Facilitating Single IRB Review for Multi-site Research: The OneIRB IT Platform

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Background

- University of South Florida serves as the Coordinating Center for several multi-site studies encompassing large number of sites.
- Generally, these participating sites are organized into networks that have many studies.
- The studies can involve different combinations of sites and have different IRBs of record.

Background

- 25 protocols
- 5 SIRBS
- 380 sites
- 600 registered users.

Background

Group	# of studies	# of sites participating in studies (range)	# of sites who have signed the OneIRB Reliance Agreement	# of sites who have signed the SMART IRB Reliance Agreement
TrialNet	4	17 – 186	120	28
CReATe	5	2 – 14	14	0
RLDC	3	2 – 19	20	0
PIDTC	4	32 – 39	22	3
VCRC	5	6 – 17	10	8
INC	4	3 – 12	1	3

Project Goals

- Develop tools to reduce the burden on the study team and the IRB of record to facilitate single IRB review for multi-site research.

- Develop an IT platform:
  - For automated tracking of protocol submission, review and status.
  - To make available smart forms for study tracking and IRB reporting.
  - To provide confidential and secure records retention across sites.

Primary Focus

- **Study Team (Coordinating Center):**
  - Keep track of protocol review status at relying sites.
  - Communicate with relying sites and sIRB.
  - Compile and complete sIRB required forms (report writing capability).

- **Relying sites:**
  - Upload documents.
  - Track data/information requests.

- **sIRB (IRB of Record):**
  - Need to communicate with only Study Team.

Primary Focus

- **All users:**
  - **Messaging system**
  - **Study document repository**

- **Relying sites:**
  - **Upload documents.**
  - **Track data/information requests.**

Messaging system

- From study team:
  - Requests for documents.
  - Comments on forms submitted.
  - sIRB review status.
  - Can send to multiple recipients.
  - Can denote ACTION Required.

- From relying sites:
  - Responses to queries.
  - SIRB Completed forms
  - Site delegation log

Study Document Repository

- Study-wide:
  - Reliance agreement
  - Protocol
  - Recruitment materials
  - Consent form templates

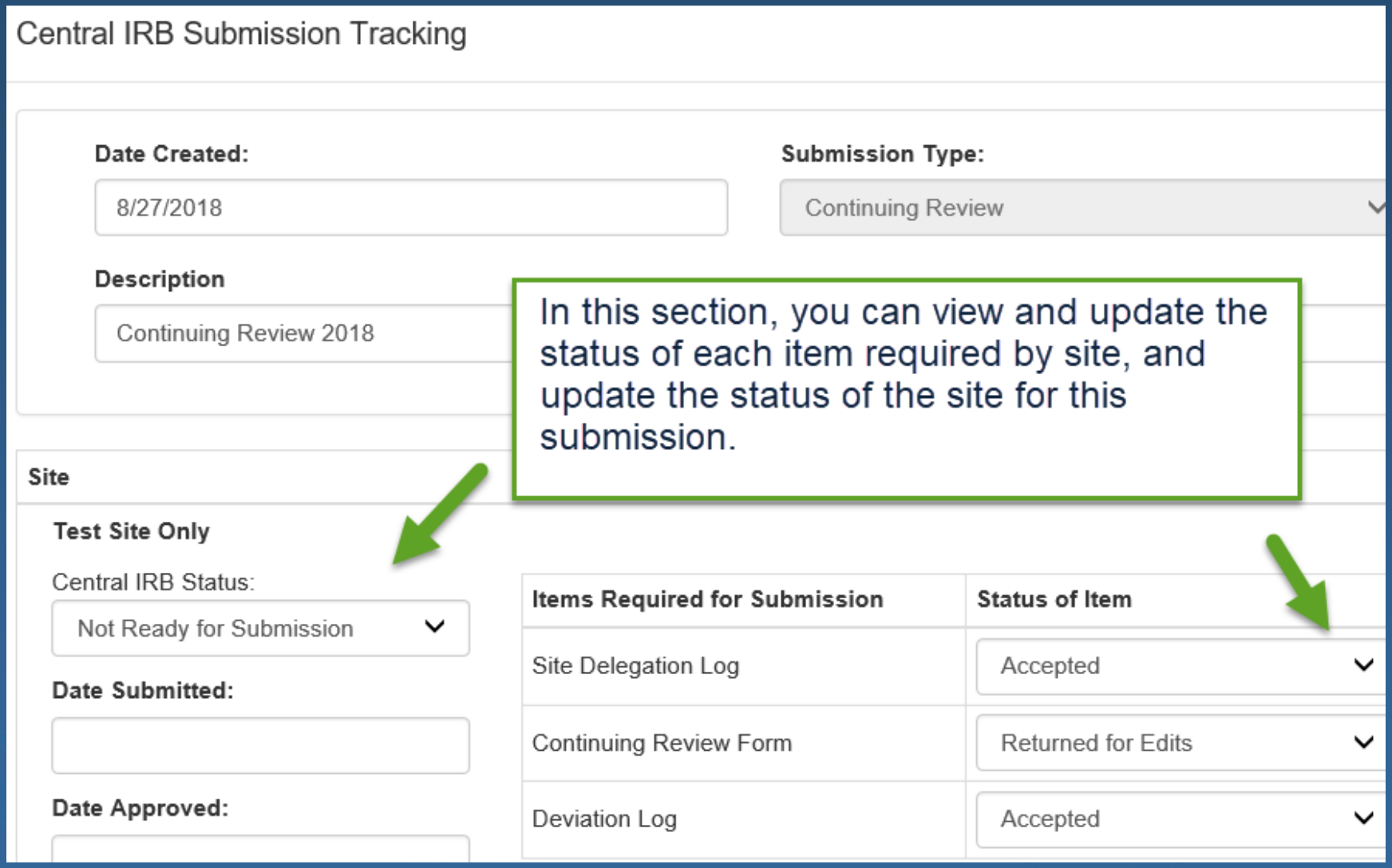
- Site-specific:
  - sIRB approval letters
  - sIRB approved informed consent forms
  - Site delegation log

Primary Focus

- **Study Team (Coordinating Center):**
  - **Create a new study entry and associate sIRB and sites with that study.**
  - **Review documents uploaded by relying sites.**
  - **Compose/send documents and messages to relying sites.**
  - **Create submissions to sIRB.**

Tracking SIRB Submissions

- Displays status of each document that is required for submission by site and status of site in regards to the submission
- Lead study team can view all sites
- Each site can view only their site's status
- Example: status of reliance agreement
    - In review by relying institution
    - In CIRB review
    - Pending signature from CIRB
    - Completed


Central IRB Submission Tracking
Date Created:
8/27/2018
Submission Type:
Continuing Review
Description
Continuing Review 2018
In this section, you can view and update the status of each item required by site, and update the status of the site for this submission.
Site
Test Site Only
Central IRB Status:
Not Ready for Submission
Date Submitted:
Date Approved:
Items Required for Submission
Status of Item
Site Delegation Log
Accepted
Continuing Review Form
Returned for Edits
Deviation Log
Accepted

Tracking SIRB Submissions

Assists lead study team in tracking submissions to SIRB

- Type of submission
  - Initial Approval
  - Amendment
  - Continuing Review
  - Reportable Event
- Status of items required by site

  (Ex: local context review, consents, site delegation log, etc.)
- Date Submitted
- Date Approved

Tracking SIRB Submissions

- Other forms such as Continuing Review and Local Context Review can be marked as Not Received, Returned for Edits, or Accepted

- Status of Each Site
  - Not Ready for Submission
  - Ready for Submission
  - Date Submitted
  - Date Approved
  - Modification Requested by CIRB

Electronic Smart Forms

- Electronic Forms for site preparation
  - Local Context Review
  - Continuing Review
  - Reportable Events
- Automated Reports for sIRB submission
  - Accrual
  - Reportable events

Continuing Review Form

Study Title: Take 2 Practice Demo

Protocol Number: T2PD

For Review Period Ending: 10/02/2019

Site Name: Demo Site 1

Data entered into electronic forms can be compiled into a report for the SIRB with summary of all sites at the bottom of the report.

Please provide the following information for your site:

1. The study status is* Please Select item from the list

2. Have there been any changes in financial or other interests that you, or any of the study personnel, have in this research project since the last review?* ○ Yes ○ No

3. Do all study team members have current certification in human subject protections?* ○ Yes ○ No

4. Number of subjects enrolled/consented at your site since initial IRB review:* ☐ N/A

5. Number of subjects enrolled/consented at your site since last IRB review:* ☐ N/A

6. Number of subjects still actively participating:* ☐ N/A

7. Number of subjects in long term follow-up:* ☐ N/A

8. Number of subjects who have completed all participation:* ☐ N/A

9. Number of screen failures since last IRB review:* ☐ N/A

IT Platform Summary

- **Assists lead study team**
  - Manage flow of documents between sites and the SIRB
  - Track status of sites and submissions to SIRB
  - Compile documents for submission to the SIRB into a zip file
  - Communicate with sites in the platform

- **Assists sites**
  - Upload, download, and manage documents in a single repository
  - View status of their site's submissions at any time

- **Assists sIRBs**
  - Summary reports of data from all sites for continuing review

sIRB Advisory Group

- **Tracy Ziolek, MS CIP**
- Director, Human Research Protections
- University of Pennsylvania

- **Patrick Stanko, CIP**
- IRB Assistant Director
- University of Pennsylvania
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- **Laurie Herraiz, CIP, CCRP**
- HRPP Director
- University of California, San Francisco

- **Jessica Phillips**
- IRB Assistant Coordinator
- University of California, San Francisco

- **Julie Moore, J.D., M.S PA, CIP** -
  Associate Director, Regulatory Affairs
- University of South Florida

Broad Scope

Impact:	Improve management practices, reduce costs and burden.
Generalizability:	Open source tools.
Best practices:	Introduction of smart forms as an example of providing consistency across sites.
SMART IRB?	OneIRB tool set provides work flow enhancements for any single IRB model.

Thank You