IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR STUDY MANAGERS

October 18, 2019

• User Training • Study Support	• System Development • Data analysis	• Project Manager	• Site Onboarding • Study Support	• User Support • Study Support
Natalie Dilts 	***Asri Mumpuni*** 	***Emily Serdoz*** 	***Bridget Swindell*** 	***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

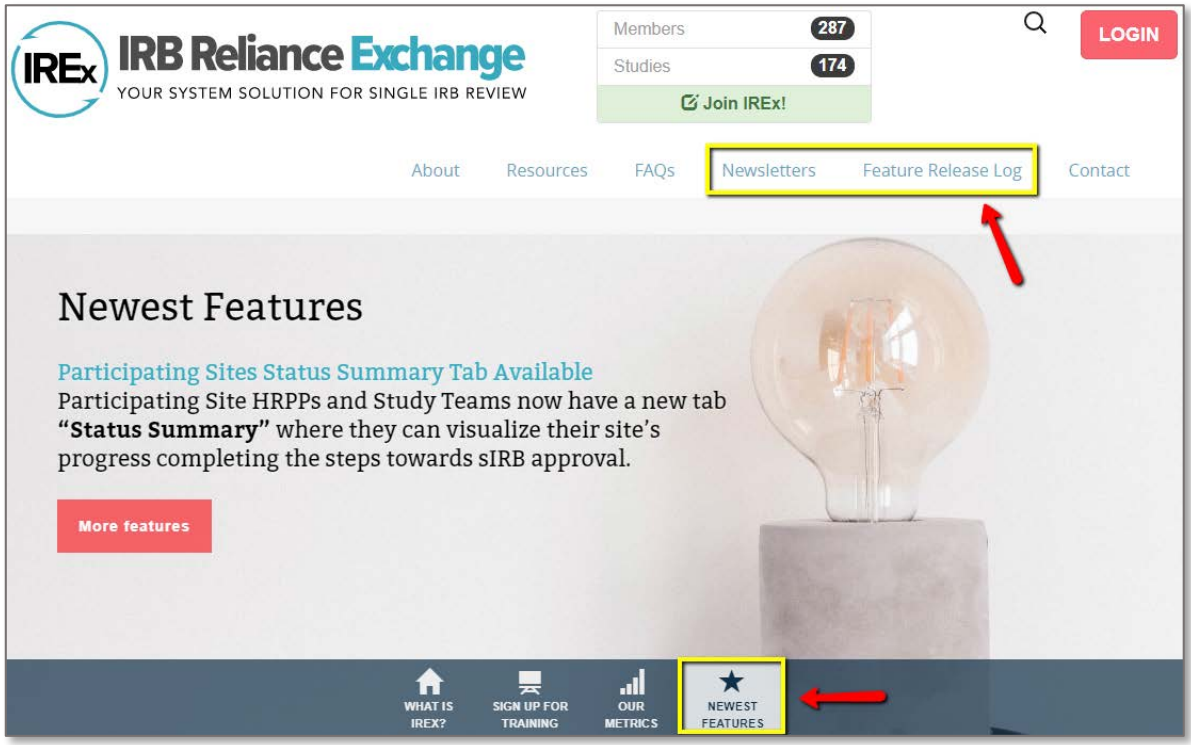
IN CASE YOU MISSED IT…

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

Linda

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)*

287 partner institutions

44 states

>2000 users:

including HRPP/IRB, Coordinating Center, and Study Team staff

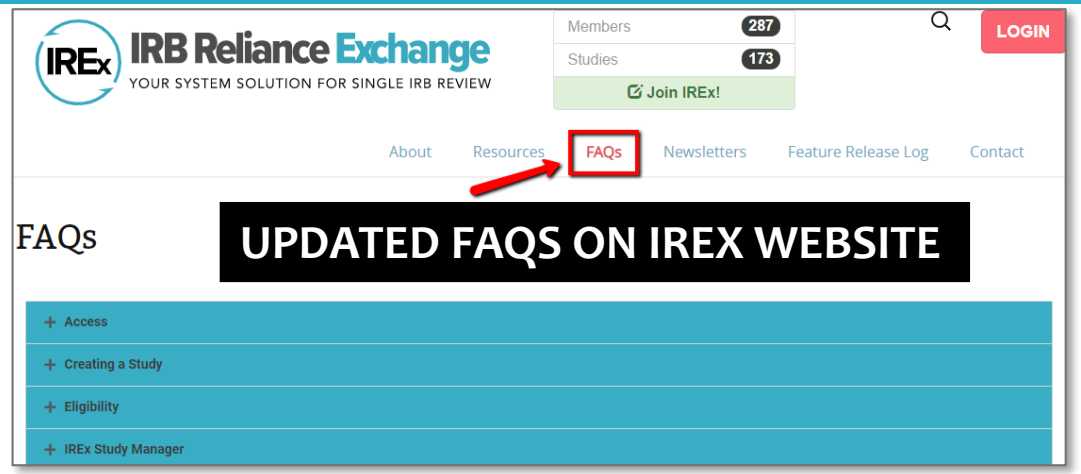
studies in progress

174 50 Trial Innovation Network (TIN) studies
124 Non-TIN studies

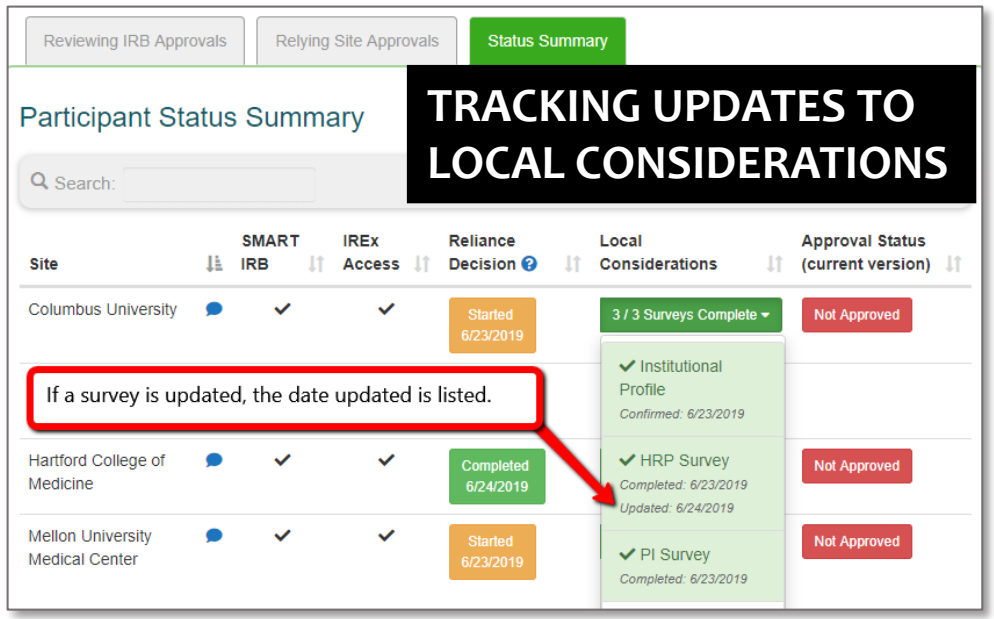
Reminders from the Last Call

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

REMINDERS FROM JULY CALL

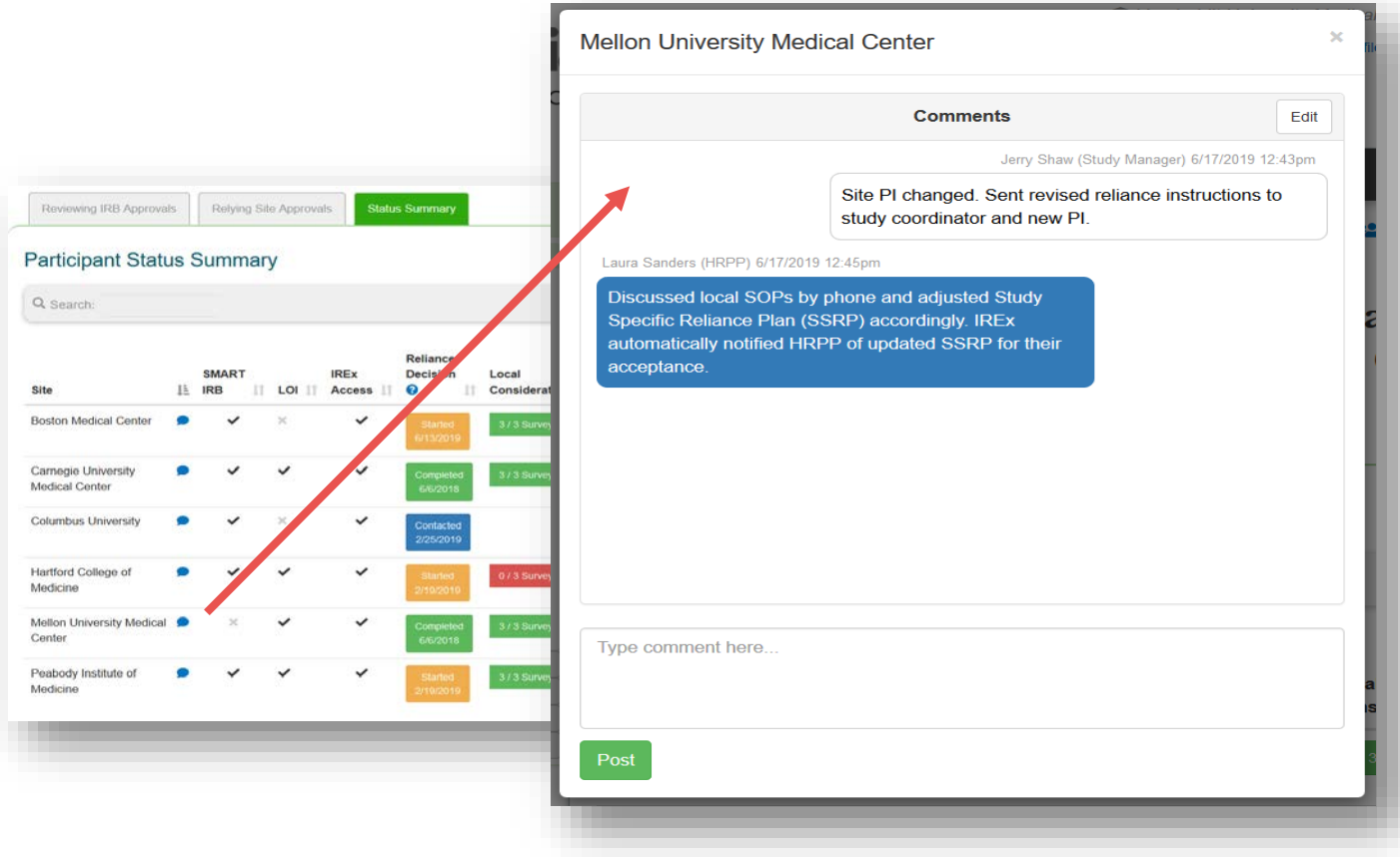


UPDATED FAQS ON IREX WEBSITE



TRACKING UPDATES TO LOCAL CONSIDERATIONS

SITE-SPECIFIC COMMENTS/NOTES



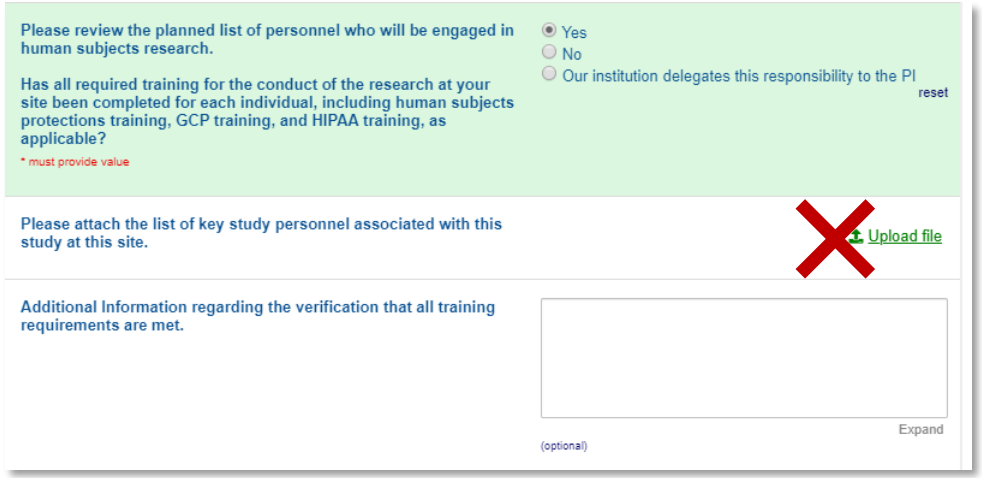
UPDATE TO HRP & PI SURVEYS

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

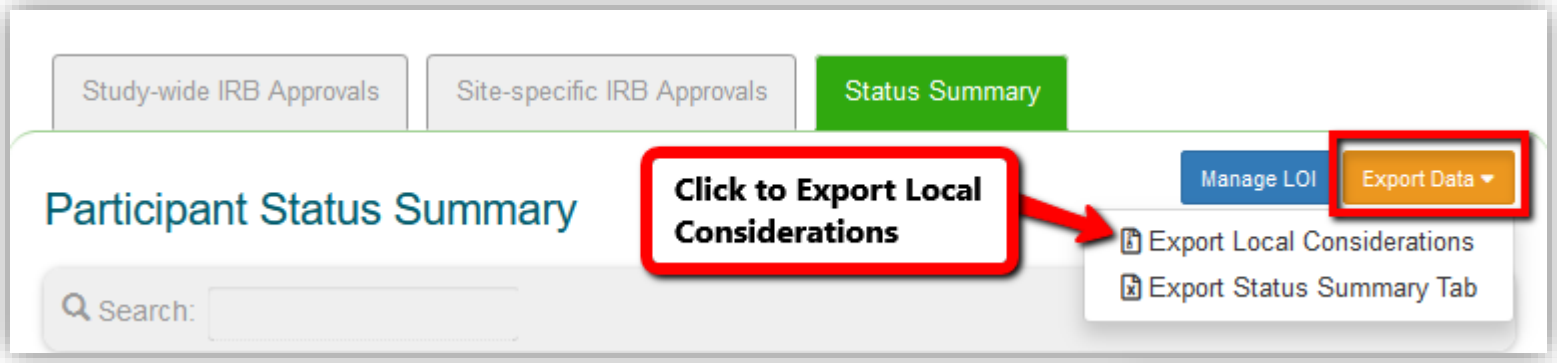
4. Responsibilities of the Participating Institution(s):
4.1 Education/Training/Qualifications. To ensure that its Research Personnel have adequate education, training, and qualifications to perform the Research and safeguard the rights and welfare of research subjects. This includes, but is not limited 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.

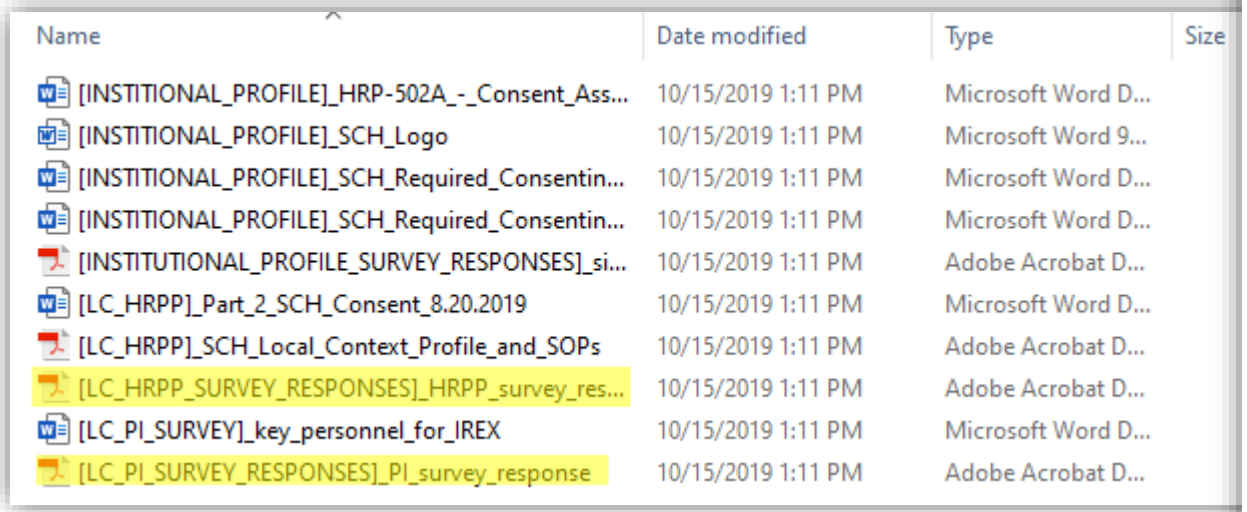
IREx Local Considerations Surveys

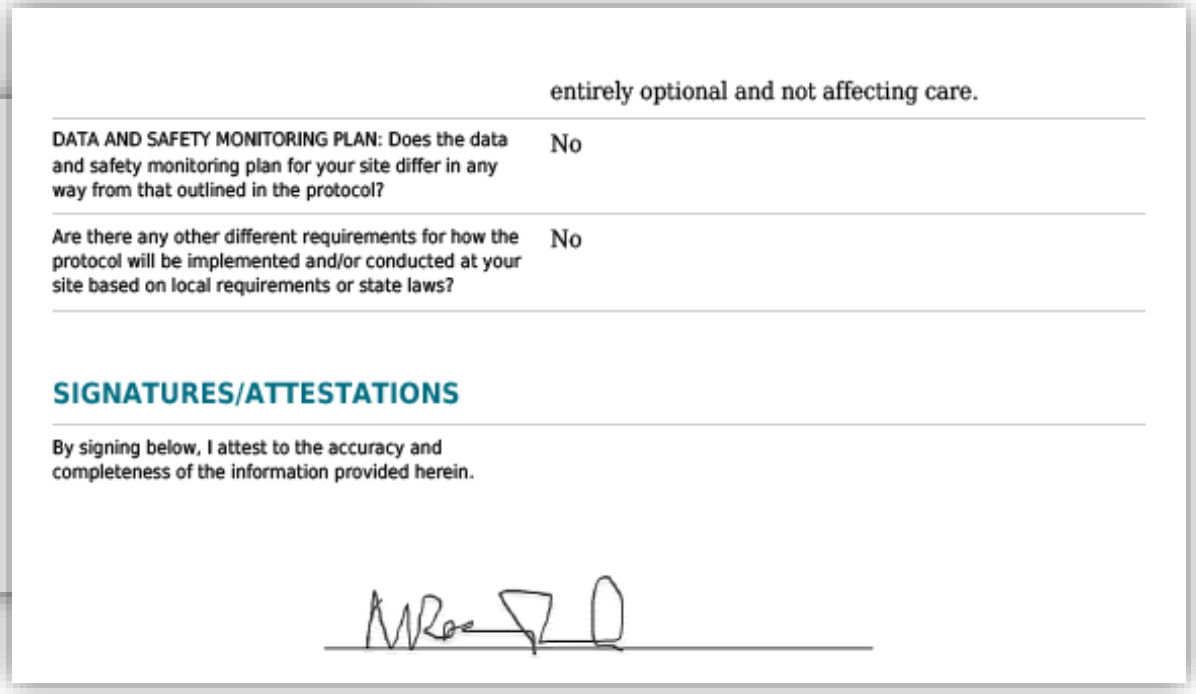
- **Require sites to verify KSP training/qualifications/credentials.**
- **REMOVING -- optional file upload of site personnel at the recommendation of the TIN SIRBs because…**
  1. Providing verification of training, credentialing, and qualifications is sufficient.
  2. Personnel list is not reviewed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



SURVEY SIGNATURES EMBEDDED







New System Features!

Natalie

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)

Completed by the Reviewing IRB

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 ☐ This file is a dr

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,

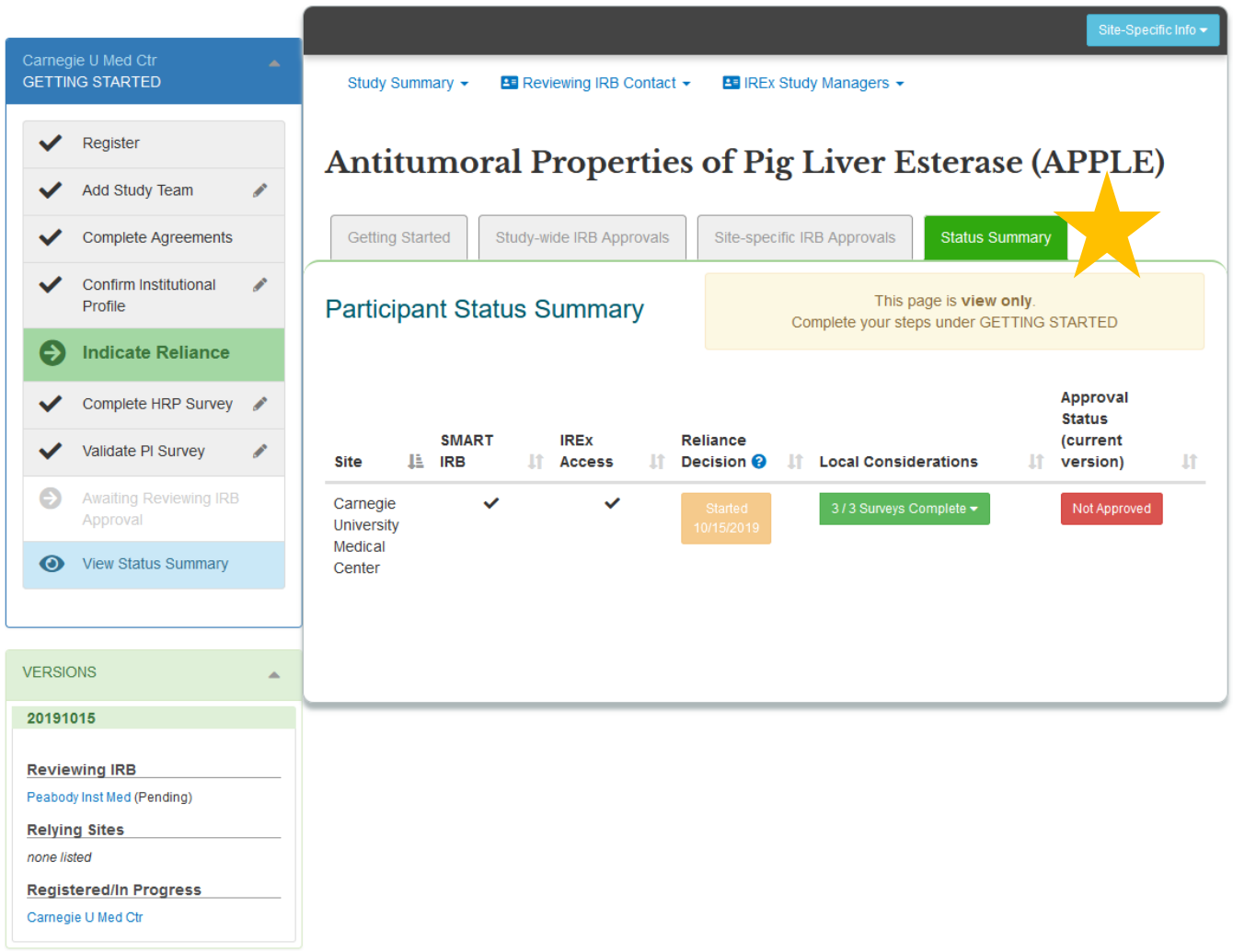
Vanderbilt University Medical Center has shared IRB approval for your institution, Carnegie University Medical Center, in IREx for the study below:

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

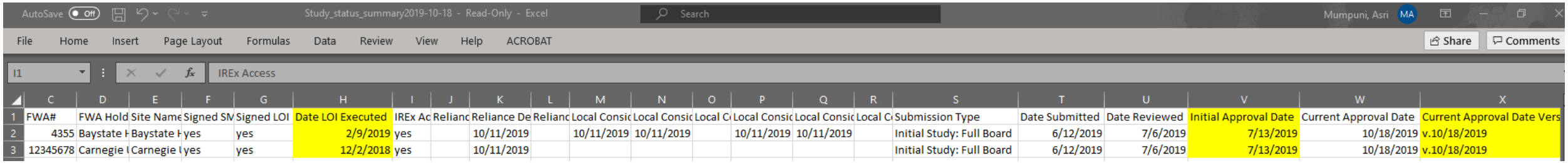
STATUS SUMMARY TAB AVAILABLE TO ALL!



- For participating site HRPPs and study teams
- View only

STATUS SUMMARY EXPORT UPDATES

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

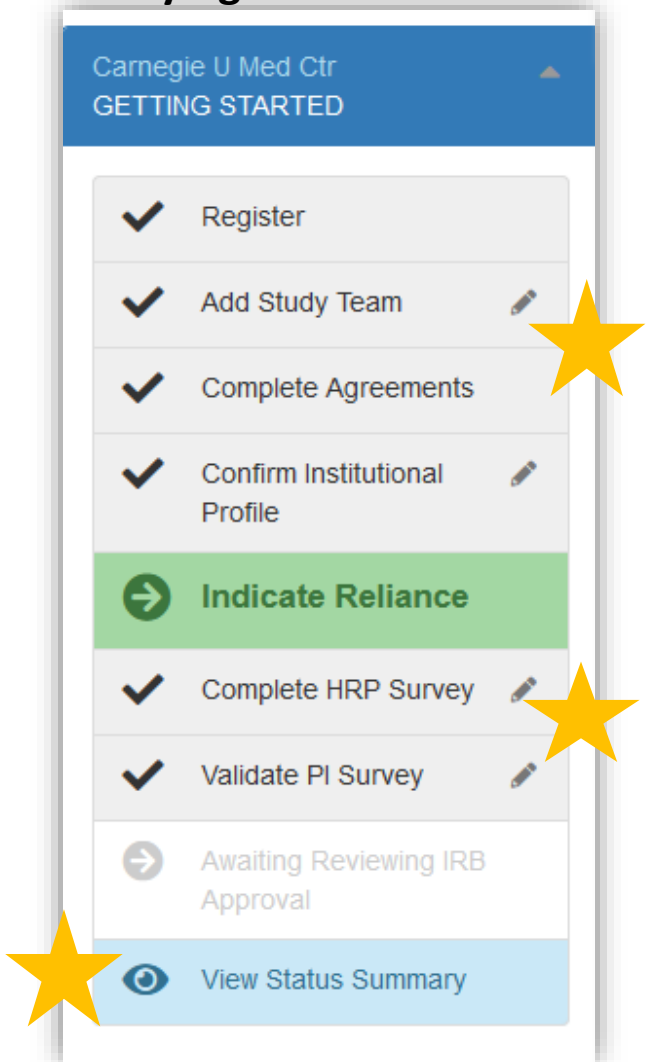


Study_status_summary2019-10-18 - Read-Only - Excel

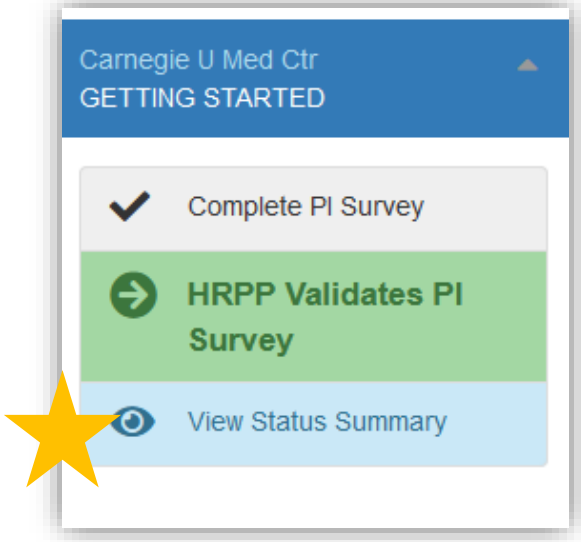
	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X
1	FWA#	FWA Hold	Site Name	Signed SM	Signed LOI	Date LOI Executed	IREx Ac	Reliand	Reliance De	Reliand	Local Consi	Local Consi	Local C	Local Consi	Local Consi	Local C	Submission Type	Date Submitted	Date Reviewed	Initial Approval Date	Current Approval Date	Current 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 I	Carnegie I	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



PI Checklist



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.

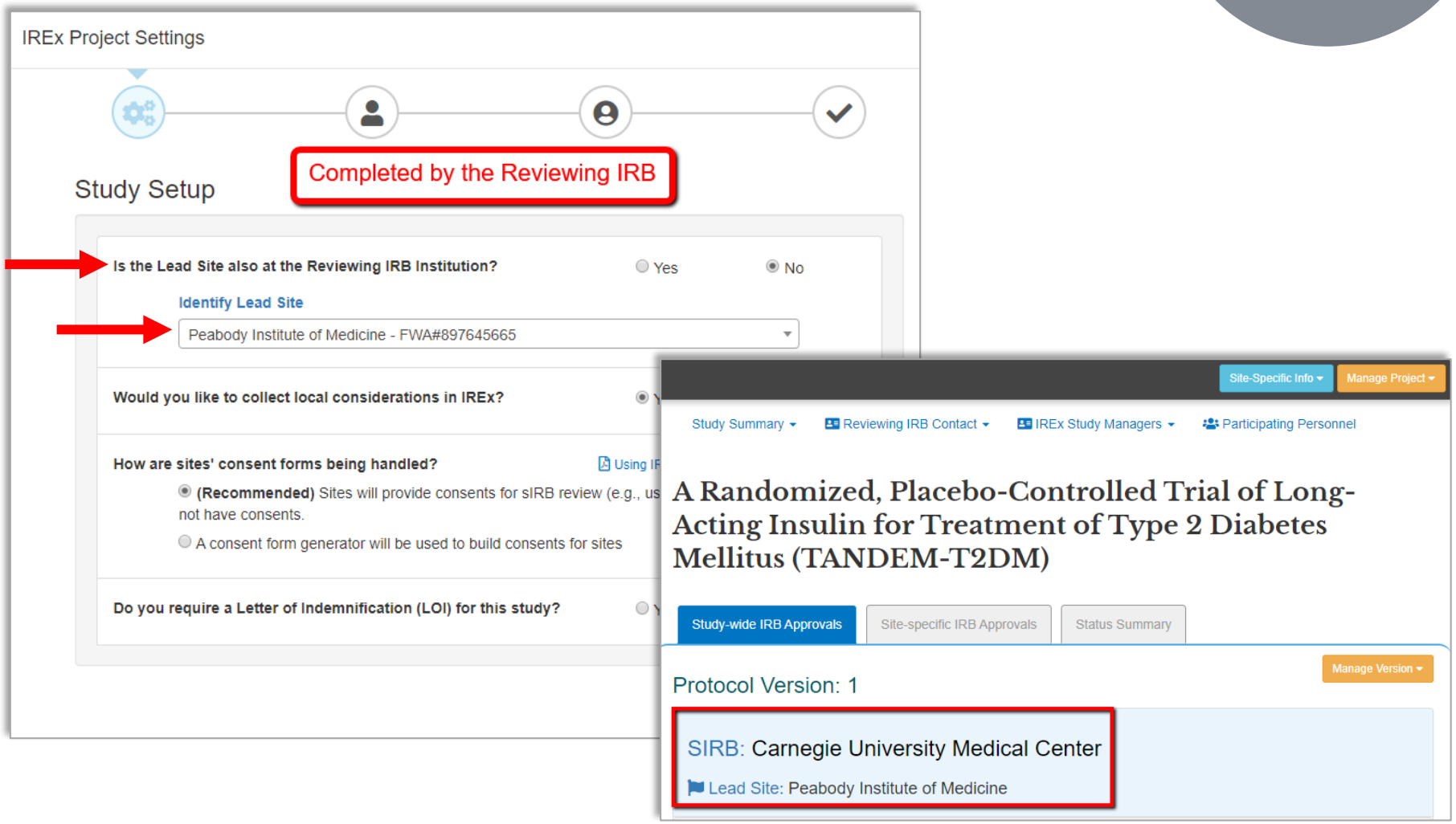
Note: the completed surveys are now viewable on the Status Summary tab in IREx; however, **please allow up to ten minutes for the Export feature to be available for download.**

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

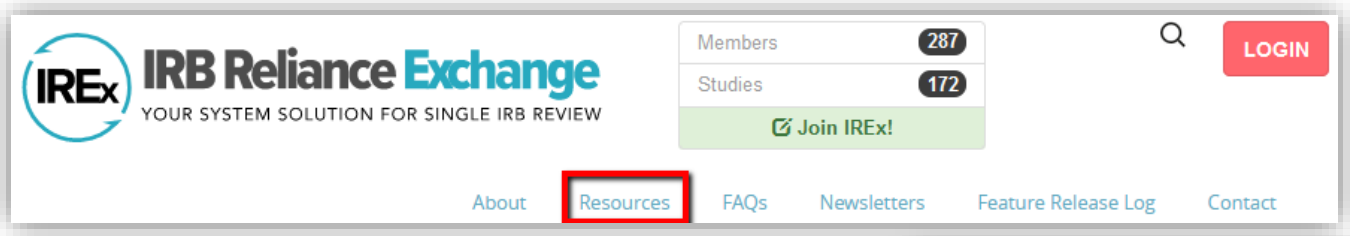


DISTINGUISHING BETWEEN TYPES OF STUDY APPROVALS

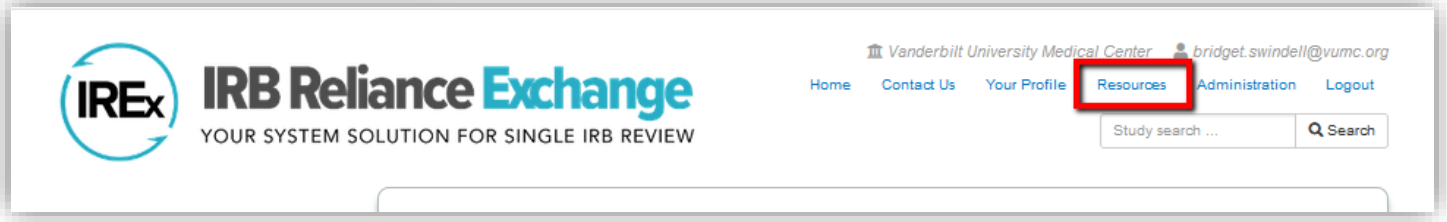
The study approvals tabs have been renamed "Study-wide IRB Approvals" and "Site-specific Approvals"

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