

# Symposium on *Human Subjects in Energy Technology and Policy Research*

October 2024

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Office of Science

[Energy.gov/science/](https://energy.gov/science/)

# Human Subjects Protection Program - Overview

## Vision

- Ensure that risks to subjects are minimized and reasonable in relation to benefits of the research

## Mission

- Support research enterprise by ensuring the protection of individuals who participate in research
- Ensure compliance with pertinent federal, state, and agency laws and regulations
- Foster ethical conduct of human subjects research
- Provide education and other services related to regulatory requirements and best practices

## DOE HSR

- Must be conducted by organizations with a current Federalwide Assurance ([FWA](#))
- Must have institutional review board (IRB)/bioethics committee review
- Must comply with Federal/DOE-specific HSR requirements

Research Integrity: HSR must have Scientific/Technical Merit

# Human Subjects Research Governance

## Federal Requirements

- [10 CFR 745](#) (DOE's implementation of [45 CFR 46](#), Subpart A, or Common Rule; (eCFR :: 10 CFR Part 745 -- Protection of Human Subjects))
- 45 CFR 46, Subparts B, C, D and E (eCFR :: 45 CFR Part 46 -- Protection of Human Subjects)

## DOE Specific Requirements

- DOE Order 443.1C, *Protection of Human Research Subjects* (or current version: <https://www.directives.doe.gov/>)
- DOE-IN Policy Guidance 202.1

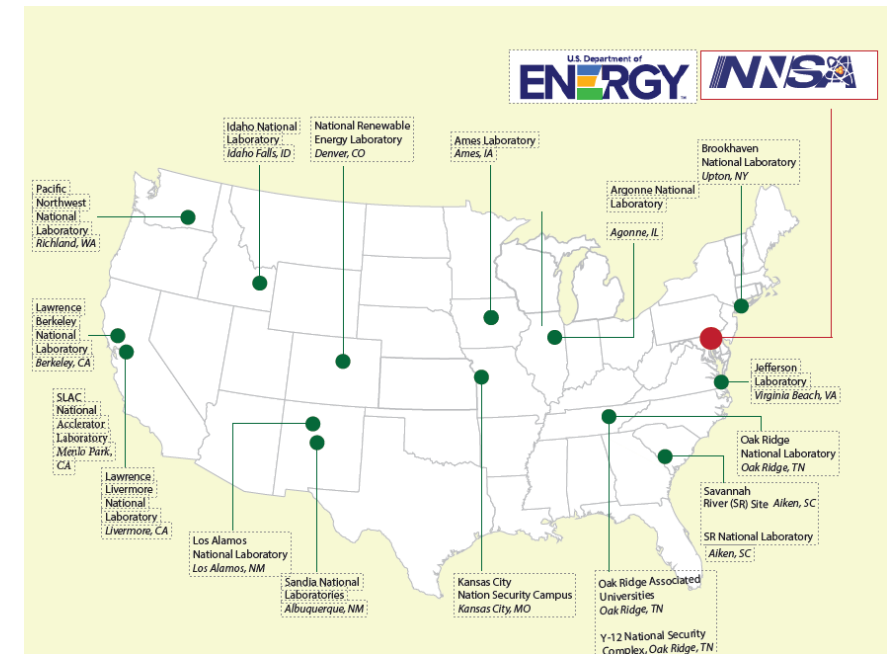
## Belmont Principles

- Respect for Persons
- Beneficence
- Justice



# Human Subjects Protection Program - Structure

- Responsibility delegated by Secretary to SC/BER
- Senior Institutional Official (IO) for HSR
  - Oversees DOE/NNSA Human Subjects Protection (HSP) Program
- DOE & NNSA HSP Program Managers
  - Functionally report to DOE IO
  - Manage day-to-day program and Central DOE IRBs
  - Provide implementing policy/guidance
- DOE & NNSA Labs/Sites Conducting HSR
  - Have site HSP Programs
  - Many have IRBs



# Increase in HSR that Solicits Community Input

## Transformative Energy Technologies and Equitable Energy and Climate Solutions



# What Makes Research HSR?

## Urban Integrated Field Laboratories (Urban IFLs) Program



Involves Interaction With a (Living) Human Subject – e.g., **focus groups**

Uses humans to evaluate environmental alterations – e.g., **testing of energy-saving devices in buildings/homes**



Research

Uses existing identifiable information collected for another purpose– e.g., **information collected in social media chat room on users of electric vehicles**



Involves generation of identifiable information –e.g., **collection of homeowners' demographic data and energy use over time**



**DATA STUDIES**  
Track energy usage, such as electric vehicle charging (e.g., station data and vehicle purchase data), home energy use after installation of a smart thermostat, or home energy use with load shifting.

# October 2023 Virtual Symposium

## *Human Subjects in Energy Technology and Policy Research*

### Purpose:

Increase awareness of what is HSR in this area of research

Foster collaboration among program managers, researchers, and IRBs

Share requirements, lessons learned and best practices for consideration by program managers, researchers, and IRBs

# Symposium Planning/Conduct

## Steering Committee:

- DOE/NNSA HSP Program Managers
- Representative group of HSP leads from labs/sites: LBNL, ANL, PNNL, ORAU, LANL, INL
- Steering Committee Chair: Kelsey Miller, LBNL

## Planning:

- Meetings with researchers, program managers and IRB professionals to identify interests/goals

## Conduct:

- Presentations from DOE leadership, experts in HSP policy & IRB administration, program managers, researchers
- Federal & DOE requirements overview
- Workshops for PIs and IRBs
- Project showcase (including BER's Urban IFLs) and discussion of best practices/lessons learned

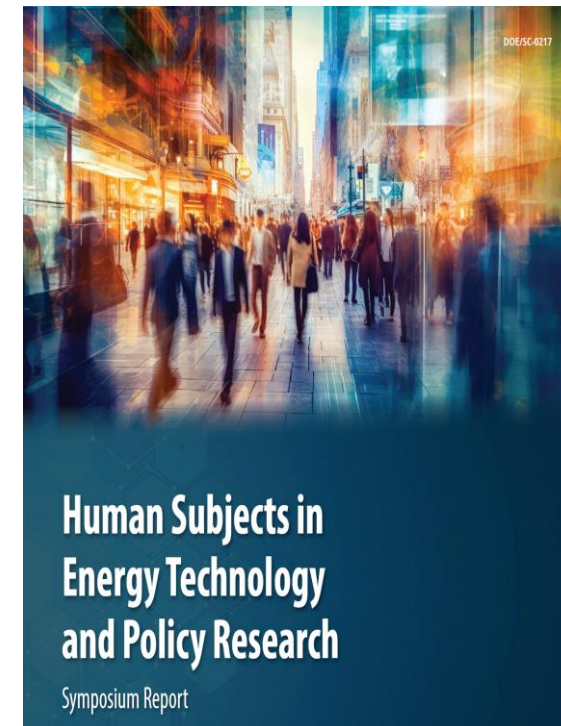


# Focus during Symposium on Protecting Human Subjects as a Shared Responsibility



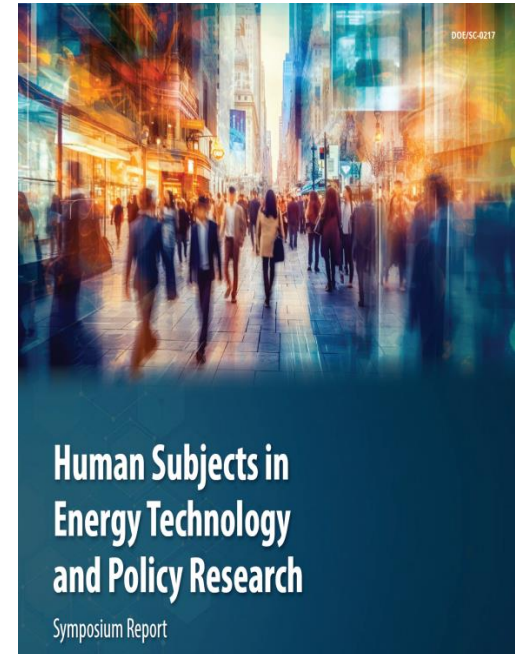
# Symposium Report

- Resource for researchers, IRB professionals, and program managers
- Core themes
  - Collaboration and Communication Among Stakeholders
    - Establish partnerships early - sponsor (program manager), PI, and IRBs
    - Clarify expectations and requirements
    - Involve research communities
    - Communicate regularly and frequently
  - Ethical Considerations for Research Participants
    - Share responsibilities to protect research participants
    - Engage marginalized communities
    - Compensate participants
    - Ensure consent forms use clear language (8<sup>th</sup> grade reading level)



# Additional Take Aways

- Include language regarding HSR in Solicitations and award documents
  - Clarify when HSR may be included and DOE requirements
- Inform reviewing IRB(s) as early as possible
  - If external IRB, clarify DOE expectations and requirements
- Ensure studies involving survey research or focus groups
  - Use consistent survey mechanisms/questions across participants
  - Engage participants who are representative of the larger community



# Future Directions

- Continue outreach efforts to program offices
- Make available additional user-friendly information on the DOE/NNSA HSPB website for program managers, contracting officers and researchers
- Plan another virtual symposium, *Community Engagement in HSR* - will look at HSR engaging various communities, including local communities, tribal nations, employees

# Human Subjects Protection Program – Website/Personnel

Human Subjects Protection Program Website: <https://science.osti.gov/ber/human-subjects>

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