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

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

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

OHRP Issued Draft Guidance about Single IRB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Access the draft guidance at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

SMART IRB
Resource Reminders

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/

Harmonization Steering Committee Recommendations
https://smartirb.org/harmonization/

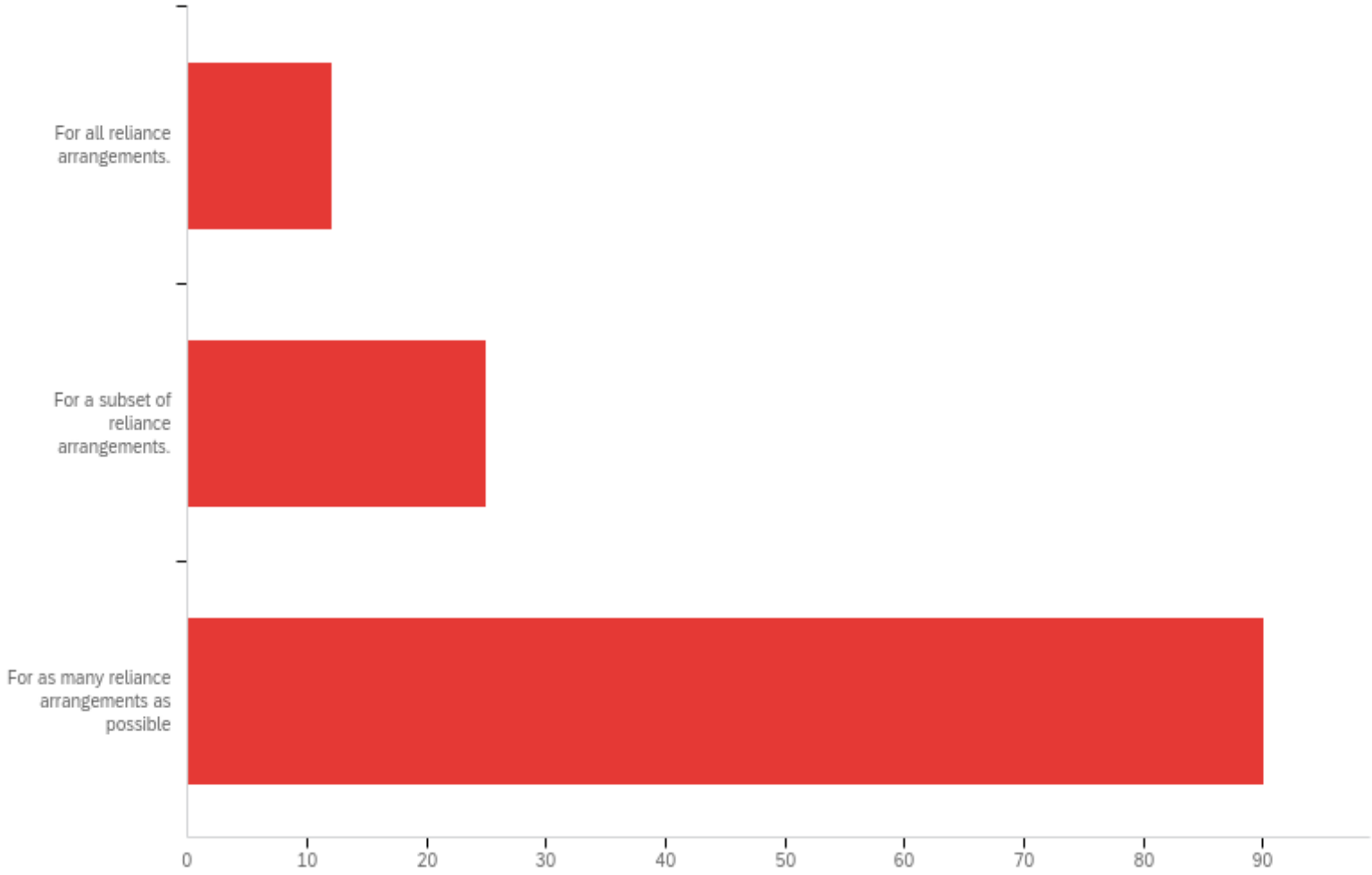
- Ancillary Review
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document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

In progress:
Local considerations recommendations

Are People Using the SMART IRB Agreement?

2021 SMART IRB Survey Says…

Which of the following describes your institution's use of the SMART IRB Agreement for reliance arrangements?

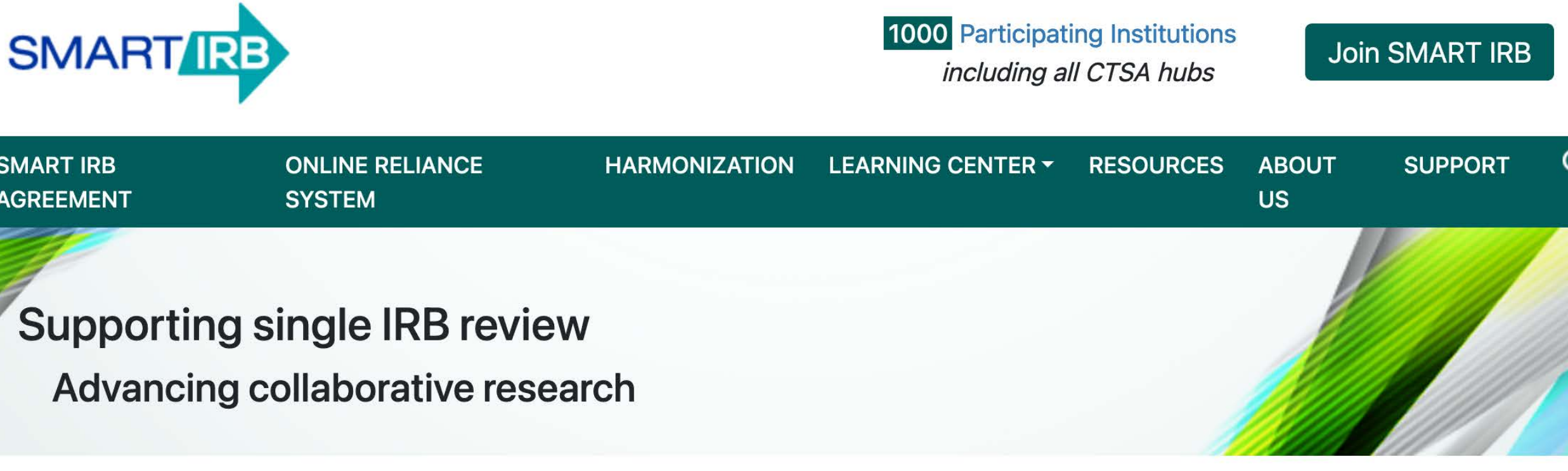


Rate your overall experience using the SMART IRB Agreement for reliance arrangements.

Overall Experience Using SMART IRB – Positive – Write-in responses received (n=71)

- Ease of documenting the arrangement (x33)
- Simplifies the reliance process (x15)
- Standardizes the reliance process (x9)
- Streamlines the reliance process (x4)
- Provides clear documentation (x3)
- Makes the reliance process more efficient (x5)
- Better then traditional reliance agreements
- Fosters collaboration between institutions
- Fulfills AAHRPP requirements

Participating Institutions – 1000!



A Conversation with the DOD, DOE, and VA about sIRB

Panelists:

Stephanie Bruce, Director, Department of Defense Office for Human Research Protections (DOHRP), Office of the Under Secretary of Defense for Research and Engineering

C. Karen Jeans, Director of Regulatory Affairs, Office of Research Protections, Policy, and Education, VHA Office of Research and Development, Department of Veterans Affairs

Elizabeth "Libby" White, Department of Energy Human Subjects Protection Program Manager

Moderator: Barbara Bierer, Director of Regulatory Policy, SMART IRB (and so much more!)

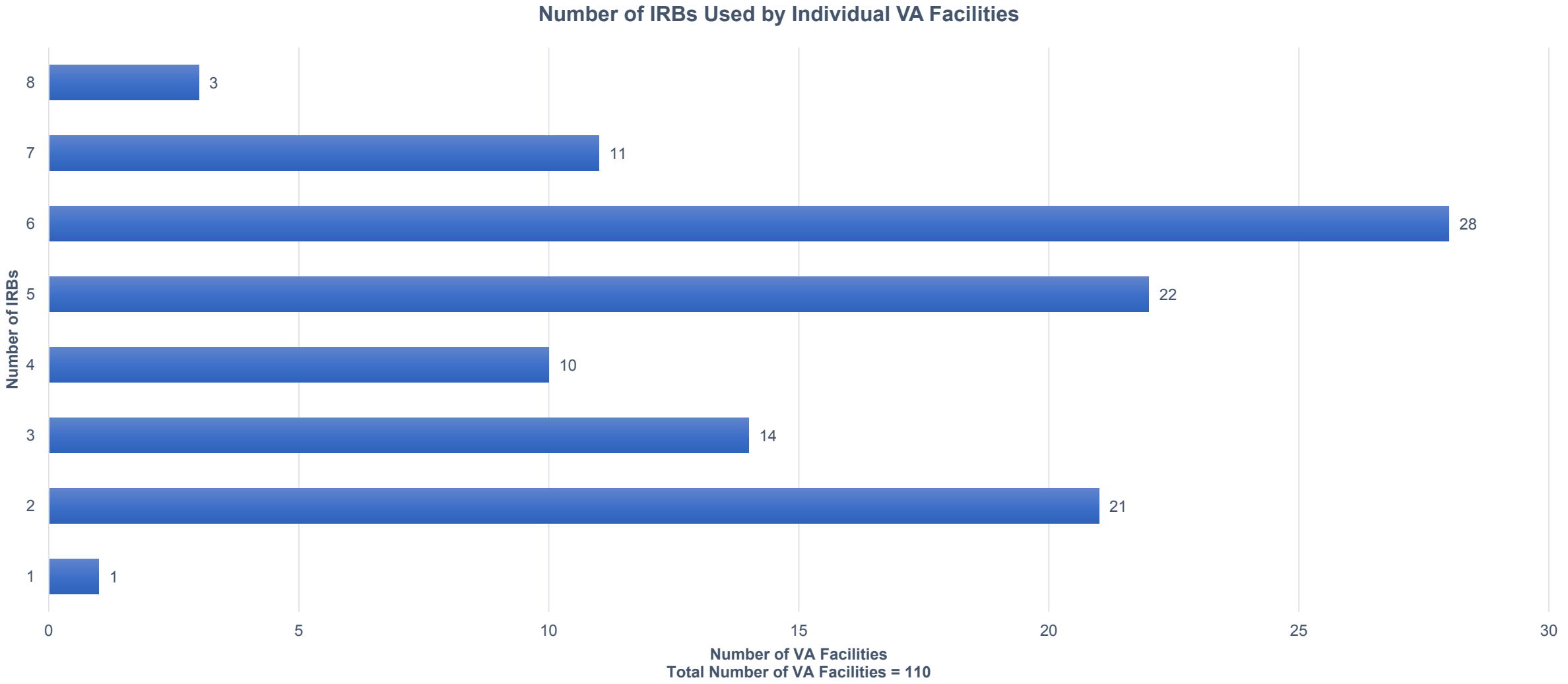
Department of Veterans Affairs (VA): Cooperative Research (Single IRB) Key Points

July 20, 2022

Overview of VA Facility Programs Conducting Human Subjects Research

- 110 VA Facilities are currently approved to conduct human subjects research by the Department of Veterans Affairs (VA)
- 110 IRBs are currently approved for use by the VA for at least one VA Facility
  - The VHA Central IRB 1
  - Other federal agency IRBs: 3
  - Commercial IRBs 3
  - University IRB (affiliated or non-affiliated with a VA Facility): 45
  - VA Facility: 58

Number of IRBs used by Individual VA Facilities



VA National Policy Requirements for VA Facility IRBs

- VA Facilities may rely upon:
  - the facility's IRB(s) of Record (if the VA Facility chooses to have one);
  - VHA Central Office IRB (VA Central IRB);
  - an IRB of another VA facility;
  - the IRB(s) of a medical or dental school;
  - the IRB of another Federal agency;
  - an IRB for multi-site protocols that has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities; and
  - ORD-designated commercial IRBs.

VA National Policy Requirements for VA Facility IRBs

- A VA IRB may serve as an IRB of Record for
  - Other VA Facilities,
  - a Department of Defense (DoD) facility,
  - Department of Energy laboratory, and
  - VA Nonprofit Corporation.

VA's Implementation of the Cooperative Research Provisions

- As a signatory federal agency to the Common Rule (codified as 38 CFR Part 16), VA agreed to adhere to the cooperative research provisions.
- VA has the ability under the Common Rule cooperative research provisions to allow an exception to use of a single IRB for cooperative research for VA institutions when VA determines as an agency that is not appropriate for a given context for the participating VA institutions:
  - 2020: 211 single IRB exceptions granted
  - 2021: 185 single IRB exceptions granted
  - 2022: 68 single IRB exceptions granted
- Most common reasons VA issues single IRB exception:
  - Inability for proposed reviewing IRB to adhere to federal information security requirements.
  - Reviewing IRB refuses to follow VA regulatory requirements, such as refusal to include the VA required language in informed consent documents that VA will pay for all research-related costs.

U.S. Department of Energy (DOE): Current Approach for Collaborative Human Subjects Research

Overview of the DOE Human Subjects Protection Program:

- Responsibility for policy development for and oversight of the Human Subjects Protection Program (HSPP) complex-wide is delegated by the Secretary to the DOE Institutional Official (IO), the Associate Director of Science for Biological and Environmental Research.

- The DOE HSP Program Manager and the HSP Program Manager from DOE's semi-autonomous National Nuclear Security Administration (NNSA), report functionally to the DOE IO to co-run the program and oversee the 2 central DOE IRBs.

- DOE/NNSA national laboratories that conduct HSR have their own HSPPs, Federalwide Assurances (FWAs), IOs and responsible day-to-day personnel. Some have their own IRBs; others rely on the central DOE IRBs.

U.S. Department of Energy (DOE): Current Approach for Collaborative Human Subjects Research

Collaborative Research Internal to DOE/NNSA:

- Is reviewed by one of the Central DOE IRBs, per DOE Order 443.1C;
- DOE HQ and each DOE national laboratory (site) conducting human subjects research sign an IRB Authorization Agreement documenting the reliance on the Central DOE IRB(s) for multi-site studies, as well as expectations and requirements of DOE HQ and sites.

Collaborative Research with Organizations Outside of DOE:

- DOE HQ and site IRBs may:
  - Serve as the single IRB for research with another Common Rule agency, university, or other outside organization (*e.g., several collaborative studies with DOD*);
  - Cede review to another Common Rule agency's IRB (*e.g., collaborative HSR between DOE site(s) and the VA using VA health record data; VA Central IRBs are used*);
  - Cede review to a university or other outside non-Federal organization's IRB.

- Process Used:
  - Verify that the institution with which collaborative HSR will be conducted has an assurance of compliance (e.g., FWA) in place;
  - Determine which IRB will be used;
  - Using template reliance agreement, prepare the agreement for review/signature by senior officials in each institution, noting any institution-specific requirements;
  - Finalize, and following IRB review/approval and any additional required agency-specific reviews, initiate research.

U.S. Department of Energy (DOE): Approach for Collaborative Human Subjects Research

Questions?
Contact the Human Subjects Protection Program Managers at DOE:

Libby White (elizabeth.white@science.doe.gov)

Cheri Hautala-Bateman (cheri.hautala-bateman@nnsa.doe.gov)

Further Information:
See DOE's Human Subjects Protection Program Website:
https://science.osti.gov/ber/human-subjects/About

Discussion & Questions

Save the date for the next
SMART Talk
August 17, 2022
2:00-3:30 pm ET

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

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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