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 number 3UL1TR002541-04S2.

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Reminder: OHRP Issued Draft Guidance about Single IRB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

Access the draft guidance at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

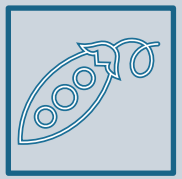
Moderator: Nichelle Cobb*, Senior Advisor for SMART IRB and Senior Advisor for Strategic Initiatives for the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

SMARTIRB.org

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

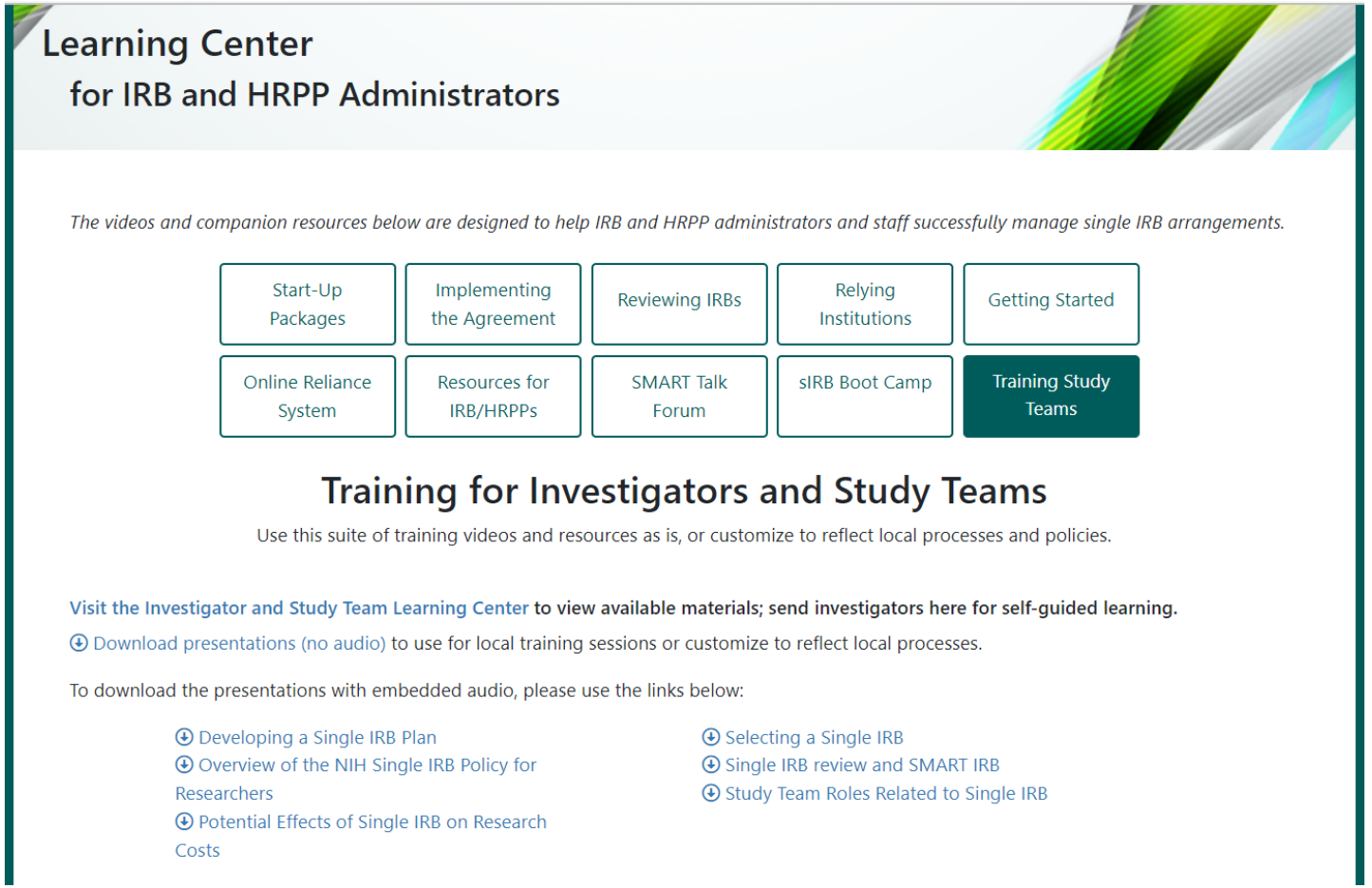
Available at
https://smartirb.org/resources/

SMART IRB Boot Camp

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!



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.

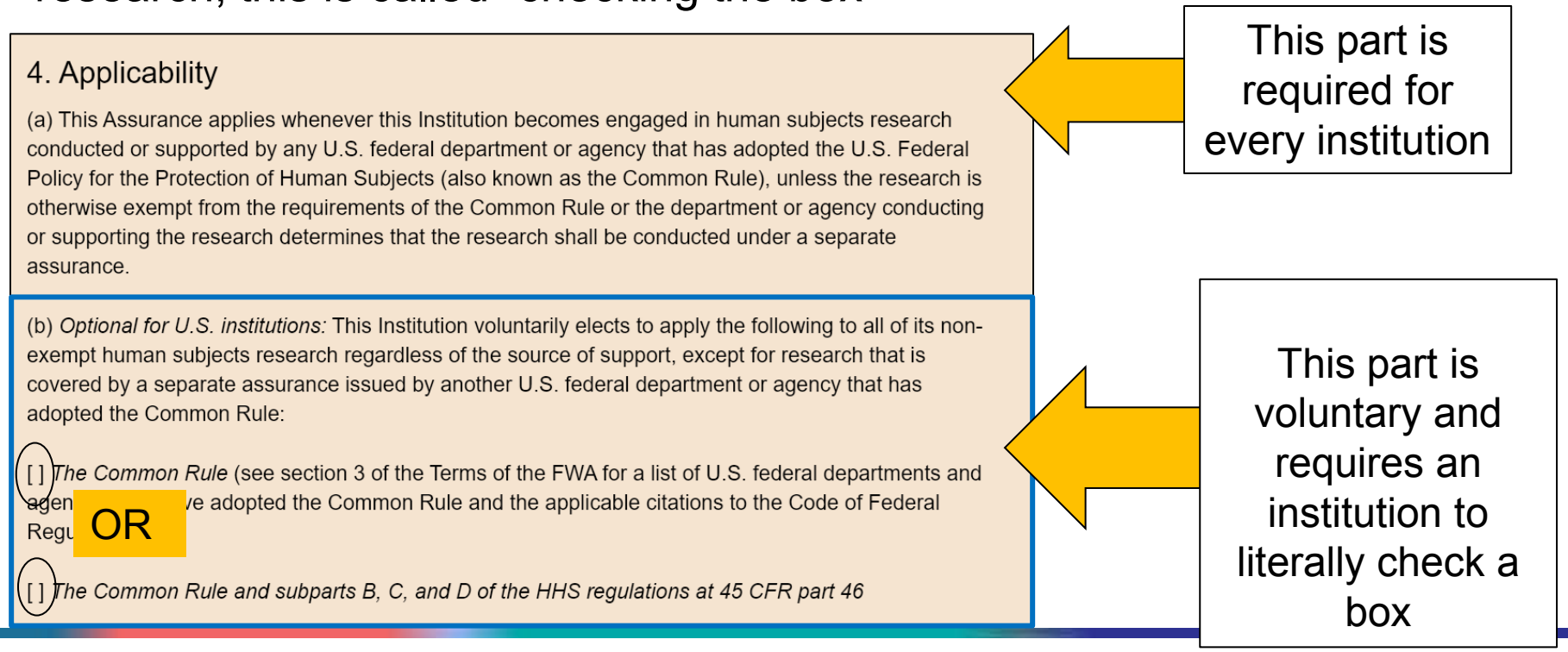
What is an Federalwide Assurance (FWA)?

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"



IRB Registration

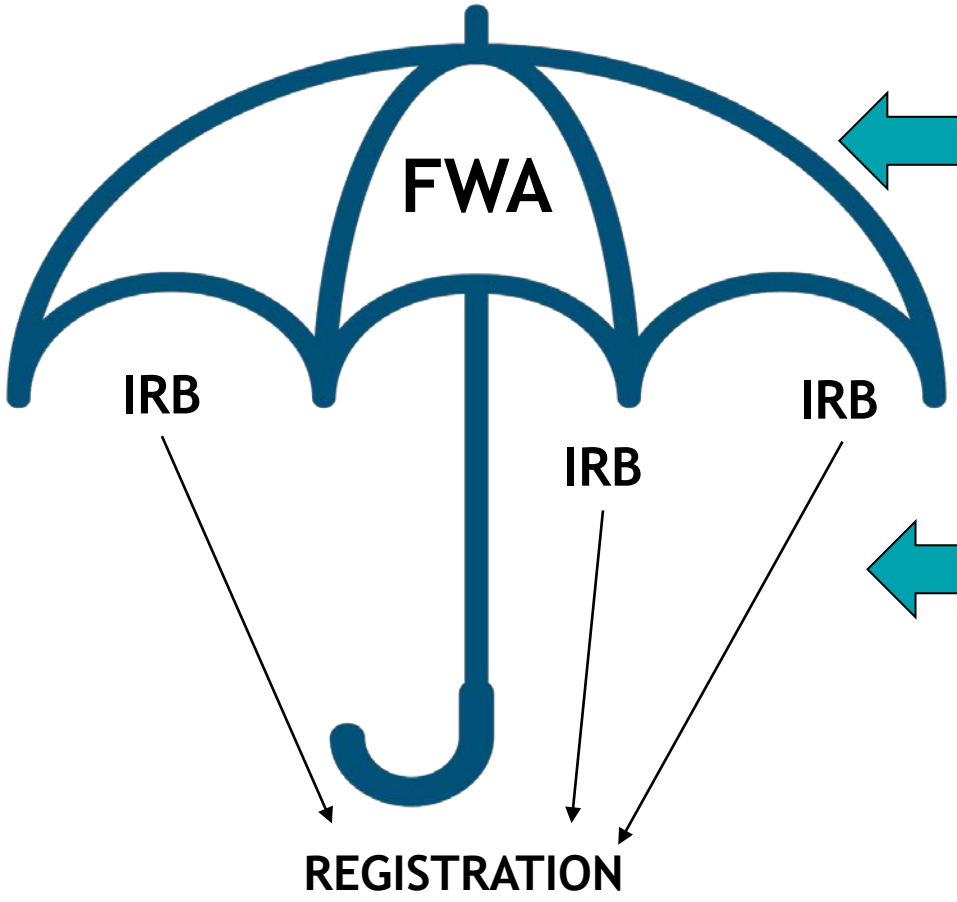
An FWA requires an organization to designate any internal IRB(s) that it will rely on

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

Institution

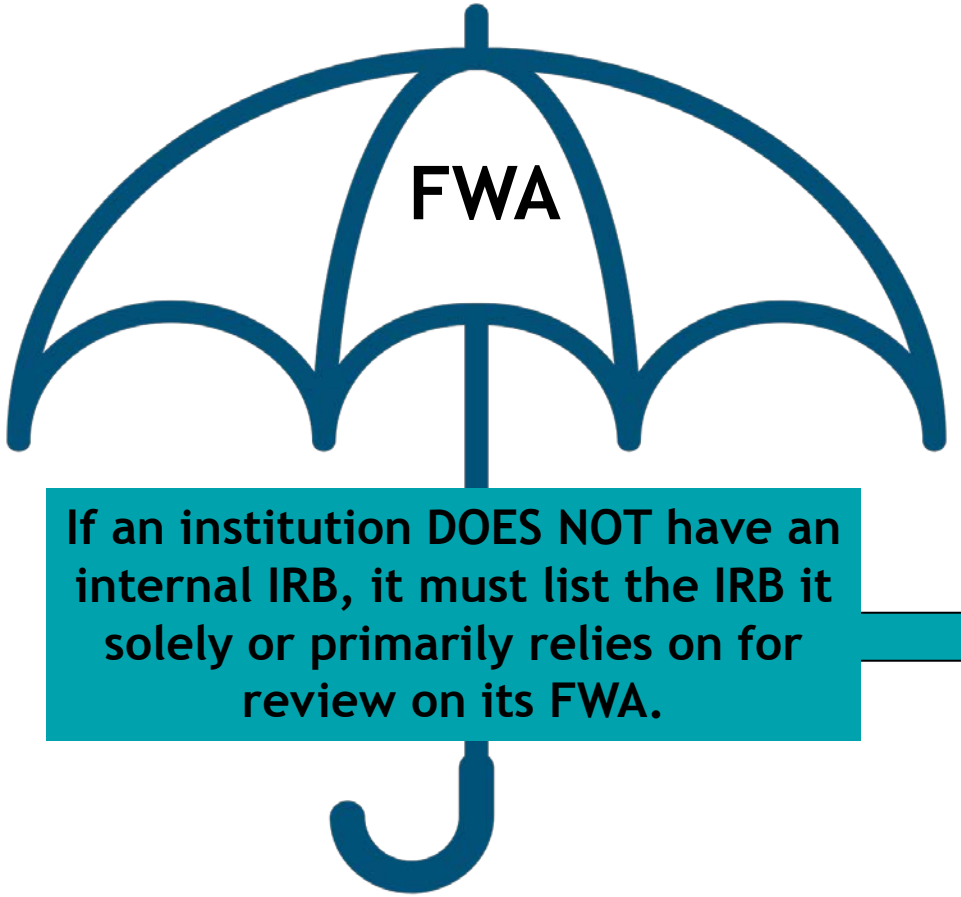


The FWA covers the Institution regardless of whether it has an IRB

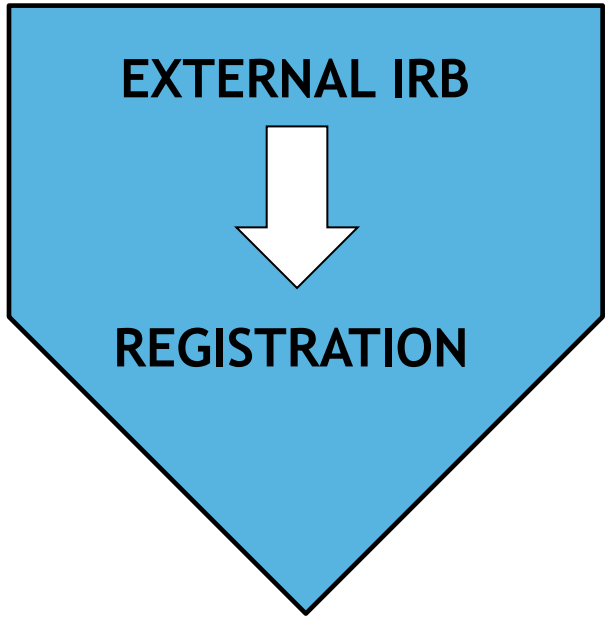
If an institution has internal IRBs, they must be registered and listed on its FWA.

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 Acce

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 • 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 • 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

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