



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

October 18, 2019

- User Training
- Study Support

Natalie Dilts



- System Development
- Data analysis

Asri Mumpuni



- Project Manager

Emily Serdoz



- Site Onboarding
- Study Support

Bridget Swindell



- User Support
- Study Support

Linda Tan





Asri Mumpuni, MPH

- Background in clinical trials
- Thinks IREx testing is “fun”
- Positive, energetic, upbeat
- Data-minded

HRPPs QUARTERLY CALL AGENDA



- Welcome
- IREx Utilization Update
- Reminders from the Last Call
- New System Features
- Next Call

IN CASE YOU MISSED IT...



Catch IREx improvements as they are released

- Check out the [IREx Feature Release Log](#)
- Read our monthly [IREx Newsletter](#)

New to IREx or need a refresher? Join a training!

- [Lead Study Teams/Coordination Centers](#) (Oct 23)– using IREx to support your sIRB study
- [Reviewing IRB trainings](#) (Nov 13)– setting up your study in IREx
- [Relying HRPP trainings](#) (Nov 20)– using IREx to document reliance/ local considerations
- Can't make the monthly trainings? [Request a demo](#) for your team

The screenshot displays the IREx website interface. At the top left is the IREx logo with the tagline 'YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW'. To the right, there are statistics for 'Members' (287) and 'Studies' (174), along with a 'Join IREx!' button and a 'LOGIN' button. A navigation menu includes 'About', 'Resources', 'FAQs', 'Newsletters', 'Feature Release Log', and 'Contact'. The 'Newsletters' and 'Feature Release Log' links are highlighted with a yellow box, and a red arrow points to the 'Feature Release Log' link. Below the navigation is a 'Newest Features' section with a lightbulb image. The featured article is titled 'Participating Sites Status Summary Tab Available' and describes a new 'Status Summary' tab for HRPPs and Study Teams. A 'More features' button is visible below the article. At the bottom of the page, there is a footer with icons for 'WHAT IS IREX?', 'SIGN UP FOR TRAINING', 'OUR METRICS', and 'NEWEST FEATURES'. The 'NEWEST FEATURES' icon is highlighted with a yellow box, and a red arrow points to it.

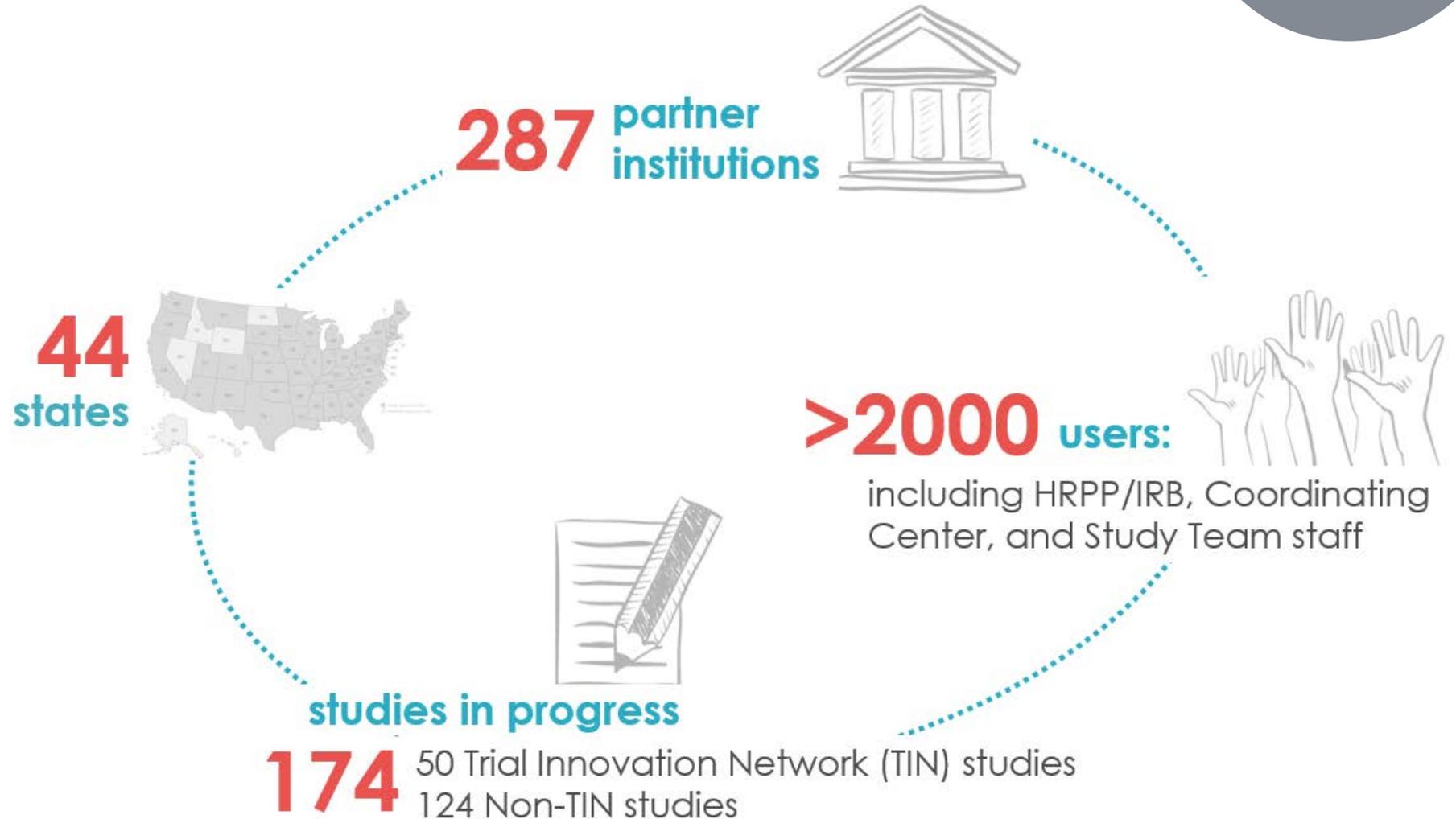
IREx Utilization – A Look at IREx Metrics

IREX UTILIZATION



STATISTICS

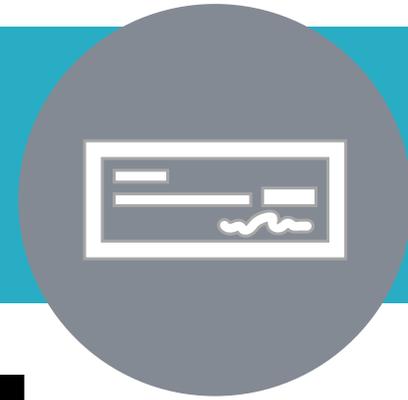
- **157%** increase in the # of studies created from Jan-Sept 2018 and Jan-Sept 2019
- **27** sIRBs in IREx
- **13** median days from sIRB submission to sIRB approval for relying sites
(does not include local review time)
- **7** average sites per study
(Range: 2-100 sites)



Reminders from the Last Call

- FAQs on website
- Site-specific comments
- Tracking updates to local considerations

REMINDERS FROM JULY CALL



UPDATED FAQs ON IREX WEBSITE

Members 287
Studies 173
Join IREx!

About Resources **FAQs** Newsletters Feature Release Log Contact

FAQs

- + Access
- + Creating a Study
- + Eligibility
- + IREx Study Manager

SITE-SPECIFIC COMMENTS/NOTES

Participant Status Summary

Reviewing IRB Approvals Relying Site Approvals **Status Summary**

Search:

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Boston Medical Center	✓	✗	Started 6/13/2019	3 / 3 Surveys	Not Approved
Carnegie University Medical Center	✓	✓	Completed 6/6/2019	3 / 3 Surveys	Not Approved
Columbus University	✓	✗	Completed 2/25/2019	3 / 3 Surveys	Not Approved
Hartford College of Medicine	✓	✓	Started 2/19/2019	0 / 3 Surveys	Not Approved
Mellon University Medical Center	✓	✓	Completed 6/6/2019	3 / 3 Surveys	Not Approved
Peabody Institute of Medicine	✓	✓	Started 2/19/2019	3 / 3 Surveys	Not Approved

Mellon University Medical Center

Comments Edit

Jerry Shaw (Study Manager) 6/17/2019 12:43pm
Site PI changed. Sent revised reliance instructions to study coordinator and new PI.

Laura Sanders (HRPP) 6/17/2019 12:45pm
Discussed local SOPs by phone and adjusted Study Specific Reliance Plan (SSRP) accordingly. IREx automatically notified HRPP of updated SSRP for their acceptance.

Type comment here...

Post

TRACKING UPDATES TO LOCAL CONSIDERATIONS

Search:

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Columbus University	✓	✓	Started 6/23/2019	3 / 3 Surveys Complete	Not Approved
Hartford College of Medicine	✓	✓	Completed 6/24/2019	<ul style="list-style-type: none"> ✓ Institutional Profile Confirmed: 6/23/2019 ✓ HRP Survey Completed: 6/23/2019 Updated: 6/24/2019 ✓ PI Survey Completed: 6/23/2019 	Not Approved
Mellon University Medical Center	✓	✓	Started 6/23/2019	3 / 3 Surveys Complete	Not Approved

If a survey is updated, the date updated is listed.

UPDATE TO HRP & PI SURVEYS



The SMART IRB Agreement requires that Participating Sites verify their Key Study Personnel (KSP) are trained/qualified/credentialed for a study.

4. Responsibilities of the Participating Institution(s):

4.1 Education/Training/Qualifications. To ensure that its Research Personnel have adequate education, training, and qualifications to perform the Research and safeguard the rights and welfare of research subjects. This includes, but is not limited to, having any locally institutionally required professional staff appointments, credentialing, insurance or other liability coverage, training in human subjects protections, and background checks for their assigned role in the Research. A Participating Institution's selection of appropriate education/training requirements and other qualifications for its Research Personnel is at its discretion. A Participating Institution shall provide information or documentation regarding its Research Personnel's education, training, and qualifications in connection with a Ceded Review as requested by the Reviewing IRB.

IREx Local Considerations Surveys

- **Require sites to verify KSP training/qualifications/credentials.**
- **REMOVING -- optional file upload of site personnel at the recommendation of the TIN SIRBs because...**
 1. Providing verification of training, credentialing, and qualifications is sufficient.
 2. Personnel list is not reviewed by Reviewing IRB
 3. Providing KSP list may promote the idea that the Reviewing IRB *is* responsible for this, but they are not.

Please review the planned list of personnel who will be engaged in human subjects research.

Yes
 No
 Our institution delegates this responsibility to the PI reset

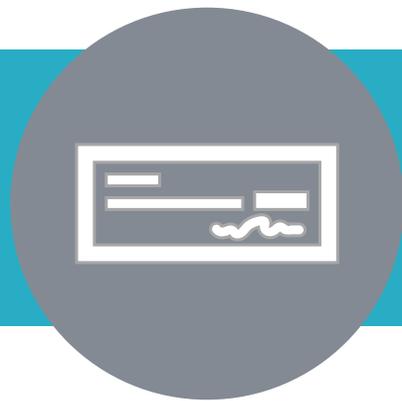
Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?
* must provide value

Please attach the list of key study personnel associated with this study at this site.  Upload file

Additional Information regarding the verification that all training requirements are met.

(optional) Expand

SURVEY SIGNATURES EMBEDDED



Study-wide IRB Approvals Site-specific IRB Approvals **Status Summary**

Participant Status Summary

Search:

Click to Export Local Considerations →

Manage LOI **Export Data** ▾

- Export Local Considerations
- Export Status Summary Tab

Name	Date modified	Type	Size
[INSTITUTIONAL_PROFILE]_HRP-502A_-_Consent_Ass...	10/15/2019 1:11 PM	Microsoft Word D...	
[INSTITUTIONAL_PROFILE]_SCH_Logo	10/15/2019 1:11 PM	Microsoft Word 9...	
[INSTITUTIONAL_PROFILE]_SCH_Required_Consentin...	10/15/2019 1:11 PM	Microsoft Word D...	
[INSTITUTIONAL_PROFILE]_SCH_Required_Consentin...	10/15/2019 1:11 PM	Microsoft Word D...	
[INSTITUTIONAL_PROFILE_SURVEY_RESPONSES]_si...	10/15/2019 1:11 PM	Adobe Acrobat D...	
[LC_HRPP]_Part_2_SCH_Consent_8.20.2019	10/15/2019 1:11 PM	Microsoft Word D...	
[LC_HRPP]_SCH_Local_Context_Profile_and_SOPs	10/15/2019 1:11 PM	Adobe Acrobat D...	
[LC_HRPP_SURVEY_RESPONSES]_HRPP_survey_res...	10/15/2019 1:11 PM	Adobe Acrobat D...	
[LC_PI_SURVEY]_key_personnel_for_IRES	10/15/2019 1:11 PM	Microsoft Word D...	
[LC_PI_SURVEY_RESPONSES]_PI_survey_response	10/15/2019 1:11 PM	Adobe Acrobat D...	

entirely optional and not affecting care.

DATA AND SAFETY MONITORING PLAN: Does the data and safety monitoring plan for your site differ in any way from that outlined in the protocol? **No**

Are there any other different requirements for how the protocol will be implemented and/or conducted at your site based on local requirements or state laws? **No**

SIGNATURES/ATTESTATIONS

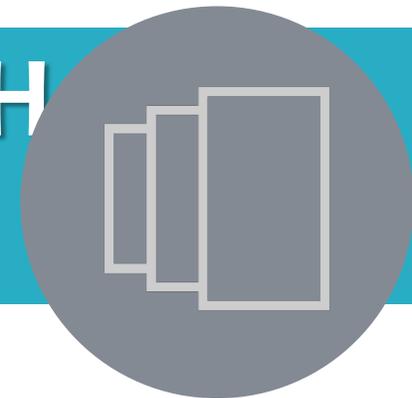
By signing below, I attest to the accuracy and completeness of the information provided herein.



New System Features!



AMENDMENT NOTIFICATIONS WITH VERSION # AND SUMMARIES



Add Study-Wide Amendment

A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-FIRST)

Does this amendment change Protocol [10.11.2019]? Yes No

New protocol date / version

As entered on the protocol

▲ Required

Upload new protocol

Choose File No file chosen

▲ Required

Summary of changes

Amendment 2 - Includes clarification to use of divided dose and reduced dose of the study medication due to intolerance and a correction to the schedule of events table.

169 / 3999 characters

Include the Amendment # in the description of changes

Dear Liaisons and Study Contacts,

Vanderbilt University Medical Center has shared IRB approval for your institution, Carnegie University Medical Center, in IREx for the study below:

Study Title: A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-FIRST)

Type of Review / Approval: Amendment: Full Board

Version 10.11.2019

Change Summary Amendment 2 - Includes clarification to use of divided dose and reduced dose of the study medication due to intolerance and a correction to the schedule of events table.

Expiration Date: 1/9/2020

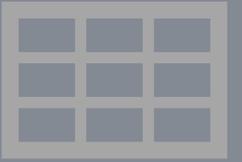
Study Link: <https://staging.irbexchange.org/study/index/?proj=70199>

Principal Investigators & Study Contacts:

Your approval documents are available in [IREx](#). If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

Thank you for using IREx,
The IREx Team

STATUS SUMMARY TAB AVAILABLE TO ALL!



Carnegie U Med Ctr
GETTING STARTED

- ✓ Register
- ✓ Add Study Team
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile
- ➔ Indicate Reliance
- ✓ Complete HRP Survey
- ✓ Validate PI Survey
- ➔ Awaiting Reviewing IRB Approval
- 👁 View Status Summary

VERSIONS

20191015

Reviewing IRB
Peabody Inst Med (Pending)

Relying Sites
none listed

Registered/In Progress
Carnegie U Med Ctr

Site-Specific Info

Study Summary | Reviewing IRB Contact | IREx Study Managers

Antitumoral Properties of Pig Liver Esterase (APPLE)

Getting Started
Study-wide IRB Approvals
Site-specific IRB Approvals
Status Summary

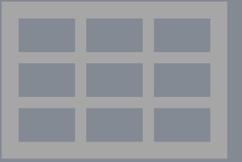
This page is **view only**.
Complete your steps under GETTING STARTED

Participant Status Summary

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie University Medical Center	✓	✓	Started 10/15/2019	3 / 3 Surveys Complete	Not Approved

- For participating site HRPPs and study teams
- View only

STATUS SUMMARY EXPORT UPDATES



- LOI Execution Date
- Initial Approval Date
- Current Approval Date & Version

	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X
1	FWA#	FWA Hold Site Name	Signed SM	Signed LOI	Date LOI Executed	IREx Ac Reliance	Reliance De Reliance	Local Consic	Local Consic	Local C	Local Consic	Local Consic	Local C	Submission Type	Date Submitted	Date Reviewed	Initial Approval Date	Current Approval Date	Current Approval Date Vers			
2	4355	Baystate F	Baystate F	yes	yes	2/9/2019	yes		10/11/2019		10/11/2019	10/11/2019		10/11/2019	10/11/2019		Initial Study: Full Board	6/12/2019	7/6/2019	7/13/2019	10/18/2019	v.10/18/2019
3	12345678	Carnegie C	Carnegie C	yes	yes	12/2/2018	yes		10/11/2019								Initial Study: Full Board	6/12/2019	7/6/2019	7/13/2019	10/18/2019	v.10/18/2019

UPDATED CHECKLISTS



Relying HRPP Checklist

A screenshot of a mobile application interface for the 'Relying HRPP Checklist'. The header is blue with the text 'Carnegie U Med Ctr' and 'GETTING STARTED'. Below the header is a list of checklist items, each with a checkmark icon on the left and a pencil icon on the right. The items are: 'Register', 'Add Study Team', 'Complete Agreements', 'Confirm Institutional Profile', 'Indicate Reliance' (highlighted in green), 'Complete HRP Survey', 'Validate PI Survey', 'Awaiting Reviewing IRB Approval', and 'View Status Summary' (highlighted in light blue). Three yellow stars are overlaid on the right side of the list, marking 'Add Study Team', 'Indicate Reliance', and 'Validate PI Survey'. A fourth yellow star is at the bottom left corner of the screenshot.

PI Checklist

A screenshot of a mobile application interface for the 'PI Checklist'. The header is blue with the text 'Carnegie U Med Ctr' and 'GETTING STARTED'. Below the header is a list of checklist items: 'Complete PI Survey', 'HRPP Validates PI Survey' (highlighted in green), and 'View Status Summary' (highlighted in light blue). A yellow star is overlaid on the left side of the 'View Status Summary' item.

TRACKING CHANGES TO THE HRP SURVEY



- If a site edits an HRP survey that was previously completed, the SIRB and Study Manager will receive an email that notes the changes
- The email will indicate whether DOCUMENTS changed, too

From: admin@irbexchange.org <admin@irbexchange.org>
Sent:
To:
Subject: IREx: Site Updated Local Considerations Responses

Dear Coordinating Center / Lead Study Team,

Hartford College of Medicine has modified their responses to the **HRP Survey** on the following study:

Influenza-associated pneumonia hospitalizations in Jupiter

Survey response changes are noted below:

Survey Field	Previous Response	Updated Response
Please review the protocol and template consent, as provided to you by your local study team, and identify any institutional requirements (e.g., recruitment, data security, remuneration) that apply to this study and any steps that must be taken to adhere to these requirements.	None	Protocol and template consent have been updated with additional radiation safety information.
Please identify any ancillary reviews required at your site [e.g. radiation safety review, review for research with biospecimens, etc.] that will be required before this study may be initiated at your site.	None	This site now requires annual radiation safety review completed by the participating site's safety board.

information has already been submitted to the Reviewing IRB for review, please be sure to communicate these changes to the Reviewing IRB for this site.

Note: the completed surveys are now viewable on the Status Summary tab in IREx; however, **please allow up to ten minutes for the Export feature to be available for download.**

[Click here to view the study.](#)

*Thank you for using IREx,
The IREx Team*

DISTINGUISHING THE REVIEWING IRB & LEAD SITE



You can designate the Lead Site when completing the study's IREx Setup

GETTING STARTED

- Complete IREx Setup**
- Confirm SSRP
- Upload Overall Study Approval
- Publish Approval

IREx Project Settings

Study Setup

Is the Lead Site also at the Reviewing IRB Institution? Yes No

Identify Lead Site

Peabody Institute of Medicine - FWA#897645665

Would you like to... [Site-Specific Info] [Manage Project]

Study Summary | Reviewing IRB Contact | IREx Study Managers | Participating Personnel

A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-T2DM)

Study-wide IRB Approvals | Site-specific IRB Approvals | Status Summary

Protocol Version: 1 [Manage Version]

SIRB: Carnegie University Medical Center

Lead Site: Peabody Institute of Medicine

DISTINGUISHING BETWEEN TYPES OF STUDY APPROVALS



The study approvals tabs have been renamed “Study-wide IRB Approvals” and “Site-specific Approvals”

The screenshot displays a web interface for a study titled "A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-T2DM)". At the top right, there are buttons for "Site-Specific Info" and "Manage Project". Below these are navigation links: "Study Summary", "Reviewing IRB Contact", "IREx Study Managers", and "Participating Personnel". The main title of the study is prominently displayed. Below the title, there are three tabs: "Study-wide IRB Approvals" (highlighted with a red box), "Site-specific IRB Approvals", and "Status Summary". At the bottom right, there is a "Manage Version" button. The text "Protocol Version: 1" is visible at the bottom left of the interface.

IREX API UPDATE



- IREx API available to Single IRBs to integrate their e-IRB system with IREx
- The goal is to streamline the work of the **Single IRB & Study Manager**

Phase I – LIVE

- **STUDY CREATION IN IREX:** The sIRB can push a study from their e-IRB System to IREx.

Phase II – LIVE

- **UPLOAD LEAD SITE APPROVAL TO IREX:** The sIRB can push the initial study approval for the lead site

Phase III – *Ready for pilot*

- **IMPORT LOCAL CONSIDERATIONS FROM IREX:** The sIRB can pull local considerations and all reliance documentation into e-IRB system for review.

Phase IV – *Ready for pilot*

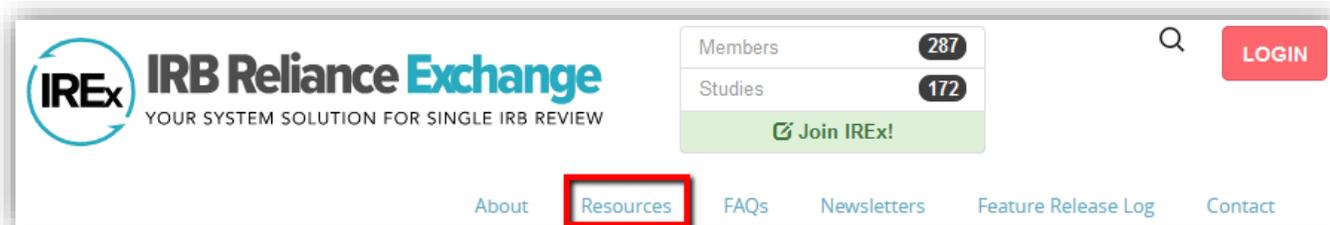
- **UPLOAD SITE APPROVALS:** The SIRB can push approvals for relying sites into IREx

Email
admin@IRBExchange.org
if you want more information 😊

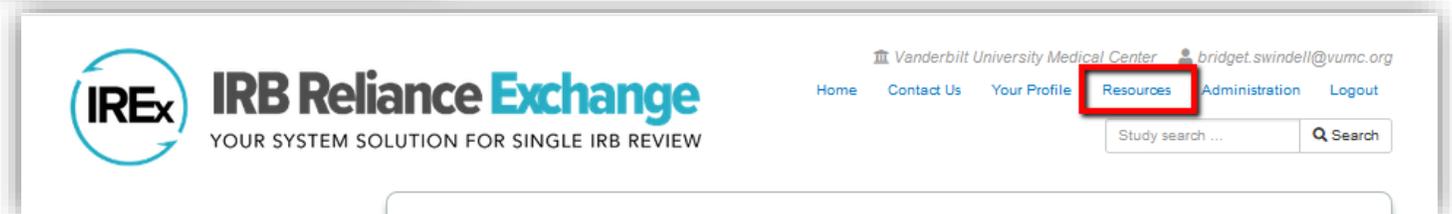
UPDATED RESOURCE MATERIALS



- Several IREx Resources materials have been updated to include our new features (Study-wide IRB Approvals & Site-Specific IRB Approvals, Lead Site, etc.)
 - [Reviewing IRB Quick Guide](#)
 - [Relying HRPP Quick Guide](#)
 - [Study Manager Step by Step](#)
 - [Participating Site Study Team Quick Guide](#)



Resources are accessible from the IREx website & at the top of the page once logged into IREx



Next Call

- January 17, 2019 @ 1 PM ET/10 AM PT