SMART IRB & Reliance Processes

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HUMAN RESEARCH PROTECTIONS PROGRAM
Reliance Mandates

• NIH - Single IRB for Multi-Site Research
  – Compliance date: January 25, 2018

• Revised Common Rule 45 CFR 46 - Single IRB for Cooperative Research
  – Compliance date: January 20, 2020
(a) Cooperative research projects are those projects covered by this policy that involve more than one institution.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
**sIRB – Common Rule**

- Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

- (c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.
sIRB Common Rule

• Exceptions:

  – Research approved prior to January 2020
Common Rule Agencies

- Department of Agriculture
- Department of Energy
- NASA
- Department of Commerce
- Agency for International Development
- Department of Defense
- Department of Education
- Department of Homeland Security
- Department of Veterans Affairs
- Department of Labor
Common Rule Agencies

• Environmental Protection Agency
• Department of Health and Human Services
• National Science Foundation
• Department of Transportation
• Office of the Director of National Intelligence
• Central Intelligence Agency
• Consumer Product Safety Commission
• Social Security Administration
sIRB - NIH

• The National Institutes of Health (NIH) issued this policy on the use of a single Institutional Review Board (IRB) for multi-site research

• Establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.
sIRB NIH

• Goal
  – Enhance and streamline the IRB review process in the context of multi-site research
  – Research can proceed as effectively and expeditiously as possible.
• Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections.
• The shift in workload away from conducting redundant reviews is also expected to allow IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight.
Food and Drug Administration

- The Food and Drug Administration (FDA) is an HHS agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices.

- FDA is not considered a Common Rule agency because its regulations differ from the Common Rule. However, FDA is required to harmonize with the Common Rule whenever permitted by law (see section 1002 of the 21st Century Cures Act, Public Law 114-255)
• On September 28, 2022, the U.S. Food and Drug Administration ("FDA") issued two Notices of Proposed Rule Making to harmonize FDA’s regulations pertaining to human subjects research and the review of cooperative research by a single institutional review board with those of the Federal Policy for the Protection of Human Subjects.

Stay tuned.............
Processes

* Reliance on an external IRB
  • Multi-site/cooperative
  • CICERO - Truncated application
  • Regardless of funding

* UMB is IRB of record
  • Multi-site/cooperative
  • CICERO – Full application
  • Regardless of funding
Reliance Processes

• CICERO
  • Departmental review

• Ancillary reviews
  – Conflict of interest
  – Radiation Safety (RSC)
  – Institutional Biosafety (IBC)
  – Investigational Drug Service
  – GCRC (as applicable)
Reliance

• SMART IRB
  – Platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018).
  – https://smartirb.org/
  – Provides an easy way for investigators and institutions to track and document reliance arrangements on a study-by-study basis.
SMART IRB

- SMART IRB
  - Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform
  - Designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants.
SMART IRB

- Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.
SMART IRB

Learning Center for Investigators and Study Teams

The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution’s SMART IRB Point of Contact.

SMART IRB Start-Up Packages

- Start-Up Packages
- Introduction to sIRB Review
- NIH sIRB Policy
- Selecting an sIRB
- Developing an sIRB Plan
- Effects on Research Costs
- Study Team Roles
- Online Reliance System

These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understand and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included resources.
SMART IRB

• SMART IRB
  – Is not an IRB
  – Rather, it's a platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System)
  – Provides a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements.
SMART IRB

• Master Common Reciprocal Institutional Review Board Authorization Agreement

• Institutional Profile

• 1042 participating institutions

  – CTSA hubs and affiliates, universities, academic medical centers, community hospitals, cancer centers, independent IRB organizations
SMART IRB

• Master Reciprocal Agreement

• Reliance requests
  – Institutional official
  – Reviewed individually
  – Approved/acknowledged on a case-by-case basis
RESOURCES
RELIANCE PROCESSES

• Consult with the UMB Human Research Protections Office prior to grant submissions and IRB submissions
  – Reliance on external IRB
  – Grant letter of support
Getting Started

Required Trainings:

– Collaborative Institutional Training Initiative (CITI)
  • [www.citiprogram.org](http://www.citiprogram.org)
  • Course in the Protection of Human Subjects
  • Good Clinical Practices (NIH)
  • Affiliate with University of Maryland, Baltimore or Baltimore, MD-512 (VA)
    • *Note: CICERO account and CITI account are not linked!*

– HIPAA 125: Privacy and Security Review

– HIPAA 201: Human Research
Reliance Processes

• Simultaneously
  – Submit in CICERO
  – Submit in SMART IRB
    • Collaborate with other study sites
    • Roles differ based on who is IRB of record
SMART IRB Agreement
Supporting IRB reliance across the nation

⚠️ Now Available: SMART IRB Agreement v2.0

SMART IRB Agreement v2.0 incorporates revisions to the original SMART IRB Agreement that enable the NIH to participate in the Agreement. Further explanation of these changes and of the implications for Participating Institutions are provided in the cover memo and accompanying FAQs below.

As of October 1, 2020, any new institutions will sign the Joiner Agreement for SMART IRB Agreement v2.0. Current Participating Institutions may sign the updated Agreement to facilitate collaboration with NIH. For more details, see SMART IRB’s website. The Participating Institutions

Review the Current Agreement (updated October 1, 2020)

Before joining SMART IRB, review the current agreement with institution officials and counsel.

Review the Current Agreement 📡
We're Here to Help

**Investigators:** Submit/view a reliance request on the [Online Reliance System](https://smartirb.org/support/).

**IRB/HRPP Staff:** Update institution information in Joinder; view pending requests in the [Online Reliance System](https://smartirb.org/support/).

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**Joining SMART IRB**
Representing regions throughout the US, ambassadors are available to assist institutions in joining and implementing the SMART IRB Agreement.

- [Find your ambassador](https://smartirb.org/support/)

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**Expert Advice and Guidance**
Prepare to serve as a Reviewing IRB or Relying Institution. We'll connect you with other IRBs experienced in the conduct, review, and oversight of multisite research.

- [Request a consultation](https://smartirb.org/support/)

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**Help with another topic**
If you have a question about SMART IRB or the Online Reliance System, check out the Support Center, or send an email to help@smartirb.org.

- [Search Support Center](https://smartirb.org/support/)
Ask questions!

- IRB Reliance Analyst – Scott Evans
  - sevans@umaryland.edu
- IRB Manager – Jan Martinez
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- Assistant Vice President, Research Compliance
  - Julie Doherty – jdoherty@umaryland.edu
- Contact information is available at
Questions?

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