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, Federal Contract 75N95023C0008

FYI

Questions for the presenter or SMART IRB Team are welcome! Please post these under ‘Q/A’

Questions for fellow attendees should be posted under ‘Chat’

A link to today’s recording will be emailed to attendees. A recording will be posted on the SMART IRB website

Your feedback is valued! Please complete the survey at the end of the SMART Talk! The survey will be emailed as well.

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 global IRB reliance agreement

An Online Reliance System to initiate and track reliance

Zero Cost Education, Guidance, and Resources

SMART IRB is NOT…

An IRB

An electronic system for Reviewing IRBs to receive studies for review

Reach out to a SMART IRB Ambassador

Aaron Kirby
Harvard Catalyst

Polly Goodman
Harvard Catalyst

Jeremy Lavigne
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

https://smartirb.org/ambassadors/

Carissa Minder
Washington University in St. Louis

Kathy Lawry
AAHRPP

Nichelle Cobb
AAHRPP

Stacey Goretzka
Medical University of South Carolina

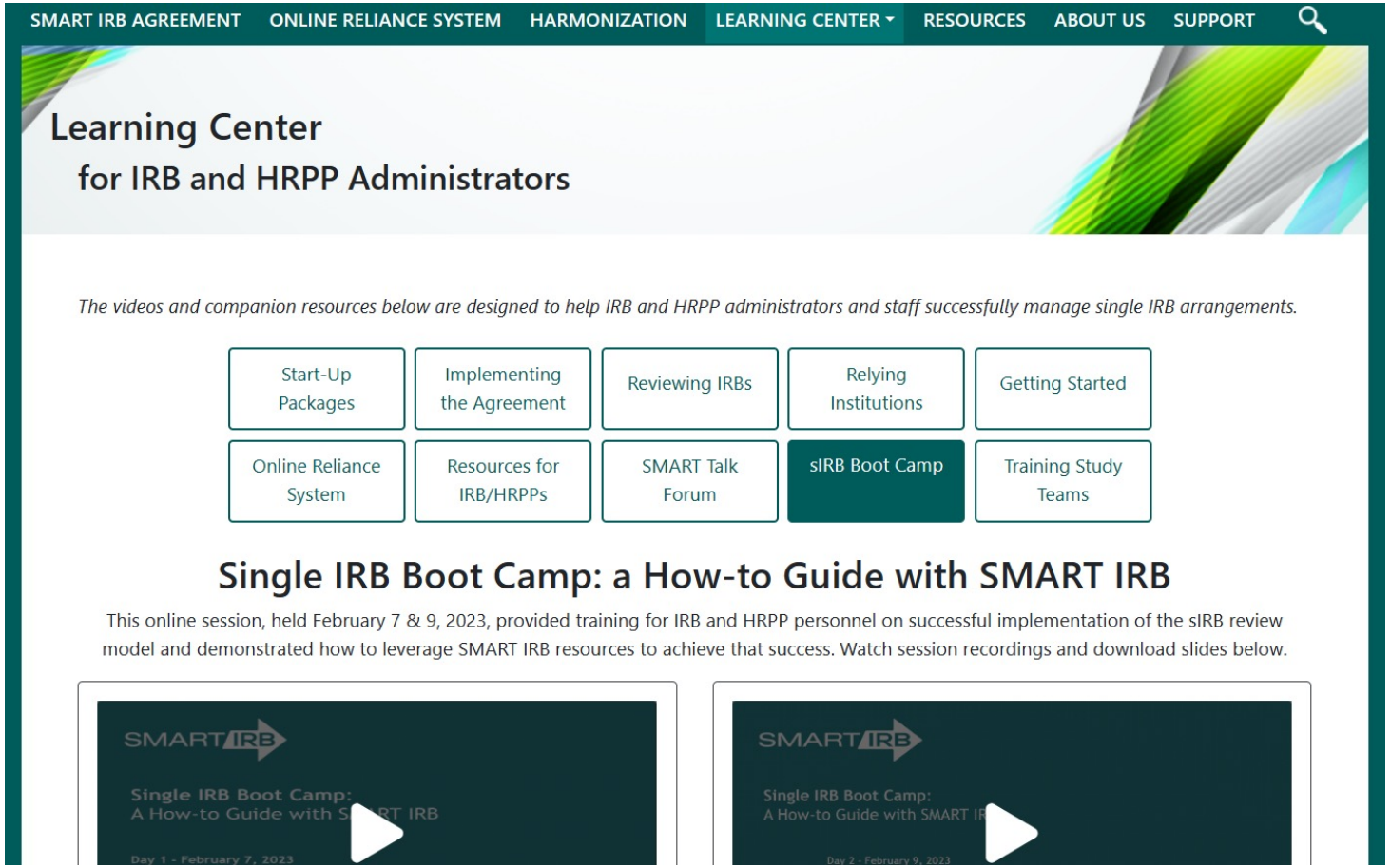
Lubabah Helwani
University of Southern California

What We've Been Up To…

New to Single IRB? Access the sIRB Boot Camp Resource

A recording is available of the beginner-level online session to train IRB and HRPP personnel on successful implementation of the single IRB (sIRB) review model and demonstrate how they can leverage SMART IRB resources to achieve that success.

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



SMART IRB Agreement V3.0 Public Comments

THANK YOU for your feedback regarding the proposed SMART IRB Version 3.0 Agreement! Public comment period ended on February 15, 2024**. Stay Tuned for next steps!**

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

- **SMART IRB Reliance for Exemptions: Recommendations drafted**
- **SMART IRB Local Context Working Group: Publication Soon!**

Understanding DOD and DOE Requirements for Single IRB Implementation

Today's presenters:

- **Stephanie Bruce,** Director, Office of Human Research Protections, Department of Defense
- **Elizabeth "Libby" White,** Human Subjects Protection Program Manager, Department of Energy

Moderator:

- **Nichelle Cobb**, Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs

USD(R&E)

2024 SMART IRB Briefing

Stephanie Bruce, CIP, CPIA
Director, DoD Office for Human Research Protections

Office of the Under Secretary of Defense for Research and Engineering

Controlled by: OUSD(R&E)
Controlled by: DoD Office for Human Research Protections (DOHRP)
Category: Unclassified
Distribution: A
POC: Stephanie Bruce

DoDI 3216.02: Unique to the DoD HRPP

- Selection of subjects is equitable
  - DOD-conducted and -supported clinical research complies with section 252 of Public Law 103-160 regarding the explicit inclusion of women and minorities
- Evaluation of risk
  - The phrase “ordinarily encountered in daily life during the performance of routine physical or physiological examinations or tests” as outlined in Federal policy for the definition of “minimal risk” shall not be interpreted to include the inherent risks DoD-affiliated personnel face in their everyday life
- Pregnant women can participate in non-medical research
- All Active Duty Service members and reservists in a Federal duty status are considered adults for the purposes of research, including cadets and midshipmen at the Service academies
- Research with detainees or prisoners of war is prohibited unless for the diagnosis or treatment of a medical condition
- Additional review of research involving genetic data and DoD-affiliated personnel
- 10 USC 980 “Limitation On Use Of Humans As Experimental Subjects”
- Outlines a framework for classified human subject research

DoDI 3216.02: Voluntariness

- The DoD HRPP recognizes that Service members and other DoD-affiliated personnel may experience inadvertent coercive pressure to participate in research because:
  - They have agreed to risk personal injury or loss of life as military members
  - They are obligated to obey lawful orders
  - They are trained to respect rank
  - The may be susceptible to orders from senior officials

- To support Voluntariness in DoD-affiliated personnel's participation in research, DoDI 3216.02 outlines:
  - Minimization of command influence
  - Chain-of-command cannot participate in recruitment
  - Ombudsperson required for recruitment in greater than minimal-risk studies
  - The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty

DoD Solicitations/Broad Agency Announcements

- DoDI 3216.02, Page 16, Section 3.6, b. (1) (a):

- All solicitations, including broad agency announcements, for DoD-supported research that include or may include HSR must contain the DFARS clause 252.235-7004, if the solicitation is for a FAR-based contract or substantially similar language if the solicitation is for a non-FAR-based agreement; and language referencing the National Policy Requirements Concerning Live Organisms Terms and Conditions, Section A.1., Human Subjects, at 81 Federal Register 78380, Appendix C to Part 1122. In addition to identifying DoD and non-DoD institutions' responsibilities, the role of the HRPO is described in these two directives.

Regulatory Framework

Federal Human Research Protections "The Common Rule"

- 20 Federal agency adherents
- Outlines the safety and rights of participants in Federal HSR

DoD Adoption of the Common Rule, 32 CFR 219

- Exact same language replicated at each Federal agency's section of the Code of Federal Register (CFR)

DoDI 3216.02 Policies and Procedures

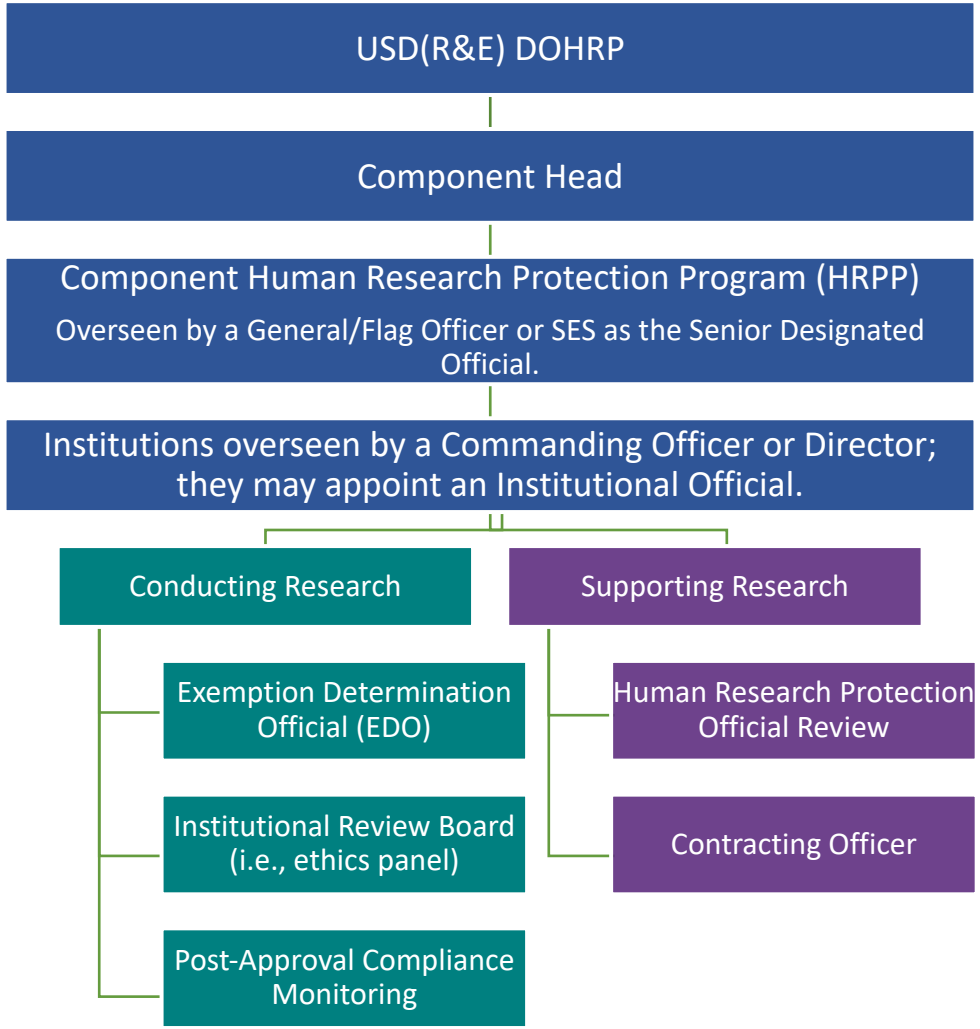
- Regulated activities: medical and non-medical; classified; international; intramurally and extramurally funded HSR

Component Human Research Protection Programs (HRPPs)

- Components create policies in keeping with best practices and regulations; these must be approved by the DOHRP before implementation

DOHRP Oversight

- A Human Research Protection Program (HRPP) is a system of interdependent elements that implement policies and practices to protect human subjects involved in research.
- An Exemption Determination Official (EDO) is a Federal employee at a DoD institution who, sufficiently qualified through experience and expertise, is designated to review research to determine whether the research involves human subjects and, if so, whether such research is exempt from 32 CFR 219.
- A Human Research Protection Official (HRPO) is a Federal employee designated by a DoD Component or institution to conduct administrative review of DoD-supported research in accordance with the requirements of Defense Acquisitions, whose review of DoD-supported research is intended to ensure compliance with DoD HSR requirements.



SHERIFF

Seminar on Human subject research Ethics for Responsible Innovation using Federal Funds, also known as the SHERIFF

17-18 September 2024

Contact Information

usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil

An Overview of Department of Energy (DOE)’s HSPP and Single IRB Requirements

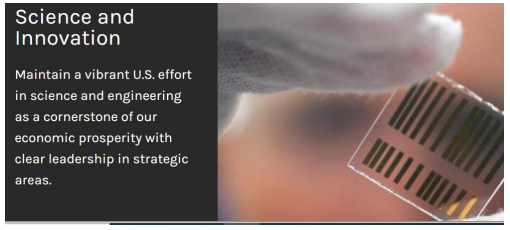
April 2024

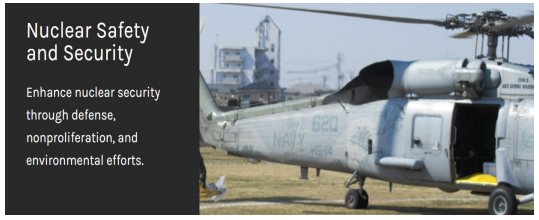
Elizabeth (Libby) White
DOE Human Subjects Protection Program Manager

DOE Mission and Structure

DOE Mission:

- To ensure America's security and prosperity by addressing its energy, environmental, and nuclear challenges through transformative science and technology solutions.





National Laboratories:

- Sixteen of the seventeen national laboratories under DOE and its semi-autonomous National Nuclear Security Administration (NNSA) are Government owned, contractor operated.
- Conduct R&D funded by DOE/NNSA and by other Federal agencies

HSR at DOE: Funding and Scope

DOE's human subjects research (HSR) portfolio includes research conducted by multiple DOE sites, as well as universities and other outside organizations.

~50% Funded by DOE:

Include:

- Biomedical/epidemiologic studies;
- Development and solicitation of input on transformative energy-efficiency technologies; and
- Analysis of large datasets.

Department of Energy Former Worker Medical Screening Program

放影研 RERF Radiation Effects Research Foundation
A Cooperative Japan-US Research Organization

~ 50% Funded by Outside Agencies:

- National security and intelligence-related research;
- Biomedical research; and
- Man-machine interface studies.

Applying advanced computing and data analytics to care for America's veterans.

HSR at DOE: Human Subjects Protection Program (HSPP) Structure

Institutional Official (IO):

- Senior manager in DOE's Office of Science

Human Subjects Protection (HSP) Program Managers:

- Include a DOE and an NNSA HSP Program Manager
- Report functionally to the DOE IO
- Co-manage DOE's HSPP

National laboratories, plants, and sites:

- Have their own HSPPs and FWAs
- Some have their own IRBs; others rely on the central DOE IRBs.

HSR at DOE:
HSPP Responsibilities

- **Develop policy/guidance**
- **Oversee Central DOE IRBs**
- **Partner with/support site HSPPs through:**
  - Human Subjects Working Group
  - QA consultations
  - Training (CITI and other)
  - Provision of IRB workflow software (IRB10)
  - Other assistance/guidance
- **Collaborate with/inform HQ program offices**
- **Coordinate with other Federal agencies**

HSR at DOE: Implementation of the Common Rule

- **Overlap**
  - Signed on to 2018 Common Rule
  - Follow all 45 CFR Part 46 Subparts
  - Use OHRP-developed guidance and resources
  - Use OHRP Education Division's approach for QA consultations at DOE/NNSA labs, plants, and sites that do HSR
  - Reportable events are reported to OHRP even if not HHS-funded

- **Differences**
  - Recognize/implement certain DOE-specific additional requirements
  - Central DOE IRBs do not generally allow broad consent for exempt HSR, category 7

HSR at DOE:
DOE-specific Requirements

- Outlined in DOE Order 443.1C
  - HSR/not HSR and exempt HSR determinations are made by the appropriate DOE IRB/IRB office.
  - Research using social media and other datasets, even if thought by PI to be publicly available or de-identified, must be submitted for HSR/not HSR determination.
  - All HSR (including exempt HSR) requires an annual check-in or CR.
  - Additional reporting requirements when something goes wrong
    - Immediate reporting to IRB
    - Additional reporting to DOE/NNSA HSPP, in some cases
  - Annual Reporting to the DOE Human Subjects Research Database
    - Information is automatically captured during submission/review process if a DOE IRB is used.

HSR at DOE:
DOE-specific Requirements (cont.)

- Outlined in DOE Order 443.1C
  - Employees are considered vulnerable subjects
    - HSR involving DOE Federal and/or contractor employees or their data must be reviewed by the appropriate DOE IRB.
    - An employee cannot be recruited or consented by a direct supervisor who is the PI and/or a member of the research team, except in unusual circumstances approved by the IRB.
  - HSR involving multiple DOE/NNSA sites is typically reviewed by the Central DOE IRB.
  - Additional quorum requirements apply for voting on new/amended HSR studies.
  - Specific additional requirements for cHSR.

HSR at DOE: Approach with Collaborative Research

- Collaborative Research Internal to DOE/NNSA:
  - Is reviewed by one of the Central DOE IRBs

- Collaborative Research with Outside Organizations:
  - DOE central and site IRBs may:
    - Serve as the single IRB for research with another Common Rule agency, university, or other outside organization
    - Cede review to another Common Rule agency's IRB
    - Cede review to a university or other outside organization's IRB

HSR at DOE: Approach with Collaborative Research (cont.)

- **Process Used:**
  - Verify that the institution with which collaborative HSR will be conducted has an active assurance of compliance (e.g., FWA);
  - Select IRB;
  - Prepare reliance agreement, noting DOE and any collaborating institution-specific requirements;
  - Finalize, and following IRB review/approval and any additional required agency-specific reviews, initiate research.

- **Note:** DOE HQ hopes to sign on to SMART IRB, version 3

Questions?

Contact the Human Subjects Protection (HSP) Program Managers at DOE: DL-DOEHSPP@hq.doe.gov

Libby White, DOE HSP Program Manager

Cheri Hautala-Bateman, NNSA HSP Program Manager

Further Information:

See DOE's Human Subjects Protection Program Website:

https://science.osti.gov/ber/human-subjects/About

TENTATIVE
Save the date for the next SMART Talk on
Version 3 of the SMART IRB Agreement

June 12, 2024
2:00-3:30 pm ET

Note the change in the usual date

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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