



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

Scope of SMART IRB

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 institutions IRB office

Getting Access

reliance.smartirb.org

SMART IRB Reliance Home

Log in

Email

Password

Log in

[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.*

Please indicate the institution or school that employs you. If you have appointments from multiple institutions, please select the institution from which you receive your paycheck.

Home Institution*

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

Cancel

Submit

Reliance System Home Page

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

Requests for Reliance

Filter by

Action Required Under Review Reliance Reached **All Requests** [?] Showing 1 - 1 of 1 requests Page 1 of 1

ID	PI Name	PI Institution	Research Title	Reviewing IRB	Request Status	Amend(s)	Last Updated
12	Fry, Philip J	Adams University	Example Research Study	Pending	In Progress		Dec 17, 2019 5:00 PM UTC

Showing 1 - 1 of 1 requests Page 1 of 1

An Overview of Online Reliance System Workflow



1. Create a reliance request

ID: 12 - Example Research Study

Principal Investigator (PI)
Philip J Fry
Adams University

NCT Number
Add NCT Number

Protocol Number(s)

Withdraw Request

Summary

► Reliance Request

Need Help?
Contact us
Suggest an improvement

Reliance Request Form

Last Updated Philip J Fry, Dec 17, 2019 5:00 PM UTC

PI / Study Sites Involved Sites Details Supporting Documents Summary

* = Required Field

Request Point Of Contact: Philip Fry, fry@planetexpress.com

Title of Research Study: Example Research Study

Overall Principal Investigator (PI) Information

The Overall PI is the principal investigator who initiates and assumes leadership and has ultimate responsibility for the conduct of, and to ensure the safety and data integrity for, this Research Study.

PI's Home Institution: Adams University

Please indicate the institution or School that employs you. If you have appointments from multiple institutions, please select the institution from which you receive your paycheck.

Existing ORS Account: fry@planetexpress.com - Philip J Fry

Select an existing Online Reliance System account or enter PI information below

PI's Email: fry@planetexpress.com

PI's First Name: Philip

PI's Middle Name: J

PI's Last Name: Fry

PI's Phone: 555-555-5555

Save Items in shaded area with an * are required to save the form.

2. POC Completes Pre-Check and Reviewing IRB is Identified

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

Principal Investigator (PI)
Ashok Gopinatha
Ridgeview Research Facility

NCT Number
Add NCT Number
Protocol Number(s)

Withdraw Request

Summary

- Reliance Request
- Reliance Pre-Check
- Reviewing IRB
- Involved Institutions
 - Anderson-McCoy University
 - Benjamin Franklin College
 - Ridgeview Research Facility
 - Determination

Contact Information
Contact List for this Request

Summary

Overall Status: Request submitted ?

Action Required

Role: Overall PI's Home Institution

- The Overall PI's home institution will determine if the research is eligible for reliance. If not, the PI must request a refusal to be the Proposed Reviewing IRB.
- Review the request
- Indicate if this research is eligible for reliance.

Enter Decision

Amendments | Comments from Reviewing IRB | Request History

A reliance has not been reached on the original request. Requests can be amended with additional institutions. A reliance has not been reached on the original request. Requests can be amended with additional institutions.



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

Principal Investigator (PI)
Ashok Gopinatha
Ridgeview Research Facility

NCT Number
Add NCT Number
Protocol Number(s)

Withdraw Request
Remove Site Involved
Authorize Revisions

Summary

- Reliance Request
- Reliance Pre-Check
- Reviewing IRB
- Involved Institutions
 - Anderson-McCoy University
 - Benjamin Franklin College
 - Ridgeview Research Facility
 - Determination

Contact Information
Contact List for this Request

Reviewing IRB Form

* = Required

[View Reliance Request Form](#)

Your institution has been proposed to serve as the Reviewing IRB for this request.

As the Reviewing IRB, you will provide IRB oversight of the research according to your own policies and procedures and in conformance with the [Reliance Agreement](#) and [SOPs](#). Use of the SMART IRB SOPs is strongly encouraged, but not required. Participating Institutions involved in research under the Agreement must communicate which policies and procedures will apply.

Is Ridgeview Research Facility willing to serve as the Reviewing IRB for this research project, pending reliance decisions by the other sites involved?* Yes No

You will have the opportunity to review the decisions of the other sites involved before issuing a final determination.

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

Cancel

3. POCs at the involved sites indicate willingness to rely

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

Principal Investigator (PI)
Ashok Gopinatha
Ridgeview Research Facility

NCT Number
Add NCT Number
Protocol Number(s)

Withdraw Request
Remove Site Involved
Authorize Revisions

Summary
Reliance Request
Reliance Pre-Check
Reviewing IRB
Ridgeview Research Facility
Involved Institutions
Anderson-McCoy University
Benjamin Franklin College
Ridgeview Research Facility
Determination

Contact Information
Contact List for this Request

Need Help?
Contact us
Suggest an improvement

Downloads
Request (ZIP)

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 reliance checklist or determination document

[Select File](#)

[Cancel](#) [Save](#) [Submit](#)

Suggested Templates

It is recommended that Relying 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:

[Protocol Specific \(Local Context\) Document ?](#)
[Institutional Profile ?](#)
[Other Resources](#)

4. The Reviewing IRB Issues the determination letter

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

Principal Investigator (PI)
Ashok Gopinatha
Ridgeview Research Facility

NCT Number
Add NCT Number
Protocol Number(s)

Withdraw Request
Remove Site Involved

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

Determination

Enter Determination Review Determination Preview Letter

* = Required Field

Proposed Reviewing IRB: Ridgeview Research Facility

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

0 Sites do NOT agree to rely

Accept All Accept None

Anderson-McCoy University
Ridgeview Research Facility Will Review Will Not Review
Comment

Benjamin Franklin College
Ridgeview Research Facility Will Review Will Not Review
Comment

Cancel Save Next

Contact Information
Contact List for this Request

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

Principal Investigator (PI)
Ashok Gopinatha
Ridgeview Research Facility

NCT Number
Add NCT Number
Protocol Number(s)

Withdraw Request
Remove Site Involved

Summary
Reliance Request
Reliance Pre-Check
Reviewing IRB
Ridgeview Research Facility
Involved Institutions
Anderson-McCoy University
Benjamin Franklin College
Ridgeview Research Facility
Determination

Contact Information
Contact List for this Request

Need Help?
Contact us
Suggest an Improvement

Downloads
Request (ZIP)

Determination Last Updated Samantha Doe, Dec 17, 2019 6:20 PM UTC

Enter Determination Review Determination Preview Letter

From: DoNotReply@smartirb.org
To: overall_pi@ridgeview.net
CC: applicant@ridgeview.net, reliance_poc@ridgeview.net, reliance_poc_backup@ridgeview.net, group@ridgeview.org, mfoy@mc coy.edu, g_peack@franklin.net, reliance_poc@anderson.edu, reliance_poc_backup@anderson.edu, group@anderson.org, reliance_poc@franklin.net, reliance_poc_backup@franklin.net, group@franklin.org

Additional CC's

Separate each email with a comma.

Subject: Determination - 7_Gopinatha: Donor Repository for Patients with Rare Diseases (DRPRD)

Determination Letter Email Text

A determination has been made regarding your request, **Application ID: 7 - 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. Approval for 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.

If you have questions, contact the Reviewing IRB to determine further required action.

Reliance Determination:
Overall Principal Investigator: Ashok Gopinatha
The Reviewing IRB is: Ridgeview Research Facility
Federal Wide Assurance (FWA): FWA0000005
Point of Contact: IRB Office, irb_office@ridgeview.org
Site Investigator: Ashok Gopinatha

Reviewing IRB accepts review for:
Anderson-McCoy University
Federal Wide Assurance (FWA): FWA0000018
Site Investigator: Marc Foy, mfoy@mc coy.edu
Benjamin Franklin College
Federal Wide Assurance (FWA): FWA0000020
Site Investigator: Greg Peck, g_peack@franklin.net

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



SMART IRB Help Desk

- 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

Joining SMART IRB	Source
Agreement, The SMART IRB Review the Master Common Reciprocal Institutional Review Board Authorization Agreement. To learn more about differences across versions of the SMART IRB Agreement read the Agreement Version Guide .	SMART IRB
Ambassadors, SMART IRB Regional Need help joining and implementing the SMART IRB Agreement? Ask your ambassador.	SMART IRB
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.	SMART IRB
FAQs Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.	SMART IRB
Joinder Checklist	SMART IRB

Support Center

support.smartirb.org

SMART IRB Support Center

Search

The SMART IRB Agreement

About SMART IRB

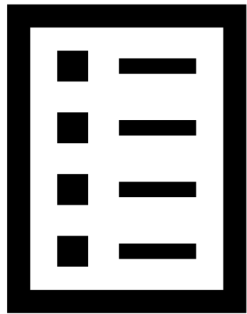
Joining SMART IRB

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
Consultations with Polly

Development Team
Technical Review
Develop scalable solution
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* 

Middle Name

Last Name*

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

^	287	Bellevue Institute	In-depth look at Pediatric Metrics	Pending	Precheck	Oct 3 2017
<p>Overall Status: Pre-check Completed No Action Required</p> <p>You have been named on this request with <i>read only access</i>.</p>						
^	335	Bellevue Institute	Advances in Knee Bracing Technology for Prevention of Knee Injuries	Pending	Reliance Reached	Nov 01 2017
<p>Overall Status: Reliance Reached Finalized Request & Amendment Determinations</p> <p>You are the submitter of this request.</p> <p>Determinations have been issued for the following institutions: Anderson McCoy University, Bellevue Institute</p> <ul style="list-style-type: none"> - 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. 						
∨	222	Golden Gate Research Institute	Solving Pain in Rheumatoid Arthritis	Pending	Submitted	Oct 3 2017
^	287	Ridgeview Research Facility	In-depth look at Pediatric Metrics	Ridgeview Research Facility(Proposed)	Reviewing IRB Identified	Oct 3 2017
<p>Overall Status: Reviewing IRB Identified No Action Required</p> <p>Sites Involved: 1 Willing to Rely 1 Awaiting Response</p> <p>You are the submitter of this request.</p> <p>Details ^</p> <ul style="list-style-type: none"> • 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


title>

Request Activity Contact List ...

Overall Status [details](#)


Reviewing IRB Identified

Proposed Reviewing IRB



Adams University

Sites Involved



- Willing to Rely
- Not Relying
- Awaiting Response
- Sites Removed

Jordan University **Awaiting Response**

[Enter Decision](#)

Anderson-McCoy University **Willing to Rely**

[Reliance Form](#) [Site-Specific Determination](#)

Comments from Reviewing IRB

Funding for phase 2 of this study was This study is on hold. Kate Harris Feb 06 2017

Belledale institute is no longer able to Kate Harris Feb 03 2017

Request History Show all status changes

Working with the
ORS:
One Institution's
Experience



University of Rochester

History w/ SMART

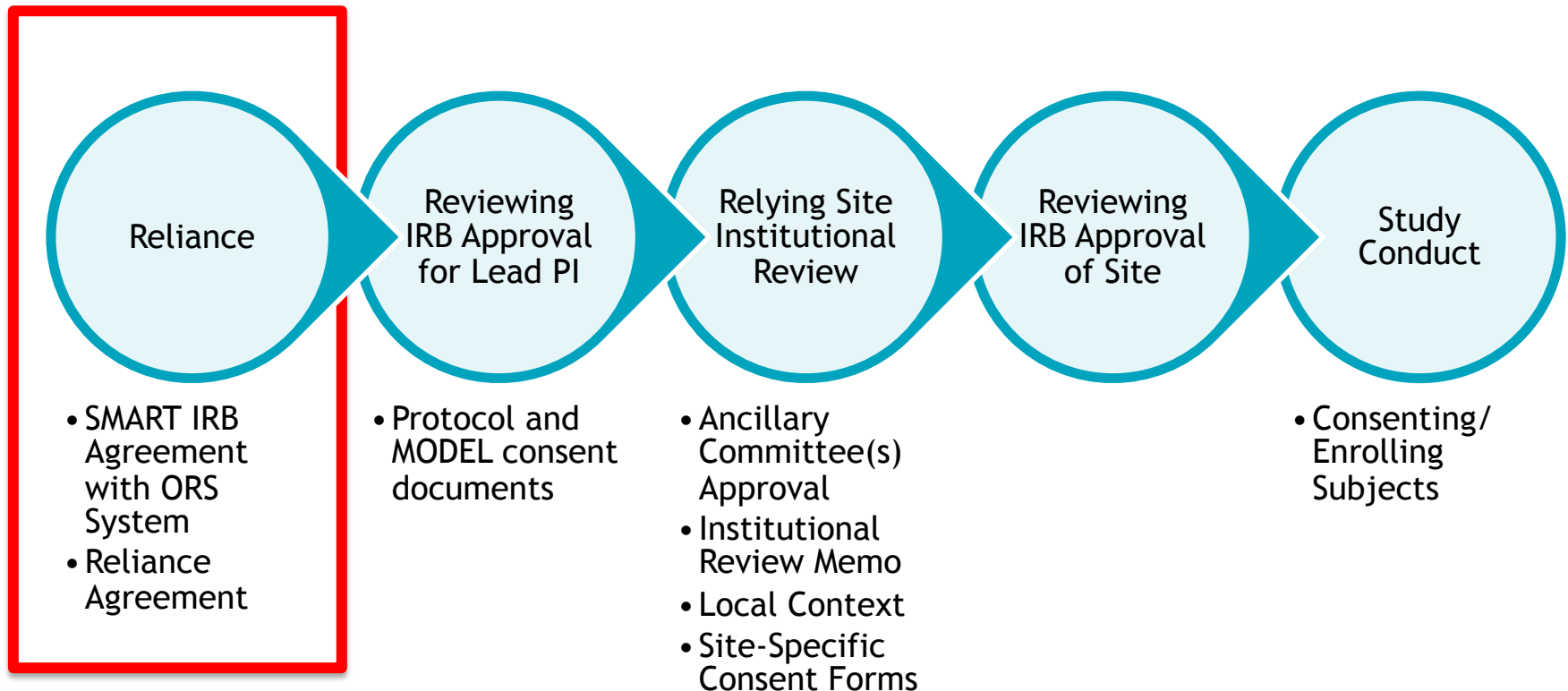
- University of Rochester signed on to the SMART Agreement in October 2016
- Joined the SMART IRB Reliance System Working Group in November 2017
 - Impressed with collaborative environment
 - Evolving with the changing needs of the industry

University of Rochester

Single IRB Research Start Up Process

ORS/SMART

Reviewing IRB Review Process



University of Rochester

Reliance Process/ORS System

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???

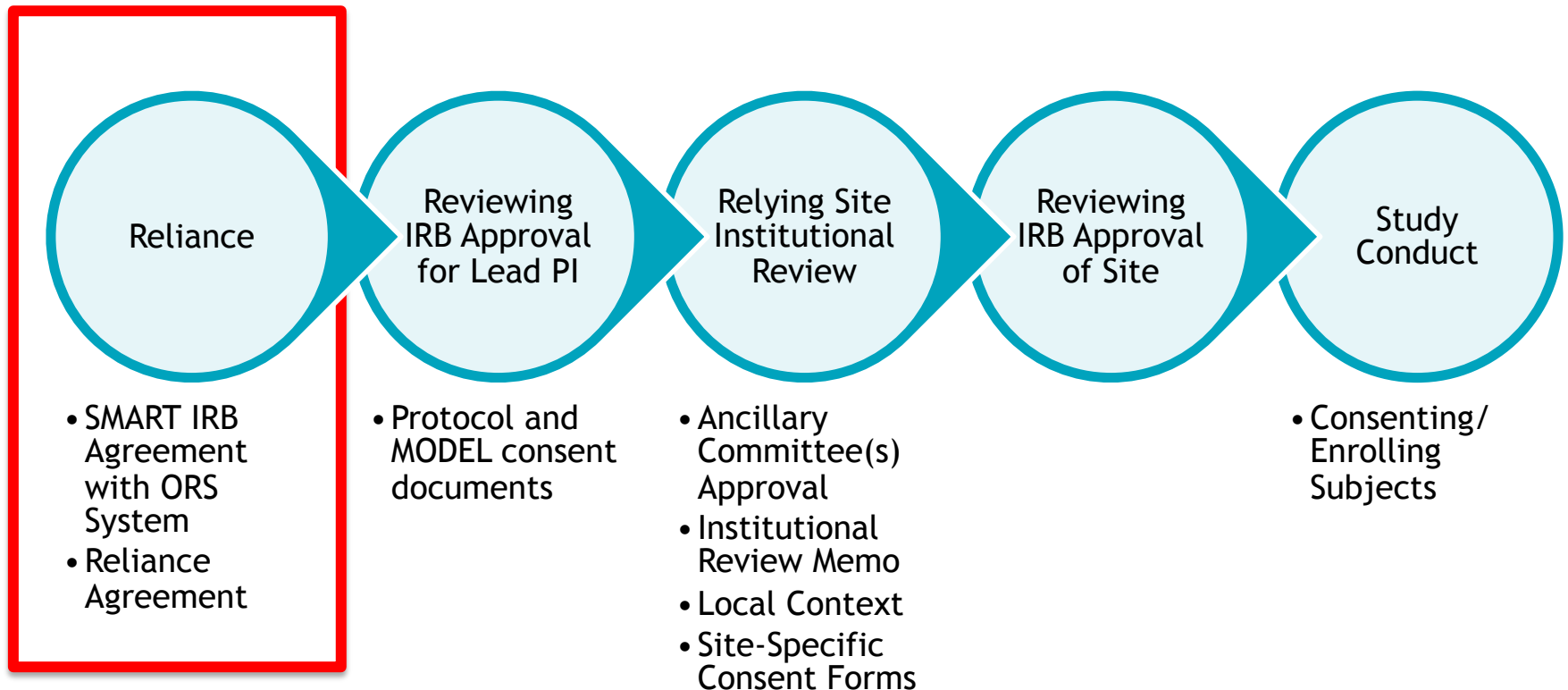
- Not an IRB Review System
 - Once Reliance is determined/confirmed, all other transactions happen within the Reviewing IRB and Relying IRB
- Not for Document Management/
Distribution

University of Rochester

Single IRB Research Start Up Process

ORS/SMART

Reviewing IRB Review Process



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...

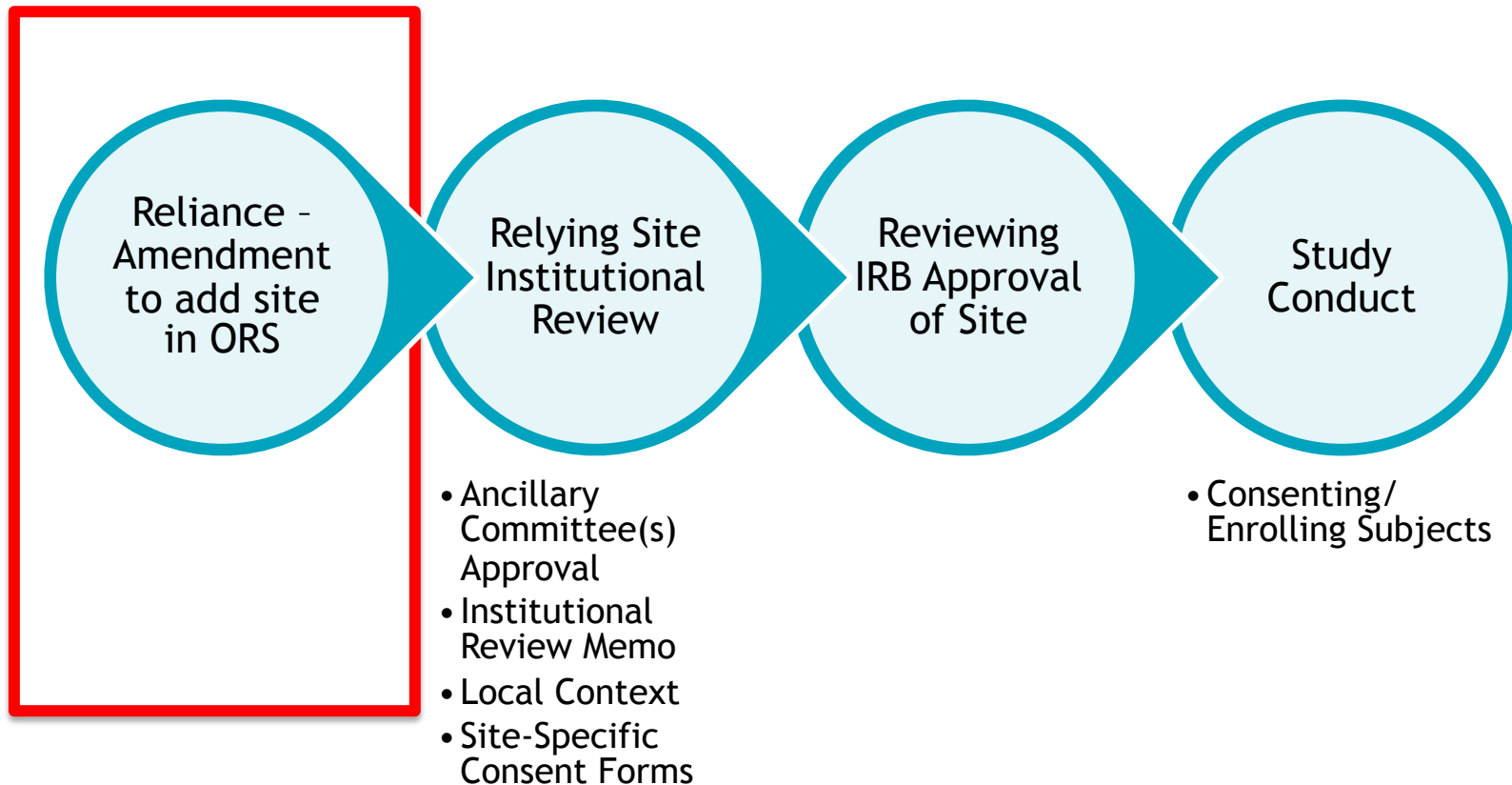
- Reliance determined one year ago. Four sites (including the lead PI). Consenting and enrolling subjects.
 - Enrollment is going slow, need to add a fifth site
 - What do I need to do?
- 1) Determine if 5th site is participating Institution in the SMART Reliance Agreement. *Good they are!!!*
- 2) Submit 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

Reviewing IRB Review



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*

Questions?
Contact help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be
notified of future offerings

Questions and Discussion