



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR STUDY MANAGERS

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

QUARTERLY CALL AGENDA



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

IN CASE YOU MISSED IT...

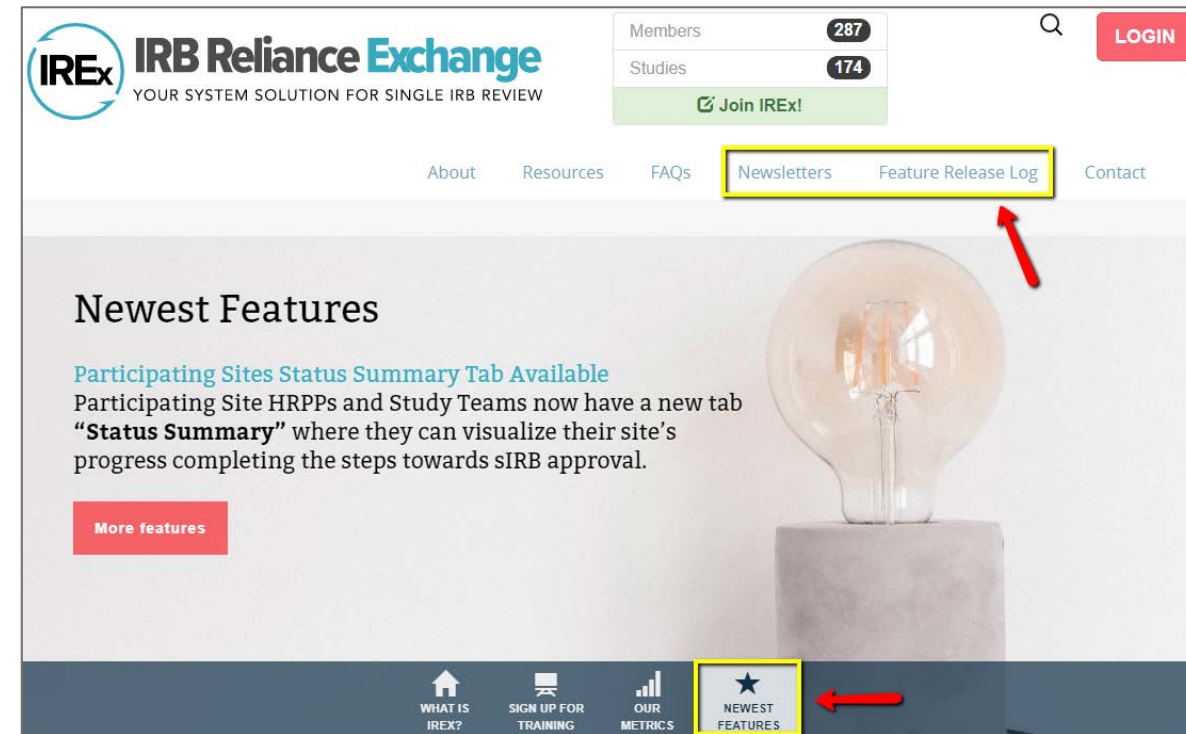


Catch IREx improvements as they are released

- 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



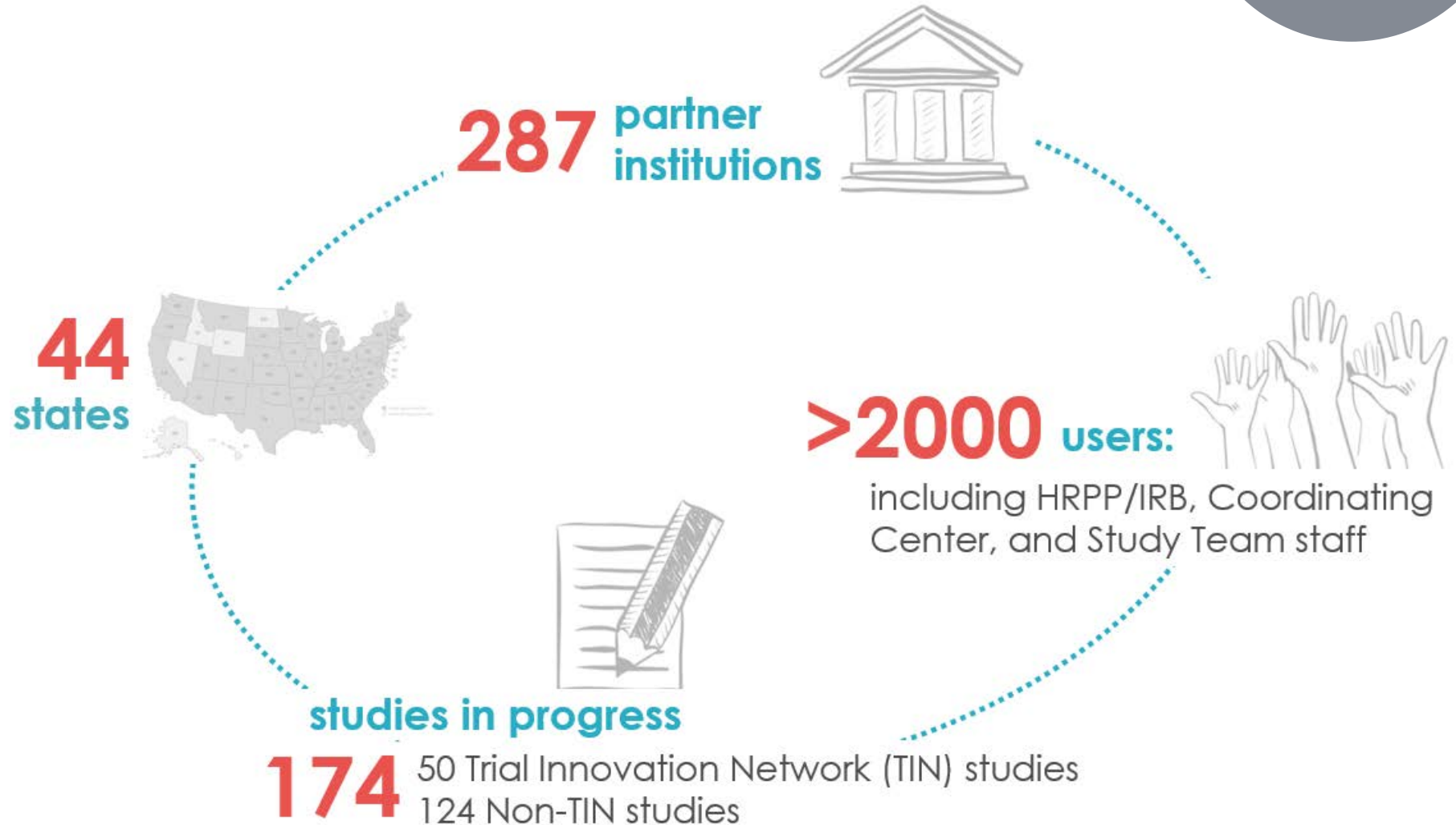
IREx Utilization – A Look at IREx Metrics

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	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

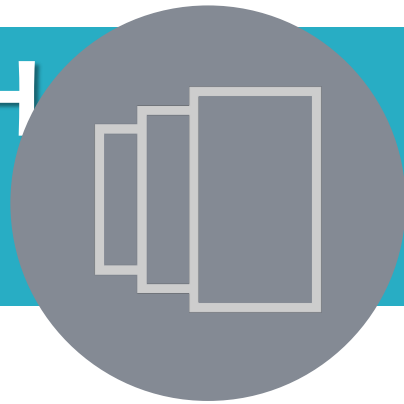
By signing below, I attest to the accuracy and completeness of the information provided herein.

MR. [Signature]

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

Completed by the Reviewing IRB

New protocol date / version

As entered on the protocol

▲ Required

Upload new protocol

Choose File No file chosen

☐ This file is a draft

▲ 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

167 / 3999 characters

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**

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

X✓fx

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	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



The Reviewing IRB will now designate the Lead Site when setting up the study in IREx

IREx Project Settings

Study Setup

Completed by the Reviewing IRB

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 collect local considerations in IREx? ☒ Yes ☐ No

How are sites' consent forms being handled? [Using IREx](#)

☒ (Recommended) Sites will provide consents for sIRB review (e.g., use of IREx consent form) and not have consents.

☐ A consent form generator will be used to build consents for sites

Do you require a Letter of Indemnification (LOI) for this study? ☐ Yes ☒ No

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



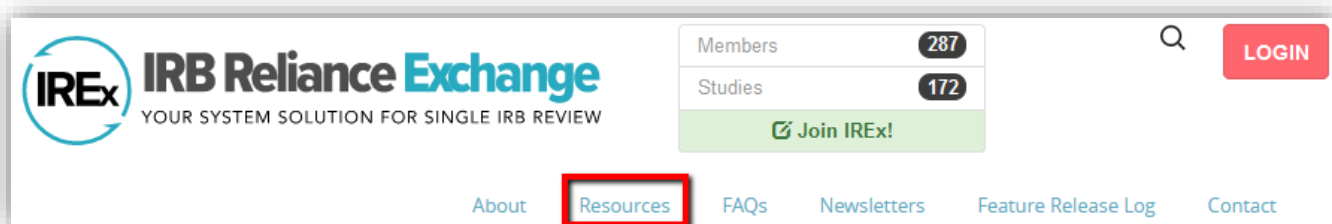
The study approvals tabs
have been renamed
“Study-wide IRB
Approvals” and “Site-
specific Approvals”

The screenshot displays a web interface for managing a study. At the top, there are two buttons: "Site-Specific Info" (blue) and "Manage Project" (orange). Below these are four navigation links: "Study Summary", "Reviewing IRB Contact", "IREx Study Managers", and "Participating Personnel". The main title of the study is "A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-T2DM)". Below the title, 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" button (orange).

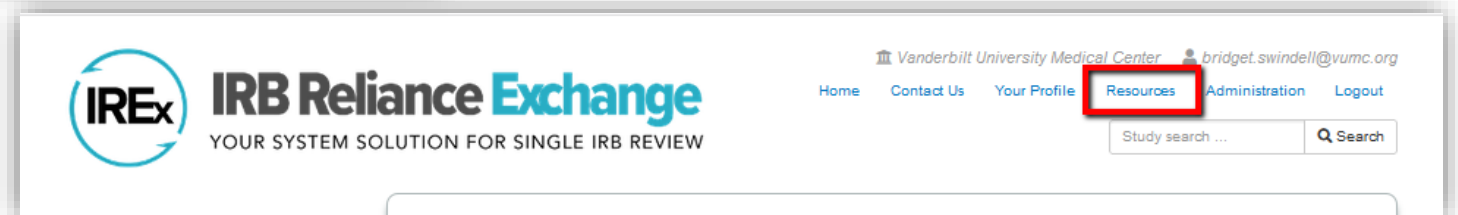
UPDATED RESOURCE MATERIALS



- Several IREx Resources materials have been updated to include our new features (Study-wide IRB Approvals & Site-Specific IRB Approvals, Lead Site, etc.)
 - [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