IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

STUDY MANAGER STEP-BY-STEP GUIDE – FOR SIRBS USING API

The **IREx Study Manager** is someone from the lead study team or coordinating center who uses IREx to oversee participating site readiness for single IRB (sIRB) review. For more detailed information on how to use IREx, check out the Study Manager Resources page here.

Some single IRBs choose to use the IREx API (Application Program Interface), which allows for the exchange of data between their local electronic IRB (e-IRB) system and IREx. In short, when the sIRB is using the IREx API, the IREx Study Manager has slightly different steps, as some items are automatically completed via the API connection.

Table of Contents

Conversation with the Single IRB 1
Step 1: Submit the Lead Site to the SIRB 2
Step 2: Add Relying Sites to the Study in IREx 2
Step 3: Request Required Agreements 3
Step 4: Upload Initial SIRB Approval for the Lead Site/Overall Study & Publish 3
Step 5: Upload Additional Non-sIRB Reviewed Documents to the Onboarding Tab 3
Step 6: Notify and Grant Access to Site 4
Step 7: Track Sites' Readiness for SIRB Review 5
Step 8: Pre-screen & Export Local Considerations 6
Step 9: Upload Initial SIRB Approval for Relying Sites 7
Additional Resources 7

Conversation with the Single IRB

A. **Discuss** the submission process with the sIRB.
   - Review the IREx Single IRB Instructions Template for participating sites
   - Process for managing consent form (e.g., if the sIRB uses a two-part consent)
   - Process for capturing local considerations from sites (e.g., via IREx surveys)
   - Process for submitting sites for review (e.g., as an amendment, as a site add)

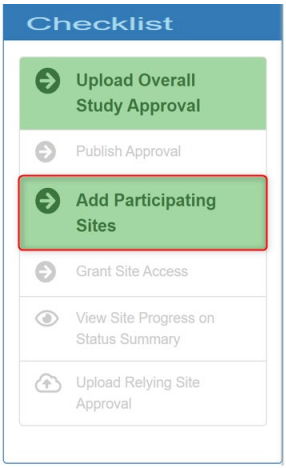
B. **Clarify** what roles you are responsible for in IREx as a Study Manger vs the sIRB. Who will:
   - Upload Initial Approval for the Overall Study/Lead Site (**done automatically via API**)
   - The below are typically the responsibility of the Study Manager:
     - Add or remove participating sites to the study
     - Request Required Agreements
     - Grant study access to relying HRPP and study teams
     - Prescreening relying sites' reliance and local review documentation for submission to the sIRB
     - Review and publish lead site initial approval pushed from API
     - Review sIRB relying site approvals pushed from API
     - Upload and publish study-wide amendments and continuing reviews (not sent from API)

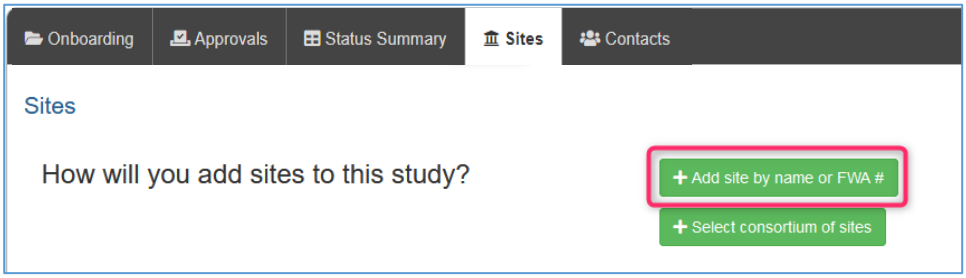
STEP 1 — SUBMIT THE LEAD SITE TO THE SIRB

- **Lead Study Team** submits the study in the sIRB's e-IRB system for sIRB review. Include two-part consent, if applicable, in your submission.
- The **sIRB** will review the submission and **create the study in IREx**.
- You will receive access to IREx via email notification after the study is created.
- While you wait for the sIRB to approve the Lead Site, you can complete steps 2 & 3 below.

STEP 2 — ADD RELYING SITES TO THE STUDY IN IREX

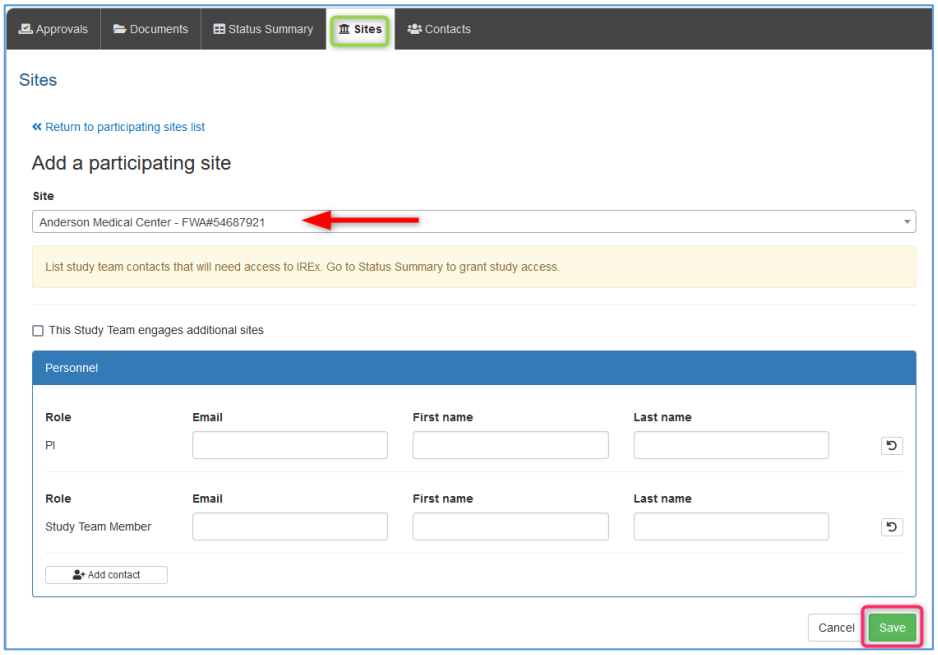
A. Click **Add Participating Sites** in your IREx Checklist, this will open your **Sites** tab.





B. Search and add site(s) by the institutions' name (avoid abbreviations, e.g. "VUMC") or by Federal-wide Assurance (FWA) # (numeric characters only) or select a consortium of sites.

- As you type, the sites that match the name/FWA # will appear. Select the site from drop-down list.
- You can add sites that do not appear in the drop-down list by typing the site name/FWA # and pressing enter on your keyboard. An IREx admin will create the site in IREx and notify you when you can add contacts.



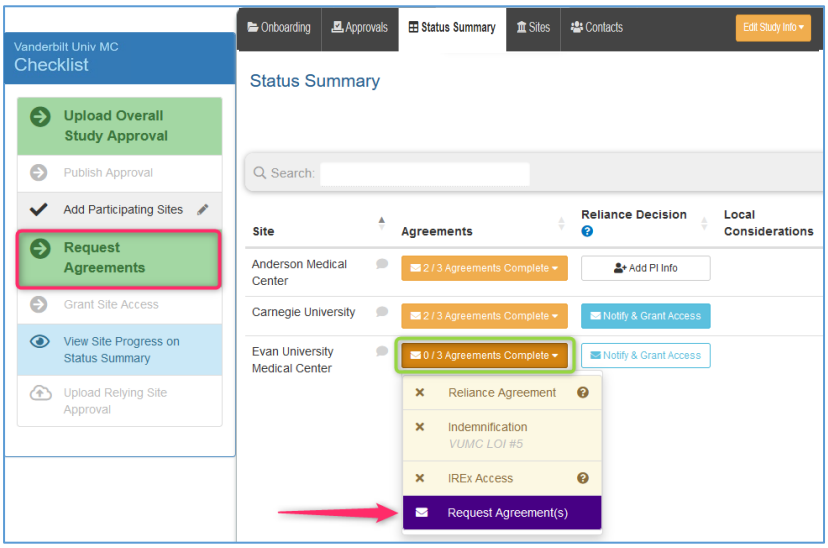
C. Enter the PI and Study Team Member contact information, if known at the time. If not, **Save** the site and return later to add this information.

STEP 3 — REQUEST REQUIRED AGREEMENTS (ONLY DISPLAYED IF A SITE HAS INCOMPLETE AGREEMENTS)

A. Click **Request Agreements** on the IREx Checklist to move to the **Status Summary** tab.

B. On the **Status Summary** tab, any institution that is missing agreements will have an orange number of **Agreements Complete** button. Click the drop-down to see the list of agreement(s) required for the study.

C. Click the purple **Request Agreement(s)** button to send an email notification to the site's HRPP and Study Team Members.

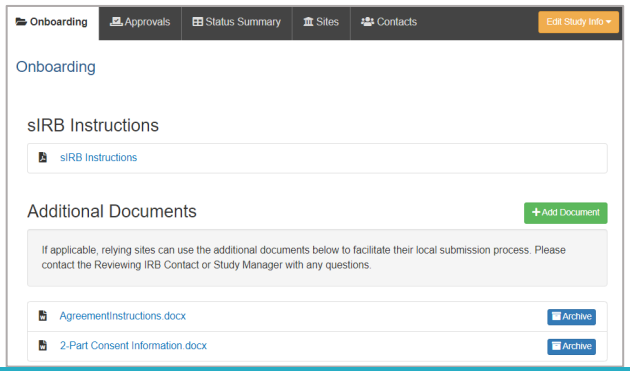


STEP 4 — UPLOAD INITIAL sIRB APPROVAL FOR THE LEAD SITE/OVERALL STUDY & PUBLISH

The sIRB will Upload the Lead Site/Overall Initial Study Approval in IREx using the API. When you receive email notification of Lead Site Overall Study Initial Approval, **log into IREx to confirm all approval data and documents have been correctly uploaded**. Make any necessary corrections and publish the approval. When confirming and publishing the approval, you may have the option to turn OFF the approval notification. If this option is selected, all sIRB liaisons and study managers will also NOT receive email notification of the approval.

STEP 5 — UPLOAD ADDITIONAL NON-SIRB REVIEWED DOCUMENTS TO THE ONBOARDING TAB

Upload the part 2 consent template (if applicable) and any support document(s) to help facilitate site's local submission process to the **Onboarding** tab. Here, sites will be able to access those documents, along with their sIRB instructions, for the life of the study. As the study moves forward, you have the ability to Archive outdated documents, and add new documents that are not sIRB approved. Do not include sIRB reviewed and approved global or site specific documents in this tab.



THE FOLLOWING STEPS SHOULD OCCUR AFTER THE LEAD SITE RECEIVES SIRB APPROVAL

STEP 6

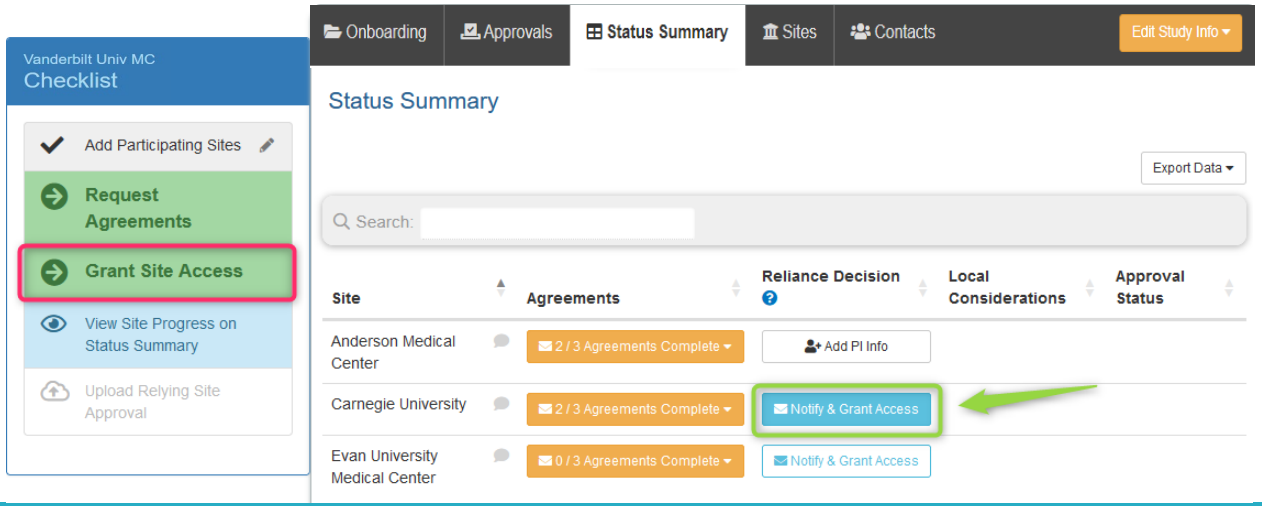
NOTIFY & GRANT ACCESS TO SITES

A. Click **Grant Site Access** on your IREx Checklist, this will open your **Status Summary** tab.

B. Click the **Notify & Grant Access** button to alert sites of their access to the study in IREx. This sends an email to the HRPP and study team giving them access to the study in IREx. This email includes single IRB instructions for the study, and prompts the relying site study team and HRPP to connect around their local reliance process.

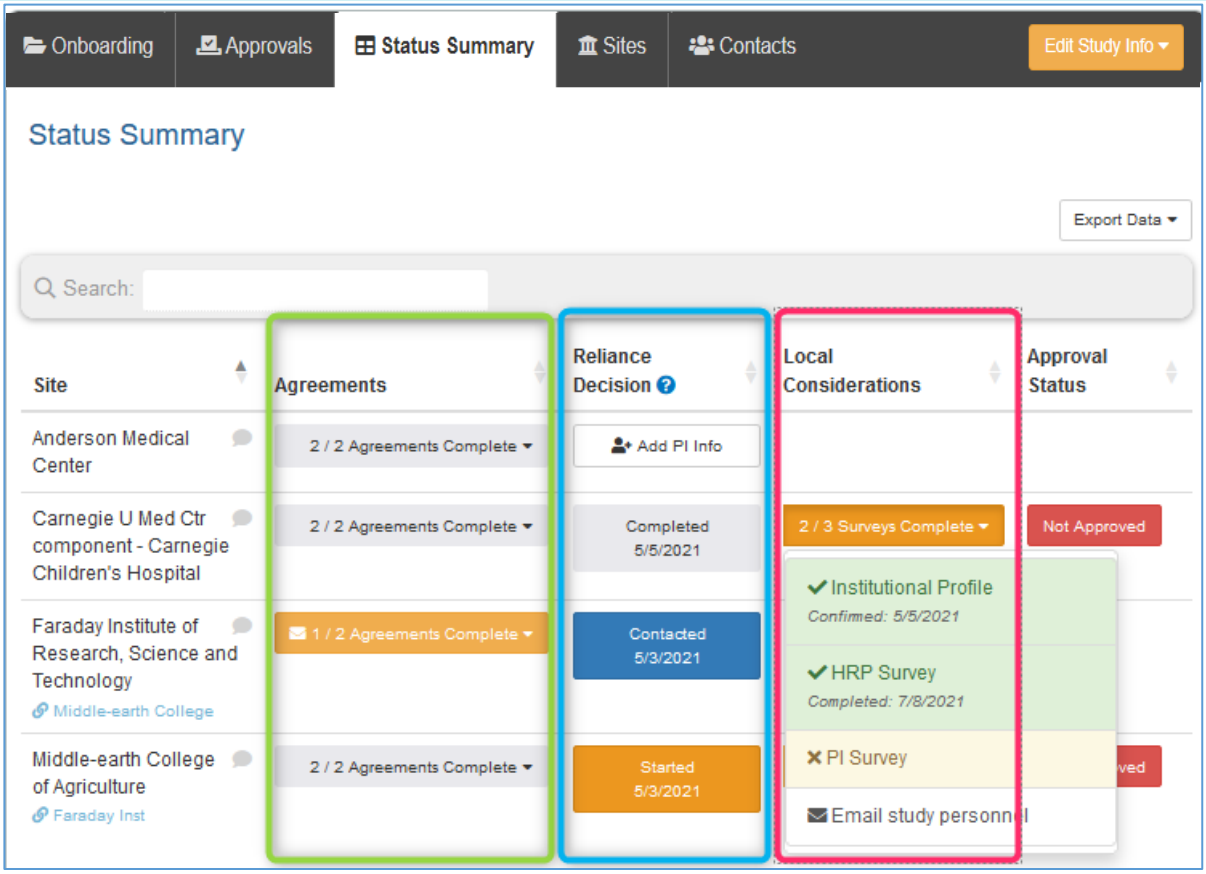
The study team can use the Study Link in the email to log into IREx and download the lead site sIRB approval documents from the Approvals tab and any additional documents (example: Part 2 ICF Template) on the **Onboarding** tab. The study team will use these for their local submission.

- Only sites that have joined IREx and have a PI listed can be Notified & Granted Access.
- You can notify sites at different times depending on when they are being onboarded to the study.

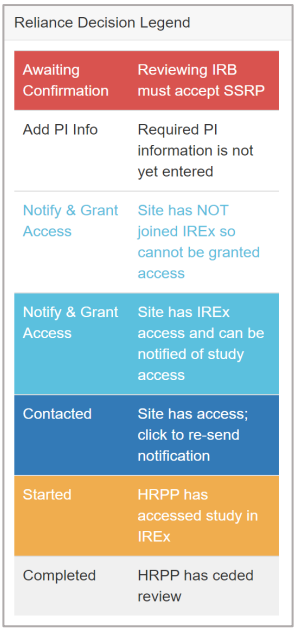


STEP 7

TRACK SITES' READINESS FOR sIRB REVIEW



Use the **Status Summary** tab to track your sites' progress.
Review each column on the Status Summary tab for step completion:



A. Has the site signed all the required AGREEMENTS?
- SMART IRB Agreement, IAA or MOU
- Indemnification (if applicable)
- IREx Access

B. Has the site's HRPP completed RELIANCE DECISION?
- See Reliance Decision Legend – Gray is Completed

C. Are LOCAL CONSIDERATIONS complete?
- Institutional Profile: Completed by the HRPP and includes institution-level information.
- HRP Survey: Completed by the HRPP and includes applicable local requirements for this study.
- PI Survey: Completed by the PI or Study Team Member; includes information about the conduct of the study and an upload of the locally reviewed consent document(s). The PI must attest to the survey, as well as any edits made by a Study Team Member or the HRPP.
- CCP Summary of Results: Uploaded by PI or Study Team Member (PI attestation required). This upload is only available for Exception from Informed Consent (EFIC) studies.

IREx Tip: If steps are incomplete, ensure the study team has submitted a request to rely on an sIRB to their local IRB. If so, ask the study team to follow up with their IREx HRPP Liaison (found here) regarding steps in IREx or additional requirements.

STEP 8

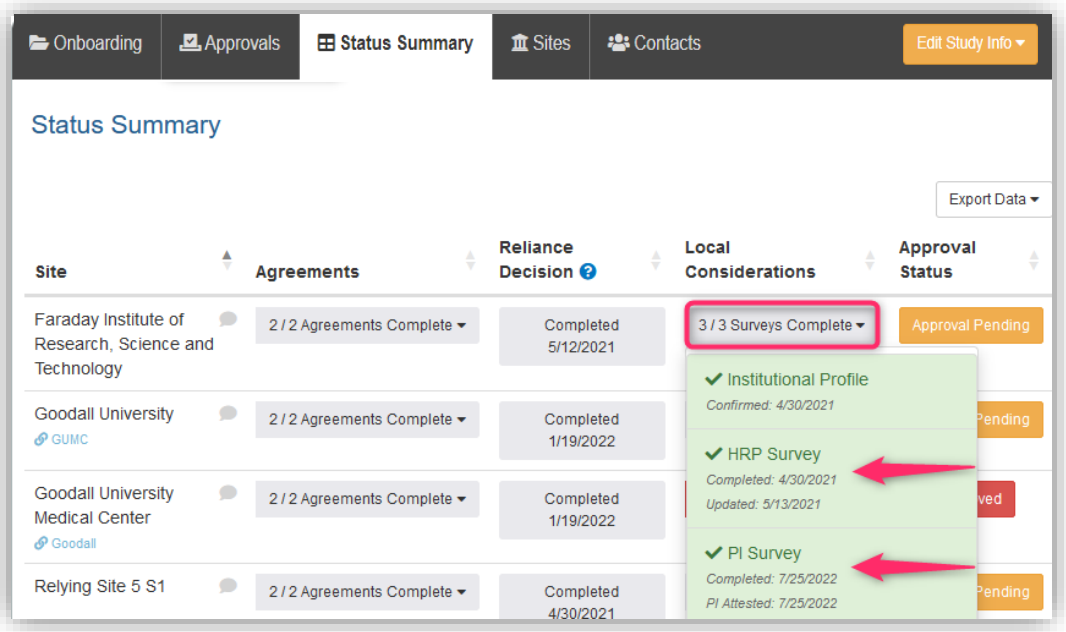
PRE-SCREEN AND SUBMIT SITE FOR SIRB REVIEW

You will receive an email when sites complete local considerations. Go to the **Status Summary** tab to:

A. **Pre-screen** the surveys for completion by clicking the 3/3 Surveys Complete dropdown to view the survey list, then click on the HRP Survey and PI Survey.

B. **Verify** a clean copy of the Part 2 consent form(s) are uploaded in the PI Survey with local language included (if applicable). If changes or clarifications are needed, the PI and Study Team Member (or HRPP Liaison) at the site can edit the PI Survey. Only the HRPP can edit the HRP survey. Once the prescreening is complete, the site is ready for sIRB review.

C. **Submit** the site addition in the sIRB's e-IRB system. Confirm the submission type with the sIRB. The API connection will pull the documents needed for the submission directly from IREx.



For EFIC Studies ONLY: Exception from Informed Consent (EFIC) studies have four Local Considerations surveys, rather than three. The fourth survey is the CCP Summary of Results, which does not get uploaded by the Relying Site Study Team until the Community Consultation Plan has been implemented. Follow the steps below for EFIC studies.

1. **Documenting CCP Acceptance**
   - You will receive an email when sites complete their Institutional Profile, HRP Survey, and PI Survey (which contains an upload of the CCP for sIRB review. Follow Step 8, A – C above to submit to the sIRB as you would for a non-EFIC study.
   - Document the sIRB's CCP acceptance by clicking **Awaiting CCP Acceptance** in the **Approval Status** column and inputting the dates of submission, review, and approval. (The accepted CCP may be uploaded; this is optional.)
2. **Submitting The CCP Summary of Results for sIRB Approval**
   - Once the study team has implemented their CCP and is ready to submit their CCP Summary of Results, they will do so via IREx, and you will receive another IREx notification. Return to the **Status Summary** tab and follow Step 8, A – C above to submit the CCP Summary of Results to the sIRB for review.

Once the CCP Summary of Results is approved and you are ready to document the Relying Site's initial approval, continue to Step 9.

STEP 9	**UPLOAD INITIAL sIRB APPROVALS FOR RELYING SITES** The sIRB will Upload & Publish the Relying Site's Initial Study Approval to IREx using the API. When you receive the email notification of a Relying Site's Initial Approval, **log into IREx to confirm all approval data and documents have been correctly uploaded**. If edits are made, check the box to turn OFF study approval notification if desired. Turning off approval notifications, will also NOT send an email to sIRB liaisons and study managers.
STEP 10	**UPLOAD sIRB APPROVALS THROUGHOUT THE LIFE OF THE STUDY** [Not available via API] Study Managers upload Continuing Review, Study-Wide Amendment, and Site Amendment Approvals manually in IREx. See resource links below for detailed instructions.

ADDITIONAL RESOURCES

A. **Uploading approvals manually, as needed**
- Overall Initial Study Approval
- Relying Site Initial Approval
- 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 the history of sIRB site approvals.
- Study Closure Quick Guide