IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR STUDY MANAGERS

July 19, 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***

QUARTERLY CALL AGENDA – HRPPs

- Welcome
- IREx Utilization – A Look at IREx Metrics
- Reminders from the Last Call
- Recent System Updates
- SNEAK PEAK: User Interface Updates Coming Soon

IREx Utilization – A Look at IREx Metrics

IREX UTILIZATION

STATISTICS

- **120%** increase in studies created from Jan-June 2018 with same time in 2019
- **22** sIRBs in IREx
- **14** median days from CIRB submission to CIRB approval *(not including local review time)*
- **8** average sites per study *(Range: 2-96 sites)*

265 partner institutions

80% have indicated reliance in IREx

42 states

>2000 users:

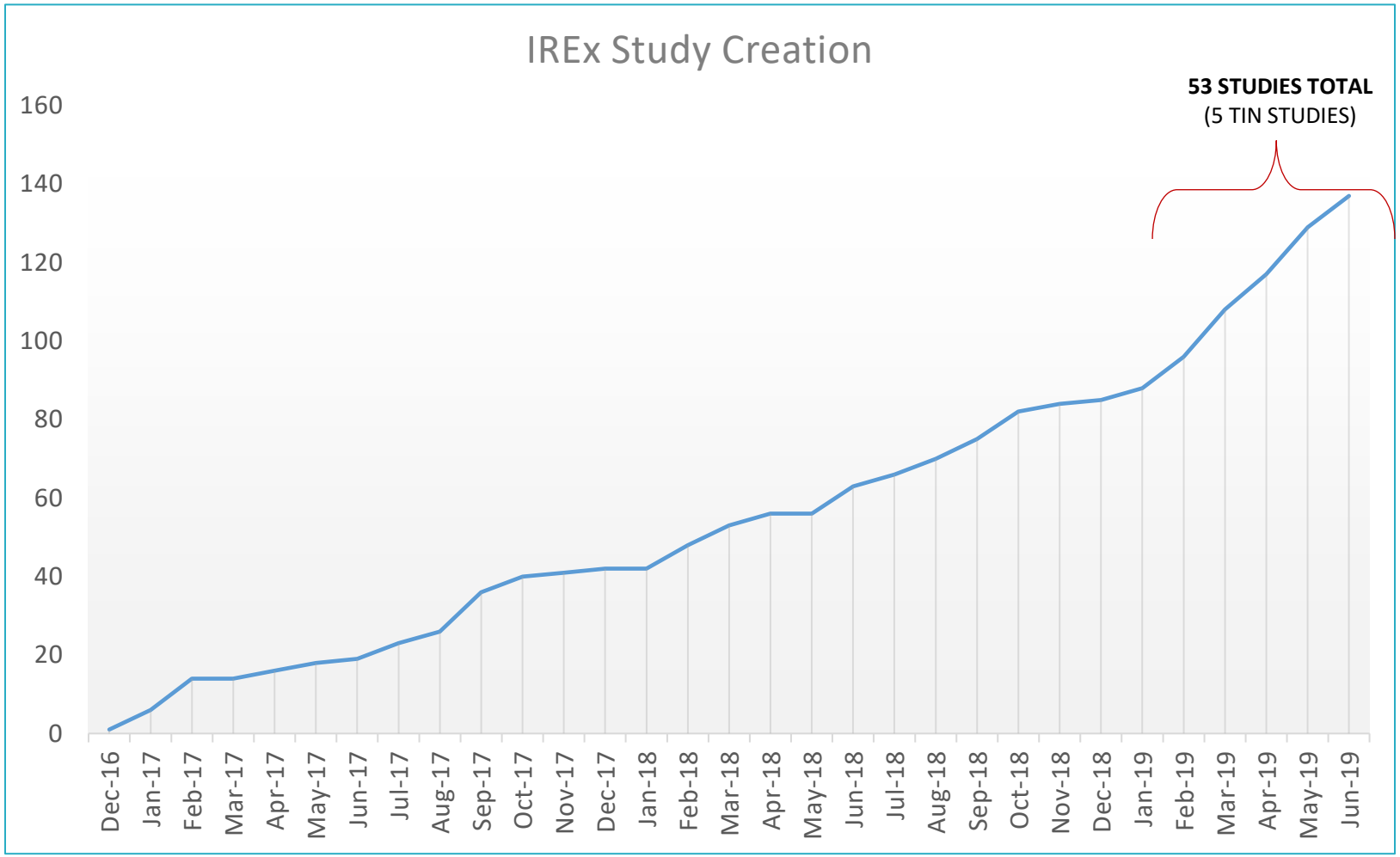
including HRPP/IRB, Coordinating Center, and Study Team staff

studies in progress

139 46 Trial Innovation Network (TIN) studies
93 Non-TIN studies

Supporting more than 700 reliance decisions;
76% of relying sites have sIRB Approval in IREx

IREX UTILIZATION

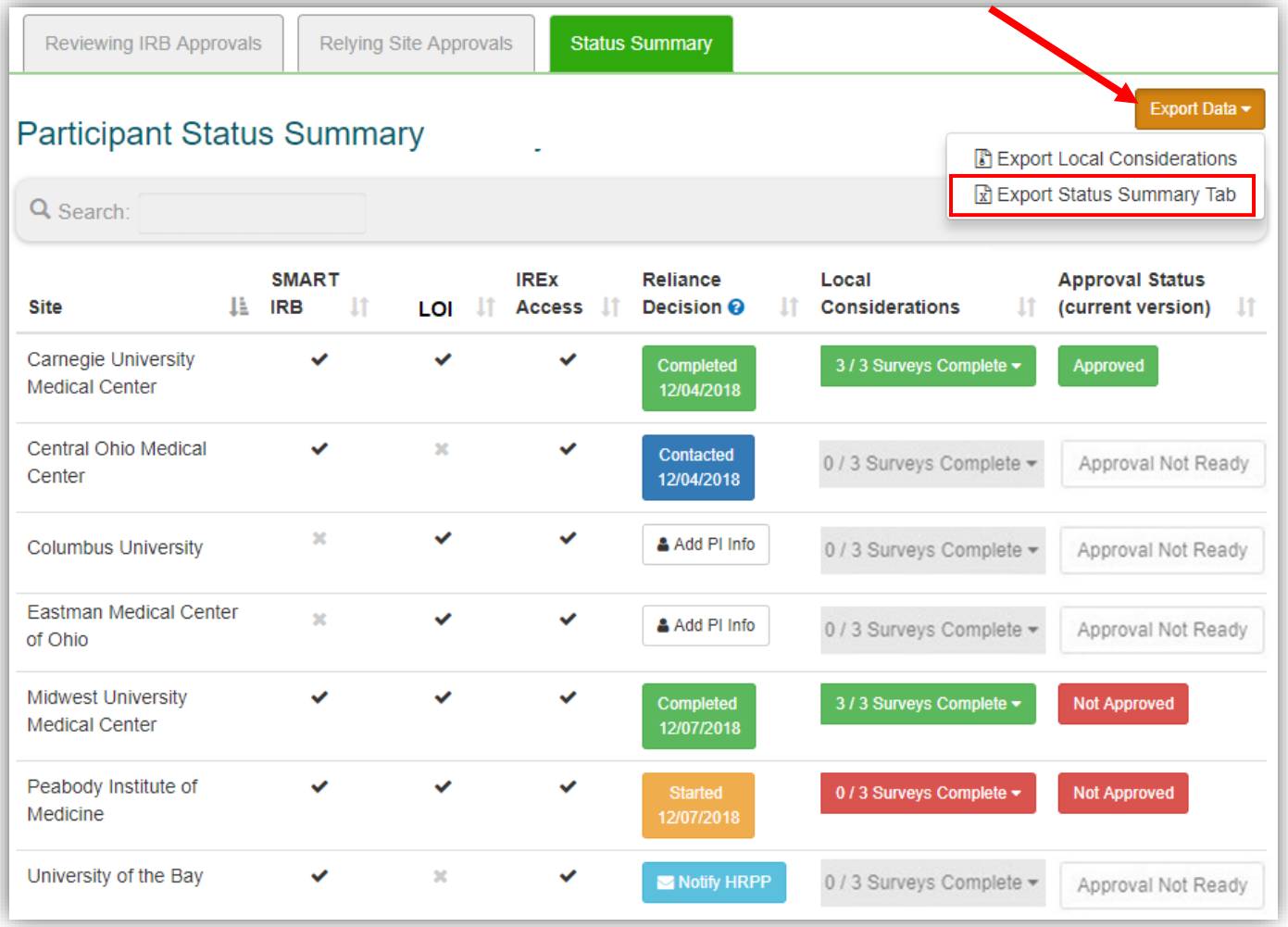


Reminders from the Last Call

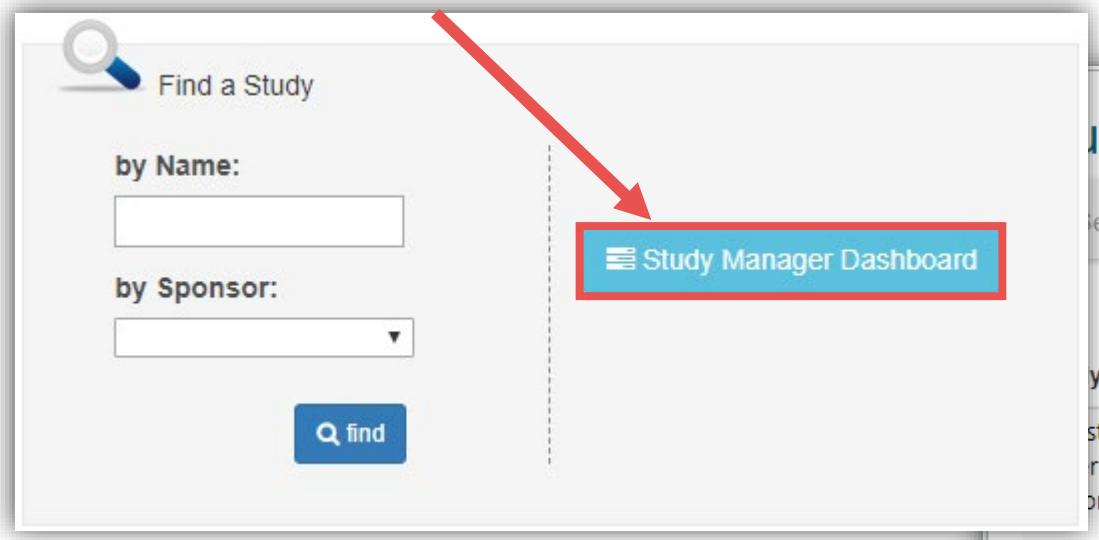
IN CASE YOU MISSED IT…

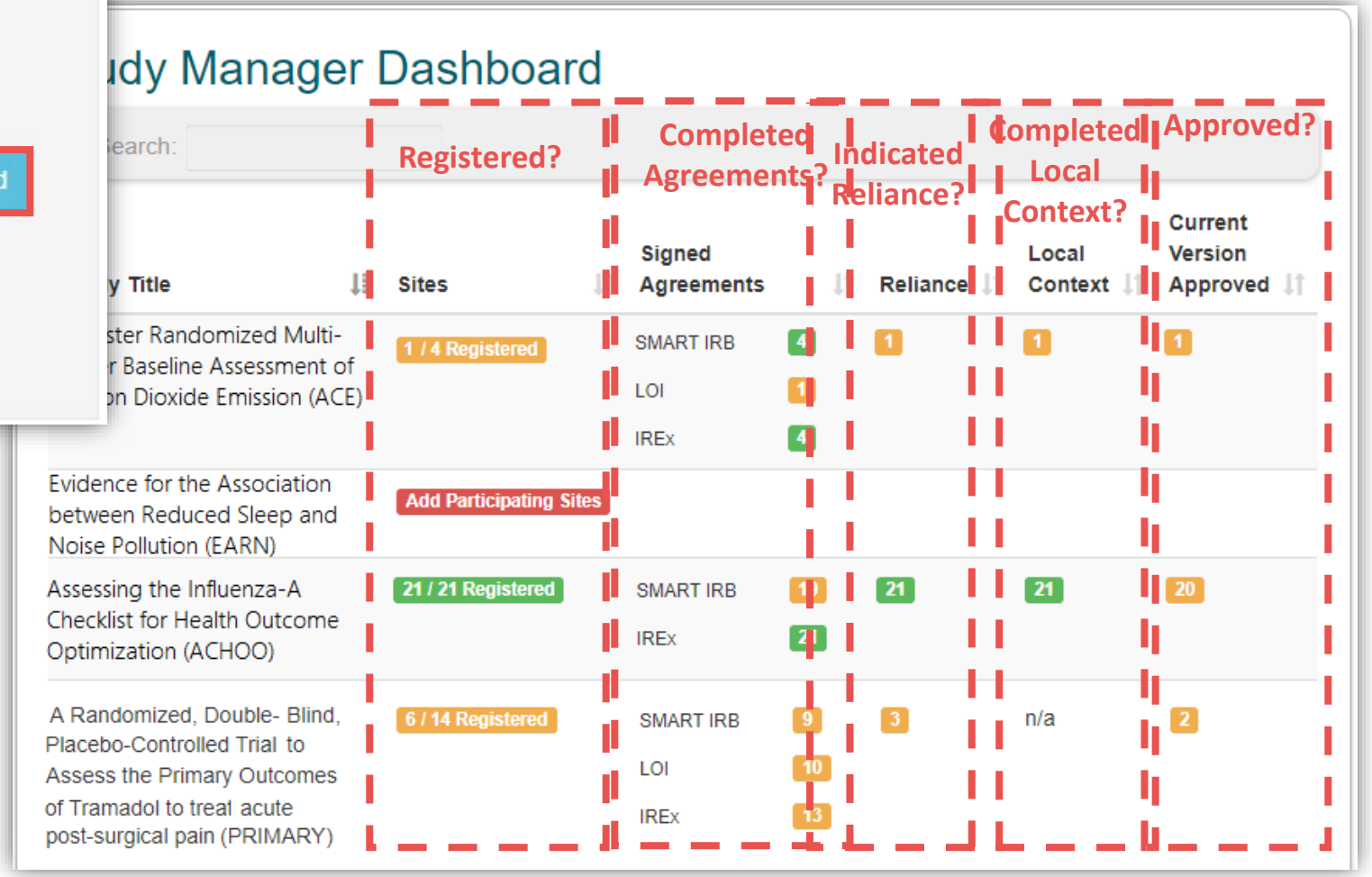
- Catch IREx improvements as they are released
  - Check out the IREx Feature Release Log
  - Read our monthly IREx Newsletter
- New to IREx or need a refresher? Join a training!
  - Reviewing IRB trainings – setting up your study in IREx
  - Relying HRPP trainings – using IREx to document reliance/ local considerations
  - Lead Study Teams/Coordination Centers – using IREx to support your sIRB study
  - Can’t make the monthly trainings? Request a demo for your team
- IREx Functionality Updates…

EXPORT STATUS SUMMARY TAB



NEW STUDY MANAGER DASHBOARD

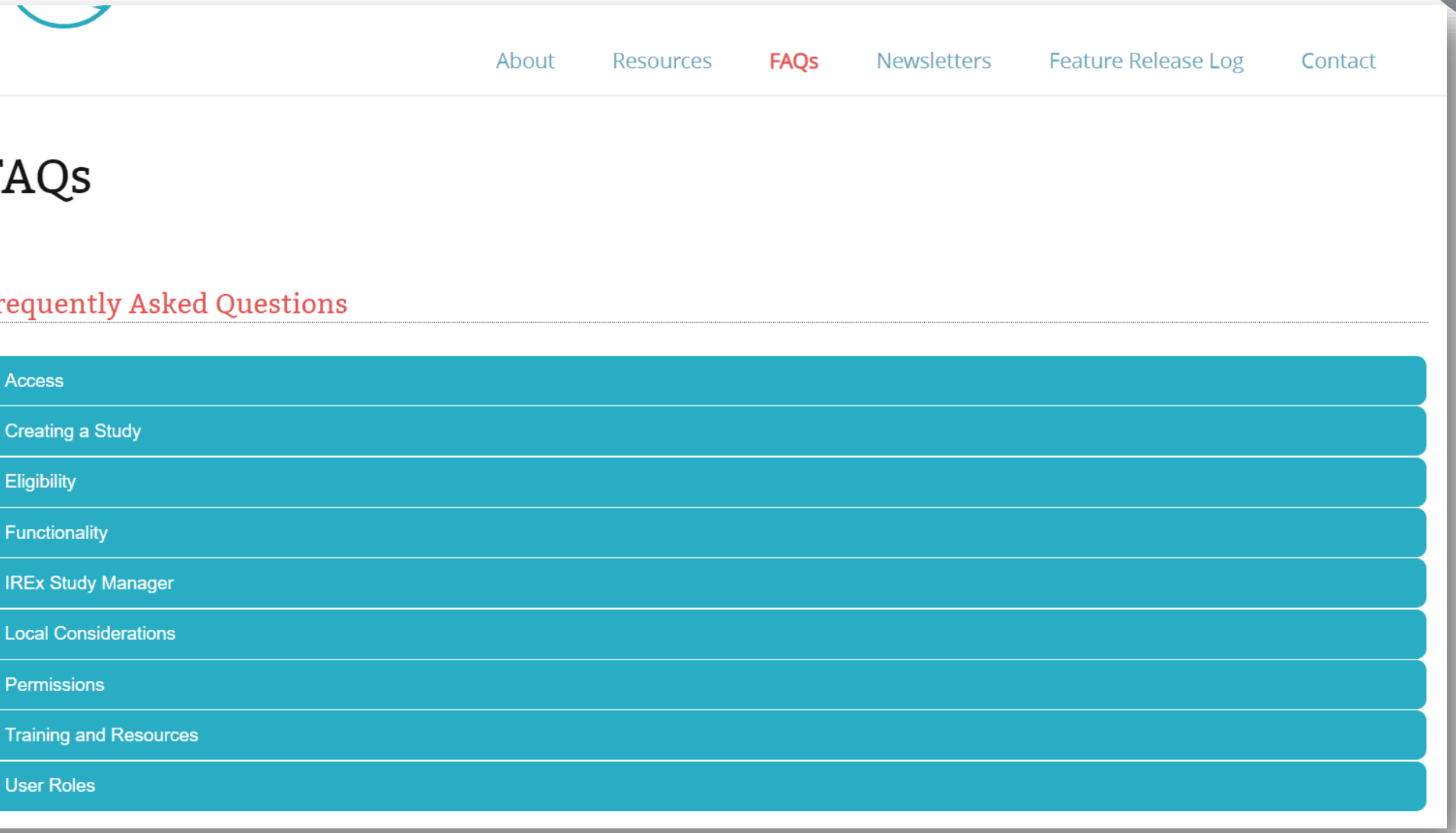




*Note: Each counter will turn green when **all** the participating sites listed on the study have completed the step.*

Recent System Updates

UPDATED FAQS ON IREX WEBSITE

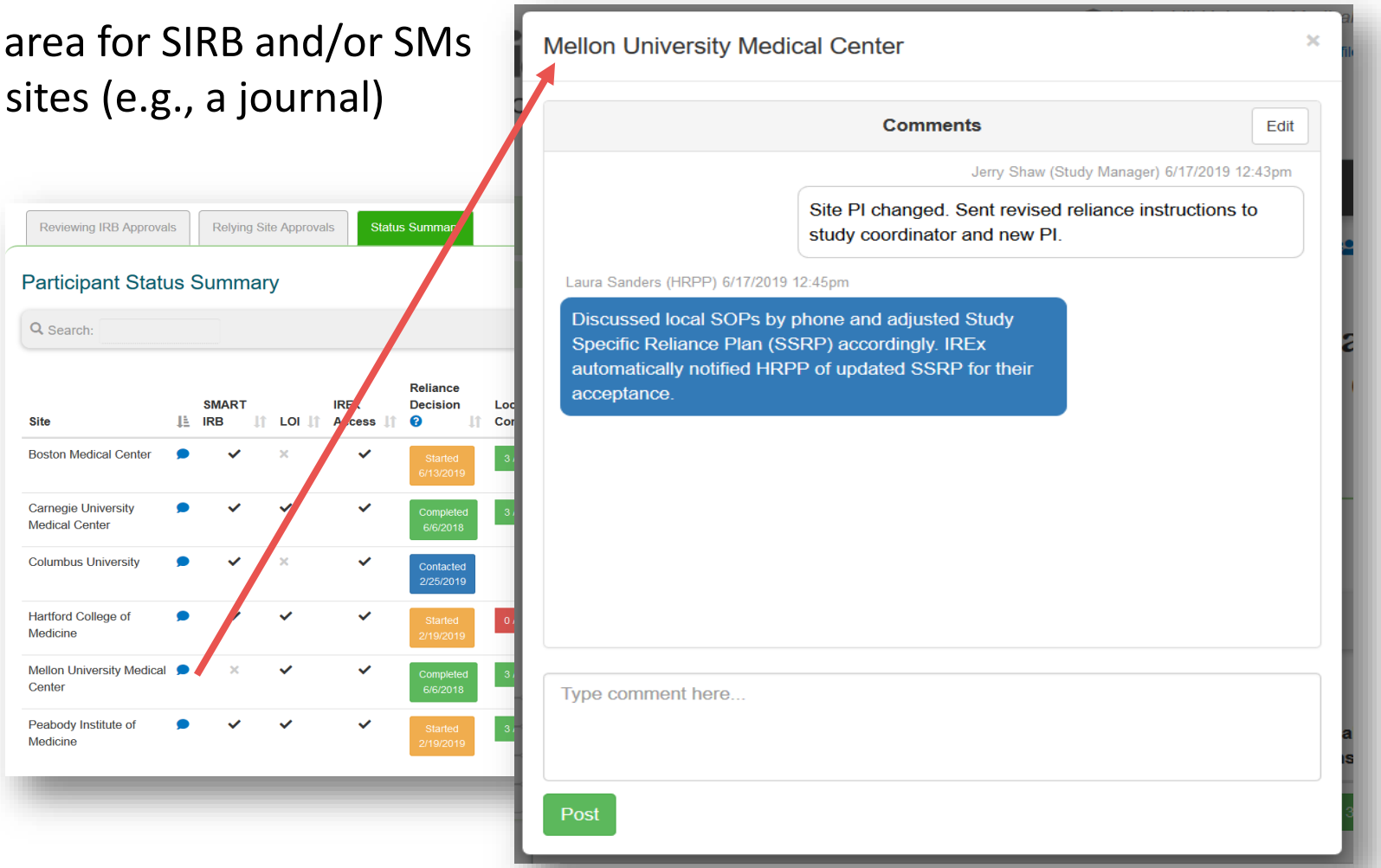


SITE-SPECIFIC COMMENTS/NOTES

GOAL: To provide dedicated area for SIRB and/or SMs to log history of outreach to sites (e.g., a journal)

HOW IT WORKS:

- SIRB liaison can make comments
- SM can make comments
- Automatically logs date and time and user
- SIRB and SM can see each others comments
- Does NOT generate notifications

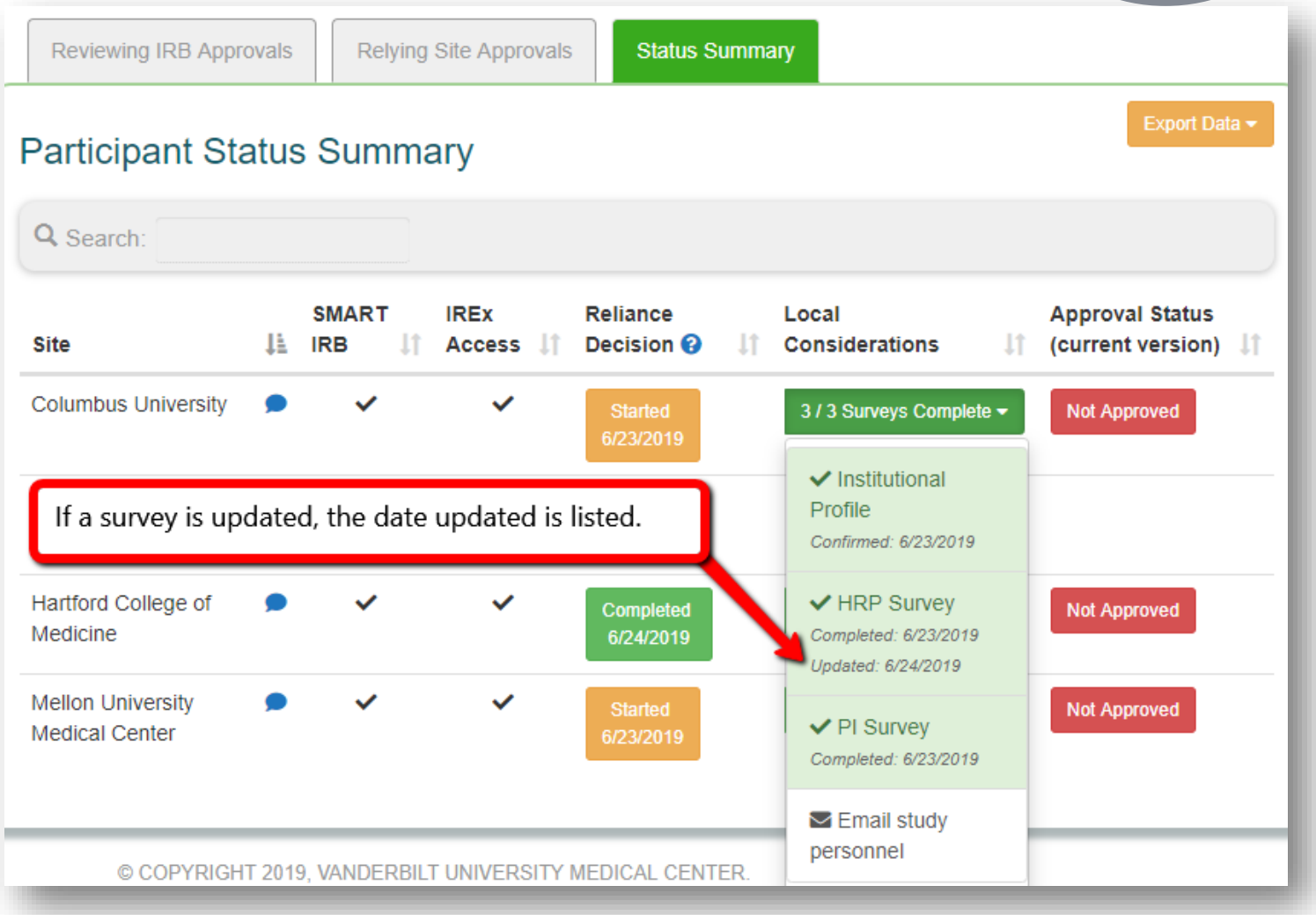


TRACKING UPDATES TO LOCAL CONSIDERATIONS

GOAL: To indicate when surveys were last updated

HOW IT WORKS:

1. Site HRPP is asked to provide clarification on survey
2. Site HRPP logs in and updates information
3. sIRB and Study Manager are notified that information was updated
4. Status Summary (and export) note where surveys were updated



SNEAK PEAK: User Interface Updates Coming Soon

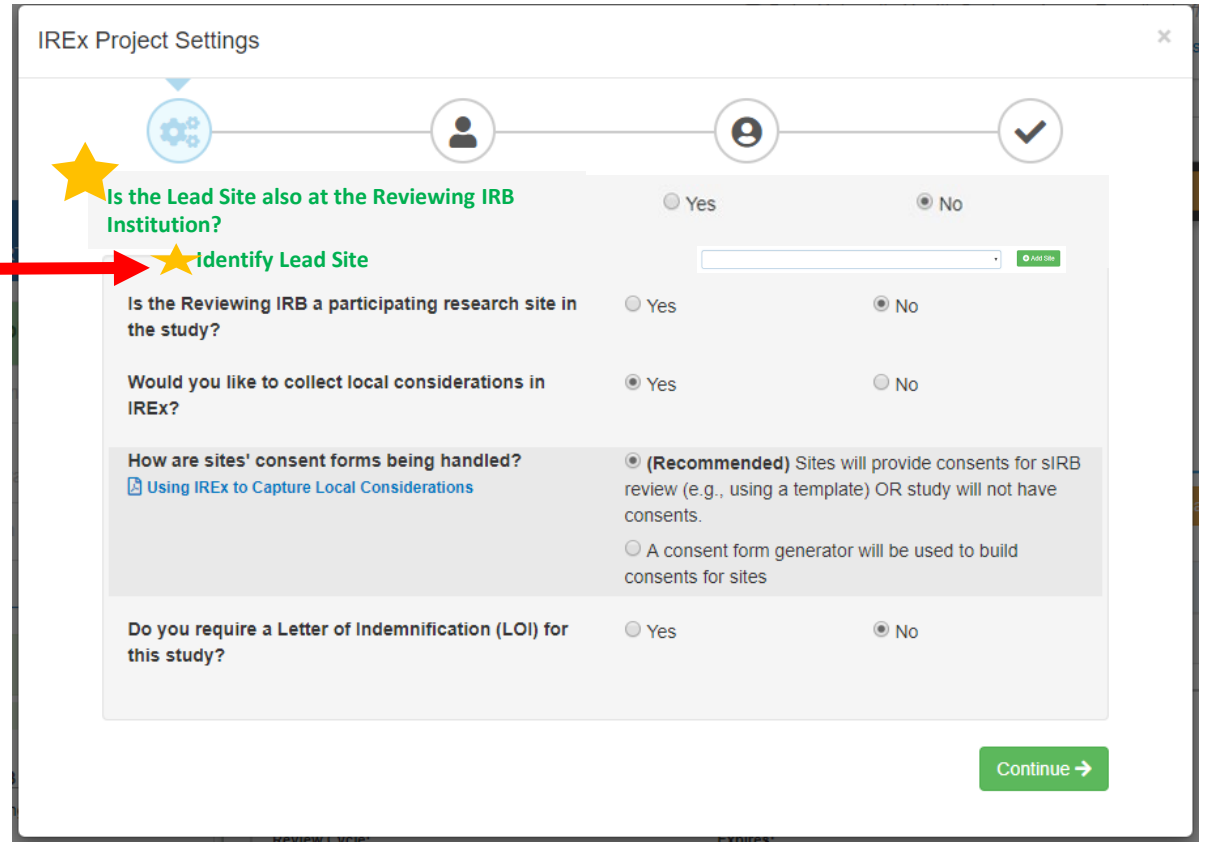
DISTINGUISHING THE REVIEWING IRB & LEAD SITE

CURRENT ISSUE:

IREx assumes the sIRB is also the Lead Site, causing confusion about where to find documents.

SOLUTION PART 1:

1. Rewording question in IREx setup to ask whether Reviewing IRB is also the Lead Site
2. If not, the Lead Site can be identified



DISTINGUISHING THE REVIEWING IRB & LEAD SITE

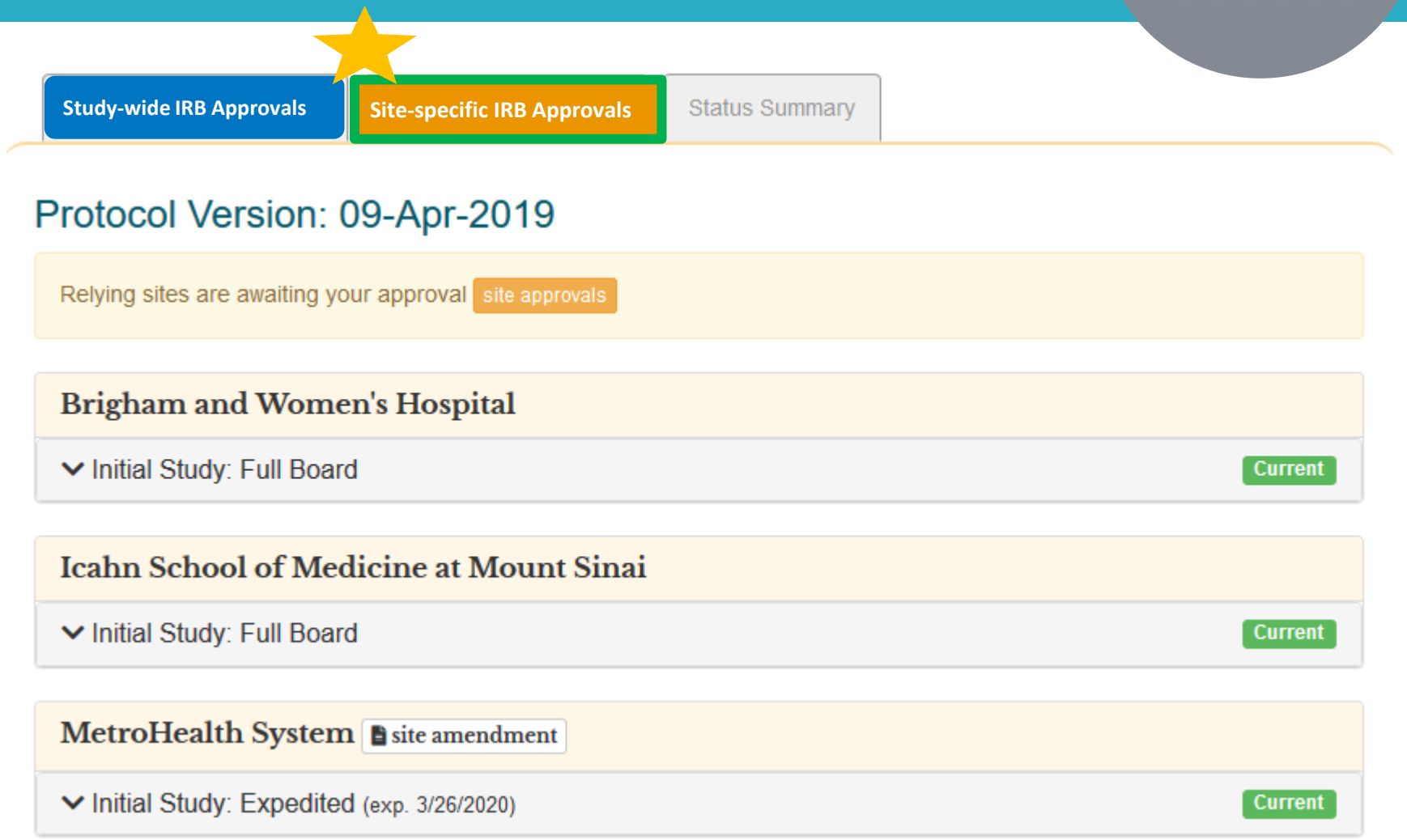
SOLUTION PART 2

- Renaming the Reviewing IRB Approvals tab
- Labeling the SIRB
- Including the name of the Lead Site, which may be different from the SIRB

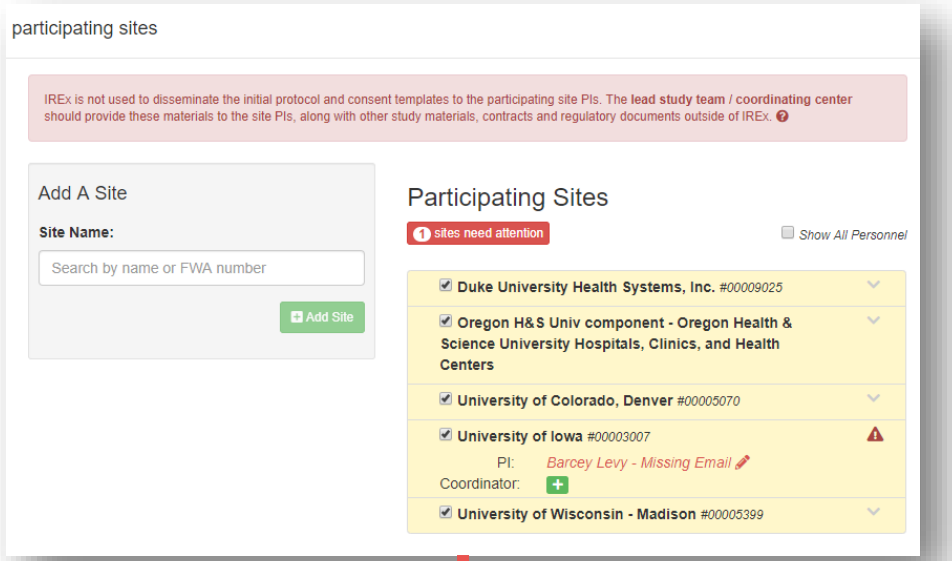
DISTINGUISHING THE REVIEWING IRB & LEAD SITE

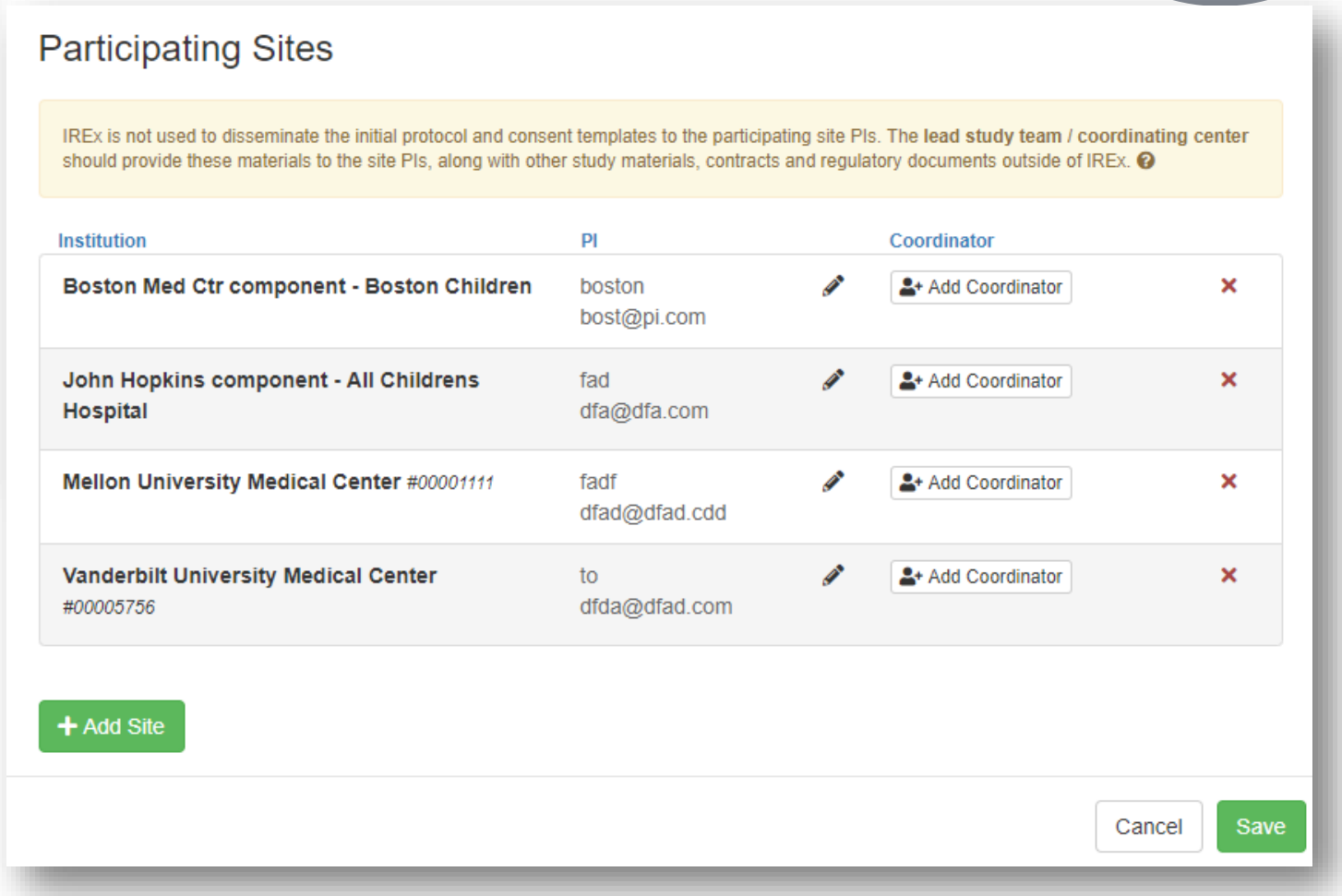
SOLUTION PART 3

- Renaming the Relying Site Approvals tab



ADD PARTICIPATING SITE DIALOGUE (SIRB & STUDY MANAGER)





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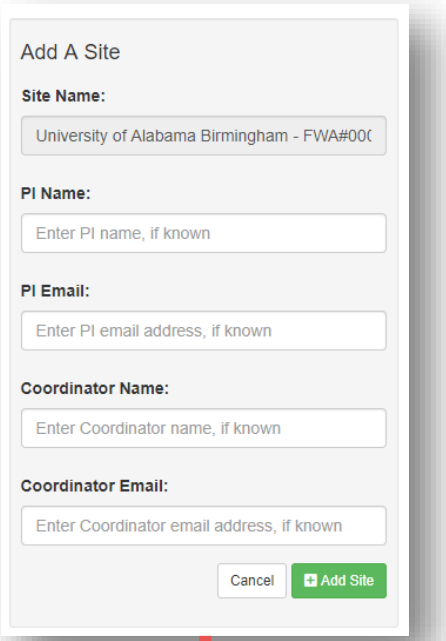
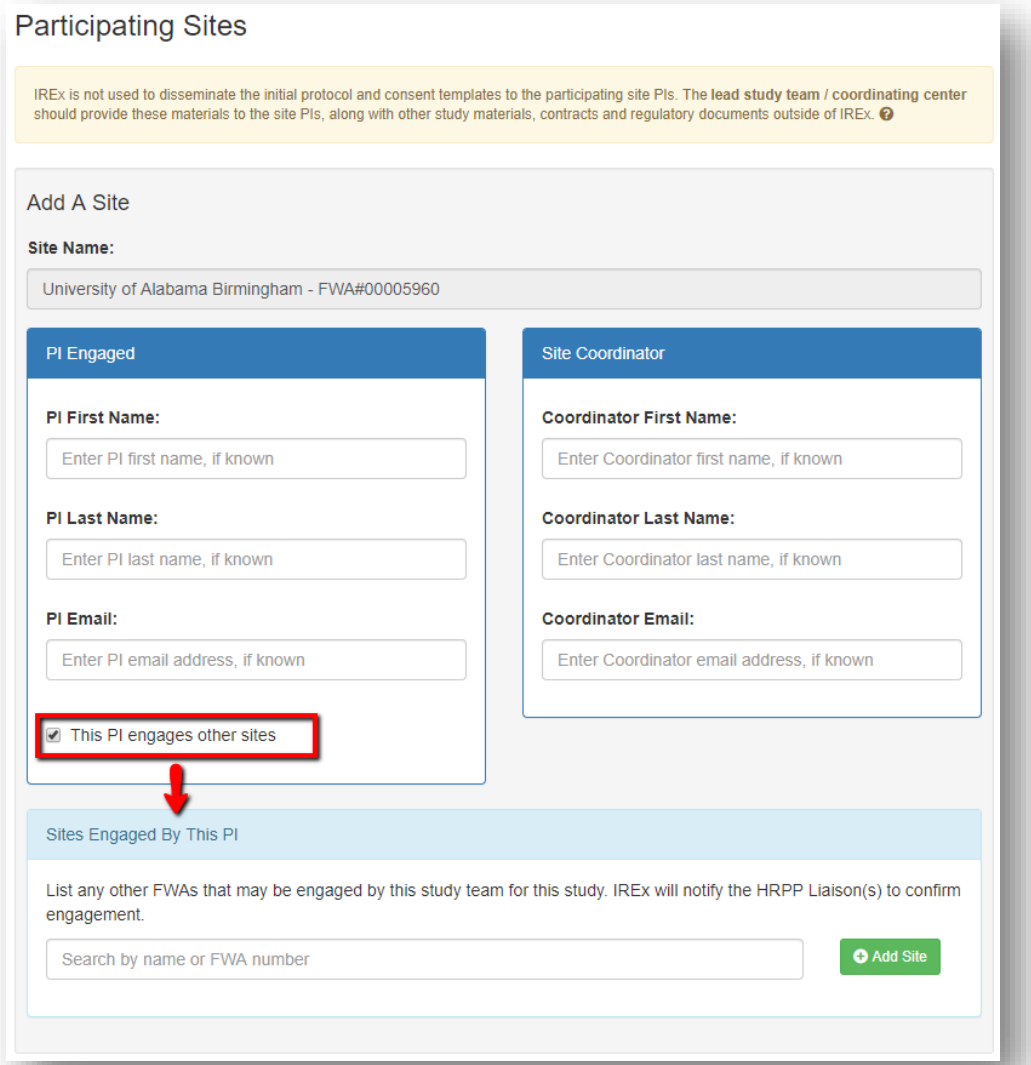
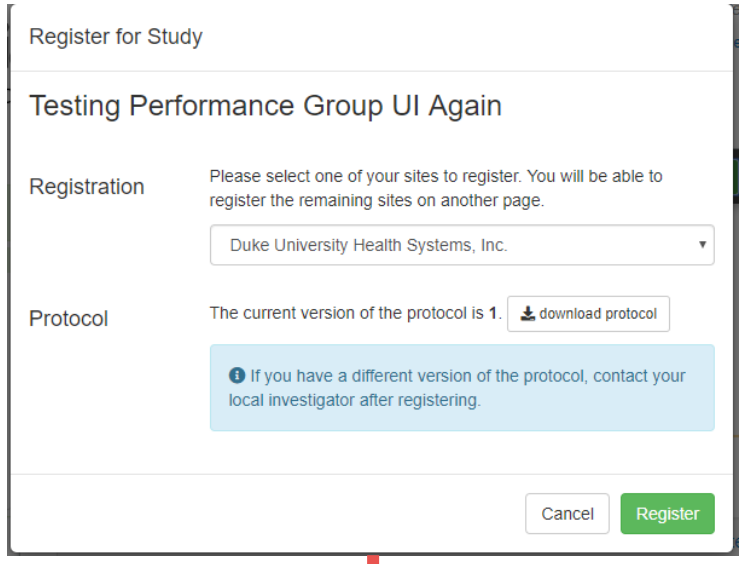
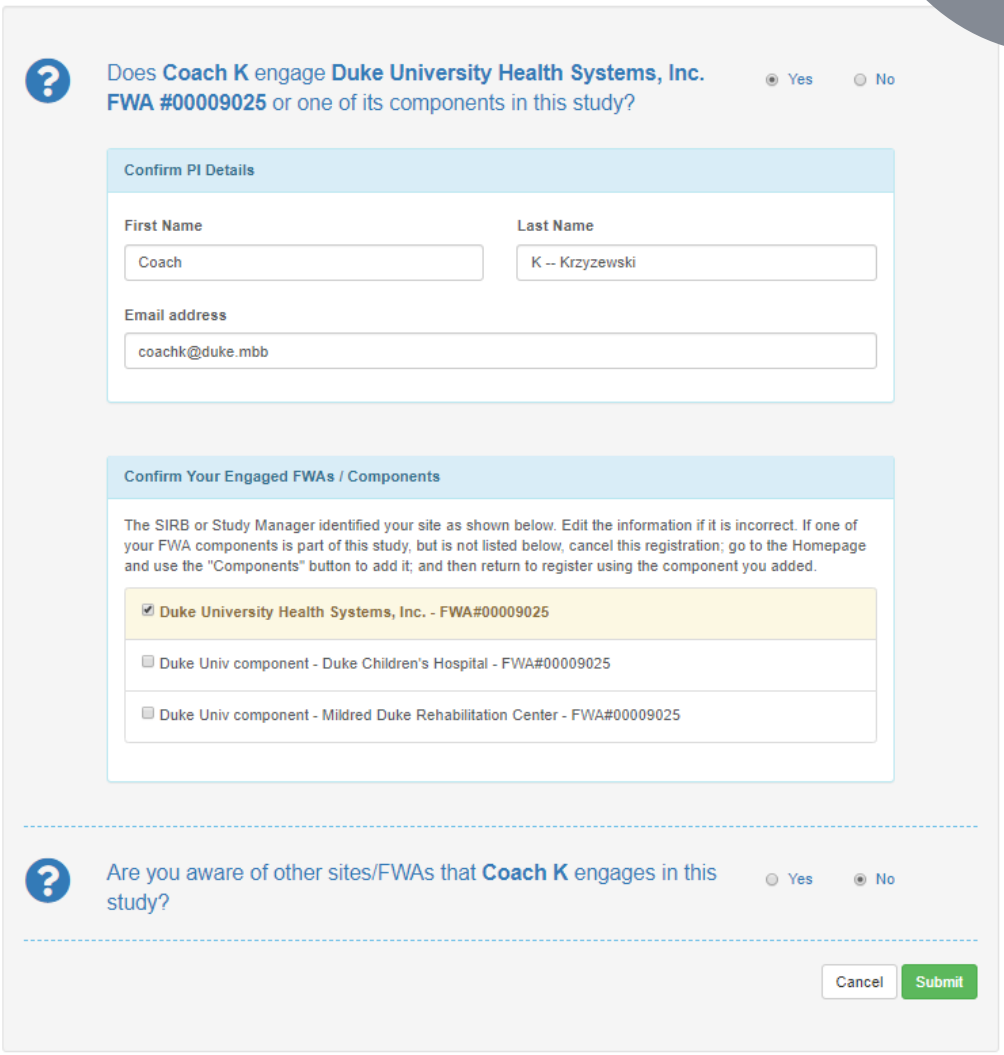




STUDY REGISTRATION DIALOGUE (RELYING SITE HRPPS)

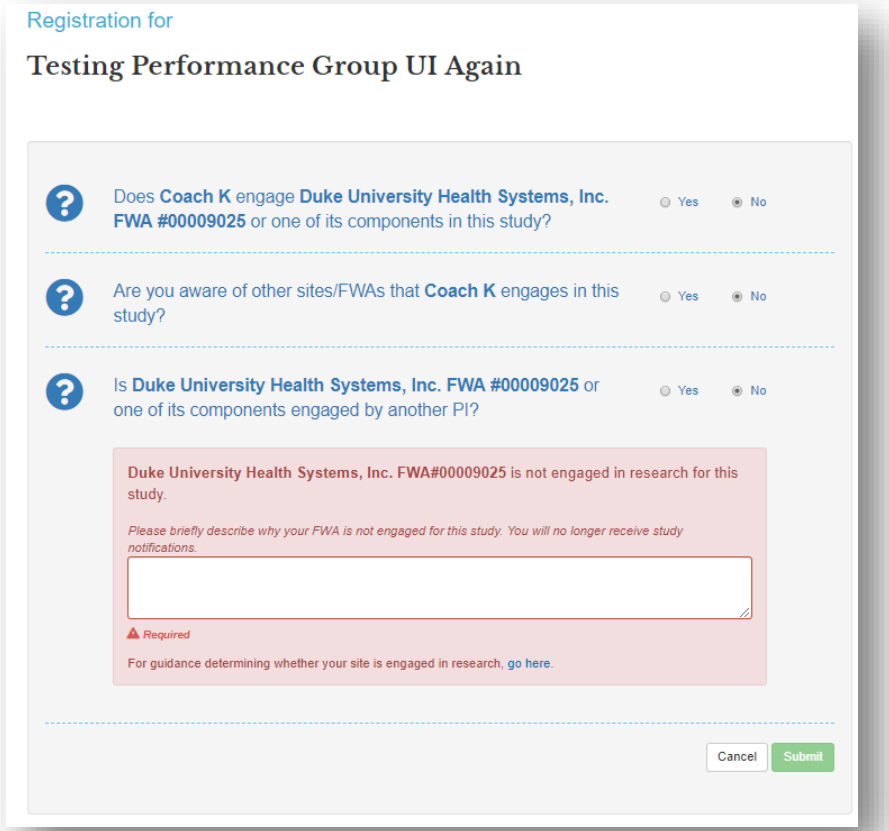


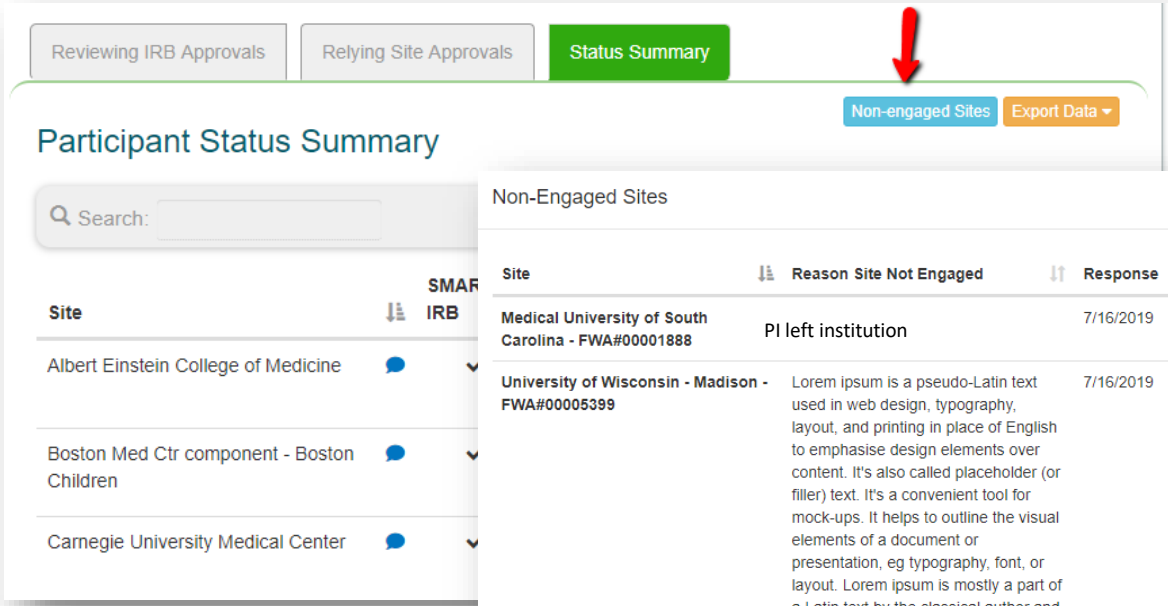


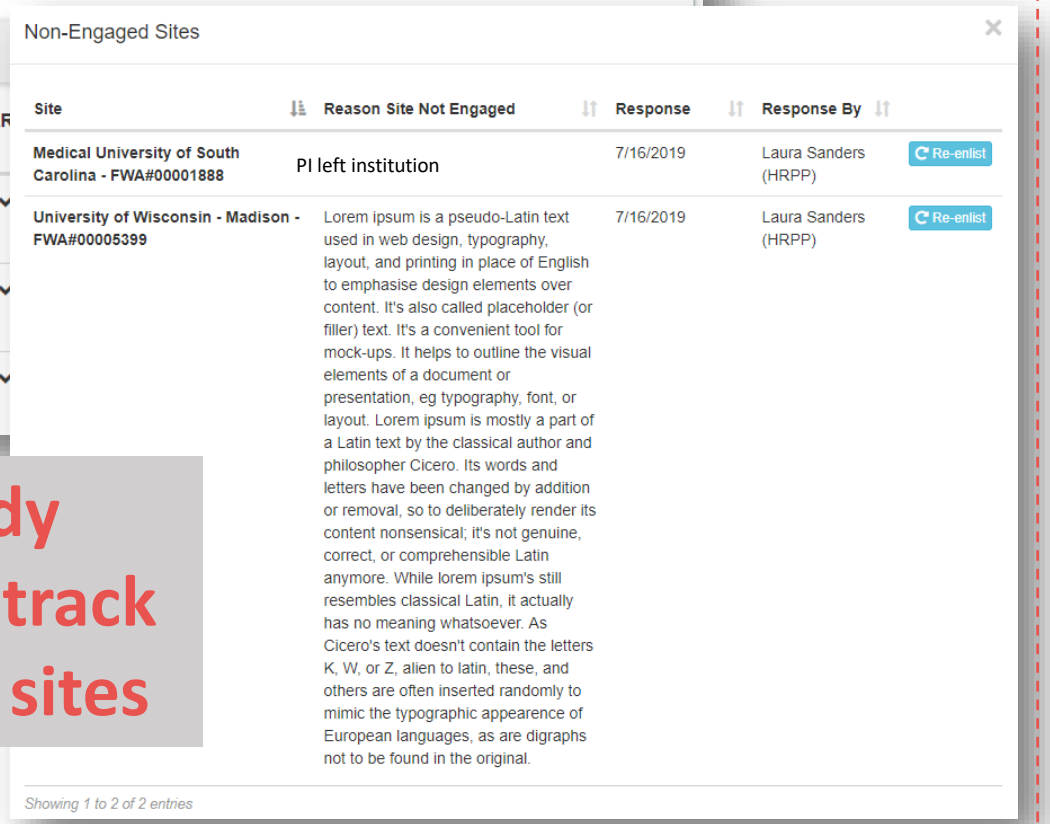
Investigator will get access here and you do not have to re-enter their contact info

STUDY REGISTRATION DIALOGUE (RELYING SITE HRPPS)

Your site is not engaged + why



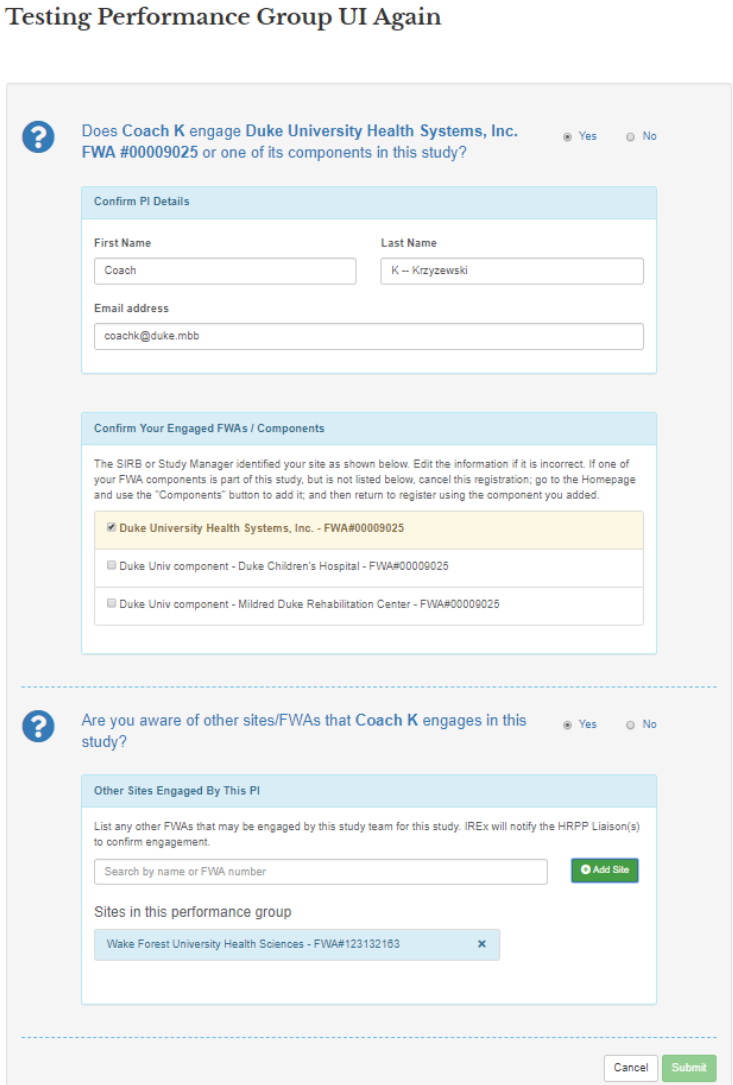




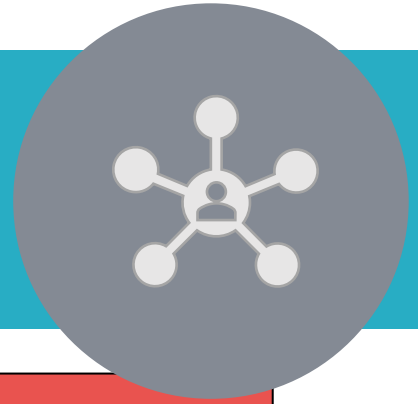
sIRB + Study Manager can track non-engaged sites

STUDY REGISTRATION DIALOGUE (RELYING SITE HRPPS)

Your site is engaged
+ another FWA may be, too



ONE STEP CLOSER:
COMBO SITES IN IREX



Streamline Reliance Documentation		
	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	

Next Call

- October 18, 2019 @ 2 PM ET/11 AM PT