IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

July 16, 2021

- User Materials Development
- User Support

Katelyn Benhoff

- Onboarding
- Study Support

David Crenshaw

- Training
- Study Support

Natalie Dilts

- Lead Application Developer

Bryce Embry

- System Development

Asri Mumpuni

- Project Director

Emily Serdoz

- Onboarding
- Study Support

Bridget Swindell

- Application Developer

Jason Tan

- Website & System Dev
- Study & User Support

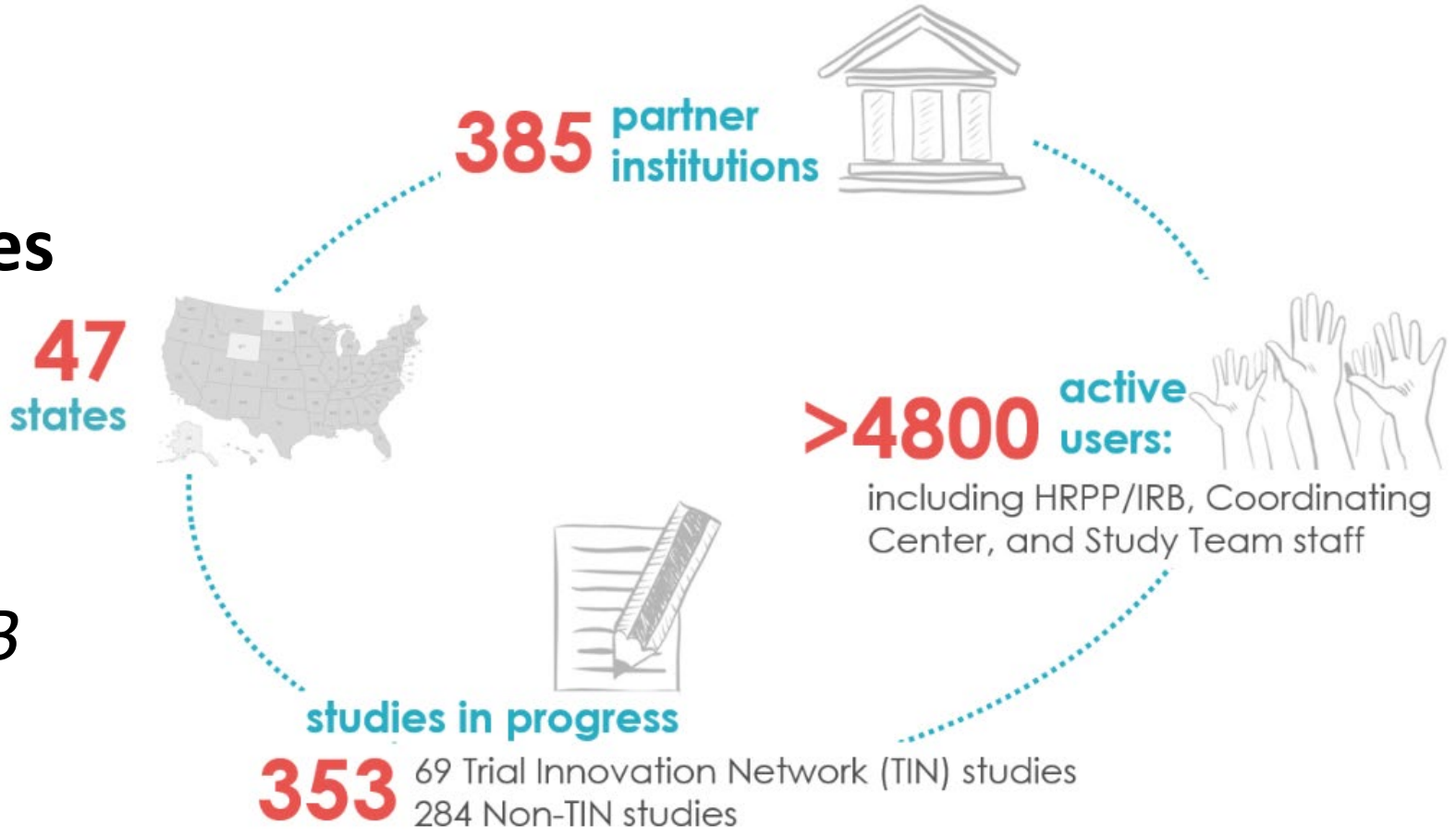
Linda Tan

- Application Developer

Evan Wimberly

QUARTERLY CALL AGENDA

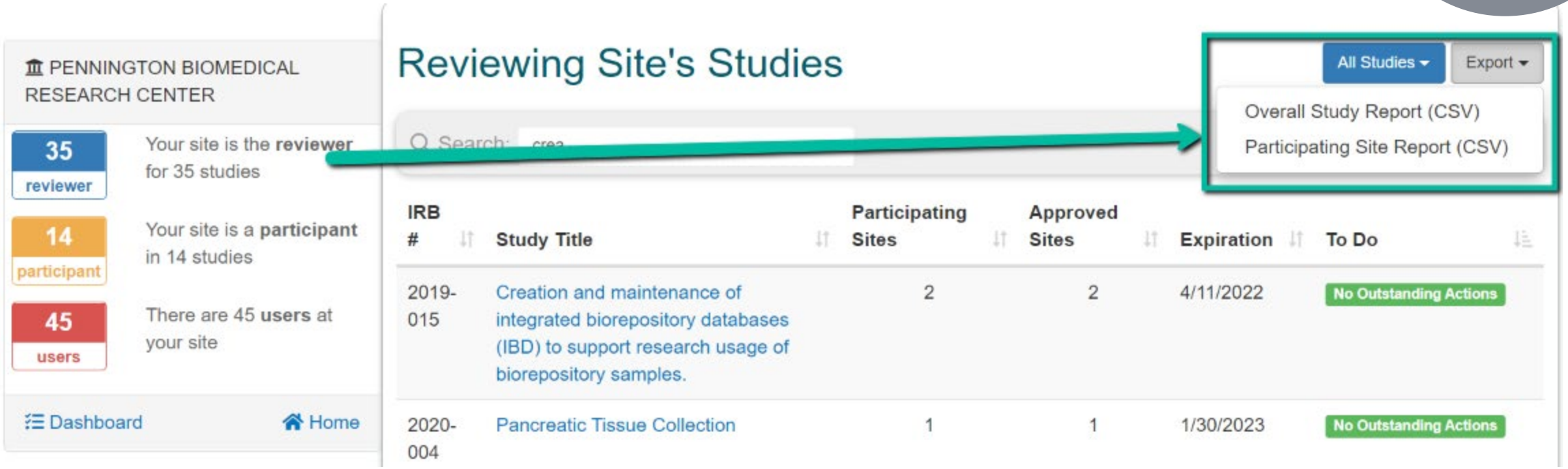
- **Welcome!**
- **Recent System Updates**
- **Upcoming System Updates**
- **Hear from the Pros –** *University of Utah sIRB Team*



Recent System Updates

Since April 2021

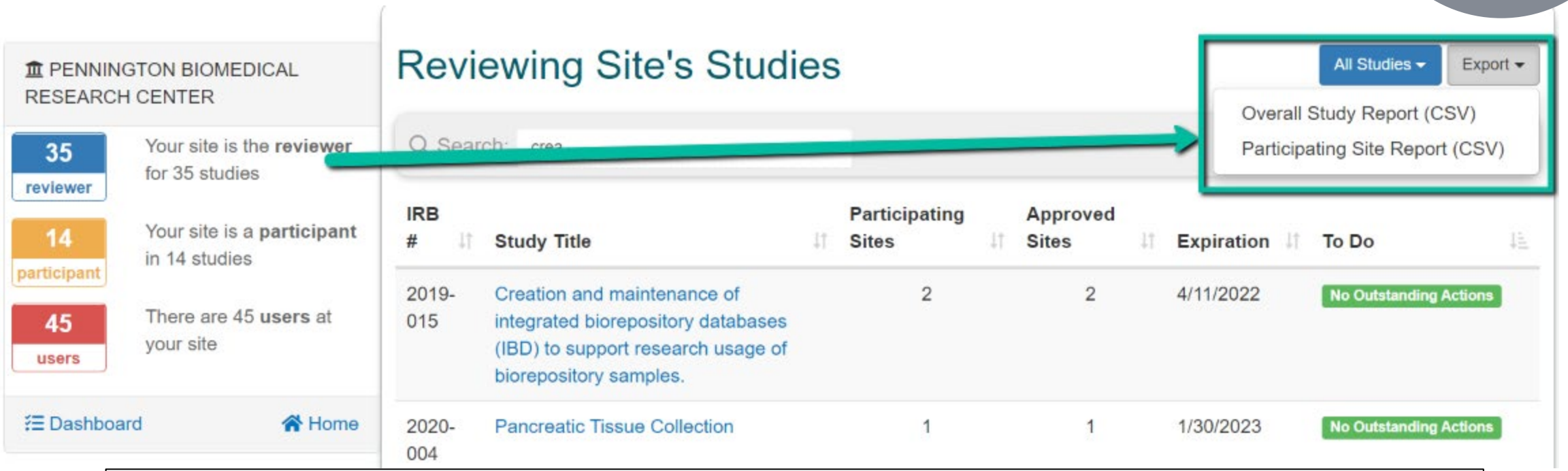
New Exports Available for SIRBs



Overall Study Report includes the following for each sIRB study:

- Date study created in IREx
- Risk Type (GTMR, MR)
- Lead PI
- Initial review dates for lead site
- # Participating Sites
- # Registered Sites
- # Sites indicating reliance
- # Sites with initial approval

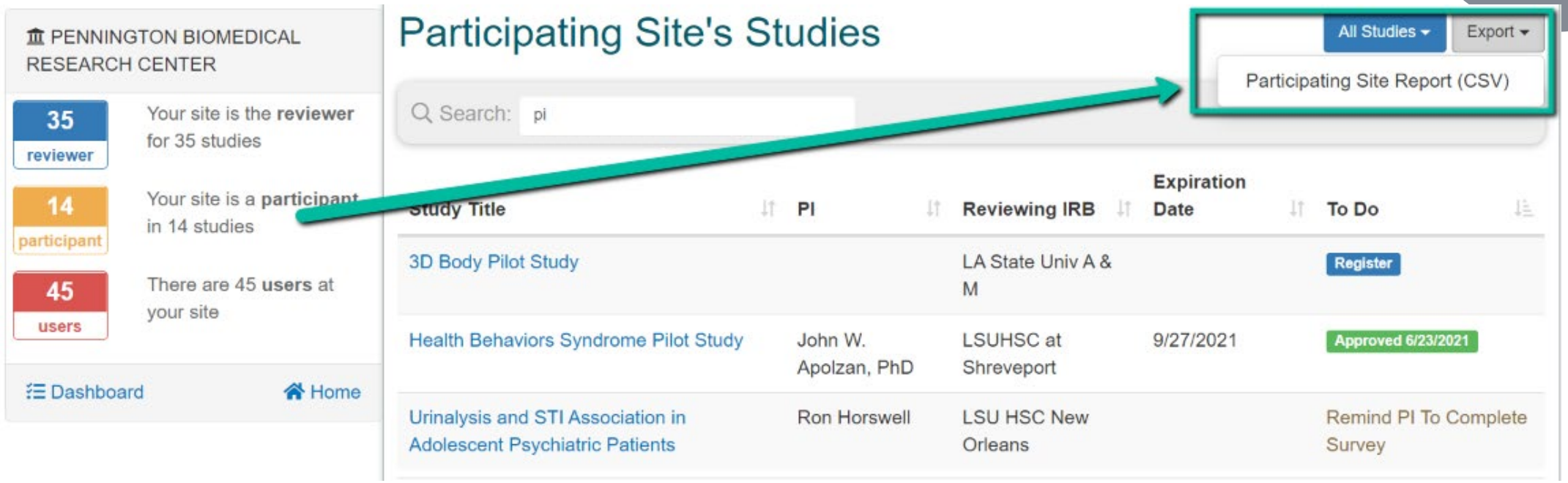
New Exports Available for SIRBs



Participating Site Report includes the following for each site on your sIRB studies:

- Relying site FWA and name
- Whether site signed SMART IRB, LOI, other IAA
- Site PI
- Dates of each sIRB approval (initial, CR, mods)
- Date site notified/contacted about study
- Date site registered
- Date site relied
- Local submission/review dates (if provided)
- Date HRP and PI Surveys completed, updated

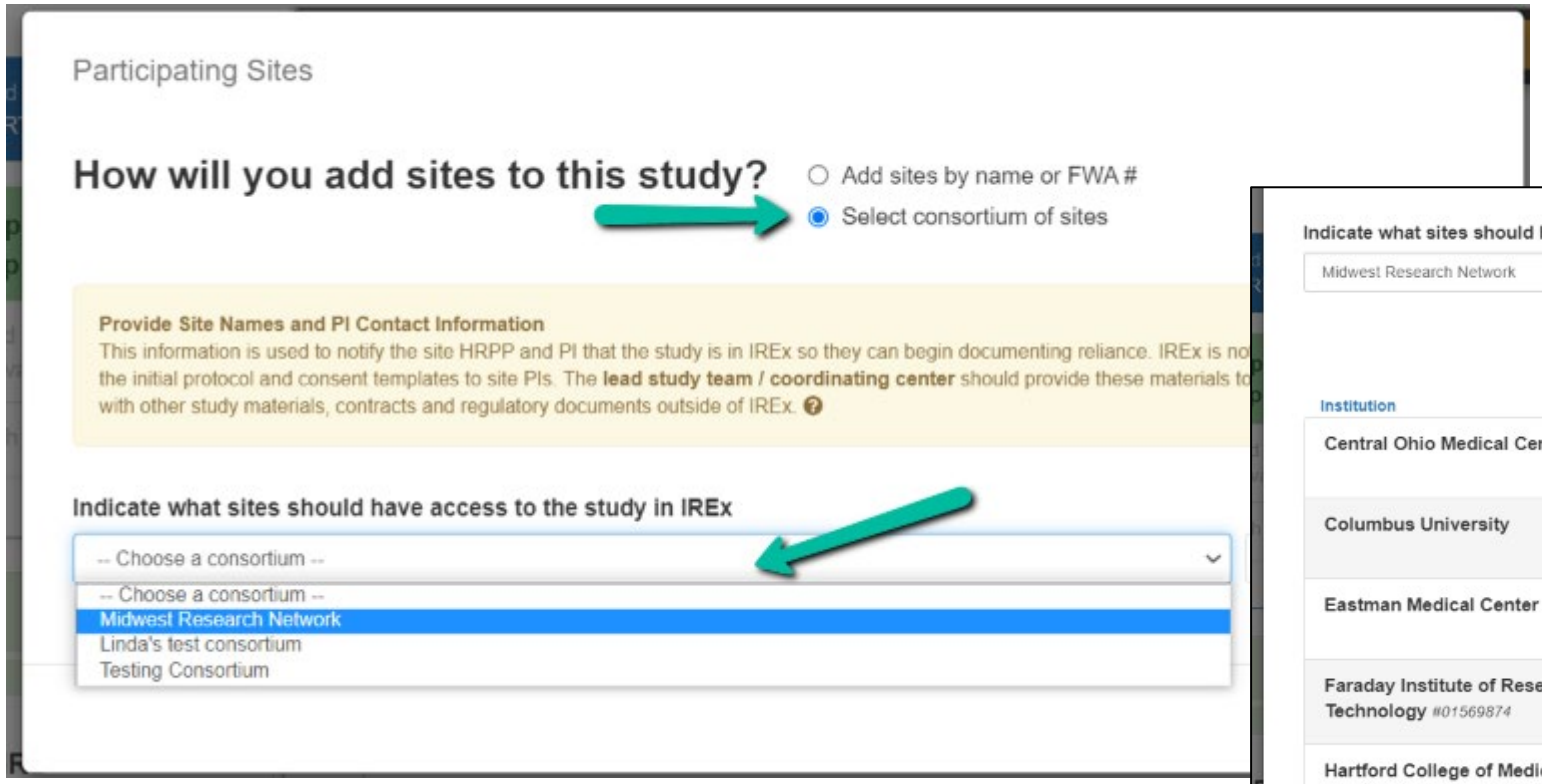
New Exports Available for Participating Site HRPPs

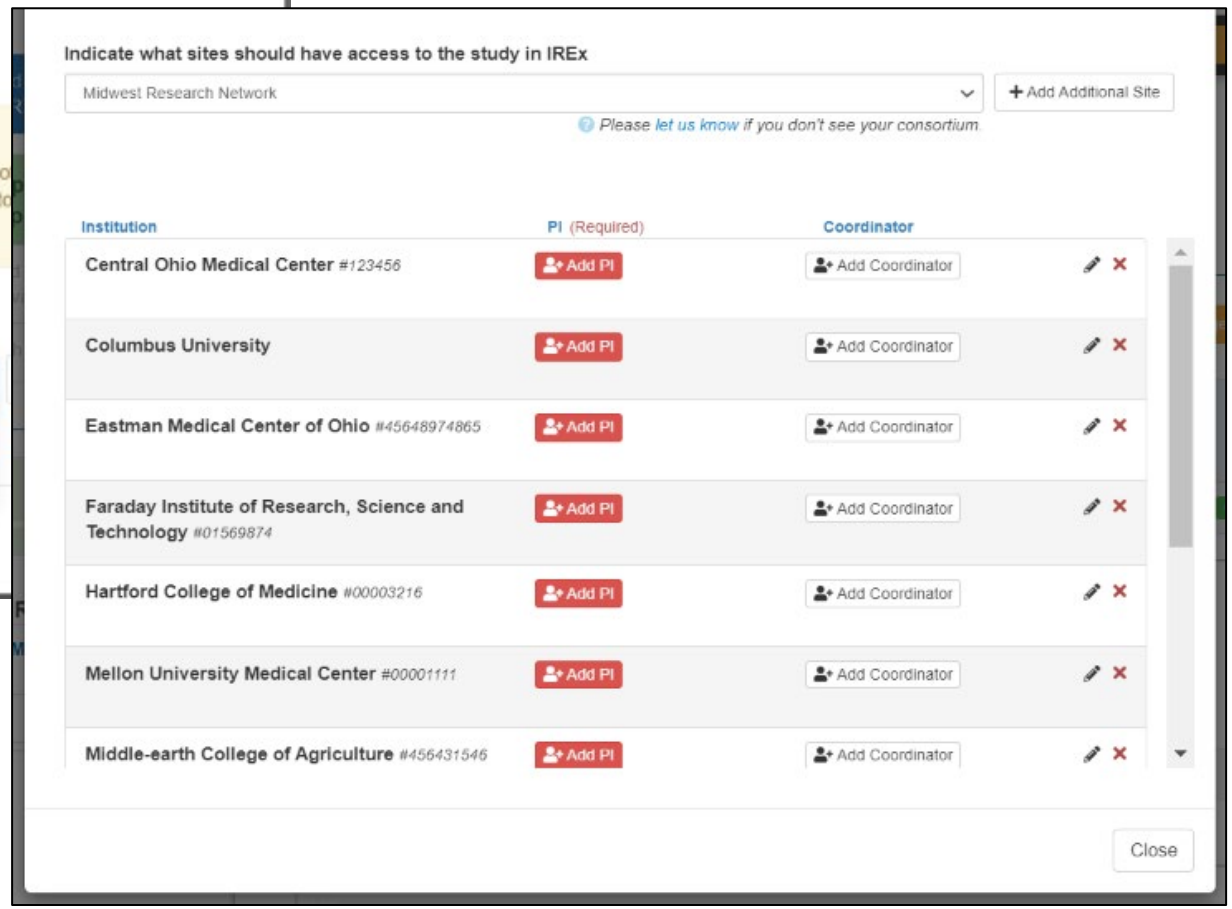


Participating Site Report includes the following for each study where your site is relying on an sIRB:

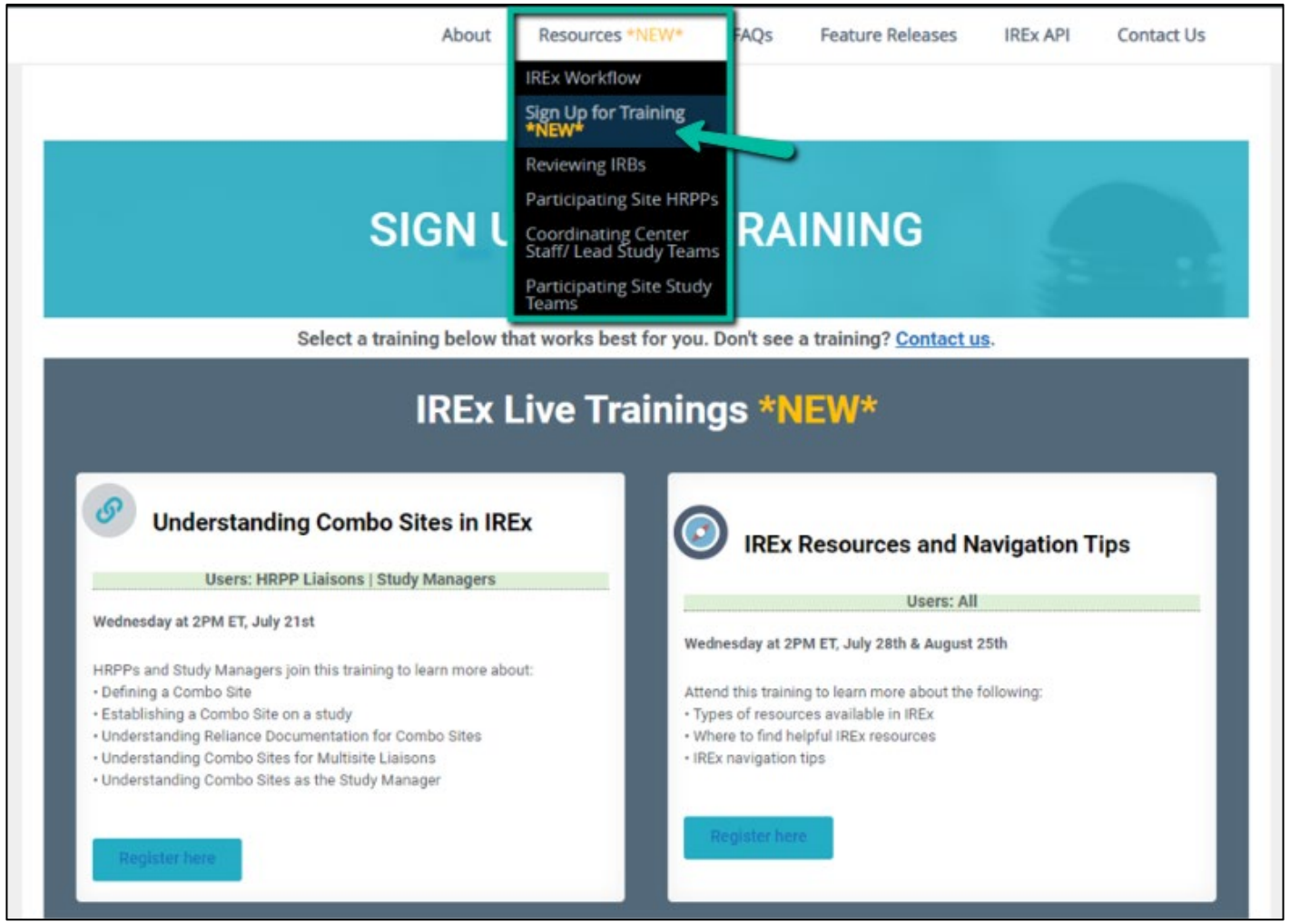
- Reviewing IRB name & FWA
- Local PI
- Dates of each sIRB approval for your site (initial, CR, mods)
- Date your site was notified/contacted about study
- Date your site registered
- Date your site relied
- Your Local submission/review dates (if provided)
- Date your HRP and PI Surveys completed, updated

Add Consortiums to Studies





New Training Offerings



WEDNESDAYS AT 2 ET/1 CT/12 MT/11 PT

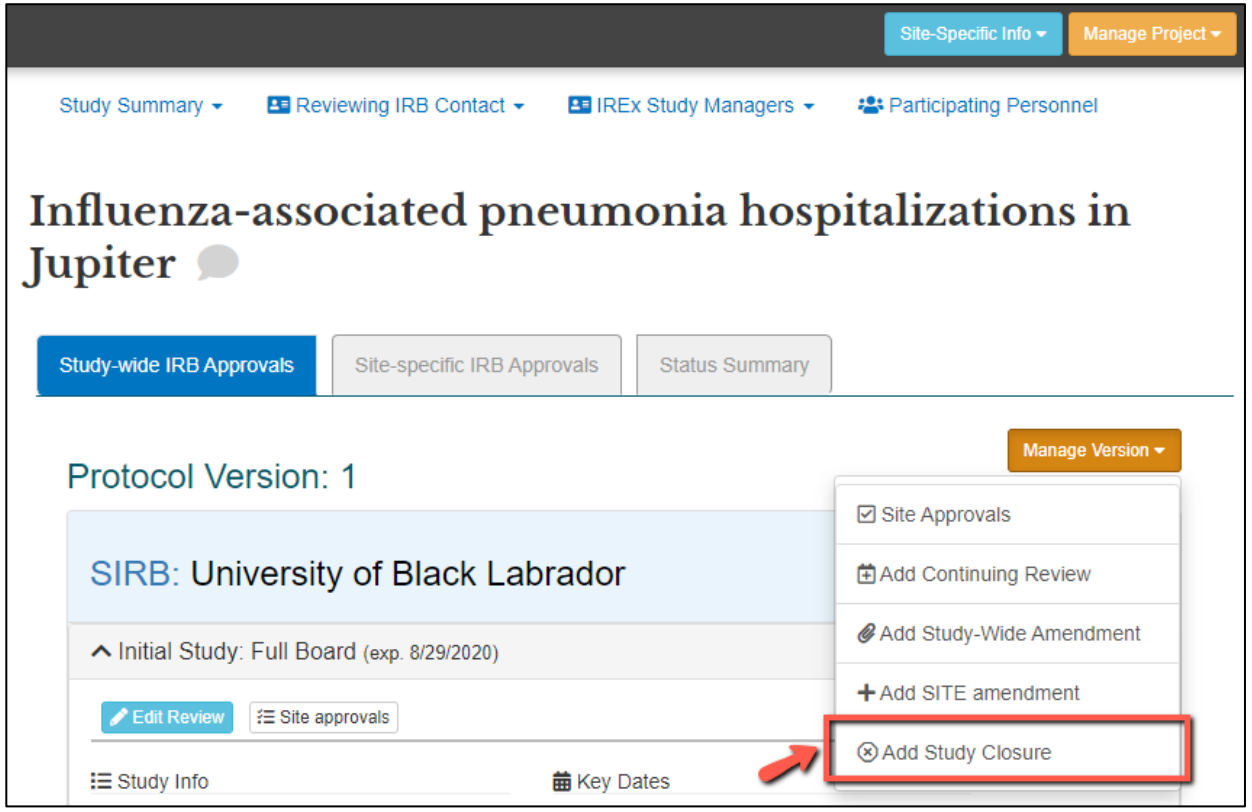
JULY

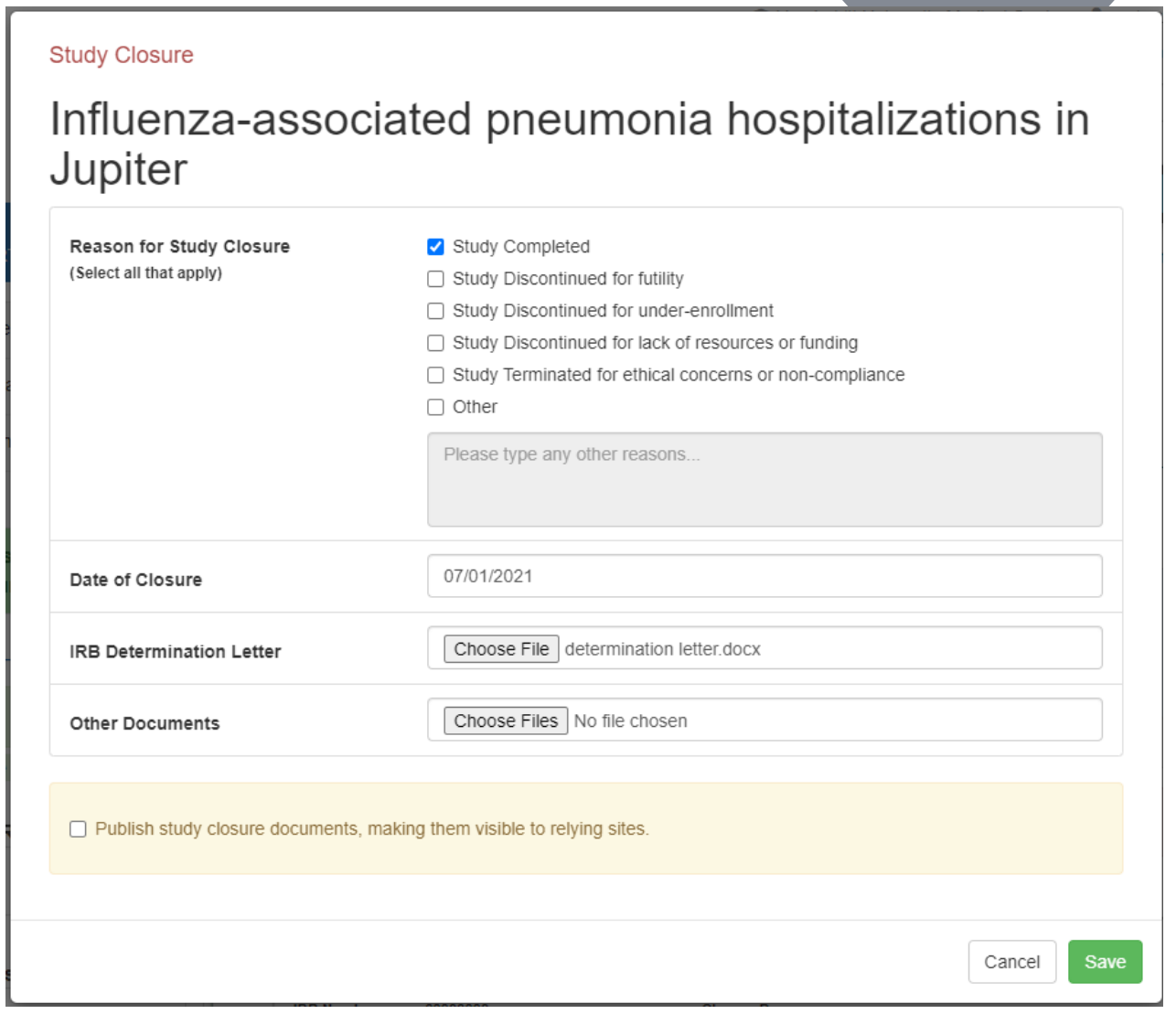
- Understanding Combo Sites in IREx
- IREx Resources & Navigation Tips

AUG

- How to Document Study Closures in IREx
- How to Upload Continuing Reviews and Amendments
- sIRB Workflow Spotlight: Wake Forest
- IREx Resources & Navigation Tips

Document Study Closures





sIRBs (only) can document study closures.
This option is not available to Study Managers (yet?)

Document Study Closures

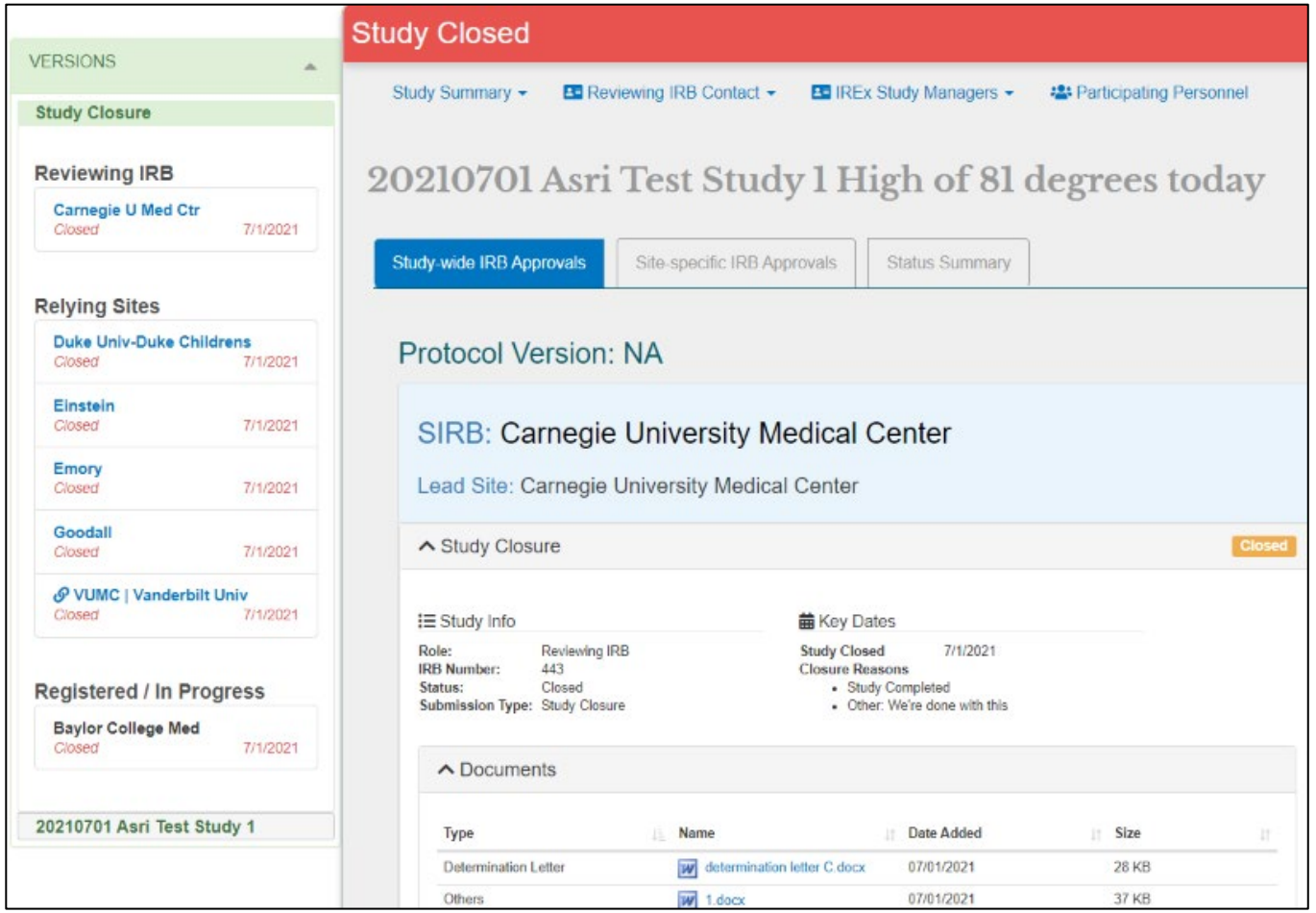
Dear Liaisons and Study Contacts,

Carnegie University Medical Center has issued a closure notification for the following study for your institution, Albert Einstein College of Medicine, in IREx:

Study Title	Influenza in Jupiter
Type of Determination	Study Closure
Reason for Study Closure	Study Completed
Date of Closure	7/1/2021
Study Url	https://test.irbexchange.org/feature-branch/public/study?proj=1028876

Principal Investigators & Study Contacts:
You can access the study closure information in IREx. Prior approval information will remain accessible in read-only format. Please contact your local HRPP, as needed, regarding your local submission requirements for study closure.

Thank you for using IREx,
The IREx Team



Upcoming System Updates

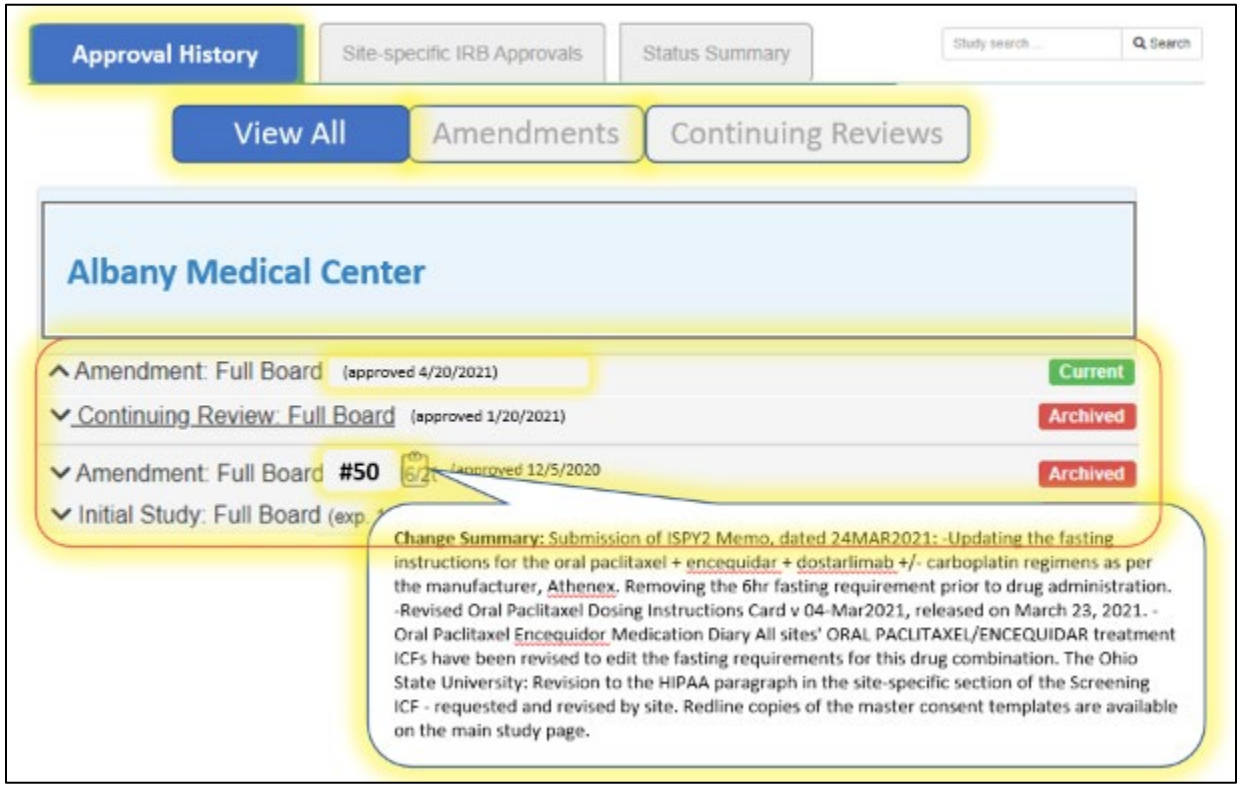
Summer/Fall 2021

Site Closures

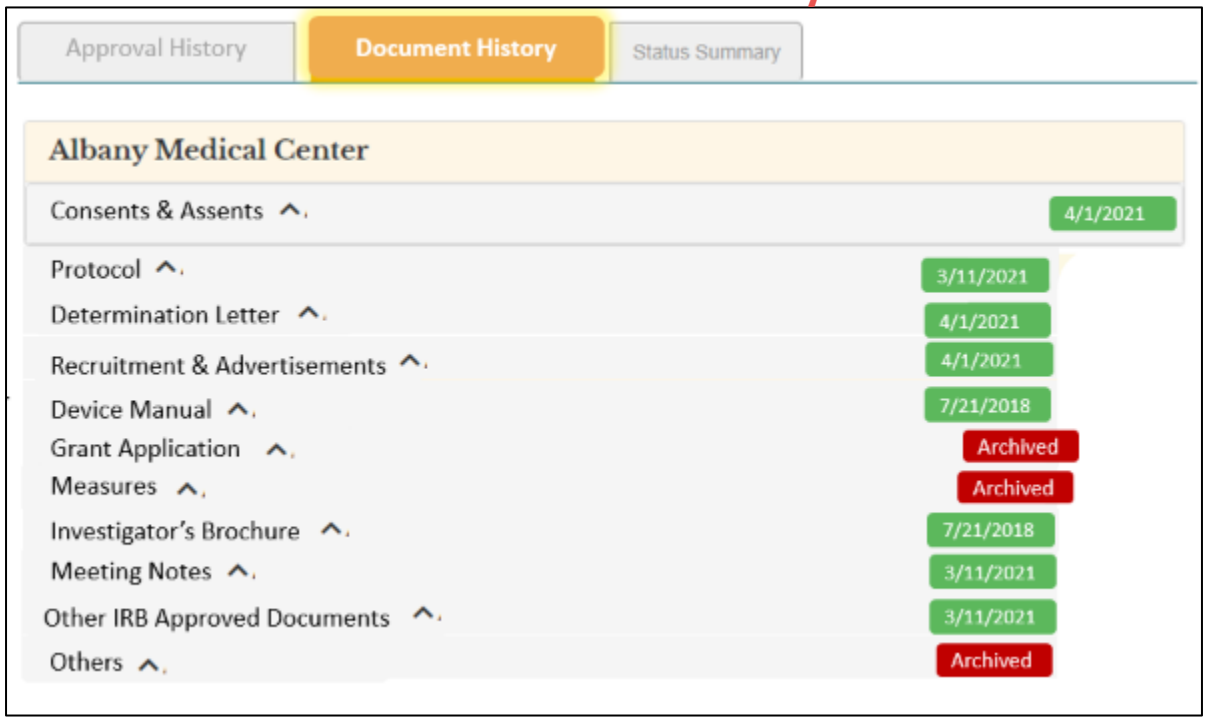
- Allow sIRB to close a single site on an active study
- Bonus feature: Allow an sIRB to indicate a study is “closed to enrollment”, but has ongoing approval (i.e., may not have approved consents, but has CR approval)
- *ETA August 2021*

Reorganizing Approval Documents

Provide all site's approval documents on one tab

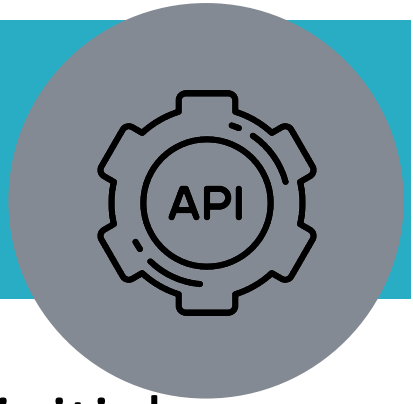


Provide Document History Tab



ETA October 2021

Enhancing IREx API

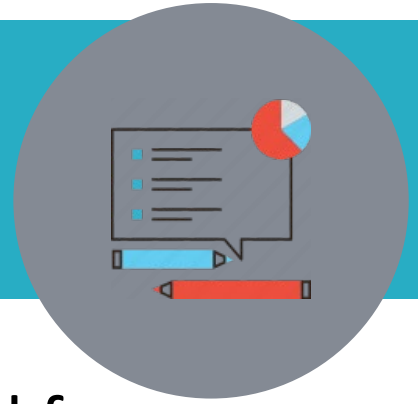


- Allow e-IRB systems to send ANY IRB approval to IREx, not just initial IRB approval
- Note: tips for connecting from API with Huron system and homegrown are available.
- *ETA December 2021*

Public Service Announcement

For Trial Innovation Network

TIN / University of Utah Consent Builder



- Utah Trial Innovation Center has created “Consent Builder” tool for coordinating centers/lead study teams.
- Goal is to streamline the creation of consent forms

Next Call

- October 15, 2021

University of Utah IRB Workflow: Using IREx

IREx Quarterly HRPP Call – July 16, 2021

University of Utah Operations Managers

Gary Henderson
Ammon Pate
Lisa Rigtrup
Annie Risenmay

UU SIRB Workflow

STEP 1
Reliance Consultation

- "Reliance Consultation Request" or application submitted
- Assigned to IRB Operations Manager, who meets with study team to discuss SIRB process and participating sites
- Follow-up instructions sent to meeting attendees
- Study team sends reliance invitations to study site PIs and HRPP contacts

STEP 2
Reliance Confirmation/ Local Requirements

- Study submitted in application submission system, ERICA
- Manager reviews and ensures completion of applicable reliance agreements
- Communication between IRB manager and study team/local HRPP to ensure local requirements are considered and that local review is underway

STEP 3
Pre-Review & Board Review

- IRB Administrator reviews application and sends necessary revision requests
- Local HRPP may be working on their review in tandem and notifying UU IRB of site-specific items
- Study is reviewed at board (or Expedited)

STEP 4
Initial Approval

- Approval notification and approved documents are disseminated
- Protocol-only/Lead site/>1 participating site
- Site HRPPs may review documents and require changes (amendment)

STEP 5
Site Addition(s)

- Participating sites are added when reliance requirements and met
- Multiple sites may be added at a time

STEP 6
Continuing Review/ Amendments/Report Forms

- Main study + sites can be reviewed at the same time or separately (Continuing Reviews, Amendments)
- Lead study team-driven or assigned to site study teams
- Report Forms come through main application

UU SIRB Workflow – IREx Usage

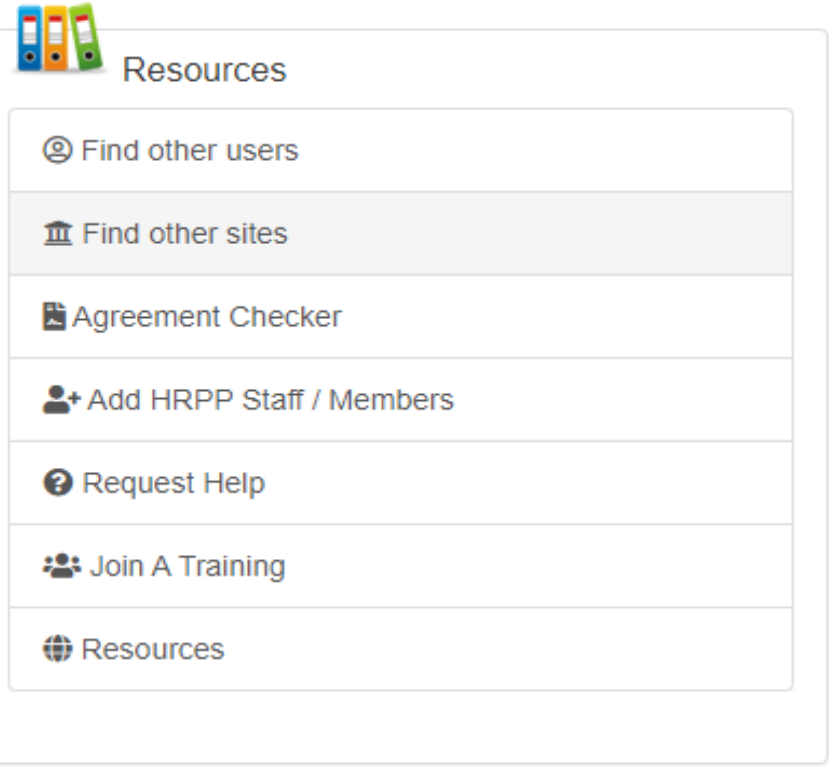
STEP 1
Reliance Consultation

- Assess participating sites
  - IREx Registration
  - SMART IRB
  - Protocol vs. Institutional Profile

Search: university of Utah

Name	SMART IRB V1	SMART IRB V2	IREx Access	Profile	Download
University of Utah ctsa smart v1 smart v2 tin	✓	✓	✓	view profile	download profile

- *Huntsman Cancer Institute*
- *Associated Regional & U Pathologists (ARUP)*
- *Eccles Institute of Human Genetics*
- *Moran Eye Center*
- *South Jordan Health Center*
- *Farmington Health Center*



UU SIRB Workflow – IREx Usage

STEP 2
Reliance Confirmation/ Local Requirements

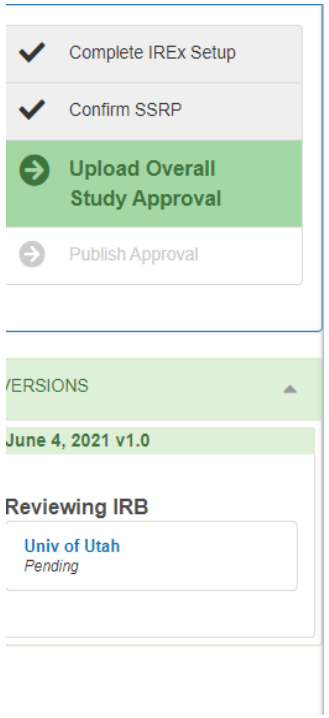
- Create study in IREx using drafts
  - Collecting local context?
- Establish a Study Specific Reliance Plan (SSRP)
- Invite sites to rely as applicable

STEP 3
Pre-Review & Board Review

UU SIRB Workflow – IREx Usage

STEP 4
Initial Approval

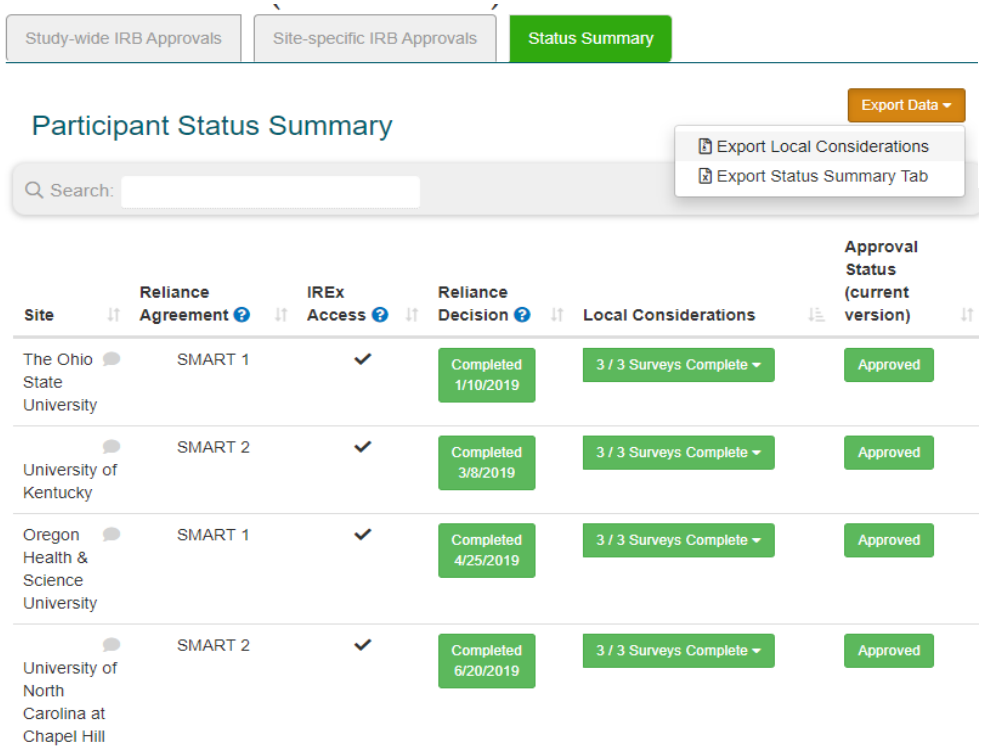
- Upload/publish overall study approval
  - Approved protocol/consent forms
  - IRB determinations
- Invite any remaining sites to rely
  - ‘Notify HRPP’



UU SIRB Workflow – IREx Usage

STEP 5
Site Addition(s)

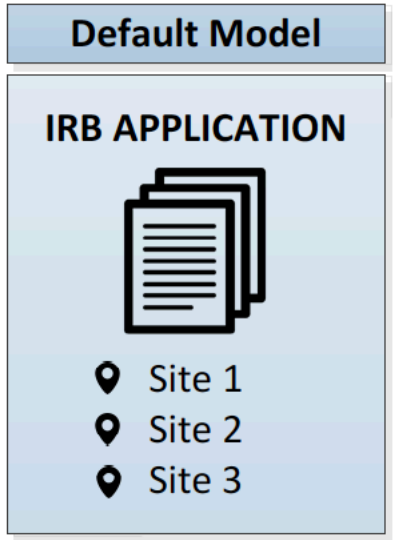
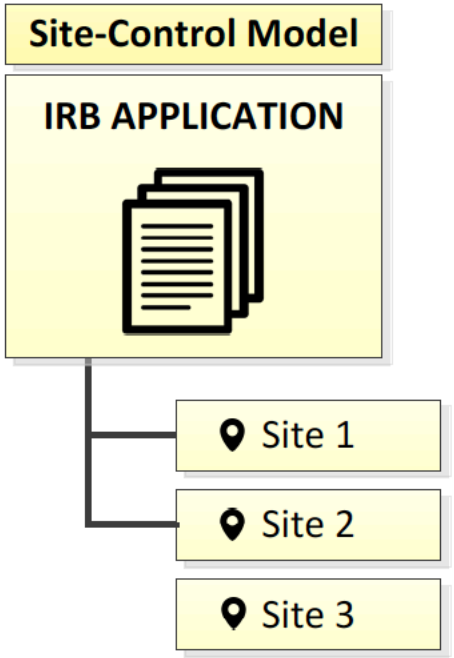
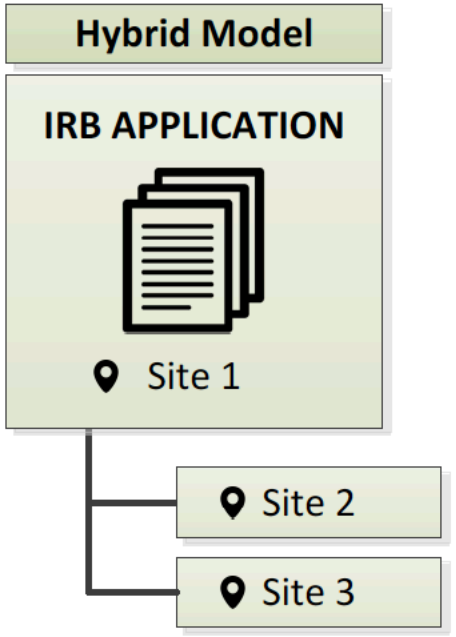
- Confirm reliance decision is established
- Collect local considerations
- SIRB review includes local considerations
- Upload site approval



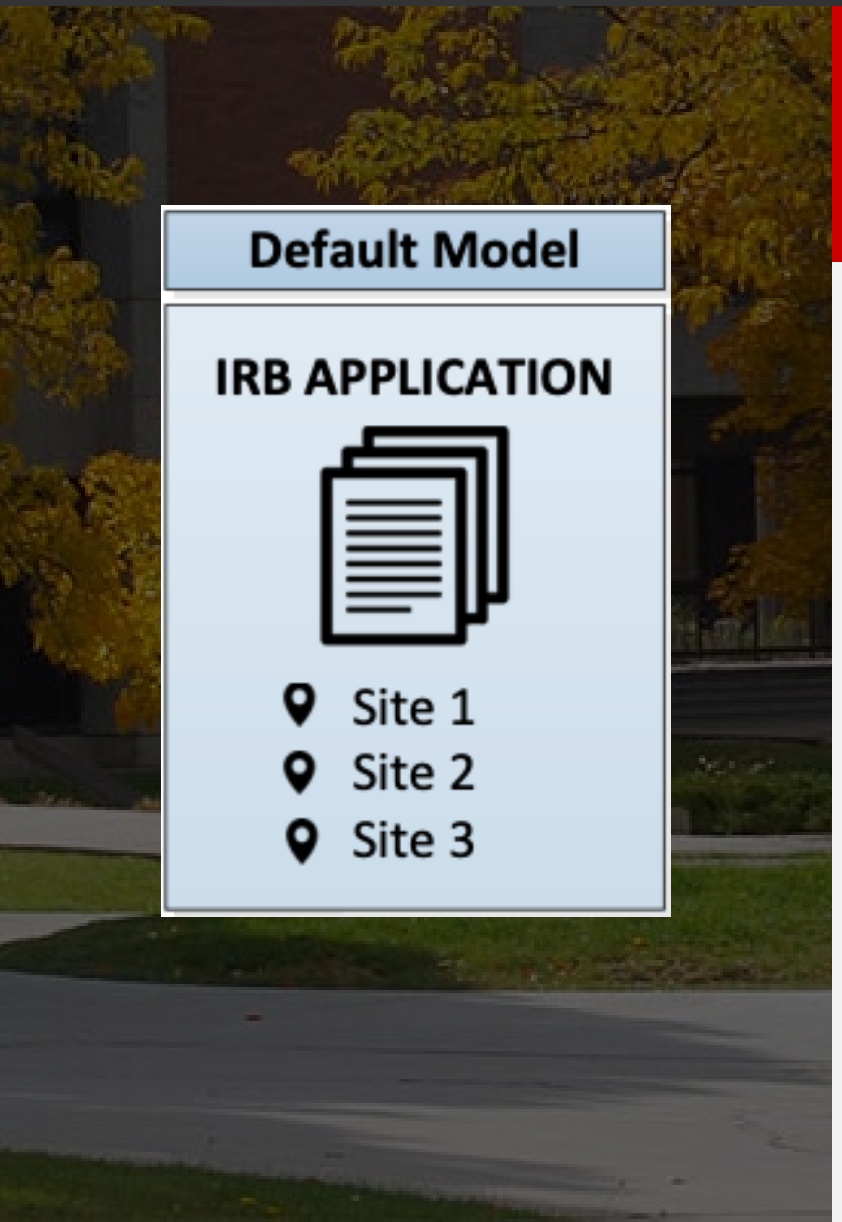
STEP 6
Continuing Review/ Amendments/Report Forms

- Create CR and/or AM
- Publish approval

3 Models for Multi-Site Management

Default	Site-Control	Hybrid
		

Default Model



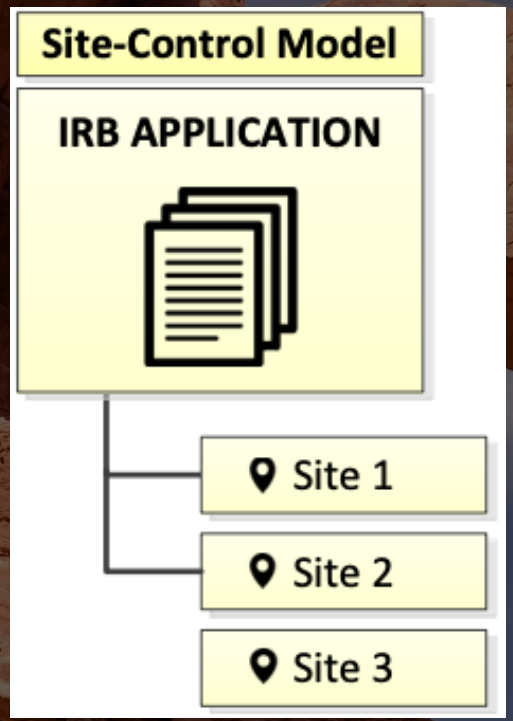
Benefits

- Provides the benefit of having multiple sites and the protocol reviewed and approved within one process

Challenges

- If one or more of the listed sites are not fully prepared for IRB review, the review process is halted until every site is fully prepared for IRB review
- Sites do not receive automated study notifications, unless they have an ERICA profile and are listed in the application. In this case, sites receive *all* notifications, regardless of the relevance or applicability to their site

Site-Control Model



Benefits

- Allows participating sites to be managed independently from the main IRB application
- Main application can go through IRB review process while participating sites are working on completing reliance and site-specific requirements
- Sites can be submitted for IRB review as they are ready and are not beholden to the progress/delays caused by other sites
- Sites receive automated notices relevant to their site

Challenges

- Sites that have their own participating site application must have a Site Investigator (SI) listed. The SI must have an ERICA account and profile in order to have access to the application, enter the required information, and receive study notifications

Hybrid Model

Benefits

- Provides the benefits of both the Default and Site-Control Models

Challenges

- Determining which sites to keep with the main application and which sites to “peel off” into their own participating site applications can be challenging in the early stages of the review process
- Once a site has been “peeled off” and given their own site application workspace, they cannot be re-integrated into the main application

When Do We Choose to Use IREx?

- When the University of Utah is serving as the SIRB, we decide on a case-by-case basis when to use the IREx system.

When We Use IREx	When We Don't Use IREx
• When the study is from the TIC • When there are lots of sites to manage • When the majority of the sites are already signed onto SMART and have used IREx before • When the study coordinator is from an external institution and may need an extra site management tool	• When it is not a TIC study (sometimes) • When the majority of sites aren't signed onto SMART • When the study only has a couple of sites or the other sites are inside our state (Utah) • When we have a master agreement with sites or a SIRB and don't need to execute a study-specific reliance agreement (e.g. cooperative groups)

Pros & Cons of Using IREx

An Academic IRB's Perspective

Challenges to Consider

- **System saturation**: Yet *another* electronic system for study teams and HRPPs to learn; however, IREx is easier than most to use, more aesthetically user-friendly, and more useful to SIRBs
- **IREx is <u>not</u> a document management/distribution system**, but sites may get that impression because the system allows/requires you to upload documents – can lead to sites using versions of documents that are not the most recent version approved by the SIRB
- For the UU IRB, IREx is not as helpful after initial IRB approval because our own electronic system, ERICA has the "site-control model" available**. Our electronic system allows external users to get an account and have access to their own site application.

***If your institution doesn't have this ability, you will need to come up with a way to manage each site's documents and distribute them to site PI's, who then need to keep their HRPPs informed per their local policies.*

Pros & Cons of Using IREx

An Academic IRB's Perspective

Features that Make Life Easier

- The hard part is over: Many academic HRPPs already know how to use the system
- Study teams can keep up with the status of each of their sites' reliance without sending the SIRB an email
- It can help a SIRB figure out which sites need to rely when a combo site/group relationship isn't clear
- Clean, easy to read "**Study Summary**" tab
- Collects local considerations in an easy, streamlined manner – can prevent lengthy email threads and conference calls with sites because there's a simple way for them to communicate concerns and requirements to the SIRB
- The Institutional Profile database is a game changer
- The IREx team is extremely responsive, open to feedback, and friendly – there's a real person available to help you if you need it
- Prevents HRPPs from having to use institution specific systems – one central hub for reliance and local considerations (vs. SMART IRB reliance system, which stops at indicating reliance)

Questions?

Join the IREx User Feedback Group!

- Open to HRPP Liaisons and Study Managers
- Members provide input on upcoming features and priorities.
- Current membership includes:
  - Indiana
  - Johns Hopkins
  - Ohio State
  - Oregon
  - Pennington Biomedical
  - Utah
  - Vanderbilt
  - Wake Forest
  - WashU
- Meets the 3rd Friday each month at 1 ET.
- Sign up here