Your Roadmap to Single IRB Review

Getting Started with SMART IRB & the Online Reliance System

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number 3 UL1 TR002541-01S1
Now that your institution has joined SMART IRB, what’s next?

Start using the Agreement right away for IRB reliance arrangements.

The SMART IRB Agreement is responsive to the NIH Single IRB Policy and proposed revisions to the Common Rule.
Using SMART IRB to streamline IRB review for multi-site research

As an IRB or INSTITUTION
Use the SMART IRB Agreement to facilitate single IRB review

As a PRINCIPAL INVESTIGATOR
Work with your institution’s SMART IRB Points of Contacts (POCs) to determine an appropriate reliance arrangement and discuss your responsibilities related to single IRB review

The Reviewing IRB
takes on all IRB oversight responsibilities

Relying Institutions
provide Reviewing IRB with local context regarding state law, study team member training / qualifications, and any applicable conflicts of interest
Access SMART IRB Resources at smartirb.org

**Expertise and Guidance**
Connect with an ambassador or request a peer consultation

**Support for Single IRB Review**
Access a growing library of FAQs, SOPs, templates, checklists, and guidance

**Online Reliance System**
Request, track, and document reliance arrangements on a study-by-study basis
SMART IRB Online Reliance System

Provides a single point of entry to standardize reliance processes

Serves as communication portal to eliminate tracking requests via email or other methods

Guides investigators and institutions through the workflow, making clear when action is required

The system works for institutions:

1. With and without significant reliance experience
2. Familiar or unfamiliar with one another
3. With limited or substantial infrastructure to support single IRB review

This system allows all SMART IRB Participating Institutions to work together to establish reliance decisions
**Flexibility for Institutions**

1) Customize the displayed contact information for your institution, in case someone needs to reach you about a request.

2) Add a cc email to be included on all system notifications (e.g. an office or group email).

3) Add one or more backups; can perform same actions in the system as the POC, with regard to processing requests.

Various configurations are available to meet your needs – contact help@smartirb.org to learn more.
# Centralized Tracking of Reliance Requests/Arrangements

On-demand reporting for POCs

Filtered listview allows you to see all your requests and easily sort those requiring your action

## Requests for Reliance

<table>
<thead>
<tr>
<th>ID</th>
<th>PI Name</th>
<th>PI Institution</th>
<th>Research Title</th>
<th>Reviewing IRB</th>
<th>Request Status</th>
<th>Latest Amendment Status</th>
<th>Last Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Davis, Betsy</td>
<td>Adams University</td>
<td>Advances in Knee Bracing Technology for Prevention of Knee Injuries</td>
<td>Adams University (Proposed)</td>
<td>Reviewing IRB</td>
<td>Identified</td>
<td>Jan 15, 2018 4:24 PM UTC</td>
</tr>
<tr>
<td>14</td>
<td>Halters, Sarah</td>
<td>Adams University</td>
<td>Effects of co-parenting on neonatal care</td>
<td>Pending</td>
<td>Submitted</td>
<td></td>
<td>Jan 15, 2018 4:19 PM UTC</td>
</tr>
<tr>
<td>13</td>
<td>Halters, Sarah</td>
<td>Adams University</td>
<td>Effects of co-parenting on neonatal care</td>
<td>None</td>
<td>Withdrawn</td>
<td></td>
<td>Jan 15, 2018 4:16 PM UTC</td>
</tr>
<tr>
<td>2</td>
<td>Halters, Sarah</td>
<td>Adams University</td>
<td>The Effects of Group Education on Patients and Their Next of Kin</td>
<td>None</td>
<td>No Reliance</td>
<td></td>
<td>Jan 15, 2018 3:16 PM UTC</td>
</tr>
<tr>
<td>1</td>
<td>Travers, Morgan</td>
<td>Adams University</td>
<td>Primary Prevention of Cardiovascular Disease, with Emphasis on Pharmacological Interventions</td>
<td>Adams University</td>
<td>Reliance Reached</td>
<td>In Progress</td>
<td>Jan 15, 2018 3:16 PM UTC</td>
</tr>
</tbody>
</table>
Central access to arrangement details for each study

Each request “package” provides:

- Overall details of study/arrangement
- Clear picture of request status
- Contact info for key personnel
- Comments from Reviewing IRB
- Request history
Adding a site to a reliance arrangement

This amendment feature is ideal for sites that join a study at a later date, or for those that were not yet ready to rely when the original arrangement was documented.

The process is simple:

1. An investigator or study team member completes and submits a brief site amendment form.

2. The POC at the new site indicates whether they are willing to rely on the Reviewing IRB.

3. The Reviewing IRB POC confirms whether they will review for the new site and issues the determination.

About the amendment process

- Only the submitter of the original request can submit an amendment.
- One site added per amendment; one amendment may be under consideration at a time.
- Requests that are under review cannot be amended until a reliance determination is issued.
### The Reliance System Is...  

| For Investigators  
<table>
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<tr>
<th>(or their designees)</th>
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<tbody>
<tr>
<td>A centralized mechanism to request single IRB review for their studies and track the status of those requests</td>
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<table>
<thead>
<tr>
<th>For Institutions</th>
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<tr>
<td>A platform to review reliance requests and determine and record appropriate reliance arrangements for each study</td>
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### The Reliance System Is NOT...  

<table>
<thead>
<tr>
<th>A mechanism to submit an application for IRB review and approval</th>
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<tr>
<td>A document storage system</td>
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Benefits for INVESTIGATORS

Clarity and Guidance
The system guides you through the request process, collecting the information institutions need to determine an appropriate arrangement for your study.

Automatic Notifications
Email notifications ensure you are informed at key points in the decision-making process.

Reliance Tracking
The system gives you a window into the decision-making process and provides a single place to track reliance arrangements for your studies.
**Benefits for INSTITUTIONS**

<table>
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<tr>
<th>Benefit</th>
<th>Description</th>
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<tr>
<td>Provides a centralized place to record and track reliance arrangements</td>
<td>on a study-by-study basis</td>
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<tr>
<td>Connects you with the appropriate POC for each site, eliminating the</td>
<td>need to track down their information</td>
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<tr>
<td>Guides you through the decision-making process, making clear when your</td>
<td>action is required</td>
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<tr>
<td>Provides a central, transparent platform to communicate local context</td>
<td>issues</td>
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With the short video that follows we highlight key features of the SMART IRB Online Reliance System.