IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

January 17, 2020

• 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*** 

HRPPs QUARTERLY CALL AGENDA

- Welcome
- IREx Utilization Update
- Reminders from the Last Call
- New System Features
- Upcoming Development Releases
- Bonus Discussion!
- Next Call

Linda

IREX UTILIZATION

311 partner institutions

44 states

>2000 users:

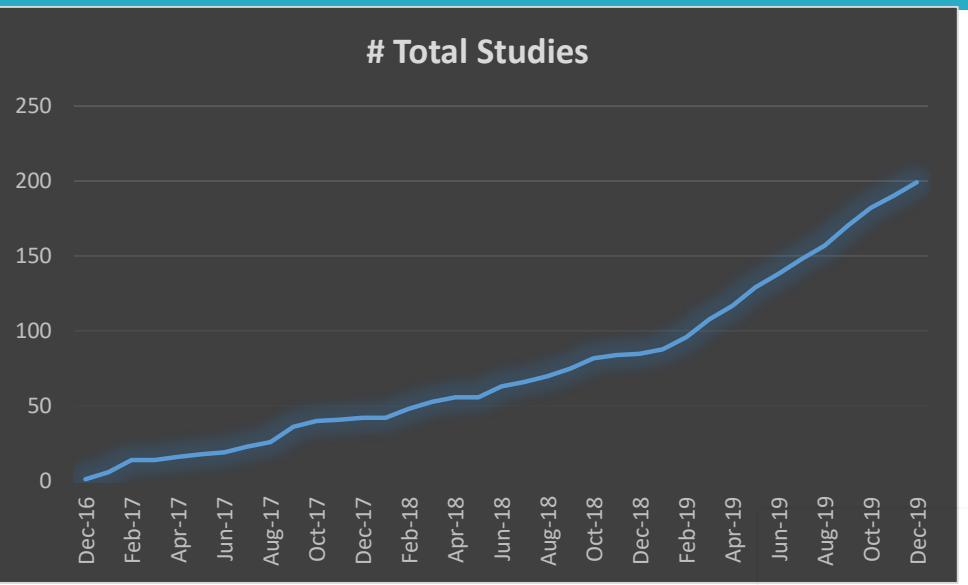
including HRPP/IRB, Coordinating Center, and Study Team staff

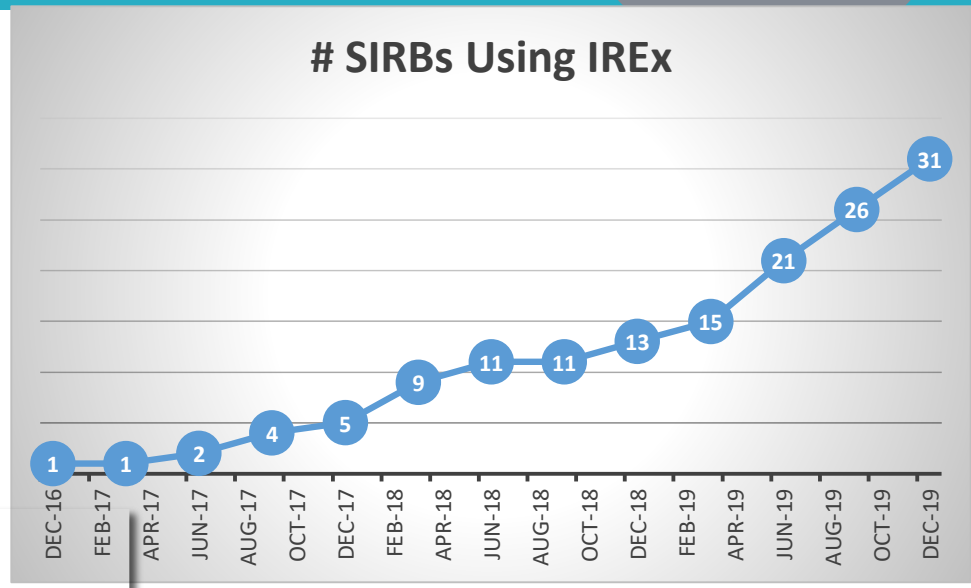
studies in progress

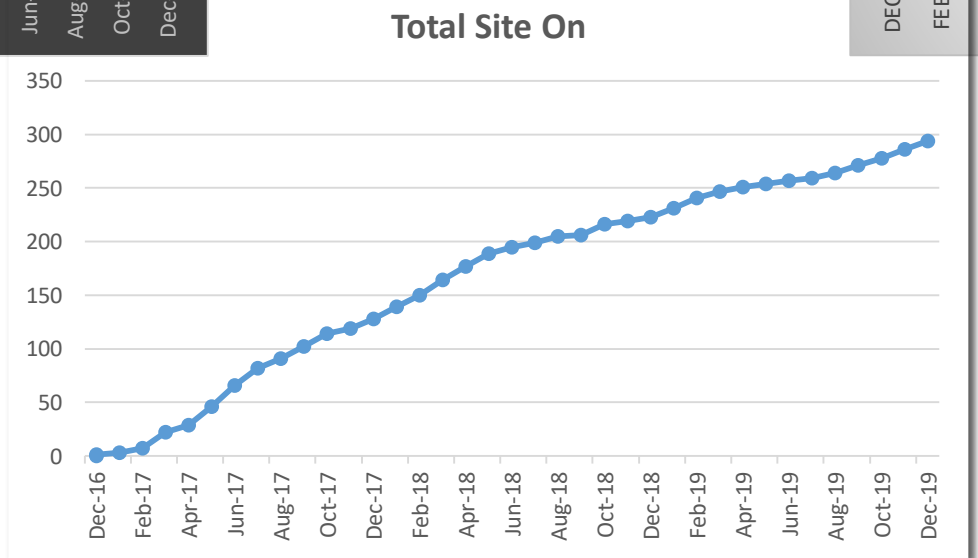
199 53 Trial Innovation Network (TIN) studies
146 Non-TIN studies

Linda

IREX UTILIZATION







Reminders from the Last Call

REMINDERS FROM THE LAST CALL

Dear Liaisons and Study Contacts,

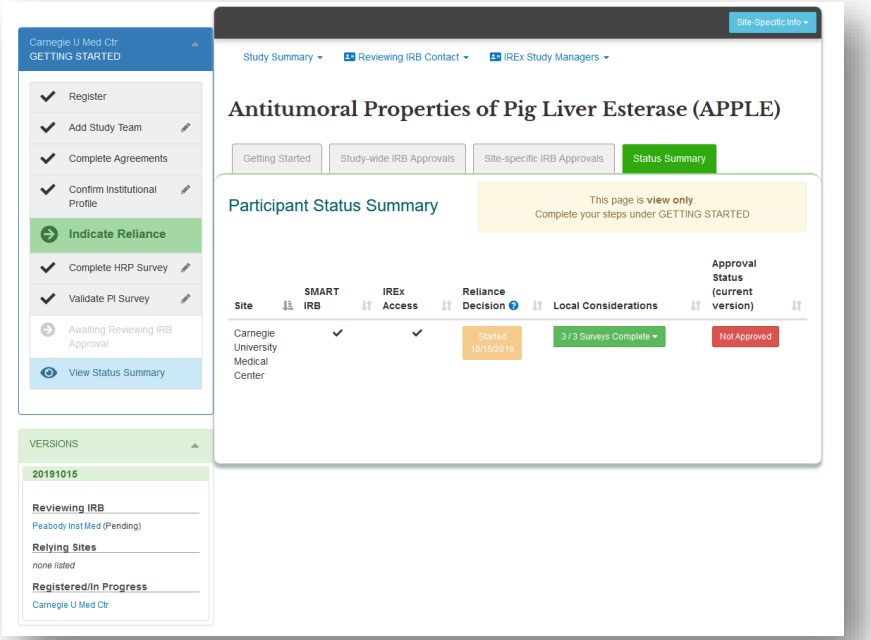
Vanderbilt University Medical Center has shared IRB approval for your institution, Carnegie University Medical Center, in IREx for the study below:

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

The version # and change summary you enter for amendments are included on notifications



Relying Sites (HRPPs & PIs) can view their site's status on the Status Summary

REMINDERS FROM THE LAST CALL

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

Edits made to the HRP and PI Surveys are tracked and sent via email.

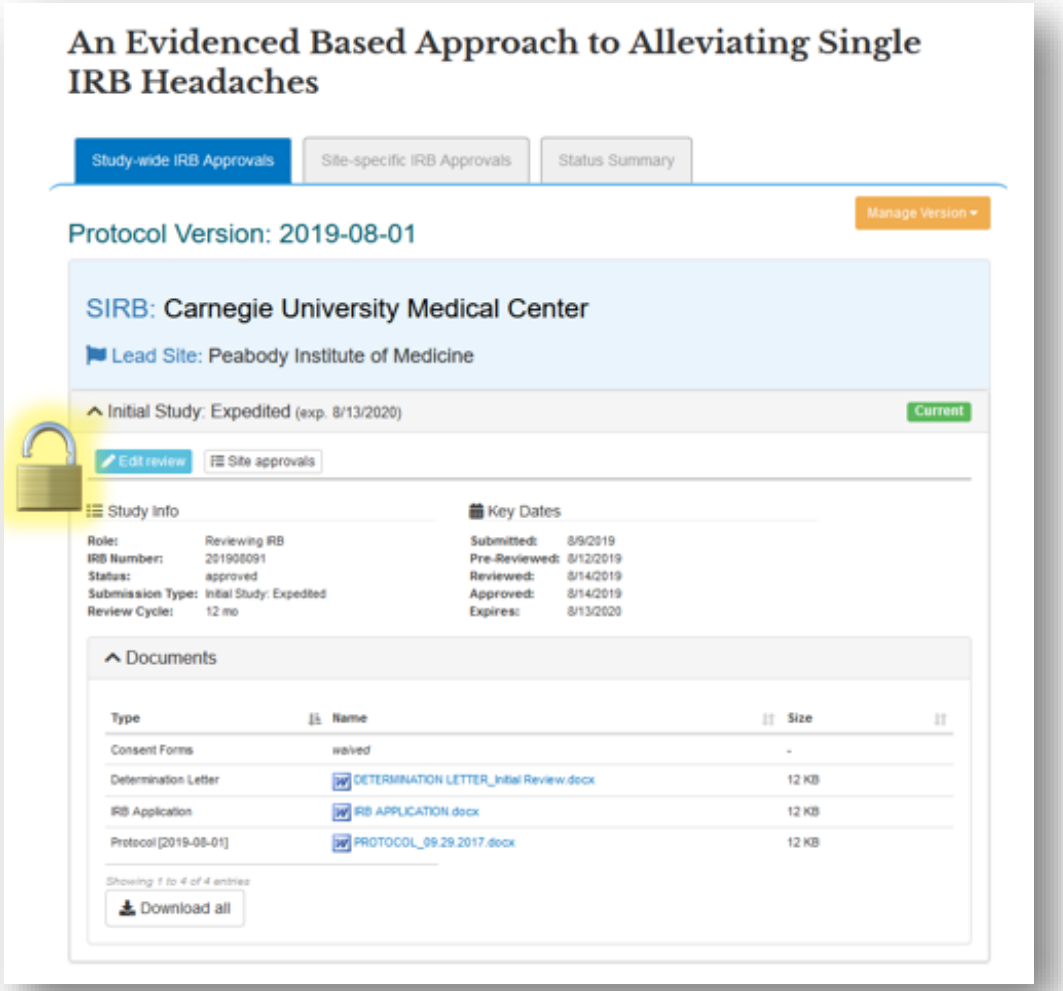
Distinguish the Single IRB from the Lead Site, when needed

REMINDERS FROM THE LAST CALL

Distinguishing study-wide and site-specific approval documents.

New System Features!

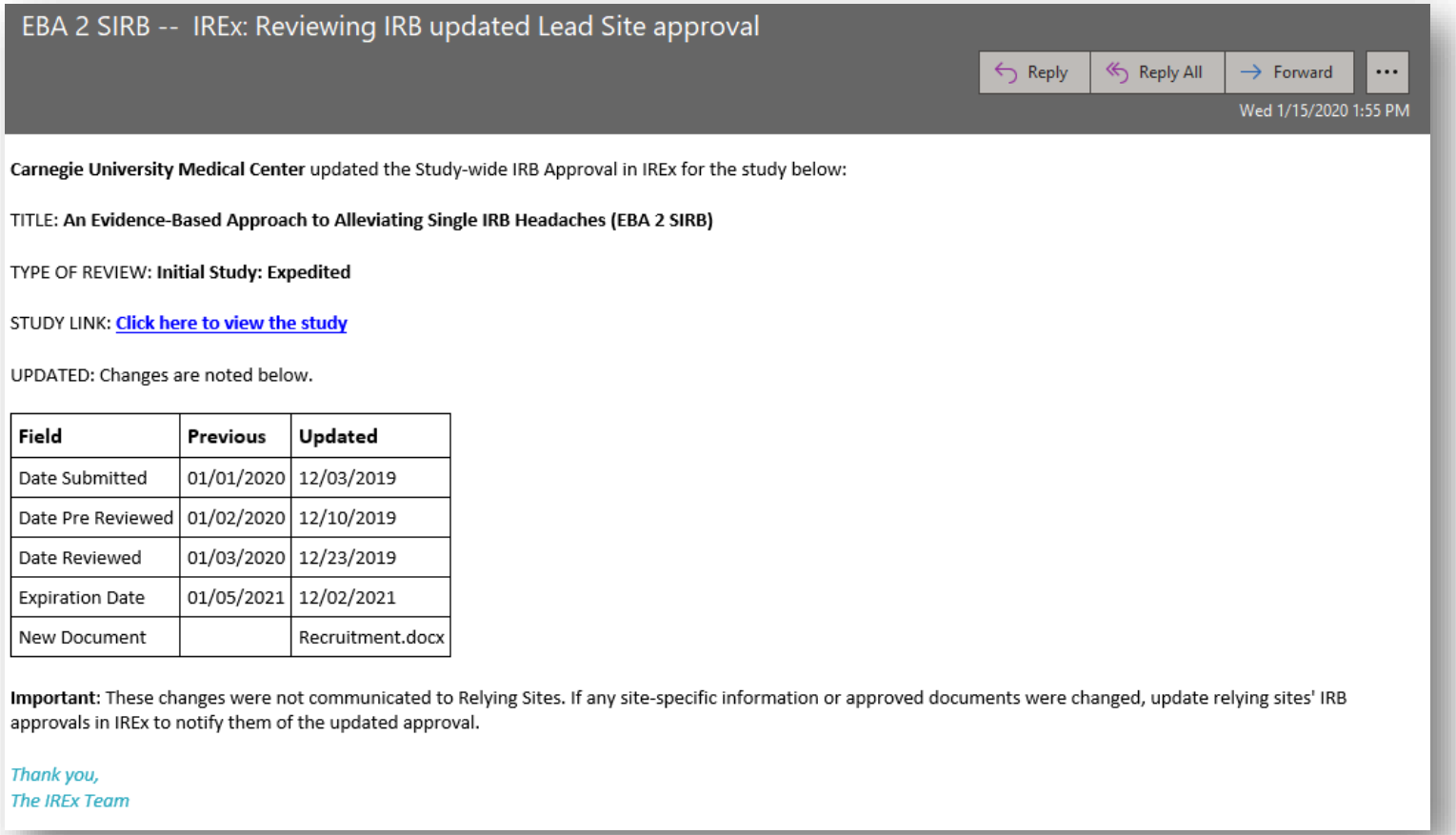
HEADS UP: REVIEWING IRB CAN EDIT APPROVALS ANYTIME



- **Reviewing IRB Liaisons can edit / update an existing approval at any time.**
- This is **NOT** for amendments or new approvals. Only *additions & corrections* to existing approvals.

STUDY MANAGER NOTIFIED OF LEAD SITE'S UPDATED APPROVAL

- If the Lead Site's materials are changed, the Study Manager (SM) is notified.
- If Participating Sites have changes, the SM can update their approvals & they will be notified.



EBA 2 SIRB -- IREx: Reviewing IRB updated Lead Site approval

Reply | Reply All | Forward | ...

Wed 1/15/2020 1:55 PM

Carnegie University Medical Center updated the Study-wide IRB Approval in IREx for the study below:

TITLE: **An Evidence-Based Approach to Alleviating Single IRB Headaches (EBA 2 SIRB)**

TYPE OF REVIEW: **Initial Study: Expedited**

STUDY LINK: Click here to view the study

UPDATED: Changes are noted below.

Field	Previous	Updated
Date Submitted	01/01/2020	12/03/2019
Date Pre Reviewed	01/02/2020	12/10/2019
Date Reviewed	01/03/2020	12/23/2019
Expiration Date	01/05/2021	12/02/2021
New Document		Recruitment.docx

Important: These changes were not communicated to Relying Sites. If any site-specific information or approved documents were changed, update relying sites' IRB approvals in IREx to notify them of the updated approval.

Thank you,
The IREx Team

IF A PARTICIPATING SITE'S APPROVAL IS UPDATED, THEY ARE NOTIFIED

EBA 2 SIRB -- IREx: Updated Approval For Your Site

Reply | Reply All | Forward | ...

Wed 1/15/2020 1:57 PM

Dear Liaisons and Study Contacts,

Carnegie University Medical Center updated the approval for your institution, Mellon University Medical Center, in IREx for the study below:

Study Title: **An Evidence-Based Approach to Alleviating Single IRB Headaches (EBA 2 SIRB)**

Study Link: https://staging.irbexchange.org/study/index/?proj=132975

Updated: Changes are noted below.

Field	Previous	Updated
Added Document		Flyer.png
Added Document		CONSENT FORM Spanish.docx

Your updated approval documents are available in IREx. If you have any questions about your approval or future submissions, please contact the IREx Study Manager or Reviewing IRB. If needed, contact information for the Study Manager is provided on your study page, just above the study title.

Thank you for using IREx,
The IREx Team

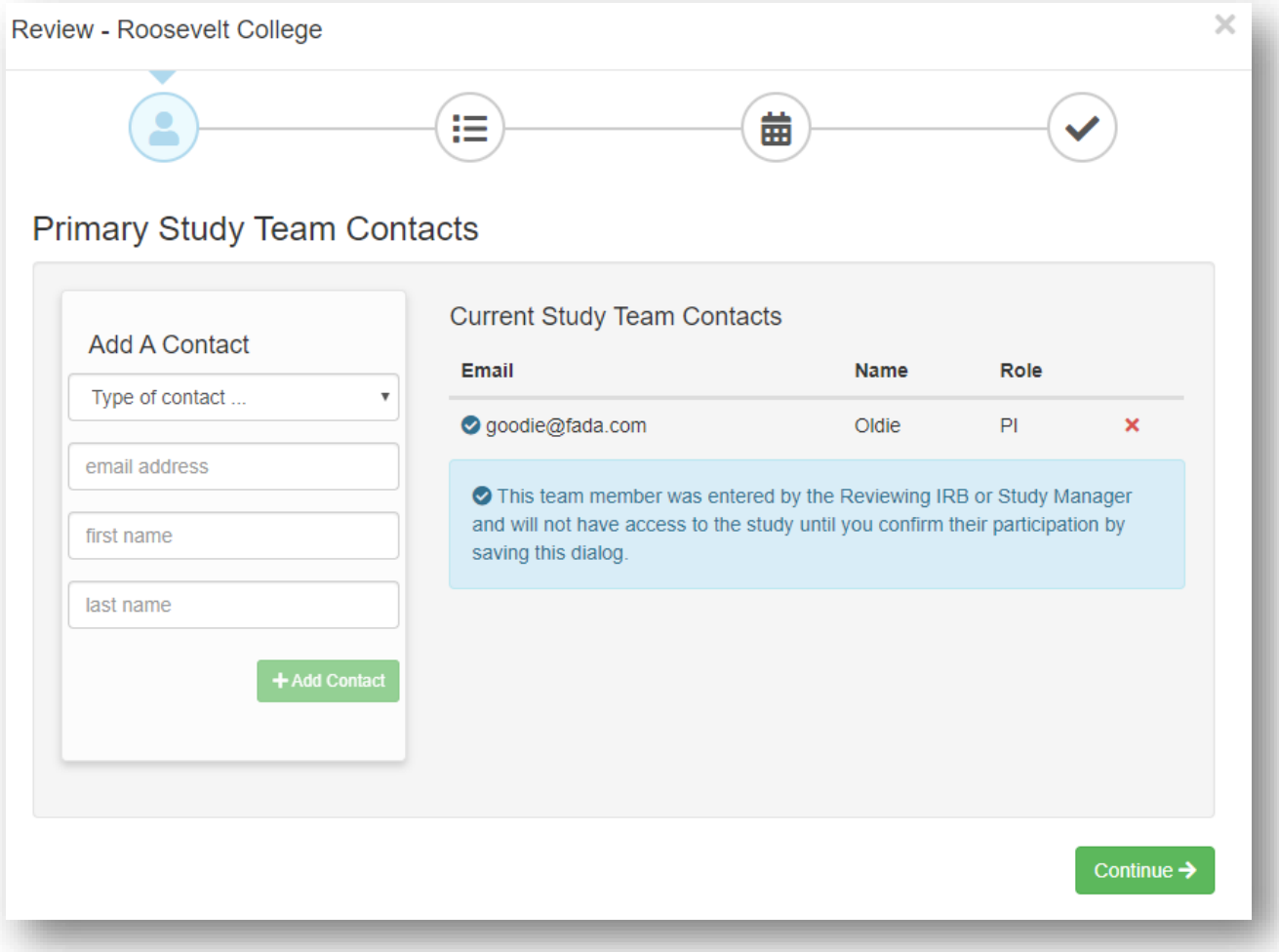
NEW QUESTION ON THE INSTITUTIONAL PROFILE

WHERE: Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.

WHAT: **"After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site's sIRB approved documents before your site is activated/enrollment can begin?"**

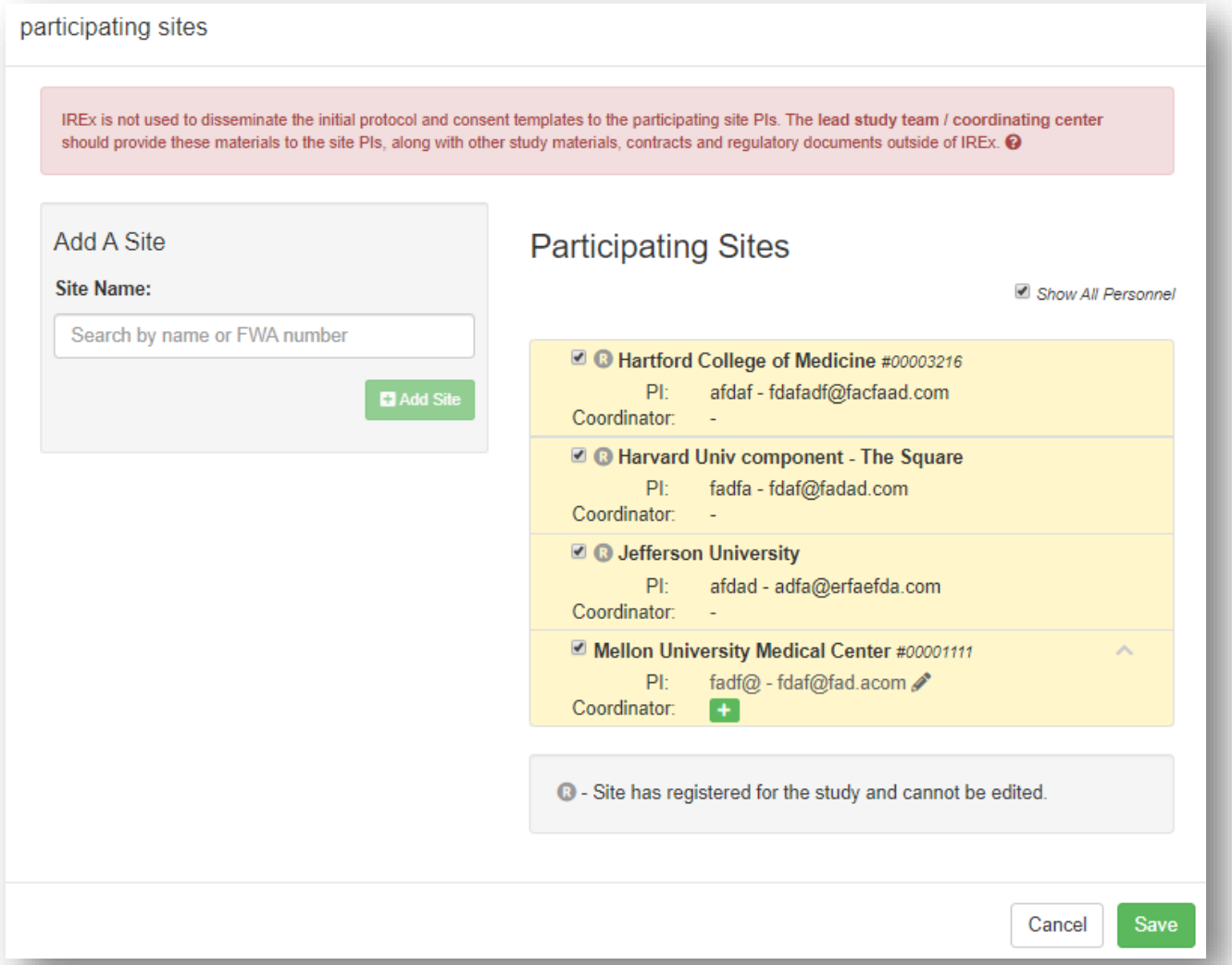
WHY: To help coordinating centers / lead study teams know when a site is fully activated to begin enrollment.

STUDY TEAM CONTACTS AUTO-POPULATE



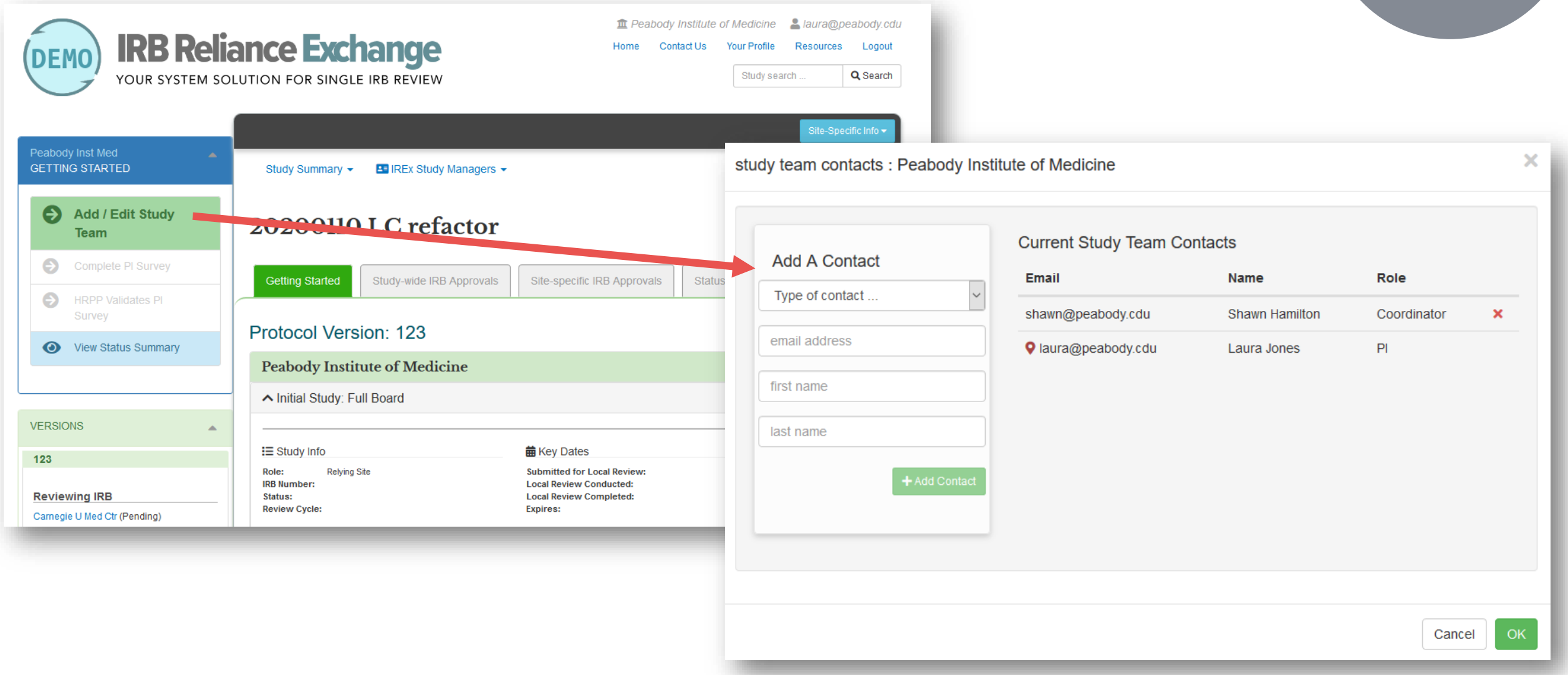
- **Relying HRPPs** confirm the contacts are correct, remove and /or add new contacts.

STUDY TEAM CONTACTS LOCKED AFTER SITE REGISTERS



- After a site registers, contacts can longer be edited by the Study Manager.
- Sites become responsible for the contacts and access at their site.

ADD/EDIT STUDY TEAM IN PI CHECKLIST



UPDATED RESOURCE MATERIALS

- Revamped website resources pages
  - https://www.irbexchange.org/p/reviewingirb/
  - https://www.irbexchange.org/p/participating-site-hrpps/
  - https://www.irbexchange.org/p/irexstudymanager/
  - https://www.irbexchange.org/p/participating-site-study-teams/
- Organization of each page
  - Quick link to sign up for training
  - Quick link to general video for specific user type
  - Brief descriptions of how the user type uses IREx
  - Newly organized resources for the user type

UPDATED RESOURCE MATERIALS

- NEW VIDEOS ON YOU TUBE
  - Local considerations video: https://www.youtube.com/watch?v=iN3mEDQ9kx8&feature=youtu.be
  - How to Add HRPP/IRB Contacts: https://www.youtube.com/watch?v=870HCtnCAWI
  - How to Remove HRPP/IRB Contacts: https://www.youtube.com/watch?v=LUo0uVE-bvQ

Upcoming Development Releases

COMBO SITES: A BRIEF INTRODUCTION TO A FEW NEW FEATURES

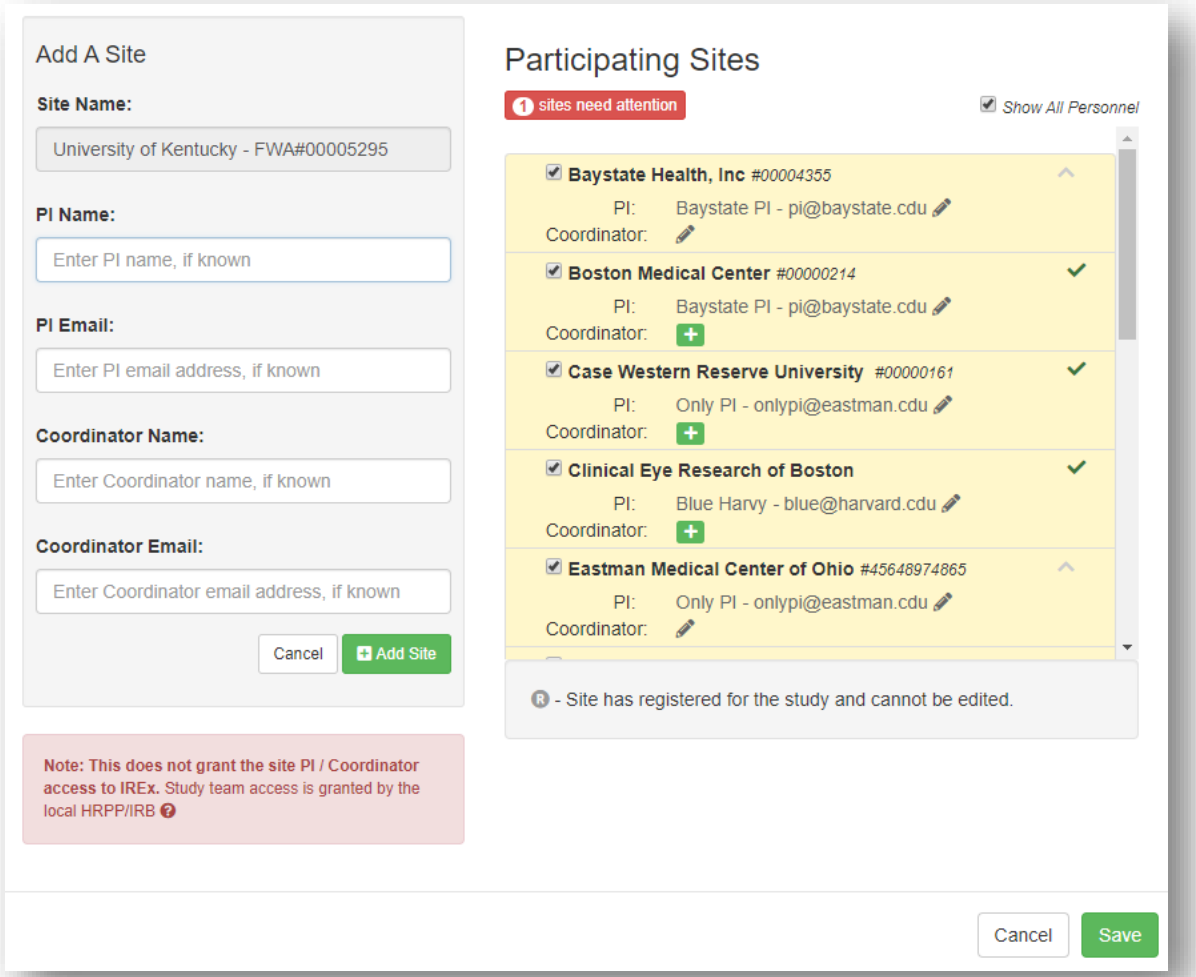
- Facilitating reliance documentation for a **single study team** that **engages multiple FWAs** for a study
  - For example, if a PI engages University of Pittsburgh Medical Center (FWA 00006735) & University of Pittsburgh (FWA 00006790).

- Reviewing IRB needs cede decision & local considerations from both FWAs before they review "the site"
- Only need 1 PI survey & 1 set of approval documents

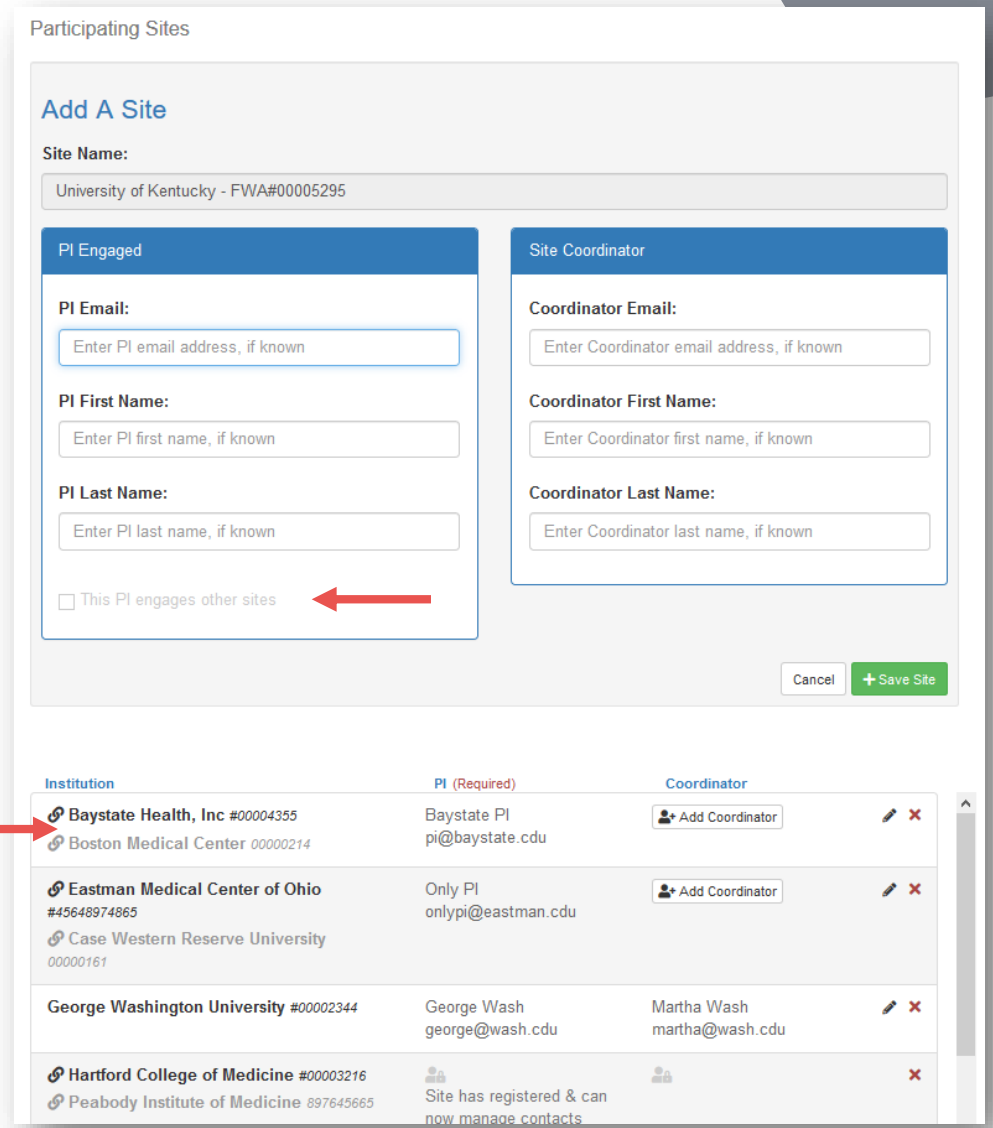
	FWA #1 "Primary"	FWA #2
Cede Decision	Required	Required
Institutional Profile	Required	Required
HRP Survey	Required	Option to default to Primary HRPP
PI survey	**One survey**	
Validate PI survey	Required	View only
Approval docs from sIRB	**One set of documents**	

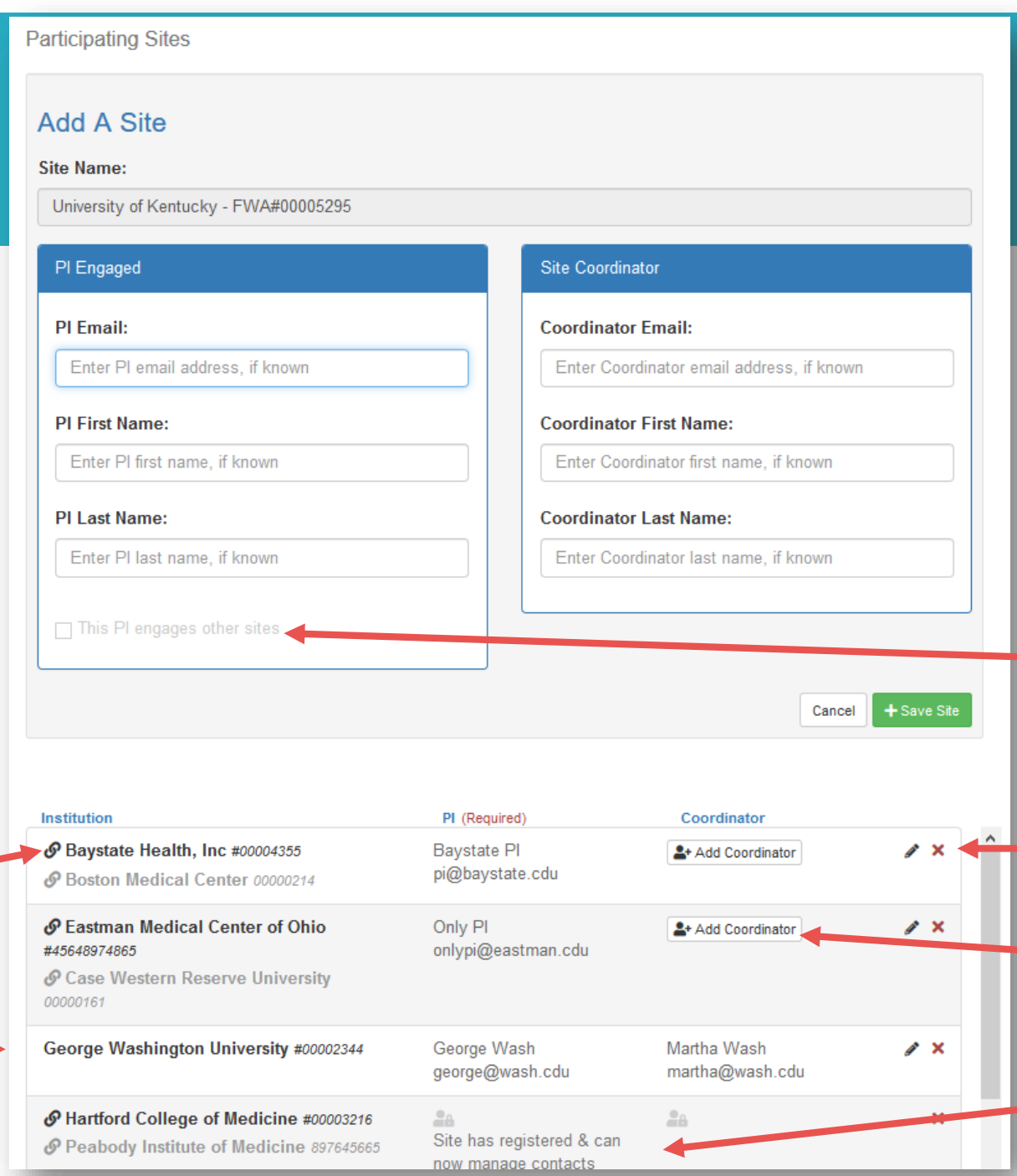
COMBO SITES – ADD PARTICIPATING SITES DIALOG UPDATES

CURRENT:



COMING SOON:





Checkbox to indicate "combo site"

Combo site "Primary" is bold & listed first

Edit / delete

Optional information missing

Single site

Site has registered; contacts are managed by the site

BONUS DISCUSSION!

STUDY MANAGER FOCUS GROUP

MORE FEATURES FOR COORDINATING CENTERS & LEAD STUDY TEAMS

- **Ability to disseminate the overall study approval to sites (**Protocol, ICF templates, reliance instructions)
- **Ability to track other study documents (e.g., SOPs, MOPs) and documentation** (Key Study Personnel Training)
- **Ability to capture regulatory information from sites post-initial approval** (continuing review information)

We hear you and we want you to join our focus group to inform new system features and priorities!

Next Call

- April 17, 2020 @ 1 PM ET/10 AM PT