Reliance Agreement Basics

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Meeting Objectives

Overview
Gain a basic understanding of what reliance is

Eligibility
Learn about what constitutes as eligible for reliance

Execution & Responsibilities
Set-up Instructions / Lead site vs. Participating site responsibilities
What is reliance and why do I need it?
## Why do I need reliance?

<table>
<thead>
<tr>
<th><strong>NIH sIRB Policy</strong></th>
<th><strong>Revised Common Rule</strong></th>
<th><strong>Reduce Burden</strong></th>
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<tbody>
<tr>
<td>January 25, 2018</td>
<td>January 20, 2020</td>
<td>Always been the practice of choice</td>
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<tr>
<td><strong>NIH funded</strong> multi-site studies involving <strong>non-exempt</strong> human subjects research</td>
<td>“Cooperative Research” – more than one institution</td>
<td></td>
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<tr>
<td><strong>“Same protocol”</strong> – same research questions, involving same methodologies and outcomes</td>
<td><strong>Any US site</strong> engages in cooperative research that is <strong>subject to the Common Rule</strong></td>
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<td></td>
<td>45 CFR 46.114</td>
<td>Reduces duplication of efforts and administrative burden</td>
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Reliance Eligibility
Let’s talk about human subjects’ research...

For reliance to take place we need to ensure we are engaged in non-exempt, human subjects research.
Types of IRB Review

1. **Not Research**
   Activities do not meet the regulatory definition of “research”

2. **Not Human Subjects Research**
   Activities do not meet the regulatory definition of research involving “human subjects”

3. **Exempt**
   Research activities involving human subjects that fall into one of the eight categories

4. **Expedited**
   Research activities involving human subjects that involve no more than minimal risk

5. **Reliance Eligible**

6. **Convened IRB**
   Research involving human subjects that does not qualify for Exempt or Expedited review, typically involving greater than minimal risk to subjects.
Reliance Execution
Three Essential Elements

1. IRB approval notice (lead site)
2. IRB Authorization Agreement or IAA (typically SMART IRB)
3. Institutional Authorization (home site)
Harvard Serves as Lead IRB (aka Reviewing IRB, IRB of Record)

1. Harvard Site Team
   • Identify how sites will be involved

2. Harvard Site Team
   • Make sure ESTR app indicates reliance

3. Harvard Site Team
   • Begin either SMART IRB or IAA process

4. Reliance Coordinator
   • Finalize IAA after all sites have completed their portion

5. Reliance Coordinator
   • IAA is attached in ESTR and reliance is confirmed

6. Harvard Site Team
   • Provide notice to sites and add them in ESTR
Harvard Serves as Lead IRB (ESTR app)

Step 2
Visit a main study workspace (in any state), where it is indicated on the Basic Information page of the SmartForm that BOTH:

This is a **collaborative or multisite study**

**AND**

**Harvard will act as the IRB of record** for any project

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4. *What kind of study is this?*
   - Multi-site or Collaborative study
     - Choose 'multi-site or collaborative' where there is more than one site conducting the study, if there is possible collaboration with non-Harvard researchers, or if it is unclear if there will be additional sites.

5. *Will an external IRB act as the IRB of record for this study?*
   - [ ] Yes
   - [x] No

6. *Will your IRB act as the single IRB of record for other participating sites?*
   - [ ] Yes
   - [ ] No

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2. Harvard Site Team

- Make sure ESTR app indicates reliance
Harvard Serves as Lead IRB (Begin IAA process)

Step 3

If both sites are utilizing the SMART IRB platform then an IAA can be initiated through that process

OR

IAA process can occur independently outside of SMART IRB system and an IAA document will be produced separately

SMART IRB Example

https://smartirb.org/reliance/
Harvard Serves as Lead IRB (Reliance Coordinator)

Steps 4 & 5

Reliance Coordinator finalizes IAA in SMART IRB and in ESTR

4. Reliance Coordinator
   - Finalize IAA after all sites have completed their portion

5. Reliance Coordinator
   - IAA is attached in ESTR and reliance is confirmed
Harvard Serves as Lead IRB (Begin IAA process)

Step 6
Each participating site needs to be added in to ESTR

Reliance has not been achieved until receipt that site has been added has been confirmed
Harvard is a Participating Site (aka Relying Site, pSite)

1. Lead Site Team
   • Works together with Harvard to determine what study activities are occurring at this site

2. Harvard Site Team
   • Make sure ESTR app indicates collaboration (include IRB approval letter from lead site)

3. Harvard Site Team
   • Work with Lead Site to complete IAA either through SMART IRB or via individual agreement.

4. Reliance Coordinator
   • Finalize IAA after all sites have completed their portion.

5. Reliance Coordinator
   • IAA is attached in ESTR, reliance is confirmed, and a letter is issued.
Harvard is a Participating Site (ESTR app)

Step 2

Visit a main study workspace (in any state), where it is indicated on the Basic Information page of the SmartForm that BOTH:

This is a **collaborative or multisite study** AND
**Harvard will act as the IRB of record** for any project

It will also be important to fill in the Basic Local Site and External IRB information
Harvard is a Participating Site (Begin IAA process)

Step 3

If both sites are utilizing the SMART IRB platform then an IAA can be initiated through that process

OR

IAA process can occur independently outside of SMART IRB system and an IAA document will be produced separately

SMART IRB Example

https://smartirb.org/reliance/

3. Harvard Site Team

- Work with Lead Site to complete IAA
Step 4

Reliance Coordinator finalizes IAA in SMART IRB or through other methods

Harvard is a Participating Site
(Reliance Coordinator)

4. Reliance Coordinator

- Finalize IAA after all sites have completed their portion
Harvard is a Participating Site
(Reliance Coordinator)

Step 5
Reliance Coordinator will send a letter from the ESTR system confirming the reliance process. It will note the institution providing oversight.
Lead Site Responsibilities

The lead site is responsible for providing IRB review of the study just as they would be independent of reliance – but for ALL sites.

While the lead site is ultimately “in charge”, the participating site is not without monitoring responsibilities.

Participating Site Responsibilities

HRPP at participating sites will be responsible for meeting all of its current related responsibilities described in the HHS regulations (45 CFR 46)

- reviewing conflicts of interest
- radiation safety
- ensuring that site investigators obtain informed consent from prospective research participants
- ensuring that site investigators meet local training requirements
- overseeing the implementation of the approved protocol
- reporting local unanticipated problems involving risks to subjects or others, and study progress to the single IRB.
What are the PI responsibilities?

**Lead Site PI**
- Appendix D (Investigators Manual)

**Relying Site PI**
- Appendix E (Investigators Manual)
References & Resources


Questions ?
Thanks!

Do you have any questions?
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