Your Roadmap to Single IRB Review

Serving as a Reviewing IRB

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Nichelle Cobb, PhD
Director, Health Sciences IRBs Office
University of Wisconsin-Madison

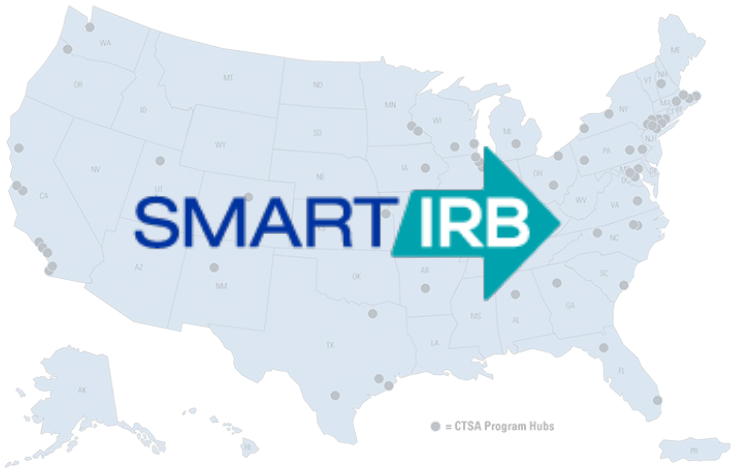
Chief Regulatory Operations Officer for
Implementation, SMART IRB

Presentation Goals

- Provide a brief overview of the SMART IRB Program
- Describe the responsibilities of Reviewing IRBs under the SMART IRB Agreement
- Discuss the impact of single IRB review on key Reviewing IRB processes

SMART IRB OVERVIEW

Advancing research together



A Roadmap to Single IRB Review

Funded by NCATS beginning in July 2016

As of July 2018, led by Harvard University and University of Wisconsin-Madison, along with a team of Ambassadors from across the U.S.

GROW
A national IRB reliance network

SUPPORT
Use of SMART IRB

EDUCATE & TRAIN
Institutions & Investigators

HARMONIZE
sIRB review processes across the nation

Supporting single IRB review

Informatics

SMARTIRB.org
Resources and supportive services freely available to support sIRB review

Joinder platform
Allows institutions to join the SMART IRB Agreement

Online Reliance System
Provides a central system and process to request, track, and document reliance arrangements for each study

SMART IRB Agreement

Single IRB Authorization Agreement

Sign once and implement

SOPs

Clear roles and responsibilities for investigators and institutions

Flexibility to use other SOPs as agreed upon or required

Expertise Across the Nation

Ambassadors
Help institutions join and implement SMART IRB

Education & Training
Tools, templates, FAQs, checklists, guidance, peer consultations, and webinars support adoption of SMART IRB

Harmonization Steering Committee
Leaders in the field promote best practice

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

REVIEWING IRB RESPONSIBILITIES: OPERATIONAL

IRB Operations

Comply with federal policies for:

- IRB registration with OHRP
- IRB membership

Recordkeeping

- Maintain records of
  - Membership
  - Review activities
  - Determinations
  - Other, as required by applicable regulations and the policies of the Reviewing IRB
- Make records accessible to designated officials at the Relying Institution(s), upon reasonable request, including portions of meeting minutes relevant to the ceded research and the Relying Institution.

Research Oversight Responsibility

The Reviewing IRB performs

- Initial review
- Continuing review
- Reviews of:
  - Amendments
  - Unanticipated problems that may involve risks to subjects or others
  - Potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB

REVIEWING IRB RESPONSIBILITIES: CONSIDERATION OF "LOCAL CONTEXT"

Local Considerations

The Reviewing IRB considers communicated local requirements, such as:

- Applicable state or local laws, regulations, institutional policies, standards, or other local factors, including ancillary reviews, relevant to the research that would affect the conduct or approval of the research at the Relying Institution
- Site-specific information requested/identified in the customizable sections of the Reviewing IRB's consent form
- Conflict of interest determinations, prohibitions, and management plans
- Local requirements and restrictions on use and disclosure of PHI that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization with respect to the Relying Institution

Conflicts of Interest

The Reviewing IRB:

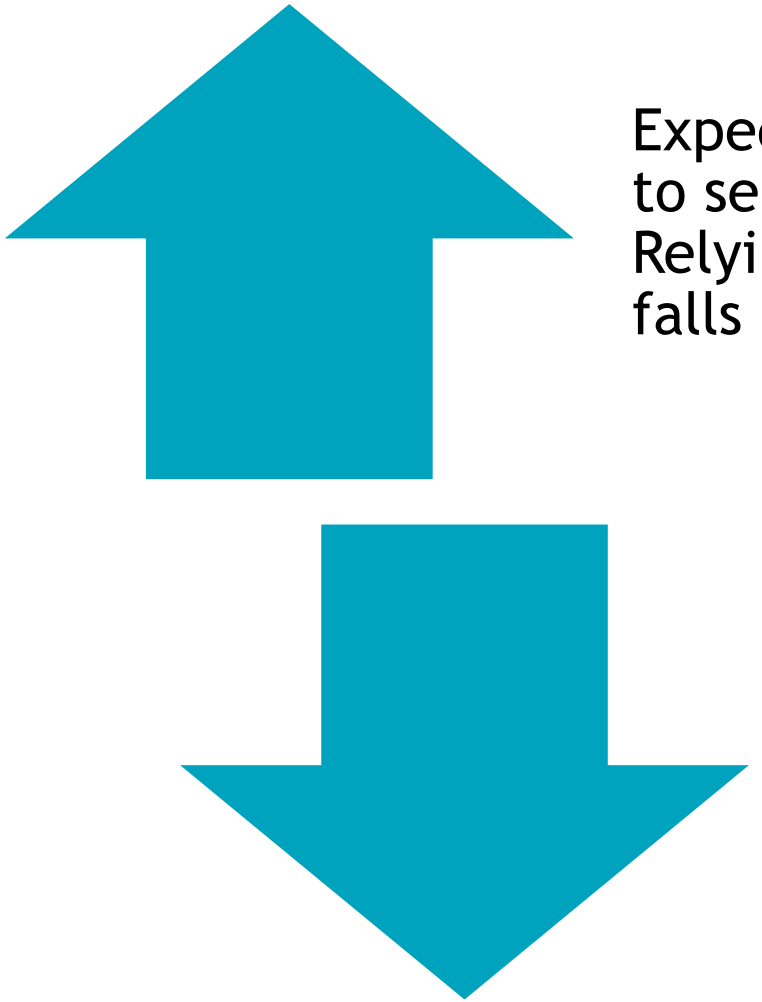
Ensures any COI management plan is incorporated into its initial or other deliberations, as applicable, such as including disclosures to subjects in consent forms

Retains the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than proposed by a Relying Institution

Will not modify or change any management plan or mandated disclosure to subjects without discussion with and acceptance by the Relying Institution

REVIEWING IRB RESPONSIBILITIES: HIPAA PRIVACY RULE

Agreement Default Position



Expectation for the Reviewing IRB to serve as the Privacy Board for Relying Institutions, when a study falls under the HIPAA Privacy Rule

Reviewing IRB and Relying Institutions can make alternate arrangements, such that some or all Relying Institutions can perform Privacy Board determinations instead of the Reviewing IRB

Determinations Related to PHI Disclosure

Reviewing IRB ensures Protected Health Information (PHI) will not be used or disclosed unless one of the following options is met:

- Written authorization is obtained from participants
- Waiver of alteration of authorization is granted
- Use of a Limited Data Set pursuant to a Data Use Agreement

HIPAA Authorization Language

When an authorization is required, the Reviewing IRB will provide the authorization language

- Authorization language may be incorporated into the informed consent documents

  OR

- The Relying Institution may obtain agreement from the Reviewing IRB to use a separate authorization form

  In this case, the Relying Institution is responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule

Combined Consent/Authorization Forms

For conducting, reviewing, and overseeing the Research (including investigation and evaluation of events)

Ensures that the any authorization under its purview permits PHI to be used by and disclosed to:

- the Reviewing IRB and the Reviewing IRB Institution
- all Relying Institutions (whether listed individually or described as a group)

REVIEWING IRB RESPONSIBILITIES: COMMUNICATION & NOTIFICATIONS

Policies & Procedures

The Reviewing IRB makes its policies and procedures available to Relying Institutions, when applicable and upon request.

Consent Forms

The Reviewing IRB provides Relying Institutions and Site Investigators with approved informed consent templates (when informed consent required)

Permits Relying Institution/Site Investigator to customize limited site-specific sections of the form:

- availability of treatment/compensation for research-related injury
- payment or reimbursement of research costs incurred by subjects
- local contacts

Provides final approved consent form(s) to Relying Institutions/Site Investigators (either directly or through a designee, such as a Lead Study Team)

IRB Decisions and Lapses in Approval

The Reviewing IRB promptly notifies the Overall PI, Site Investigators, and the Relying Institutions of:

- Determinations (e.g., exemption)
- Review decisions (e.g., approval, disapproval, required modifications)
- Lapses in IRB approval and any applicable corrective action plans

IRB Findings and Actions

The Reviewing IRB promptly notifies Overall PI, Site Investigators and Relying Institution(s) about findings of and actions related to:

- Apparent serious and/or continuing noncompliance
- Serious and/or continuing noncompliance, including any steps it deems necessary for remediation of the noncompliance at the Relying Institution
- Unanticipated problems involving risks to subjects or others
- Subject injuries related to research participation
- Significant subject complaints (e.g., those that could affect the conduct of the research)
- Suspension or termination of IRB approval of the research

Conducting Audits

The Reviewing IRB can:

- Conduct audits of the research;
- Request a Relying Institution conduct an audit/investigation and report its findings to the Reviewing IRB; OR
- Work cooperatively with a Relying Institution to conduct an audit/investigation

When a Relying Institution conducts the audit/investigation, the Reviewing IRB will reasonably cooperate with the institution

- Provide research review records and related information
- Meet with representatives from the Relying Institution
- Help implement corrective actions, as applicable

Audits and Corrective Actions

If the Reviewing IRB requires an audit or investigation, it will promptly notify the Relying Institution and will report its findings of fact to the Relying Institution within a reasonable timeframe.

The Reviewing IRB informs the Relying Institution of any corrective actions in connection with the audit or investigation

External Reporting

The Reviewing IRB notifies a Relying Institution in advance if the Reviewing IRB determines that a report is required to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority of any:

- Unanticipated problems involving risks to human subjects or others
- Serious and/or continuing noncompliance
- Any suspensions or terminations of IRB approval

Reporting Responsibility

Typically, the Reviewing IRB/Institution will draft the report and provide the involved Relying Institution(s) the opportunity (no fewer than five (5) business days) to review the draft report before sending to the external recipients

The Reviewing IRB/Reviewing IRB Institution is under no obligation to adopt comments of a Relying Institution

Communications from Regulatory Agencies

The Reviewing IRB promptly notifies the Relying Institutions of any communications received from the FDA, OHRP, and/or other regulatory agencies regarding:

Unanticipated problems	Suspension or termination of IRB approval	Serious and/or continuing noncompliance	Other regulatory compliance concerns regarding the research

IMPACT OF SINGLE IRB REVIEW ON REVIEWING IRBs: KEY PROCESSES

Assessments of Engagement

The Reviewing IRB should have processes in place to determine which institutions or individuals are engaged in human subjects research and thus require oversight

For individuals not associated with institutions but who are engaged in human subjects research, individual/independent investigator agreements may be necessary instead of a reliance agreement

Resource: Emory IRB Reliance Agreement Worksheet

Also available via smartirb.org/resources/

Documentation of Reliance Arrangements

When using the SMART IRB Agreement, an additional IRB authorization agreement is not required for institutions that have joined, but use of the agreement needs to be documented

The documentation that the SMART IRB agreement will be used for a reliance arrangement does NOT require signature

No supplemental agreements are required

Resources: SMART IRB Online Reliance System or template Letter of Acknowledgement (see smartirb.org/resources).

One Solution:
The SMART IRB Online Reliance System

- Provides investigators and institutions a centralized workflow to initiate, document, and track reliance arrangements
- Standardizes the information collected to assess whether a study is eligible for a reliance arrangement
- Connects institutions with the appropriate point of contact (POC) for each institution involved in the reliance request
- Built-in Flexibilities: Add sites by amendment; customize institution contact information; designate multiple POCs within institution; send reminders; pull reports on-demand

SMART IRB Online Reliance System Documentation: Determination Letter Information

Reliance Determination:

Overall Principal Investigator: Stacy Miller

The Reviewing IRB is: Belledale Institute
Federal Wide Assurance (FWA): FWA0000001
Point of Contact: Thomas Werner, institution_poc@belledale.org
Site Investigator: John Dorean

Reviewing IRB accepts review for:

Adams University
Federal Wide Assurance (FWA): FWA0000014
Site Investigator: Christopher Turk, example@test.com

Belledale Institute
Federal Wide Assurance (FWA): FWA0000001
Site Investigator: John Dorean, example@test.com

Golden Gate Eye Research Institute
Federal Wide Assurance (FWA): FWA0000002
Site Investigator: John Doe, jdoe@gmail.com

Ridgeview Research Facility
Federal Wide Assurance (FWA): FWA0000005
Site Investigator: Stacy Miller, applicant@ridgeview.net

The following institutions will NOT rely upon the Reviewing IRB:
Approval for each must be obtained from the IRB for that site (or through other arrangement, as applicable) prior to initiating study activity at that site. Please consult the institution's Point of Contact for further instructions:

Salk University for Medical Sciences, Point of Contact: Sarah Alonzo, institution_poc@salk.edu

Identifies the Reviewing IRB

Identifies the institutions the IRB will oversee

Identifies the institutions the IRB will NOT oversee

Watch the Online Reliance System in action at smartirb.org/reliance

Reliance Walkthrough Video

View Full Video [11:20]

View by Topic

- Overview of the decision making process [1:53]
- Investigator submits a request [2:44]
- Identifying a proposed reviewing IRB [2:30]
- Recording Institution decisions [1:40]
- Issuing the determination [3:17]

To learn more about the Online Reliance System, check out the Reliance System Resources

Communicating Implementation of Flexibility in the SMART IRB

The SMART IRB Agreement provides for flexibility related to:

- The Reviewing IRB serving as a Privacy Board
- Requiring insurance or indemnification agreement
- Requiring an auditing mechanism or who performs audits
- Whether HIPAA authorization language will be included in consent form
- Who performs COI analyses
- Responsibilities for reporting events/actions to federal agencies/sponsors

Resource: *SMART IRB Implementation Checklist* at smartirb.org/resources/

Communicating Key Policies to Study Teams

The Reviewing IRB should inform study teams of policies that will affect them

- Common examples:
  - Reportable events
  - Personnel changes
- Example communication methods:
  - IRB approval notice
  - Investigator responsibilities letter

Local Context

The Reviewing IRB should identify how it will obtain and track:

- Local context information from Relying Institutions
- Information about variations in study implementation across sites from research teams

Resources: Local Context Survey and Survey for Relying Site Study Teams

Available at smartirb.org/resources

Assessing Study Team Qualifications and Adequacy of Research Sites

Per FDA guidance, Reviewing IRBs are expected to assess

- Qualifications of investigators to conduct and supervise the proposed research
- Training and experience of investigators specifically related to the proposed study
- The site where the proposed research will take place to ensure it can adequately execute the protocol requirements (e.g., equipment and staff)

The Reviewing IRB should have processes in place to assess these factors

- SMART IRB Agreement expects Points of Contact at Relying Institutions to provide this information to the Reviewing IRB

Communication with Study Teams

The Reviewing IRB should identify how it will:

- Communicate with relying site study teams, including its determinations and approved study documents
- Obtain information from relying site study teams

Example approaches

- Allowing relying site study teams direct access to the Reviewing IRB's electronic system
- Requiring a lead study team to be responsible for the distribution of IRB documents and communicating on behalf of relying site study teams to the Reviewing IRB

Resource: Communication Plan for Single IRB Review

Available at smartirb.org/resources

Template Consent Forms

- Create and distribute consent templates with clearly marked areas that study teams/institutions can update
- Ensure institutional sign-off regarding local consent form requirements

Points to Consider

Tailoring implementation of the SMART IRB Agreement and collection of local context information based on study type and risk level

- Some terms of the Agreement, such as requiring insurance or a mechanism to conduct audits, may not be necessary for certain reliance arrangements
- If Relying Institution engages in limited activities, the local context information the Reviewing IRB needs to oversee that site may also be limited

Considering which of the Reviewing IRB's policies may need to be flexible to accommodate differing requirements of a Relying Institution

IRB Fees

If the Reviewing IRB will charge for its review it should:	
have a mechanism for communicating its fee schedule to the institutions involved in the study that may incur charges for IRB review	communicate this information to potential Relying Institutions before the decision is made for a reliance arrangement to avoid surprises

RESOURCES

If you need help:
email
help@smartirb.org

SMART IRB

Access SMART IRB Resources at SMARTIRB.ORG

Expertise and Guidance

Connect with an ambassador or request a peer consultation

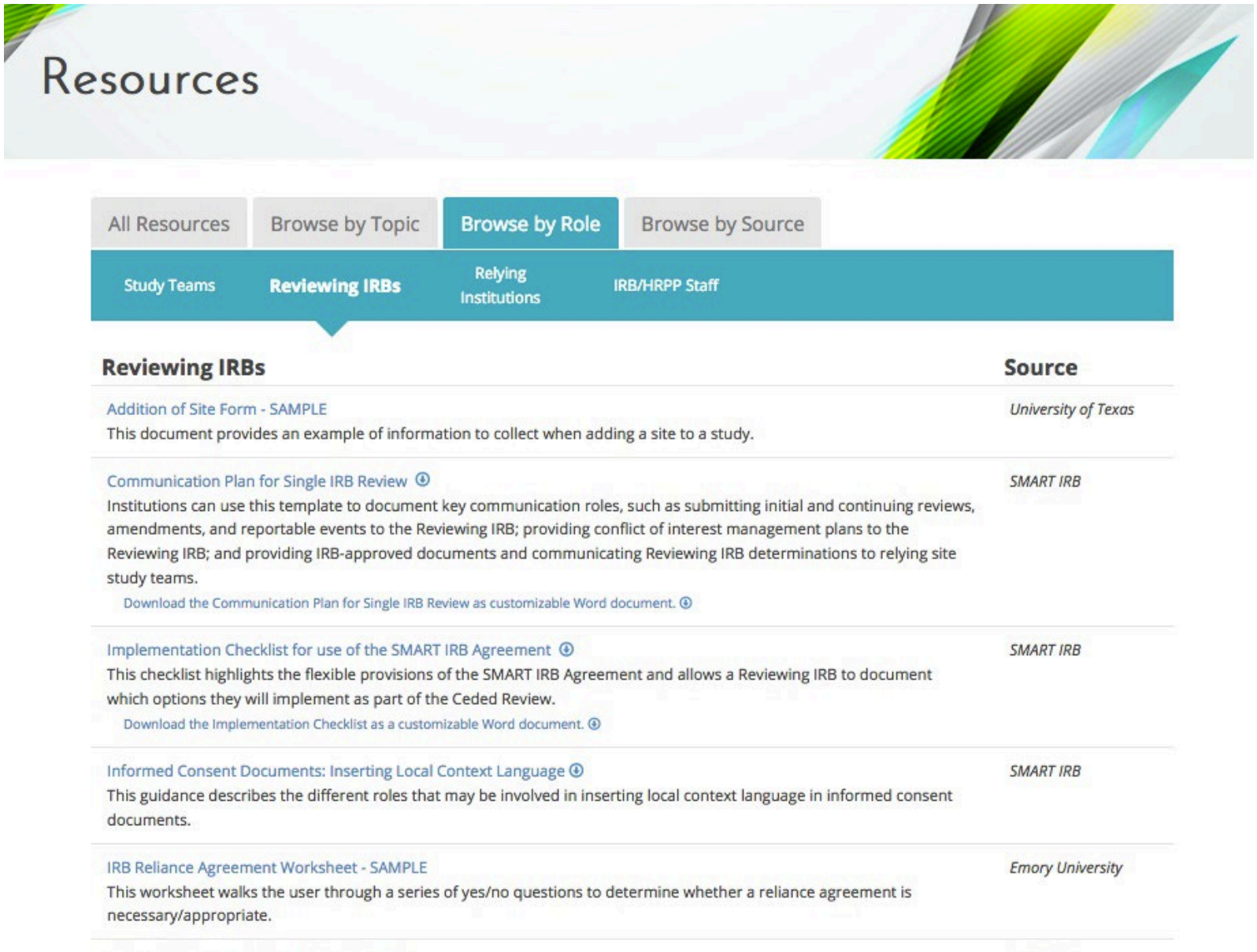
Support for Single IRB Review

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 Resources Page: smartirb.org/resources



Questions and Discussion