FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

FDP / SMART IRB Reliance Agreement Taskforce

Speakers: Barbara E. Bierer, M.D., Harvard Medical School
Megan Kasimatis Singleton, Johns Hopkins University
Martha Jones, Washington University
Marti Dunne, New York University

Moderators: Lynette Arias, University of Washington
Alex Albinak, Johns Hopkins University

FDP Meeting – Jan 2018

Agenda

Agenda Section	Lead	Time
Panel Introductions	Lynette/Alex	10
Session Goals		
Taskforce members & purpose		
SMART IRB Background / Overview / Update	Barbara	20
University Implementation Examples	Martha/Marti/Megan	10
Taskforce areas of Discussion & Top 3 key areas	Alex	
• FWA Requirement	Martha/Barbara	5
• Quality Assessment	Megan/Barbara	5
• Minimal Risk Studies	Marti/Barbara	5
Planned next steps	Barbara/Lynette	5
Open discussion	All	15

Session Goals

1) Share information about collaboration that has been formed between FDP and SMART IRB
2) Provide brief orientation & update on SMART IRB
3) Share details about key areas Task Force has been discussing – challenges & opportunities
4) Provide enough background and education on Agreement content and implications to support group discussion
5) Allow attendees to share feedback:
   - Experiences implementing & using SMART IRB Agreement
   - If not using, share information about why not

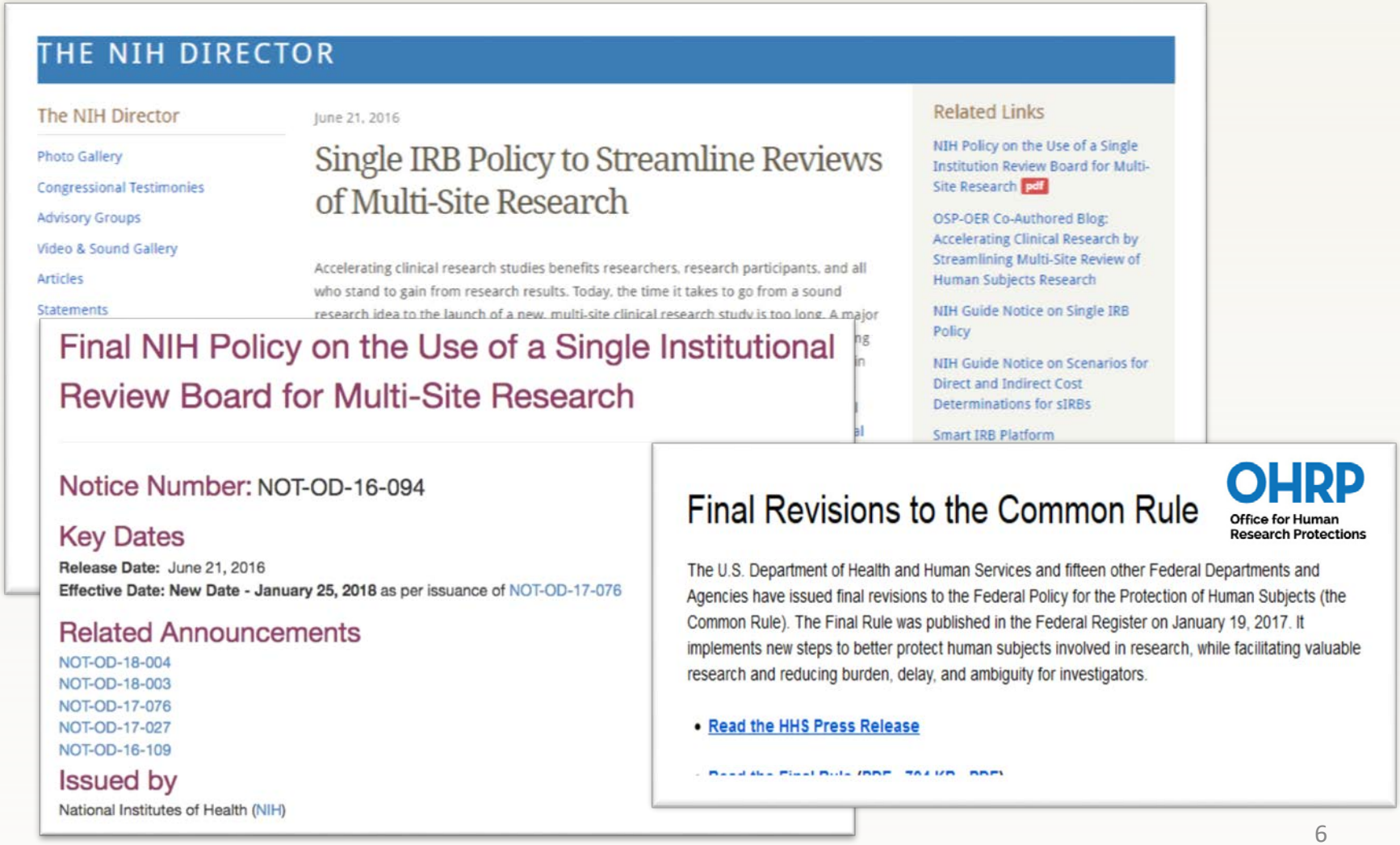
Taskforce Members

Member	Organization	Contact email
Lynette Arias (co-facilitator)	University of Washington	ariasl@uw.edu
Alex Albinak (co-facilitator)	Johns Hopkins University	amckeow1@jhu.edu
Barbara Bierer	Harvard University	bbierer@bwh.harvard.edu
Nichelle Cobb	University of Wisconsin	nlc@medicine.wisc.edu
Marti Dunne	New York University	marti.dunne@nyu.edu
Martha Jones	Washington University	jonesma@wustl.edu
Megan Singleton	Johns Hopkins University	msingl16@jhmi.edu
Cheryl Kitt	NIH	kittc@od.nih.gov
Patrice Brown-Longenecker	NIH/OD	petrice.brown@nih.gov
Jane McCutcheon	New York University	jam2@nyu.edu
Debra Murphy	Arizona State University	debra.murphy@asu.edu
Kerry Peluso	Florida State University	kpeluso@fsu.edu
Lisa Nichols	COGR	lnichols@COGR.edu

FDP & SMART IRB Partnership Taskforce Purpose / Intent

- Utilize broad FDP membership for **input & advocacy**
- Assist SMART IRB with **broad adoption** and support through FDP member involvement
- **Provide feedback** on Reliance Agreement and HSC documents, tools and resources
- **Discuss use cases** and specifics of implementation
- **Maintain open dialogue** for bidirectional opportunities

Single IRB Review: The Time is Now



THE NIH DIRECTOR

The NIH Director

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Advisory Groups
Video & Sound Gallery
Articles
Statements

June 21, 2016

Single IRB Policy to Streamline Reviews of Multi-Site Research

Accelerating clinical research studies benefits researchers, research participants, and all who stand to gain from research results. Today, the time it takes to go from a sound research idea to the launch of a new, multi-site clinical research study is too long. A major

Related Links

NIH Policy on the Use of a Single Institution Review Board for Multi-Site Research pdf

OSP-OER Co-Authored Blog: Accelerating Clinical Research by Streamlining Multi-Site Review of Human Subjects Research

NIH Guide Notice on Single IRB Policy

NIH Guide Notice on Scenarios for Direct and Indirect Cost Determinations for sIRBs

Smart IRB Platform

Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Notice Number: NOT-OD-16-094

Key Dates

Release Date: June 21, 2016
Effective Date: New Date - January 25, 2018 as per issuance of NOT-OD-17-076

Related Announcements

NOT-OD-18-004
NOT-OD-18-003
NOT-OD-17-076
NOT-OD-17-027
NOT-OD-16-109

Issued by

National Institutes of Health (NIH)

Final Revisions to the Common Rule

OHRP
Office for Human Research Protections

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). The Final Rule was published in the Federal Register on January 19, 2017. It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

- Read the HHS Press Release

Single IRB Review: Evolution

2008 – 2014

Harvard Catalyst/New England; UC Braid; Wisconsin/MARCH; Ohio Collaborative; U Texas; U New Mexico; Vanderbilt

2014 - 2015

IRBrely

2016 –

SMART IRB

Advancing Research Together

A roadmap to implement the NIH Single IRB Policy

JOIN
SMART IRB

ENABLE
multi-site research

HARMONIZE
across the nation

Funded by NCATS: July 2016-April 2018

Harvard University, University of Wisconsin-Madison & Dartmouth College

A team of SMART IRB Ambassadors from CTSAs across the nation

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

Master IRB Reliance Agreement and SOPs

8 CTSAs came together to develop a national IRB reliance agreement

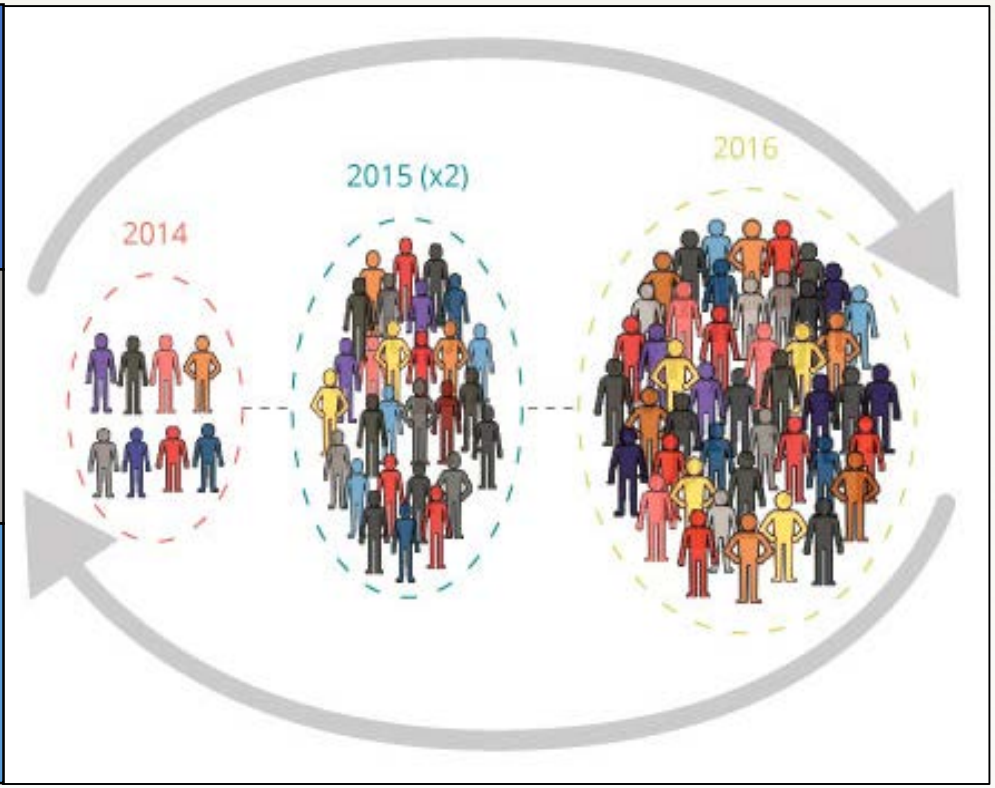
- Public & private universities
- Academic healthcare centers

Shared with 72 Institutions

+ 25 CTSAs in 19 states
+ Community hospitals
+ Independent/commercial IRBs

Shared with 115+ Institutions

+ 64 CTSAs in 33 states
+ NIH agencies



Developed with broad stakeholder input.

Intended to be a flexible and inclusive solution for many kinds of institutions/organizations and all types of clinical research.

Nature of the SMART IRB Agreement

The Agreement is a "master" agreement which means:

No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB	**Reliance arrangements, however, need to be documented for each study**

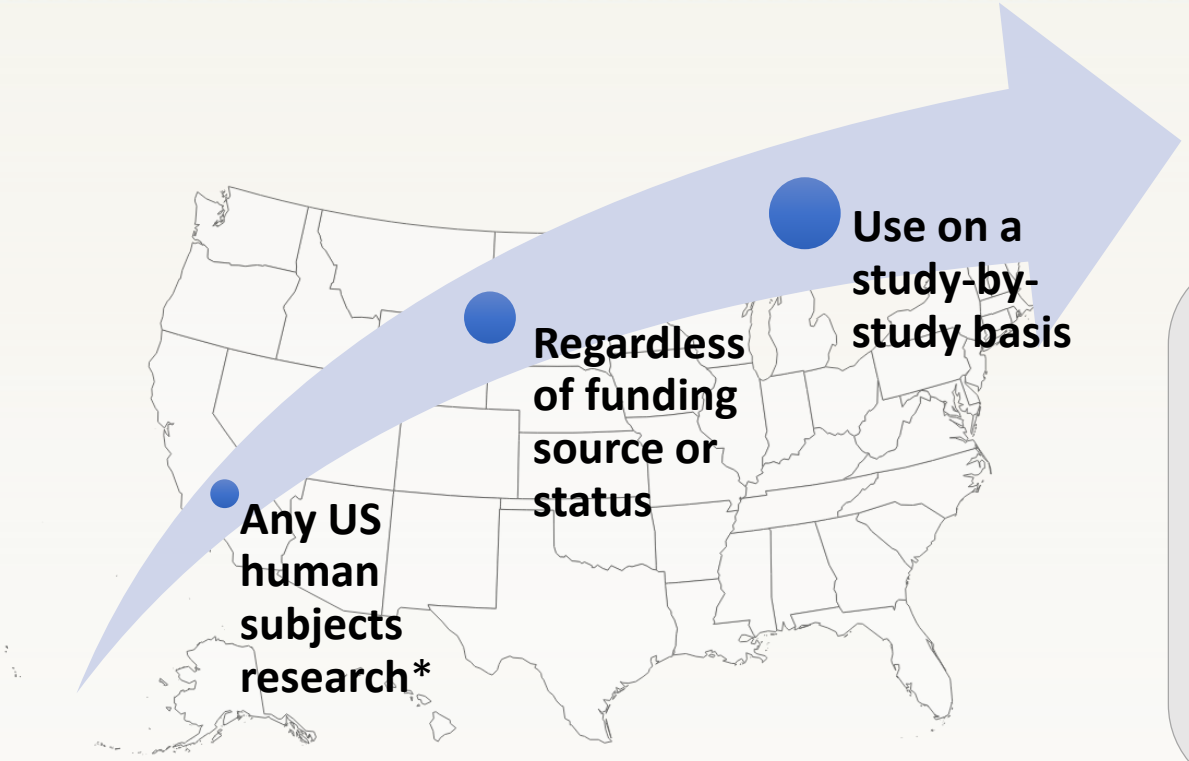
Use SMART IRB on a study-by-study basis

Default allocation of responsibilities

Flexibility

- Who serves as privacy board
- Who reports reportable events
- Need for or waive insurance
- Etc

Supports National Collaboration



SMART IRB allows for national implementation of the NIH single IRB policy *BUT*, it's not just for NIH-funded studies.

A treaty agreement

* Research for which local IRB review is required by law or otherwise is not eligible

No need to negotiate agreements for each study

No obligation to enter into reliance or serve as reviewing IRB

Any Eligible Institution May Join

Eligibility Criteria

An eligible institution:

1. **Has an FWA or is an IRB Organization** AND **provides institutional oversight of all human subjects research.***
2. **Has undergone or initiated assessment of the quality of its HRPP within five years prior to joining.****
3. **Establishes a Point of Contact (POC) responsible for initial and ongoing implementation and communication regarding SMART IRB Agreement. Alternate designee permitted and may be outside IRB office or institution.**

* May have checked or unchecked the box, but must inform participating institutions.
**Only required if the institution maintains an IRB or is an IRB organization.

Any Eligible Institution May Join

Eligibility Assessment

Quality Assessment:

- Within 5 years of joining SMART IRB.
- Flexibile process:
  - Accreditation through external organization (e.g. AAHRPP)
  - Proxy (e.g. OHRP's Self Assessment, FDA or other audit, external/internal evaluation, or other substantial equivalent).

SMART IRB Streamlines IRB Review

IRBs or INSTITUTIONs

Use the SMART IRB Agreement to facilitate single IRB review

PRINCIPAL INVESTIGATORs

Work with their institution's SMART IRB Points of Contacts (POCs) to determine an appropriate reliance arrangement and discuss their responsibilities related to single IRB review

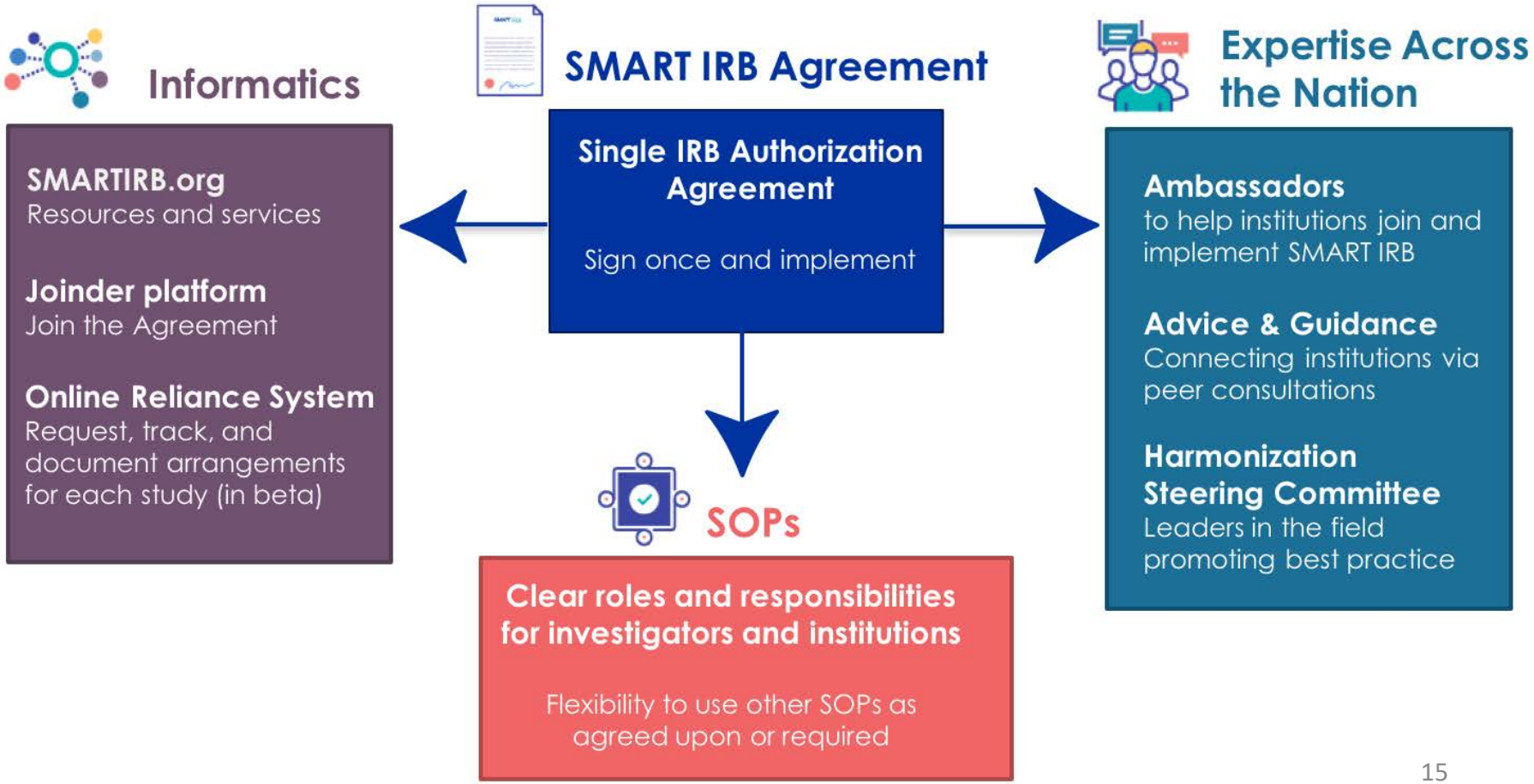
The Reviewing IRB

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

Supporting Single IRB Review



SMART IRB – Year 1

- Launch and sign-on status
- Joining SMART IRB: Joinder Platform
- Using the SMART IRB Agreement
  - Documenting arrangements: Online Reliance System
  - Flexibilities in the Agreement
  - SMART IRB SOPs
  - Resources and guidance
- Advancing harmonization on a national scale

Building a National Platform

350+ have joined since Sep. 2016

from 44 states and DC, including

- *All* CTSA hubs
- Universities
- Academic Medical Centers
- Community Hospitals
- Cancer Centers
- PPRNs
- Independent IRBs
- others

Building participation through partnership:

- CTSAs
- PCORnet
- Trial Innovation Network

Building a diverse community

A team of regional ambassadors assist institutions in joining and implementing SMART IRB.

The process starts at smartirb.org/join.

Online Reliance System: Request, Track, Document Agreements

SMART IRB Online Reliance System

Launched in beta May 2017

Single point of entry standardizes reliance processes

Communication portal eliminates tracking via email or other methods

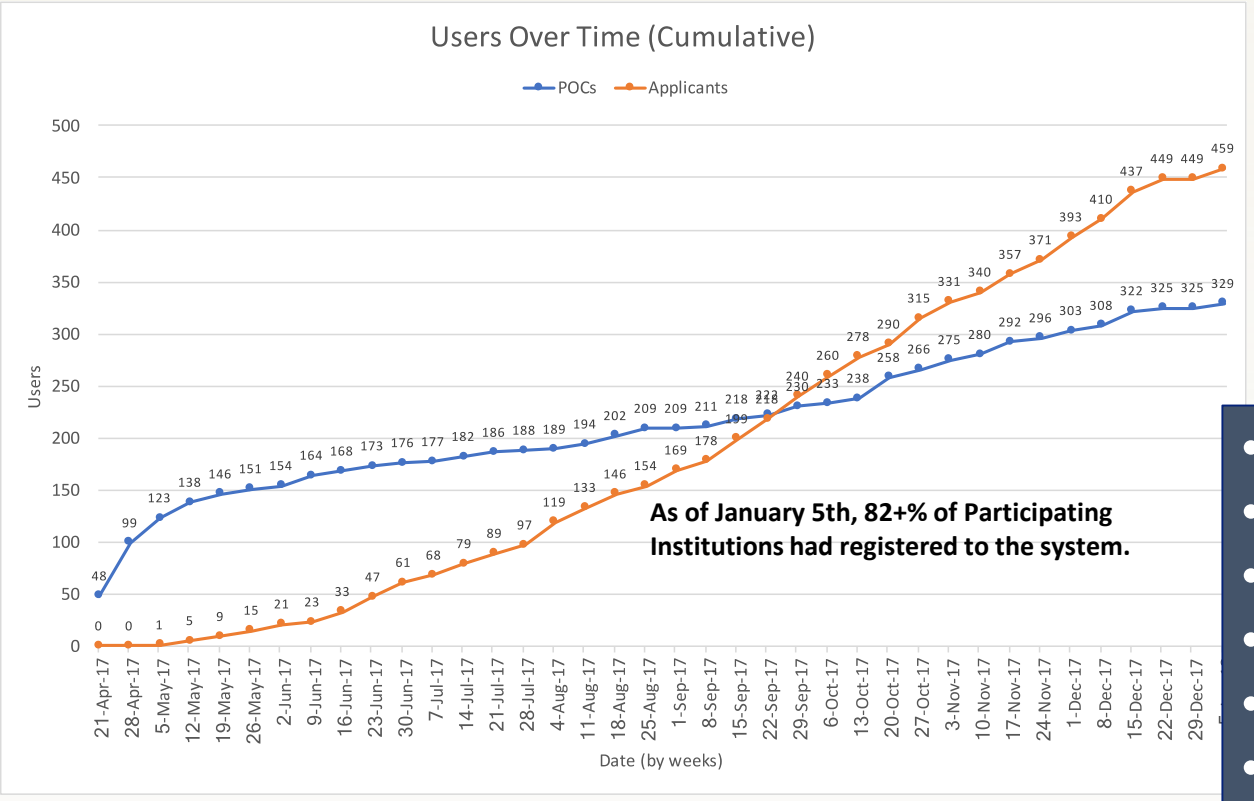
Guided workflow makes clear when action is required

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**

Allows all SMART IRB Participating Institutions to work together to establish reliance arrangements on a study-by-study basis

Users over time

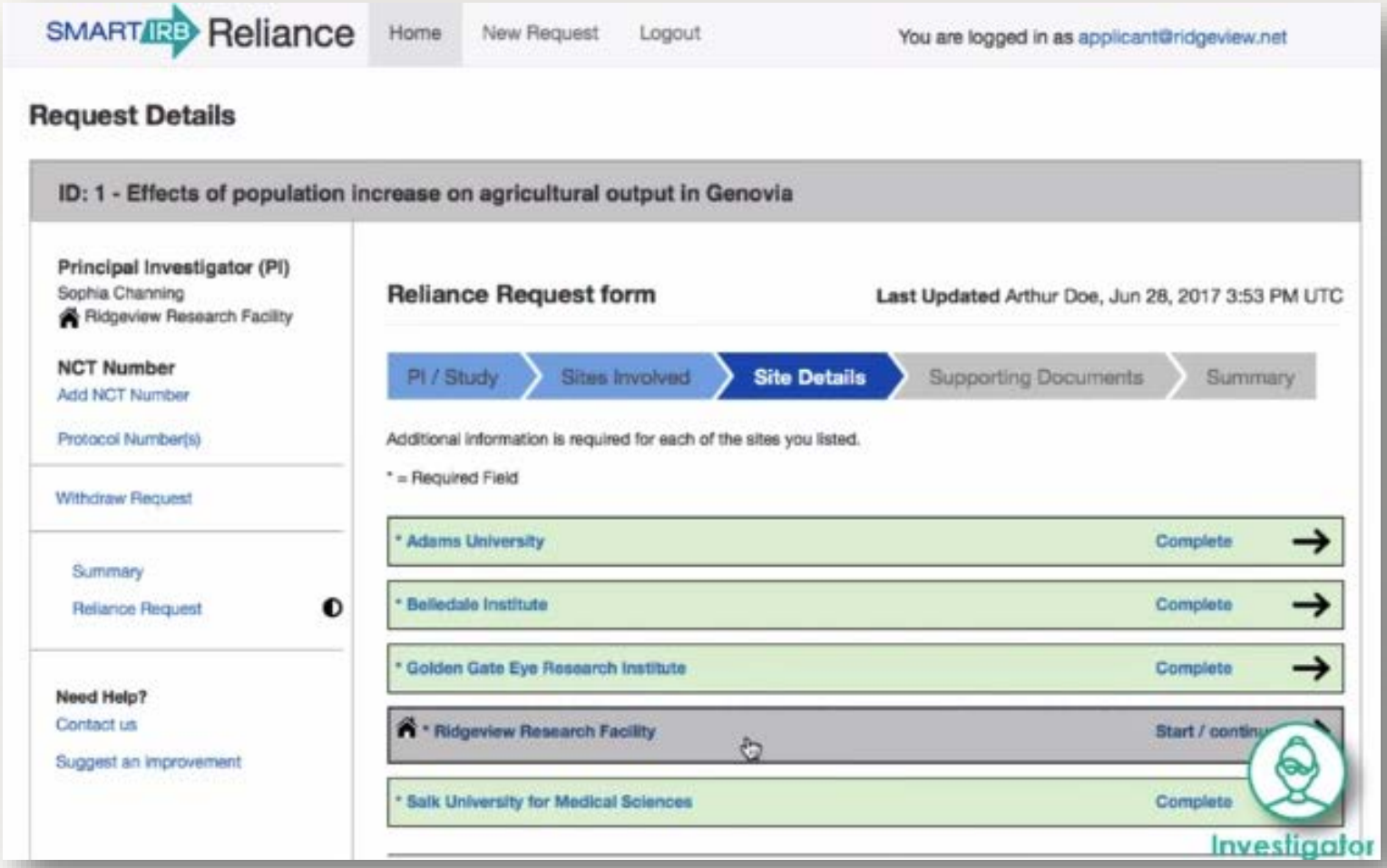


Metrics from ORS (7 mo):
~360 Reliance requests
~165 Reliance reached
~140 In process
~ 50 Non-reliance

- Clarity and transparency
- Automatic POC connect
- Step by step process
- Document of local context
- Automatic Notification
- Visibility into process
- Tracking
- System of record

A Look Inside the System

Full video at smartirb.org/reliance.



SMART IRB SOPs: Flexible Alignment of Processes

- SOPs provide clarity on key roles and responsibilities, including study teams
- Describe processes related to reliance
- Use of SMART IRB SOPs is not mandated
- SMART IRB supports networks with existing SOPs
- Institutions communicate whether other policies/procedures apply to the research

The greater the adoption of standardized processes, the greater the compliance and the easier it is for all

Institution Points of Contact (POCs)

Serve as local resource for the institution and local study teams

Determine whether to serve as Reviewing IRB or cede review

Communicate institution decisions regarding IRB reliance requests

- Provide local context information
- Provide local informed consent requirements
- Authorize any changes to institutional requirements
- Affirm local study team personnel training
- Respond to requests for assistance/information from Reviewing IRB POC (e.g. COI)

Reviewing IRB

"IRB of record" for an instance of Research under the Agreement

Study Oversight

Oversees study on behalf of relying sites from "cradle to grave"

- Initial submission
- Amendments
- Continuing review
- Reportable events
- Approves limited site-specific consent form language

COI

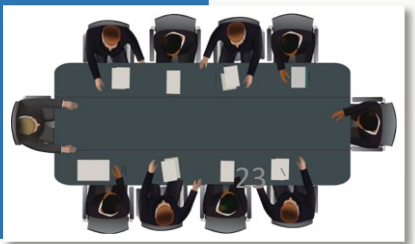
Reviews COI management plans provided by the relying institution

Can be more restrictive than provided plan

HIPAA

Acts as "HIPAA Privacy Board"

Makes determinations regarding waivers and alterations of authorization



Relying Institutions

Participating Institutions ceding review to a Reviewing IRB

KEY RESPONSIBILITIES

- Ensure study teams are **trained**
- Review and manage **COI;** disclose management plans to Reviewing IRB
- Ensure study teams **comply** with conditions of IRB approval, institutional policies, and applicable regulations
- **Notify** Reviewing IRB of relevant changes in institution/research team status
  - Unanticipated problems or findings of serious/continuing noncompliance
  - Suspension/restriction of Study Team member(s) to conduct human subjects research
- **Notify** Reviewing IRB of any **communications** about studies covered under the Agreement to/from **FDA, OHRP, and/or other regulatory agencies**
  - e.g., regarding unanticipated problems or serious and continuing noncompliance

Resources & Guidance

smartirb.org/resources

- For Institutions Interested in Joining SMART IRB
- Using the SMART IRB Online Reliance System
- Implementing the SMART IRB Agreement: Start-up Package
- For Institutional Review Board/Human Research Protection Program Staff
- For Reviewing IRBs
- For Relying Institutions
- For Study Teams
- NIH Requirements

A growing library of collaboratively-developed resources support IRBs, institutions, and investigators.

Resources & Guidance

A sampling of SMART IRB resources:

- FAQs & SOPs
- Consultations: Expert Advice and Guidance
- Communication Plan for Single IRB Review
- FAQs for Research Teams - Relying on an External IRB
- Grant Applications, Template Description of SMART IRB
- Implementation Checklist
- Joinder Checklist
- Joining SMART IRB: Guidance for Affiliates
- Letter of Acknowledgement, Template
- Local Context Survey
- Online Reliance System: Sample Reliance Request Form
- Overall PI (and Lead Study Team) Checklist
- PI Checklist, Relying Institution
- Relying Site Study Team Survey
- SMART IRB Support Center
- View Past Webinars
  - Getting Started with SMART IRB and the Online Reliance System;
  - Implementing the SMART IRB Agreement;
  - Responsibilities of Relying Institutions; and
  - Serving as a Reviewing IRB

See smartirb.org/resources for a complete list as well as collected resources on NIH requirements and sample tools, training, and guidance generously shared by our colleagues across the nation.

Investigator Guidance at
www.smartirb.org/go

Ongoing Learning and Help

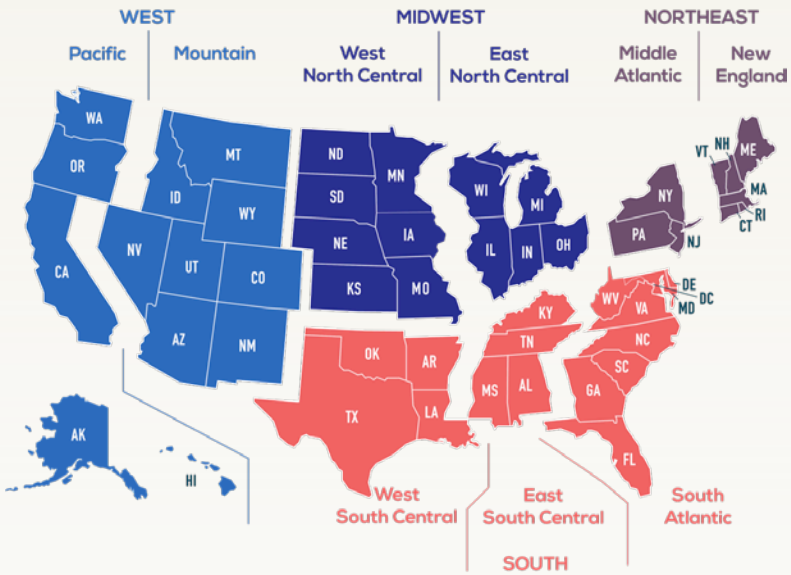
SMART IRB Webinar series

Getting Started with SMART IRB & the Online Reliance System

Implementing the SMART IRB Agreement

Responsibilities of Relying Institutions

Serving as a Reviewing IRB



- Regional Ambassadors
- Peer Consultation

smartirb.org/support/

Focus on Advancing Harmonization Across the Nation

Harmonization Steering Committee (HSC) Vision

To promote a more strategic, effective, efficient and cooperative approach to policies, processes and procedures related to single IRB review of multi-site studies

Standardize processes:
Increase compliance
Decrease burden

Co-chairs:
Barbara E. Bierer, MD
Director of Regulatory Policy, SMART IRB

Valery Gordon, PhD, MPH
Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

HSC Membership

Broad and Diverse Representation

- AAHRPP
- Federal Demonstration Partnership
- Food and Drug Administration
- Harvard Catalyst
- National Cancer Institute Central IRB
- National Center for Advancing Translational Sciences
- NeuroNext IRB
- NIH Division of Intramural Research
- NIH Office of Extramural Research
- NIH Office of Science Policy
- Office of Human Research Protections
- Patient-Centered Outcomes Research Institute
- PedsNet
- Quorum IRB
- Rare Diseases Clinical Research Network
- Schulman IRB
- TransCelerate BioPharma Inc.
- Trial Innovation Network
- UC BRAID: University of California Biomedical Research Acceleration, Integration, & Development
- University of California, San Diego
- University of Cincinnati/StrokeNet
- University of Kansas Medical Center
- University of Kentucky
- University of Texas Health Science Center at San Antonio
- University of Wisconsin-Madison
- US Department of Defense
- US Department of Veteran Affairs
- Washington University in St. Louis/Council on Governmental Relations
- WIRB-Copernicus Group IRB

Harmonizing Practices, Policies, and Procedures

Advancing harmonization in the implementation of single IRB review.

Phase 1:

- Institution/local/state responsibilities
- Institution v. IRB responsibilities
- Fees and charging models
- Reportable events
- Standard templates

SMART IRB

SMART IRB: The Essentials
Winter Wonderland Edition

Do you hear what we hear?
New year, new Single IRB Policy.
Along with a brand spanking new year, there's more fun than ever in store when the **NIH Single IRB Policy** takes effect on January 25th.

And we're here to help you get ready. Regardless of funding source or study type, SMART IRB can help support your IRB reliance arrangements.

The first step is for your institution to **join SMART IRB**. Then, start using the **SMART IRB Agreement** and **SOPs** to enable single IRB review for your studies. Request, track, and document reliance arrangements with the **Online Reliance System**. Read on for more on the tools, resources, and real live people (aka **SMART IRB Ambassadors**) here to help.

The perfect gift for the investigator on your list.
Help study teams get SMART.
Send investigators to **smartirb.org/go** for an introduction to SMART IRB, helpful tips when relying on an external IRB, and instructions for getting started.

Bundle up.
Templates, checklists, and FAQs to get you through the season.

Let it grow, let it grow, let it grow.
A virtual blizzard of institutions are joining SMART IRB.
Check out the full list.

It's a party.
And everyone's invited.
The more the merrier. Spread the word to your affiliates and collaborators; we have **guidance** to help them **join SMART IRB**.

SMART IRB Participating Institution

SMART flair.
Add a little sparkle.
Once you've joined, **add a badge to your website.**

Commit to a SMART resolution - early.
Register for an upcoming webinar.

Update and Comment at
www.smartirb.org/harmonize

Subscribe at:
https://smartirb.org
be added to newsletter

University Implementations

- Washington University
- New York University
- Johns Hopkins University

Taskforce Discussion Areas

- **Clarity around Terminology & Language used – need to be harmonized with sIRB**
- **Specific terminology**
  - **"Participating Institution" -** An institution (including an IRB organization) that meets the eligibility requirements set forth in the Agreement and agrees to accept the terms and conditions of the Agreement through the execution of a a Joinder Agreement, thereby becoming a signatory party to this Agreement.
  - **"IRB Organization" -** An independent IRB organization that provides IRB review services and has agreed to become the Reviewing IRB for another Participating Institution for an instance of research under this Agreement.
  - **"Reviewing IRB"** - The "IRB of record" (including an IRB Organization) to which authority for IRB review and oversight has been ceded by another Participating Institution for an instance of Research under the Agreement.
  - **"Relying Institution"** - A Participating Institution that cedes IRB review to a Reviewing IRB for an instance of Research under the Agreement.
  - **"Overall PI"** - The lead multisite principal investigator with ultimate responsibility for the conduct and integrity of research (generally, the initiating principal investigator or funding principal investigator, as applicable).
- **Language included in agreement that could be moved out of actual agreement:**
  - Explanatory
  - Procedural
  - FAQ related

Taskforce Discussion Areas

- Clarity around specific requirements & responsibilities
  - **HIPAA** – flexible; presumes Reviewing IRB will make determinations (but authorizing agreement is not always done by the IRB)
  - **COI** – Relying institution analyzes and provides management plan Reviewing IRB implements plan; may impose additional requirements (but scope could be limited to how the COI relates to human subjects)
  - **Audits / investigations** – may be done by Reviewing IRB or Relying Institution; cooperation (default to Relying Institution?)
  - **Reporting –** Reviewing IRB, with review of Relying Institution; may agree on alternate approach (default to Relying Institution?)
  - **Policies and Procedures Governing the Agreement**
    - Reviewing Institutions' policies take precedence (how will our faculty handle numerous policies?)

Taskforce Discussion Areas

- Bigger and broader areas:
  - sIRB culture change over last year
  - Use for Federal AND non-Federal
  - Use in minimal risk studies
  - Need to require FWA
  - Need for quality assurance program

FWA Requirement

- "…the institution must maintain an OHRP-approved Federalwide Assurance ("FWA"), regardless of whether it engages in federally funded human subjects research that is subject to the Federal Policy for the Protection of Human Subjects ("Federal Policy")
  - Creates a common baseline for documenting agreement to apply 45 CFR 46 regulations for protection of human subjects
  - Impacts only those entities that do not currently receive federal funding for human subjects research

FWA Requirement

- All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.
  - This statement of principles may include (a) an appropriate existing code, declaration (such as the World Medical Association's Declaration of Helsinki), or statement of ethical principles (such as the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research), or (b) a statement formulated by the institution itself.

FWA Requirement - Challenges

- Hesitancy from non-academic entities to obligate themselves to the federal government for collaborative research:
  - Through the FWA and the Terms of the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.
- Imparts additional administrative burden:
  - If entity is multiple legal entities, must maintain multiple FWAs
  - The institution must update its FWA(s) within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official. The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA.

FWA Requirement - Challenges

- Applicability of FWA limits it to only federally funded studies
  - These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported* by any U.S. federal department or agency that has adopted the Common Rule
- For discussion
  - Replace requirement to obtain FWA with requirement that entity obligated to key terms of the FWA for all research
    - Be guided by appropriate human subject principles
    - Conduct all research under the requirements of the common rule or equivalent protections

Quality Assessment Requirement

Section 1: Eligibility and Process to Participate in the Agreement

1.2 HRPP Quality. If it has an IRB or is an IRB Organization, the institution must have undergone or have initiated an assessment of the quality of its human research protection program ("HRPP"). Such assessment must have occurred or have been initiated within the past five (5) years prior to the institution joining the Agreement. The assessment may be accomplished by accreditation through an external organization, or through OHRP's Quality Assessment Program, or other equivalent approach.

For clarity, it is not a requirement for participation as a Relying Institution in this Agreement for an institution to have an IRB.

Quality Assessment Requirement

Discussion Areas:

- **Uncertainty about the intent [given the limited application]**
  - Language restricts this requirement to organizations that have an IRB or those that are an IRB Organization
  - A parallel requirement for a quality assessment is not included for signatory organizations that do not have an IRB

- **Uncertainty about what qualifies as "initiated"**
  - The Institution must have undergone or have initiated an assessment of the quality of its human research protection program ("HRPP").

- **Uncertainty about what qualifies as "an assessment of HRPP quality"**
  - Each participating institution as part of its Joinder Agreement must represent and warrant that it meets the eligibility criteria for participation.

"SMART IRB does not proscribe the nature of the assessment; it can be a third-party assessment or a self-assessment. Accreditation through an external organization, use of OHRP's QA Self-Assessment Tool or FDA's Self-Evaluation Checklist for IRBs, use of the Association for the Accreditation of Human Research Protection Programs ("AAHRPP") Evaluation Instrument for Accreditation with self-documentation of satisfaction of requirements, or another approach with a comparable, comprehensive scope of review of the HRPP that includes assessment of the IRB are sufficient to meet this criterion. Depending on the scope of audit, an audit of the institution's IRB by a federal agency, with no major issues identified and any minor issues corrected/resolved, may also be sufficient. The Agreement provides that Participating Institutions may obtain information about how any other Participating Institution satisfied SMART IRB's HRPP quality assessment requirement prior to determining whether to participate in a ceded review with that institution."
https://smartirb.org/sites/default/files/faq.pdf

Quality Assessment Requirement

Case Example: Johns Hopkins University

The University has three IRB "offices" [Different FWAs]

- **Johns Hopkins Medicine IRB** [Covers the Schools of Medicine & Nursing & the Johns Hopkins Hospital & Health System]
- **Johns Hopkins School of Public Health IRB**
- **Johns Hopkins Homewood IRB** [Schools of Arts and Sciences, Engineering, Education, Business International Studies]

  - Only JHM IRB is accredited by AAHRPP [since 2005]
  - Although there are three "IRBs" only JHM will serve as a "reviewing IRB"
  - JHM IRB is signed onto the SMART IRB agreement and regularly uses the SMART agreement
  - JH-SPH and Homewood have not undergone a "quality assessment" that the organization feels meets the eligibility requirement

Use for minimal risk studies

- Challenge: Will social and behavioral IRBs be able/willing to sign onto the terms of the SMART IRB agreement and use it exclusively?
  - Anecdotal evidence suggests that even signators of the Agreement use simplified alternatives
  - HRPP Quality; Extend terms of FWA to ALL research, whether or not federally-funded
  - Must be harmonized with AAHRPP
  - The length of the Agreement will make it difficult for our faculty
- Could the Agreement be modified for minimal risk and behavioral and social sciences research. Recommendations have been drafted:
  - Forego the requirement for institutions to have or have access to a quality assurance program
  - Don't require an Indemnification clause
  - Don't require Participating Institutions to have insurance coverage if they don't already have it
- Rationale for going beyond the regulations is that you need assurance of quality of the HRPP for organizations you don't know, but could the Agreement allow modification or elimination of certain clauses for FDP institutions' (who we know and trust!)collaborations?

Planned next steps

- SMART IRB utilizing feedback to determine whether a version 2.0 of Reliance Agreement should be undertaken:
  - FDP / SMART IRB Taskforce
  - Participating organizations during 1st year of implementation
  - Implications of Common Rule
  - Other committees and groups (HSC, etc.)
  - Add others, as appropriate , including feedback in this session
- Clarifications vs. significant revisions that would require resigning of the Agreement?
- If substantive revisions proposed, comment period for broad audience will be provided

Questions & Discussion

- Implementation successes & challenges?
- What is the best way to gather feedback from your organizations?

Taskforce Members

Member	Organization	Contact email
Lynette Arias (co-facilitator)	University of Washington	ariasl@uw.edu
Alex Albinak (co-facilitator)	Johns Hopkins University	amckeow1@jhu.edu
Barbara Bierer	Harvard University	bbierer@bwh.harvard.edu
Nichelle Cobb	University of Wisconsin	nlc@medicine.wisc.edu
Marti Dunne	New York University	marti.dunne@nyu.edu
Martha Jones	Washington University	jonesma@wustl.edu
Megan Singleton	Johns Hopkins University	msingl16@jhmi.edu
Cheryl Kitt	NIH	kittc@od.nih.gov
Patrice Brown-Longenecker	NIH/OD	petrice.brown@nih.gov
Jane McCutcheon	New York University	jam2@nyu.edu
Debra Murphy	Arizona State University	debra.murphy@asu.edu
Kerry Peluso	Florida State University	kpeluso@fsu.edu
Lisa Nichols	COGR	lnichols@COGR.edu