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

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In collaboration with
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University of Pennsylvania
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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

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

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?* 

3. Do all study team members have current certification in human subject protections?* 

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

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

6. Number of subjects still actively participating:* 

7. Number of subjects in long term follow-up:* 

8. Number of subjects who have completed all participation:* 

9. Number of screen failures since last IRB review:* 

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.
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

* 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

<table>
<thead>
<tr>
<th><strong>Impact:</strong></th>
<th>Improve management practices, reduce costs and burden.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Generalizability:</strong></td>
<td>Open source tools.</td>
</tr>
<tr>
<td><strong>Best practices:</strong></td>
<td>Introduction of smart forms as an example of providing consistency across sites.</td>
</tr>
<tr>
<td><strong>SMART IRB?</strong></td>
<td>OneIRB tool set provides work flow enhancements for any single IRB model.</td>
</tr>
</tbody>
</table>
Thank You