IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

# USING IREx AS THE REVIEWING/SINGLE IRB

IREx can be used to capture all single IRB (sIRB) documentation (e.g., cede decisions, local considerations, sIRB approvals) and coordinate communications between the sIRB and site study teams and HRPPs. See how to get started below.

# Table of Contents

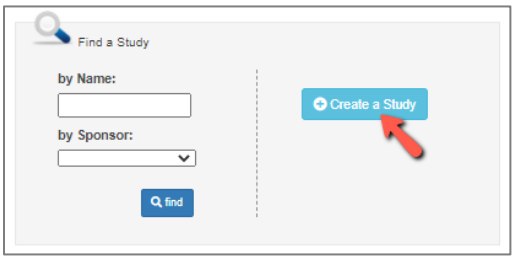
**CONSIDERATIONS BEFORE CREATING A STUDY IN IREx** ..... 1
**CREATE THE STUDY IN IREx** ..... 2
**COMPLETE THE IREx SETUP** ..... 2
**CONFIRM PRIMARY STUDY CONTACTS** ..... 4
**CONFIRM THE STUDY-SPECIFIC RELIANCE PLAN (SSRP)** ..... 4
**CONFIRM STUDY ELEMENTS *(Only Available if Collecting Local Considerations in IREx)*** ..... 4
**UPLOAD OVERALL STUDY APPROVAL** ..... 5
**PUBLISH APPROVAL** ..... 5
**ADD PARTICIPATING SITES** ..... 5
**TRACK SITES' AGREEMENTS (sIRB ONLY)** ..... 6
**ADDITIONAL RESOURCES** ..... 7

## CONSIDERATIONS BEFORE CREATING A STUDY IN IREx

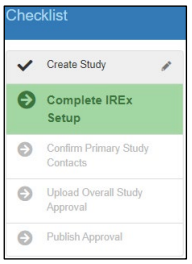
1. **Complete** or update your institution's IREx Institutional Profile (see Quick Guide)
2. **Review** the IREx Single IRB Instructions Template for participating sites
3. **Educate** the lead study team or coordinating center staff ("IREx Study Manager") on your sIRB processes, such as:
    - Required sIRB-related agreements
    - Process for managing consent forms (e.g., whether a template is being used)
    - Process for capturing local considerations from sites (e.g., via IREx surveys; including if the study will be requesting updates to local considerations after study-wide amendments)
    - Process for submitting sites for review (e.g., as an amendment, as a site add)
    - **IREx Tip:** Because you're using IREx to document cede decisions, local considerations, and site approvals, Lead Study Teams do not need to submit the study on the SMART Online Reliance System. Doing so can create confusion and duplication.
4. **Delegate** IREx responsibilities to the lead study team/coordinating center (see Study Manager Quick Guide). The Reviewing IRB can also complete these tasks in IREx, if needed.
    - Upload Initial Approval for the Overall Study/Lead Site & Publish Approval
    - Add or remove participating sites; Notify & Grant study access to participating HRPP and study teams
    - Export participating sites' reliance and local review documentation for submission to the sIRB
    - Upload sIRB approvals for participating sites
    - Manage study-wide amendments and continuing review

## CREATE THE STUDY IN IREx

Studies are typically created after you receive the submission from the lead site. You do not have to wait for the overall study to be approved before creating the study in IREx.



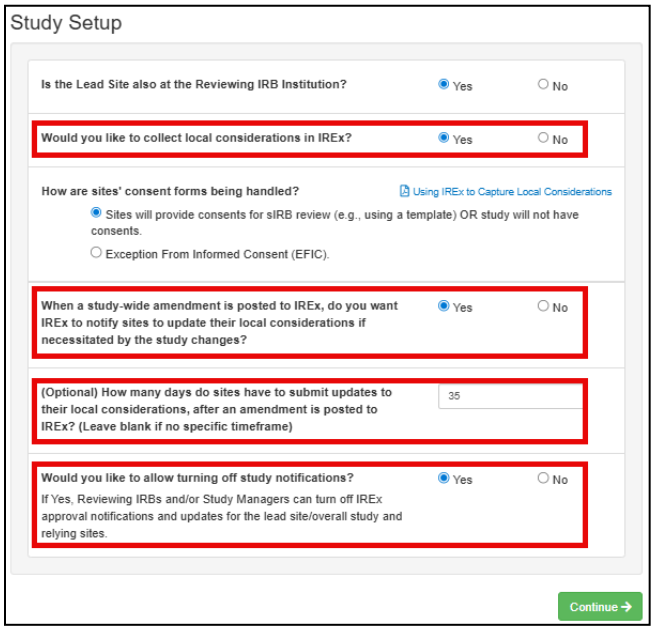

1. Login to IREx and click **Create a Study** on the main homepage.
   A. Enter basic study information like the title, study summary, NCT #, sponsor and click **Continue**.
   B. Enter the protocol date/ version and upload key study documents (e.g., protocol) and click **Continue**.
   **IREx Tip:** Document(s) uploaded here can be changed later when uploading the initial study approval.
   C. Review and Submit; click **Save**.




After saving the information, you will see your **Checklist** with the remaining steps to setup the study.

## COMPLETE THE IREx SETUP

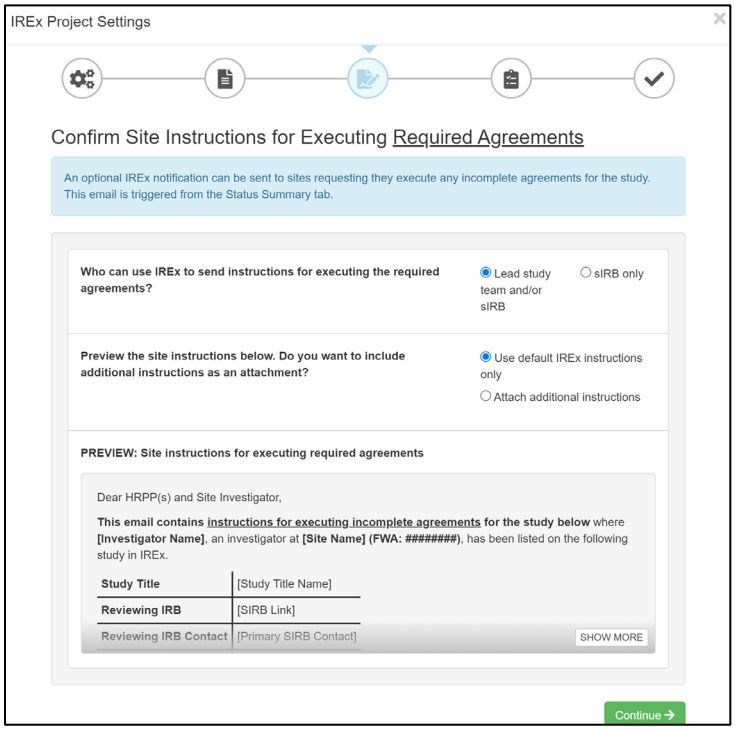
2. Click the **Complete IREx Setup** step on your Checklist.
   A. **Indicate** if the lead site is also the Reviewing IRB and if you are using IREx to capture local considerations.
      - Double check the lead site is listed correctly, as you will not be able to edit this without contacting the IREx team once the study is created.
      - Choose the **Exception from Informed Consent (EFIC)** option for all EFIC studies, as this will trigger the necessary workflow.
      - If you would like to capture local considerations in IREx, you can also indicate if you want IREx to notify sites to update their local considerations if necessitated by a study change during a study-wide amendment. If needed, you can set a date for when your sites should submit updates.




   **IREx Tip:** IREx will notify sites of the timeframe (if selected) but will not restrict sites from making changes after that date.
      - On a study-by-study basis, the sIRB decides if approval notifications can be turned off by the person uploading the approval. Turning off notifications is done on an approval-by-approval basis, i.e., choosing 'Yes' here does NOT turn off notifications for all approvals throughout the life of the study.

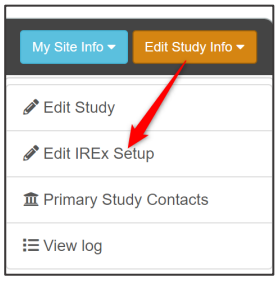
   B. **Identify** the Required Agreement(s):
      - Reliance Agreement(s): The Reviewing IRB can offer SMART IRB and/or Other Reliance Agreements ("ORA"), such as IAAs or MOUs. Sites that have signed onto SMART IRB default to that agreement when it is offered.
      - Indemnification Agreements: Given 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.

C. **Confirm** Site Instructions for Executing Required Agreements.
   - An optional IREx notification can be sent to sites requesting they execute any incomplete agreements for the study. This email is triggered from the Status Summary tab.



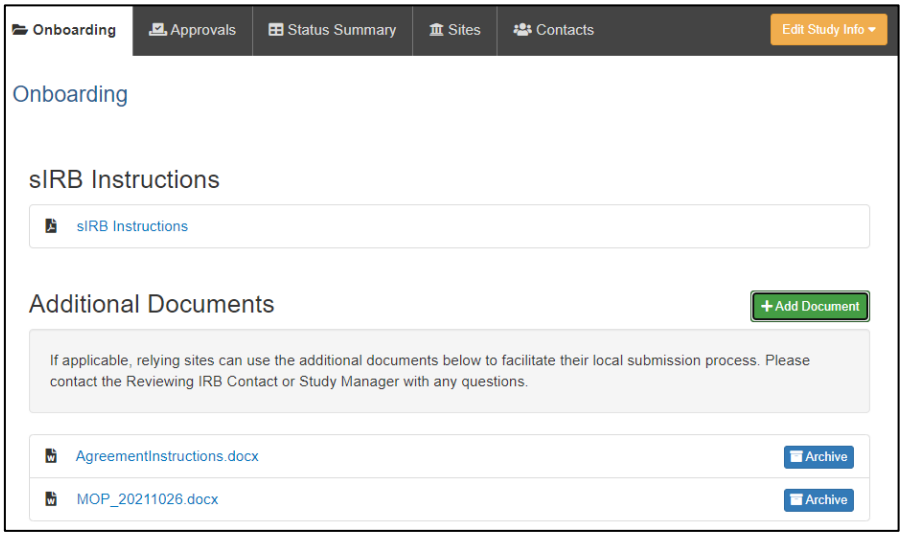

D. **Confirm** Site Instructions for Completing the Single IRB Process. SIRBs can confirm the instructions sites should receive when they are granted access to the study in IREx. You can use the default IREx instructions or attach custom instructions.
   - **Optional**: Upload additional guidance documents to be sent along with the default (or custom) single IRB instructions from IREx. These are documents that might help relying site HRPPs or study teams understand your sIRB process and/or how to prepare their local consent form (e.g., Reviewing IRB SOPs, Reviewing IRB Communication Plans, and Part 2 consent form templates and guidance for completing consent forms). These documents will be housed in the **Onboarding** tab in IREx, and Relying Sites will be instructed on how to retrieve them in their IREx Access email.

E. Review and Submit; click **Save**.



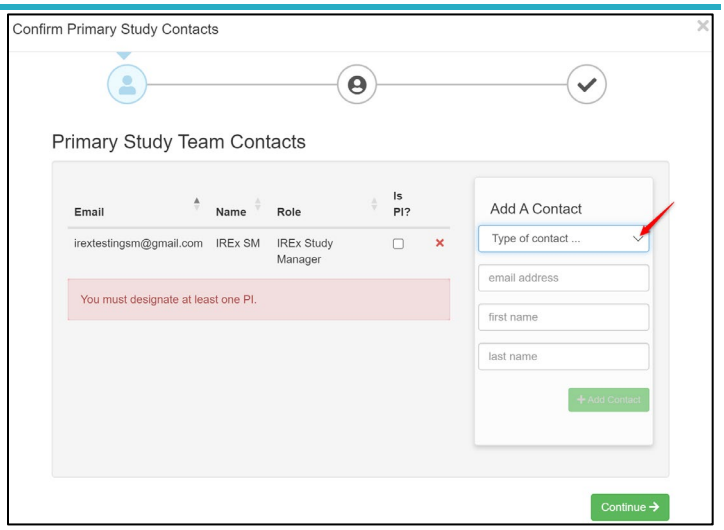

**IREx Tip:** If you would like to enable the ability to request local considerations updates through the life of the study on an existing IREx study, you can make that change anytime through the **Edit IREx Setup**.

**IREx Tip:** Along with any Reviewing IRB SOPs, Communication Plans, etc. you may have uploaded to the **Onboarding** tab, sites will also be able to access their sIRB instructions throughout the life of the study on this tab. Study Managers can also upload/manage the documents in the **Onboarding** tab.



## CONFIRM PRIMARY STUDY CONTACTS

3. Click **Confirm Primary Study Contacts** on your Checklist.
   A. Use the Add a Contact box, to **indicate** the IREx Study Manager & Lead PI. Click **+Add Contact button**. You must enter a Study Manager first. However, you can check the box to indicate the Study Manager is also the PI. Then click **Continue**.
   B. **Identify** a Primary sIRB Liaison for the study and others who need to receive study notifications. All sIRB Liaisons can access the study and perform all functions.
   C. Review and Submit; click **Save**.



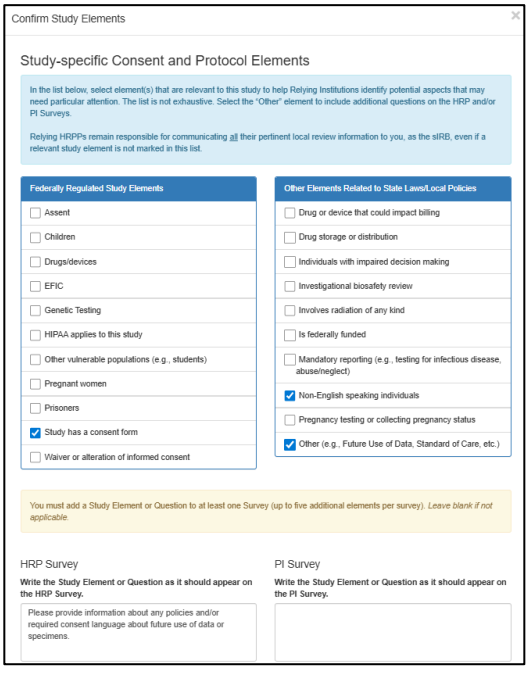

## CONFIRM THE STUDY-SPECIFIC RELIANCE PLAN (SSRP)

4. Click **Confirm SSRP**.
   - The SSRP is automatically generated from your Institutional Profile and outlines how the flexible elements of reliance will be handled when using the SMART IRB Agreement. The Reviewing IRB can edit the SSRP for the study (all sites) or individual sites.
   - Relying HRPPs using the SMART IRB Agreement indicate reliance by accepting the SSRP; Relying HRPPs using an Other Reliance Agreement indicate reliance, but do not accept an SSRP.
   - Use the **SSRP Quick Guide** for guidance on making changes before or after the SSRP has been accepted.

## CONFIRM STUDY ELEMENTS *(Only Available if Collecting Local Considerations in IREx)*

5. Click **Confirm Study Elements.**
   A. Select all the study elements that apply to this study.

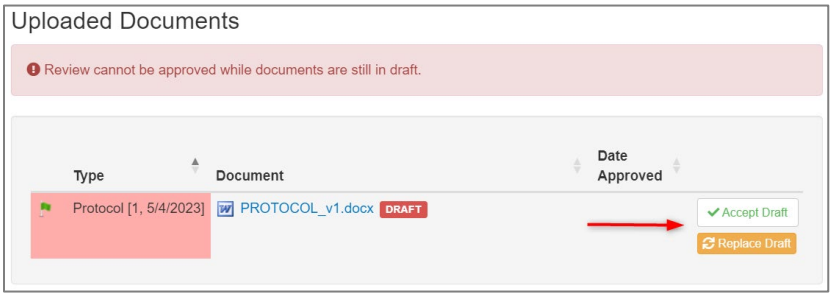
**IREx Tip:** Whatever elements are indicated here will populate into the Relying Sites' HRP Surveys from their Institutional Profiles. For more information on this feature and how it works, please view the Automating Local Considerations Overview.




**TO HELP REDUCE THE REVIEWING IRB BURDEN, IREx RECOMMENDS DELEGATING THE TASKS BELOW TO THE IREx STUDY MANAGER. IF DESIRED, THE REVIEWING IRB CAN ALSO COMPLETE THESE TASKS, AS SHOWN BELOW:**

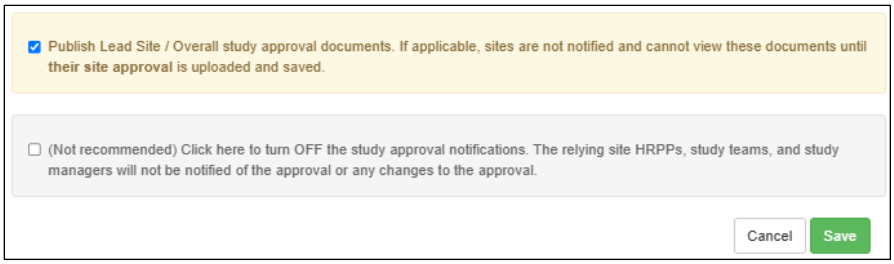
## UPLOAD OVERALL STUDY APPROVAL

6. Click **Upload Overall Study Approval**. For more detailed instructions see this Quick Guide.
   A. Change the Status to **Approved** and indicate the reviewing type and cycle. All required fields and documents will be highlighted in red.
   B. Enter the dates for when it was submitted, approved, reviewed, and expires.
   C. Upload your documents.
      - Remember to click **Accept Draft** if the original protocol uploaded to IREx was approved or click **Replace Draft** if it was modified during the review, in which case be sure to change the version of date BEFORE uploading the new protocol file.
      - Replace or accept other draft documents, as needed.

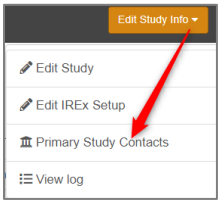



## PUBLISH APPROVAL

7. **Publish Approval** to make the approved global documents visible to the participating sites once they have study access. Check the box at the bottom of the Review & Submit page and click **Save.** Leave the box unselected and click **Save** if you want to return to Publish Approval later. If available and desired, check the second box to turn OFF study approval notifications. If there are sites with study access, they will not receive the approval notification. By checking this box, any sIRB liaisons and study managers will also NOT receive the email approval notification. *(This is not recommended for the initial approval.)*

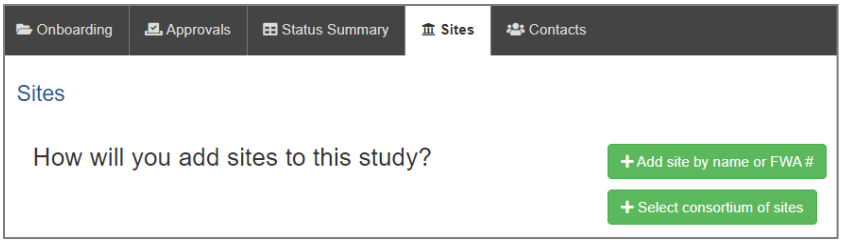



**IREx Tip:** After the lead site approval is published, use the **Edit Study Info** button to edit the IREx Study Setup and/or the Primary Study Contacts.

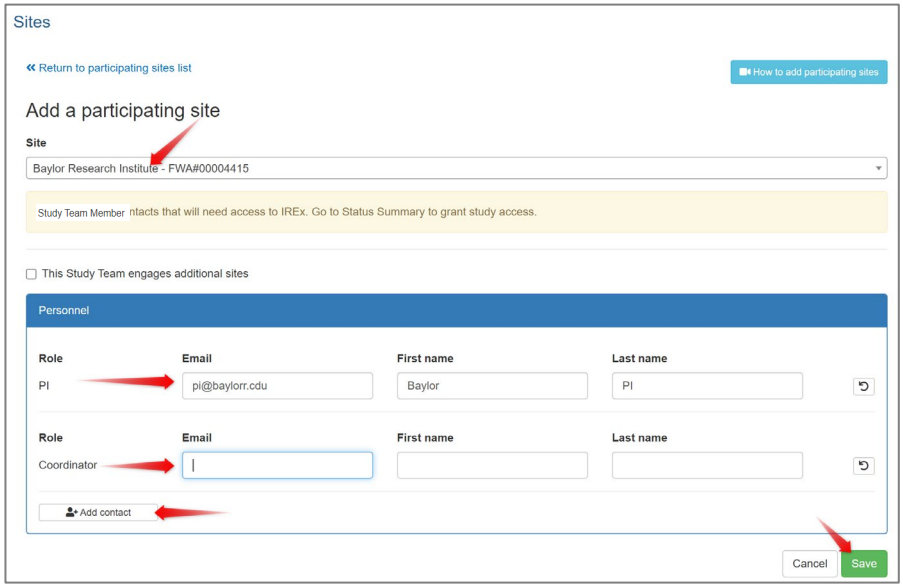



## ADD PARTICIPATING SITES

8. Click the **Sites** tab in the top navigation bar. See the Add/Remove Site Quick Guide for more information.
   A. **Indicate** whether you will **Add sites by name or FWA #** (recommended) or **Select consortium of sites**, if applicable.



B. **Search** by the site's full name (avoid abbreviations, e.g., "VU") or by FWA number only. As you type, the sites that match the name/FWA you have entered will appear. **Select** the site from the drop-down menu.
   - The FWA-holding site appears first, followed by any components, if provided by the HRPP.
   - Sites that do not appear in the search can also be added by typing their name and FWA number. The IREx Admin will create the site and notify you when you can add contacts.




C. **Enter** the PI and Study Team Member contact information, if known at the time. If not, **Save** the site and return later to add this information. The PI contact information must be added to be able to grant the site study access.

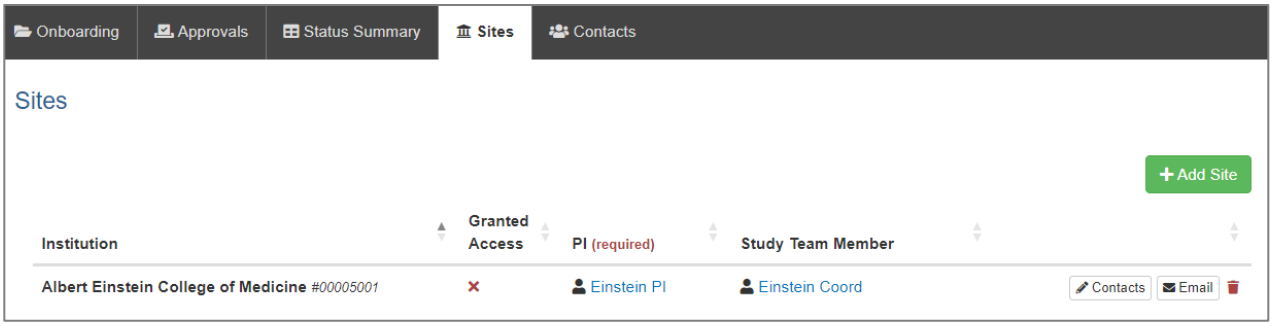
D. If the PI/study team engages another site, check the box "This Study Team engages additional sites" and select the other site from the drop down.

E. **Click** the +**Add Contact** button to add additional study team members.

F. Click **Save** to list the site on the study.

G. **Click** the **trash can icon** to remove any sites that will *not* be participating in the study.

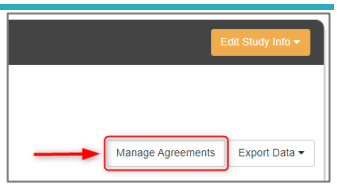
H. **Click** the **+Add Site** button to add additional sites.




## TRACK SITES' AGREEMENTS (sIRB ONLY)

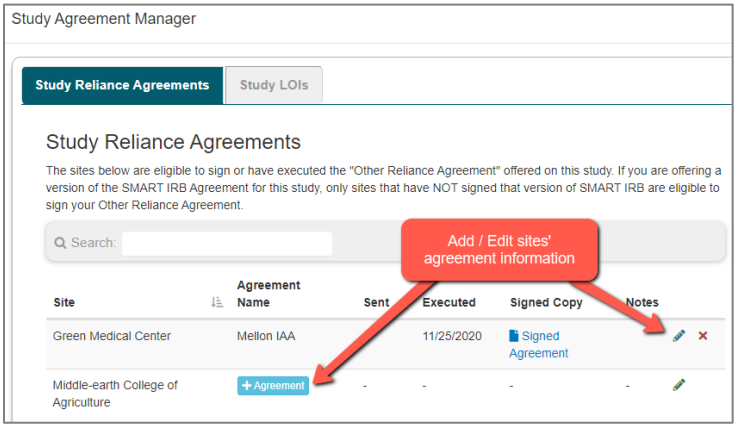
**9.** Request sites' execute required agreements while the lead site is being reviewed by the sIRB.

A. On the **Status Summary**, click the **Manage Agreements** button to track and log required institutional reliance and indemnification agreements from participating sites.



- Institutions that sign the SMART IRB Agreement are tracked and updated by IREx Administrators.

B. Use the **+Agreement** button to indicate a site will be signing an institutional reliance and/or indemnification agreement before it is executed. The Date Executed is required to indicate completion and a copy of the executed agreement(s) can be uploaded.




## ADDITIONAL RESOURCES

**A. Uploading other approvals** (see quick guides below)

- Continuing Review
- Study-wide Amendments
- Site Amendments

**B. Site closures**

- Closing a site ensures that only active sites retain access to ongoing studies.
- Site Closure Quick Guide

**C. Study closures**

- Closing a study ensures all sites are aware that the study ended but retains a record of the reliance and a history of sIRB site approvals.
- Study Closure Quick Guide