The Trial Innovation Network and SMART IRB Exchange: *Promoting Innovation and Standardization around sIRB Review*

Emily Serdoz, MPA
Manager of Translational Research
SMART IRB Exchange Project Manager
Vanderbilt University Medical Center
Trial Innovation Network

CTSA Clinical & Translational® Science Awards

TRIAL INNOVATION NETWORK

Objectives

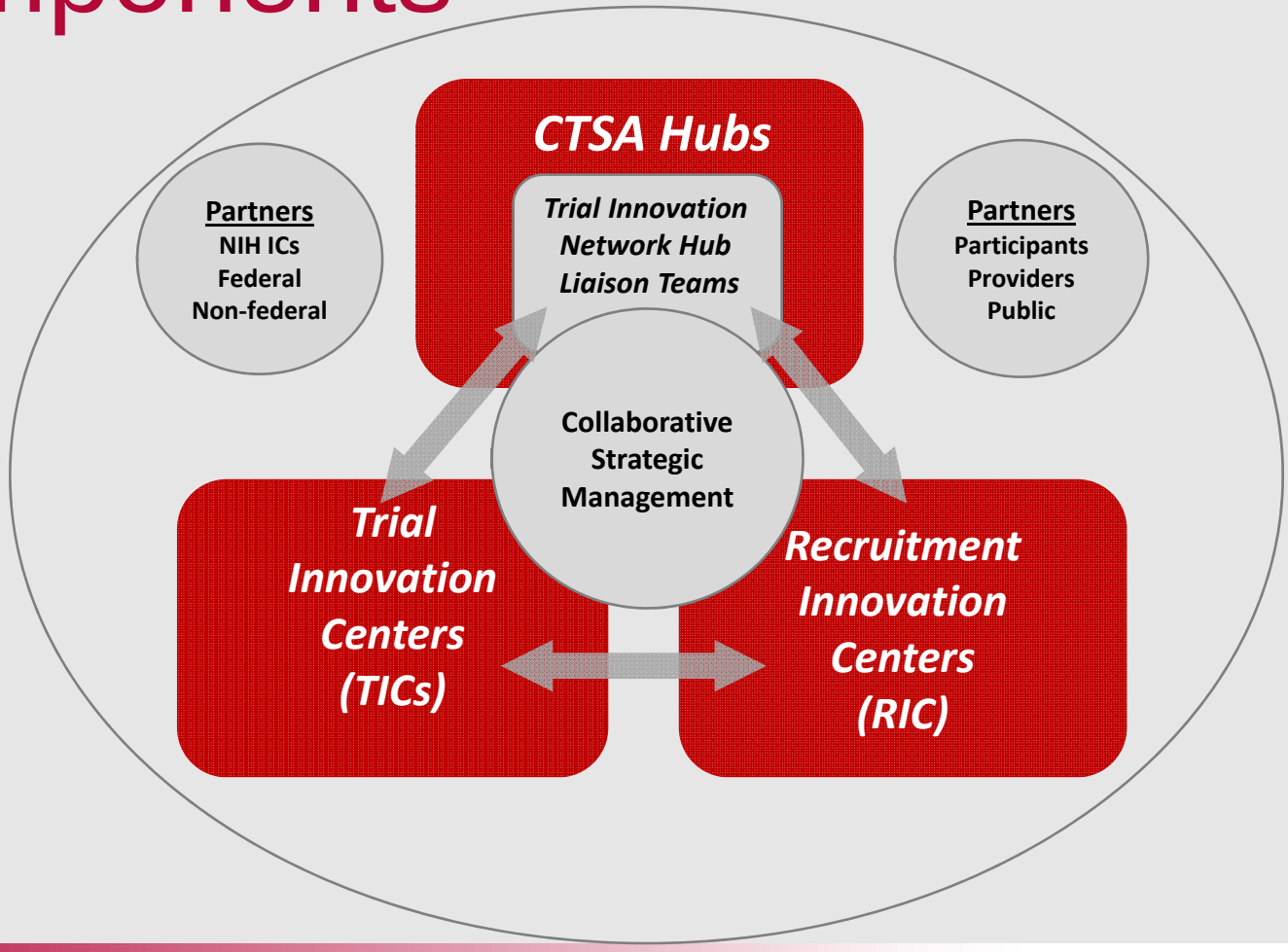
- Provide an Overview of the Trial Innovation Network
- Provide an overview of the SMART IRB Exchange
- Describe current efforts to innovate and standardize processes

Trial Innovation Network

CTSA Clinical & Translational Science Awards

TRIAL INNOVATION NETWORK

Trial Innovation Network Components



Trial Innovation Network

- Initiative launched by NCATS to leverage the resources of the CTSAs and help accelerate clinical trials
- **Three Trial Innovation Centers [TICs] each with their own central IRB [CIRB]:**
  - University of Utah
  - Duke University/Vanderbilt University
  - Johns Hopkins University School of Medicine/Tufts University
- **Recruitment Innovation Center [RIC]: Vanderbilt University**
- Trial Assignment through the Proposal Assessment Team [PAT]

CIRB Working Group Goals

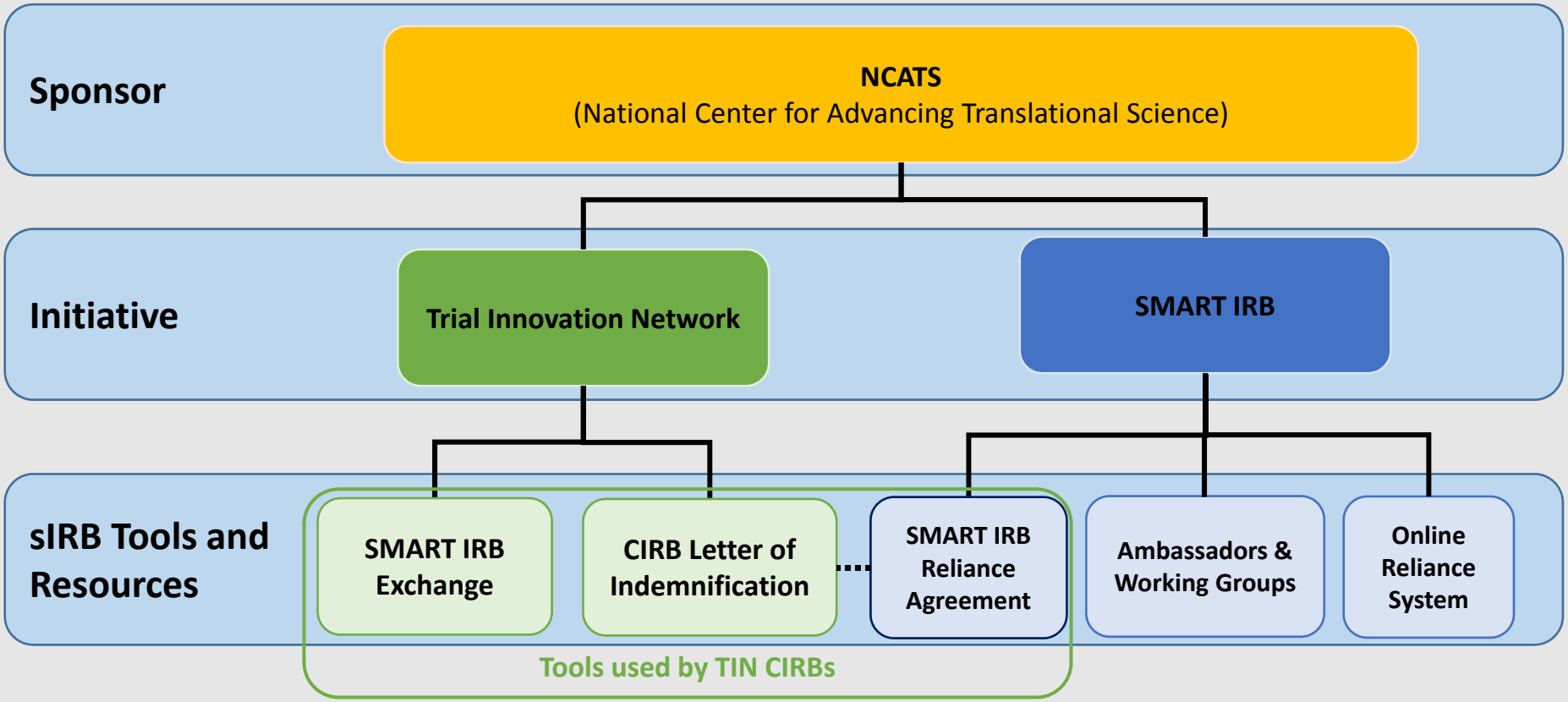
- ❖Develop systems and tools to support the activities of the CIRB
- ❖Develop plans to monitor the IRB approval process and develop metrics to evaluate CIRB success
- ❖Work with other TICs to develop innovative strategies for operationalizing CIRB review

Activity of the TIC CIRBs is support by a platform hosted by Vanderbilt:

SMART IRB EXCHANGE

Trial Innovation Network

Key Federally-Funded Resources that Support Single IRB Review and TIN CIRBs

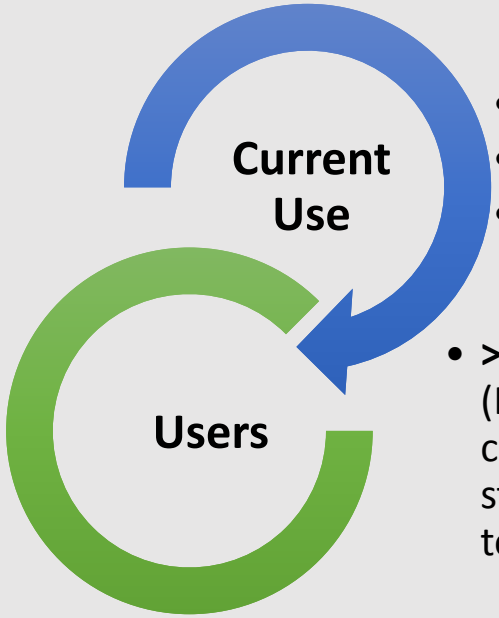


Trial Innovation Network

TIN CIRB Infrastructure

SMART IRB	SMART IRB Exchange	CIRB LOI
>300 sites	112 sites	72 sites

SMART IRB EXCHANGE



- Launched Feb 2017
- **27 TIN studies**
- **20 Non-TIN studies**

- **>400 users** (IRB staff, PIs, coordinating center staff, and study teams)

Trial Innovation Network

TIN CIRB Studies

27 TIN Studies with CIRB Services

- Supporting more than 319 reliances across all studies
- 12 studies in pipeline pending NIH funding

Diverse Study Demographics

- Vary in Size: # of participating sites ranges from 2 to ~60
- Include Diverse Types of Institutions: sites include academic medical centers, VA hospitals, small clinics, and adult day centers
- Cover the Lifespan: study participants range from neonates to adults with limited decision making capacity

SMART IRB Exchange

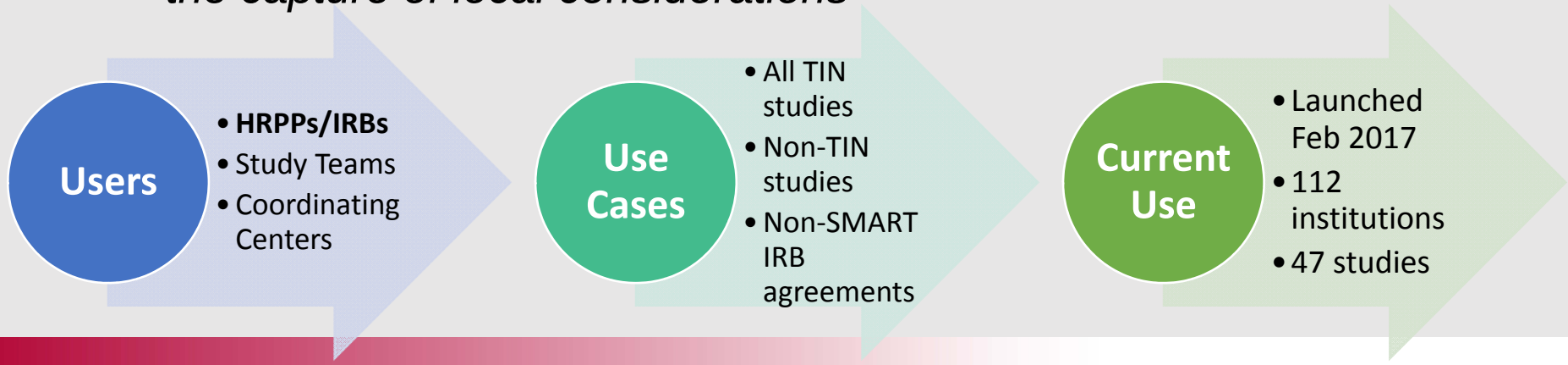
A web-based platform to support single IRB workflow and implementation

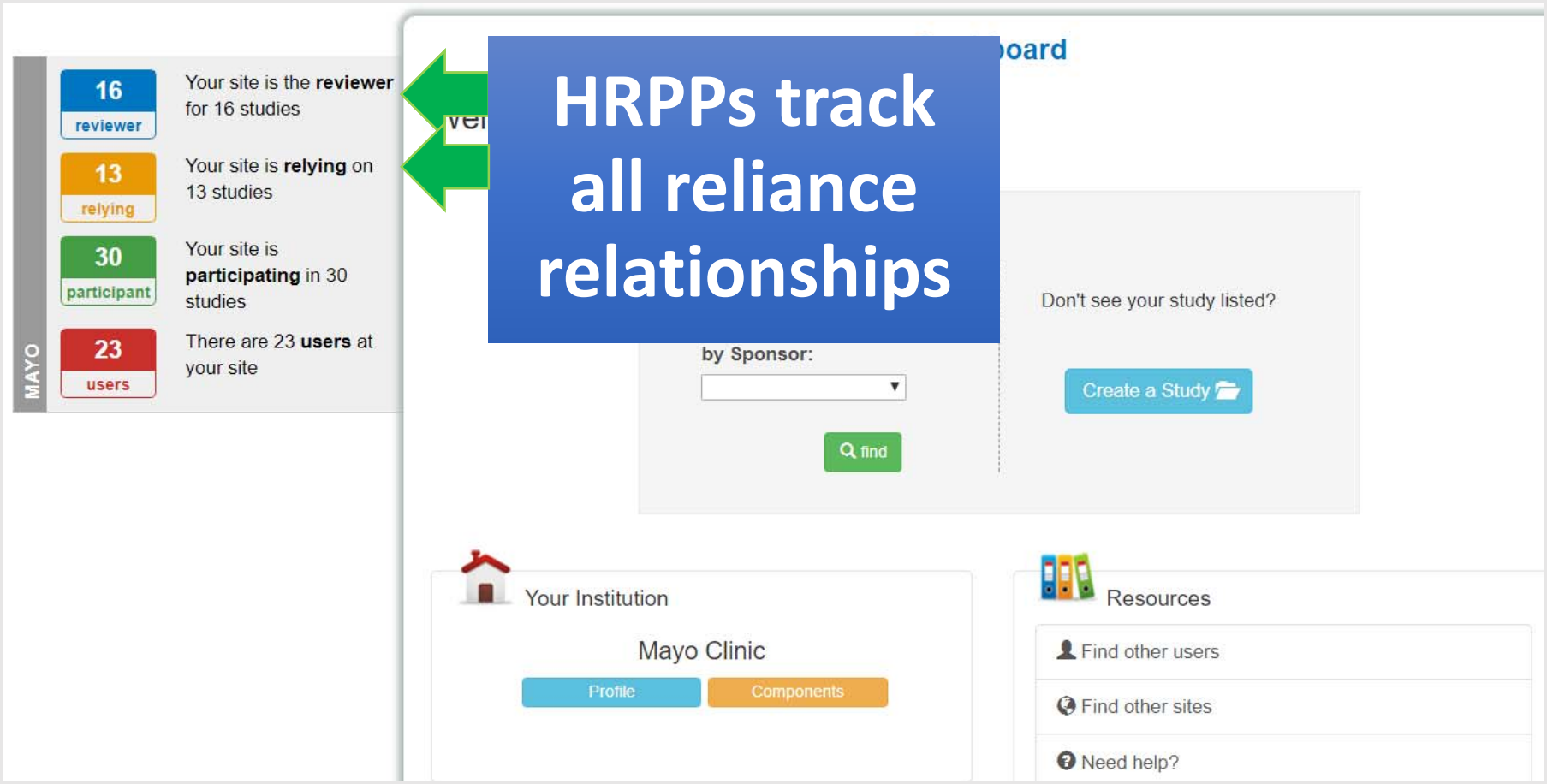
CTSA Clinical & Translational Science Awards

TRIAL INNOVATION NETWORK

SMART IRB Exchange

- **SMART IRB Exchange Supports sIRB Implementation**
  - **IRBs** document and track IRB reliance relationships
  - **IRBs** and **study teams** manage all IRB approval documents for Participating Sites
  - **IRBs and/or Coordinating Centers** streamline and automate study-related notifications to Participating Sites
  - **Lead Study Teams or Coordinating centers** monitor study start up and manage approvals
  - ***Coming Soon: IRBs and study teams*** *centralize and standardize the capture of local considerations*




MAYO
16
reviewer
Your site is the reviewer for 16 studies
13
relying
Your site is relying on 13 studies
30
participant
Your site is participating in 30 studies
23
users
There are 23 users at your site
HRPPs track all reliance relationships
by Sponsor:
find
Don't see your study listed?
Create a Study
Your Institution
Mayo Clinic
Profile
Components
Resources
Find other users
Find other sites
Need help?

Current Tracking Tool

Participant Status Summary

Search:

Site	SMART IRB	SMART IRB Exchange	Reliance Decision
Baylor College of Medicine	✔	✔	Complete
Boston Medical Center	✔	✖	Not registered
Clinical Eye Research of Boston	✖	✔	Pending acceptance
Cornea Associates of Texas	✔	✔	Complete
Cornea Consultants of Nashville	✔	✔	Complete
Dartmouth College	✔	✖	Not registered
Delray Eye Associates, PA	✔	✔	Complete
Duke University Health Systems, Inc.	✔	✔	Not registered
Eyecare MD of New Jersey	✔	✔	Complete

HRPPs, CCC, Lead Study Teams track site progress on specific studies

COMING SOON: Capture & Track Local Context

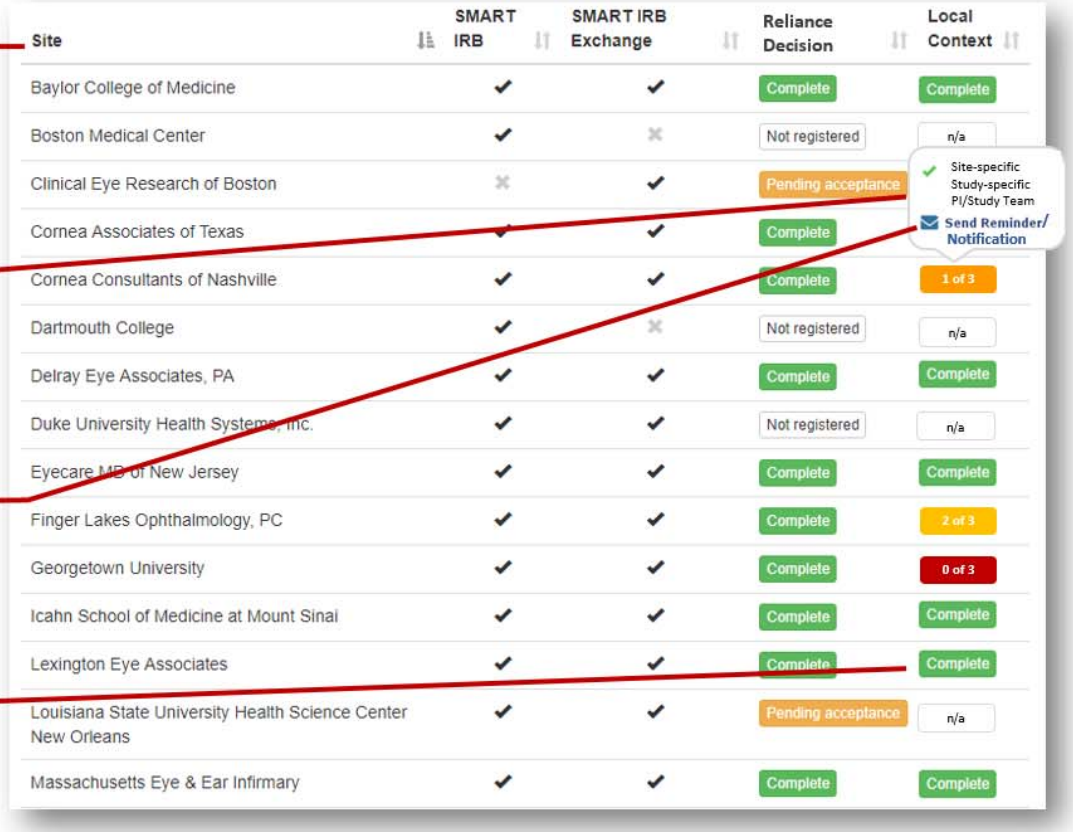
Track site's progress towards reliance

Track submission of local considerations:

- Site-specific
- Study-specific
- PI/Study Team

Send reminders to or notify sites about questions or clarifications

Export completed information



Site	SMART IRB	SMART IRB Exchange	Reliance Decision	Local Context
Baylor College of Medicine	✔	✔	Complete	Complete
Boston Medical Center	✔	✖	Not registered	n/a
Clinical Eye Research of Boston	✖	✔	Pending acceptance	
Cornea Associates of Texas	✔	✔	Complete	
Cornea Consultants of Nashville	✔	✔	Complete	1 of 3
Dartmouth College	✔	✖	Not registered	n/a
Delray Eye Associates, PA	✔	✔	Complete	Complete
Duke University Health Systems, Inc.	✔	✔	Not registered	n/a
Eyecare MD of New Jersey	✔	✔	Complete	Complete
Finger Lakes Ophthalmology, PC	✔	✔	Complete	2 of 3
Georgetown University	✔	✔	Complete	0 of 3
Icahn School of Medicine at Mount Sinai	✔	✔	Complete	Complete
Lexington Eye Associates	✔	✔	Complete	Complete
Louisiana State University Health Science Center New Orleans	✔	✔	Pending acceptance	n/a
Massachusetts Eye & Ear Infirmary	✔	✔	Complete	Complete

Part I: Institutional Local Context

Section 2: LOCAL CONTEXT	
In what **state** is your institution located?	TN
Age of majority in your state?	18
How does a **minor become emancipated** in your state?	☑ By judicial petition with age limitations ☑ By judicial petition ☑ By married ☐ By joining the armed forces ☐ Temporarily while in policy custody to consent to medical treatment ☐ After giving birth ☑ Other
Please describe how a minor becomes emancipated in your state.	See attached Department of Health definition of emancipated minor
What **circumstances affect age of consent** in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment	Only adults 18 year or older and emancipated minors can consent.
Do you have any state or local laws or institutional policies that require **record keeping** for longer than federal law requires under the Privacy Rule or Common Rule?	No
Please indicate the diseases below that require **mandatory reporting** to health authorities in your state. Please do not include all diseases; only list those diseases for which there would likely be a reason for testing in a research setting.	☑ Cancer ☑ Hepatitis A ☑ Hepatitis B ☑ Hepatitis C ☑ HIV ☑ All communicable disease ☐ Other (upload or describe below)
Do you require **specific language in your consent form to describe what requires mandatory reporting** to authorities?	Yes

Institutional Profiles:

General overview of the organization:
FWA number & legal components
Is the organization a HIPAA covered entity?
Is the organization accredited?

Over-arching state laws or institutional policies that affect all research at the organization?

Organizational Noncompliance:
Have there been any recent findings [OHRP/FDA] about your site?

How your site works
Is your organization willing to serve as the privacy board?
Does your site permit the use of short forms?

Part 2: Study-Specific Local Context Questionnaire

Process

- Completed by the Relying Organization on a study-specific basis
- Allows the Relying Organization to provide site-specific information with consideration for the specific study
  - What are the institutional policies that are relevant for THIS study?
    - What ancillary reviews are required for THIS study?
- Completion can be concurrent with the process to ensure all other responsibilities have been addressed [training, COI, etc.]

Content

- Whether any FCOIs been identified specific to this study & provision of management plans
- Verification of appropriate training/credentials for site study personnel
- Study-specific consent requirements [general consent requirements may be collected up front]
- Identification of ancillary reviews that may impact the review of the sIRB
- Site specific requirements based on state law/institutional policy relevant to the study [data security, recruitment, community considerations]

COMING SOON: Capture & Track Local Context

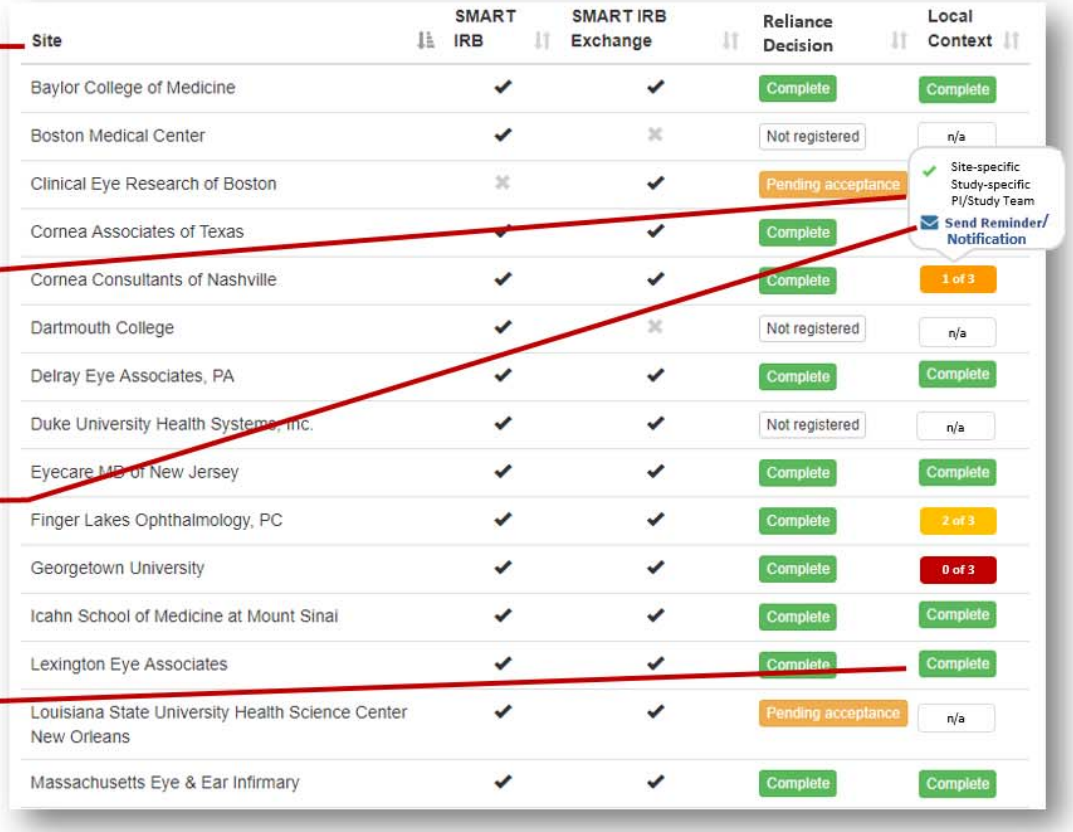
Track site's progress towards reliance

Track submission of local considerations:

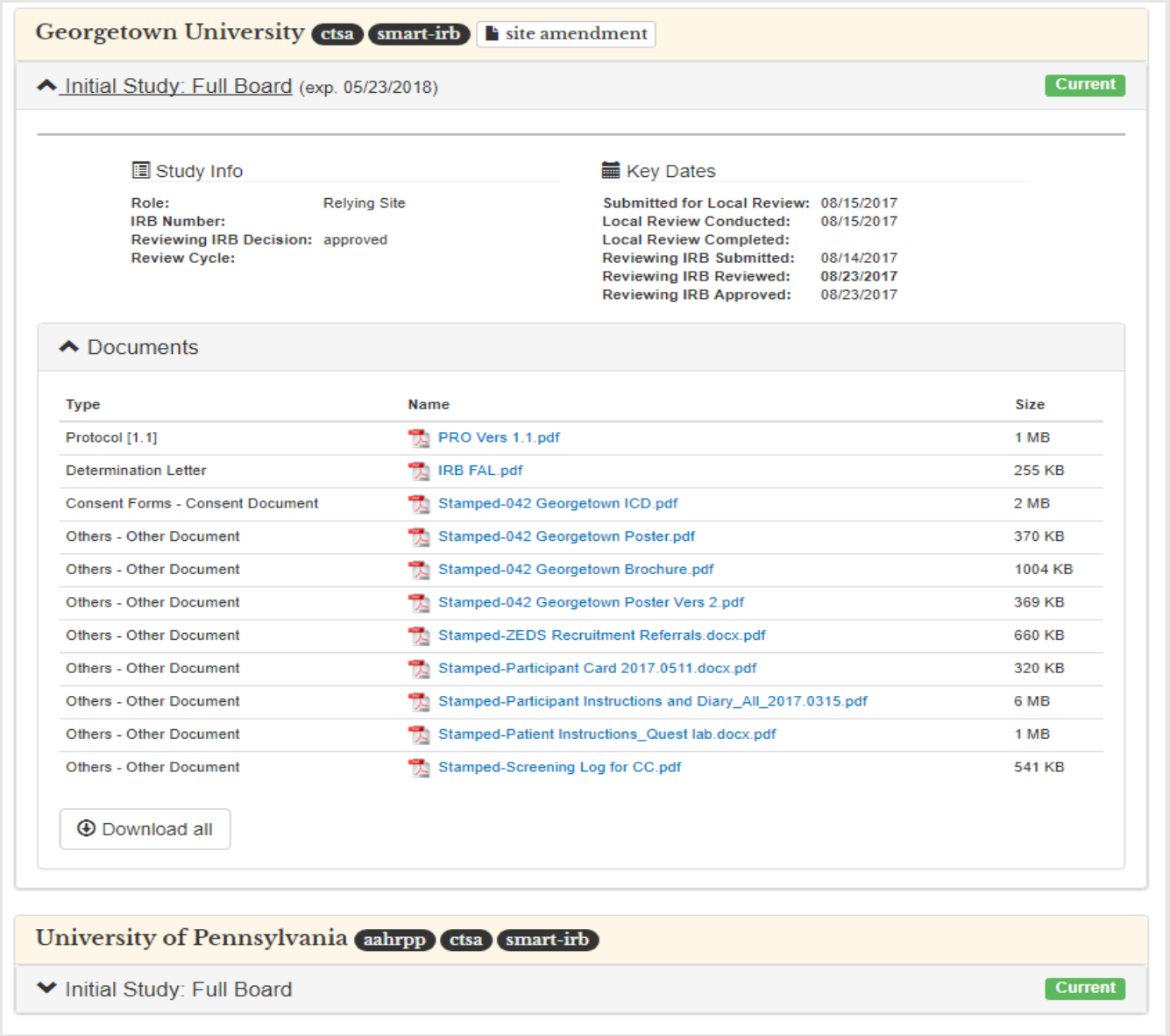
- Site-specific
- Study-specific
- PI/Study Team

Send reminders to or notify sites about questions or clarifications

Export completed information

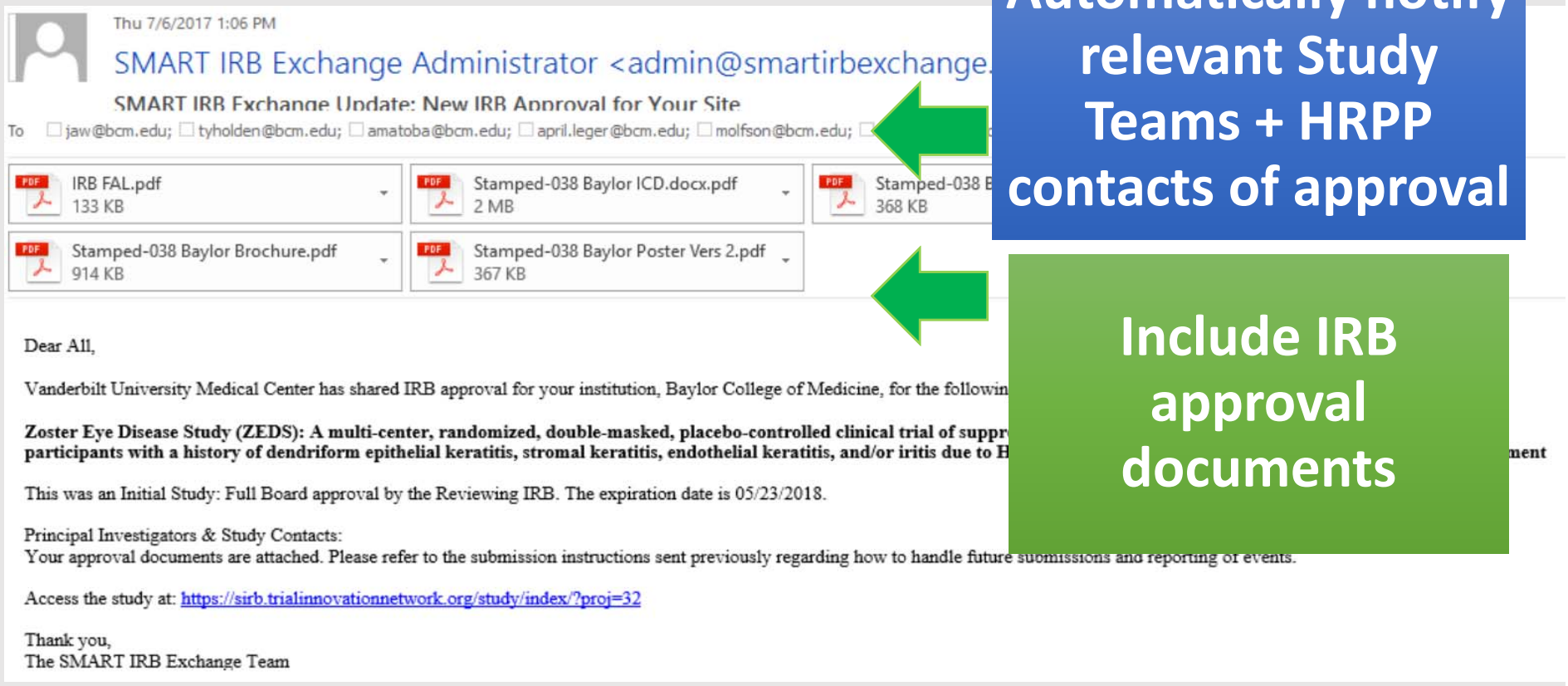


Site	SMART IRB	SMART IRB Exchange	Reliance Decision	Local Context
Baylor College of Medicine	✔	✔	Complete	Complete
Boston Medical Center	✔	✖	Not registered	n/a
Clinical Eye Research of Boston	✖	✔	Pending acceptance	
Cornea Associates of Texas	✔	✔	Complete	
Cornea Consultants of Nashville	✔	✔	Complete	1 of 3
Dartmouth College	✔	✖	Not registered	n/a
Delray Eye Associates, PA	✔	✔	Complete	Complete
Duke University Health Systems, Inc.	✔	✔	Not registered	n/a
Eyecare MD of New Jersey	✔	✔	Complete	Complete
Finger Lakes Ophthalmology, PC	✔	✔	Complete	2 of 3
Georgetown University	✔	✔	Complete	0 of 3
Icahn School of Medicine at Mount Sinai	✔	✔	Complete	Complete
Lexington Eye Associates	✔	✔	Complete	Complete
Louisiana State University Health Science Center New Orleans	✔	✔	Pending acceptance	n/a
Massachusetts Eye & Ear Infirmary	✔	✔	Complete	Complete



Capture site-specific approval documents

Sites can download all docs in single file



Automatically notify relevant Study Teams + HRPP contacts of approval

Include IRB approval documents