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Reliance Agreements

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What is a Reliance Agreement?

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research.

A Reliance Agreement can be in many different forms, but some of the main agreements are:

- Institutional Authorization Agreements (IAA)
- Memorandum of Understanding (MOU)
- Master Reliance Agreement (MRA).

What is a Reliance Agreement? Cont.

Investigators working at multiple institutions, each having an IRB, may choose to have one IRB become the IRB of record over some or all participating sites (commonly referred to as ceded review, reliance agreements, or deferral of IRB oversight.)

Institutional Authorization Agreement (IAA)

An IAA is an agreement between your institution and another institution that holds a Federal Wide Assurance (FWA) with the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS).

- This agreement type is used to establish the IRB-of-Record. The IAA is signed by the Institutional Officials or designee at each institution.
- Each institution listed must have an FWA

Memorandum of Understanding

An MOU may be drafted to acknowledge an ongoing and strategic relationship between institutions that is intended to be long term, and/or to support a specific research study. The information in the agreement generally describes a very broad concept of mutual understanding, goals, and plans shared by the parties. It may also list areas of possible joint activities, without creating financial obligations or committing resources.

Master Reliance Agreement (MRA)

An MRA can be utilized when multiple studies are ceding review to a specific external IRB. Master Agreements may be reciprocal in that signatory institutions can act as the site providing IRB review and oversight or the site relying. Master Reliance Agreements may be for a single protocol or a number of protocols and are negotiated on a case by case basis.

Individual Investigator Agreement (IIA)

An IIA is an agreement between an institution and an individual collaborator who is not affiliated with an FWA institution. This agreement type outlines the responsibilities of the individual investigator for the protection of human subjects.

The IIA should be signed by:

- Individual Investigator
- Principal Investigator (PI)
- Institutional Official or designee

Key Tips

Key Tip 1

Create a template specific to your institution

- What is important to your institution?
- Outline responsibilities.
- Specific language outlining life of agreement.
- Determine which forms should be made available to research teams or those that you would want the study team to engage with you prior to execution.

Key Tip 2

IRB Reliance Email Address

- Method to streamline communication.
- Metrics measurements.

Key Tip 3

Master Agreements

- Minimize multiple agreements per institutions/studies.
- Local Context Information for each institution.
- SmartIRB (https://smartirb.org/)
  - Numerous Resources
  - Checklists
  - Initiated by Overall PI or designee

Key Tip 4

Maintain agreements in an open source available to all staff

- Electronic IRB System/Shared Folder.
- Final Executed Versions of Agreements.

Key Tip 5

Develop resources for research community

- Dedicated Reliance Webpage.
- SOP's (Cede/Rely_IRB of Record) outlining steps and responsibilities.
- High Level Workflow Information.

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eIRB+ Overview and Instructions

News & Announcements

IRB Closed for Independence Day Holiday
The IRB Office on both campuses will be closed Tuesday, July 4, to celebrate the Independence Day holiday. Read More »

IRB Closed for Memorial Day Holiday
The IRB Office on both campuses will be closed in observance of the Memorial Day holiday. Read More »

ATTENTION: eIRB+ Outage

Events

Jul 19 — Chicago
Reliance Agreements
More information

Aug 16 — Chicago
Single IRB (NIH Policy)
More information

Sep — Chicago
Media Relations (How

Information

- Need to Report A Concern?
- eIRB+ FAQs
- Research Participants
- AAHRPP Accreditation
- IRB Members
- CRC Researchers

Key Reminders

- Finalize Institutional Decisions Surrounding Single IRB Review.
- Review All Applicable Requirements/Guidelines for Single IRB Review.
- Institutional Reviews Must Still Remain a Part of Final Study Approval.
- Remember State Law Requirements for Human Research Vary per State.
- Create a Tracking Method for Agreements.
- Maintain Institution to Institution Communication when Executing an Agreement.
- We Are All In This Together!!!!

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Reliance Agreements: Compliance Perspective

Eileen Yates
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Northwestern University IRB Office

SACHRP committee recommendations- IRB Key Responsibilities

- **Monitoring and Auditing**
  - Agreement must identify which IRB/Institution will have responsibility for monitoring and auditing or otherwise supervising
    - Routine activities
    - For-cause investigations
- **Complaints from Research Participants**
  - Establish a notification process
  - Work together towards resolution
- **Responsibility for Conducting Investigations**
  - While the reviewing institution has the authority to conduct fact finding investigations, the reviewing IRB will need to rely on obtaining information from the relying institution, since the relying institution typically have the greater need and capacity to manager the fact finding investigation.
- **Reporting Responsibilities**
  - IRBs have reporting responsibility to officials, regulatory agencies, etc.

SACHRP- https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-november-2-2016-letter/index.html

NIH-Single IRB Policy for Multi-site Research (FAQs)

Section E. Reliance Agreements

(7) **What should be documented in a Reliance Agreement?**

In general, a reliance agreement should describe the responsibilities of all parties, and how communication between parties will occur, for example, notification of the outcome of regulatory review, how protocol changes will be handled and who will responsible for reporting of unanticipated problems and non-compliance

Section F. Responsibilities of the Single IRB and Participating Sites

(4) **The NIH single IRB policy states specific responsibilities for the Awardee, such as maintaining copies of Reliance Agreements and other documentation. May the awardee delegate tasks to another person or institution?**

Yes. As noted in the NIH single IRB policy, responsibilities may be delegated, as appropriate, and as specified in Reliance Agreements.

(5) **How will the single IRB be made aware of a participating site's local context?**

Participating sites need to inform the single IRB about relevant local context issues (e.g., state laws). A communication plan should be developed as part of the Reliance Agreement and should describe how such communication will be handled.

(6) **What should the single IRB in an NIH-funded multi-site study do if serious or continuing non-compliance with the protocol is suspected or identified at a participating site?**

These responsibilities should be defined in the Reliance Agreement. In general, the single IRB will refer instances of serious or continuing non-compliance to OHRP and/or the FDA, the participating sites' IRBs and the funding NIH Institute or Center as required.

NIH- https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm

Assessment

- **Current Practice**
  - How is monitoring/auditing/external reporting currently being done?
  - What change may occur as a result of becoming a single IRB?
- **Communication Plan**
  - How do I communicate currently with affiliates?
- **Resource assessment**
  - What are my current resources?
  - Do I have data to adequately forecast future needs?
- **Network/Establishing Best Practices**
  - NCATS SMART IRB Platform
    - https://ncats.nih.gov/expertise/clinical/smartirb
  - AAHRPP- new standard I-9
    - https://admin.aahrpp.org/Website%20Documents/Standard%20I.9%20(2017-10-04).pdf

Remember:

The reliance agreement is paramount, but do not underestimate the importance of:

- ✓Communication
- ✓Compliance

Contact Information

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QUESTIONS?