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# Single IRB

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IRB Reliance and Education Lead

# NIH Single IRB Policy

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.

This policy, which is consistent with 45 CFR Part 46.114, is intended to:

- Enhance/streamline IRB review process in multi-site research
- Eliminate duplicative IRB review
  - Reduce administrative burdens/inefficiencies
  - Maintain human subject protections
  - All IRB's to concentrate on single site protocols

# NIH Single IRB Policy cont.

Effective date: January 25, 2018

- Applies to: Domestic sites of NIH funded studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported by grants, cooperative agreements contracts or the NIH Intramural Research Program.  It does not apply to Foreign Sites, career development (K), research training (T) or fellowship awards (F) and current awards.
- Exceptions: VA sites; international sites; sites involving tribal nations.

# Roles and Responsibilities

Applicant/Offeror: Submit a plan describing the use of a Single IRB that will be the IRB of Record for all study sites. NIH acceptance will incorporate the plan into the terms and conditions of the award.

Awardees: Ensure authorization agreements are in place and ensure communication between the Single and participating sites.

Funding Institute or Center: Manage and oversee awards, communicate with awardee about the Single IRB compliance plan.

# Roles and Responsibilities cont.

## Overall PI and Lead Study Team

### Overall Study PI

- Assumes leadership and responsible for conduct of the research
- Designates the Lead Study Team

### Lead Study Team

- Submits materials to the Reviewing IRB for all sites, including study-wide and site-changes of protocol, continuing reviews, and reportable events
- Provides draft study materials to all site study teams, including proposed consent form template
- Provides IRB-approved study documents to all sites
- Communication Plan

# Single IRB Plan

A Single IRB Plan should include the following elements:

- Name of the sIRB of record
- Indicate that: (1) All sites, including any added after award, agree to rely on the sIRB; (2) Sites will sign a reliance agreement that will include a communication plan; (3) Indicate who will maintain records of the reliance agreements

# Single IRB Selection

- Identify the “lead” institution for the proposal and allow that institution “right of first refusal” to be the sIRB for all participating sites.
- NIH reserves the right to refuse the selected sIRB.

# Reviewing IRB Responsibilities

The selected sIRB is responsible for:

- Review of study and each site including any local context specific to the conduct of research.
- Mechanism for notifying each site of IRB review outcomes (i.e. initial review, modifications, continuing review, etc.).
- Maintaining Reliance Agreements for each site.

# Relying Site Responsibilities

The selected relying site is responsible for:

- Providing local context information to the reviewing IRB.
- Not initiating any study procedures without External IRB approval specific to their site.
- Providing their local IRB with information regarding External IRB review.
- Ensuring the lead site PI is notified immediately of any reportable events that occur.
- Establishing a point of contact for their site.

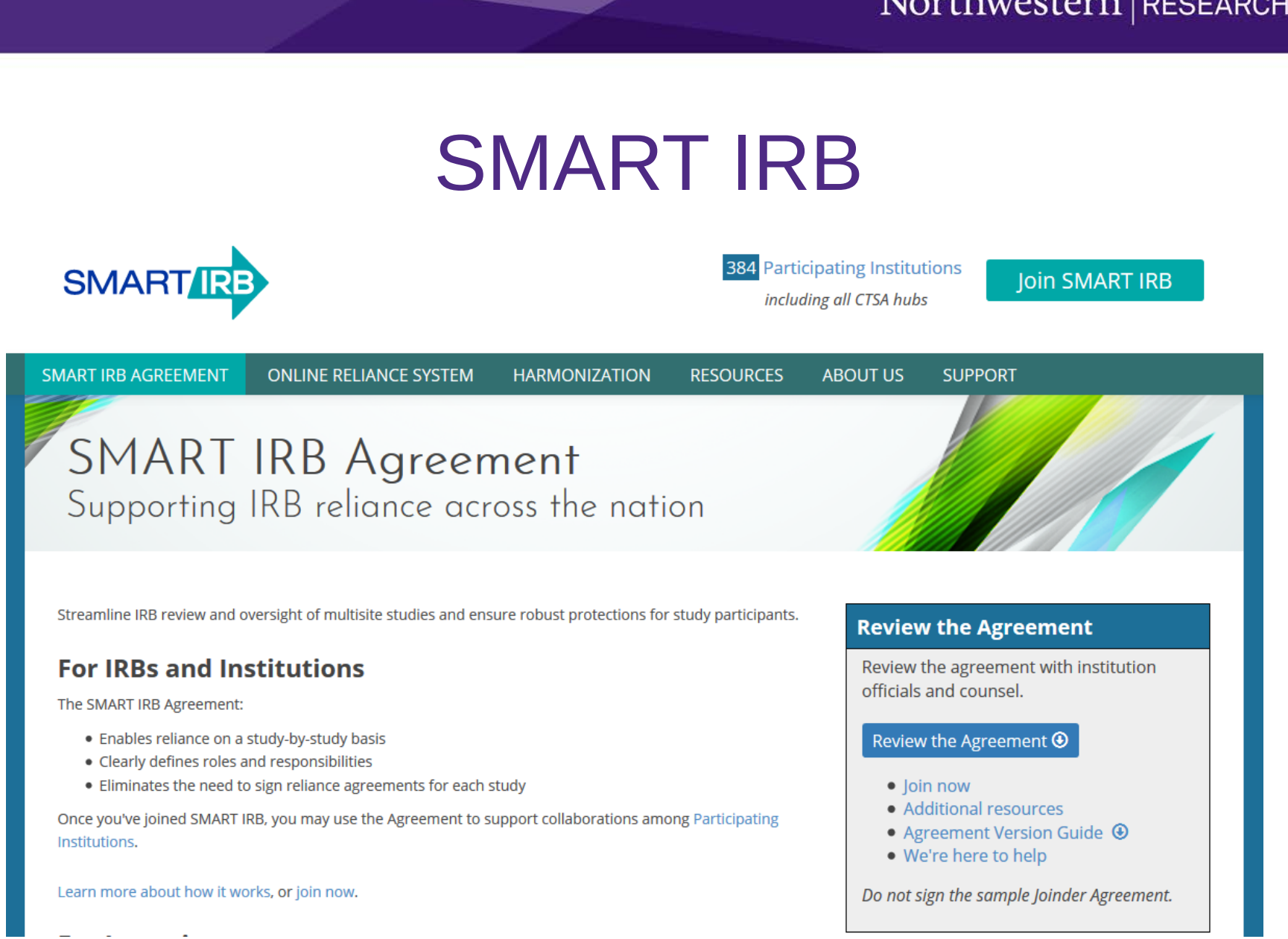
# Reliance Agreements

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.

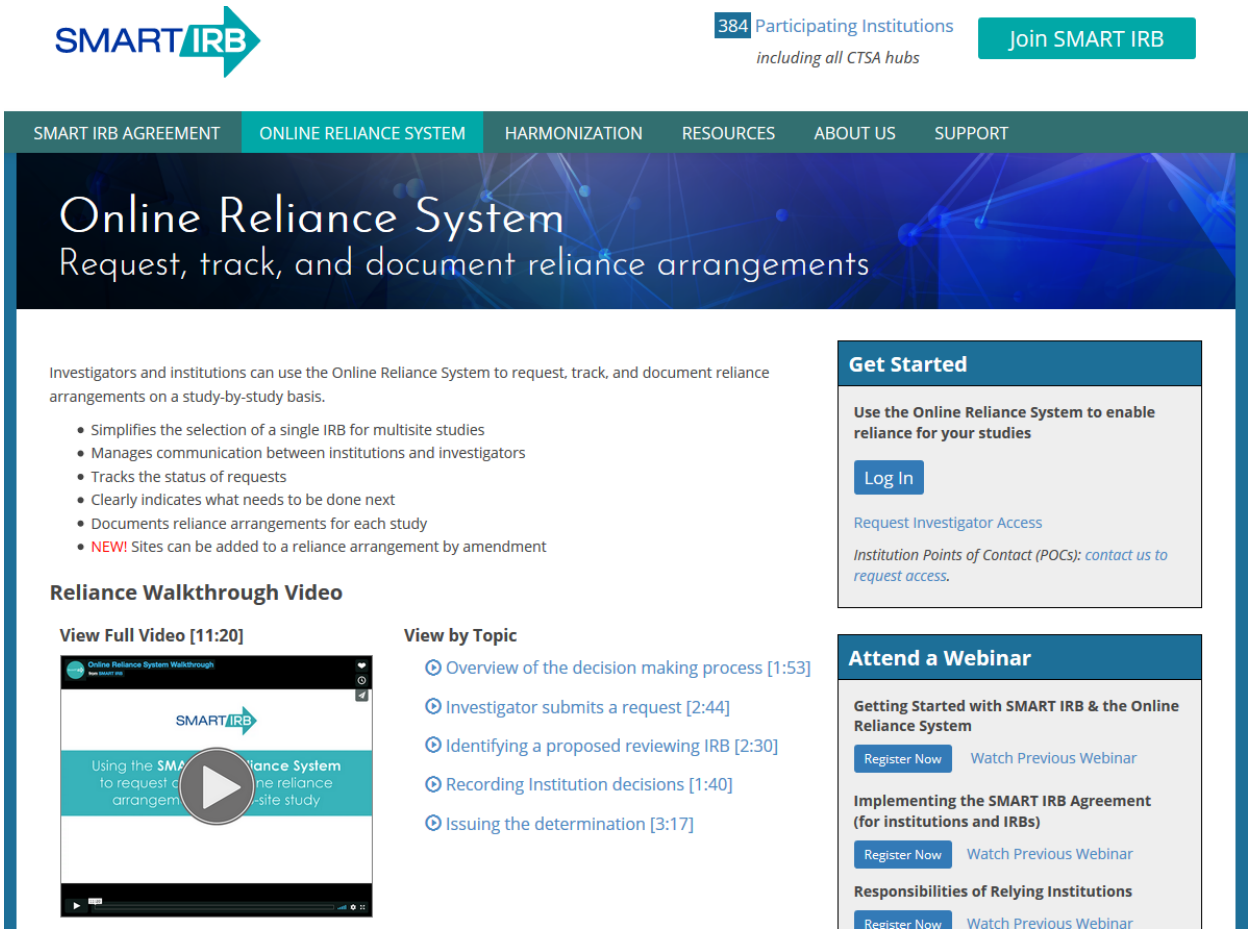
A Reliance Agreement can be in many different forms, but some of the main agreements are:

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

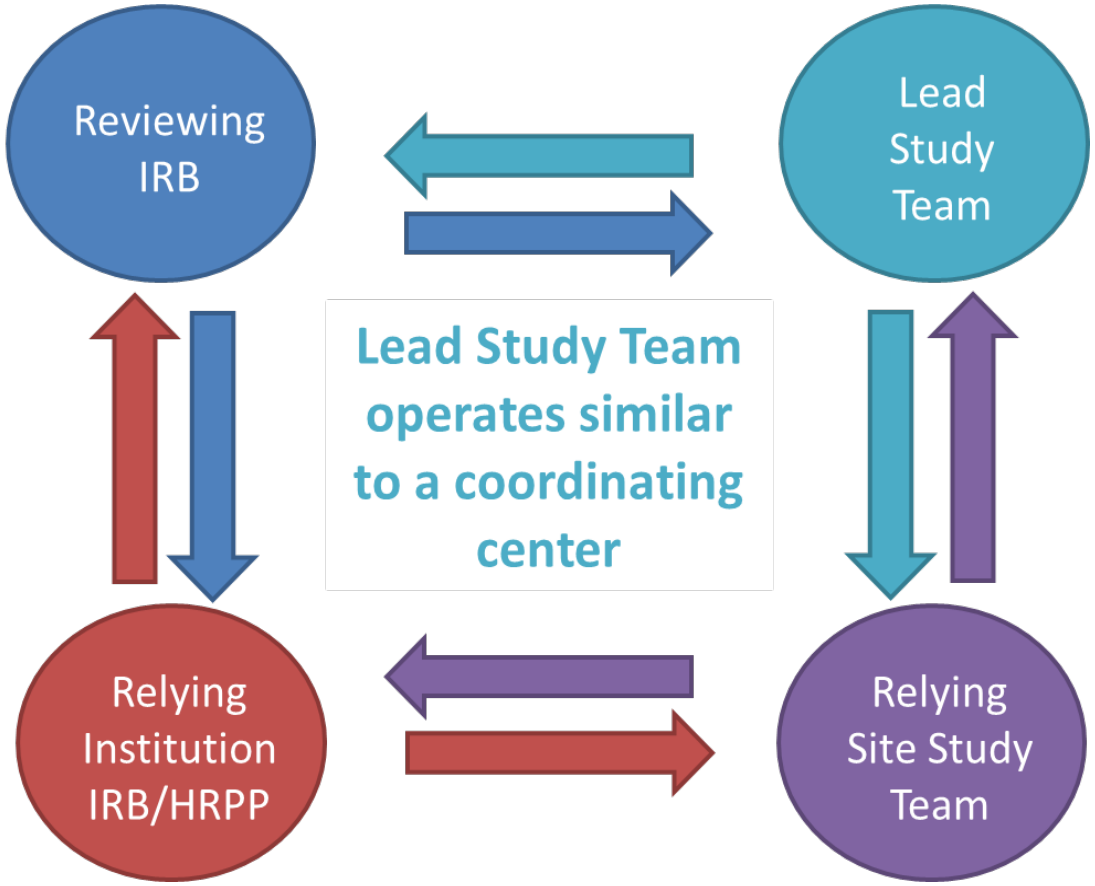
# SMART IRB


SMART IRB
384 Participating Institutions
including all CTSA hubs
Join SMART IRB
SMART IRB AGREEMENT
ONLINE RELIANCE SYSTEM
HARMONIZATION
RESOURCES
ABOUT US
SUPPORT
SMART IRB Agreement
Supporting IRB reliance across the nation
Streamline IRB review and oversight of multisite studies and ensure robust protections for study participants.
For IRBs and Institutions
The SMART IRB Agreement:
Enables reliance on a study-by-study basis
Clearly defines roles and responsibilities
Eliminates the need to sign reliance agreements for each study
Once you've joined SMART IRB, you may use the Agreement to support collaborations among Participating Institutions.
Learn more about how it works, or join now.
Review the Agreement
Review the agreement with institution officials and counsel.
Review the Agreement
Join now
Additional resources
Agreement Version Guide
We're here to help
Do not sign the sample Joinder Agreement.

# SMART IRB cont.



# SMART IRB Communication Model



# NIH Single IRB Implementation Plan (Phase 1)

- Pre-Consultation
- Dedicated Webpage
- Template Letters of Support
- SOP's (HRP-092_External IRBs and HRP-093_NU IRB_IRB of Record for Multi-Site Research)
- OSR/IRB Workflow
- Independent/Commercial IRB Questionnaire

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- **MODIFICATIONS**
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- **REPORTABLE NEW INFORMATION**
- **COMPLIANCE AND AUDITS**

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*

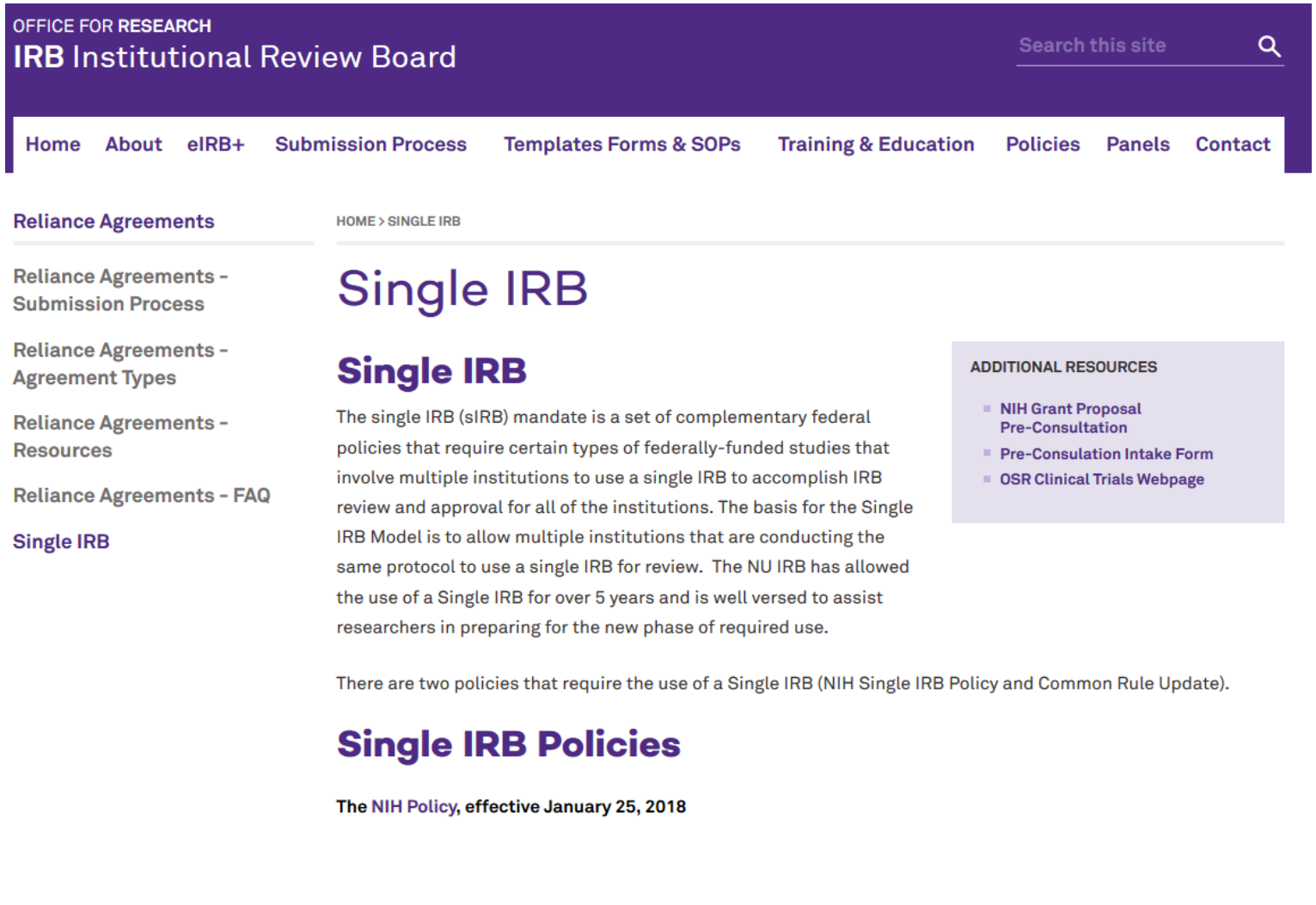
Aug 16 — Chicago
**Single IRB (NIH Policy)**
*More information*

Sep — Chicago
**Media Relations (How**

## Information

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

# Single IRB Webpage



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## Single IRB

### Single IRB

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. The basis for the Single IRB Model is to allow multiple institutions that are conducting the same protocol to use a single IRB for review. The NU IRB has allowed the use of a Single IRB for over 5 years and is well versed to assist researchers in preparing for the new phase of required use.

ADDITIONAL RESOURCES

- NIH Grant Proposal Pre-Consultation
- Pre-Consulation Intake Form
- OSR Clinical Trials Webpage

There are two policies that require the use of a Single IRB (NIH Single IRB Policy and Common Rule Update).

### Single IRB Policies

**The NIH Policy, effective January 25, 2018**

# Pre-Consultation

During pre-consultation, the NU IRB will evaluate on a case-by-case basis whether we are suited to serve as the sIRB for the proposed multi-site project.

- The risk level of the proposed research
- Number of sites
- The experience level of the NU PI
- Whether the NU site is the main funded site of the grant
- Conflict of Interest Assessment

# Pre-Consultation Intake Form

**Record ID**

**Name**
* must provide value

**Email**
* must provide value

**PI Name (If different than above)**

**NIH Grant Type**
* must provide value

**NIH Proposal Due Date**
* must provide value
Today M-D-Y

**Research Type**
* must provide value
○ Biomedical
○ Social-Behavioral
reset

**InfoEd ID Number**
* must provide value

**Type of IRB Request**
* must provide value

**Study Synopsis (Please provide a brief description of the proposed research)**
Expand

Response Options:

1, NU IRB_IRB of Record for Overall Study and External Sites
2, NU IRB_Ceding Review to an External IRB

# eIRB+ Multi-Site Process

STU00206919: Multi-Site Test Study (MO)

**Principal investigator:** Marcella Oliver
**Submission type:** Initial Study
**Primary contact:** Marcella Oliver

**IRB office:** IRB Office
**IRB coordinator:** Marcella Oliver
**Regulatory authority:** Pre-2018 Requirements


This project has at least one unsubmitted project site(s). Make sure you have completed all required information for each site, so the IRB Office can review them. You can access them in the Sites tab below.

History | Sites | Funding | Project Contacts | Documents | IRB Assignment Details | Reviews | Study Team Training | Snapshots

Filter | Activity | Enter text to search for | Go | + Add Filter | ✖ Clear All

Activity | Author | ▾Activity Date

# eIRB+ Multi-Site Process cont.

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**Submission type:** Initial Study
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## Participating Sites

| ID | Name | SmartForm | Institution | Principal Investigator |
|---|---|---|---|---|
| IRBSITE00000021 | Columbia University IRB Participating Site for Multi-Site Test Study (MO) | [Edit] | Columbia University IRB | Marcella Oliver |

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# NIH Single IRB Implementation Plan (Phase 2) – Coming Soon!

- Single IRB Plan Template
- Updated Authorization Agreement Templates
- Fee Structure Analysis
- Process Analysis
- Investigator Workgroup


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# Contact Information

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# QUESTIONS?