IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

October 19, 2018

• User Training • Study Support	• System Development • Data analysis	• Project Manager	• Site Onboarding • Study Support	• User Support • Study Support
Natalie Dilts 	***Adoma Manful*** 	***Emily Serdoz*** 	***Bridget Swindell*** 	***Linda Tan*** 

QUARTERLY CALL AGENDA – HRPPs

- Introductions
- New Features for Reviewing IRBs
- IREx switches to Terms of Use
- IREx Resources Update
- Next Call Info

New Features for Reviewing IRBs

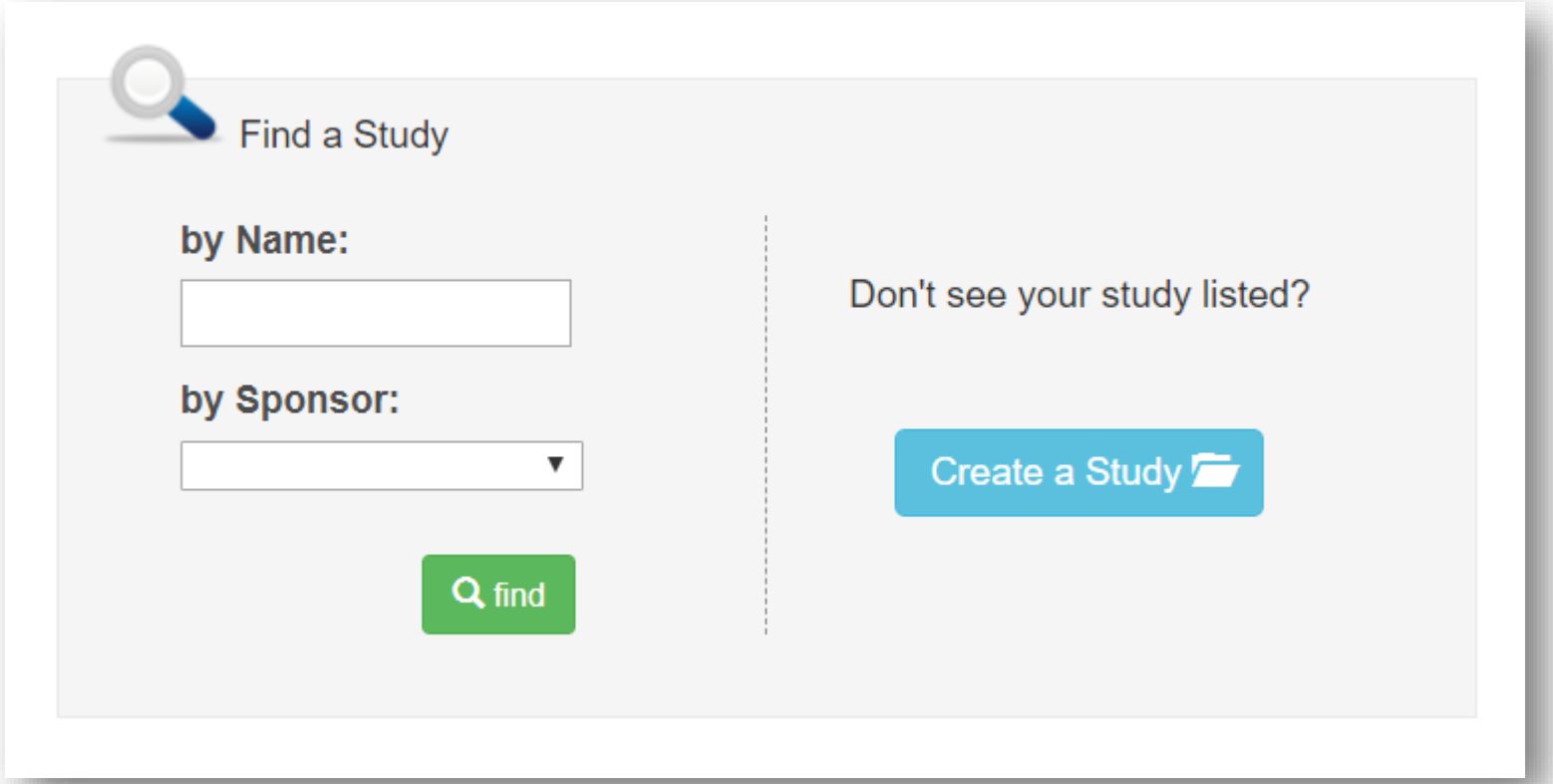
Streamlined Study Creation

Empower the IREx Study Manager (Lead Study Team or Coordinating Center)

Using IREx to Capture Local Considerations/Context

STREAMLINED STUDY CREATION

- Streamlined study set up
- Identify the Primary IRB Liaison for the sIRB to better streamline communications
- IREx Study Manager is now required (i.e., Lead Study Team coordinator or Coordinating Center contacts)



IREX STUDY MANAGER NOTIFICATION

Dear Taylor Jansen,

You have been given access, as an IREx Study Manager, to the study below in IREx. If this is your first study on this platform, a separate email was also sent with your login information.

Study Title	A Cluster Randomized Multi-Center Baseline Assessments of Carbon Dioxide Emission (ACE)
Reviewing IRB	Vanderbilt University Medical Center
Study Link	https://victrtest.irbchoice.org/embryb/irex/public/study/index/?proj=50349

Your Next Steps

Visit the resources page for detailed instructions on these steps:

1. **Designate the Participating Sites and site PIs in IREx.**
   Please login and enter the participating sites and their corresponding study PIs to help the Human Research Protection Program (HRPP)/IRB Liaisons check on the status of the study at their sites.

2. **IREx notifies the participating site HRPPs of the study.**
   After you send the study start up packet (protocol, consent templates, regulatory documents, etc) to your participating site study teams, click the "Notify HRPP" button in IREx to notify the participating site HRPPs/IRBs about the study. The HRPP/IRB will confirm their institution's engagement in research, begin the cede review process, and provide the study team with access to IREx when appropriate. Generally, a local submission is required before the HRPP/IRB will begin completing their steps in IREx.

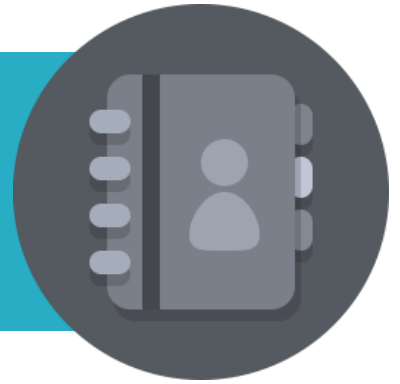
   IMPORTANT: Participating site study teams should receive the study start-up packets BEFORE IREx notifies their HRPP/IRB about the study. Study teams need these materials to begin preparing their local IRB submission. IREx is not used to disseminate the study start up materials as study teams can not get access until their local HRPP/IRB receives a local submission.

3. **Use IREx to track site progress towards reliance and initial IRB approval.**
   You will receive notifications from IREx as sites complete the required steps.

If you have questions about using IREx, you can email us your questions (admin@irbexchange.org) or request additional training.

Thank you for using IREx,
The IREx Team

EMPOWER THE IREX STUDY MANAGER
(Lead Study Team or Coordinating Center)



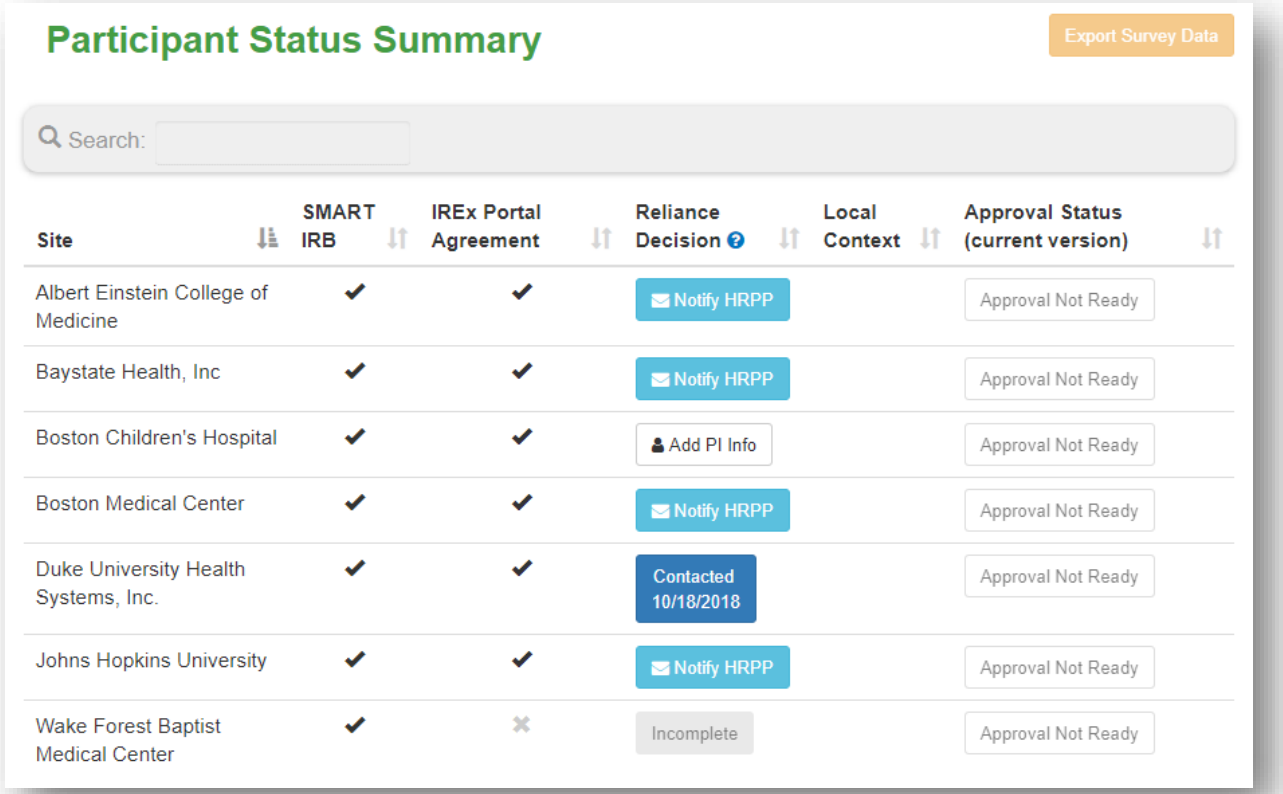
IREx IRB Liaisons Permissions

- Create studies in IREx
- Confirm study-specific reliance plan (SSRP)
- Upload overall/lead site approvals
  - Initial
  - Continuing review
  - Study amendments (affecting all sites)
- Perform all "IREx Study Manager" activities

IREx Study Manager Permissions

- Add other IREx Study Managers
- Add sites and list their PI
- *New* **Indicate when to send the IREx study notification to PS HRPPs *(requires SSRP be completed by sIRB)***
- Export local considerations
- Upload Relying Site approvals
  - Initial
  - Continuing review
  - Study amendments
  - Site amendments (e.g., PI change)

NOTIFYING SITE HRPPS OF STUDIES IN IREX



After the sIRB has confirmed the SSRP for the study…

- **IREx SM** manually notifies site HRPP of the study.
  - Sites can no longer be contacted without listing their local PI
  - Local PI is copied on notification email

IREX STUDY NOTIFICATION

NEW →

NEW →

Dear Liaison(s) and Study Investigator,

Carnegie University Medical Center (FWA:00009856) has been listed as a participating site in IREx for the following study:

TITLE: A Cluster Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission (ACE)

REVIEWING IRB: Vanderbilt University Medical Center

LOCAL INVESTIGATOR: James Anderson

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 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) If you have not received a local submission, you may want to contact your study PI (cc'd here) to let him/her know how they can initiate reliance at your institution.

2) When you are ready, login to IREx confirm your site's engagement by registering for the study and provide access to your local PI. This is not a cede decision. **Email the contact(s) below if the wrong FWA is listed or another FWA should also be listed. You will receive a new email with the correction:**

- Taylor Jansen (tjansen@vumc.org)
- Adrian Leto (aleto@vumc.org)
- Teresa Banks (tbanks@vumc.org)

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.

Should we cc the IREx Study Manager on these emails?

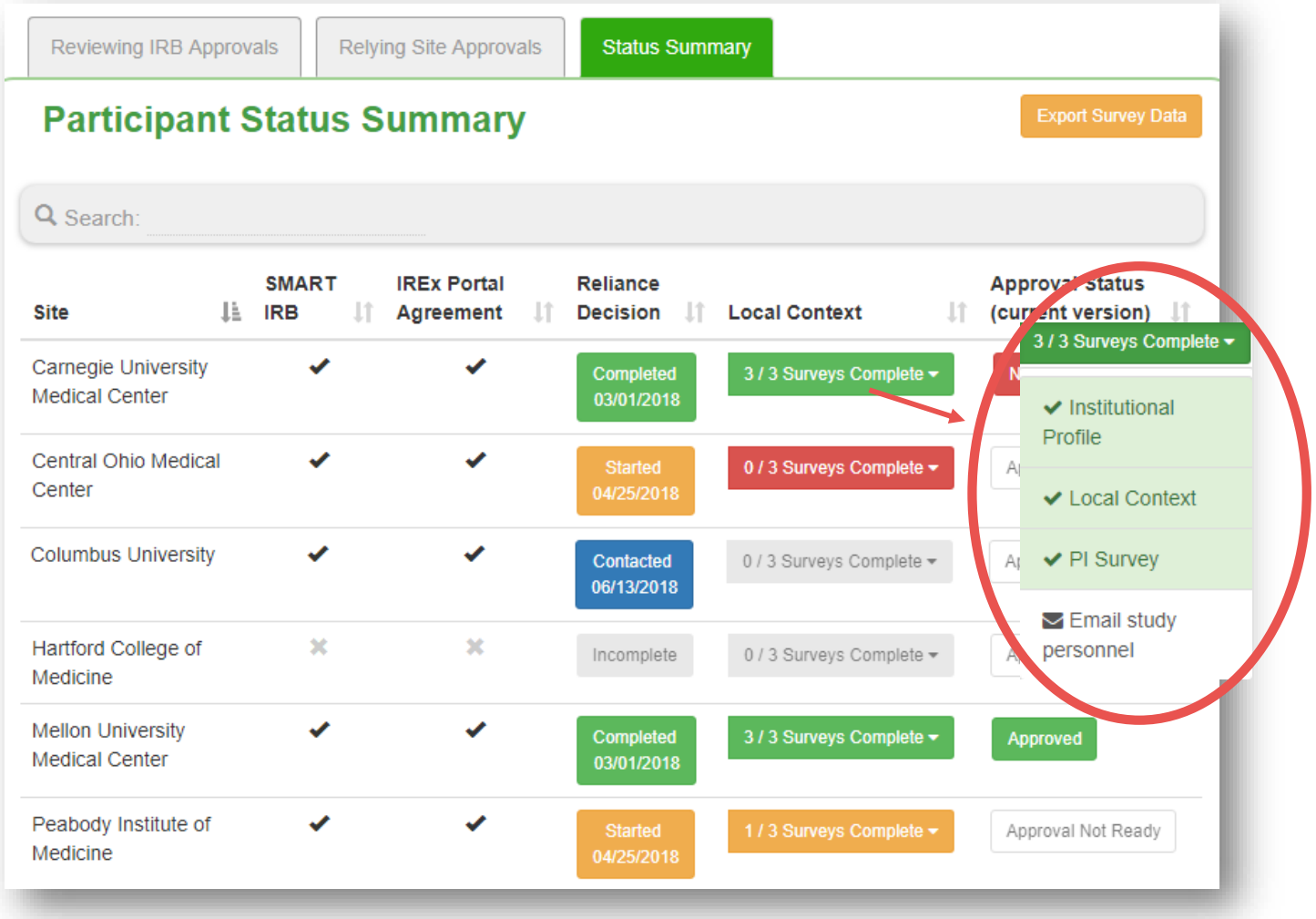
+ Confirmation that email notification went out and can follow up with the study team
- Could follow up with relying site HRPP

EMPOWER THE IREX STUDY MANAGER
(Lead Study Team or Coordinating Center)

- **What YOU do before naming IREx Study Manager(s) for a study:**
  - Educate the Study Manager(s) on the sIRB process
  - Provide reliance instructions so they can education and inform site study teams on the requirements and sIRB process
  - Discuss when sites should be notified of studies in IREx
  - Instruct them to attend or request IREx training
- **What IREX does to support Study Managers**
  - Offer standing or ad hoc trainings
  - Sends automated notifications as site complete their steps
  - The IREx Team sends manual updates on (1) site progress and (2) how to use the Status Summary
  - Resources: https://rocket.app.vumc.org/index.php?doc_id=21990

USING IREX TO CAPTURE LOCAL CONSIDERATIONS/CONTEXT

- **Standardize** questions and processes
- **Centralize** the collection of information (minimize need to provide access to folks outside your institution)
- **Guarantee** HRPP sign off
- **Facilitate** site-specific tracking and documentation on a study-by-study basis



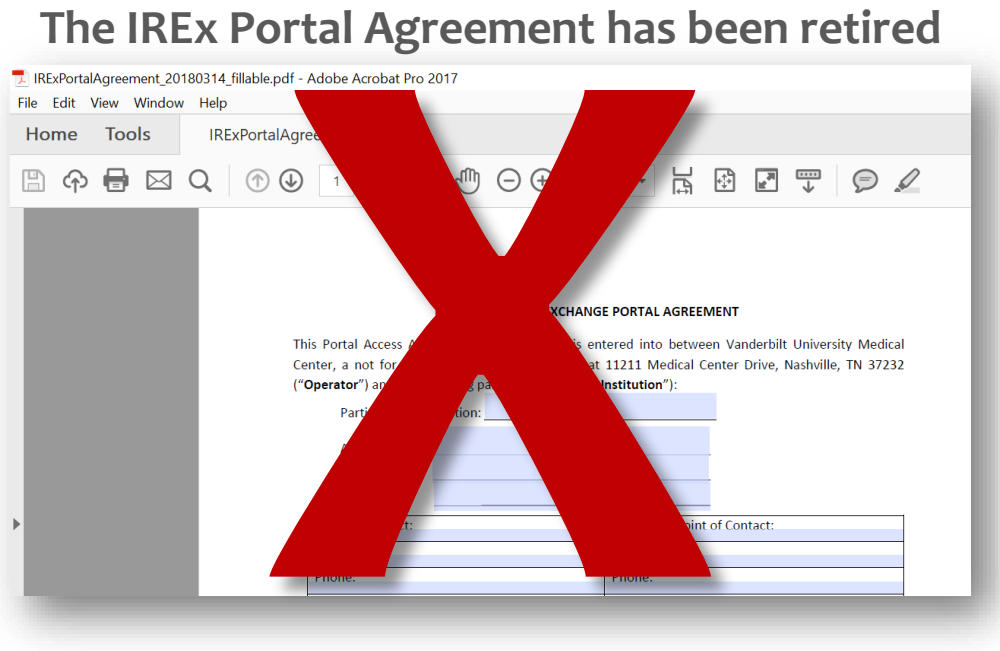
Want more info? Sign up for a training:
https://attendee.gototraining.com/rt/485841592003962113

IREx switches to Terms of Use

NEW PROCESS FOR JOINING IREX

- **WHAT DOES THIS MEAN FOR ME?**
  - In early November, the first time you and anyone from your institutions logs in you will be asked to accept the terms of use.

- **HOW DO NEW SITES JOIN?**
  - The HRPP Director or Manager can create their institutions access via the link on the IREx Members Page.



IREx Resources Update

IREx Videos on YouTube

IREx Institutional Profile is Public

Reliance Instruction Template

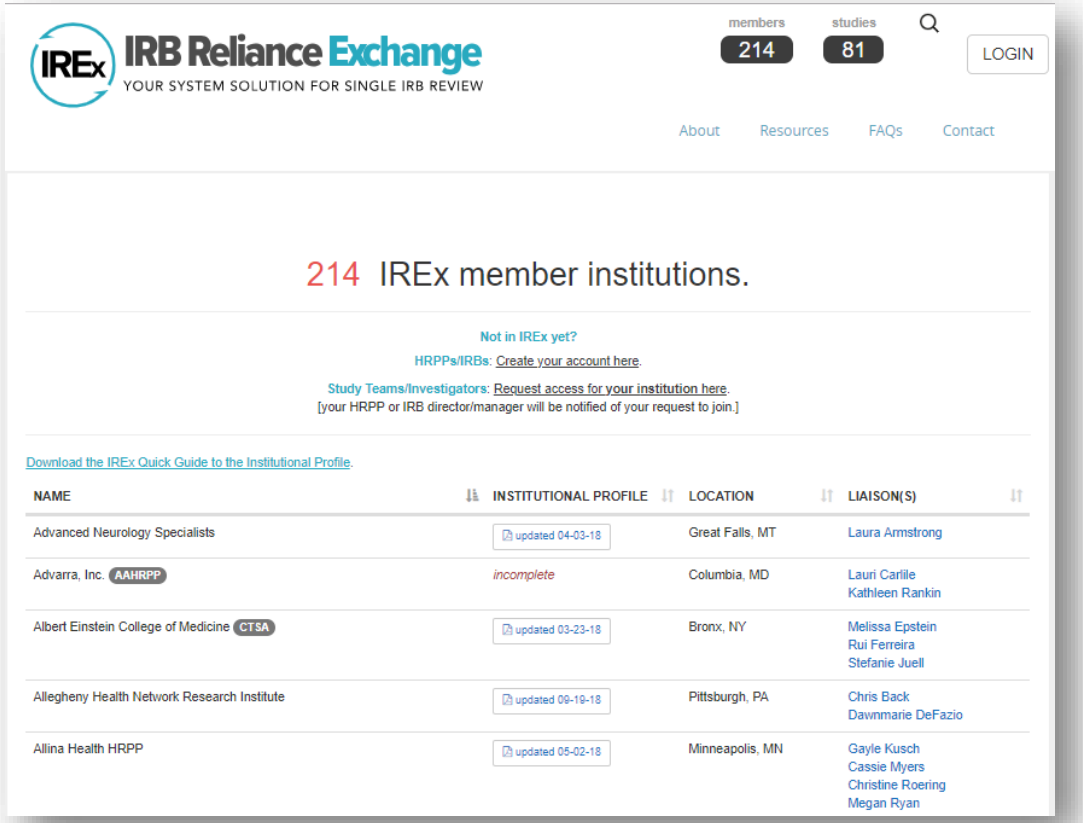
Request a Demo or Training

IREX VIDEOS ON YOUTUBE

https://www.youtube.com/channel/UCVXKpNczhlPcsQRwF7oWcwA/videos

Video Title	Approximate Length	Link
What is IREx?	~2 minutes	https://www.youtube.com/watch?v=NV94eUBylMg&t=11s
How to: Register and Cede Review	4 minutes	https://www.youtube.com/watch?v=-yW-TS-z6So
What is the Study Specific Reliance Plan (SSRP)?	90 seconds	https://www.youtube.com/watch?v=T9FbOV6oN7U
How HRPP / IRB Liaisons use the IRB Dashboards	90 seconds	https://www.youtube.com/watch?v=TKyoZ9_yhf4&t
How to Add/Remove Study Team Members from a study in IREx	2 minutes	https://www.youtube.com/watch?v=f_hKS8nqbb8
Using IREx as a Participating Site Study Team	4 minutes	https://www.youtube.com/watch?v=iKjO47QsIws
New Features Highlight (coming October 26)		
How to Add Amendments (study-wide and site-specific)		

IREX INSTITUTIONAL PROFILE IS PUBLIC



TRANSPARENCY

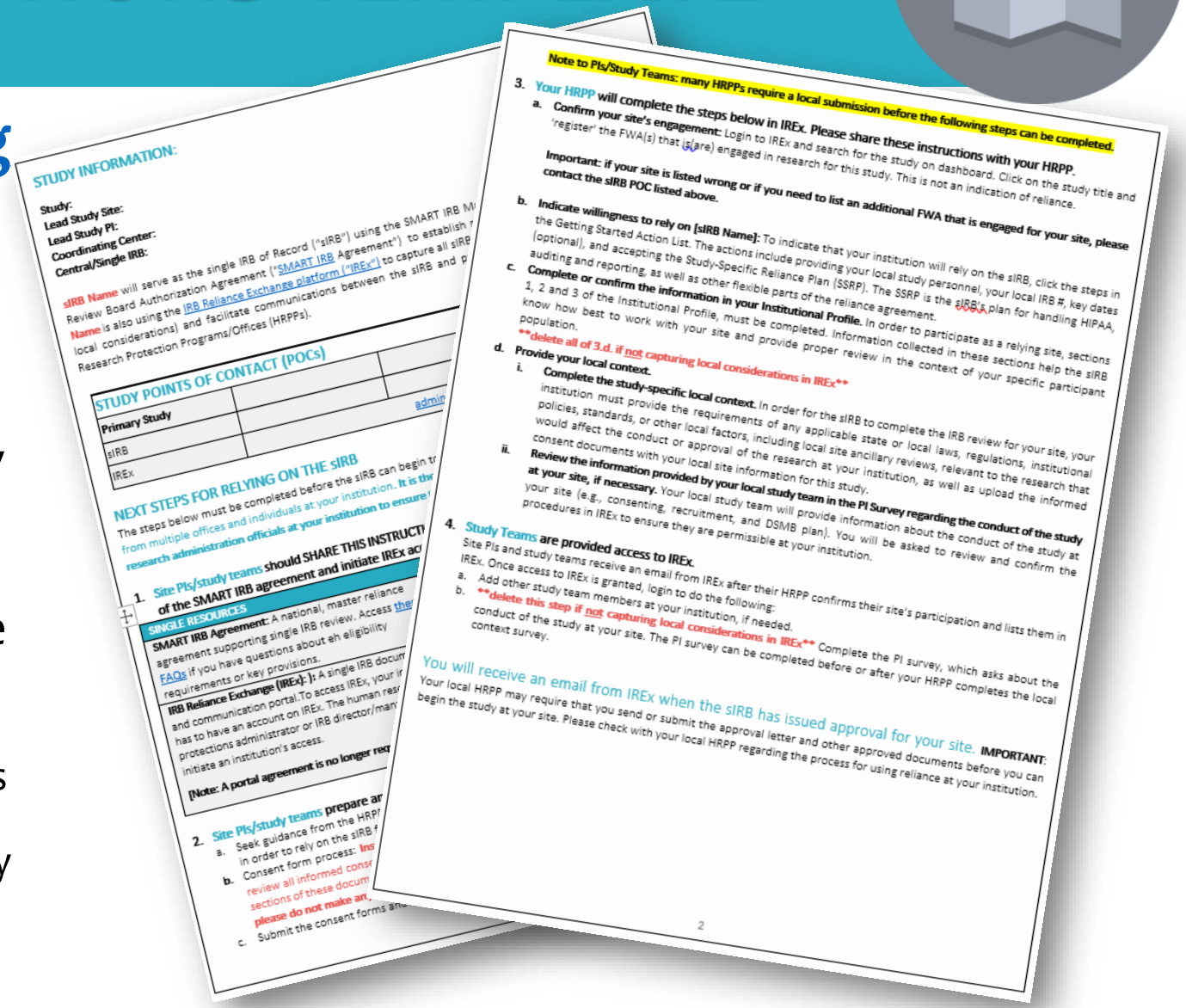
HIGH QUALITY DATA SHARING

STREAMLINE ACCESS TO INFORMATION

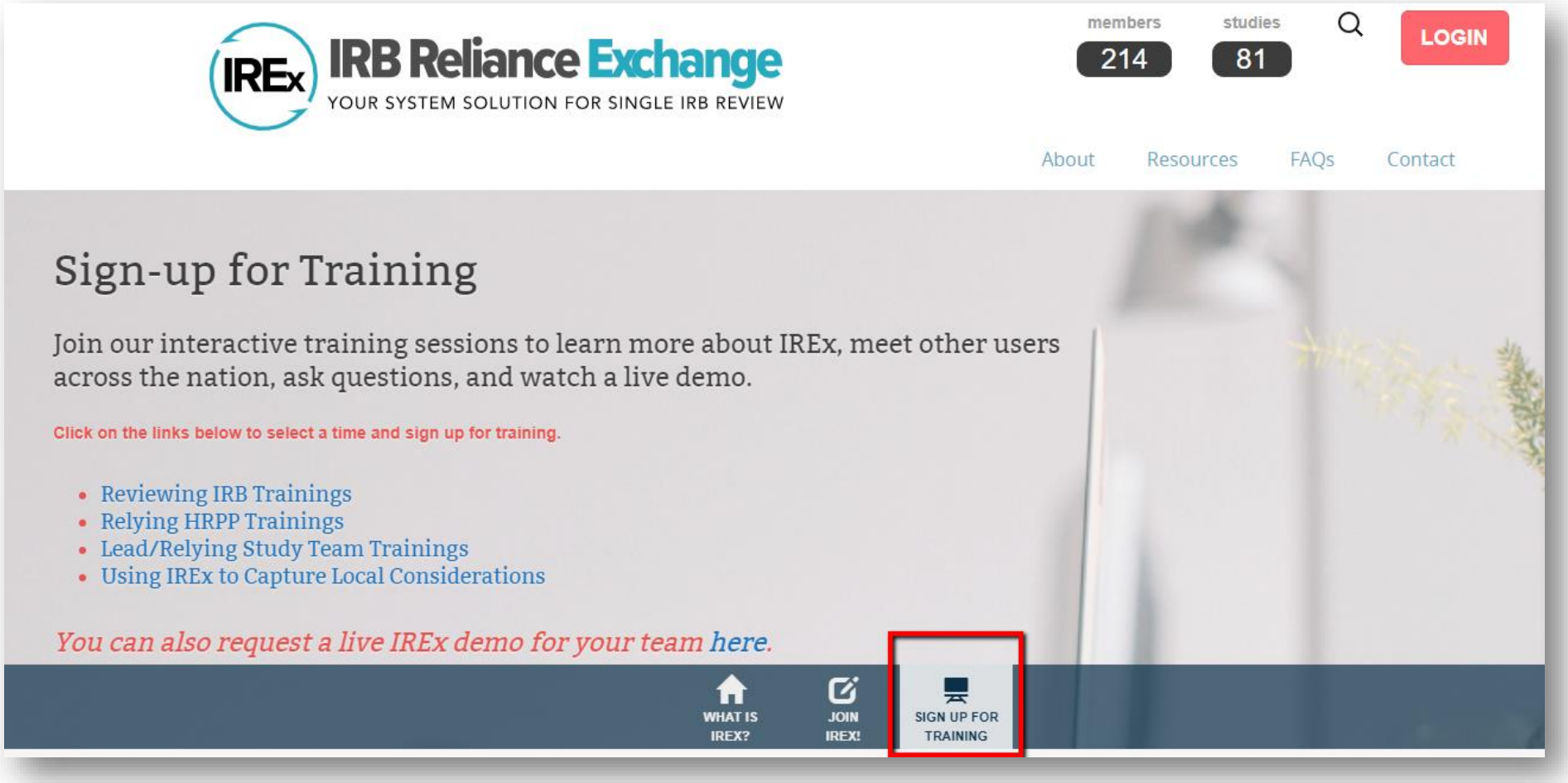
RELIANCE INSTRUCTIONS TEMPLATE

https://www.irbexchange.org/p/resources/reviewingirb/

- **Process**
  - Finalized by the sIRB
  - Disseminated to relying site study teams by the lead study team/ccc
- **Content**
  - Points of contact for IREx and the sIRB
  - Process for relying on the sIRB:
    - Required agreements and systems used to support the sIRB process
    - Responsibilities of the site PI/study team
    - Responsibilities of the site's HRPP



REQUEST A DEMO OR TRAINING



Next Call

- **January 18, 2019 @ 1 PM ET/10 PT**
- **Performance Sites that engage multiple FWAs**