IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

October 15, 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

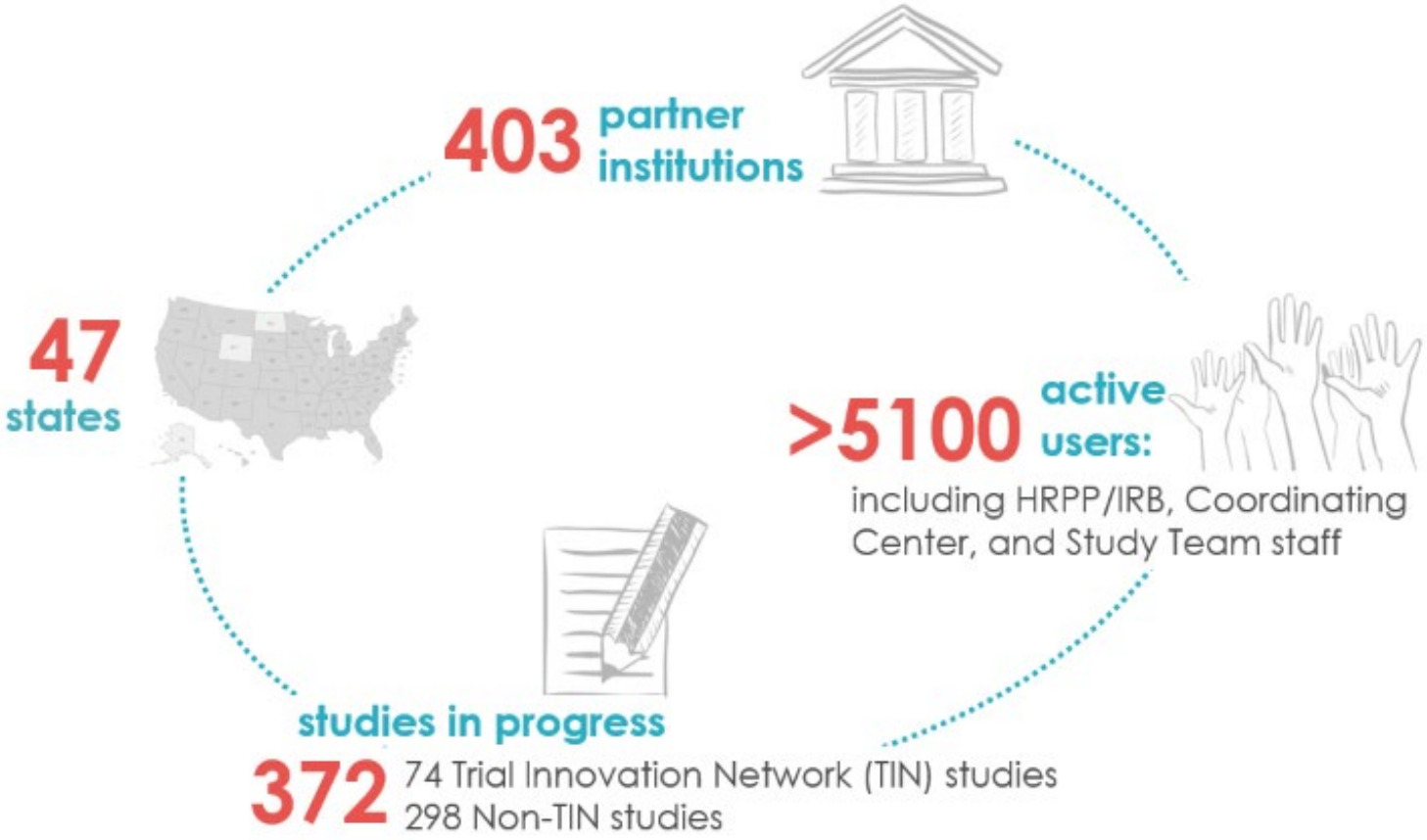
Linda Tan

- Application Developer

Evan Wimberly

QUARTERLY CALL AGENDA

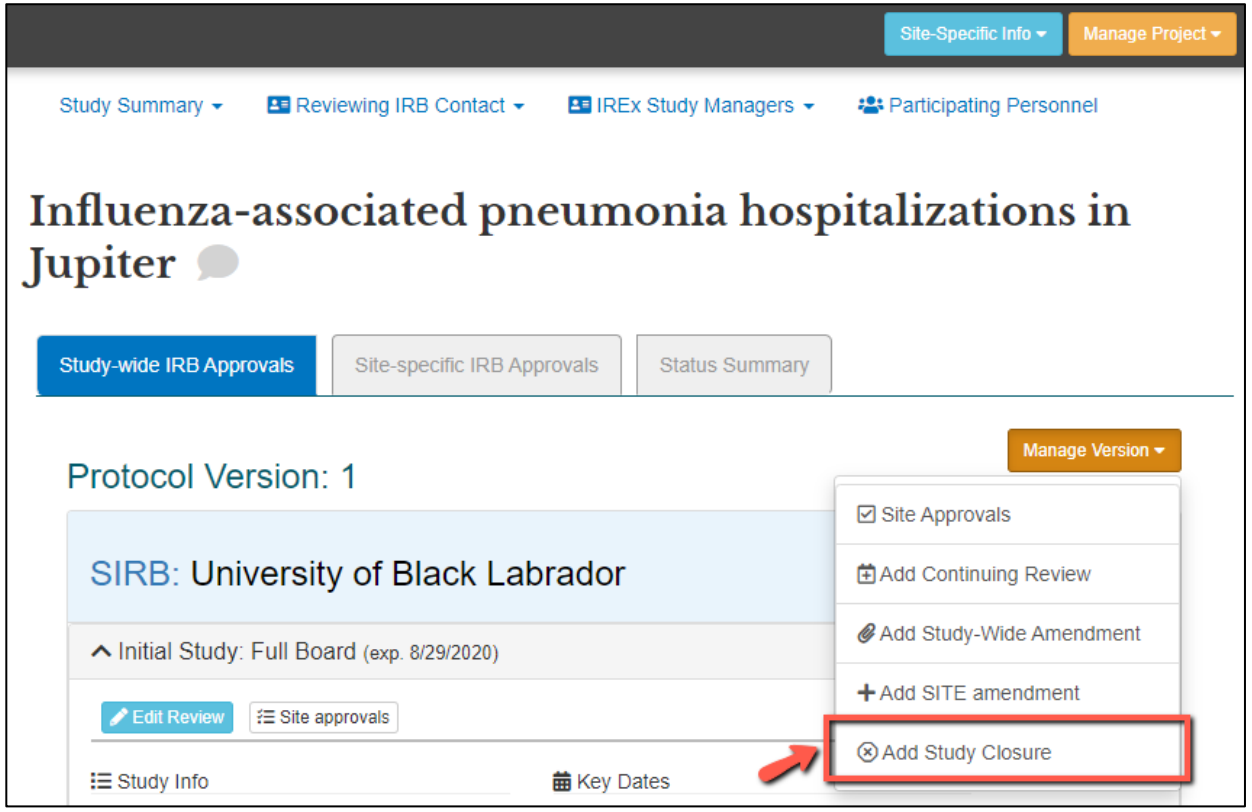
- **Welcome!**
- **Recent System Updates**
- **Upcoming System Updates**
- **Hear from the Pros –** *Jenni Beadles, VUMC HRPP*

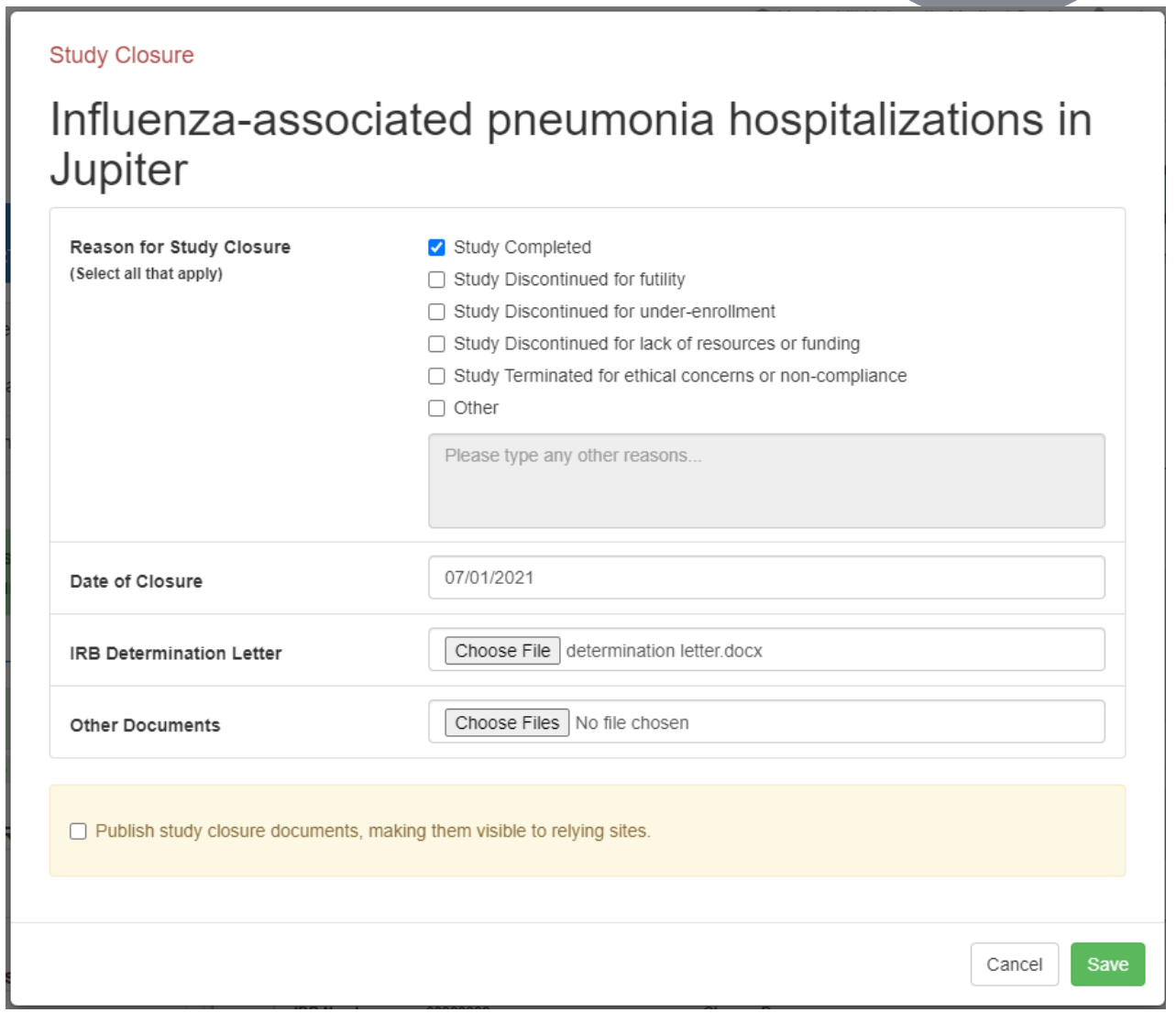


Recent System Updates

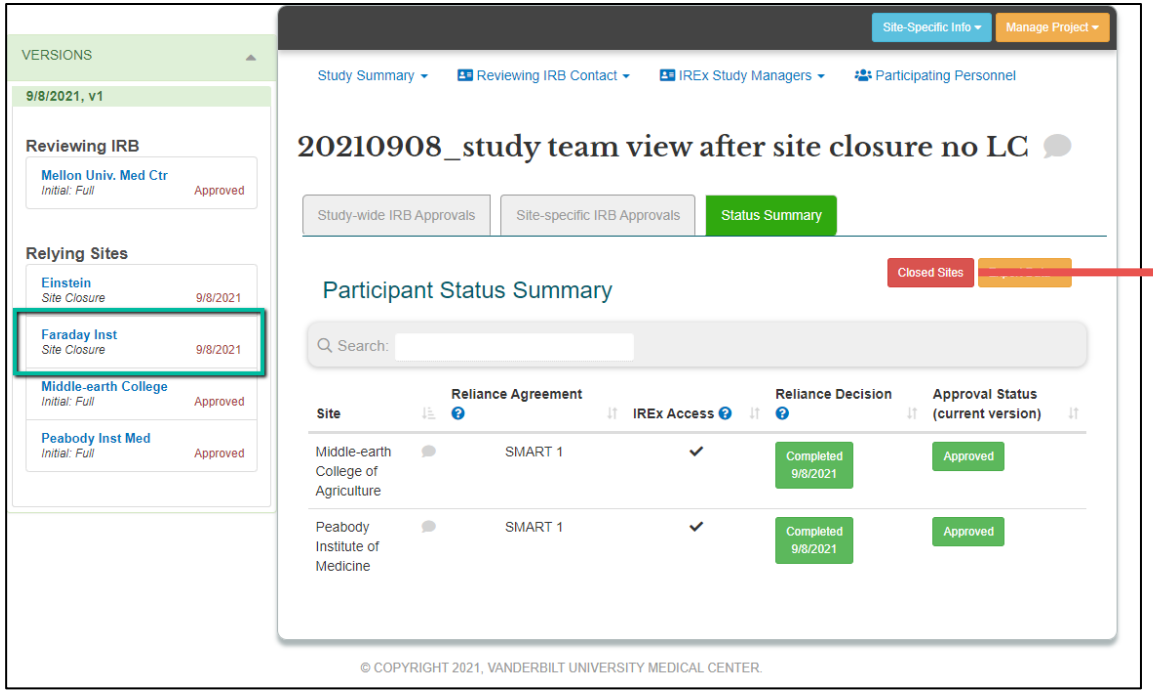
Since July 2021

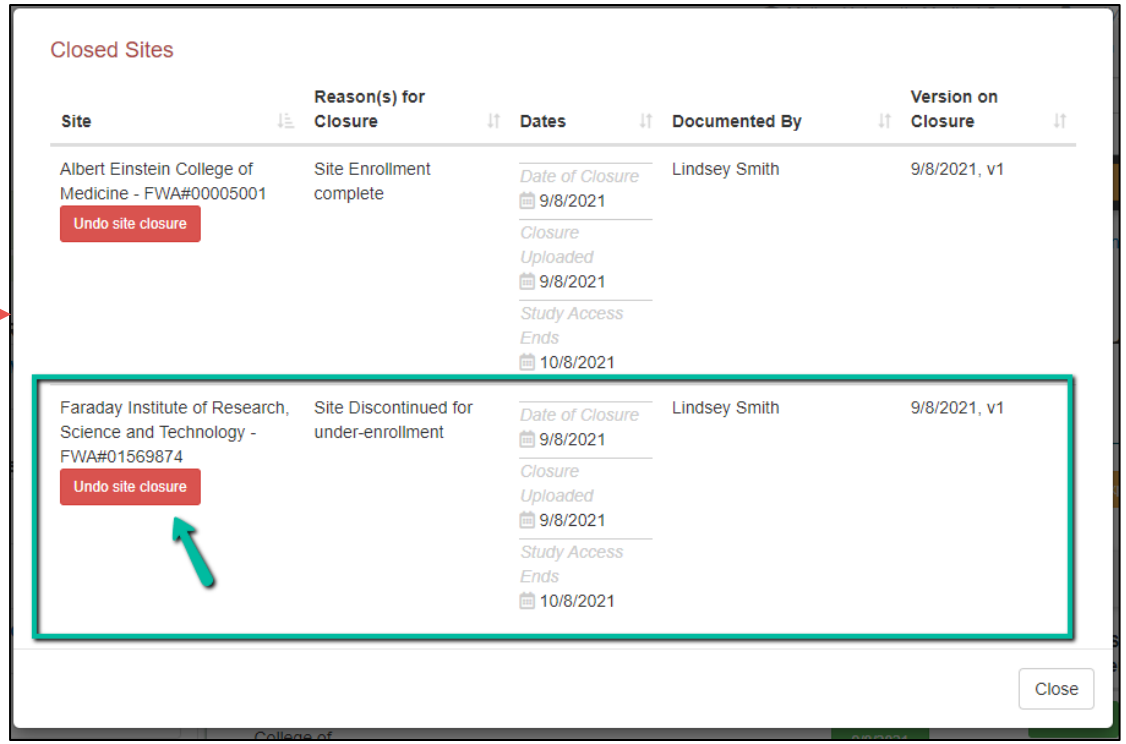
Document Study Closures (sIRBs and SMs)





Document Site Closures (sIRBs and SMs)





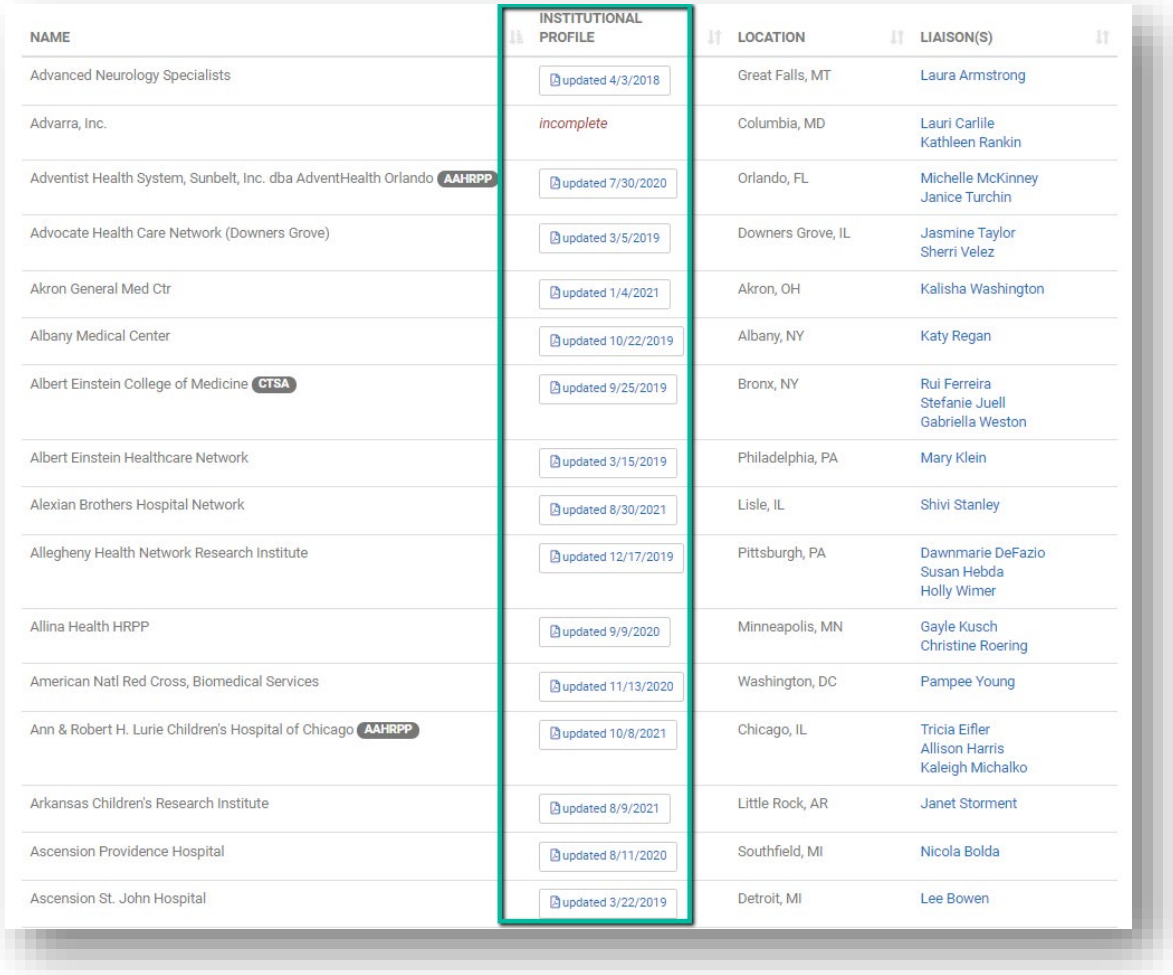
Upcoming System Updates

Fall/Winter 2021

New Questions on the IREx Institutional Profile (IP)

THANK YOU!

89% of IREX Institutions have completed their IP!



NAME	INSTITUTIONAL PROFILE	LOCATION	LIAISON(S)
Advanced Neurology Specialists	updated 4/3/2018	Great Falls, MT	Laura Armstrong
Advarra, Inc.	*incomplete*	Columbia, MD	Lauri Carlile Kathleen Rankin
Adventist Health System, Sunbelt, Inc. dba AdventHealth Orlando AAHRPP	updated 7/30/2020	Orlando, FL	Michelle McKinney Janice Turchin
Advocate Health Care Network (Downers Grove)	updated 3/5/2019	Downers Grove, IL	Jasmine Taylor Sherri Velez
Akron General Med Ctr	updated 1/4/2021	Akron, OH	Kalisha Washington
Albany Medical Center	updated 10/22/2019	Albany, NY	Katy Regan
Albert Einstein College of Medicine CTSA	updated 9/25/2019	Bronx, NY	Rui Ferreira Stefanie Juell Gabriella Weston
Albert Einstein Healthcare Network	updated 3/15/2019	Philadelphia, PA	Mary Klein
Alexian Brothers Hospital Network	updated 8/30/2021	Lisle, IL	Shivi Stanley
Allegheny Health Network Research Institute	updated 12/17/2019	Pittsburgh, PA	Dawnmarie DeFazio Susan Hebda Holly Wimer
Allina Health HRPP	updated 9/9/2020	Minneapolis, MN	Gayle Kusch Christine Roering
American Natl Red Cross, Biomedical Services	updated 11/13/2020	Washington, DC	Pampee Young
Ann & Robert H. Lurie Children's Hospital of Chicago AAHRPP	updated 10/8/2021	Chicago, IL	Tricia Eifler Allison Harris Kaleigh Michalko
Arkansas Children's Research Institute	updated 8/9/2021	Little Rock, AR	Janet Storment
Ascension Providence Hospital	updated 8/11/2020	Southfield, MI	Nicola Bolda
Ascension St. John Hospital	updated 3/22/2019	Detroit, MI	Lee Bowen

New Questions on the IREx Institutional Profile (IP)

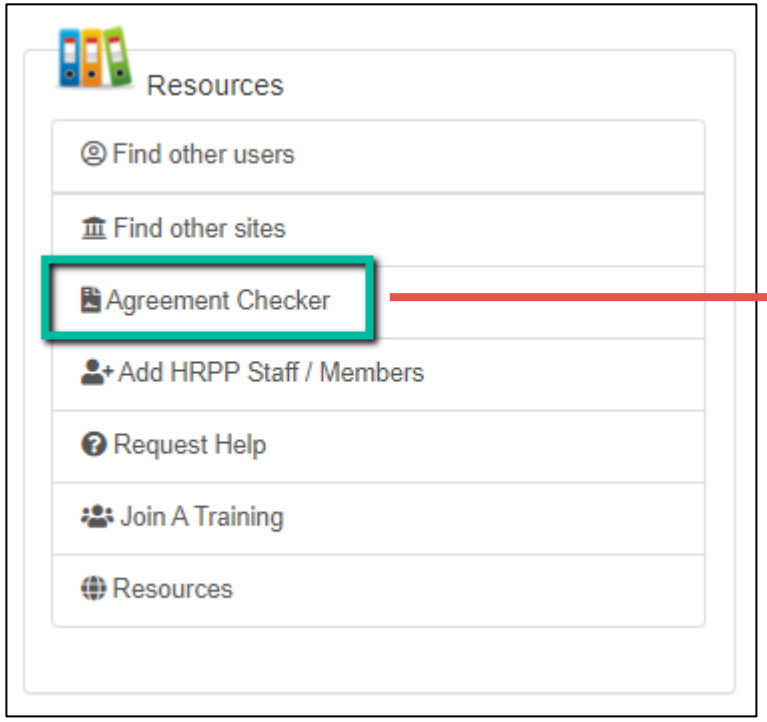
1. Does your site use an **eConsent platform** if needed for a trail
2. If your site will enroll **non-English speakers**, does your site allow the use of a short form?
   - How many times can the **short form** be used before needing a fully translated consent? [or no limit]
   - Does your site require a **Translator/Witness to sign** the Short form?
   - Does your site require a Translator/Witness to sign the full English consent document?'
   - Does your site have **additional policies** related to the consent of non-English speakers? [upload]
3. Does your site's **consent process require any additional documents or riders**? For example, Subject Bill of Rights.
4. For trials providing **compensation**, does your site have specific guidelines, policies, or language that will need to be incorporated into the consent?
5. Describe how your institution has **assessed the quality of its HRPP/IRB**.

- Set your infrastructure

New Questions on the IREx Institutional Profile (IP)

- Institutions are encouraged to update their IREx Institutional Profile annually.
- New questions will be added in November – we'll notify you by email.
- Institutions will be required to respond to the new questions in the IP before they can complete the reliance process for a study.

Agreement Checker Available Prior to Creating Study



Agreement Checking Tool

Report Parameters

SIRB: Faraday Institute of Research, Science and Technology

Add Participating Site: Select a site

Download CSV

Sites may be part of multiple reliance agreements. Each site is only required to execute one of the reliance agreements offered on a study.

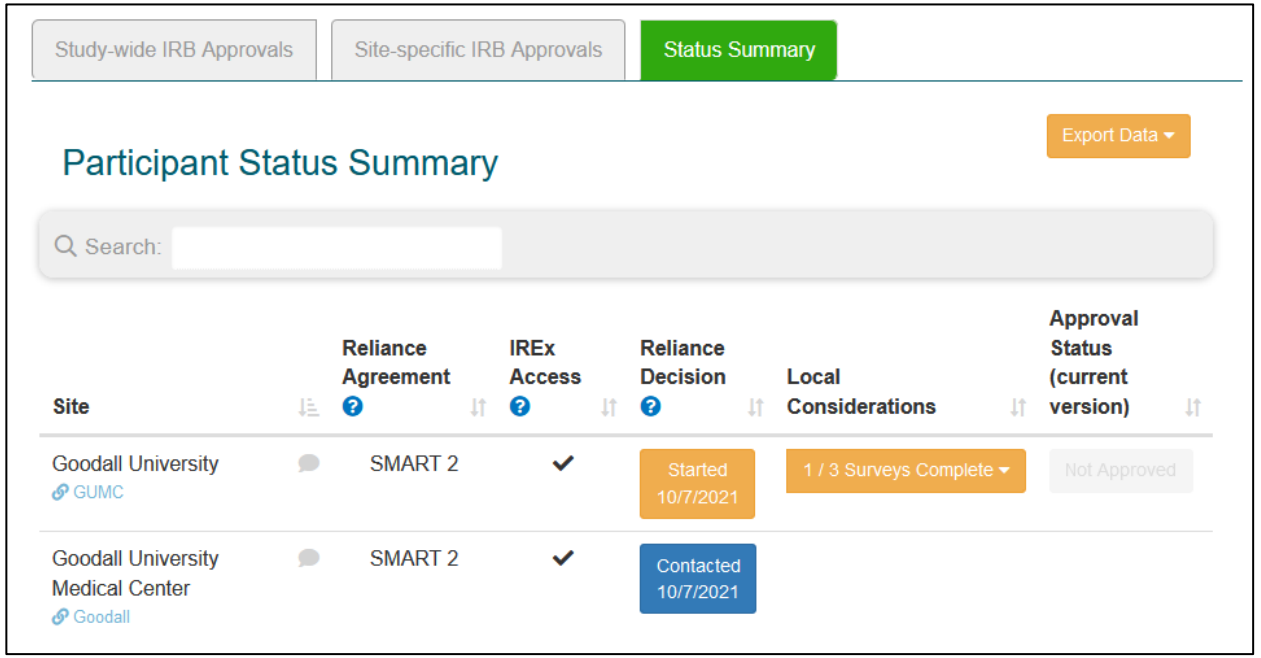
Site Name	FWA	SMART 1	SMART 2	Other Reliance	IREx	
Carnegie University Medical Center	#12345678	✓	✓	✗	✓	Remove
Eastman Medical Center of Ohio	#45648974865	✓	✓	✗	✓	Remove
Mellon University Medical Center	#00001111	✓	✓	✗	✓	Remove
Middle-earth College of Agriculture	#456431546	✓	✗	✗	✓	Remove

New Flexibility for Combo Sites

- "Combo Sites" occur when a single study team engages multiple FWAs.
- Each FWA must provide reliance documentation (cede decision + local considerations)
- IREx required ALL FWA in the combo to complete documentation before it could be exported for sIRB review.

PROBLEMS

- Held up study initiation at some sites.
- Addition of new recruitment sites interfered with already approved sites.



Solution (coming late October!)

- Local considerations can be exported individually, as they are completed
- sIRB Approvals can be posted to IREx as they are issued

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

!SPECIAL GUEST!

- Incorporating IREx into Your Single IRB Workflow -

Guest Speaker:

Jenni Beadles, MEd, CIP
Assistant Director External Partners
Human Research Protections Program
Vanderbilt University Medical Center

INCORPORATING IREX INTO YOUR SIRB WORKFLOW

JENNI BEADLES, MEd, CIP
ASSISTANT DIRECTOR EXTERNAL PARTNERS
VANDERBILT HUMAN RESEARCH PROTECTIONS PROGRAM (VHRPP)
VANDERBILT UNIVERSITY MEDICAL CENTER

VANDERBILT

OBJECTIVES

- Establishing infrastructure
- Maximizing systems solutions
- Working together as a team

IREX AS PART OF SIRB INFRASTRUCTURE

SINGLE IRB INFRASTRUCTURE AT VANDERBILT

Agreements are completed one time per institution to avoid lengthy negotiations on a study-by-by study basis

1. **SMART IRB Reliance Agreement:** A national, master reliance agreement supporting single IRB review

2. **SIRB Letter of Indemnification:** (LOI) for the SMART IRB Reliance Agreement may be required. The SIRB LOI is a separate agreement concerning indemnification and related terms that may be required by the sIRB.

IRB Reliance Exchange (IREx): A single IRB documentation and communication portal.

To access IREx, a human research protections administrator or IRB director/manager can request to create an account and accept the terms of use.

[A portal agreement is no longer required to join IREx.]

VANDERBILT

SINGLE IRB INFRASTRUCTURE AT VANDERBILT

- Message consistently communicated to in all consultations and education
- Requirements for SIRB on website
- Efforts to assist sites in signing on to all aspects
- Whenever possible, no exceptions (which means there are sometimes exceptions☺, but rarely)

SYSTEM SOLUTIONS

API WORK BETWEEN DISCOVR-E (VANDERBILT'S ONLINE SUBMISSION SYSTEM) AND IREX

NEW STUDY

VANDERBILT AS THE LEAD SITE

When the lead site is VUMC, then the new study submission will be similar to a regular standard/expedited new study submission.

HOW IS THE PROCESS THE SAME?

- The initial review will include the following applicable documents:
  - Protocol
  - IRB application
  - Informed Consent Documents
  - Investigator's Brochure and/or package inserts
  - Device Manual
  - Recruitment Materials, Study Measures, Study Materials, etc.

HOW IS THE PROCESS DIFFERENT?

- Protocol ⇨ should be applicable for all sites. Site-specific references should not be included.
- IRB Application ⇨ should only reference VUMC. Relying site details are submitted with the external site surveys.
- Recruitment materials ⇨ should be written as template at the study wide level.
- Informed Consent Documents (ICD) ⇨ should utilize the two-part consent format.
  - Part 1 Master ICD
  - Part 2 Study Site Information

  Short Form ICDs for non-English speaking participants ⇨ should be written as a template

VANDERBILT

NEW STUDY SOLUTIONS

- New study can be pushed from DISCOVR-e to IREx when the analyst finishes the pre-review
  - This step requires a one-time log-in to IREx by our staff to complete the Study Set up
  - Also alerts the IREx team there is a new study so our team collaboration can begin

- Once review and approved by the IRB, the approved study documents can be pushed from DISCOVR-e to IREx

SITE ADDITIONS

Site Additions are expected to be submitted AFTER the SIRB's initial approval of the overall study and local review by the relying sites. Site Additions should include the following information PER RELYING SITE – all of the following items are exported from IREx and checked for completion by the Study Coordinator or Coordinating Center prior to submission to the VUMC SIRB:

- Institutional Profile – complete with responses to all questions
- Human Research Protection (HRP) Survey – should include:
  - Responses to all questions
  - Uploaded Part 2 ICD (when applicable) complete with respective site's required local language
  - Signature of HRP Representative
- Principal Investigator (PI) Survey – should include:
  - Responses to all questions
  - Signature of respective site's PI
- Study-Specific Reliance Plan (SSRP)
- Part 2 ICD (when applicable)
- Site-specific Assent Form (when applicable)
- Stand-alone HIPAA forms: these are accepted with the site's information, but are not approved/stamped by the VUMC SIRB

Note: incomplete surveys will not be accepted. Sites with incomplete surveys will be considered 'not ready' for review and removed from the submission to facilitate review of the sites that are ready. Site Additions are limited to 5 'ready' sites per submission..

VANDERBILT

SITE ADD SOLUTIONS

- When sites have completed their surveys in IREx, that information pushes from IREx to DISCOVR-e.
- DISCOVR-e sends a notification to the study team that they have a site considered 'ready' to add to the study
- When in DISCOVR-e, all of the documentation required for a site add can be imported from IREx by the study team as they are preparing their submission

TEAM WORK

IREX & IRB COLLABORATION

- Leverage resources across teams – the IREx team is a huge help
- Create efficiency for study teams (and the IRB!)
- Explore opportunities for how your teams can uniquely work together
- Communication is key

QUESTIONS?

Next Call

- January 21, 2022

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