



SMART TALK

A Community Forum to Explore
Issues Surrounding Single IRB
Review

Funded by the NIH National Center
for Advancing Translational Sciences
through its Clinical and Translational
Science Awards Program, grant
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What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

September: A Conversation with the FDA about Single IRB

October: Single IRB and Noncompliance - A Case Study

FYIs

Please provide feedback by completing the survey - a link will be posted in chat and emailed.

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

Reminder: OHRP Issued Draft Guidance about Single IRB

Submit written comments by August 30, 2022.

Federal Register Notice at:

<https://www.govinfo.gov/content/pkg/FR-2022-07-01/html/2022-14123.htm>

The screenshot shows the OHRP website navigation menu with the following items: About OHRP, Regulations, Policy & Guidance, Education & Outreach, Compliance & Reporting, News & Events, Register IRBs & Obtain FWAs, SACHRP Committee, and International. Below the menu is a breadcrumb trail: HHS > OHRP > Regulations, Policy & Guidance > Requests for Comments > Use of a Single Institutional Review Board for Cooperative Research. The page header includes a text resize tool (AAA), a print icon, and social media share icons for Facebook, Twitter, and Email. The main content area displays the title "Use of a Single Institutional Review Board for Cooperative Research" and a note: "NOTE: These Frequently Asked Questions are consistent with the 2018 Requirements (i.e., the revised Common Rule)." Below the note is the word "Draft".

Access the draft guidance at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-use-single-institutional-review-board-for-cooperative-research/index.html>



Everything You Wanted to Know about Single IRB but Were Afraid to Ask

Panelists: SMART IRB Ambassadors* and Advisors

- Aaron Kirby*, Harvard Catalyst
- Ada Sue Selwitz*, University of Kentucky
- Carissa Minder*, Washington University in St. Louis
- Jonathan Green, NIH Office of Human Subjects Research Protections
- John Baumann*, Indiana University
- Kathy Lawry*, AAHRPP
- Lubabah Helwani*, University of California, Los Angeles
- Mike Linke, University of Cincinnati
- Polly Goodman*, Harvard Catalyst
- Stacey Goretzka*, Medical University of South Carolina

Moderator: Nichelle Cobb*, Senior Advisor for SMART IRB and Senior Advisor for Strategic Initiatives for the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

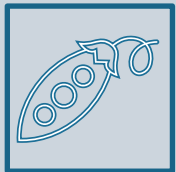
A few questions and
answers to start off with...



What Is Single IRB Review?



Single IRB review refers to the use of one IRB to review and approve all or most sites participating in a multisite research study, rather than each site obtaining approval for their activities from a different IRB.



Other terms for a single IRB include:

Central IRB

Reviewing IRB

What Is SMART IRB?



SMART IRB is...

A federally funded project to support institutions and researchers in the implementation of single IRB



SMART IRB provides...

A master IRB reliance agreement
An Online Reliance System to initiate and track reliance
Other resources free to institutions and researchers



SMART IRB is NOT...

An IRB
An electronic system for Reviewing IRBs to receive studies for review

Where to start in understanding Single IRB?

A Selection of Previous SMART Talks and Webinars

- A Conversation with NIH and OHRP about Single IRB
- Process for Review of PI and Non-PI Personnel for Multi-Site Studies
- Recommendations for Harmonization of Post-Approval Auditing of Studies Subject to sIRB Review
- Relying Institution Roles, Responsibilities, and Opportunities
- Reviewing IRBs: Working with Relying Institutions and Study Teams
- Single IRB & Continuing Review
- Single IRB for Social, Behavioral, and Education Research
- Single IRB from the Perspective of Research Teams
- Single IRB Resources: What, When, Why, & How to Use Them
- Tackling Informed Consent under the Single IRB Model

Available at

<https://smartirb.org/resources/>

SMART IRB Boot Camp



SMART IRB AGREEMENT ONLINE RELIANCE SYSTEM HARMONIZATION LEARNING CENTER RESOURCES ABOUT US SUPPORT

Learning Center for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements.

| | | | | |
|------------------------|----------------------------|------------------|-----------------------|----------------------|
| Start-Up Packages | Implementing the Agreement | Reviewing IRBs | Relying Institutions | Getting Started |
| Online Reliance System | Resources for IRB/HRPPs | SMART Talk Forum | sIRB Boot Camp | Training Study Teams |

Single IRB Boot Camp: a How-to Guide with SMART IRB

This online session, held February 8 & 10, 2022, provided training for IRB and HRPP personnel on successful implementation of the sIRB review model and demonstrated how to leverage SMART IRB resources to achieve that success. Watch session recordings and download slides below.

sIRB Boot Camp Day 1: Watch full session [View Day 1 Slide Deck](#)

- Welcome and Objectives
- Reliance Requests
- Using the SMART IRB Agreement
- What HRPPs Need in Place for Single IRB Review

Available at

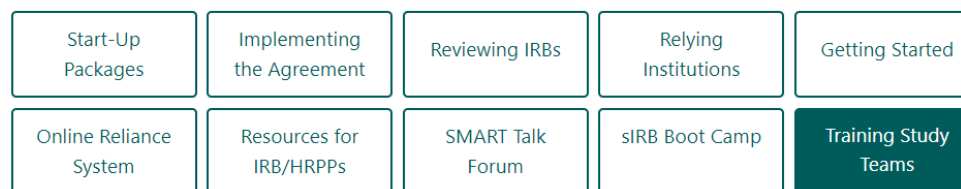
<https://smartirb.org/irb-admin/>

Training and Education for Investigators and Study Teams

These can be helpful for IRB/HRPP administrators new to single IRB as well!

Learning Center for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements.



Training for Investigators and Study Teams

Use this suite of training videos and resources as is, or customize to reflect local processes and policies.

Visit the [Investigator and Study Team Learning Center](#) to view available materials; send investigators here for self-guided learning.

⬇ Download presentations (no audio) to use for local training sessions or customize to reflect local processes.

To download the presentations with embedded audio, please use the links below:

- ⬇ Developing a Single IRB Plan
- ⬇ Overview of the NIH Single IRB Policy for Researchers
- ⬇ Potential Effects of Single IRB on Research Costs
- ⬇ Selecting a Single IRB
- ⬇ Single IRB review and SMART IRB
- ⬇ Study Team Roles Related to Single IRB

Harmonization Steering Committee Recommendations

<https://smartirb.org/harmonization/>

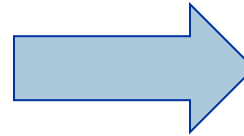
- Ancillary Review
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance

In progress:
Local
considerations
recommendations

Request for a basic overview of the different federal registrations, IORG# vs FWA etc.

What is an Federalwide Assurance (FWA)?

An FWA is the type of assurance required by HHS but is also accepted by all other Common Rule agencies



Some agencies, like the VA, require addenda to an FWA to obligate an institution to agency-specific requirements.

FWAs and “Checking the Box”?

- The FWA includes an “Applicability” section which allows institutions to voluntarily apply the Common Rule, including all of its Subparts, to all of their research regardless of the source of support
- When institutions voluntarily apply the Common Rule to all of their research, this is called “checking the box”

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

(b) *Optional for U.S. institutions:* This Institution voluntarily elects to apply the following to all of its non-exempt human subjects research regardless of the source of support, except for research that is covered by a separate assurance issued by another U.S. federal department or agency that has adopted the Common Rule:

The Common Rule (see section 3 of the Terms of the FWA for a list of U.S. federal departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations) **OR**

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46

This part is required for every institution

This part is voluntary and requires an institution to literally check a box

IRB Registration

An FWA requires an organization to designate any internal IRB(s) that it will rely on

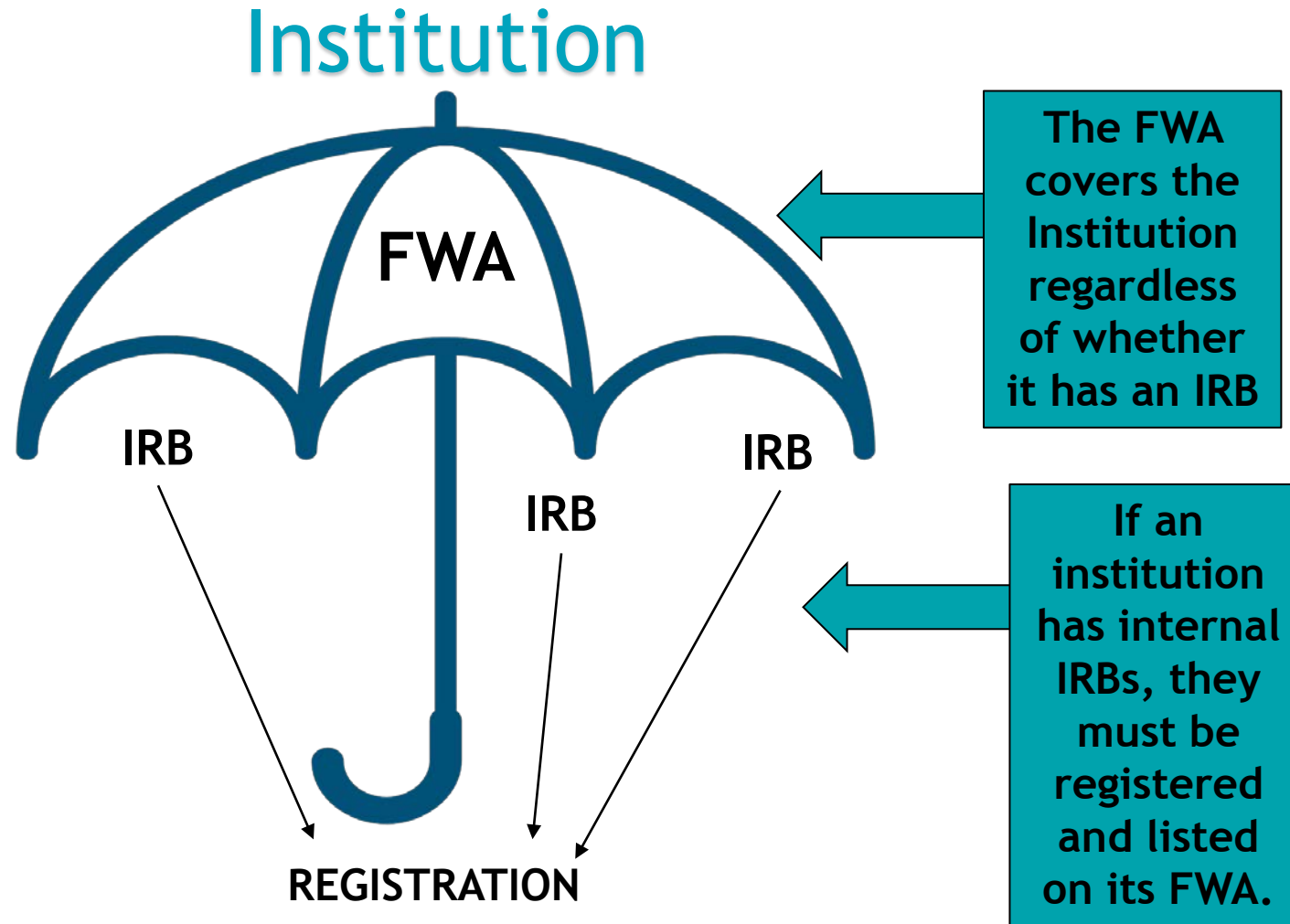


If an organization does not have an internal IRB, it must designate an external IRB that either reviews all or the largest percentage of research to which the FWA applies



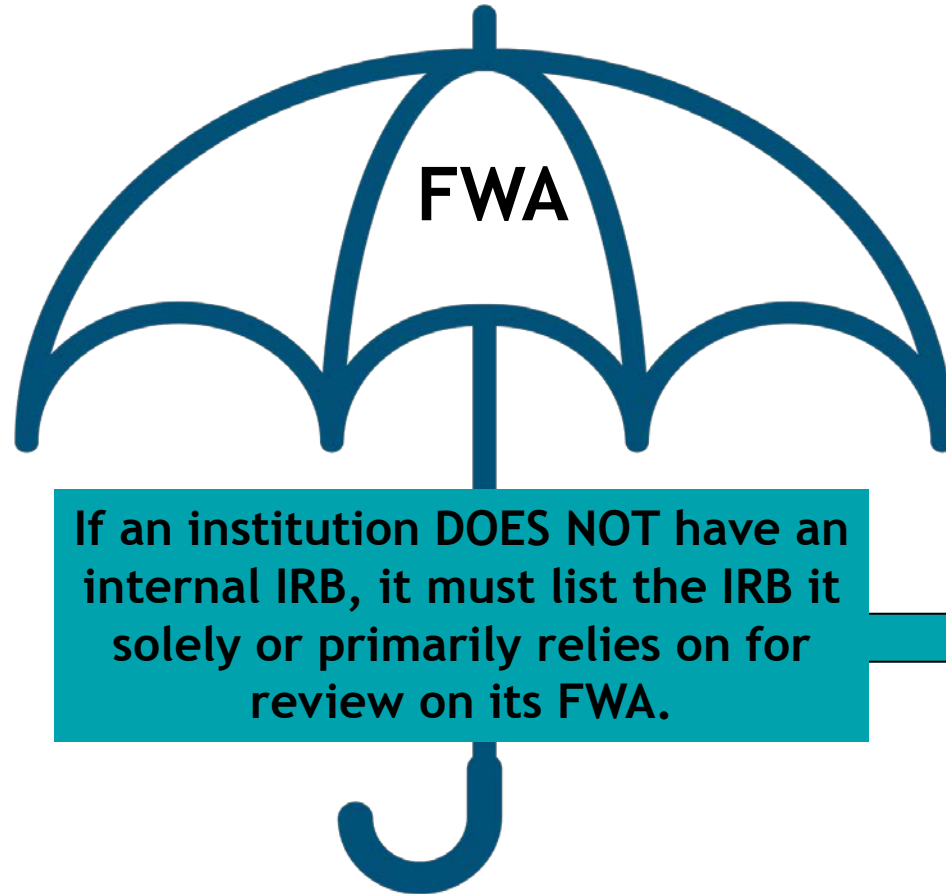
IRB registration is also required for clinical investigations regulated by the FDA

The Difference Between an FWA and IRB Registration

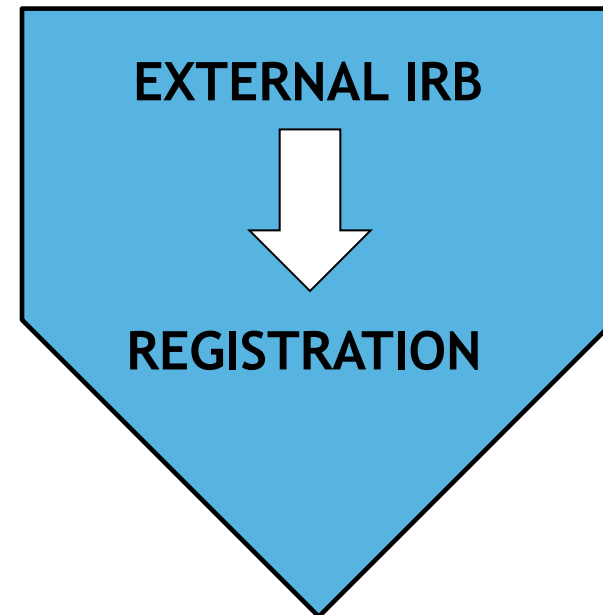


The Difference Between an FWA and IRB Registration

Institution



If an institution DOES NOT have an internal IRB, it must list the IRB it solely or primarily relies on for review on its FWA.



What is an IRB Organization?

Institution or organization that operates an IRB

Independent IRBs

Institution-based IRBs, such as at universities, hospitals, or community organizations



The IORG number is a unique number assigned by OHRP to an institution or organization the first time the institution or organization registers an IRB



The IORG number is not the same as an FWA or IRB registration number

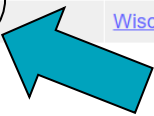
Numbers: FWA, IORG, and IRB Registration

Office for Human Research Protections Database (Current Data)

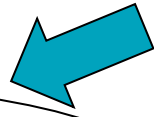
Find Assurance in table below and click the corresponding name to view details:

Total Records: 2 Total Pages: 1 Results per page: 20 Go

| Assurance | Institution | City | Type | Status |
|-------------|---|---------|-----------|--------|
| FWA00005399 | U Wisconsin-Madison | Madison | FWA | Active |
| FWA00005399 | Wisconsin Ste Lab Hygiene | MADISON | Component | Active |



FWA #



IORG #

IRB Organization Information

IORG0000218 - University of Wisconsin-Madison (Active)

Located at: Madison, WISCONSIN
Expires: 02/23/2024

IRB REGISTRATION #

IRBs for this Organization: Agency Only Access

| IRB# | IRB Name | City | State/Country | Status | IRB Type |
|-------------|--|---------|---------------|--------|-----------|
| IRB00000366 | U Wisconsin-Madison (Hlth Science) IRB #1 - Health Sciences | Madison | WISCONSIN | Active | OHRP/FDA |
| IRB00000368 | U Wisconsin-Madison (Social & Behavioral Sci) IRB #3 - Education & Social/Behavioral Science | Madison | WISCONSIN | Active | OHRP Only |
| IRB00003739 | U Wisconsin-Madison (Minimal Risk) IRB #5 - Minimal Risk (Health Sciences) | Madison | WISCONSIN | Active | OHRP/FDA |



What are the roles and responsibilities of different stakeholders?

- Webinars

- Serving as a Reviewing IRB

- Guidance for institutions preparing to serve as a Reviewing IRB under the SMART IRB Agreement.

- Responsibilities of Relying Institutions

- Guidance for institutions preparing to serve as a Relying Institution under the SMART IRB Agreement.

- Study Team Roles Related to Single IRB

- Learn about key study team roles, responsibilities, and communication structures required for single IRB review.

Does single IRB apply to international research collaborations?

| | NIH Policy | 2018 Common Rule |
|-----------------------|--|--|
| Effective date | Grant applications received and contracts solicitations issued on or after January 25, 2018 | January 20, 2020 |
| Terminology | Refers to “multi-site studies” | Refers to “cooperative research” |
| Scope | Applies to domestic sites for NIH-funded, non-exempt, multi-site studies in which each site conducts the same human subjects research protocol | Applies to any institution located in the US engaged in non-exempt, federally supported cooperative research for portion of research conducted in the US |
| Exceptions | Single IRB is not required <ul style="list-style-type: none"> • For certain types of grants • For foreign sites • If review by a single IRB would be prohibited by a federal, tribal, or state law, regulation, or policy | Single IRB is not required when <ul style="list-style-type: none"> • More than single IRB review required by law • A Federal department/agency supporting/conducting research determines use of single IRB not appropriate |

Any update on the Single IRB mandate for minimal risk studies?

- OHRP does not make an exception from the Cooperative Research requirement for single IRB review for non-exempt research that is determined to be minimal risk nor is it likely for changes to be made to the Cooperative Research requirement at this time

When multiple institutions are relying on a single IRB, can your researchers begin human subjects research if other institutions are still pending?

- Yes, if the single IRB has approved both the study and your specific site

A large teal arrow pointing to the right, with a white rounded rectangle in the top-left corner and another in the bottom-left corner. The text "More Questions" is centered within the teal area.

More Questions

Save the date for the next
SMART Talk
September 21, 2022
2:00-3:30 pm ET

A Conversation with the FDA about Single IRB

**Questions?
Contact
help@smartirb.org**

**Register at
smartirb.org**

**Sign up for our mailing list to
be notified of future offerings**