Your Roadmap to Single IRB Review

Responsibilities of Relying Institutions

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Presentation Goals

Provide a brief overview of the SMART IRB Program

Describe the responsibilities under the SMART IRB Master Agreement of Relying Institutions

Discuss the impact of single IRB review on institutional policies & 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.
Supporting single IRB review

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
Sign once and implement

SOPs
Clear roles and responsibilities for investigators and institutions
Flexibility to use other SOPs as agreed upon or required

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 |
Nature of the SMART IRB Model

The Reviewing IRB is responsible for overseeing:

- Initial Reviews
- Reportable events (e.g., noncompliance, unanticipated problems)
- Personnel changes
- Continuing reviews for the entire study
- Study wide & local amendments
Eligibility to Join SMART IRB

Institution has a Federalwide Assurance

Institution provides oversight of all research, including exempt and not federally funded

If the institution is or has an IRB, must have initiated or completed an evaluation of the quality assurance of its human research protection program (HRPP) within past 5 years of joining the agreement

Institution must assign a Point of Contact (POC)
Responsibilities of All Institutions that Join

Maintain, implement, or have access to a human subjects research QA/QI process/function/program/service that can conduct and report to the Participating Institution the results of for-cause and not-for-cause audits

UNLESS the Reviewing IRB waives this requirement

Maintain sufficient insurance coverage (includes self-funded liability coverage in the case of state institutions) to cover their activities related to the reliance arrangement

UNLESS the Reviewing IRB waives this requirement
SMART IRB MASTER AGREEMENT: RELYING INSTITUTION RESPONSIBILITIES
Ensuring Study Teams:

Do not initiate any study or changes of protocol* without approval from the Reviewing IRB

(*except those to eliminate an apparent immediate hazard)

Provide the Reviewing IRB with information about local study conduct for continuing review

Maintain research records (e.g., consent forms, HIPAA authorization)
Ensuring Study Teams Notify the Reviewing IRB of:

- Unanticipated problems
- Potential noncompliance
- Suspension or restriction of study team personnel authority to conduct study
Provide information or documentation to a Reviewing IRB regarding:

its research personnel’s education, training, and qualifications as requested
Institutional Communication with the Reviewing IRB

Local context that would affect the conduct or approval of the research at the Relying Institution, such as:

- State and local laws & regulations
- Institutional policies
- Local factors
- Ancillary reviews
Providing site-specific information in the customizable sections of the Reviewing IRB’s consent form, such as:

- Compensation for injury language
- Variations in costs
- Local contact information
Conflicts of Interest (COI)

- Maintain & share COI policies
- Perform COI analysis (unless alternate arrangement agreed upon with Reviewing IRB)
- Communicate COI determinations (e.g., management plans, restrictions) to the Reviewing IRB
- Abide by Reviewing IRB COI determinations
Work with Reviewing IRB to establish whether a separate HIPAA authorization form or combined consent/authorization will be used for the research.

Provide any language specific to the Relying Institution to the Reviewing IRB.

Notify the Reviewing IRB of any specific local requirements and restrictions on use and disclosure of protected health information (PHI) that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization for the Relying Institution.
If a separate HIPAA authorization form will be used, the Relying Institution will ensure:

1. The accuracy of the information within the form
2. Compliance of the form with the HIPAA Privacy Rule
3. That the form permits PHI to be used by and disclosed to the Reviewing IRB, the Reviewing IRB Institution, and all Relying Institutions as necessary for conducting, reviewing and overseeing the Research (including investigation and evaluation of events)
Injury Coverage

Ensuring the provisions of any applicable grant or contract that address financial coverage for research-related injuries in connection with research:

Are consistent with the approved research protocol and consent form

OR

That the approved research protocol and consent form, if more protective of human subjects, will control
Complaints

The Relying Institution must have an institutional mechanism by which complaints about the research can be made by local research participants or others to a local contact.
Cooperates When the Reviewing IRB or Reviewing Institution Requests an Audit

- Provide research records and related information
- Meet with representatives from the Reviewing IRB/Reviewing IRB institution
- Help to carry out corrective action(s), as applicable
- Report its findings to the Reviewing IRB/Reviewing IRB Institution within a reasonable timeframe in the case of its own or a joint investigation
- Comply with all corrective actions required by the Reviewing IRB/Reviewing IRB Institution
Reporting to Regulatory Agencies

1. Promptly providing any comments on any draft report from the Reviewing IRB/Reviewing Institution

2. If the Reviewing IRB/Reviewing IRB Institution requests the Relying Institution make the report, promptly prepare the draft report and provide the Reviewing IRB/Reviewing IRB Institution with the opportunity to review and comment on the draft report.

3. If the Relying Institution elects to make its own additional report, provides a copy to the Reviewing IRB/Reviewing IRB Institution.

4. Promptly notify the Reviewing IRB/Reviewing IRB Institution of communications received from FDA, OHRP, and/or other regulatory agencies related to any reporting.
IMPACT OF SINGLE IRB REVIEW ON RELYING INSTITUTIONS
## Impact on Reliance Policy

Institutional policy for ceding review or serving as reviewing IRB should identify:

<table>
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<tr>
<th>WHO</th>
<th>WHAT</th>
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<tr>
<td>can make reliance determinations</td>
<td>research qualifies for reliant review</td>
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Impact on Reliance Process

Institutional process should include:

- Identification of information needed to make reliance decision and how to collect it
- A mechanism for study teams to request reliance arrangements
- A process for handling reliance requests
- A means for ensuring all institutions relying on the IRB are aware of and support reliance agreements (e.g., affiliated hospitals)
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.
### Local HRPP Infrastructure Needs Related to Reliance

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<tr>
<th>Need</th>
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<tr>
<td>A means for ensuring compliance with the terms of the IRB authorization agreement</td>
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<td>A mechanism to ensure non-IRB institutional requirements are met, such as ancillary reviews, clinicaltrials.gov registration and updates, congruency of contract/consent injury language, coverage analysis</td>
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<td>Training for study teams to understand the implications of single IRB review, including responsibilities when research ceded to an external IRB</td>
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<td>Ability to track ceded research to allow the institution to appropriately oversee its research portfolio</td>
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<td>Addressing IRB fees, if the external IRB charges or if serving as a Reviewing IRB under the NIH Single IRB Policy</td>
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<td>Communicating reliance arrangements to grants/contracts and post-approval monitoring personnel</td>
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<td>Addressing situations when the Reviewing IRB will not serve as a Privacy Board or a separate authorization form required</td>
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If you need help:
email
help@smartirb.org
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
## Relying Institutions

<table>
<thead>
<tr>
<th>Resource</th>
<th>Source</th>
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<tbody>
<tr>
<td>Consent Template Requirements (when using an external IRB) – SAMPLE</td>
<td>University of Pennsylvania</td>
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<tr>
<td>This document provides an example of step-by-step guidance to revise</td>
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<td>informed consent form templates when relying on an external IRB.</td>
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<td>FAQs for Research Teams - Relying on an External IRB (Word Template)</td>
<td>SMART IRB</td>
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<tr>
<td>Institutions may use this template to create guidance for study teams</td>
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<td>whose research study is ceded to an external IRB.</td>
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<tr>
<td>Informed Consent Documents: Inserting Local Context Language</td>
<td>SMART IRB</td>
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<tr>
<td>This guidance describes the different roles that may be involved in</td>
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<td>inserting local context language in informed consent documents.</td>
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<td>Online Reliance System</td>
<td>SMART IRB</td>
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<td>Helps investigators and institutions request, track, and document</td>
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<td>reliance arrangements for each study.</td>
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<tr>
<td>Online Reliance System: Sample Reliance Request Form</td>
<td>SMART IRB</td>
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<td>Online Reliance System: Support Center</td>
<td>SMART IRB</td>
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<td>Online Reliance System Terms of Use and Privacy Policy</td>
<td>SMART IRB</td>
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<tr>
<td>Webinar: Responsibilities of Relying Institutions</td>
<td>SMART IRB</td>
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<tr>
<td>Guidance for institutions preparing to serve as a Relying Institution</td>
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<tr>
<td>under the SMART IRB Agreement. Check our homepage for upcoming</td>
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<td>webinars.</td>
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**Note:** The source for each resource is indicated in the 'Source' column.
Questions and Discussion