



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
Serdos*



- 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...

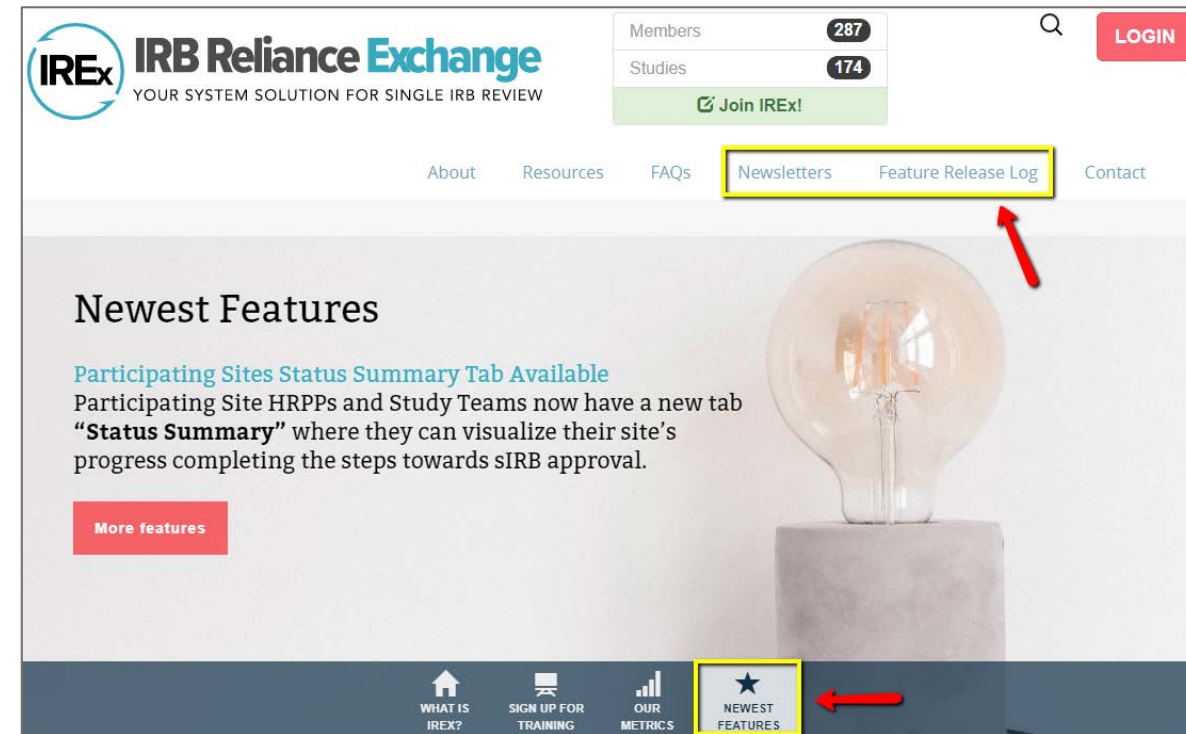


Catch IREx improvements as they are released

- 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



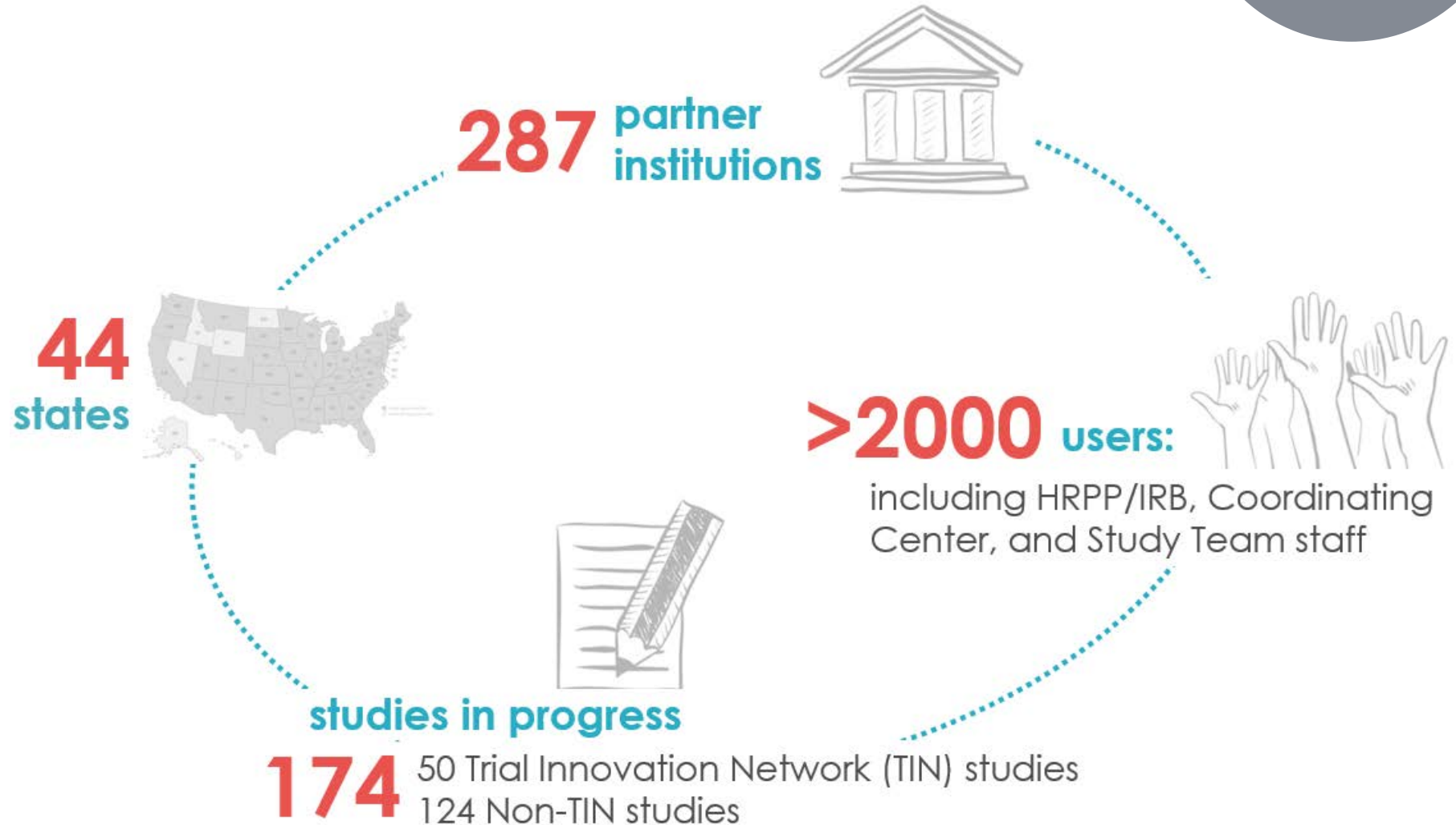
IREx Utilization – A Look at IREx Metrics

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



IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Members **287**
Studies **173**
[Join IREx!](#)

[About](#) [Resources](#) **FAQs** [Newsletters](#) [Feature Release Log](#) [Contact](#)

FAQs

UPDATED FAQs ON IREX WEBSITE

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

[Reviewing IRB Approvals](#) [Relying Site Approvals](#) **Status Summary**

Participant Status Summary

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	✓ Institutional Profile Confirmed: 6/23/2019	Not Approved
Mellon University Medical Center	✓	✓	Started 6/23/2019	✓ HRP Survey Completed: 6/23/2019 Updated: 6/24/2019	Not Approved
				✓ PI Survey Completed: 6/23/2019	

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

SITE-SPECIFIC COMMENTS/NOTES

[Reviewing IRB Approvals](#) [Relying Site Approvals](#) **Status Summary**

Participant Status Summary

Search:

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations
Boston Medical Center	✓	✗	✓	Started 6/13/2019	3 / 3 Surveys
Carnegie University Medical Center	✓	✓	✓	Completed 6/6/2019	3 / 3 Surveys
Columbus University	✓	✗	✓	Contacted 2/25/2019	
Hartford College of Medicine	✓	✓	✓	Started 2/19/2019	6 / 3 Surveys
Mellon University Medical Center	✗	✓	✓	Completed 6/6/2019	3 / 3 Surveys
Peabody Institute of Medicine	✓	✓	✓	Started 2/19/2019	3 / 3 Surveys

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](#)

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...	

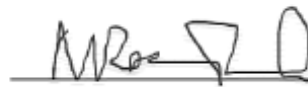
entirely optional and not affecting care.

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

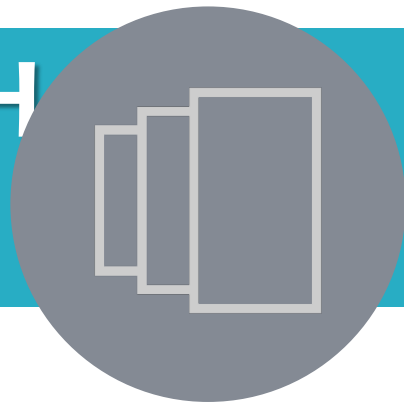
By signing below, I attest to the accuracy and completeness of the information provided herein.



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
 Required

Upload new protocol 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

Bridget

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**

Participant Status Summary

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

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

AutoSave Off

Study_status_summary2019-10-18 - Read-Only - Excel

Search

Mumpuni, Asri

FileHomeInsertPage LayoutFormulasDataReviewViewHelpACROBAT

ShareComments

I1

IREx Access

	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 Relianc	Reliance De Relianc	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 H	Baystate H	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

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

PI Checklist

Carnegie U Med Ctr
GETTING STARTED

- ✓ Complete PI Survey
- ➔ **HRPP Validates PI Survey**
- 👁 View Status Summary

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...

How are sites...

Is this a TIN...

Do you require...

Study Summary

Reviewing IRB Contact

IREx Study Managers

Participating Personnel

Site-Specific Info

Manage Project

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 application interface for study management. At the top, there are two buttons: "Site-Specific Info" (blue) and "Manage Project" (orange). Below these, a navigation bar contains four items: "Study Summary" (with a dropdown arrow), "Reviewing IRB Contact" (with a dropdown arrow), "IREx Study Managers" (with a dropdown arrow), and "Participating Personnel" (with a dropdown arrow). The main heading of the page is "A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-T2DM)". Below the heading, there are three tabs: "Study-wide IRB Approvals" (blue), "Site-specific IRB Approvals" (orange), and "Status Summary" (grey). A red rectangular box highlights the first two tabs. At the bottom left, it says "Protocol Version: 1", and at the bottom right, there is a "Manage Version" (orange) button with a dropdown arrow.

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*

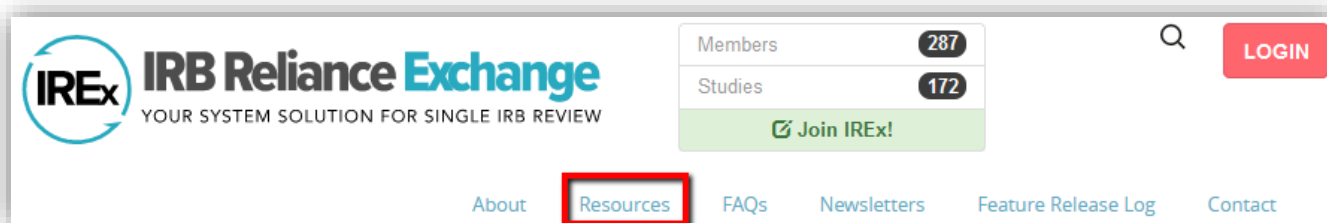
- **UPLOAD SITE APPROVALS:** The SIRB can push approvals for relying sites into IREx

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

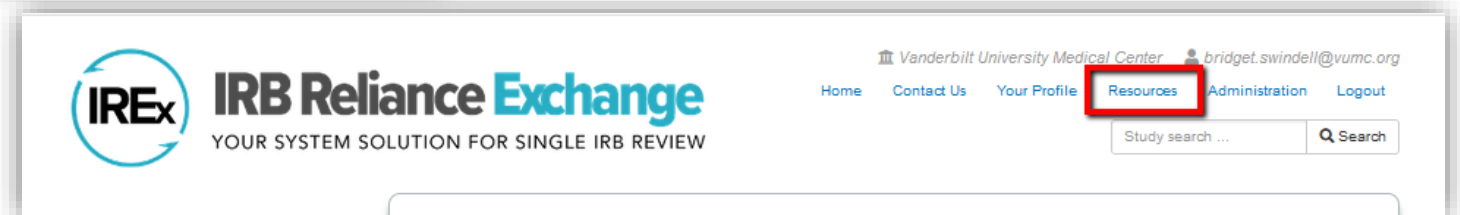
UPDATED RESOURCE MATERIALS



- 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