SMART TALK
A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.
What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest
Upcoming sessions

TODAY - Managing Reliance with the SMART IRB Online Reliance System - What’s New & Tips from the Experts

January: A Follow-Up Conversation: Getting Ready for the 2020 Single IRB Requirements

February: Review of Personnel Changes: Recommendations from the SMART IRB Harmonization Steering Committee

Single IRB Resources for Researchers
Key SMART IRB Resources at SMARTIRB.ORG

• Master Reliance Agreement
• Implementation Checklist for use of the SMART IRB Agreement
• Online Reliance System (Helps investigators and institutions request, track, and document reliance arrangements for each study)
• SMART IRB SOP Manual
• Communication Plan for Single IRB Review
• Reviewing IRB Instructions for Relying Institution Point(s) of Contact
• Reviewing IRB Instructions for Relying Site Study Teams
• FAQs for Research Teams - Relying on an External IRB
• Overall PI (and Lead Study Team) Checklist
• Relying Site Investigator Checklist
• Grant Applications: Template Description of SMART IRB
• Local Considerations: Institutional Profile
• Local Considerations: Protocol-specific Document
Managing Reliance with the Online Reliance System

Doug MacFadden, Chief Informatics Officer, Harvard Catalyst
Kelley O'Donoghue, MPH CIP, Associate Vice President of Human Subject Protection, University of Rochester
Paul Fricker, Project/Content Support Coordinator, Harvard Catalyst
Katherine Sao, Senior Business Analyst, Harvard Catalyst
Informatics systems supporting reliance has a long history.

Various regional systems have been developed and used, including: New England Cede Review, UC Braid, IRBchoice, Wisconsin-Madison, Ohio Collaborative, Texas IRB Consortium and U New Mexico.

IRB Rely (2014 - 2016) - Step 1 to a national solution.

SMART IRB (2016 - ) - Implementation of a comprehensive suite of tools (information, joining and workflow) and training for the national solution.
A wide variety of systems for IRB review used at institutional IRBs (commercial and home grown)

Achieving reliance needs to work with all of them

SMART IRB uses a common agreement (*Master Reliance Agreement*) and provides a standard reliance Determination Letter to enter into the IRB review systems of all sites involved

Provide workflow support in order to speed achievement of reliance
Informatics Components

Joinder - allows an institution to sign-on to the SMART IRB Master Reliance Agreement

- Will be the central place for profile info about each institution
- Provides API & human readable list of all participating institutions

Online Reliance System - PI initiated process to identify all sites involved in a study, invite necessary participants, manage workflow and document the results of the process (Determination Letter)

- Uses dashboards, email reminders, “Action Required” prompting within the app and POC monitoring of all requests from their site
Metrics

Original release date: May 2017

Requests since then: 2600+

Users: 3500+

Over 50% of requests reach reliance in 3 weeks or less

The systematic workflow of the ORS captures a variety of metrics that can lead to improve the process, e.g.:

• identify steps that may be confusing or simply take longer than expected,
• how often users take advantage of certain features
• where users seem to be making work-arounds
Getting Started with the Online Reliance System
Roles in the Online Reliance System

**Investigator**
- Any user who will be submitting requests for reliance
- Generally the PI or their designee, such as a study coordinator

**Point of Contact (POC)**
- Any user who will be making reliance decisions for their institution
- Cannot submit reliance requests
- Generally a member of an institution’s IRB office
Getting Access

reliance.smartirb.org

Log in

Email
Password

Forgot your password?
Resend unlock instructions

Create an account for SMART IRB Reliance
Investigators: Request access
Institution Point of Contact: Request access

Need help? Contact us

Request Investigator Access

Access to SMART IRB Reliance allows research investigators or their designees to submit requests for IRB reliance. Use this form to request access as an investigator. If you need access as an institution point of contact, contact us. The information below will be shared with the SMART IRB Point of Contact for your Home Institution, who can grant you access.

Required Field

First Name*
Middle Name
Last Name*
Phone

Your phone will be displayed in the contact list for your requests.

Email*

Your email address will be your User ID. We highly recommend that you use your institution’s official email address.

Home Institution*

If your institution is not listed, contact us at Help@smartirb.org.

Submit
Reliance System Home Page

- View all of your requests at a glance
- Create a new reliance request

### 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>Amend(s)</th>
<th>Last Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Fry, Philip J</td>
<td>Adams University</td>
<td>Example Research Study</td>
<td>Pending</td>
<td>In Progress</td>
<td></td>
<td>Dec 17, 2019 5:00 PM UTC</td>
</tr>
</tbody>
</table>

Showing 1 - 1 of 1 requests  Page 1 of 1

New Request
An Overview of Online Reliance System Workflow
1. Create a reliance request
2. POC Completes Pre-Check and Reviewing IRB is Identified
3. POCs at the involved sites indicate willingness to rely

<table>
<thead>
<tr>
<th>Principal Investigator (PI)</th>
<th>Ashok Gopinatha</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT Number</td>
<td>Add NCT Number</td>
</tr>
<tr>
<td>Protocol Number(s)</td>
<td></td>
</tr>
<tr>
<td>Withdraw Request</td>
<td></td>
</tr>
<tr>
<td>Remove Site Involved</td>
<td></td>
</tr>
<tr>
<td>Authorize Revisions</td>
<td></td>
</tr>
<tr>
<td>Summary</td>
<td></td>
</tr>
<tr>
<td>Reliance Request</td>
<td></td>
</tr>
<tr>
<td>Reliance Pre-Check</td>
<td></td>
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<tr>
<td>Reviewing IRB</td>
<td></td>
</tr>
<tr>
<td>Ridgeview Research Facility</td>
<td></td>
</tr>
<tr>
<td>Involved Institutions</td>
<td></td>
</tr>
<tr>
<td>Anderson-McCoy University</td>
<td></td>
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<tr>
<td>Benjamin Franklin College</td>
<td></td>
</tr>
<tr>
<td>Ridgeview Research Facility</td>
<td></td>
</tr>
<tr>
<td>Determination</td>
<td></td>
</tr>
<tr>
<td>Contact Information</td>
<td></td>
</tr>
<tr>
<td>Contact List for this Request</td>
<td></td>
</tr>
<tr>
<td>Need Help?</td>
<td></td>
</tr>
<tr>
<td>Contact us</td>
<td></td>
</tr>
<tr>
<td>Suggest an improvement</td>
<td></td>
</tr>
<tr>
<td>Downloads</td>
<td>Request (ZIP)</td>
</tr>
</tbody>
</table>

**Institution Reliance Form**

- Required Field
  - View Reliance Request Form

You have the option to rely on Ridgeview Research Facility’s review and oversight of the research according to the Reliance Agreement and SOPs.

**Proposed Reviewing IRB:** Ridgeview Research Facility

**Contact:**
IRB Office, 555-555-5555, irb_office@ridgeview.org

If you have any outstanding concerns, please discuss them with the Proposed Reviewing IRB prior to completing this form.

**Does Anderson-McCoy University agree to rely on Ridgeview Research Facility?**
- Yes
- No

**Institutional requirements and local context concerns**

These comments will be visible to anyone who can view the request.

**Supporting Documentation**

Documents containing protected health information (PHI) as defined by HIPAA should not be uploaded to Reliance.

All documents must be PDFs, smaller than 10Mb, and have a unique file name.

**Supporting Document(s)**

For example, an internal reliability checklist or determination document

[Select File]

- Protocol Specific (Local Context) Document
- Institutional Profile
- Other Resources

**Suggested Templates**

It is recommended that Relaying Sites complete site-specific information local context for the Reviewing IRB. Contact the Reviewing IRB for more information. The templates below are available for use:
4. The Reviewing IRB Issues the determination letter

**ID: 7 - Donor Repository for Patients with Rare Diseases (DRPRD)**

**Principal Investigator (PI):** Ashok Goel

**NCT Number:** Add NCT Number

**Protocol Number(s):**

Withdraw Request
Remove Site Involved

**Summary:**
- Reliance Request
- Reliance Pre-Check
- Reviewing IRB
- Involved Institutions
- Anderson-McCoy University
- Benjamin Franklin College
- Ridgview Research Facility

**Determination**

* = Required Field

**Proposed Reviewing IRB:** Ridgview Research Facility

**2 Sites agree to rely**
Select the institutions for which Ridgview Research Facility agrees to serve as Reviewing IRB for this study.

- Anderson-McCoy University
- Benjamin Franklin College

**0 Sites DO NOT agree to rely**

**Contact Information**
- Contact List for this Request

**Determination Letter Email Text**

A determination has been made regarding your request. Application ID: Donor Repository for Patients with Rare Diseases (DRPRD). This decision applies only to the determination of IRB reliance, and does not reflect IRB approval of the research project itself. Approach each relying site must be obtained from the Reviewing IRB (the IRB accepting the reliance of others) prior to initiating study activity at each site.

**Reliance Determination:**
- Overall Principal Investigator: Ashok Goel
- The Reviewing IRB is Ridgview Research Facility
- Federal Wide Assurance (FWA): 1106056101
- Point of Contact: IRB Office, irb@ridgview.org
- Site Investigator: Ashok Goel

**Reviewing IRB accepts review for:**
- Anderson-McCoy University
- Benjamin Franklin College

**Download**
- Request (ZIR)
Online Reliance System
Roles

- **Lead PI/Research Team**
  - Initiate ORS Process
  - Create Reliance Request
  - Can submit amendments

- **Lead PI’s IRB/POC**
  - Reliance Pre-Check
  - Determines eligibility for Reliance

- **Reviewing IRB/POC**
  - Confirms their agreement to be the Reviewing IRB

- **Relying Site’s IRB/POC**
  - Determines if site will rely on Reviewing IRB

- **Site PI**
  - Nothing
Getting Help and Additional Resources
Since launching the Online Reliance System in May of 2017 we have received over 3500 help requests from users.

In addition to providing a means of directly supporting our users, the help desk provides us with essential feedback about the Online Reliance System.

We retain the complete details of every ticket we receive enabling us to go back and review and analyze what is working or not working well for our users.

This feedback from our users has directly led to the development of several key system features.
Common Help Desk Questions and Solutions

• Error Correction, Remove a Site Involved, and Multiple Amendments create a number of ways to deal with issues during the reliance process
  – Error Correction (i.e. reopening a request) for when there is a critical change that needs to be made to request that is in progress.
  – Remove a Site Involved when an institution is no longer participating or is holding up the determination for other site (also addressed through Site Specific Determination Letter)
  – Multiple Amendments for adding sites after the initial reliance agreement is reached
Common Help Desk Questions and Solutions

• Can’t find an institution in the system
  – They either haven’t joined SMART IRB or have chosen not to use the ORS
  – You can pursue a reliance with the institutions that are in the system, while making an additional agreement with the missing institution outside of the system
Common Help Desk Questions and Solutions

• Need access as a “POC”
  – If you need to be able to submit a reliance request, then you should have “investigator” access even if you are not the Principal Investigator.
  – POC access is generally only needed for members of an institution’s IRB office
Additional Resources

Resources Page
smartirb.org/resources

Support Center
support.smartirb.org

Resources

Joining SMART IRB
- Setting up Reliance
- Implementing the Agreement
- For Funding Applications
- About Single IRB Review

Joining SMART IRB
Agreement, The SMART IRB

Ambassadors, SMART IRB Regional
Need help joining and implementing the SMART IRB Agreement? Ask your ambassador.

Consultations: Expert Advice and Guidance
Prepare to serve as a Reviewing IRB or Relying Institution by consulting with an IRB experienced in the conduct, review, and oversight of multisite research.

FAQs
Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.

Joiner Checklist
SMART IRB

SMART IRB Support Center

Search

The SMART IRB Agreement
About SMART IRB
Joining SMART IRB
Online Reliance System

Help is always available at help@smartirb.org
The Development Process
Helpdesk requests
ORS Working Group
Prioritize list

ORS Working Group
Regulatory Consultations with Kelley

Development Team
Technical Review
Refine requirements

Build & QA Communication plan
Support Center
Main Features Released in 2019

January 24, 2019
Multiple Amendments
Add/edit multiple sites simultaneously after reliance has reached.

May 2, 2019
Site Specific Determination letter
Expedites the reliance process. Issue a site specific determination before all Institutions have submitted their Reliance decisions.

July 25, 2019
Principal & Site Investigators have access to requests they are involved in
Investigators are able to create an account and also see all the requests they are involved in.

August 22, 2019
Seamless POC registration
A member of an institution can register an ORS account without any interruptions.

September 19, 2019
Social Behavior Research details for a site
Additional site details for social behavior studies.
Site Specific Determination Letter

• Before all other institutions submit their reliance decisions
• After expressing willingness to rely, Institution POCs can request a site specific determination letter to be issued by the Reviewing IRB
• This is only a site-specific determination letter, a final determination letter for the overall request will be issued once all sites have submitted their reliance form
What is on the roadmap?
Always improving...

- Ability for POCs to withdraw requests
- Improvements to performance to the Homepage list of requests
  - <1 sec to load page
- Electronic version of the Institution Profile in Joinder
- And more...
User Account + Redesign of Password Reset

My Account

First Name*  Anupama
Middle Name
Last Name*  Maram
Phone

☑ Change password

You will be logged out after changing your password.

Current Password*

New Password*

Re-type Password*
## Adding a preview for requests on homepage

<table>
<thead>
<tr>
<th>Request ID</th>
<th>Institution</th>
<th>Title</th>
<th>Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>287</td>
<td>Belledale Institute</td>
<td>In-depth look at Pediatric Metrics</td>
<td>Pending</td>
<td>Precheck</td>
</tr>
</tbody>
</table>

**Overall Status:** Pre-check Completed  
You have been named on this request with *read only access.*

**No Action Required**

<table>
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<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>335</td>
<td>Belledale Institute</td>
<td>Advances in Knee Bracing Technology for Prevention of Knee Injuries</td>
<td>Pending</td>
<td>Reliance Reached</td>
</tr>
</tbody>
</table>

**Overall Status:** Reliance Reached  
You are the submitter of this request.

**Finalized Request & Amendment Determinations**  
Determinations have been issued for the following institutions: Anderson McCoy University, Belledale Institute |

- View the Determination Letter for more information.  
- If you need to add a site, fill out the Site Amendment form  
- Find Amendment Determinations in the Amendments.  
- If you have any questions, contact IRB Office irb_office@Anderson.org.

<table>
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<th>Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>222</td>
<td>Golden Gate Research Institute</td>
<td>Solving Pain in Rheumatoid Arthritis</td>
<td>Pending</td>
<td>Submitted</td>
</tr>
</tbody>
</table>

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<tbody>
<tr>
<td>287</td>
<td>Ridgeview Research Facility</td>
<td>In-depth look at Pediatric Metrics</td>
<td>Ridgeview Research Facility(Proposed)</td>
<td>Reviewing IRB Identified</td>
</tr>
</tbody>
</table>

**Overall Status:**  
Sites Involved:  
1 Willing to Rely  
1 Awaiting Response  
You are the submitter of this request.

**No Action Required**

**Details**

- This request will move to the next step after all Sites Involved have indicated their decision to rely / not rely.  
- Contact the POC of a specific Site with any questions or concerns.  
- To revise this request: email Help@smartirb.org and include the reason(s) for revision. If you would like to revise your reliance decision, select your institution name from the left navigation menu and...
Redesigning the Request Summary page
Working with the ORS:
One Institution’s Experience
University of Rochester
History w/ SMART

• University of Rochester signed on to the SMART Agreement in October 2016

• Joined the SMART IRB Reliance System Working Group in November 2017
  – Impressed with collaborative environment
  – Evolving with the changing needs of the industry
University of Rochester
Single IRB Research Start Up Process

ORS/SMART

Reviewing IRB Review Process

- Reliance
  - SMART IRB Agreement with ORS System
  - Reliance Agreement

- Reviewing IRB Approval for Lead PI
  - Protocol and MODEL consent documents

- Relying Site Institutional Review
  - Ancillary Committee(s) Approval
    - Institutional Review Memo
    - Local Context
    - Site-Specific Consent Forms

- Reviewing IRB Approval of Site

- Study Conduct
  - Consenting/Enrolling Subjects
UR Agrees to be the Reviewing IRB
• UR PI must submit a request to the Reliance Coordinator

Reliance Relationship
• Push to Use the SMART Agreement and Online Review System OR
• Negotiate Reliance Agreement

Reliance Determination
• ORS Determination letter (site-specific)
University of Rochester
IRB Approval Process/Click IRB Review System

UR PI submits study to UR IRB in Click IRB
- UR IRB reviews protocol documents, MODEL consent, and DRAFT local context survey

Study approved by UR IRB
- Reliance Coordinator or UR PI send approved materials to sites

Relying Sites - Institutional Review
- Ancillary Review Committee Approvals
- Institutional review memo
- Local context survey
- Create site-specific consent forms based on approved MODEL

Site materials submitted and then approved by UR IRB
ORS Benefits

• Consistency - same term agreements

• Transparency - all parties see the determinations at all times (Reviewing IRB, Lead PI, Relying IRB)
  – Internal tracking mechanisms, very little visibility
What the Online Reliance System IS NOT???

• Not an IRB Review System
  – Once Reliance is determined/confirmed, all other transactions happen within the Reviewing IRB and Relying IRB

• Not for Document Management/Distribution
University of Rochester
Single IRB Research Start Up Process

ORS/SMART

Reliance
- SMART IRB Agreement with ORS System
- Reliance Agreement

Reviewing IRB Review Process

Reviewing IRB Approval for Lead PI
- Protocol and MODEL consent documents

Relying Site Institutional Review
- Ancillary Committee(s) Approval
- Institutional Review Memo
- Local Context
- Site-Specific Consent Forms

Reviewing IRB Approval of Site

Study Conduct
- Consenting/Enrolling Subjects
Things to think about…

- Reliance determined one year ago. Four sites (including the lead PI). Consenting and enrolling subjects.
  - Site Investigator at Site #2 retires, he is being replaced with a new Site PI.
  - What do I need to do?
Things to think about...

- Reliance determined one year ago. Four sites (including the lead PI). Consenting and enrolling subjects.
  - Site Investigator at Site #2 retires, he is being replaced with a new Site PI.
  - What do I need to do?

1) Submit a modification to the Reviewing IRB
2) Notify Relying IRB

No need to do anything with SMART ORS, reliance previously determined, documentation will support the change in Site PI
Things to think about...

- Reliance determined one year ago. Four sites (including the lead PI). Consenting and enrolling subjects.
  - Enrollment is going slow, need to add another site
  - What do I need to do?
Things to think about…

• Reliance determined one year ago. Four sites (including the lead PI). Consenting and enrolling subjects.
  – Enrollment is going slow, need to add a fifth site
  – What do I need to do?

1) Determine if 5\textsuperscript{th} site is participating Institution in the SMART Reliance Agreement.  \textit{Good they are!!!}

2) Submit an amendment in SMART ORS to add this new site to your already confirmed determination

3) Submit a modification to the Reviewing IRB
University of Rochester
Single IRB - Adding a site in the middle

ORS/SMART

Reliance - Amendment to add site in ORS

Relying Site Institutional Review

Reviewing IRB Approval of Site

Study Conduct

• Ancillary Committee(s) Approval
• Institutional Review Memo
• Local Context
• Site-Specific Consent Forms

• Consent/Enrolling Subjects
Join us for the next SMART Talk
January 15, 2020
2:00-3:30 pm EST

A Follow-Up Conversation: Getting Ready for the 2020 Single IRB requirements

Register at smartirb.org
Sign up for our mailing list to be notified of future offerings

Questions?
Contact help@smartirb.org