessed at www.irbexchange.org.

Click the **LOGIN** button in the top right-hand corner of the web page, enter your email address and your password to log in.

The FIRST TIME you log in, you will need to use the temporary password emailed to you from IREx.



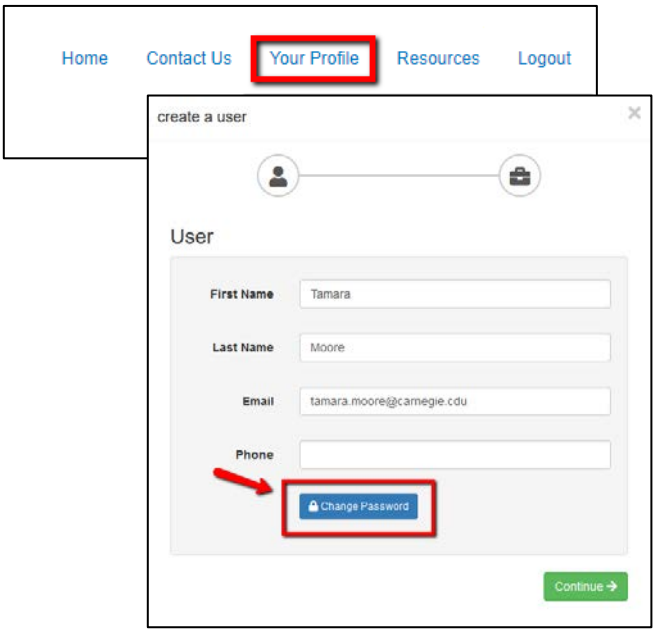


Tip: Use the email address where you received the IREx notification as your login name.

1.2 CHANGE YOUR PASSWORD

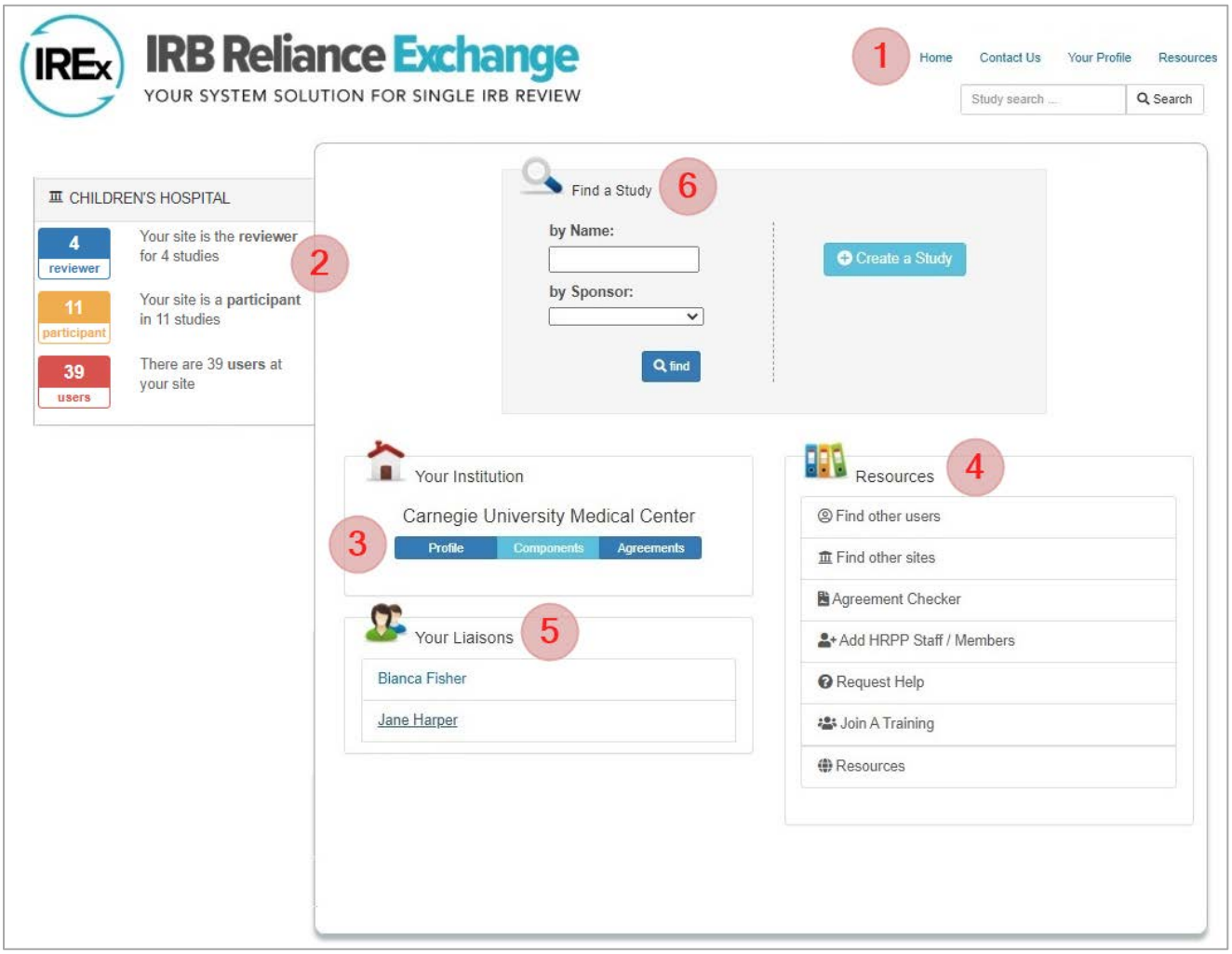
After you first log in to IREx, please change your password using **Your Profile** at the top of the dashboard.

Click **Change Password** to set a new password.



1.3 THE IRB/HRPP IREX HOMEPAGE

The IRB/HRPP IREx Homepage is tailored to your site's use of IREx.



1 Quick Links: these are visible from any page of IREx and provide quick access to edit Your Profile, Contact Us, view Resources, return to the Homepage and log out.

2 IRB Dashboards: Use these links for quick access to a list of all the studies where you are the Reviewer or Single IRB (sIRB) or a Participant – the Participating Site IRB Dashboard includes a column that lists the PI for each study so you can easily sort and find studies. You can also quickly access a list of all the individuals at your institution with access to IREx (HRPP/IRB staff + study team members).

3 Your Institution: Use these links to edit your Institutional Profile, list Components to your FWA, and track your institution's reliance agreements and indemnification agreements.

4 Resources: Use these links to Find other users or Find other sites. You can also Add HRPP Staff, Request Help, Join a Training, and access additional Resources.

5 Your Liaisons are listed on the dashboard, along with their phone number, if available. This list is also on the homepage of other users *at your institution.*

6 Use Find a Study to search for studies in IREx.

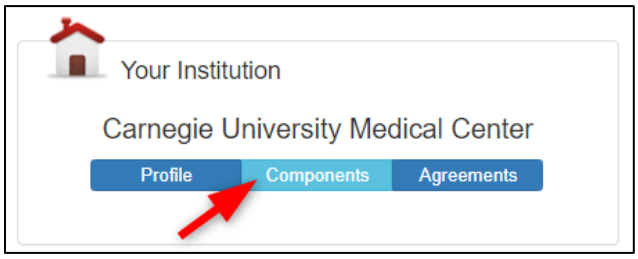
1.4 LISTING YOUR COMPONENT SITES

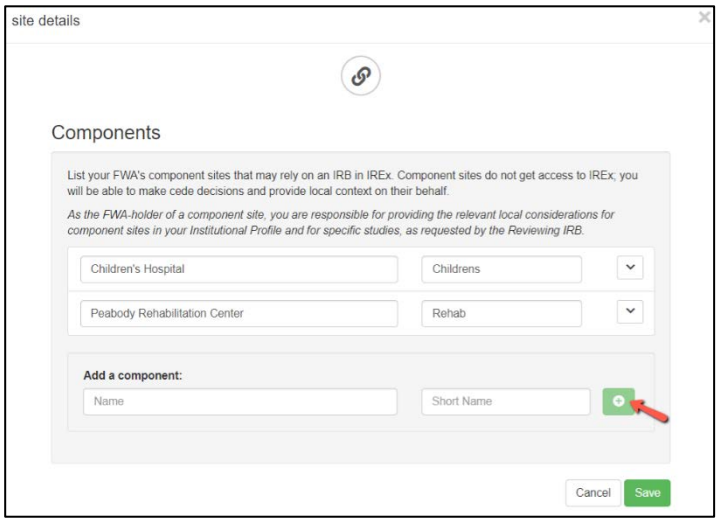
In IREx, FWA-holding entities have liaisons assigned and have an Institutional Profile. However, FWA sites can also add their component sites, as listed on the OHRP website, to IREx if they (1) are more commonly known as the name of one of their components and/or (2) wish to more specifically delineate where research is happening for a particular study. Providing component sites can also be helpful if you have more than one study team participating in a study independent from one another.

When component sites are part of studies, they are listed along with the name of the main FWA holder. For example, [FWA Holder "Short Name"] – [Component Site Name]

To list component sites in IREx:

1. Login to IREx and click the blue **Components** button on the homepage.
2. Enter the full name of the component, as well as a short name.
3. Click the **green plus +** button and **Save**.





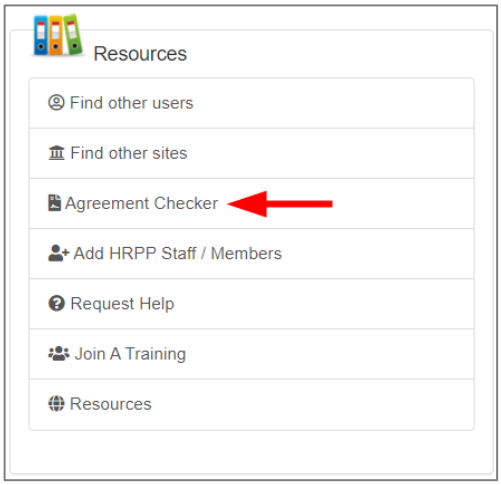
1.5 TRACKING RELIANCE AGREEMENTS

IREx can be used to support the use of any reliance agreement on a study. While we strongly encourage use of the SMART IRB Agreement v1 and v2, IREx can also be used with Other Reliance Agreements (e.g., IAAs), for sites that are unable to join SMART IRB. In fact, the Reviewing IRB can offer multiple agreements on the same study. IREx can also be used to track whether sites have executed a Letter of Indemnification.

If multiple reliance agreements are offered:

- SMART IRB is the default, if signed. The SMART IRB status for sites will be updated in IREx based on the SMART IRB website Participating Institution list. If SMART IRB and an Other Reliance Agreement (ORA) are offered on the same study, sites in SMART IRB will default to that agreement for the study.
- If the reliance involves the NIH Intramural Research Program, both the Reviewing IRB and Relying Institutions will be required to use SMART version 2.
- Joining SMART IRB does not override prior studies where a Relying Institution used an ORA.

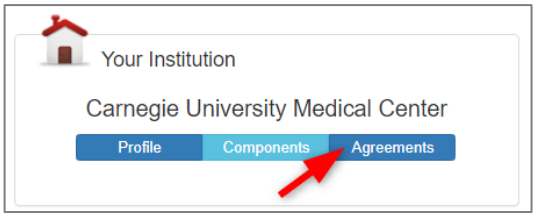
Tip: Before a study is created, use the **Agreement Checker** to see what reliance agreements have been signed by potential participating sites. The Agreement Checker also reflects whether sites have executed a broad indemnification agreement with the selected single IRB. Study-specific agreements are not reflected in the Agreement Checker since execution of those agreements cannot count towards other studies.



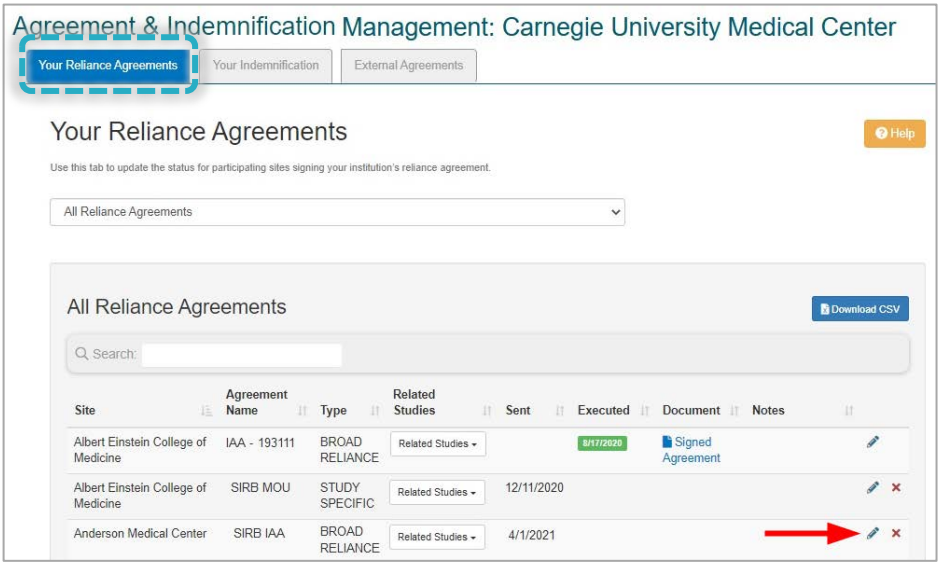
Tracking sites that have signed your institution's Reliance Agreement(s):

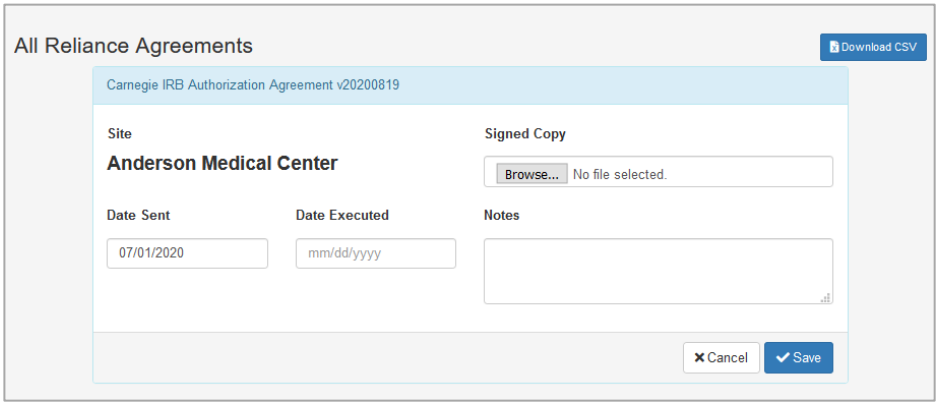
New institutional agreements are added in the IREx setup when creating a study. You can also edit the IREx Setup of an existing study to add an agreement. For **existing** agreements, the Reviewing IRB indicates when sites have executed their institutional agreements.

1. Click the blue **Agreements** button on the homepage.
2. On the **Your Reliance Agreements** tab, select the desired site and reliance agreement. Note: If a site is not listed, go to the study where they will be using the agreement and make sure they are listed as a Participating Site on the Status Summary. Then, press **+Agreement** to indicate they will be using your institutional agreement.



3. Click the **pencil icon** to update the information.
4. Enter the dates when the agreement was sent to the site (optional) and when it was executed.
5. Under **Signed Copy**, upload a copy of the executed reliance agreement, if desired.
6. Click **Save** to save the information for the site.



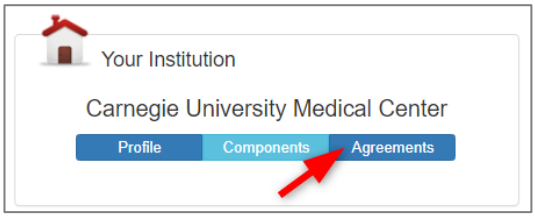


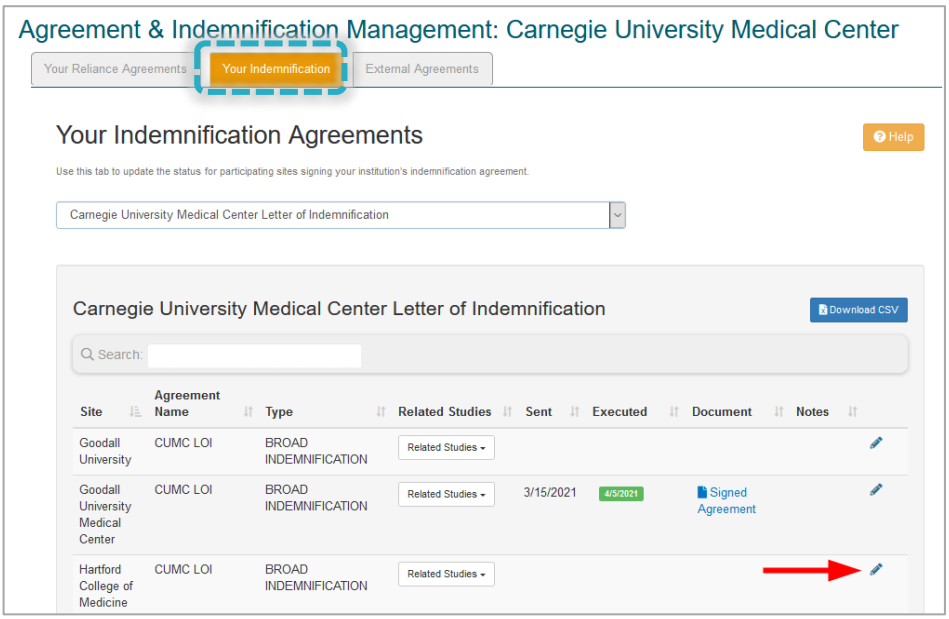
1.6 TRACKING YOUR INDEMINIFICATION

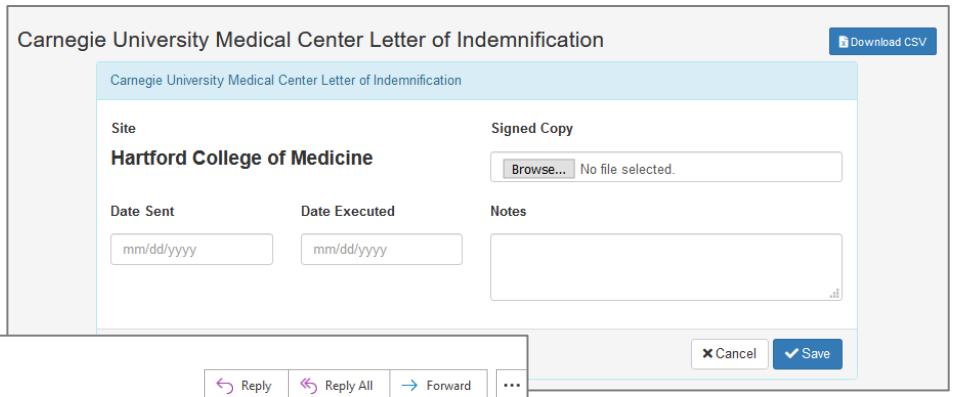
Some institutions require an indemnification agreement when serving as the Reviewing IRB using the SMART IRB Agreement, which is silent on indemnification (see section 4.11 of the SMART IRB Agreement). IREx allows Reviewing IRBs to track institutions from which they require an indemnification agreement. This can be a unique agreement between the Reviewing IRB and another institution; however, only one executed indemnification agreement can be tracked per institution on a study.

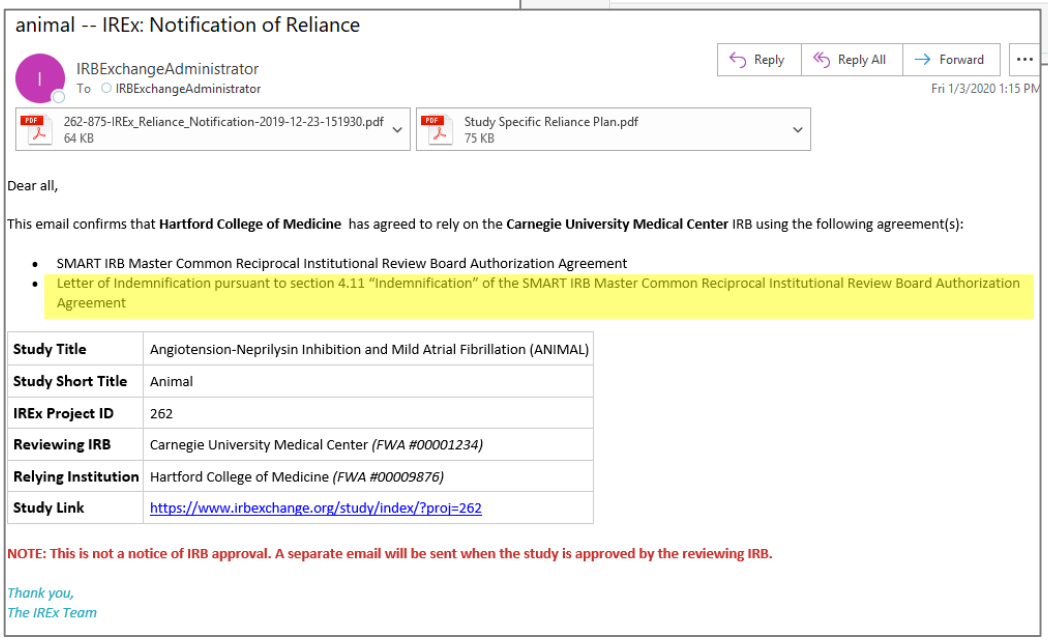
Tracking sites that have signed your Indemnification Agreement:

1. Click the blue **Agreements** button on the homepage.
2. On the **Your Indemnification** tab, select the desired site and reliance agreement. Note: If a site is not listed, go to the study where they will be using the agreement and make sure they are listed as a Participating Site on the Status Summary. Then, press **+Agreement** to indicate they will be using your institutional agreement.
3. Click the **pencil icon** to update the information.
4. Enter the dates when the agreement was sent to the site (optional) and when it was executed.
5. Under **Signed Copy**, upload a copy of the executed reliance agreement, if desired.
6. Click **Save** to save the information for site.









animal -- IREx: Notification of Reliance

IRBExchangeAdministrator
To IRBExchangeAdministrator

Reply | Reply All | Forward

Fri 1/3/2020 1:15 PM

262-875-IREx_Reliance_Notification-2019-12-23-151930.pdf 64 KB

Study Specific Reliance Plan.pdf 75 KB

Dear all,

This email confirms that **Hartford College of Medicine** has agreed to rely on the **Carnegie University Medical Center** IRB using the following agreement(s):

- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement
- Letter of Indemnification pursuant to section 4.11 "Indemnification" of the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement

Study Title	Angiotension-Neprilysin Inhibition and Mild Atrial Fibrillation (ANIMAL)
Study Short Title	Animal
IREx Project ID	262
Reviewing IRB	Carnegie University Medical Center *(FWA #00001234)*
Relying Institution	Hartford College of Medicine *(FWA #00009876)*
Study Link	https://www.irbexchange.org/study/index/?proj=262

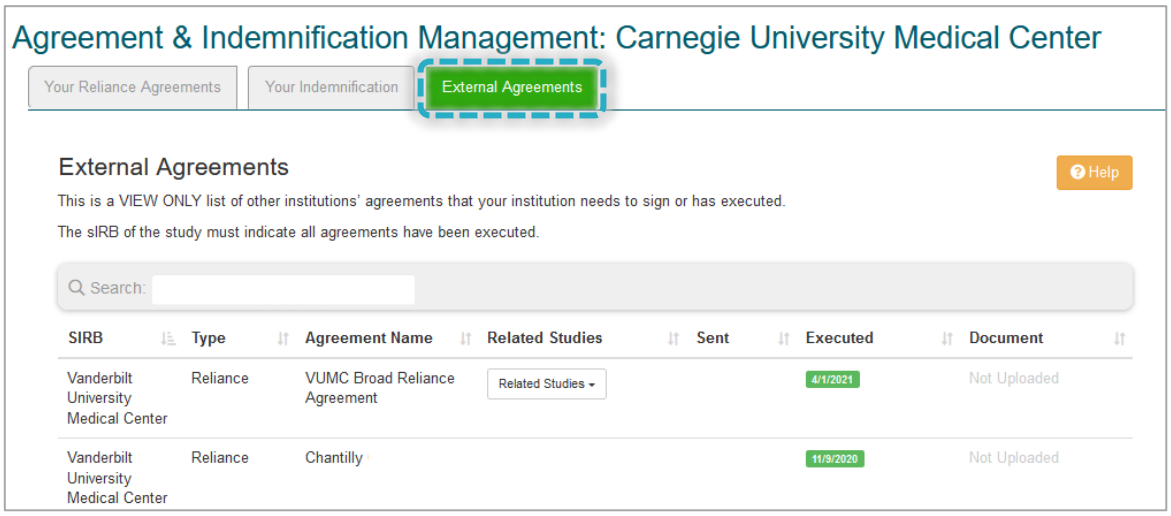
NOTE: This is not a notice of IRB approval. A separate email will be sent when the study is approved by the reviewing IRB.

Thank you,
The IREx Team

Tip: The indemnification agreement name will be referenced on the official Notification of Reliance letter when a site indicates reliance. See highlighted text.

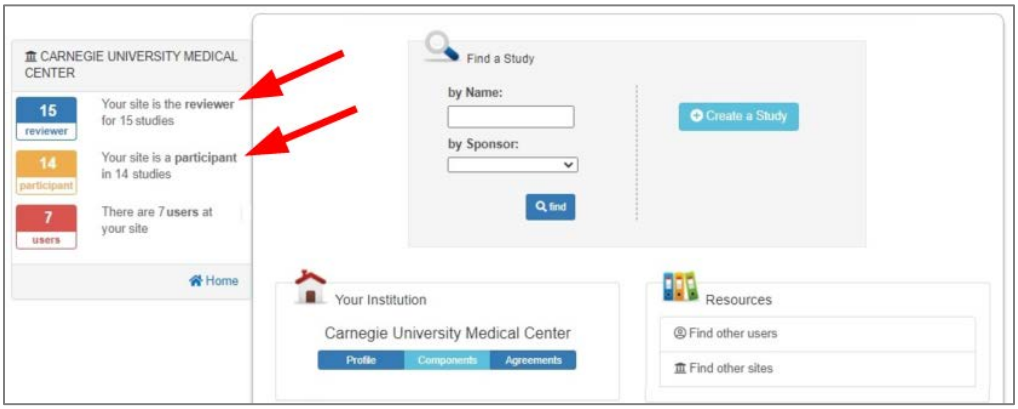
1.7 TRACKING EXTERNAL AGREEMENTS

Tracking which Reviewing IRBs have asked your institution to sign a reliance agreement:
You can see what agreements you have signed for other institutions on the **External Agreements** tab. The **SIRB, Agreement Type, Agreement Name, Related Studies, Date Sent,** and **Date Executed** will be shown if it has been logged in IREx by the Reviewing IRB. This page is View Only.



1.8 TRACKING YOUR STUDIES IN IREX

IREx offers two HRPP dashboards to help HRPPs/IRBs track the studies where (1) they are the reviewing IRB/sIRB and (2) when they are relying on an external IRB. You can access these dashboards from the left side of the screen on the homepage.

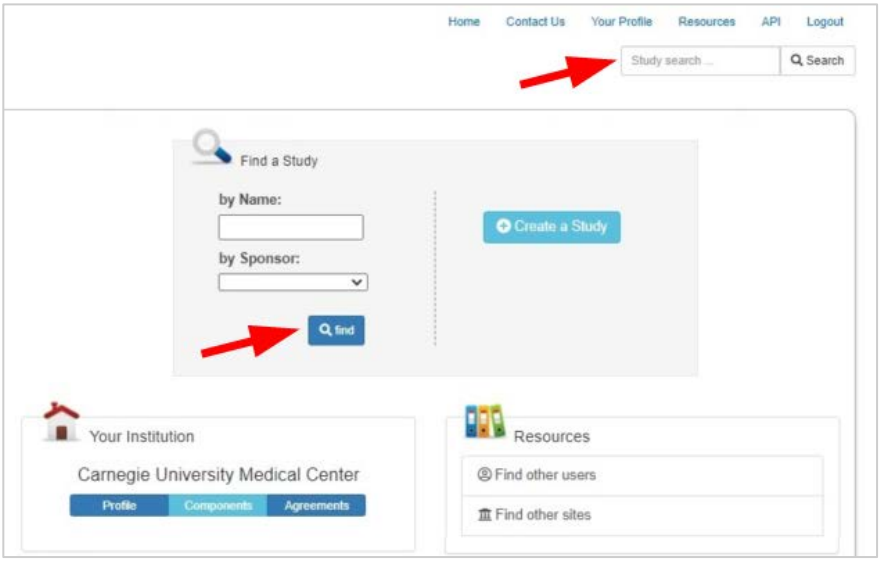


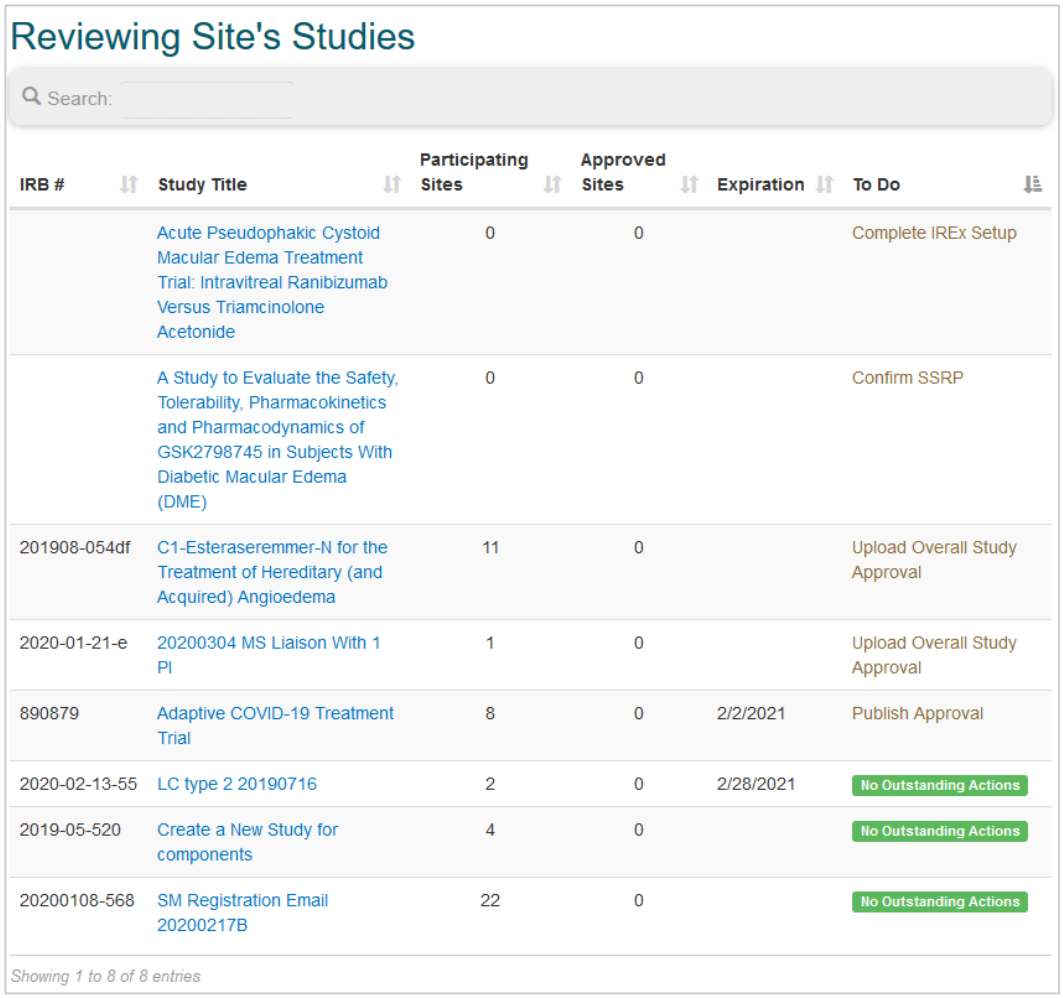
The Reviewing IRB Dashboard includes information about the IRB number, study title, number of participating sites, number of approved sites, expiration date, and sIRB's next step, if any.

1.9 FIND A STUDY

To find a study in IREx, use the Find a Study search at the top of the homepage. Search for specific studies by entering a *full* or *partial name* of the study, or by selecting *a sponsor*.

Tip: You can view the entire IREx database of studies by leaving the name and sponsor fields blank and clicking **find**.





Reviewing Site's Studies

Search:

IRB #	Study Title	Participating Sites	Approved Sites	Expiration	To Do
	Acute Pseudophakic Cystoid Macular Edema Treatment Trial: Intravitreal Ranibizumab Versus Triamcinolone Acetonide	0	0		Complete IREx Setup
	A Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of GSK2798745 in Subjects With Diabetic Macular Edema (DME)	0	0		Confirm SSRP
201908-054df	C1-Esteraseremmer-N for the Treatment of Hereditary (and Acquired) Angioedema	11	0		Upload Overall Study Approval
2020-01-21-e	20200304 MS Liaison With 1 PI	1	0		Upload Overall Study Approval
890879	Adaptive COVID-19 Treatment Trial	8	0	2/2/2021	Publish Approval
2020-02-13-55	LC type 2 20190716	2	0	2/28/2021	No Outstanding Actions
2019-05-520	Create a New Study for components	4	0		No Outstanding Actions
20200108-568	SM Registration Email 20200217B	22	0		No Outstanding Actions

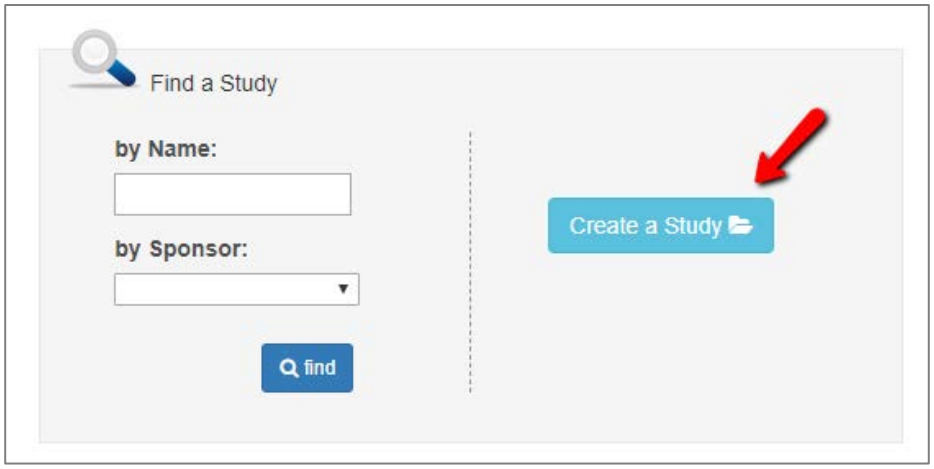
Showing 1 to 8 of 8 entries

2.0 CREATING A STUDY IN IREX

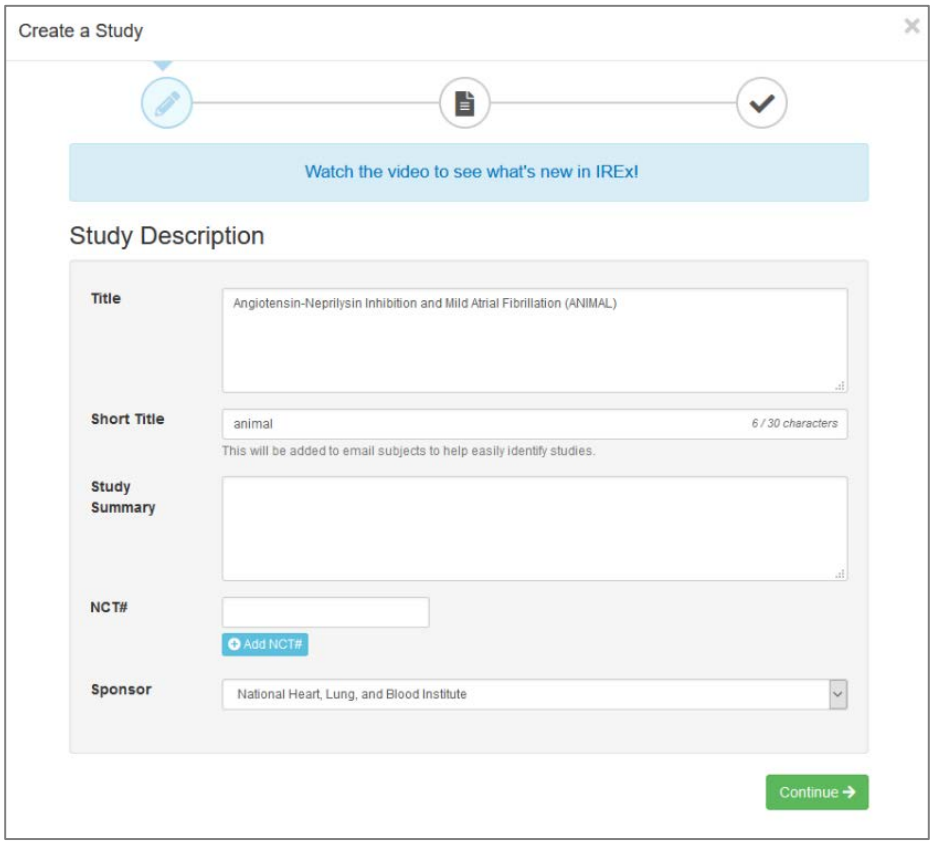
Only IREx Liaisons can create studies in IREx. Prior to creating a study, we recommend the following:

- ☐ **Agree** to serve as the sIRB for the study.
- ☐ **Complete** / update your Institutional Profile in IREx.
- ☐ **Educate** the IREx Study Manager (i.e., lead study team coordinator and/or coordinating center staff) on the sIRB process (e.g., what agreements are required; how local considerations are collected from participating sites; what consent template should be used; and how sites submit to the sIRB).
- ☐ **Prepare** instructions for Sites to be disseminated by the Study Manager. Visit the IREx Resources page for Reviewing IRBs for sample communications (see Template Reliance Instructions). https://www.irbexchange.org/p/resources/reviewingirb/

To Create a Study:

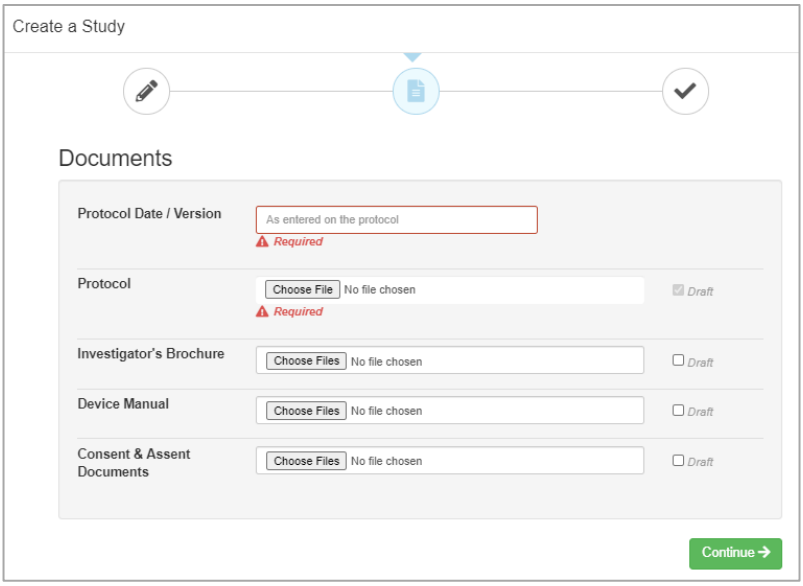


1. Click on the **Create a Study** button on the Dashboard.

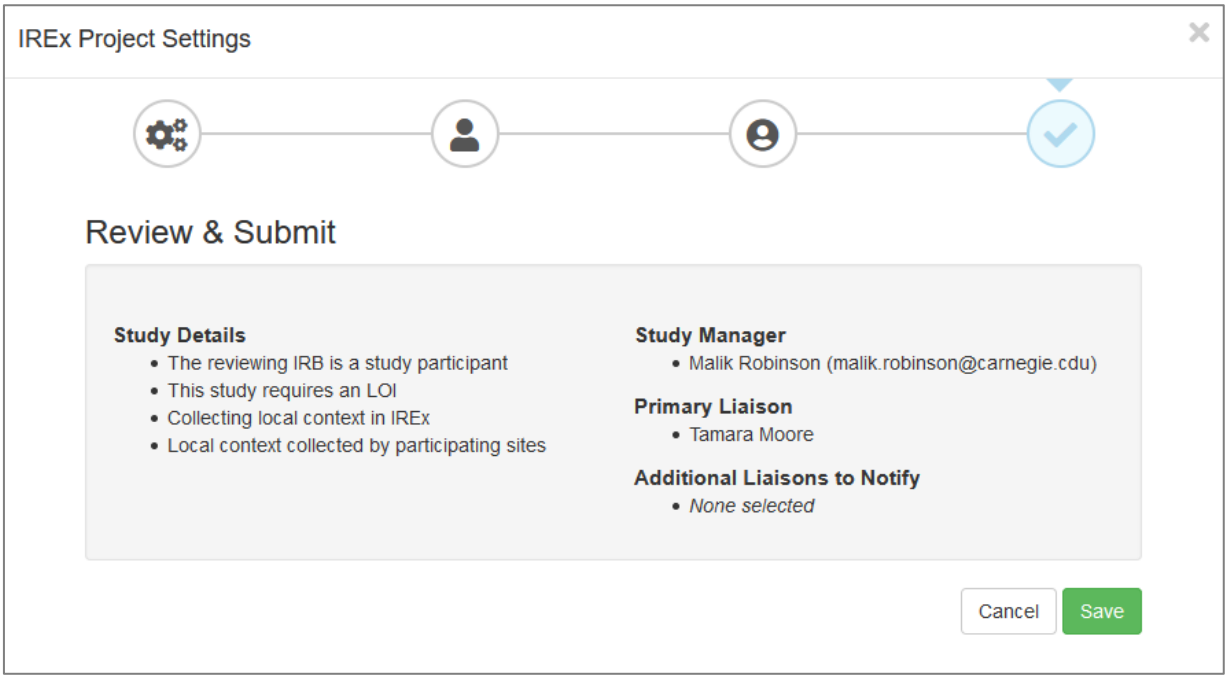


2. **Study Description:** Enter basic information about the study:
   a. *Title of study*
   b. *Short Title* (optional)
   c. *Summary* (optional)
   d. *National Clinical Trials Number(s)* (NCT #) (optional)
   e. *Sponsor*

3. **Documents:** Enter the following information and upload basic study documents:
   a. *Protocol Date and/or Version* (e.g., MM/DD/YYYY)
   b. *Protocol draft or executive summary of study*
      Tip: The protocol is automatically marked "draft" until the approval is uploaded in a future step.
   c. Other documents like the *Investigator's Brochure, Device Manual*, and *Consents* are optional at this point.



4. **Review and Submit:** Verify the information entered by clicking **Save**.

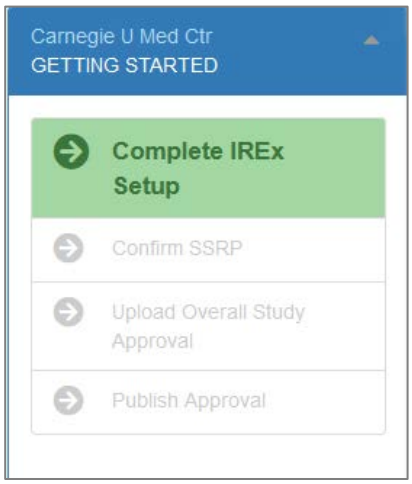


After creating the study in IREx, you will be redirected to the study page. Use the screenshot and corresponding text below to help navigate the page. **Continue to section 2.1 to finish setting up your newly created study.**

2.1 NAVIGATING THE STUDY PAGE

1. The GETTING STARTED Checklist helps track your tasks in IREx.
2. General Study & Contact Information is located just above the title and includes a Study Summary, NCT #, Risk Type, and Sponsor, as well as contacts for the Reviewing IRB, Study Manager and Participating Site Personnel that have access to IREx.
3. Study Tabs:
   a. Study-wide IRB Approvals contains the approvals for the Lead Site, separate from approvals for Sites. Here all users with access to the study can view the status of the approval, key dates & study documents for the Lead Site. *If the Lead Site is not YET approved*, the draft protocol and consent forms will be available for download for all Sites; however, they will be marked draft and a pop-up notes the documents are draft when the files are downloaded.
   b. Site-specific IRB Approvals shows the approval details and documents for Sites. Sites can only view documents for their own site, but sIRB and Study Managers can view all Sites' documents. Sites are listed in alphabetical order for the Reviewing IRB & Study Manager. However, when a Site views this tab, their site is listed at the top.
   c. Status Summary is used to track each Site's progress towards initial IRB approval, such as their agreement status, reliance decision, local considerations completion status, and their approval status. This tab is helpful for the Study Manager, if they are tracking site's readiness for sIRB review.

2.2 USING THE GETTING STARTED CHECKLIST

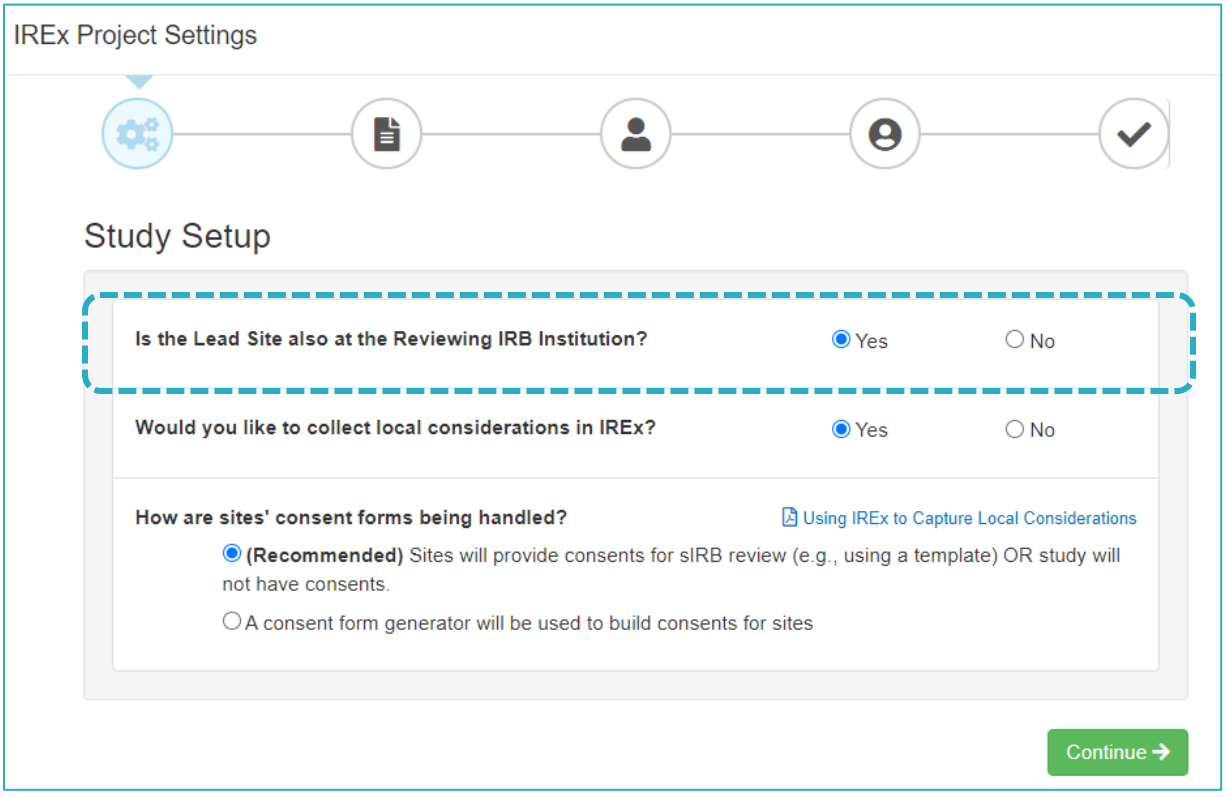


This is the GETTING STARTED Checklist, which outlines the steps the Reviewing IRB liaison must complete before the overall study approval is shared in IREx. The sections below describe what is required in each step.

2.2.1 COMPLETE IREX SETUP

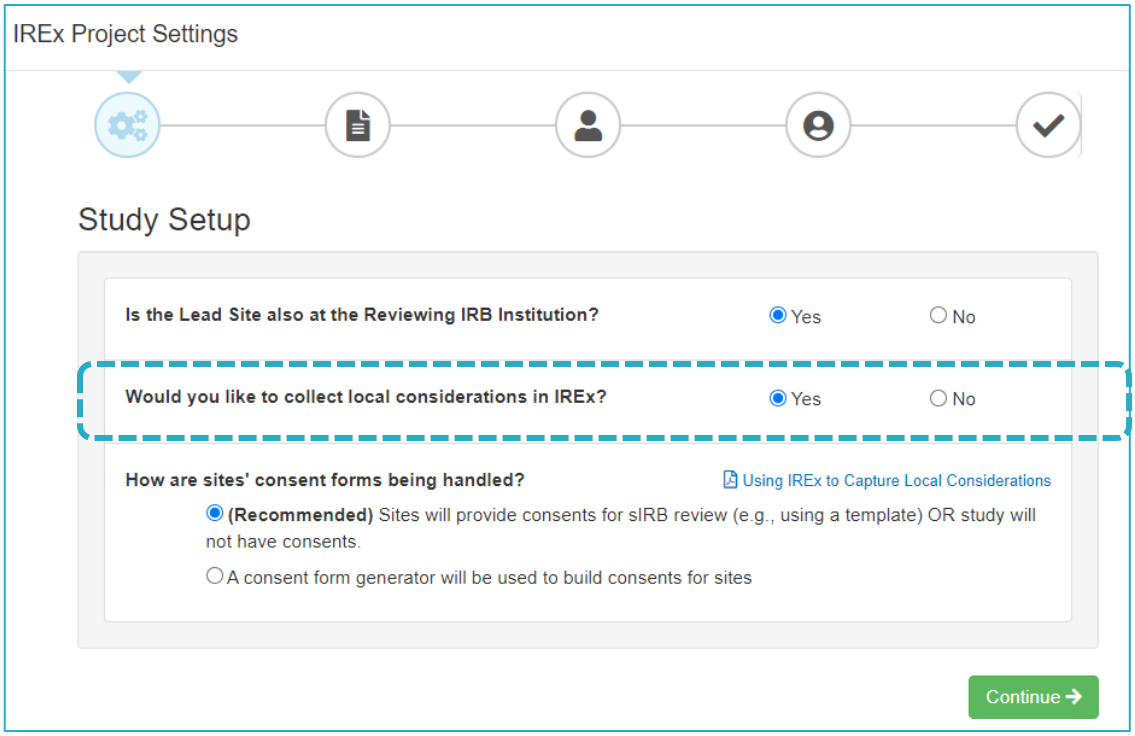
The first step in the GETTING STARTED checklist is **Complete IREx Setup** and it has four sections: Study Setup, Agreements, IREx Study Manager, and Reviewing IRB Primary Liaison(s).

1. Study Setup:
   a. Indicate whether the Lead Site is also at the Reviewing IRB Institution on the study.



If the Lead Site is not also at the Reviewing IRB Institution, the Lead Site can be identified using the drop-down.

b. Indicate whether local considerations are being captured in IREx.
We recommend collecting local considerations in IREx. If you do not, you are unable to track site completion in IREx and will need to communicate to sites on how to submit local considerations for review.



If you will collect local considerations in IREx, indicate how the consent forms for the sites are being handled:

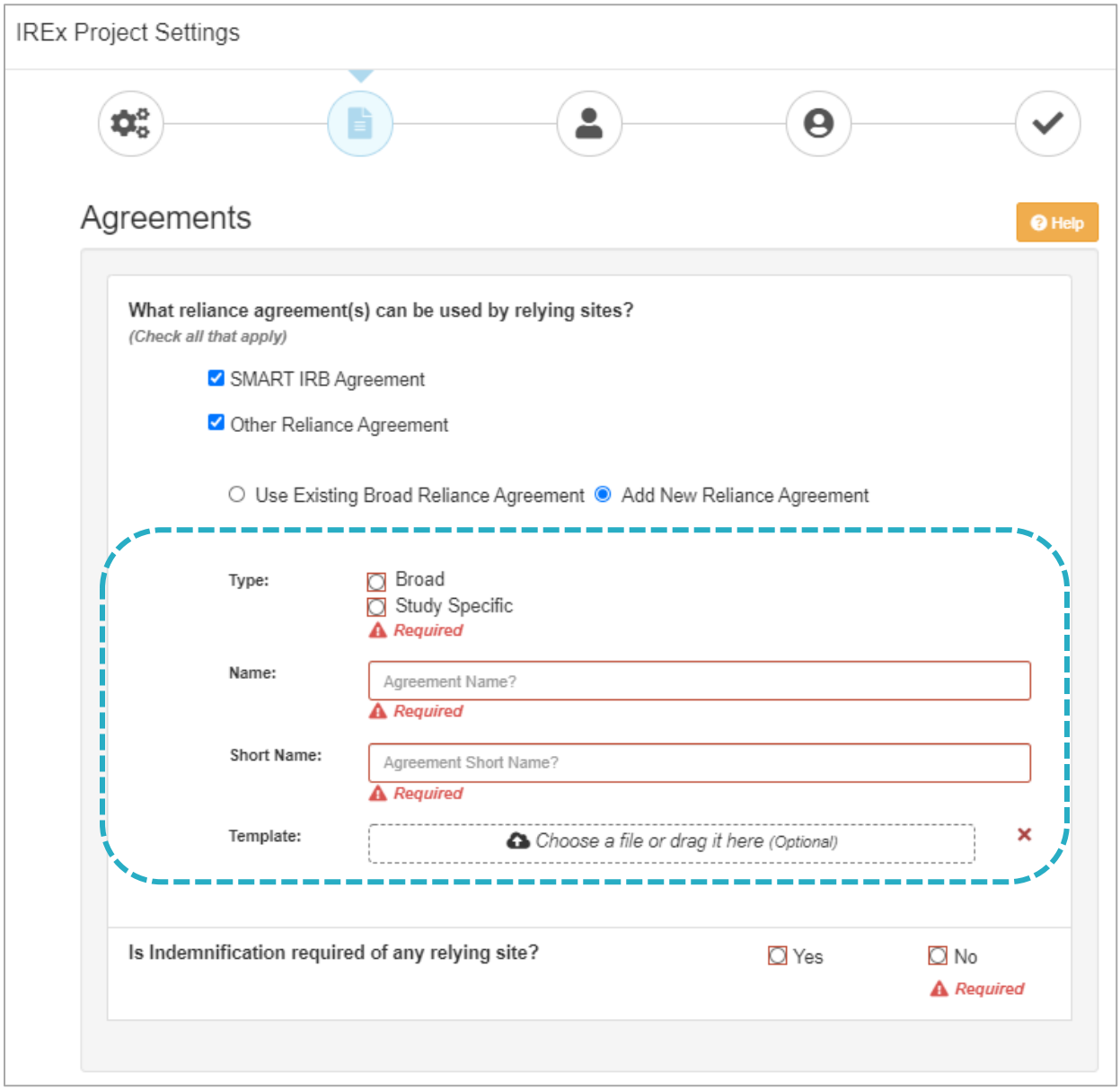
i. *(Recommended)* Select ***Sites will provide consents for sIRB*** review if sites are entering their required language directly into the consent form template. If this model is selected, study teams enter their required language directly into the consent document(s), which are provided to their HRPP for review, and the HRPP liaison uploads the verified documents into the local considerations survey in IREx.

ii. Select ***A consent form generator will be used to build consents for the sites*** if a central entity like the coordinating center or the sIRB will generate the consent forms for sites. If this model is selected, the HRPP liaison at each site will enter the locally required language into the local considerations survey in IREx, rather than directly into a consent form template.

2. Indicate what Agreements you will be using for this study.
   a. Indicate which reliance agreement(s) can be used by sites (you can offer multiple agreements, if needed).
      i. SMART IRB Agreement: A reciprocal reliance agreement that permits an institution to cede review of human subjects research to other Participating Institutions' IRBs. The Agreement sets forth the authorities, roles, and responsibilities of Participating Institutions and their IRBs when ceding or providing IRB review.
      Tip: Sites that have signed onto SMART IRB default to that agreement when it is offered.

ii. **Other Reliance Agreement (ORA):** Indicate whether you are using an existing broad reliance agreement or if you are uploading a new reliance agreement.

- **Use Existing Broad Reliance Agreement:** Select your existing broad reliance agreement from the drop down.
- **Add New Reliance Agreement:** Indicate whether the new reliance agreement is broad or study-specific. Indicate the name of the ORA and designate a short name. Choose a file to upload or drag and drop the file. Click **Save Agreement**.



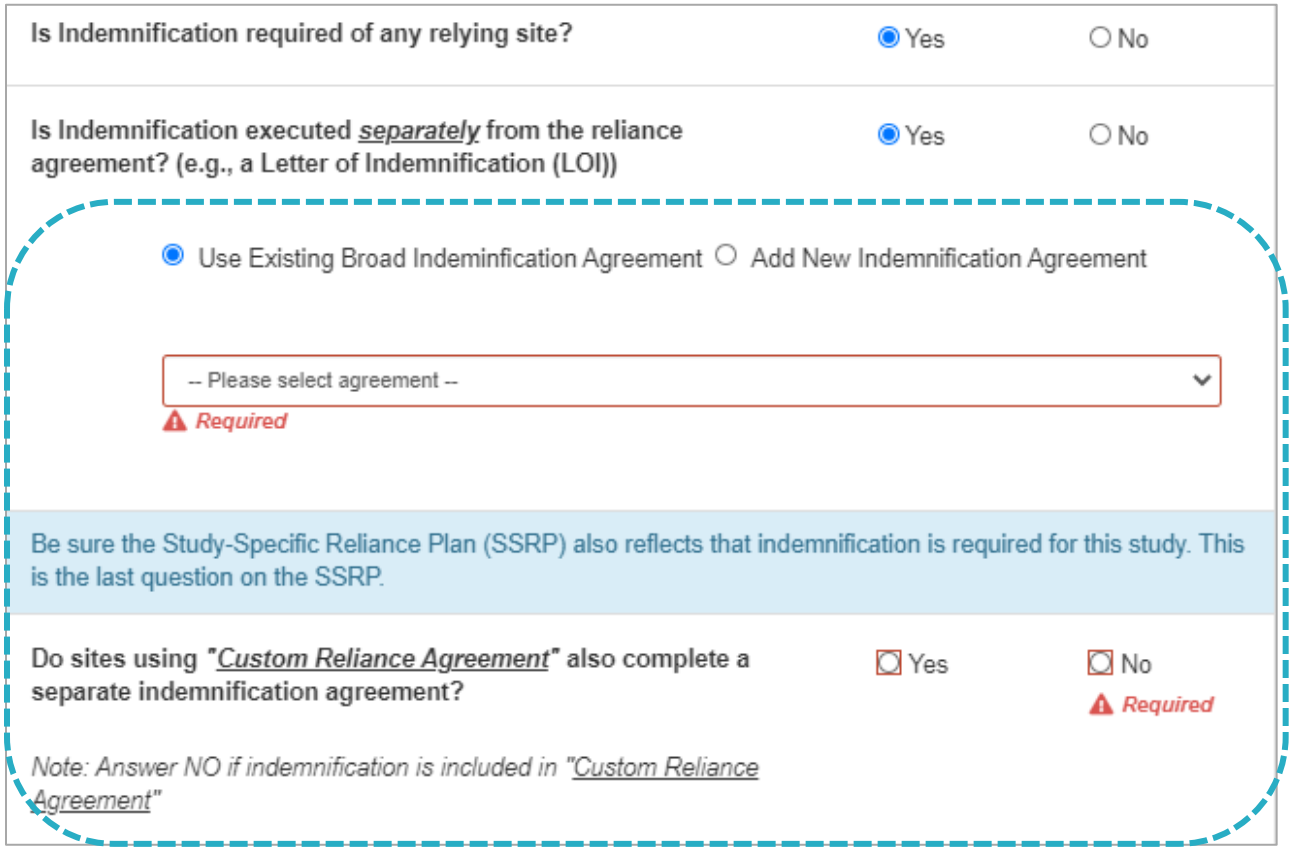
b. **Indicate whether you require an indemnification agreement** from your sites (see section 1.6 for more information about Letters of Indemnification). Given that SMART IRB is silent on indemnification, Reviewing IRBs can require a separate indemnification agreement before sites can rely on a study. Indemnification agreements can be study-specific or broad, applying to any study.

i) **Use Existing Broad Indemnification Agreement:** Select your existing broad agreement from the drop down.

ii) **Add New Indemnification Agreement:** Indicate whether the new agreement is broad or study-specific. Indicate the name of the indemnification agreement and designate a short name. Choose a file to upload or drag and drop the file. Click **Save**.

Tip: Be sure the Study-Specific Reliance Plan (SSRP) also reflects that indemnification is required for this study. This is the last question on the SSRP.

iii) **Indemnification for sites signing an Other Reliance Agreement:** Indicate if sites who sign the "Other Reliance Agreement" also need to complete the separate indemnification agreement. Answer 'No' if indemnification is included in the "Other Reliance Agreement."



3. Identify IREx Study Managers: The IREx Study Manager is the lead study team coordinator or coordinating center staff responsible for liaising with site study teams. You can have more than one Study Manager for a study.

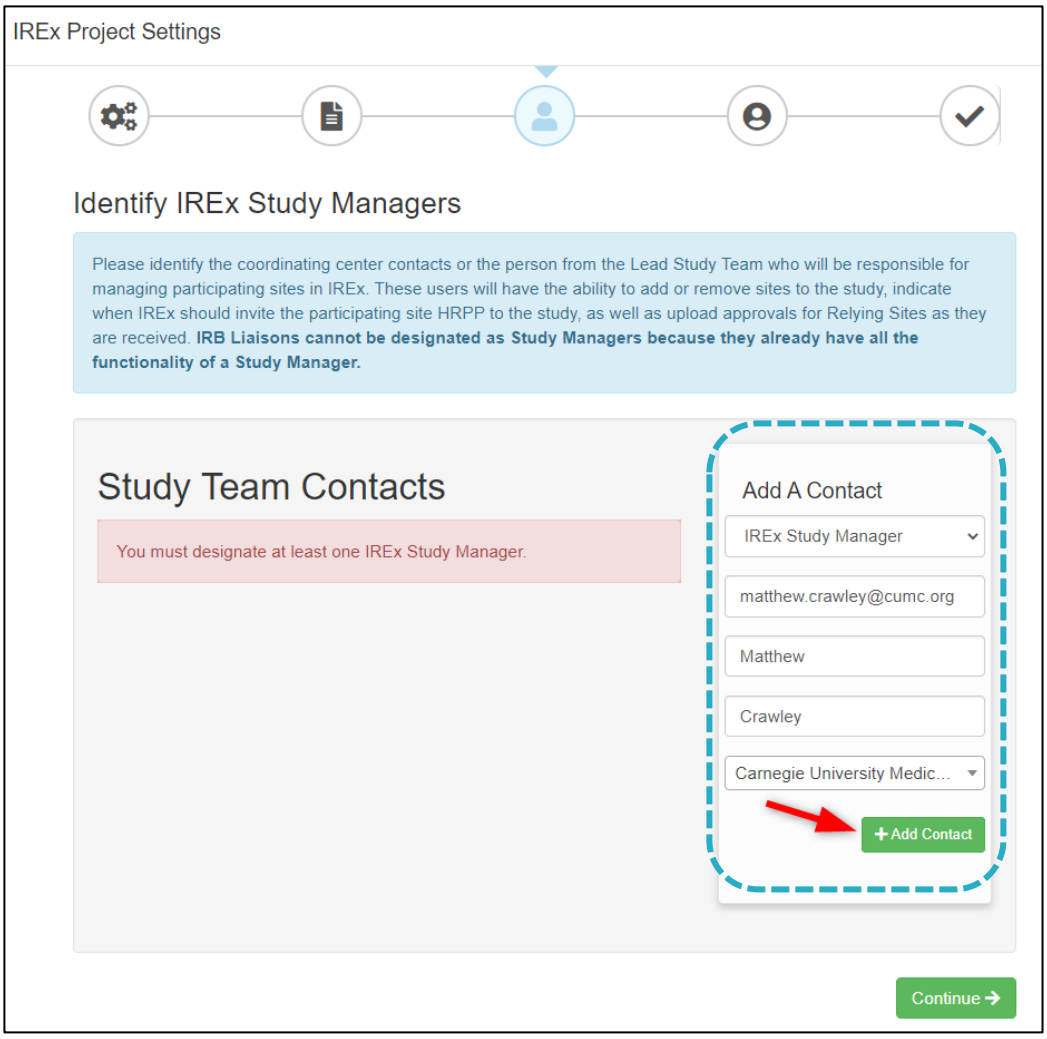
   Study Mangers have the following permissions in IREx, but the Reviewing IRB should discuss their role and appropriate actions before giving them access to IREx:

   - Add/remove sites from the study
   - Send the standard IREx study notification to participating site HRPPs and study teams
   - Export local considerations from IREx
   - Upload site approvals to IREx

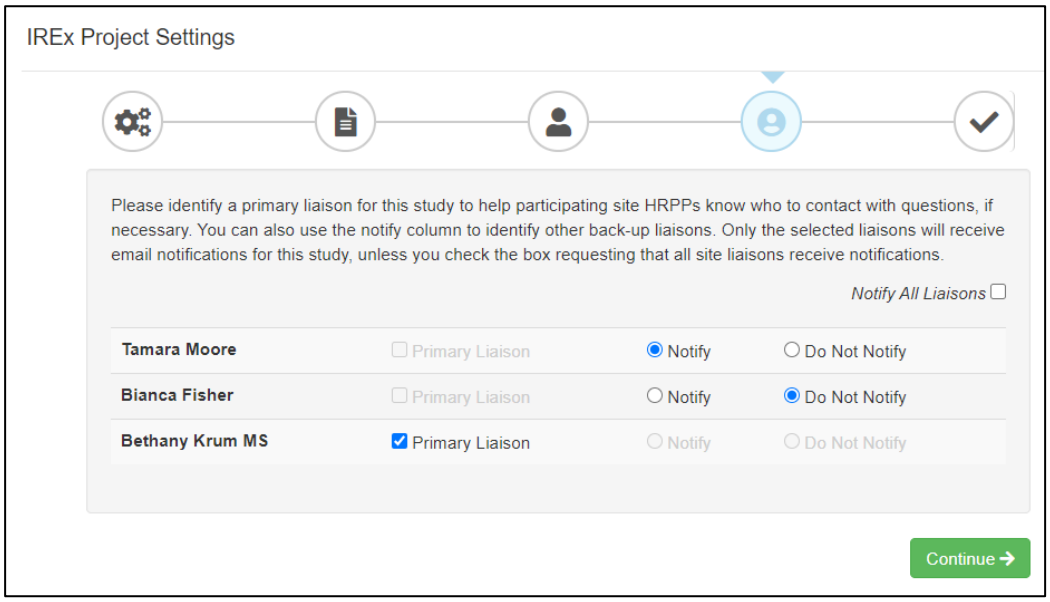
   To add an IREx Study Manager:

   a. In the Add a Contact box, search the database for existing contact(s) by typing their **email address** and selecting one from the drop-down list. If their email is not found, enter the email address for the contact(s). This will create their IREx account and access to the study.
   b. Enter the contact's first and last names if they were not auto-populated.
   c. Click **+Add Contact**.

   After saving the contact information, an email notification will be sent to the study personnel indicating they have been added to a study in IREx.

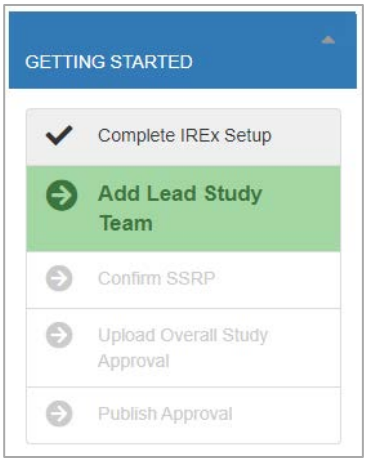


4. Identify a Primary Liaison: Select your Primary IRB Liaison for this study and indicate whether any other Liaisons should receive email notifications for the study. All Liaisons at your site retain full access and permissions for the study.



Review IREx Project Settings & Submit: Verify the information entered and click **Save**.

2.3 ADD LEAD STUDY TEAM

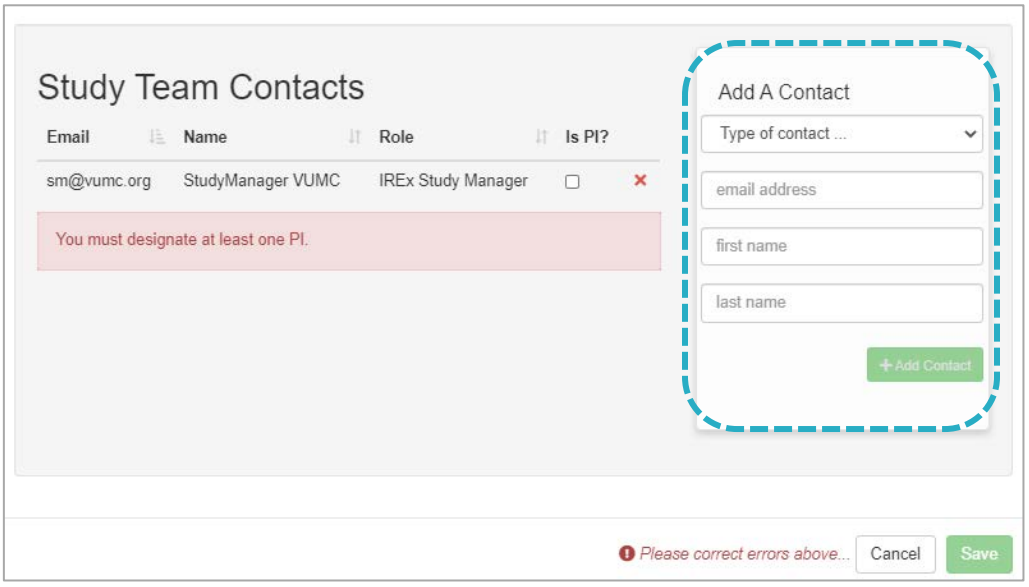


If the Lead Site is also the Reviewing IRB institution, your next step will be to enter the lead study team contacts.

Tip: A PI contact is required, but you can also add coordinators and coordinating center staff (as study managers) here.

To Add the Lead Study Team:

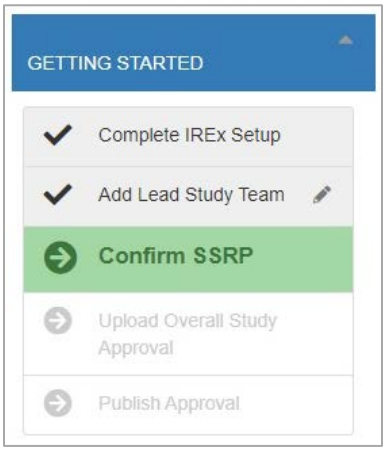
1. Click **Add Lead Study Team** in the GETTING STARTED checklist.
2. In the Study Team Contacts window, select **type of contact:** *PI (required), Coordinator* or *IREx Study Manager*.
3. Search the database for existing contact(s) by typing their **email address** and selecting one from the drop-down list. If no email is found, enter the email address for the contact(s). This will create their IREx account and access to the study.
4. Enter the contact's **first** and **last names** if they were not auto-populated.
5. Click **+Add Contact** and **OK** to save. After saving the contact information, an email notification will be sent to the study personnel indicating they have been added as to a study in IREx.



Tip: The study team contact added in this section will get a notification described above after you confirm the Study-Specific Reliance Plan.

2.4 CONFIRM STUDY-SPECIFIC RELIANCE PLAN (SSRP)

The next task in the GETTING STARTED checklist is to **Confirm the Study-Specific Reliance Plan (SSRP)**.



The SSRP is automatically generated from the last section of your Institutional Profile and outlines how things like HIPAA, auditing, and external reporting will be handled.

1. **If you answered the questions in Section 4 of your Institutional Profile, the SSRP will appear completed**. You can make edits to your responses for this specific study, if you wish, before pressing submit at the bottom of the screen.
2. **If you have not yet completed this section of your Institutional Profile, the SSRP will appear blank within the study.** Please complete and submit it. These answers will not be saved to your Institutional Profile. Please complete the questions in your Institutional Profile, as well.

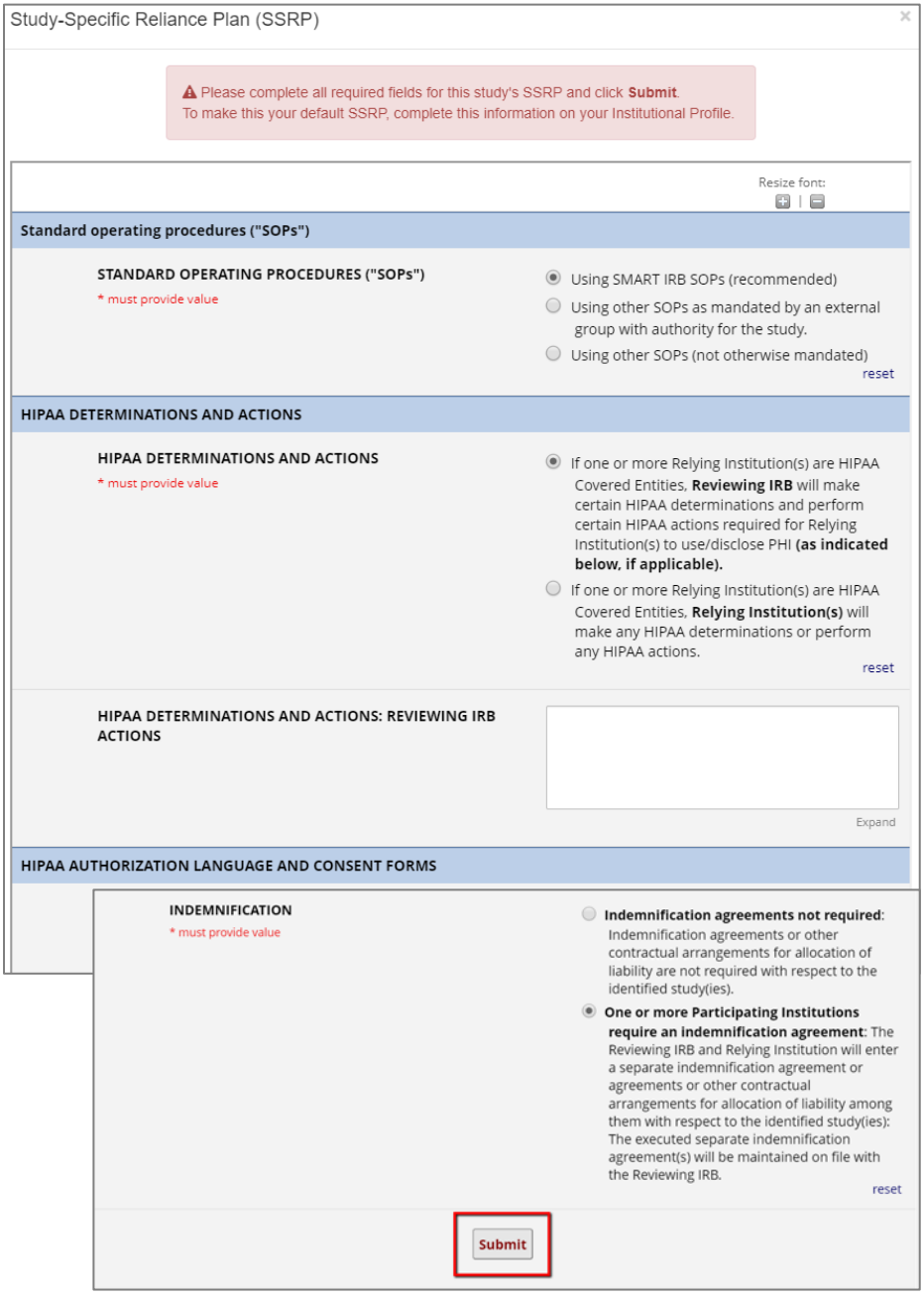
To Confirm the SSRP:

1. Complete or confirm the answers to each question
2. Press Submit at the bottom of the screen.

Sites are NOT notified of the study when you complete the SSRP.

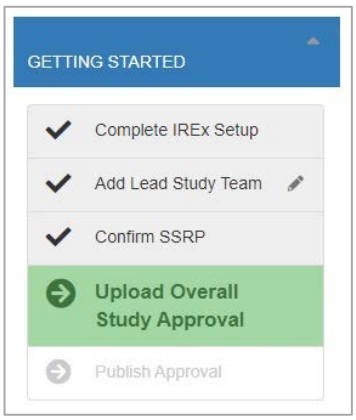
Tip: Sites using an Other Reliance Agreement indicate reliance, but do not accept an SSRP because it is specific to the SMART IRB Agreement.

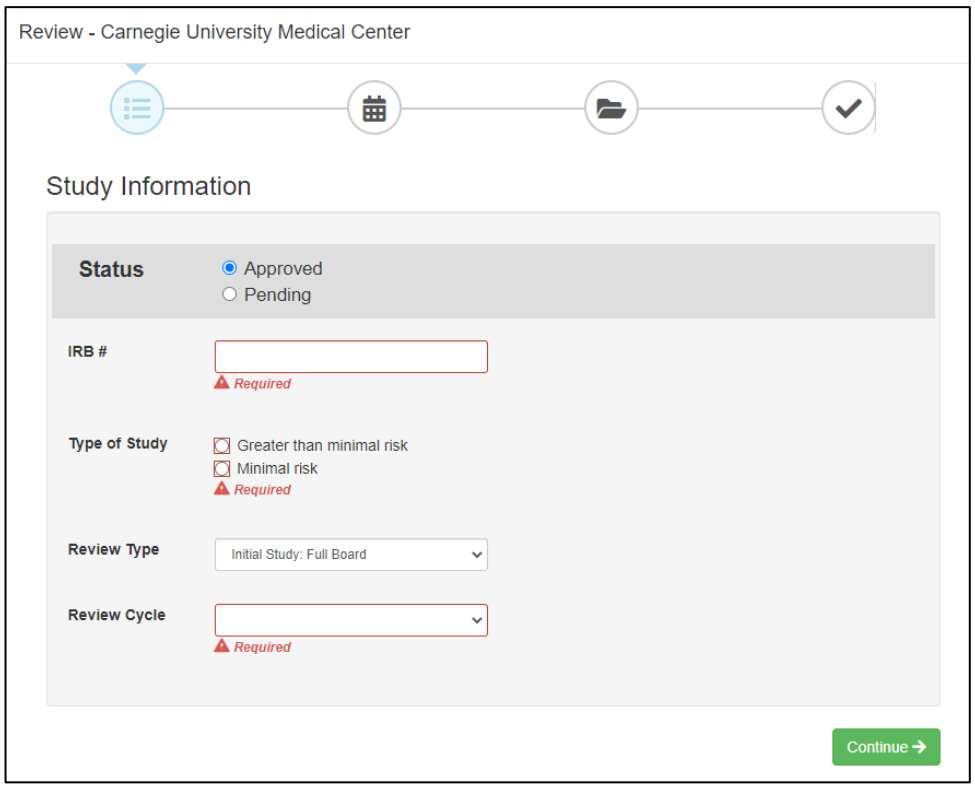
Tip: Once you confirm the SSRP, you cannot make edits to the overall SSRP for this study. However, you can make individual changes for specific sites, as needed.



2.5 UPLOAD OVERALL STUDY APPROVAL

Once the study is approved, click **Upload Overall Study Approval** on the GETTING STARTED checklist to document your initial study approval information and upload the approval documents.



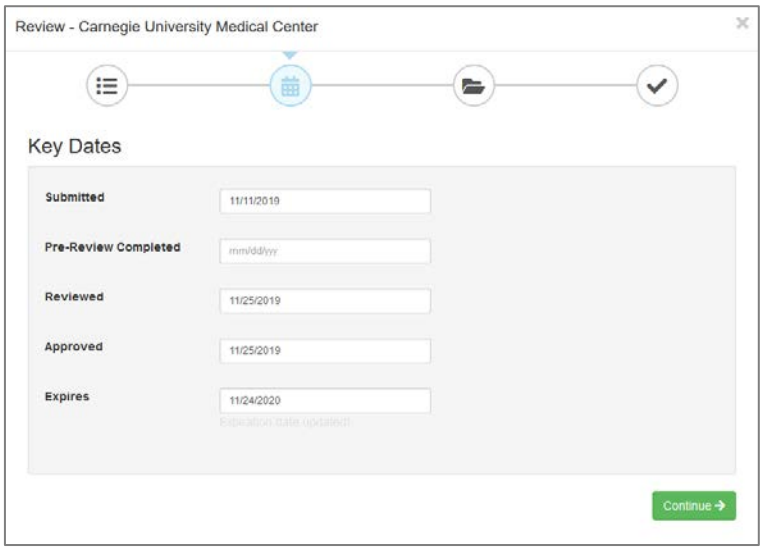


After changing the **Status** to Approved, the required fields will be highlighted red. Uploading approval requires three pieces of information:

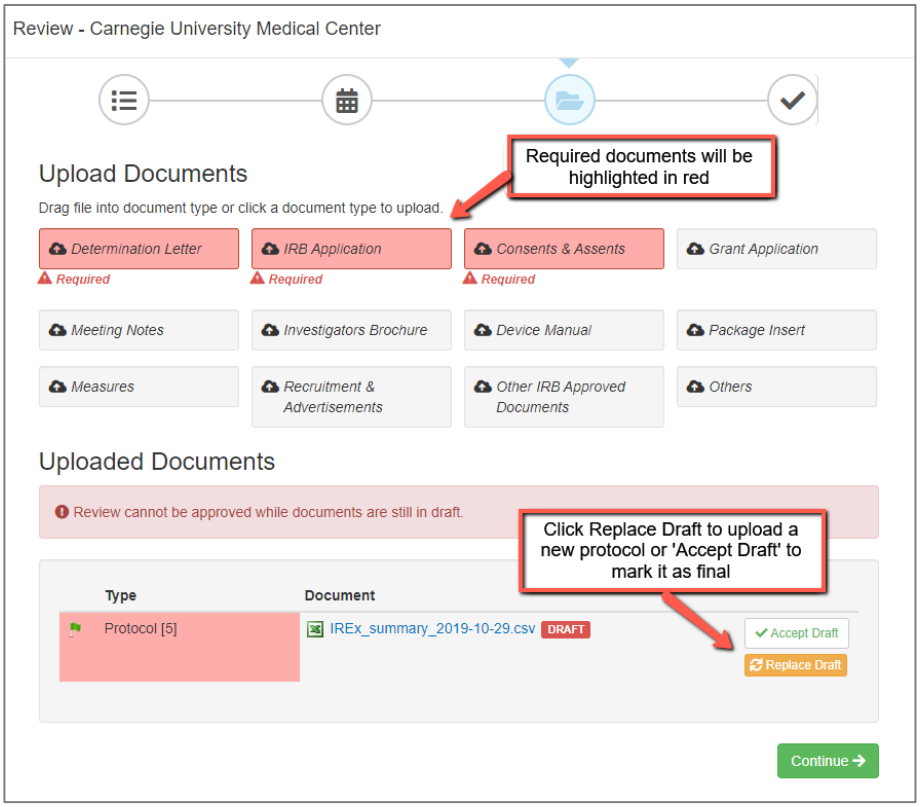
1. <u>Study Information:</u>
   a. **IRB #:** What is the IRB record, submission or tracking number for the study at your site?
   b. **Review Cycle:** How often must the study be reviewed, *3, 6, 9, 12 or >12 months*?
   c. **Type of Study:** Is the study *Greater than minimal risk* or *Minimal risk*?
   d. **Review Type:** Was the study sent to the *full board* or *expedited* (if Minimal Risk) review?

2. <u>Key Dates:</u>
   a. **Submitted:** When was the study first submitted for review?
   b. **Pre-Review Completed:** When was the pre-review completed?
   c. **Reviewed:** When did the first IRB (committee or subcommittee) review occur?
   d. **Approved:** When was the study approved without contingencies?
   e. **Expires:** When does the study expire?

   Tip: The expiration date is pre-populated based on the approval date, but it can be edited. Please check it is accurate.



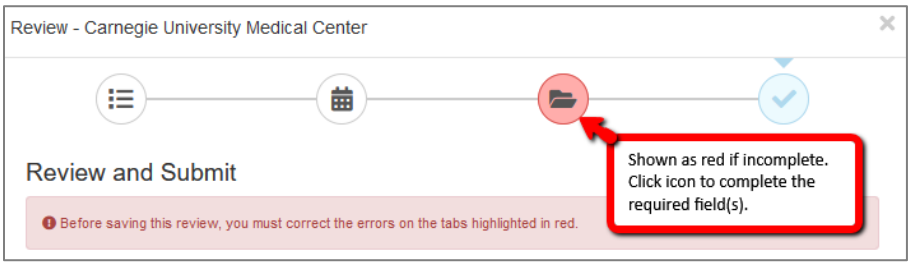
3. Documents: Upload approved Documents for the Lead Site (only):
    a. **Protocol: Protocol** (required)
    b. **IRB Application** (required)
    c. **Determination Letter** (required)
    d. **Consents & Assents** (required if greater than minimal risk; option to waive if minimal risk)
    e. Grant Application
    f. Meeting Notes
    g. Investigators Brochure
    h. Device Manual
    i. Package Insert (customizable document name)
    j. Measures
    k. Recruitment & Advertisements
    l. Other IRB Approved Documents (customizable document name)
    m. Others (customizable document name)



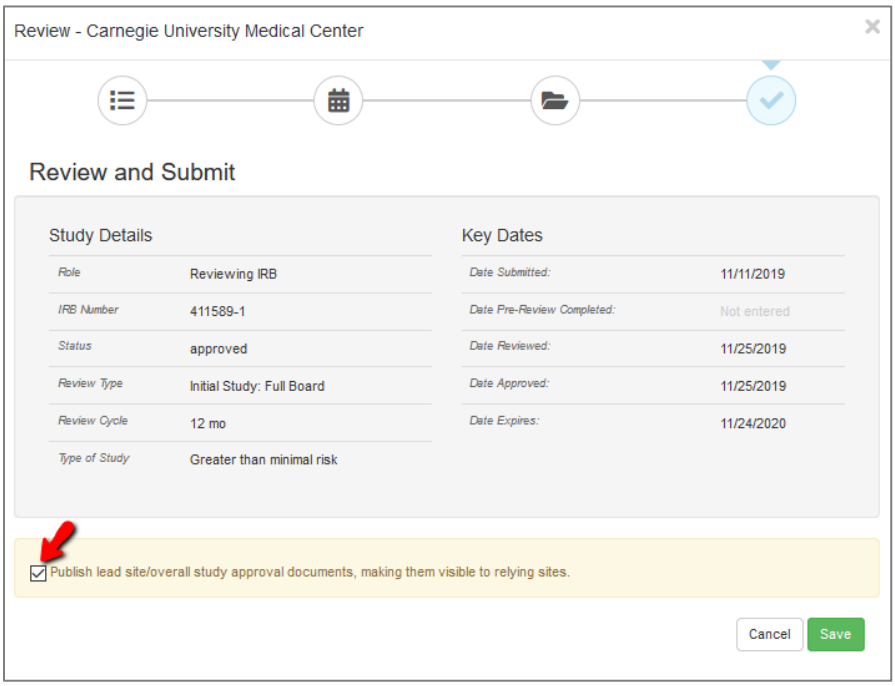
Tip: You can drag and drop multiple files of the same type (e.g., consent forms) at once or upload them individually. To remove any document, click the red Delete button.

Tip: If you upload multiple files for a document type that requires a name, each file will get the name entered. However, you can edit the name using the pencil beside the file under "Uploaded Documents".

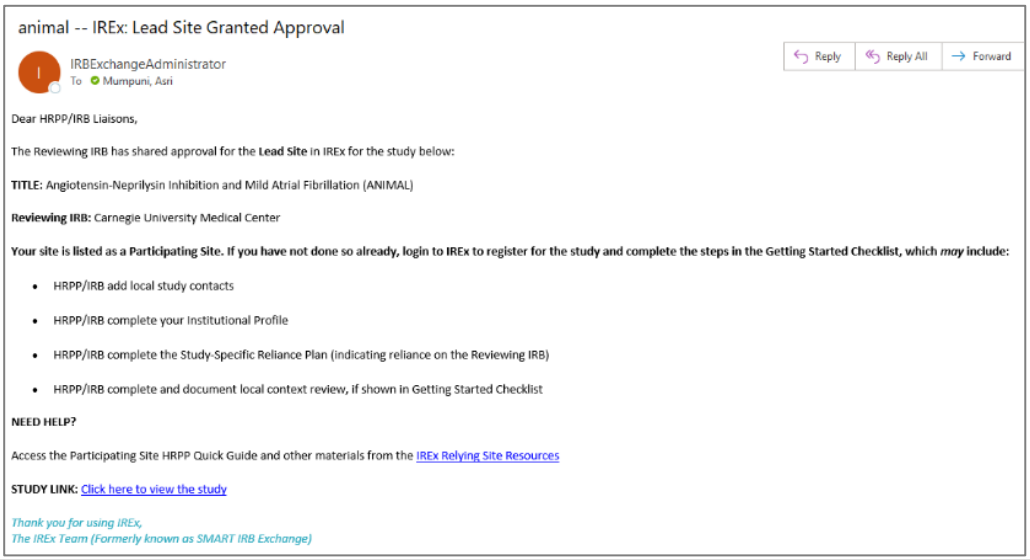
4. Review and Submit:
   a. Review your study information and click **Save** when you are ready to submit.
   b. Any sections that are missing required fields will be highlighted red.



1. You can select **Publish lead site/overall study approvals, making them visible to Relying Sites** to publish your documents and make them visible to all sites in the study, or you can save without publishing the approval, yet.

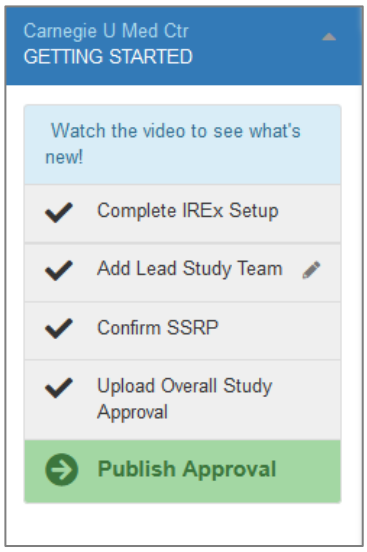


If you publish the approval, all sites that have been notified of the study will receive an email notification that you approved the Lead Site.



2.6 PUBLISH APPROVAL

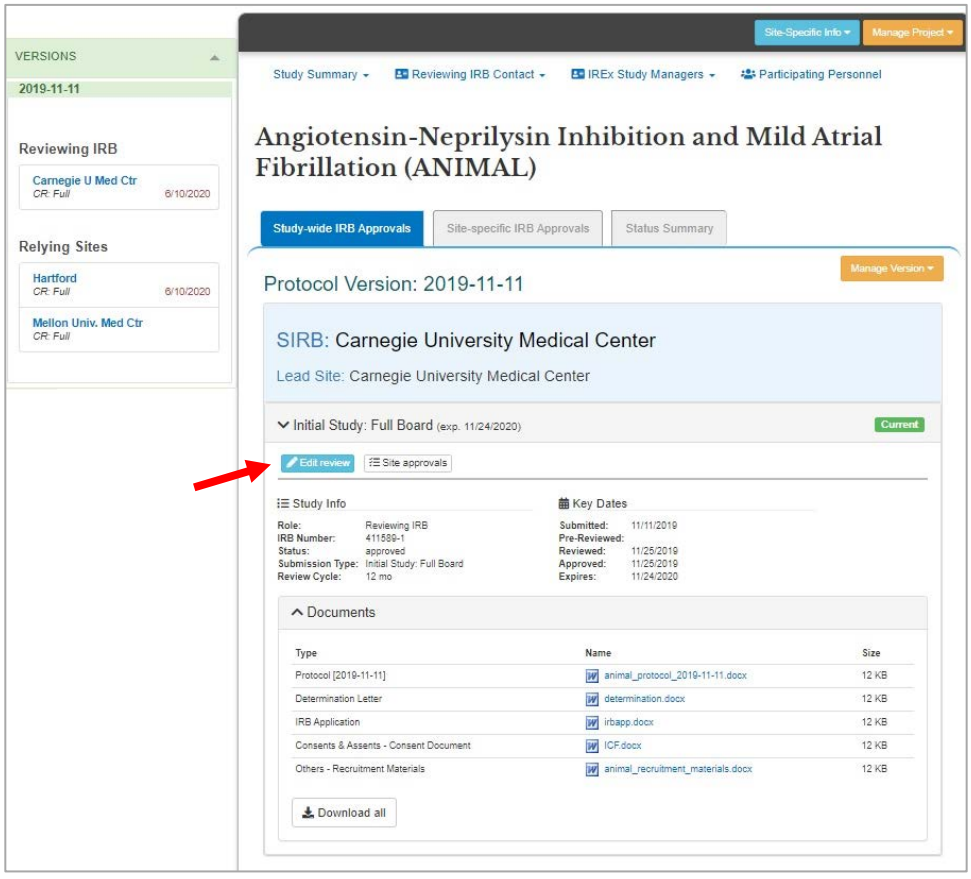
If you did not check the box to publish your approval before saving your approval documents (see previous section), **Publish Approval** will be highlighted in the GETTING STARTED checklist.



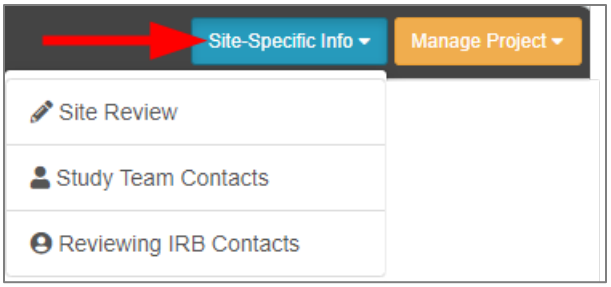
When you are ready to publish your approval, click **Publish Approval** and **OK** to notify sites of the Lead Site approval (see previous section for sample email).

After publishing the approval for the lead site, the GETTING STARTED Checklist is complete for the initial approval and will no longer be displayed. However, you can still make edits or updates to all parts of the study.

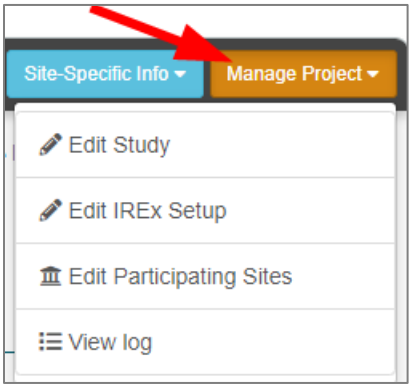
1. To make edits to the overall/lead site approval after publishing it, click **Edit review**. The Study Manager will receive a notification that the approval was updated; however, relying sites will not be notified. If relying site's approvals are edited in IREx, as well, they will receive a notification detailing what changed.



2. Use the **Site-Specific Info** button to edit your Site Review, Study Team Contacts, study Liaisons, view or download your SSRP for the study.



3. Use the **Manage Project** button to edit the study title, summary, or sponsor; IREx Setup; add or remove Participating Sites; and to view the IREx study activity in the log.



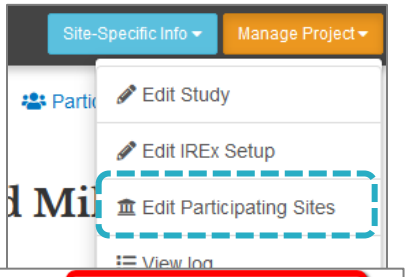
3.0 MANAGING PARTICIPATING SITE ACCESS AND INFORMATION IN IREX

It is *recommended* that the IREx Study Manager (i.e., the lead study team coordinator or coordinating center staff) complete all the tasks outlined in this section, as they relate to overseeing participating sites' readiness for sIRB review. The Study Manager is in frequent communication with site investigators and study teams regarding the study timeline, protocol, contracts, and other regulatory documents. However, IREx HRPP/IRB Liaisons have the ability to do all of the tasks recommended for Study Managers, too.

Prior to creating the study in IREx and naming a Study Manager, you should discuss with the Study Manager if you prefer they NOT complete any of these tasks.

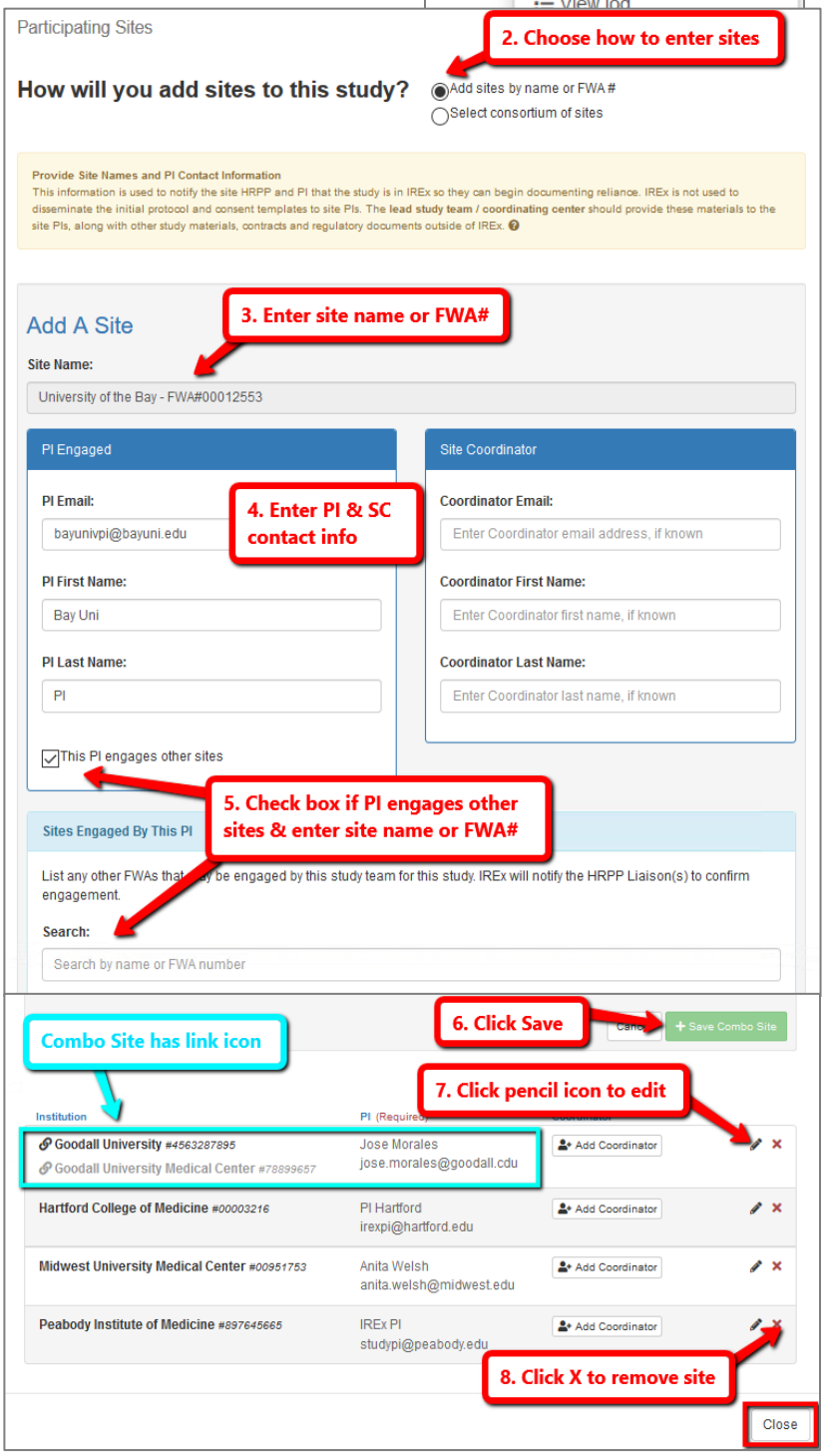
3.1 ADD PARTICIPATING SITES AND INVESTIGATORS TO THE STUDY

Only the sites listed on a study can be notified of the study and access it. Thus, the first step to managing site access to the study is to grant sites' access.



To manage Participating Sites in IREx:

1. Click the **Site-Specific Info** button and select **Edit Participating Sites**.
2. On the pop-up, indicate what sites should have access to the study in IREx – you can choose to *add sites by name or FWA#* or *select a consortium*.
3. Search by the site's FWA or full name (do not use abbreviations, e.g., "UCLA"). As you type, the sites that match your entry will appear. You can also add sites that do not appear in the search. Verify you have the correct name by referencing the OHRP FWA website, contacting the site's HRPP, or asking the local PI to confirm with their HRPP.
   NOTE: THE FWA-HOLDING PSITE APPEARS FIRST, FOLLOWED BY ANY COMPONENTS, IF AVAILABLE.
4. A PI name and email address must be entered before you can notify the PSite of study. However, you can list the site without a PI name or email and return later to enter this information. Entering the Site Coordinator email and name is also recommended. **This does not provide the PI/ study coordinator with IREx access**, but CC's them on the email to their HRPP about the study.
5. If you know that a PI is engaging more than one site, you can check this box and enter the name of the additional sites. This will create a "Combo Site" for this PI and these sites show in blue ink and have a link ∞ icon. (Watch our Combo Site video for more details).
6. Click the **+Save Combo Site** button to add the site(s) to the study.
7. Site contacts can be entered at any time before you contact the site. Once a site has registered, you cannot make edits to the personnel as they are managed by the site from that point forward. Click the pencil icon to update the contact info. Click **Close** when done with edits.



Tip: To remove sites, uncheck the box next to the site's name. You have the option to restore the site until you click **Close**.

3.2 NOTIFY PARTICIPATING SITE HRPPS OF THE STUDY

After adding Sites, you or the Study Manager can notify Sites about the study in IREx. The purpose of this notification is to connect the Site HRPP and study team around the reliance process for their site.

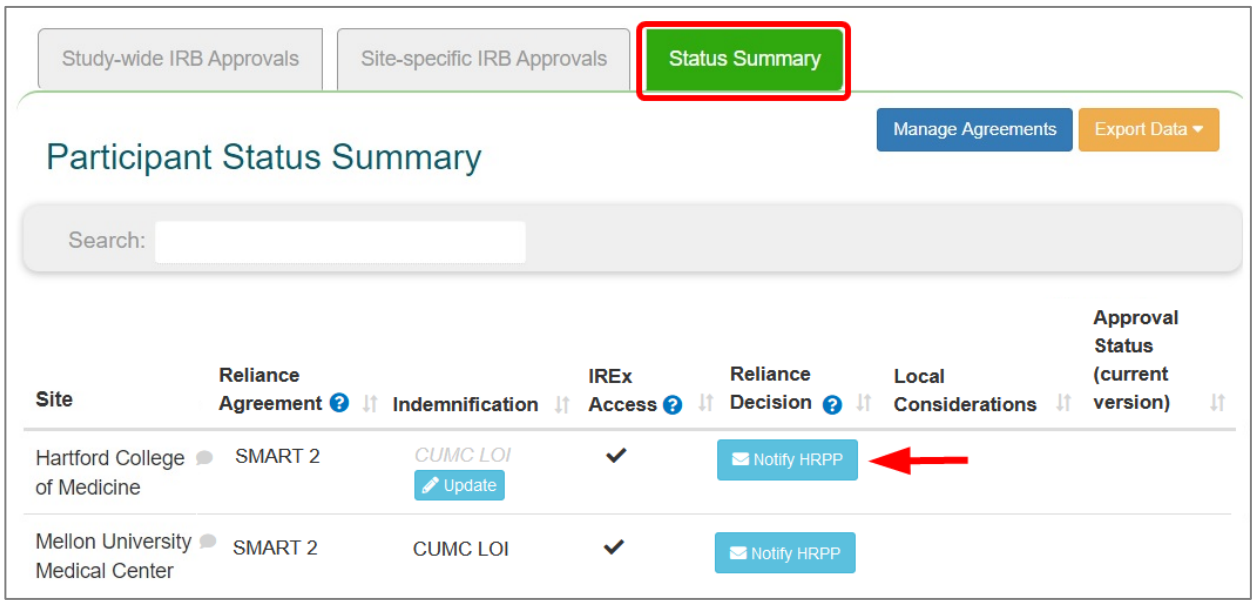
Tip: This information is used to notify the site HRPP and PI that the study is in IREx so they can begin documenting reliance. IREx is not used to disseminate the initial protocol and consent templates to site PIs. The lead study team/ coordinating center should provide these materials to the site PIs, along with other study materials, contracts and regulatory documents outside of IREx.

Study teams do not get access to studies in IREx until their HRPP confirms their site is engaged. In order to confirm engagement, most HRPPs require a local submission from the site PI to their local IRB system. Thus, study materials should be disseminated as they would be for any multi-site trial (e.g., via the lead study team or coordinating center).

We recommend using the Notify HRPP button AFTER the Study Manager has sent the sIRB-approved study protocol and other documents (i.e. consent template) to each site's investigator or study team.

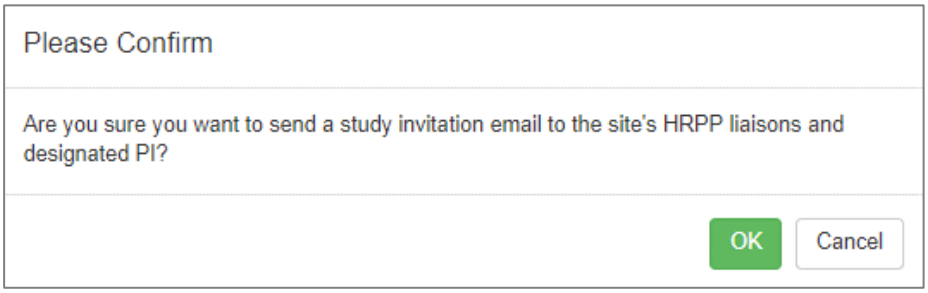
How to Notify Site HRPPs of the Study:

1. On the study page, click the **Status Summary** tab.
2. Click on the **Notify HRPP** button to send the IREx study invitation to a site.
3. A pop-up will ask you, if you are sure you want to send the study invitation email to the site, click **OK** to confirm.



Tip:

- Sites can be notified at different times, depending on when the site is being onboarded to the study.
- Only IREx members can be notified (sites with a checkmark under "IREx Access").



The site HRPP will receive the study invitation email (below). The PI and coordinator (if provided) will be cc'd on the email.

Dear Liaison(s) and Study Investigator,

Peabody Institute of Medicine (FWA: 897645665) has been listed as a participating site in IREx for the following study:

Title	Yogurt and Oatmeal Generate Inflammation II
Reviewing IRB	Mellon University Medical Center
Local Investigator	IREx PI

What do I do with this email?

Study PI

Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site.

YOU CANNOT ACCESS THE STUDY IN IREX YET.
You receive access to the study in IREx after your HRPP logs in to confirm your site is participating and lists you on the study.

HRPP Liaisons

1) **NEW: Make sure your FWA is captured correctly in IREx!**
Login to IREx to verify whether your site is engaged for this study and identified correctly. This may require contacting your local PI if they have not submitted the study for review. On the Study Registration Pop-up in IREx you can now:

a. **Correct the information** if your site is engaged, but the incorrect FWA or PI is listed.
b. **Indicate your site is not engaged**, if applicable. You will no longer receive email notifications about the study.
c. **Add other FWAs** thought to be engaged. The Liaison(s) at these sites will be notified about the study.

2) If you have not received a submission from the local investigator, consider reaching out to let him/her know how they can initiate reliance at your institution.

3) Use the Getting Started checklist on the IREx study page to walk you through ceding review and any other required steps.

Need Help?

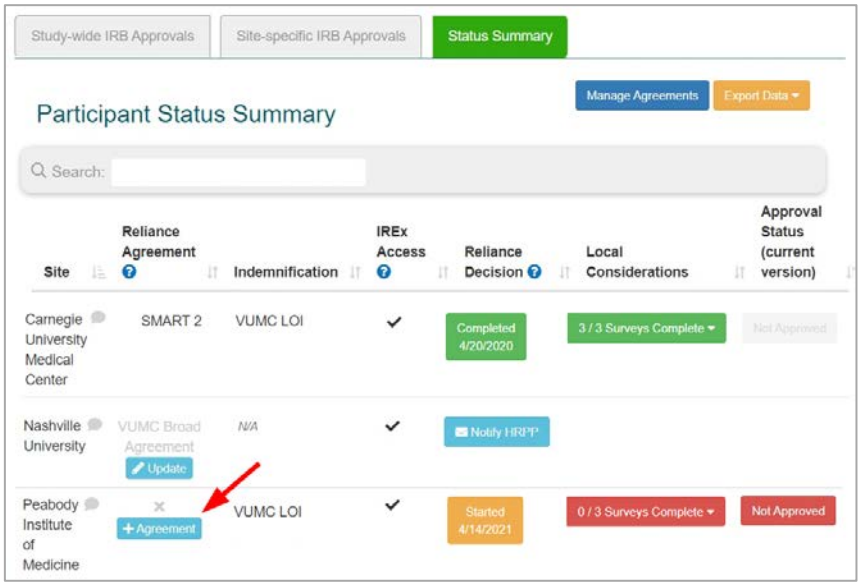
Access the user quick guides and other materials from the IREx Participating Site HRPP Resources and IREx Participating Study Teams Resources.

Thank you for using IREx,
The IREx Team

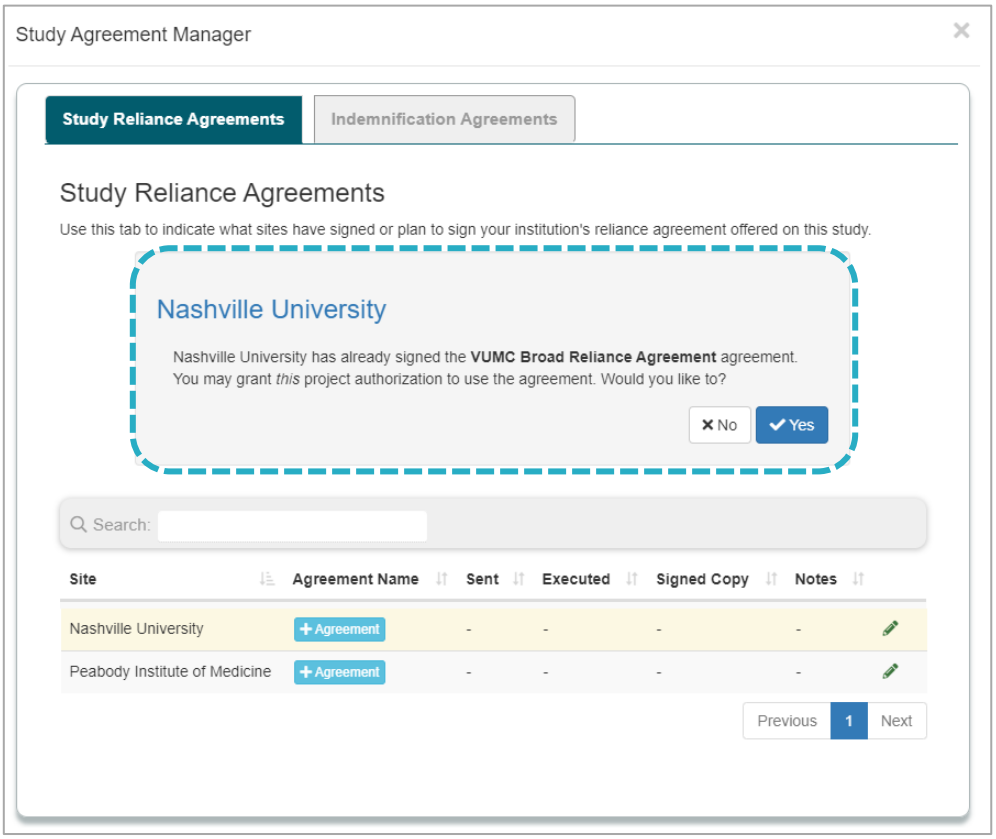
3.3 TRACK A RELIANCE AGREEMENT FOR YOUR STUDY

To track which sites have signed your Reliance Agreement(s) for a study, navigate to the Status Summary tab:

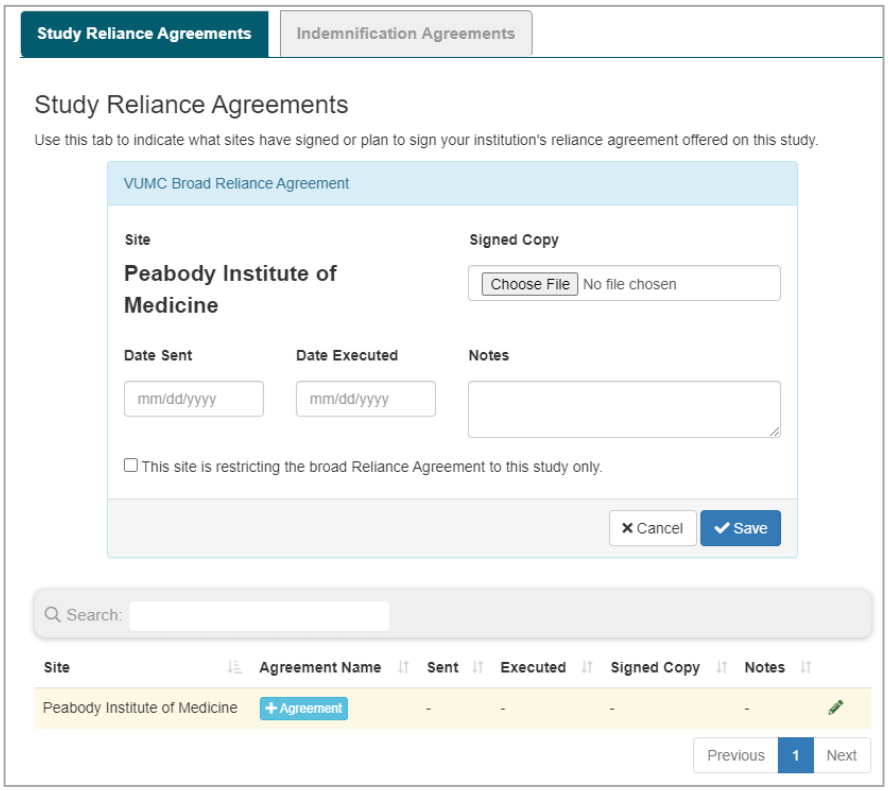
1. Click the blue **+Agreement** button next to the site's name or use the **Manage Agreements** button at the top right of the Status Summary to open the Study Reliance Agreements dialog.
2. Sites that have signed onto SMART IRB default to that agreement when it is offered.
3. Sites that are eligible to sign your Other Reliance Agreement will be listed.



4. Indicate whether sites that have already executed your Other Reliance Agreement for another project have authorization to use the same agreement for the current study.

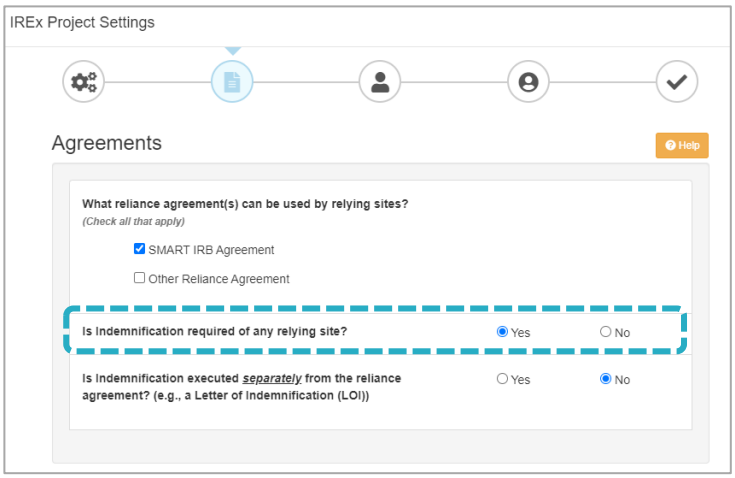


5. For sites that have never executed an Other Reliance Agreement, you can track when they sign the reliance agreement you uploaded for the current study (see Section 2.2.1).
   a. Click the blue **+Agreement** button next to the site name.
   b. Enter the date sent, date executed, and upload a copy of the Agreement, if desired.
   c. Indicate whether the agreement is study-restricted for the site.
   d. Save the information.
   e. Click the pencil icon to edit or update the agreement information at any time.



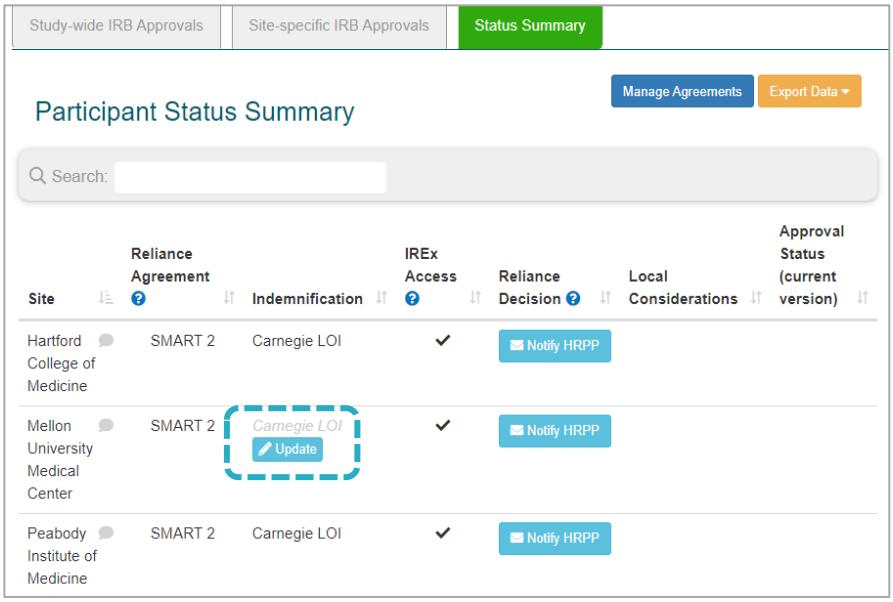
3.4 TRACK INDEMNIFICATION AGREEMENTS FOR YOUR STUDY

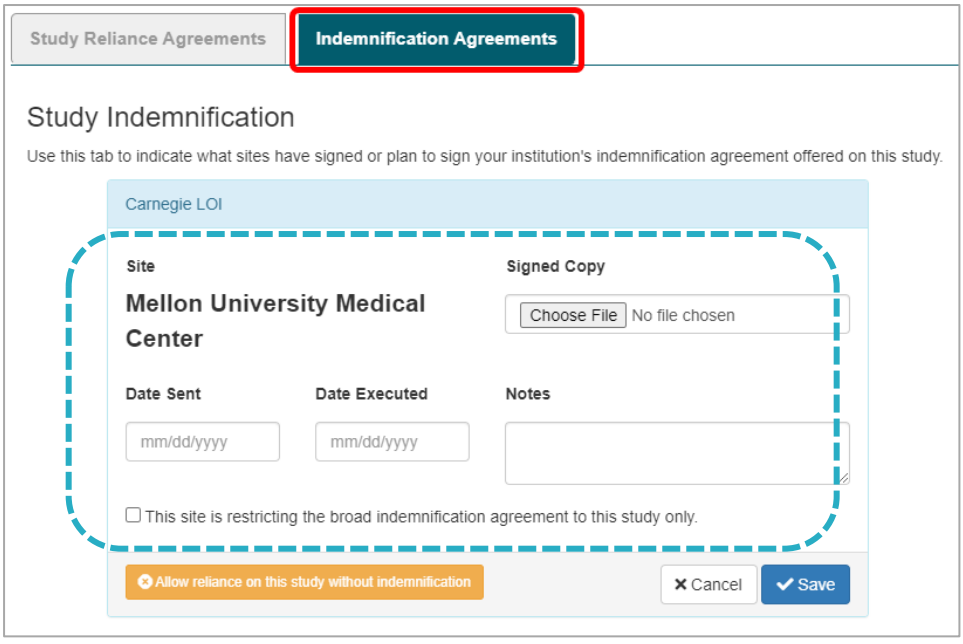
If you indicated you are requiring an indemnification agreement for the study under Complete IREx Setup, an Indemnification column will appear on the Status Summary tab indicating which of the listed sites have signed your agreement.



To update a site's Indemnification status:

1. Click the blue **Update** button in the Indemnification column beside a site's name or use the **Manage Agreements** button at the top right of the Status Summary to open the indemnification agreement dialog.
2. Click the tab that says **Indemnification Agreements**.
3. Enter the *Date Sent*, *Date Executed*, and any notes.
4. Indicate if the indemnification agreement is study-restricted for this site or if you will allow reliance without indemnification.
5. Upload the signed agreement under Signed Copy.
6. Click **Save**.
7. When an Indemnification agreement has been entered as executed in IREx, the agreement name will show as black in the Indemnification column on the Status Summary.

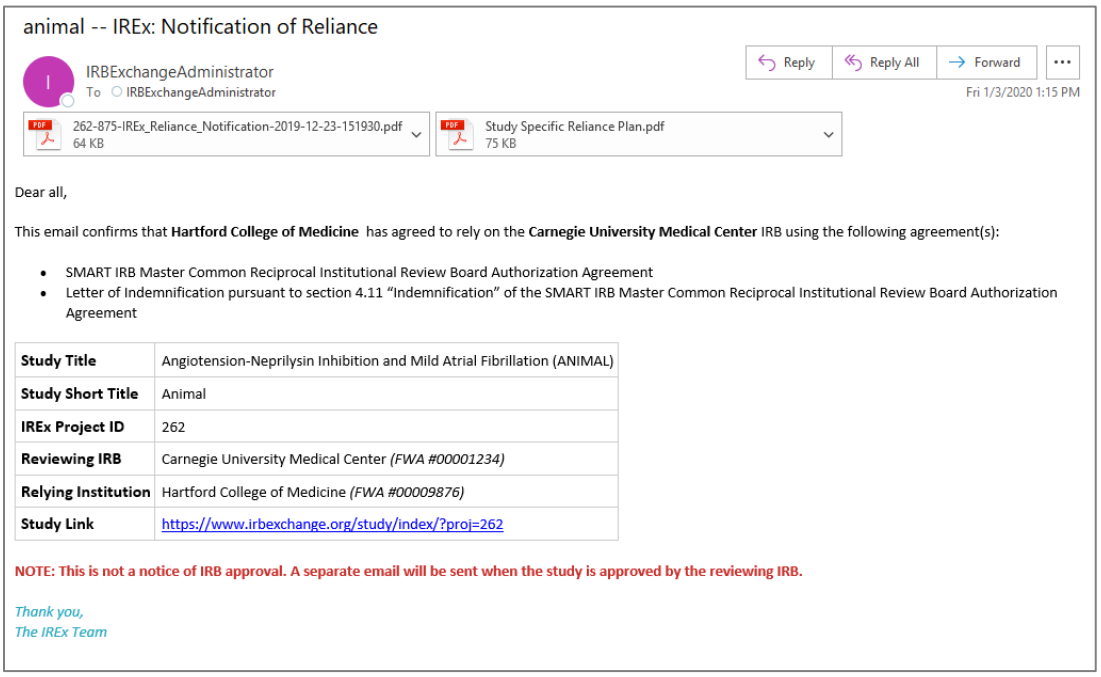




3.5 CAPTURE RELIANCE DECISIONS IN IREX

Once participating site HRPPs are notified about the study, they can begin completing the steps to reliance. One of the first steps is indicating reliance, also known as a cede decision. Sites indicate reliance by accepting your Study-Specific Reliance Plan (SSRP). Sites also have to complete or confirm their Institutional Profile (IP) in IREx before they can indicate reliance—unless you are capturing local considerations in IREx for this study, in which case the IP must be completed as part of local considerations, but not necessarily before they indicate a cede decision.

You will receive an email notification each time a site indicates reliance. The email is sent to the Primary Reviewing IRB Liaison, Study Manager, Site PI, and Relying Site HRPP Liaisons and includes a PDF of the confirmation of reliance and the SSRP.



animal -- IREx: Notification of Reliance

IRBExchangeAdministrator
To IRBExchangeAdministrator

Reply | Reply All | Forward | ...
Fri 1/3/2020 1:15 PM

262-875-IREx_Reliance_Notification-2019-12-23-151930.pdf 64 KB

Study Specific Reliance Plan.pdf 75 KB

Dear all,

This email confirms that **Hartford College of Medicine** has agreed to rely on the **Carnegie University Medical Center** IRB using the following agreement(s):

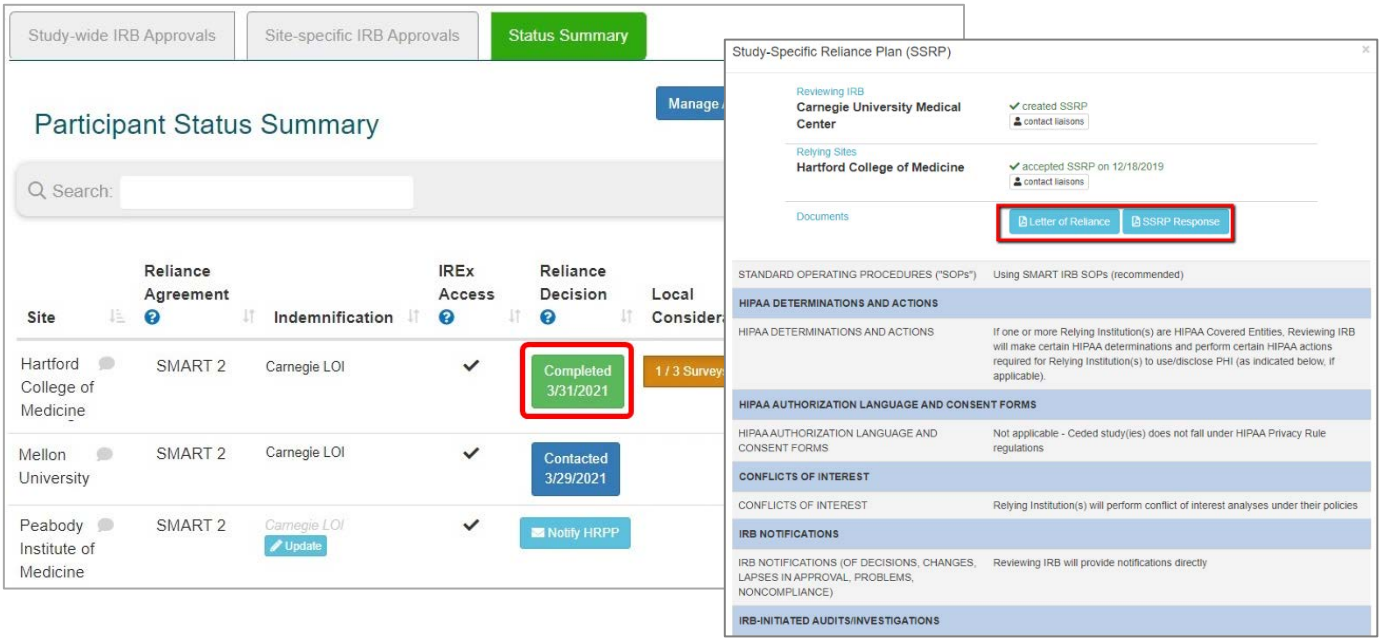
- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement
- Letter of Indemnification pursuant to section 4.11 "Indemnification" of the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement

Study Title	Angiotension-Neprilysin Inhibition and Mild Atrial Fibrillation (ANIMAL)
Study Short Title	Animal
IREx Project ID	262
Reviewing IRB	Carnegie University Medical Center *(FWA #00001234)*
Relying Institution	Hartford College of Medicine *(FWA #00009876)*
Study Link	https://www.irbexchange.org/study/index/?proj=262

NOTE: This is not a notice of IRB approval. A separate email will be sent when the study is approved by the reviewing IRB.

Thank you,
The IREx Team

You can download copies of the Letter of Reliance or SSSRP for a site by clicking on the site's reliance decision on the Status Summary tab.



Study-wide IRB Approvals | Site-specific IRB Approvals | Status Summary

Participant Status Summary

Manage

Search:

Site	Reliance Agreement	Indemnification	IREx Access	Reliance Decision	Local Consider
Hartford College of Medicine	SMART 2	Carnegie LOI	✓	Completed 3/31/2021	1 / 3 Survey
Mellon University	SMART 2	Carnegie LOI	✓	Contacted 3/29/2021	
Peabody Institute of Medicine	SMART 2	Carnegie LOI Update	✓	Notify HRPP	

Study-Specific Reliance Plan (SSRP)

Reviewing IRB
Carnegie University Medical Center ✓ created SSRP contact liaisons

Relying Sites
Hartford College of Medicine ✓ accepted SSRP on 12/18/2019 contact liaisons

Documents: Letter of Reliance | SSRP Response

STANDARD OPERATING PROCEDURES ("SOPs")	Using SMART IRB SOPs (recommended)
HIPAA DETERMINATIONS AND ACTIONS	
HIPAA DETERMINATIONS AND ACTIONS	If one or more Relying Institution(s) are HIPAA Covered Entities, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (as indicated below, if applicable).
HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS	
HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS	Not applicable - Ceded study(ies) does not fall under HIPAA Privacy Rule regulations
CONFLICTS OF INTEREST	
CONFLICTS OF INTEREST	Relying Institution(s) will perform conflict of interest analyses under their policies
IRB NOTIFICATIONS	
IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)	Reviewing IRB will provide notifications directly
IRB-INITIATED AUDITS/INVESTIGATIONS	

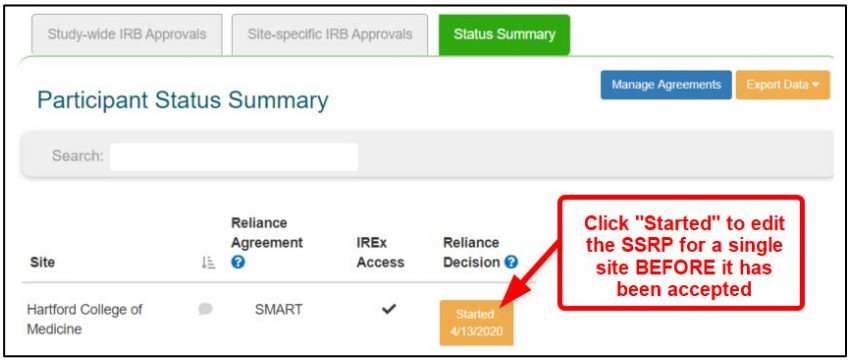
3.5.1 MAKING EDITS TO THE SSRP FOR A SINGLE SITE

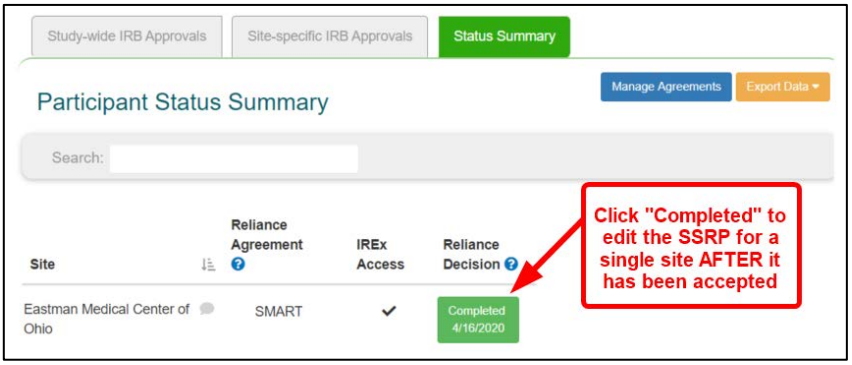
The sIRB establishes the conditions in the SSRP for each study. In order for a participating site HRPP to indicate reliance and cede review to you, they must review and accept your SSRP. However, Site HRPPs can request changes to the SSRP you initially proposed. Any changes will be requested by phone or email. Once you and the Site HRPP agree on mutual terms, you can edit the SSRP for that site to reflect the changes.

Editing the SSRP BEFORE it has been accepted

If the Reviewing IRB and Relying Institution agree on changes to the SSRP:

1. The **Reviewing IRB** can edit a site's SSRP from the Status Summary by clicking **Started** under the Reliance Decision column.
2. The **Reviewing IRB** then makes the changes discussed and presses **Submit.** IREx will notify the Relying HRPP that changes were made.
3. The **Relying Institution** can log in, press **Indicate Reliance** on the GETTING STARTED checklist, and accept the revised SSRP.
4. IREx will send a Notification of Reliance email to the Reviewing IRB and Relying Institution.

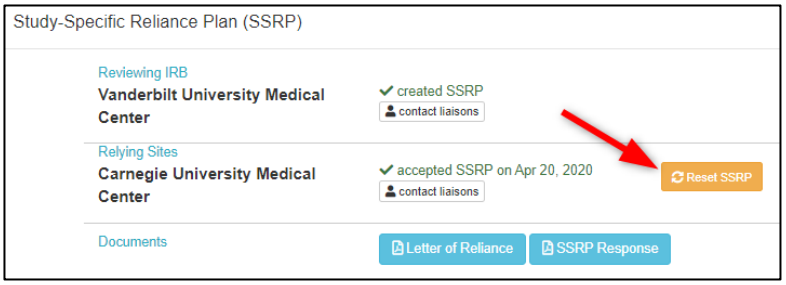


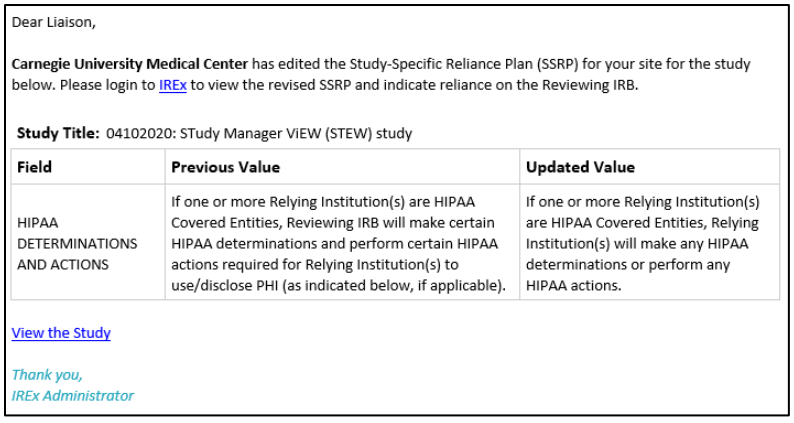


Editing the SSRP AFTER it has been accepted

If the Reviewing IRB and Relying Institution agree to change the SSRP after it has been accepted:

1. The **Reviewing IRB** accesses the site's accepted SSRP from the Status Summary tab by clicking **Completed** under Reliance Decision.
2. The **Reviewing IRB** presses **Reset SSRP** and makes the needed changes before pressing Submit.





Dear Liaison,

Carnegie University Medical Center has edited the Study-Specific Reliance Plan (SSRP) for your site for the study below. Please login to IREx to view the revised SSRP and indicate reliance on the Reviewing IRB.

Study Title: 04102020: STudy Manager ViEW (STEW) study

Field	Previous Value	Updated Value
HIPAA DETERMINATIONS AND ACTIONS	If one or more Relying Institution(s) are HIPAA Covered Entities, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (as indicated below, if applicable).	If one or more Relying Institution(s) are HIPAA Covered Entities, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.

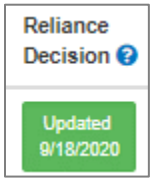
View the Study

Thank you,
IREx Administrator

This will generate an email to notify the Relying Institution of the changes made to the SSRP.

4. Next, the **Relying Institution** logs in, presses on the GETTING STARTED checklist, and accepts the revised SSRP.

5. After the revised SSRP is accepted, the Reviewing IRB and Relying Institution receive an email with a PDF of the revised SSRP. Tip: The original date of reliance is not reset in this instance. The date the revised SSRP was accepted will be noted as an "Updated" Reliance Decision on the Status Summary tab. The dates the SSRP was Reset and Updated are also noted in the Status Summary tab export.



3.6 CAPTURE LOCAL CONSIDERATIONS IN IREX

In order to review on behalf of participating sites, the sIRB must collect local considerations from site's Human Research Protection Program (HRPP) and their local investigator. Since many sIRBs do not allow investigators or HRPP/IRB staff from other institutions to submit to their local IRB system, IREx can be used to (1) **capture** the information needed by the sIRB and (2) **export** and submit the local considerations collected in IREx to the sIRB's IRB submission system on behalf of the site.

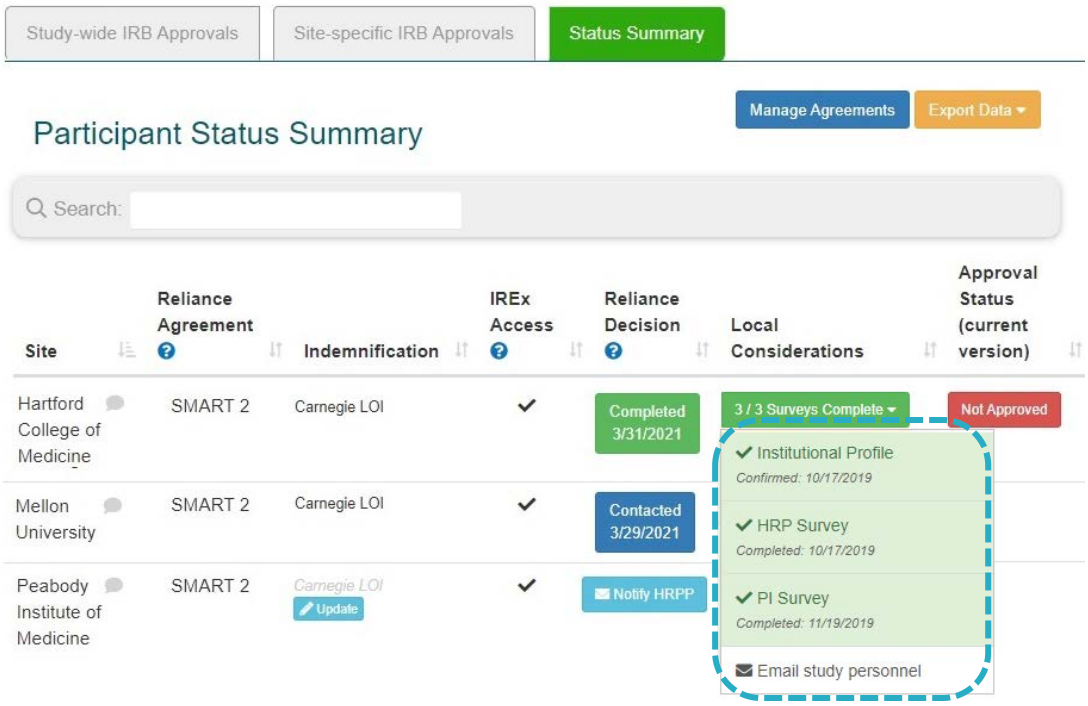
3.6.1 CAPTURING LOCAL CONSIDERATIONS FROM PARTICIPATING SITES

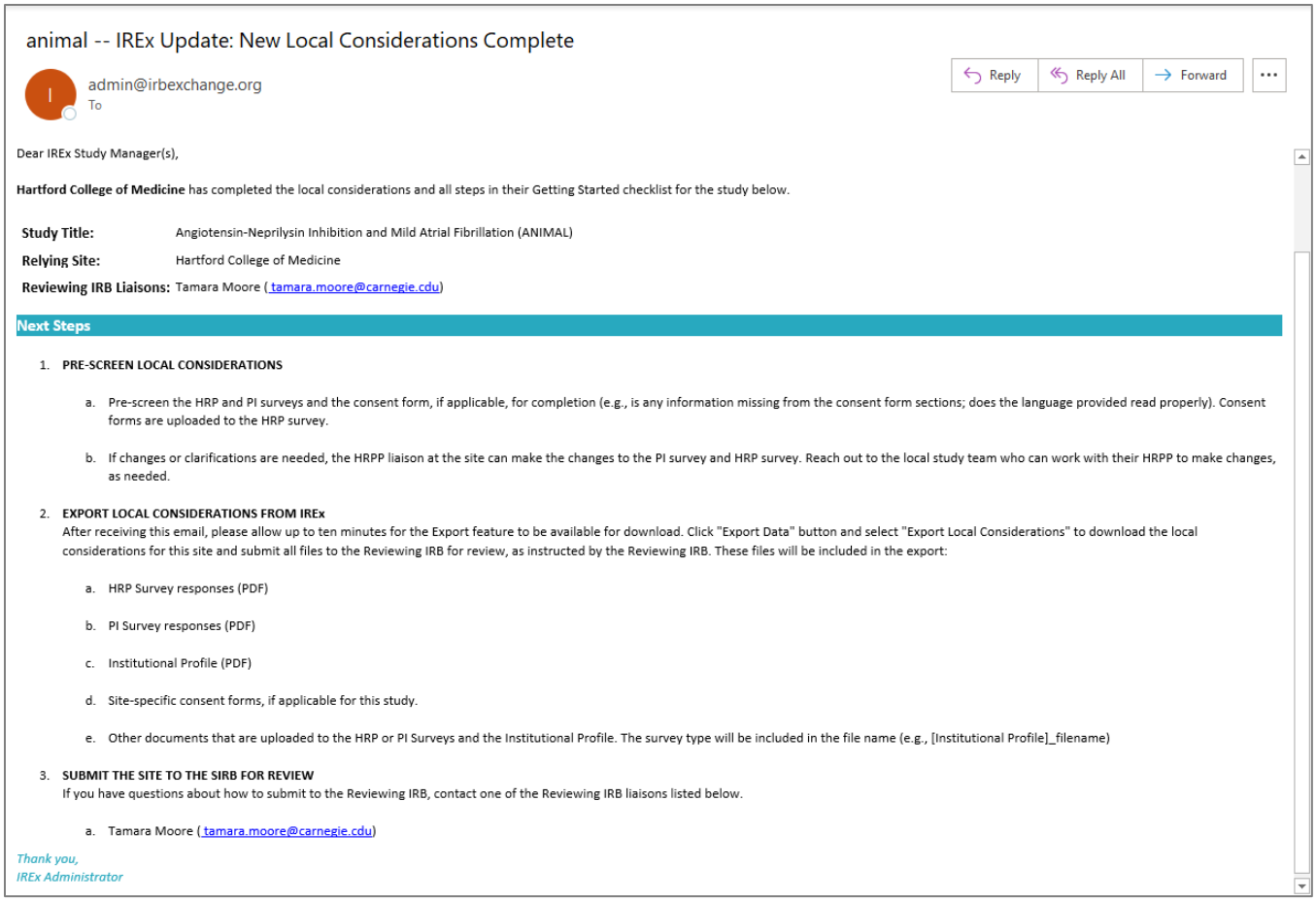
When using IREx to capture local considerations, each site has three components to complete:

1. Institutional Profile (IP): Each site HRPP completes an Institutional Profile (IP), one time. The IP captures site-specific information about the FWA, legal components, and over-arching state laws or institutional policies *that affect all research at the site.*
2. HRP Survey: **For each study**, the site's HRPP must complete the HRP Survey, communicating any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at their institution. This is also where the sites will upload the informed consent documents with their local site information for this study, if applicable.
3. PI Survey: **For each study**, site investigators are asked to complete a PI Survey where they provide information about the conduct of the study at their site and any procedures that differ from the protocol. This information must be verified by the site's HRPP.

The Status Summary shows how many elements are complete for each site. You can also click on any site's status to see what elements are complete and what is missing, if anything.

Generally, the Study Manager is expected to export the local considerations collected in IREx and submit them to the sIRB's IRB submission system on behalf of Sites. When a site's local considerations are completed, the Study Manager will receive an email with a link to the study.





animal -- IREx Update: New Local Considerations Complete

admin@irbexchange.org
To

Reply | Reply All | Forward

Dear IREx Study Manager(s),

Hartford College of Medicine has completed the local considerations and all steps in their Getting Started checklist for the study below.

Study Title: Angiotensin-Neprilysin Inhibition and Mild Atrial Fibrillation (ANIMAL)
Relying Site: Hartford College of Medicine
Reviewing IRB Liaisons: Tamara Moore (tamara.moore@carnegie.cdu)

Next Steps

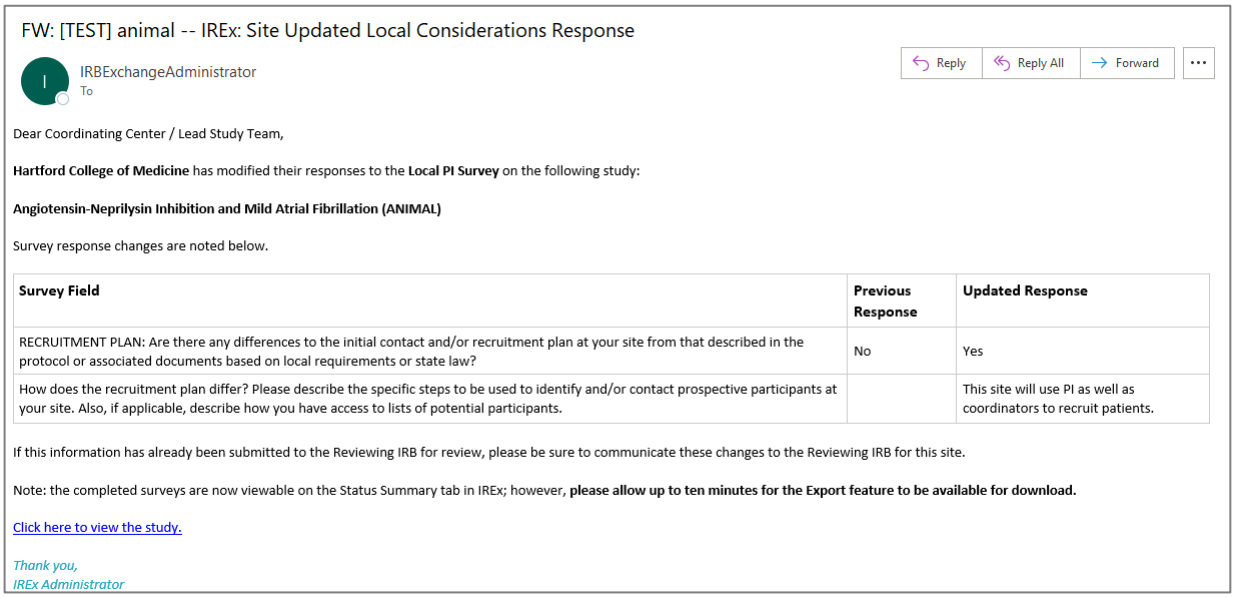
1. **PRE-SCREEN LOCAL CONSIDERATIONS**
   a. Pre-screen the HRP and PI surveys and the consent form, if applicable, for completion (e.g., is any information missing from the consent form sections; does the language provided read properly). Consent forms are uploaded to the HRP survey.
   b. If changes or clarifications are needed, the HRPP liaison at the site can make the changes to the PI survey and HRP survey. Reach out to the local study team who can work with their HRPP to make changes, as needed.
2. **EXPORT LOCAL CONSIDERATIONS FROM IREx**
   After receiving this email, please allow up to ten minutes for the Export feature to be available for download. Click "Export Data" button and select "Export Local Considerations" to download the local considerations for this site and submit all files to the Reviewing IRB for review, as instructed by the Reviewing IRB. These files will be included in the export:
   a. HRP Survey responses (PDF)
   b. PI Survey responses (PDF)
   c. Institutional Profile (PDF)
   d. Site-specific consent forms, if applicable for this study.
   e. Other documents that are uploaded to the HRP or PI Surveys and the Institutional Profile. The survey type will be included in the file name (e.g., [Institutional Profile]_filename)
3. **SUBMIT THE SITE TO THE SIRB FOR REVIEW**
   If you have questions about how to submit to the Reviewing IRB, contact one of the Reviewing IRB liaisons listed below.
   a. Tamara Moore (tamara.moore@carnegie.cdu)

Thank you,
IREx Administrator

Tip: The email indicates that the download may require a little extra time (5-10 minutes) before it is ready to download.

3.6.2 PARTICIPATING SITES EDITING LOCAL CONSIDERATIONS

Sites may edit Local Considerations after they are completed in case of additional information or clarifications. If the site's HRPP makes changes to the HRP Survey or the PI Survey after the local considerations are completed, the sIRB and Study Manager will receive an email notification. The email includes a detailed table outlining the changes that were made to each survey and notes that they may need to submit this updated information to the Reviewing IRB *if it had already been submitted.*



FW: [TEST] animal -- IREx: Site Updated Local Considerations Response

IRBExchangeAdministrator
To

Reply | Reply All | Forward | ...

Dear Coordinating Center / Lead Study Team,

Hartford College of Medicine has modified their responses to the **Local PI Survey** on the following study:

Angiotensin-Neprilysin Inhibition and Mild Atrial Fibrillation (ANIMAL)

Survey response changes are noted below.

Survey Field	Previous Response	Updated Response
RECRUITMENT PLAN: Are there any differences to the initial contact and/or recruitment plan at your site from that described in the protocol or associated documents based on local requirements or state law?	No	Yes
How does the recruitment plan differ? Please describe the specific steps to be used to identify and/or contact prospective participants at your site. Also, if applicable, describe how you have access to lists of potential participants.		This site will use PI as well as coordinators to recruit patients.

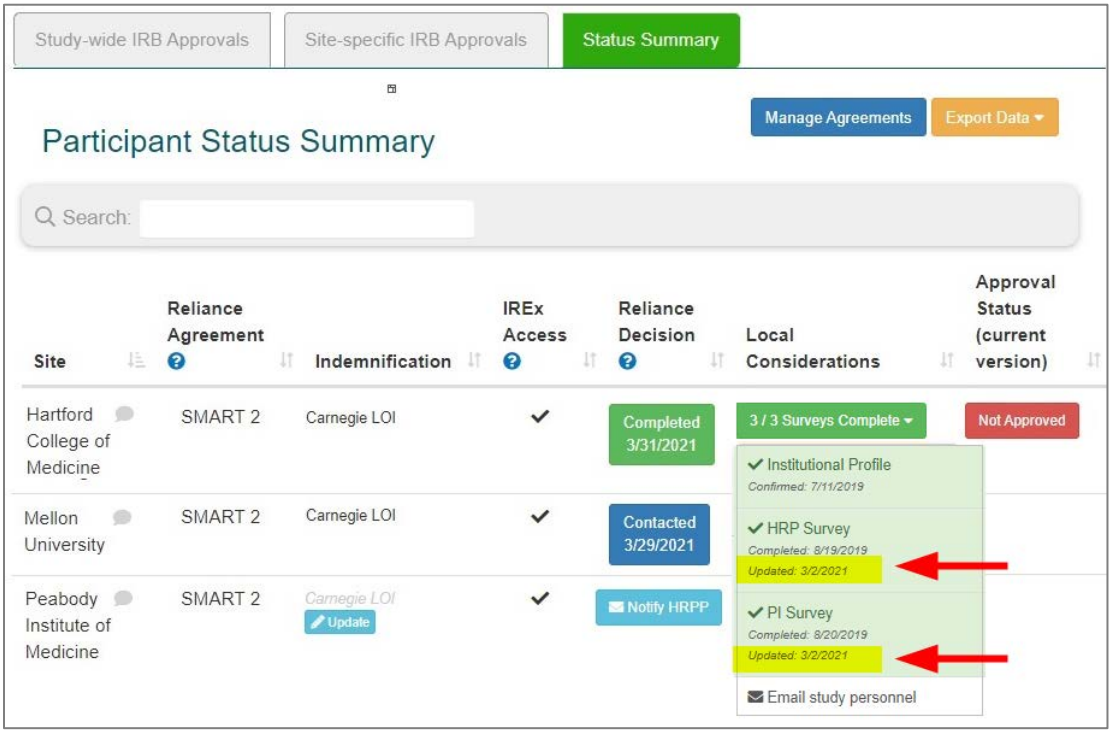
If this information has already been submitted to the Reviewing IRB for review, please be sure to communicate these changes to the Reviewing IRB for this site.

Note: the completed surveys are now viewable on the Status Summary tab in IREx; however, **please allow up to ten minutes for the Export feature to be available for download.**

Click here to view the study.

Thank you,
IREx Administrator

If an HRP or PI survey is edited by the participating site, the Local Considerations column on the Status Summary tab will reflect any of those dates.

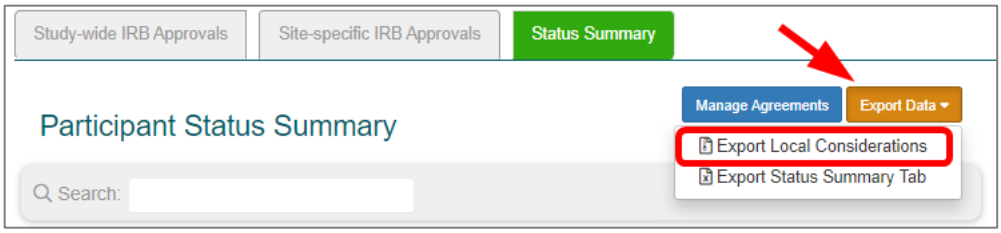


3.6.3 EXPORT LOCAL CONSIDERATIONS FROM PARTICIPATING SITES

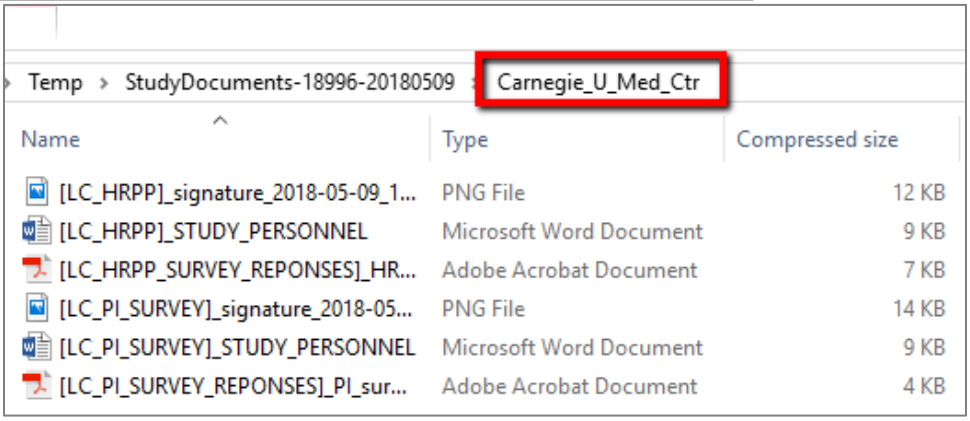
To Export the Local Considerations Information for a Participating Site:

1. Log in to IREx and access the study.
2. From the Status Summary tab, click on **Export Data.**
3. Select **Export Local Considerations** to download the information.

Tip: IREx downloads the information for all sites who are completed. You cannot download only one site at a time.



4. Click on the folder for the site(s) you need. The download will include a folder for each site who has local considerations in IREx, even if you already download it in a previous download.



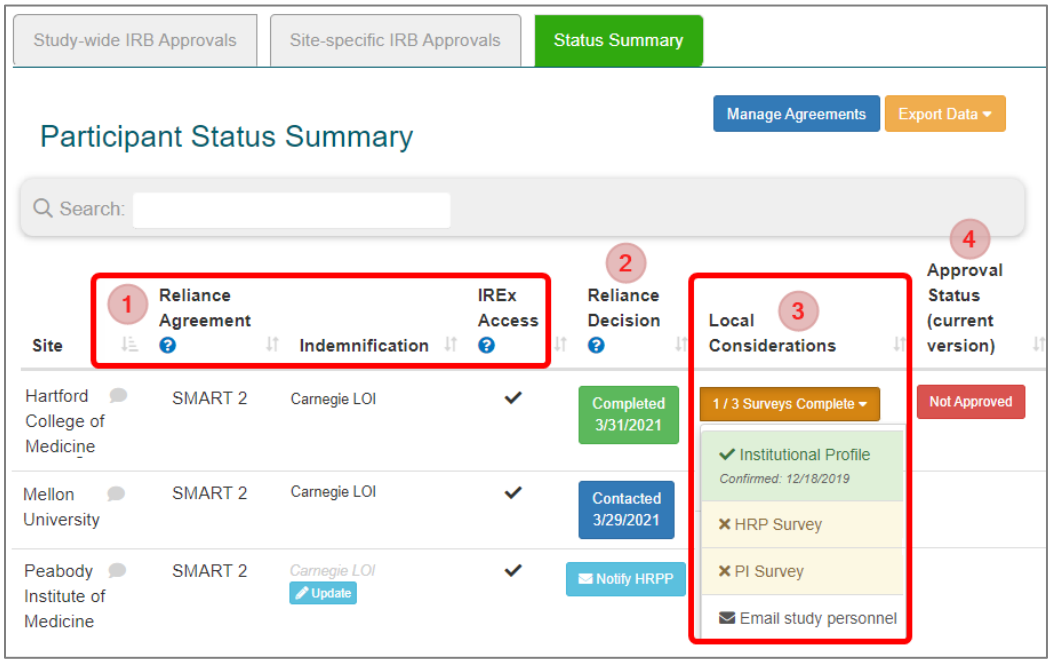
5. Save the files included in the folder, which will include:
   a. A PDF of the site's HRP Survey
   b. A PDF of the site's PI survey
   c. A PDF of the site's Institutional Profile
   d. Word and/or PDF copies of documents uploaded to the HRP and PI surveys (e.g., Site consent forms, if applicable, will be uploaded to the HRP Survey)
   e. Word and/or PDF copies of documents uploaded to the Site's Institutional Profile

Each file's name begins with the name of the local considerations element with which it is affiliated:

- LC_HRPP = Local Considerations Survey (completed by the HRPP)
- LC_PI_SURVEY = PI Survey
- INSTITUTIONAL_PROFILE

3.7 TRACK SITES' PROGRESS ON THE STATUS SUMMARY TAB

Click the blue chat button beside a site to document any communications you have had with the site, as needed. Comments are only visible to the Reviewing IRB Liaisons and Study Managers on that study and no notifications are generated by entering comments.



1 **Is the Participating Site signed onto the required platforms?**

Institution-level agreements are required to use a sIRB. The system tracks site sign-on to the following:

- ❒ **Reliance Agreement:** This column indicates which reliance agreement has been signed.
- ❒ **Indemnification** (column shown if applicable): Indemnification name appears in bold if signed by a site
- ❒ **IREx Access***:* A check indicates the site is a member of IREx. If not, their HRPP/IRB Director can create their access here.

2 **Has the Participating Site's HRPP made a reliance decision?**

NOTE: MANY HRPPS WILL NOT INDICATE RELIANCE UNTIL THEY HAVE A SUBMISSION FROM THEIR LOCAL STUDY TEAM.

- ❒ Incomplete = the HRPP cannot be contacted because they are not members of IREx yet.
- ❒ **Add PI Info** = add missing PI email & name
- ❒ Notify HRPP = site has not been contacted yet and does not have access to the study.
- ❒ Contacted = date the *"IREx study at your site"* notification was sent.
- ❒ Started = date the HRPP first accessed the study.
- ❒ Completed = date the HRPP indicated reliance.

3 **Has the Participating Site's HRPP and PI completed the local considerations, if applicable?**

A sIRB may use IREx to capture the information it needs to review for each site. The three components of local considerations can be completed concurrently:

1. **Institutional Profile**: Completed by the HRPP, this includes institutional-level information about the Participating Site.
2. **HRP Survey:** Completed by the HRPP, this includes applicable local requirements for this study at the Participating Site.
3. **PI Survey:** Completed by the PI, this includes information about the Participating Site's conduct of the study. NOTE: THIS SURVEY REQUIRES SIGN OFF BY THE HRPP. IREX EMAILS THE SITE'S HRPP LIAISON WHEN THE PI SURVEY IS READY FOR REVIEW.

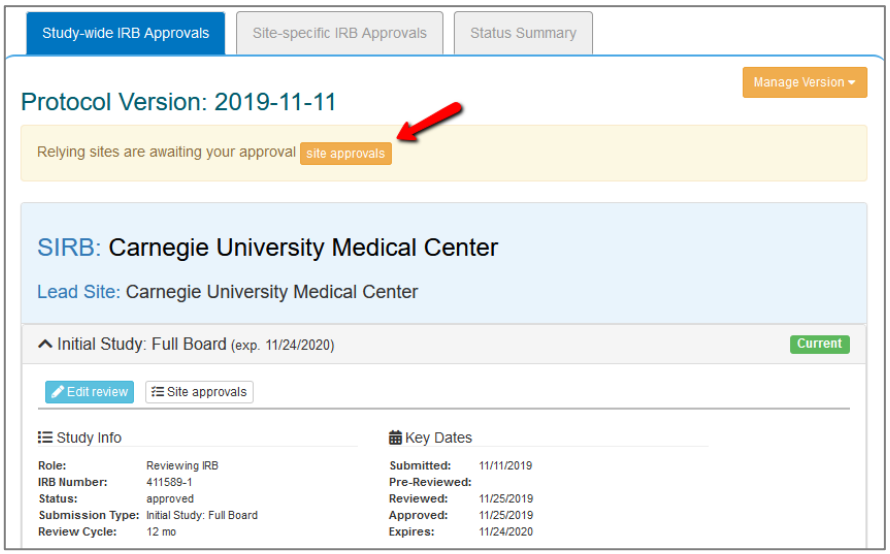
4 **Has the site received approval from the sIRB?**

Sites that have been approved by the sIRB will be listed as Approved on the Status Summary tab, have an expiration date in the versions box, and be available for viewing on the Site-specific IRB Approvals tab.

4.0 UPLOADING INITIAL APPROVAL FOR PARTICIPATING SITES

Once you have uploaded the initial approval for the Lead Site, you can add approvals for sites who have ceded review.

Tip: The first approval uploaded for a site is always their "initial" approval, even if they come on board long after the study was initially approved. For example, you may upload a site's initial approval when uploading a study-wide amendment.

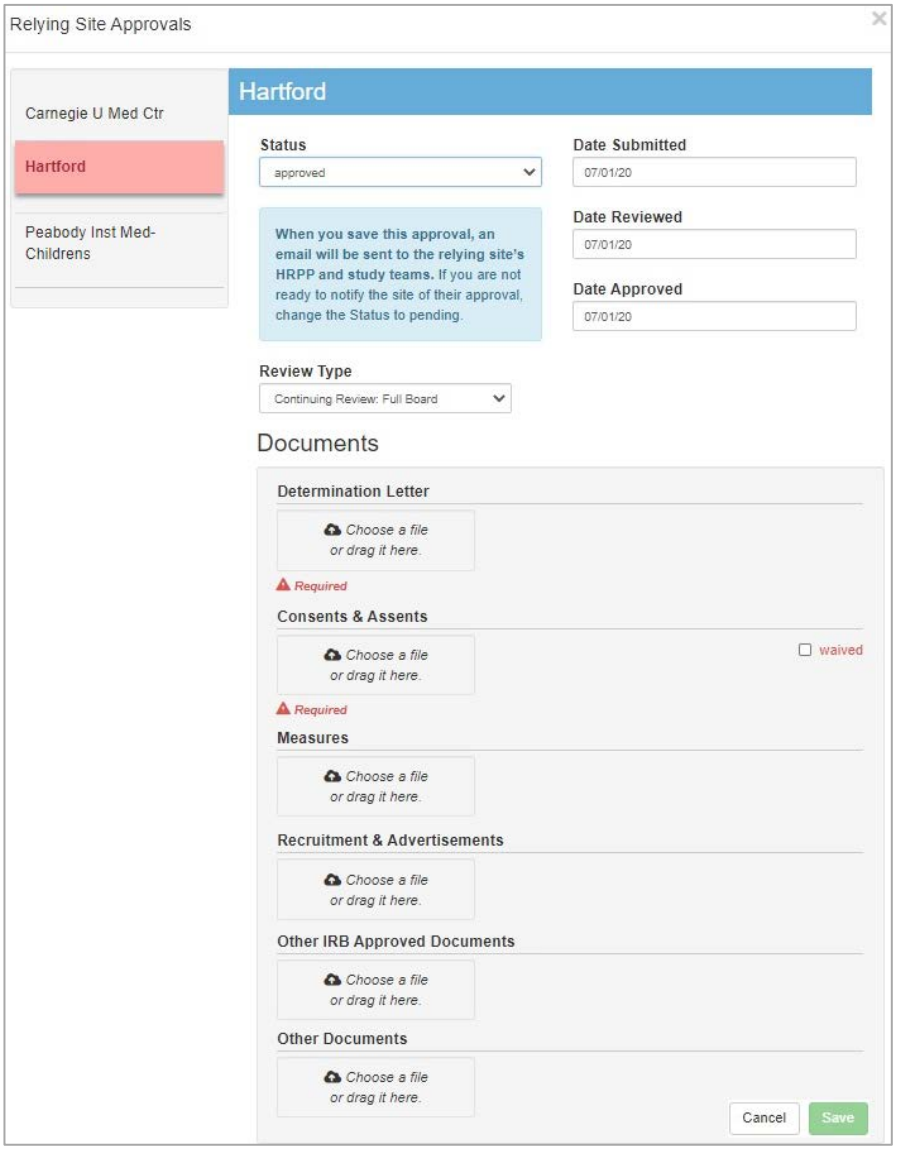


<u>To Upload Sites' Initial Approvals:</u>

1. Click on the **site approvals** icon on the Study-wide IRB Approvals tab or select the **site approvals** icon from the **Manage Version** menu. You can upload approvals for more than one site, at once.

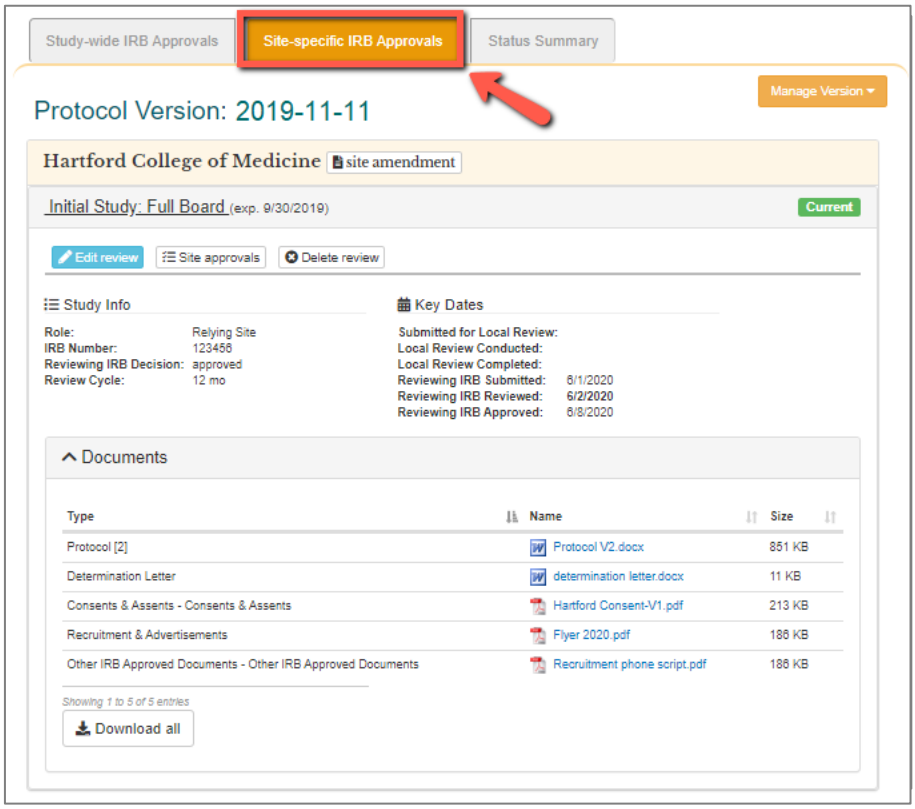
   Tip: Sites that need approval will appear towards the top of the list. Sites that have a check mark already have approval.

2. A pop-up will appear with a list of Sites who have ceded review. Click on the name of the site for which you are uploading approval.
3. Change the **Status** to *approved*. All the required fields will be indicated in red.
4. Enter the **Review Type** (*Expedited* or *Full Board*) required **Dates** as received from the sIRB.
5. Upload the **Determination Letter, Consent Form(s),** and any **other** site-specific documents (e.g., recruitment materials).
6. You can either save one site at a time or select another site for which you want to upload approval and save when you have uploaded all desired approvals. All sites do not have to have approval to save the information

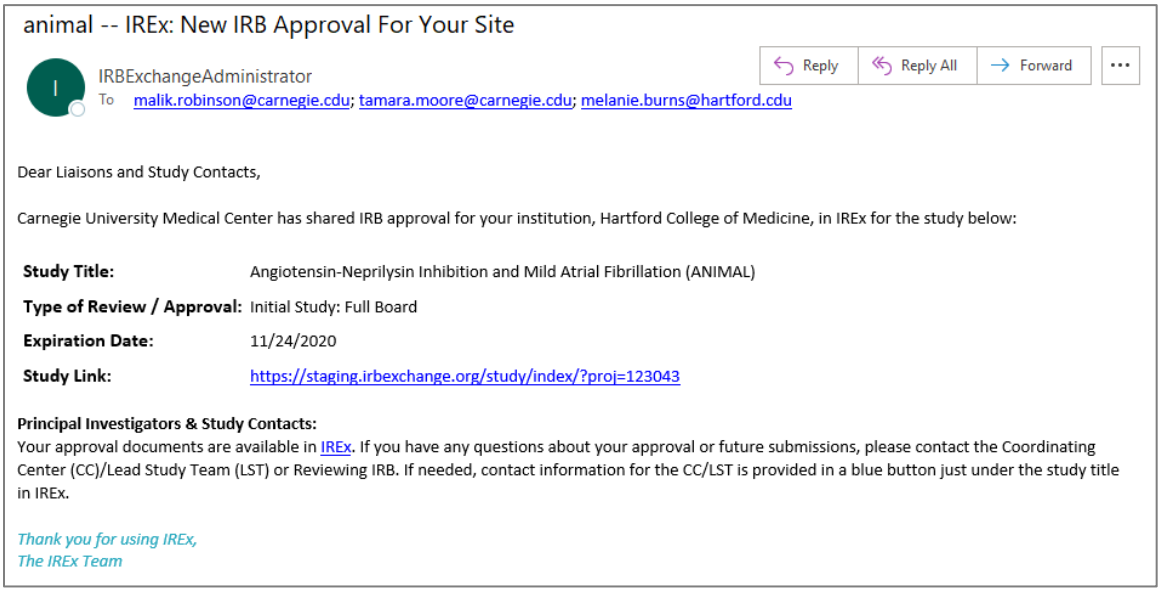


Tip: If a site is highlighted RED, that means there is an error and information has not been entered in a required field. You can either (1) Enter the required information or (2) Change the approval status to *Pending* or blank if you would like to upload the approval later.

7. Once you upload and save an approval for a site, the following happens:
   a. The site approval documents and information will be added to the Site-specific IRB Approvals tab for that site.



   b. An email notification indicating the sIRB has approved their site will be sent to the (1) the sIRB Liaisons, (2) Site Liaison(s), and (3) the site study contacts that are listed in IREx, at minimum this will include the PI.



   c. The approval letter, site-specific consent form and other study approved documents will be available for download on the study page.

5.0 ADD A CONTINUING REVIEW APPROVAL

IREx can be used to document and communicate the Continuing Review approval for participating sites. However, IREx does not currently capture the information the Reviewing IRB needs to conduct the Continuing Review for participating sites. This information must be captured outside of IREx. Uploading Continuing Reviews in IREx has three steps:

STEP A
Create the Continuing Review in IREx

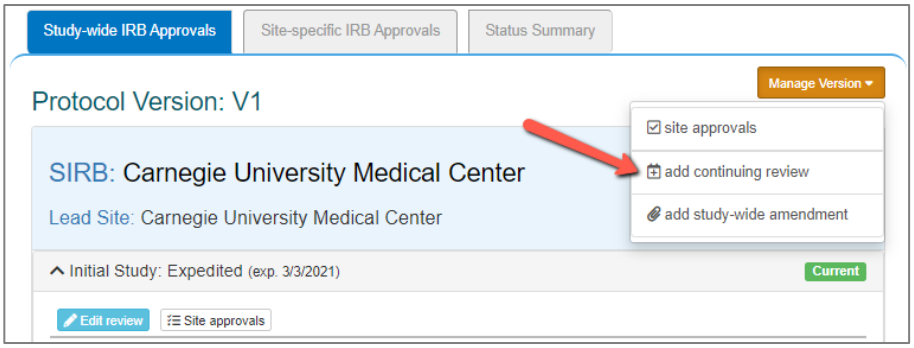
STEP B
Upload approval for the lead site / overall study

STEP C
Upload approval for relying sites

Note: Steps B and C are separate because the newly stamped consents must be uploaded for each site. However, IREx auto-fills the relevant review dates and determination letter for sites, based on those entered for the Lead Site/Overall Study.

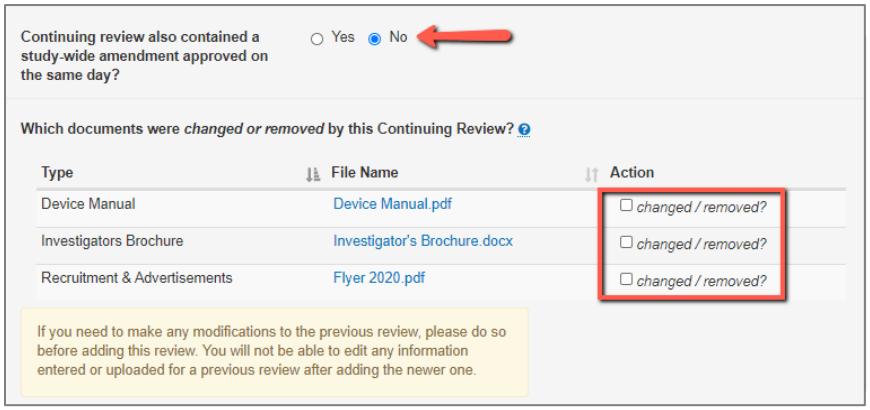
STEP A: CREATE THE CONTINUING REVIEW FOR THE STUDY

The Reviewing IRB Liaison or IREx Study Manager (if permitted by the Reviewing IRB) must first create the Continuing Review for the study and upload the Continuing Review approval for the Lead Site or Overall study. Then, Continuing Review approvals can be uploaded for relying sites (see Step C).



1. On the Study-wide IRB Approvals tab, click the orange **Manage Version** button and select **add continuing review**.

2. In the Add Continuing Review dialog, indicate whether the Continuing review also contained a study-wide amendment approved on the same day – Yes/No. If Yes, provide the required information about whether the protocol was changed and a change summary.



3. Select the ***documents that were changed or removed*** by this Continuing Review. These documents will remain in archived versions, but you should delete any that are no longer part of the currently approved set of documents.

Tip: Previously approved consents will be automatically removed. You can upload the newly stamped consents and new documents in the steps ahead.

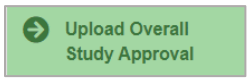
4. Click **Save** to create the Continuing Review. This will add steps to your GETTING STARTED checklist where you finish uploading the approval for the overall study.

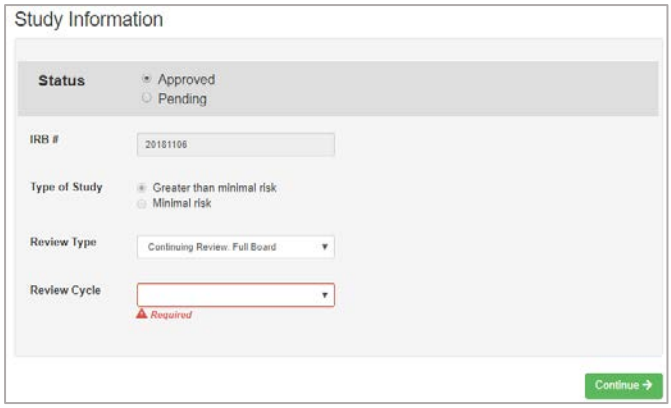
Tip: On the Status Summary tab, sites' approval status will change to "Not Approved" until their continuing review approval is uploaded in Step C.

The continuing review has been created. You can now upload the approval for the lead site/ overall study.

STEP B: UPLOADING CONTINUING REVIEW APPROVALS FOR THE OVERALL STUDY

1. Click the **Upload Overall Study Approval** step on the GETTING STARTED checklist to upload the Lead Site/Overall approval.

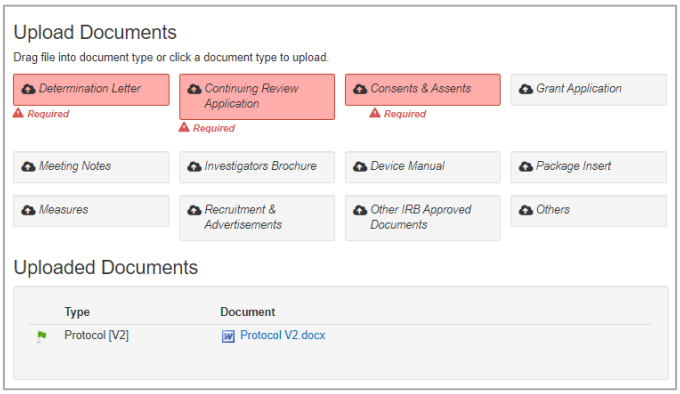




2. In the dialog under Study Information:
   a. Set the Status to **Approved.**
   b. Ensure the correct **Review Type** (***Expedited or Full Board***) is selected.
   c. Enter the **Review Cycle** and click **Continue**.

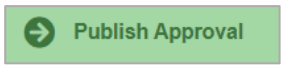
3. Enter the Key Review dates when the Continuing Review was **Submitted, Pre-Review was Completed, Reviewed,** and **Approved** and **Continue**.

4. Upload the new **Determination Letter**, the **Continuing Review Application**, the newly stamped **Consent & Assents** and any other new or updated documents for the <u>lead site only</u>. Required documents will be marked in red.



5. Review the study information and click **Save**. If required fields are missing, the section will be highlighted.

6. To make the documents visible to relying sites, click **Publish Approval** on the GETTING STARTED checklist.

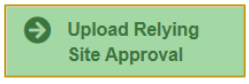


Tip: Relying sites are not notified of the new Continuing Review approval – they are notified of approval when their site-specific approval documents are uploaded in Step C.

STEP C: UPLOADING CONTINUING REVIEW APPROVALS FOR RELYING SITES

AFTER the Continuing Review Approval has been uploaded for the Lead Site or Overall study, sites' approvals can be added.

1. Click on the **site approvals** button on the Study-wide IRB Approvals tab. Study Managers can also click the **Uploading Relying Site Approvals** step on their GETTING STARTED checklist.



2. In the Relying Site Approvals dialog, select the **name of the site** for which you are uploading approval.

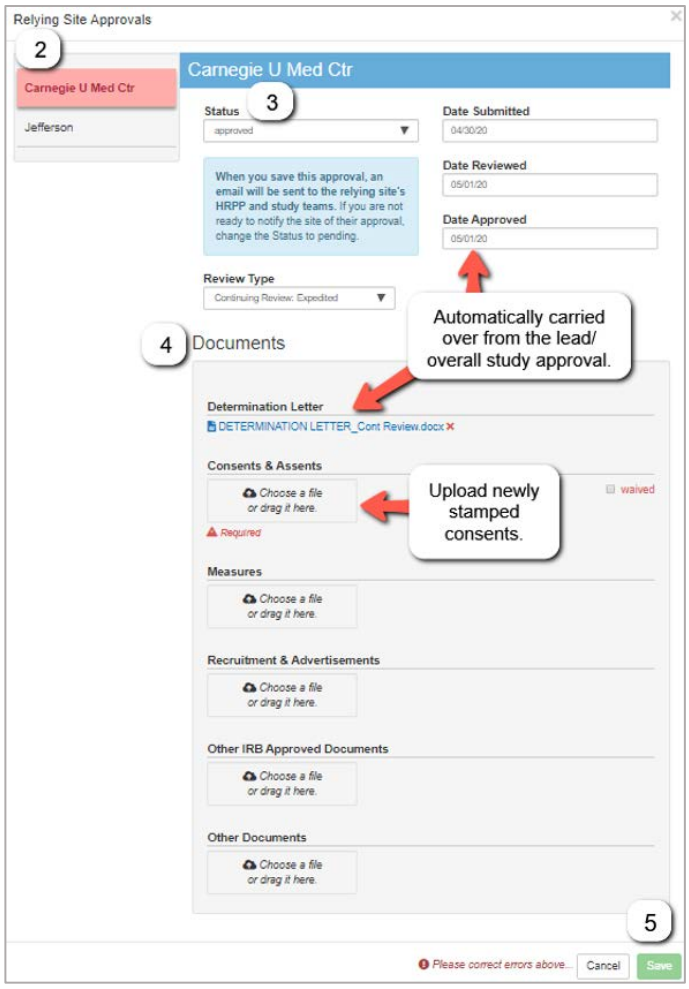
   All sites who have ceded review appear, but only sites approved on the previous version will have a review type of Continuing Review: Full/Expedited.

3. Change the Status to **approved** and ensure the correct **Review Type** is selected.

   The dates and determination letter from the overall study approval will be auto-populated for all sites that had approval on the previous version. Other site-specific documents that were approved in the previous version will also be carried forward. Please verify that these documents are still part of the approved set of documents.

4. Upload the new consent forms (or indicate a waiver was approved) and ensure the correct versions of all other approved documents are listed for the site.

5. Click **Save**. IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREX Study Manager(s), and (4) site study contacts in IREx of the new approval. The documents will appear on the Site-specific IRB Approvals tab.



ADDITIONAL TIPS:

- You can upload approvals for more than one site at once by selecting another site name and complete steps 2-4 before saving.
- To save information without notifying a site, change the approval status to *pending* or *leave blank*. You can return later to complete the approval.

6.0 ADD STUDY-WIDE AMENDMENTS

IREx can be used to document and communicate the approval of amendments to participating sites. Study-wide amendments include changes to the protocol or other study materials that apply to ALL sites. A site-specific amendment (see section 7.0) is used to upload an approved change for an already approved site, not the initial approval. Each Study-wide amendment has three steps to be complete:

STEP A
Create the Amendment in IREx

→

STEP B
Upload approval for the lead site / overall study

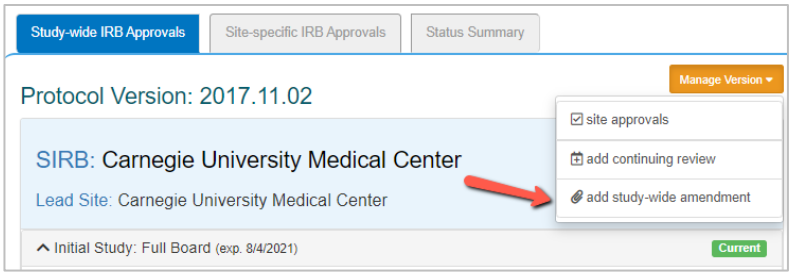
→

STEP C
Upload approvals for relying sites

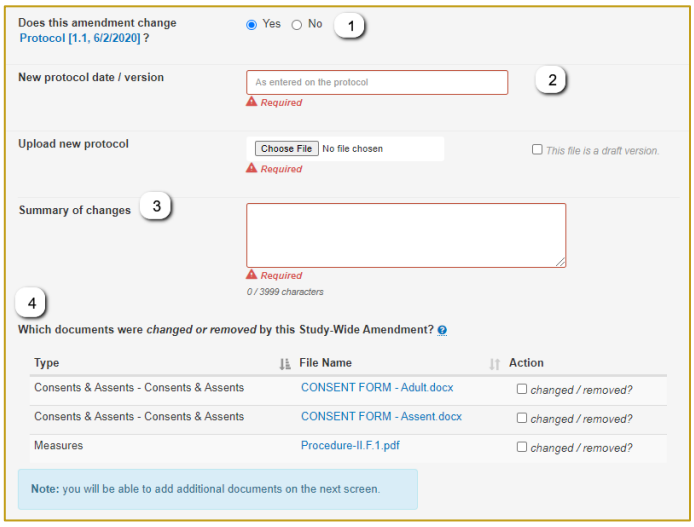
STEP A: CREATE THE STUDY WIDE AMENDMENT FOR THE LEAD SITE/OVERALL STUDY

The Reviewing IRB Liaison or IREx Study Manager (if permitted by the Reviewing IRB) must create the Study-wide Amendment & upload approval for the Lead Site or Overall Study before relying site approvals can be uploaded (Step C).

1. On the Study-wide IRB Approvals tab, click **Manage Version** and select **add study-wide amendment**.



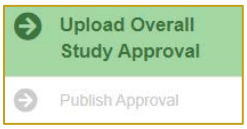
2. In the Add Study-wide Amendment dialog, indicate whether the amendment changes the current version of the protocol.
   a. If **Yes**, enter the **New protocol date/version** and **Upload the new protocol** version.
   b. If the amendment does not change the protocol version, select **No**. IREx will add a revision number (e.g., Rev. 1) to the current version to indicate changes were made, but the protocol version stayed the same.



3. Enter a **Summary of changes**. Tip: We recommend including the amendment # at the beginning of the change summary as a reference for sites.

4. Select the documents that were changed or removed by this Amendment. These documents will remain in archived versions, but you should delete any that are no longer part of the currently approved set of documents. If the consent forms were changed, select "changed / remove" so the old versions are not carried forward. You will have an opportunity to upload new documents in the steps ahead.

5. Click **Save** to create the Study-wide Amendment. This will add steps to your GETTING STARTED checklist where you can finish uploading the approval for the overall study.

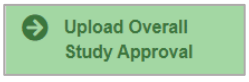


Tip: On the Status Summary tab, **sites' approval status will change to "Not Approved"** until their Study-wide Amendment approval is uploaded in Step C.

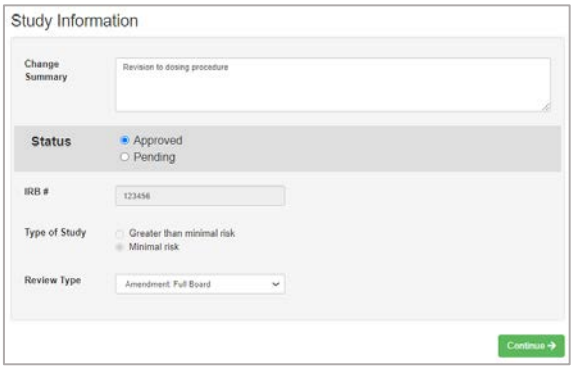
The amendment has been created. You can now upload the approval for the lead site/overall study.

STEP B: UPLOAD STUDY-WIDE AMENDMENT APPROVAL FOR THE LEAD SITE/OVERALL STUDY

1) Click the **Upload Overall Study Approval** step on the GETTING STARTED checklist to upload the Lead Site/Overall approval.

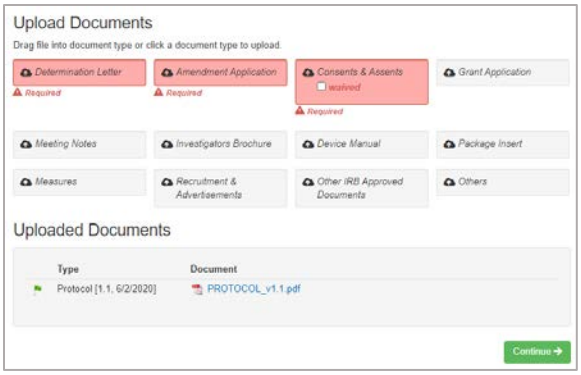


2) In the dialog, under Study Information:
   a. Set the Status to **Approved.**
   b. Ensure the correct **Review Type** (*Expedited or Full Board*) is selected and click **Continue.**



3) Enter the Key Dates when Amendment was **Submitted, Pre-Review was Completed, Reviewed,** and **Approved** and **Continue**.

4) Upload the new **Determination Letter**, **Amendment Application**, and any other new or updated documents for the lead site only and click **Continue**.
5) Review the study information and click **Save**. If required fields are missing, the section will be highlighted.
6) To make the documents visible to relying sites, click **Publish Approval** on the GETTING STARTED checklist.



Tip: Relying sites are not notified of the new Study-wide Approval – sites are notified of approval when their site-specific approval documents are uploaded in the next section in Step C.

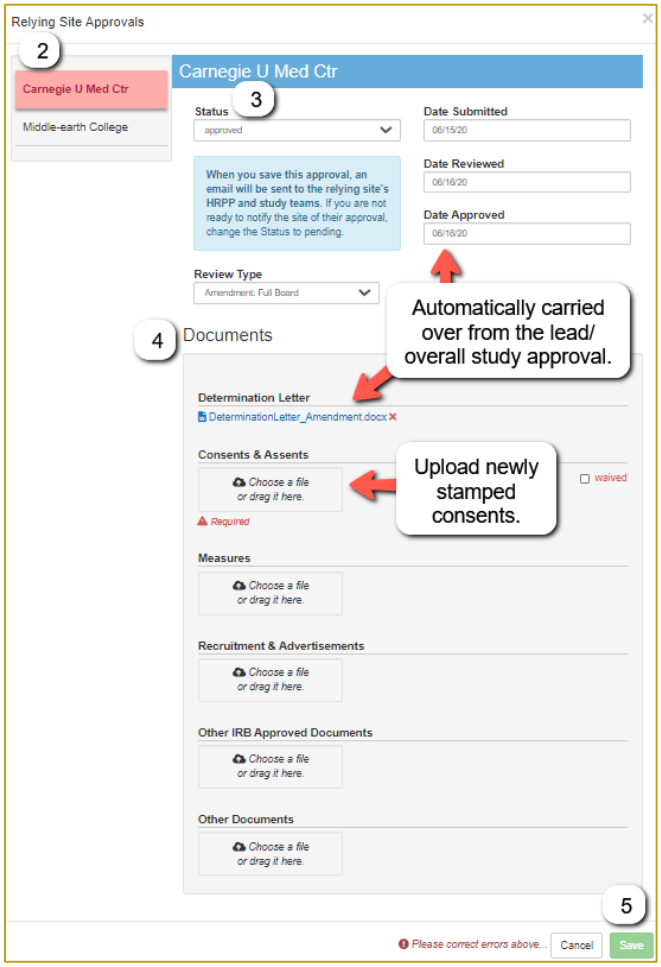
STEP C: UPLOADING STUDY-WIDE AMENDMENT APPROVALS FOR THE PARTICIPATING SITES

AFTER the Study-wide Amendment has been uploaded for the Lead Site or Overall Study, site approvals can be added.

1. Click on the **site approvals** button on the Study-wide IRB Approvals tab. Study Managers can also click the **Uploading Relying Site Approvals** step on their GETTING STARTED checklist.

Upload Relying Site Approval

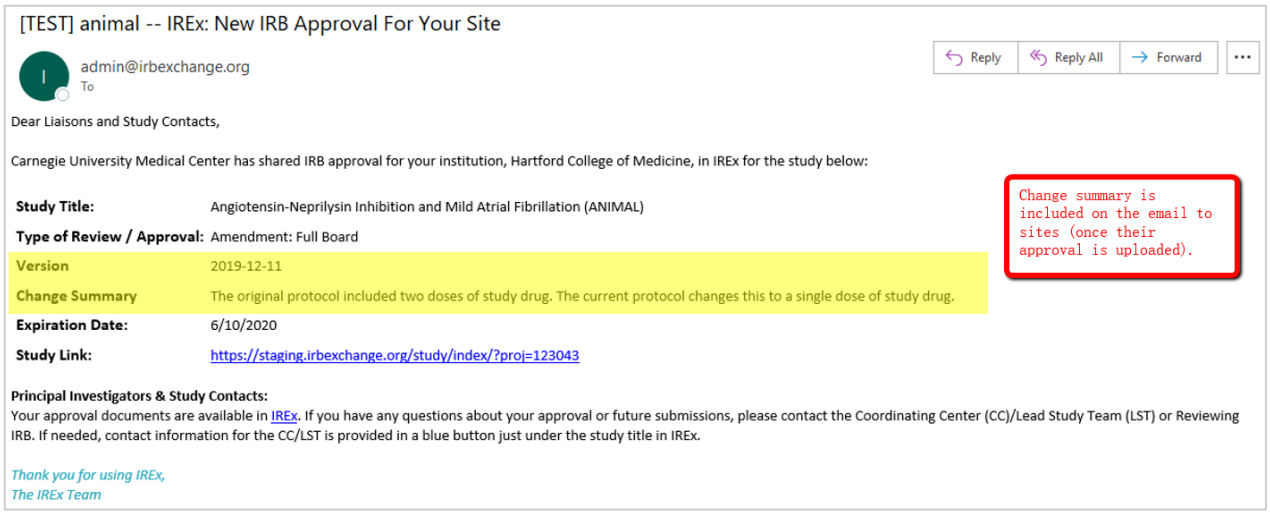
2. In the Relying Site Approvals dialog, select the **name of the site** for which you are uploading approval.
   All sites who have ceded review appear in the Relying Site Approvals dialog, but only sites approved on the previous version will have a have a review type of Amendment: Full/Expedited.
3. Change the Status to **approved** and ensure the correct **Review Type** is selected.
   The dates and determination letter from the overall study approval will be auto-populated for all sites that had approval on the previous version. Other site-specific documents that were approved in the previous version will also be carried forward. Please verify that these documents are still part of the approved set of documents.
4. Upload any new/revised documents and ensure the correct versions of all other approved documents are listed for the site. If consents or other documents changed, delete, and upload new versions.



ADDITIONAL TIPS:

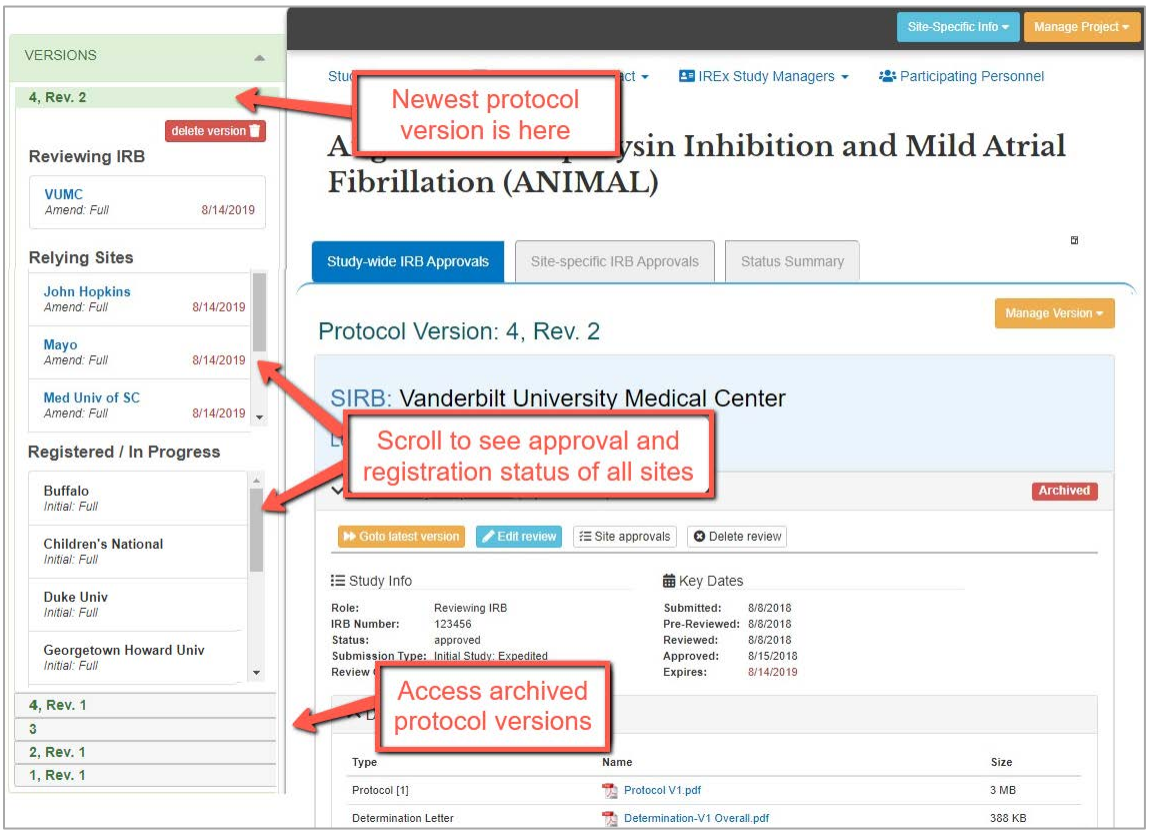
- You can upload approvals for more than one site at once by selecting another site name and complete steps 2-4 before saving.
- To save information without notifying a site, change the approval status to *pending* or *leave blank*. You can return later to complete the approval.

5. Click **Save**. IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREX Study Manager(s), and (4) site study contacts in IREx of the new approval. The documents will appear on the Site-specific IRB Approvals tab.



6. The new version will be listed in blue at the top of the Study-wide IRB Approvals tab AND in the VERSIONS box on the left side of the page.

Tip: If the study-wide amendment **did not change the protocol**, a Revision # is placed beside the protocol # to distinguish it from the previous approval. If the study-wide amendment **changed the protocol**, the new protocol version/date will appear in the versions box.



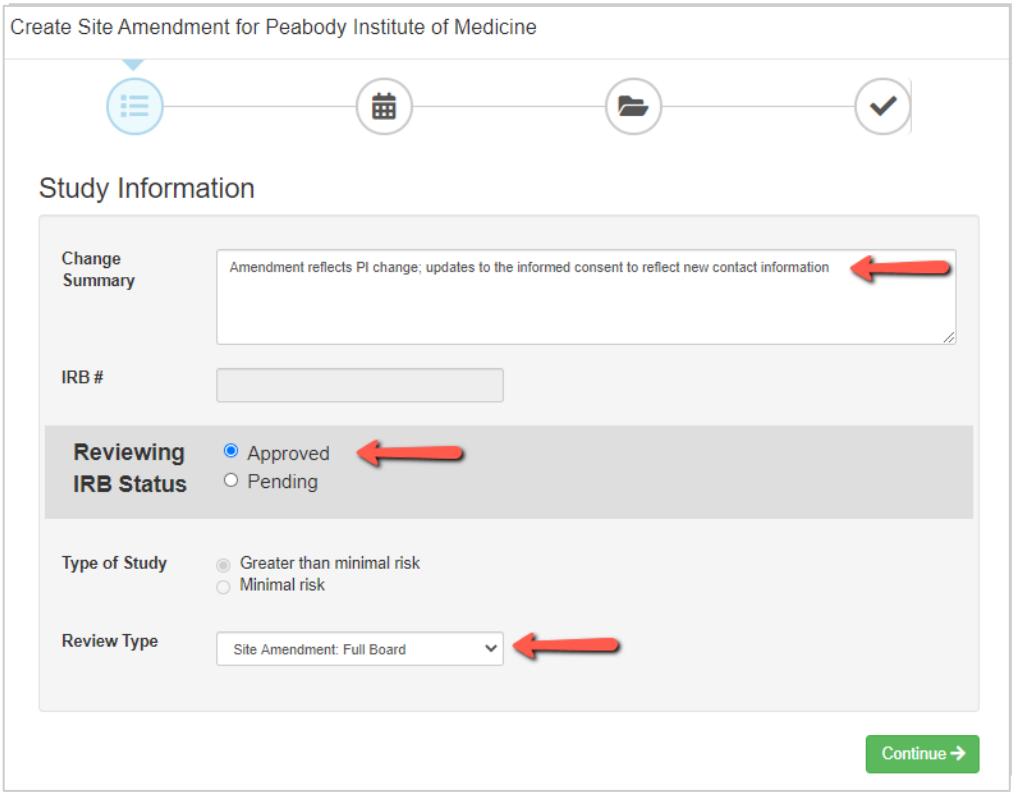
7.0 ADD A SITE-SPECIFIC AMENDMENT

A **site-specific amendment** is used to upload changes to a single, approved site, such as a PI change. Unlike study-wide amendments, site-specific amendments do not require an approval to be uploaded for the Lead Site first because the change does not affect the Lead Site or Overall Study. For this reason, the IREx study manager (or Reviewing IRB) can upload the approval. The sIRB or Study Manager can upload site-specific approvals.

To Add a Site-specific Amendment for a Site:

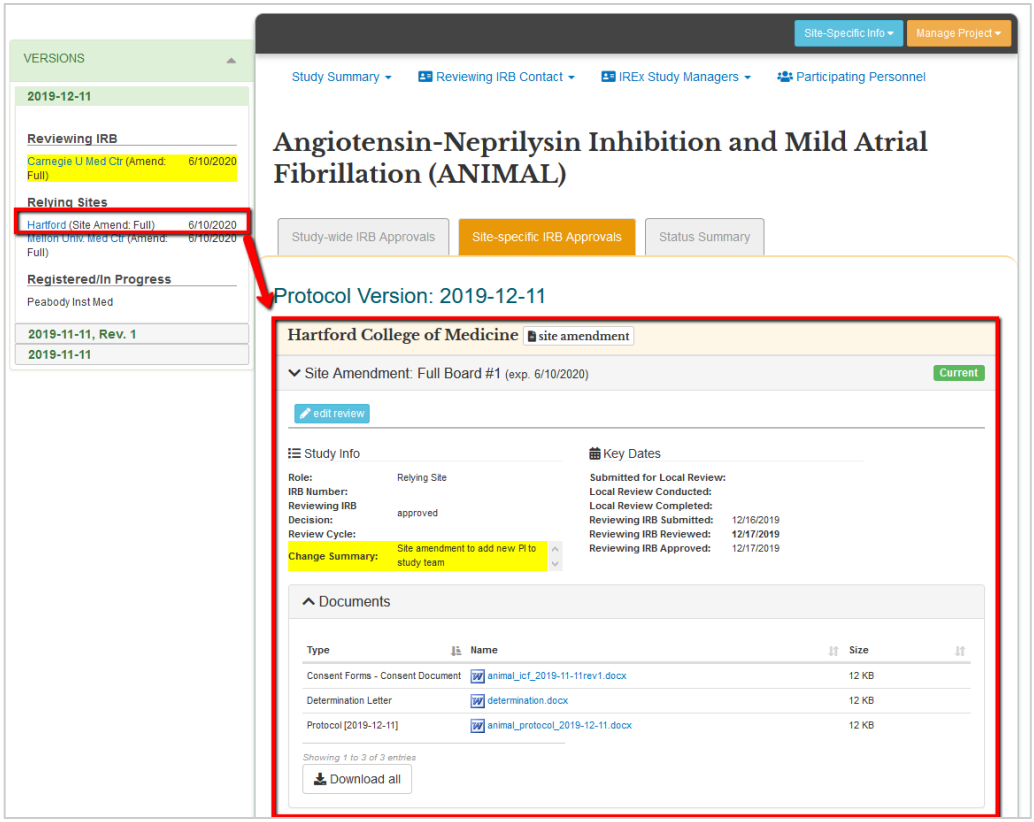
1. Click on the **Site-specific IRB Approvals** tab.
2. Find the site that has a change and click on the **site amendment** button beside the site's name.

3. In the Create Site Amendment dialog,
   a. Enter a **Change Summary**;
   b. Change the Reviewing IRB Status to **approved**; and
   c. Select the appropriate **Review Type**.
   d. Click **Continue** to enter the *dates of submission, review* and *approval*.
   e. Click **Continue** to upload any updated documents and remove any documents that are no longer current.
   f. Click **Save.**

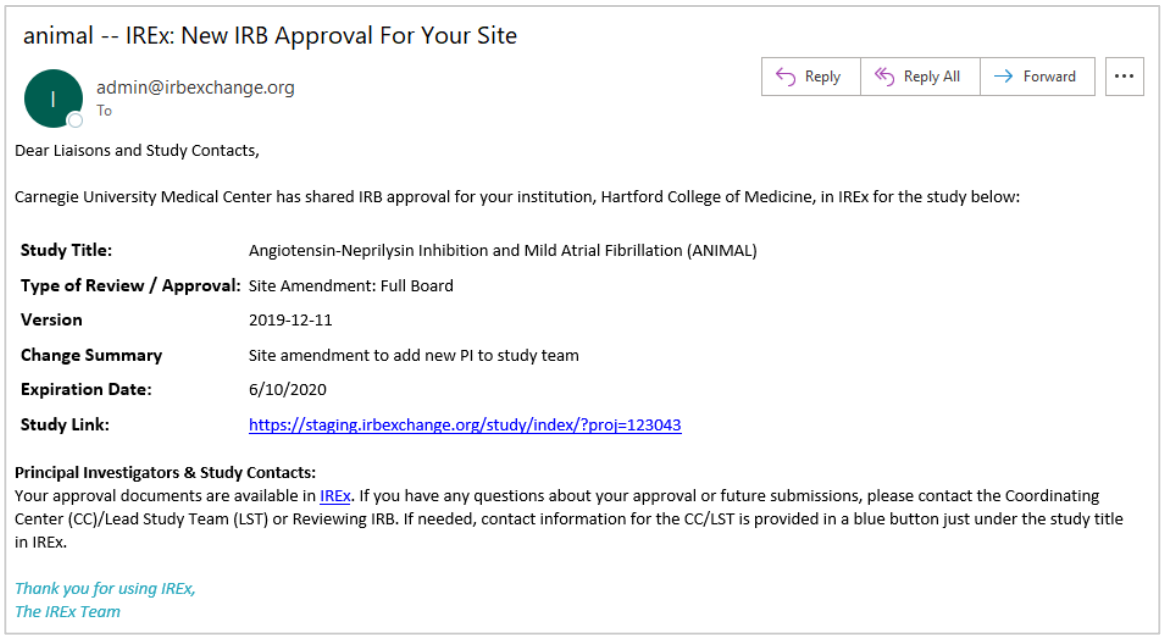


Once you upload and save an approval for a site, the following happens:

   a. The amendment will be listed in the site's review information on Site-specific IRB Approvals Tab AND in the "VERSIONS" box on the left side of the page.



b. IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREX Study Manager (s), and (4) site study contacts in IREx of the new approval. The documents will appear on the Site-specific IRB Approvals tab.



animal -- IREx: New IRB Approval For Your Site

admin@irbexchange.org
To

Reply | Reply All | Forward

Dear Liaisons and Study Contacts,

Carnegie University Medical Center has shared IRB approval for your institution, Hartford College of Medicine, in IREx for the study below:

Study Title:	Angiotensin-Neprilysin Inhibition and Mild Atrial Fibrillation (ANIMAL)
Type of Review / Approval:	Site Amendment: Full Board
Version	2019-12-11
Change Summary	Site amendment to add new PI to study team
Expiration Date:	6/10/2020
Study Link:	https://staging.irbexchange.org/study/index/?proj=123043

Principal Investigators & Study Contacts:
Your approval documents are available in IREx. If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

Thank you for using IREx,
The IREx Team