



BERKELEY LAB

Bringing Science Solutions to the World



Office of Science

Information Session

Data From People

HARC Office

December 12, 2025

Format for Today:

INFORMAL

**ANSWERING YOUR
QUESTIONS!**

**Let's Start with
a Quick
Introduction!**



AND... YOU ARE?



WHO THE HECK ARE YOU?

PARTMENT OF
ERGY
e of Science



Who is Speaking Today

Human and Animal Regulatory Committees
(HARC) Office

Program Manager, Kelsey S. Miller

Human Subjects Protection Program (HSPP)

Human Subjects Committee (HSC)
i.e., Institutional Review Board (IRB)

Dr. Margaret Taylor, Chair

LBNL Deputy Director of Research
Chief Research Officer
Institutional Official - Human & Animal Research

Dr. Carol J. Burns

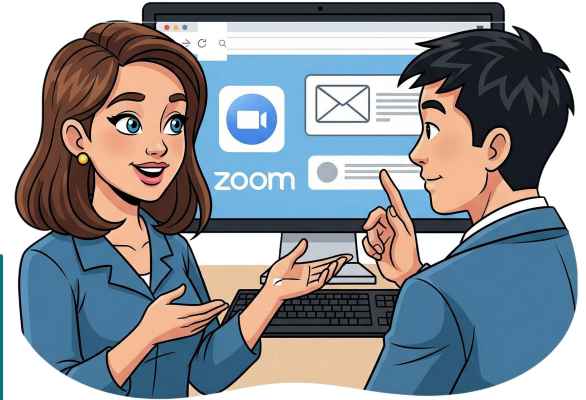
Research Compliance Office

Research Compliance Officer, Dr. Joerg Heber



Human & Animal Regulatory Committees (HARC)

- ★ Helps the lab comply with human research requirements
- ★ Guides you throughout the research workflow
- ★ Streamlines research processes and approvals
- ★ Serves as a liaison to the Human Subjects Committee



Office-wide Email: HARC@lbl.gov

Help Desk: HARC-Help@lbl.gov; [customer portal](#)

Phone: (510)486-6005

Office Hours: <https://calendar.app.google/3SwAgJ77mTiGNehm6>

Human and Animal Regulatory Committees (HARC) Office

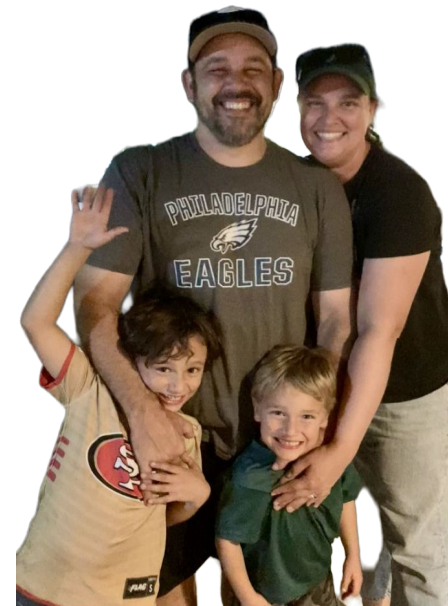
Program Manager, Kelsey S. Miller

The HARC Office Program Manager

- **Kelsey Sharkey Miller** is the program manager for HARC
- In this role, Kelsey serves as the Lab's Subject Matter Expert on human subjects research (HSR) and animal research.
- Kelsey started at CHORI as a bench researcher working on vaccines and medical devices; conducting research with both animal and human subjects.
- Kelsey's #1 Goal - **Collaborate** with you to find the best way to conduct world-changing **science** through **ethical** and **regulatory** best practices!

"Time and time again Kelsey has made the complex process of creating and renewing protocols **easy**. Her guidance has been invaluable."

Silvia Crivelli, CSA



"The HARC Office is a true partner to scientists. They **help us get science done** while navigating complex legal and human subjects issues."

Axel Visel, JGI

"I view the HARC experience not simply as an approval process but as a **process improvement strategy**, continually providing recommendations to improve the research experience both for us researchers as well as the participants. I view the HARC team as **strong and dedicated partners** in helping me design a robust research protocol."

- Kripa Jagannathan, EESA

"I can't count how many times Kelsey's guidance helped with decisions to **improve subject experience and expedite approvals**. Her early feedback has been super-helpful for our protocol prep, and her guidance was invaluable for our study."

Brett Singer, ETA

The Human Subjects Committee (HSC)

We are 14 Volunteers

- ★ **8 LBNL Researchers**, including Dr. Margaret Taylor (Chair)
- ★ **3 non-scientist LBNL employees**
- ★ **3 community members not from LBNL**

Once a project is determined to be HSR, our roles are to:

- ★ **Protect** → Safeguard the rights and welfare of human subjects
- ★ **Review** → Evaluate, monitor, and provide constructive feedback on research protocols to ensure ethical, regulatory, and scientific integrity
- ★ **Act independently** → Serve both Lab and community while maintaining freedom from outside pressure

When we serve:

- ★ **On an ongoing basis:** Review protocols, amendments, incidents, and more
- ★ **At a monthly meeting:** Discuss major reviews and other business

**NOTE: THERE IS A [POSTED SCHEDULE FOR MEETINGS](#)
& DEADLINES FOR NEW BUSINESS**



Human Subjects Protection Program (HSP)
Human Subjects Committee (HSC)
i.e., Institutional Review Board (IRB)
Dr. Margaret Taylor, Chair

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**ANSWERING YOUR
QUESTIONS!**

WHO

WHAT

WHERE

WHEN

WHY

WHY?



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Office of Science

DOE ORDER 443.1C

Protection of Human Research Subjects

**2024 updates require review by
the IRB or IRB office**

Format for Today:

**ANSWERING YOUR
QUESTIONS!**

WHO does this apply to?

WHAT do I do?

WHERE do I go?

WHEN do I do this?

~~**WHY** do I have to do it?~~

WHO Requires Review?

**Anyone conducting
Research
with
Data
from
People!**



Does this still apply if...

- I work in Operations, and want to publish a paper on our work with students?
- I perform evaluations for my program using data from people, but I don't publish?
- I am doing surveys for my ERG so we can decide what to work on next year?
- I'm interviewing experts in my field for a DOE report?
- My data is residential energy use from a utility and already protected under and NDA?
- All of my data is downloaded from publicly-available websites like census.gov?

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ANSWERING YOUR
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~~WHO~~ does this apply to?

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WHEN do I do this?

~~WHY~~ do I have to do it?

HUMAN SUBJECTS DETERMINATION



A human subjects determination is when an expert looks at your project and decides if you are studying people or not. If you are, then special rules apply to protect them. If you are not, then those rules don't apply.

1. Fill out this [FORM!](https://app.smartsheet.com/b/form/1b59c601e3fd430197f34e5b3a45c638)

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WHERE IS THE FORM?!

<https://go.lbl.gov/DatafromPeople>

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1. Fill out this [FORM](#)
2. Wait for HARC to reach out
3. Have a Discussion, if needed
4. Receive your Determination

Email HARC@lbl.gov with issues

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ANSWERING YOUR
QUESTIONS!

~~WHO~~ does this apply to?

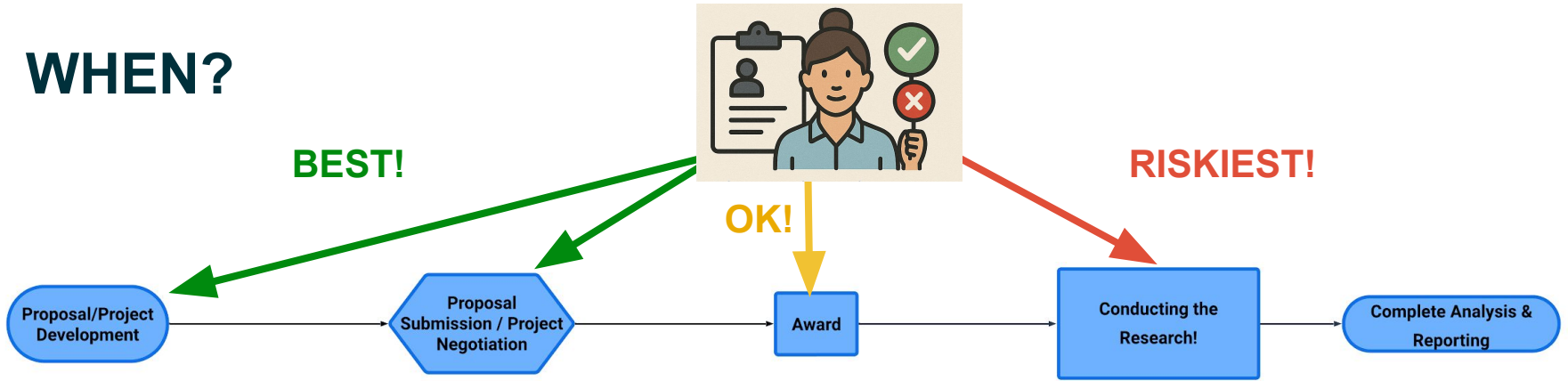
~~WHAT~~ do I do?

~~WHERE~~ do I go?

WHEN do I do this?

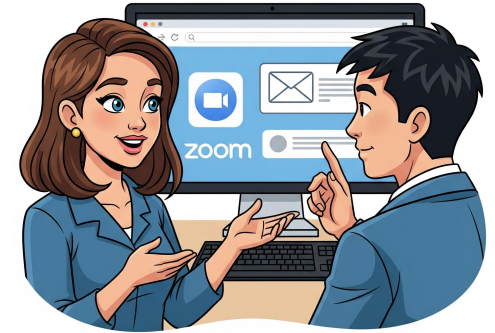
~~WHY~~ do I have to do it?

WHEN?



Consider the Research Lifecycle

- Especially while this is new, consultations are highly recommended to help you understand what will be needed!
- Get your requests in early, so no surprises can derail your budget or timeline!



CONSULTATION ON HUMAN DATA USE

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KEY TAKEAWAYS



**Dept of Energy
Order 443.1C**

Requires HSR

**Determinations be made through
the HARC Office**

What does this mean for you?

**> You cannot make your own
determination of whether a
project is Human Subjects
Research (HSR) when it uses
DATA from PEOPLE.**

★ **HARC is committed to ongoing collaboration
and flexibility based on your feedback!**

★ **Full Compliance by February 2026!**

★ **NEW! HSR Determination Form**

★ **BONUS!!**

**HARC streamlines your
research process by helping
to identify requirements and
make connections**



Contacts & Resources

Websites:

<https://go.lbl.gov/DatafromPeople>

<https://go.lbl.gov/HumanSubjects>

<https://go.lbl.gov/HSCEvents>

Individual Contacts

Program Manager:

Kelsey Miller, ksmiller@lbl.gov

HSC Chair:

Margaret Taylor, mtaylor@lbl.gov



Office
Hours



Help
Desk



Email

HARC@lbl.gov



Call
x6005

Feedback

- [General HARC Feedback Form](#)
- **In-form Feedback on Determinations**

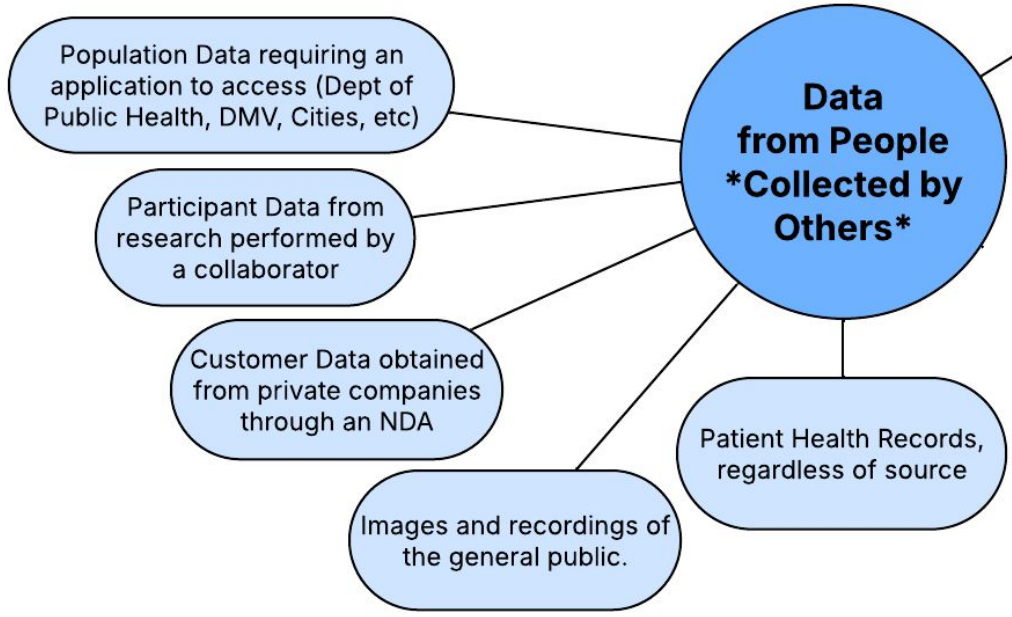
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Supplemental Slides



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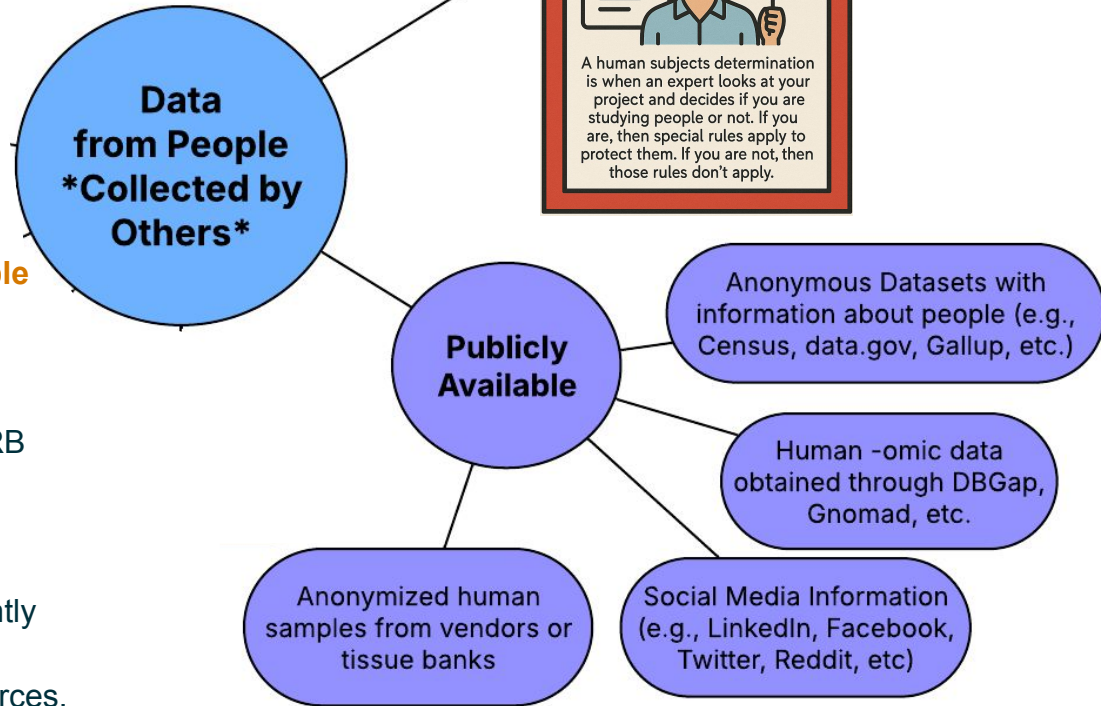
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NEW Order Requirement!

Ensure that research that uses [...] **publicly available data about individuals or publicly available biospecimens**, even if [...] **appear(s) to be de-identified**, is submitted for HSR/not HSR determination through the appropriate IRB and/or IRB office.

Why?

- Definition of de-identified and private is constantly evolving
- By combining many datasets from different sources, sometimes it becomes HSR



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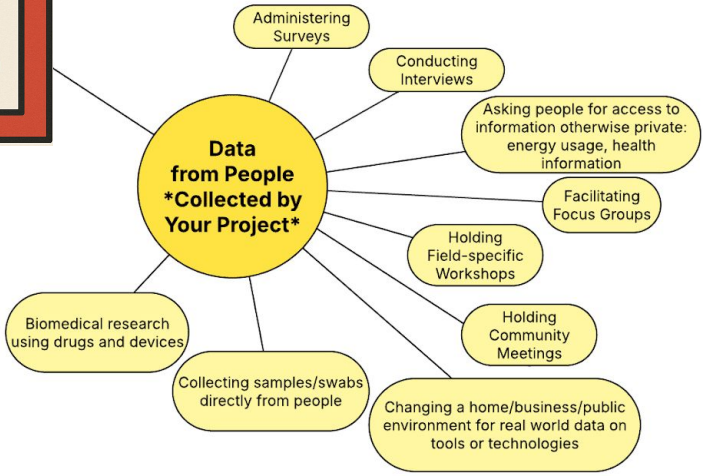
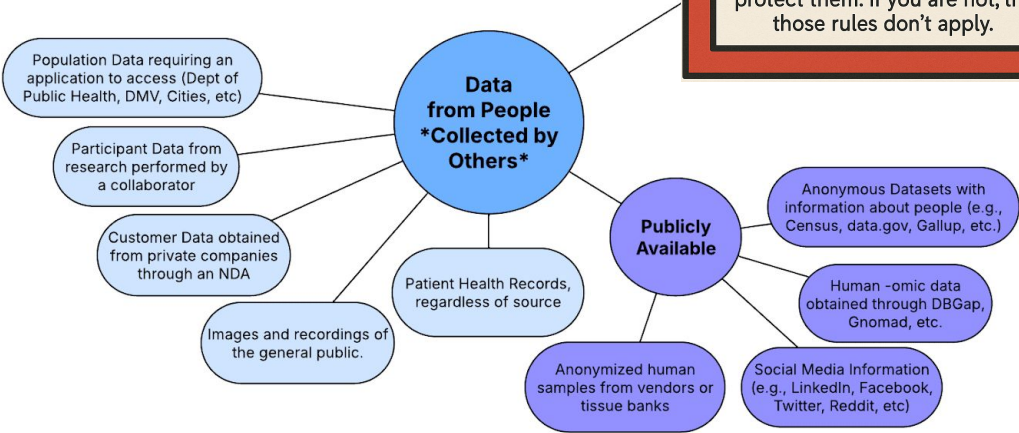
Many of your research projects will NOT be determined to be human subjects research.

HUMAN SUBJECTS DETERMINATION



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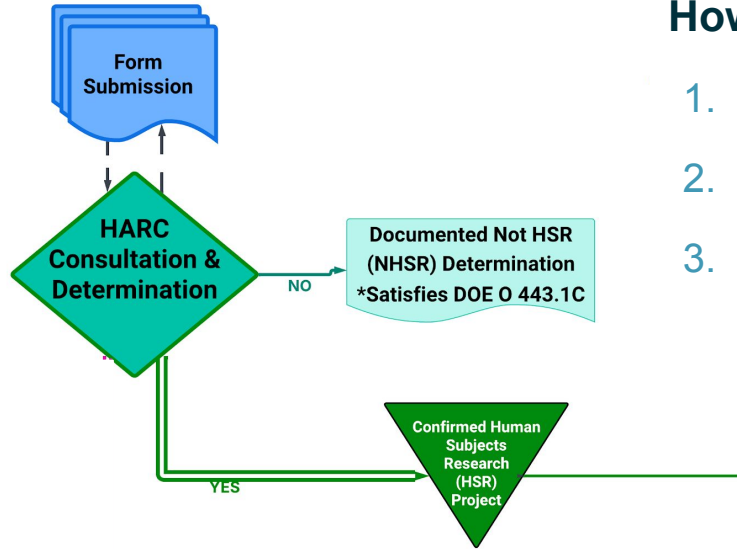


Some logistics



How do I get a determination?

1. Consult with HARC Office (Kelsey), if needed
2. Submit a form
3. Kelsey will review and determine whether Human Subjects Research (HSR) requirements apply

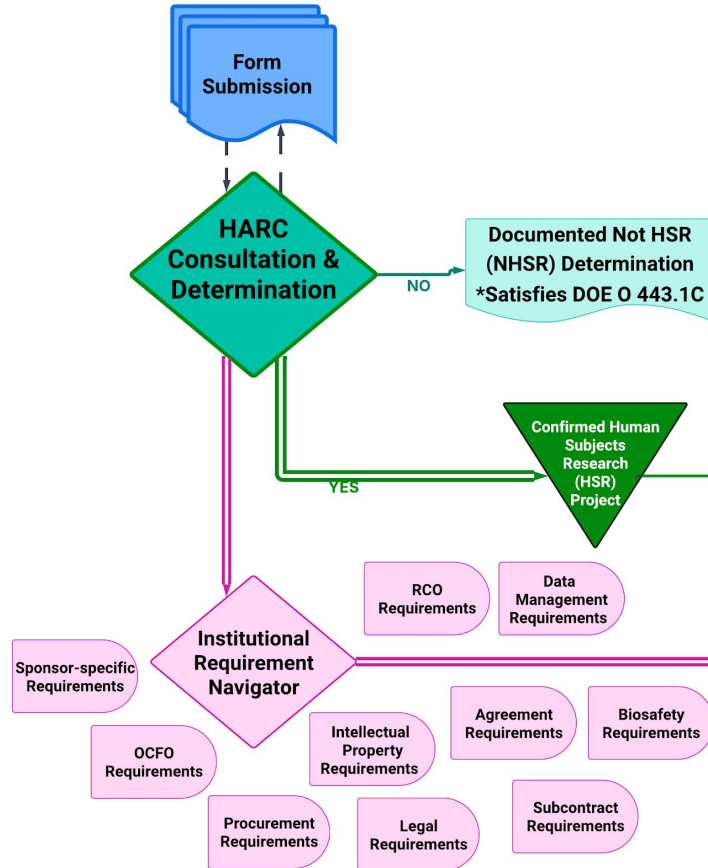


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BONUS!!

Kelsey will connect you with other LBNL Offices whose requirements may apply.



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 - Any changes to your study (*i.e.* "amendments")
 - Reportable events or unexpected issues
 - Annual updates
 - Study closeout when your project ends

Q: When can I start my study?

Fun fact: We are faster than DOE Central IRB & many universities

A1: Review timing depends on the risk the study might pose to people

FULL BOARD



- **Higher-risk** studies reviewed at a monthly Human Subjects Committee (HSC) meeting
- **Examples:** studies with vulnerable populations or research using advanced imaging (such as PET scans with radioisotopes in Alzheimer's research).
- **Typical timeline after pre-review: 2–8 weeks.**

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- **Minimal-risk** studies that are often discussed at the monthly HSC meeting.
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PRO TIP: Don't let perfectionism stop you from submitting your protocol. We help you improve it, plus you can refine an approved protocol with an amendment that typically takes <1 week for us to approve



A2: Higher quality protocols often receive faster reviews!

Protocol sections correspond to criteria that the HSC must evaluate for approval

They start with training for all study staff

Take a look at our review checklists to see what we're looking for!

The screenshot shows the Berkeley Lab protocol review interface. On the left is a navigation menu with sections: Protocol ID, Staff, Training, and Type; Study Population; Recruitment, Eligibility, and Screening; Data Collection Procedures; Behavioral and Biomedical Procedures; Biological and Radiation Safety; Risks, Benefits, and Alternatives; Informed Consent; Data Privacy & Confidentiality; Data Safety & Monitoring (highlighted); and Submission Complete. The main content area is titled 'Reading: Pro00023388' and contains a table of protocol details. A large blue bracket on the left side of the screenshot connects the text on the left to the 'Data Safety & Monitoring' section of the menu.

Reading: Pro00023388		
Protocol Title and Key Personnel		
<i>All items marked with a red asterisk (*) are required. If you don't know the answer to a required field you can use the Jump-to Menu instead of the continue button to go to page. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.</i>		
	Protocol File Number: 301NR007	
1.0	If this protocol was previously reported in the DOE Human Subjects Research Database, what is the HSRD ID number? (If not known, leave this for completion by an IRB/HSC administrator):	
2.0	Protocol Title: Business Models for Demand Flexibility	<i>This Title will be provided to satisfy annual report HSRD, which is a public-facing HSRD as required by DOE.</i>
3.0	Protocol Description: <i>* This protocol is for an interview study of organizations that are parties to California's Demand Flexibility Rulemaking (R.22-07-005) or have played other roles in shaping this proceeding (e.g., through working group participation). The purpose of these interviews is to understand the approaches these organizations are taking to monetize demand flexibility, given the emergence of dynamic tariffs in California in 2027. This work should benefit California and other U.S. States that are interested in incentivizing continuous load flexibility as a way to support grid needs (e.g., through highly dynamic prices).</i>	
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UPCOMING IMPROVEMENTS!!



The Human & Animal Research Protocol (HARP) System

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Starting in FY26: Google Workspace Workflow for Exempt Protocols

- ★ **Easy to use:** Works like other Google Docs with familiar sharing and editing
- ★ **Collaborator-friendly:** Can include external partners without firewall barriers
- ★ **Flexible & responsive:** Easier for us to update wording and clarify questions as we roll this out

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They start with training for all study staff

Take a look at our review checklists to see what we're looking for!

The screenshot shows the Berkeley Lab protocol review interface. The left sidebar lists protocol sections: Protocol ID, Staff, Training, and Type; Study Population; Recruitment, Eligibility, and Screening; Data Collection Procedures; Behavioral and Biomedical Procedures; Biological and Radiation Safety; Risks, Benefits, and Alternatives; Informed Consent; Data Privacy & Confidentiality; Data Safety & Monitoring (highlighted); and Submission Complete. The main content area displays the protocol details for Pro00023388, including the protocol title and key personnel. The protocol title is "Business Models for Demand Flexibility". The protocol description is: "This protocol is for an interview study of organizations that are parties to California's Demand Flexibility Rulemaking (R.22-07-005) or have played other roles in shaping this proceeding (e.g., through working group participation). The purpose of these interviews is to understand the approaches these organizations are taking to monetize demand flexibility, given the emergence of dynamic tariffs in California in 2027. This work should benefit California and other U.S. States that are interested in incentivizing continuous load flexibility as a way to support grid needs (e.g., through highly dynamic prices)."

UPCOMING IMPROVEMENTS!!



The Human & Animal Research Protocol (HARP) System

Protocol Title and Key Personnel	
All items marked with a red asterisk (*) are required. If you don't know the answer to a required field you can use the Jump-to Menu instead of the continue button to go to page. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.	
Protocol File Number:	301NR007
1.0	If this protocol was previously reported in the DOE Human Subjects Research Database, what is the HSRD ID number? (If not known, leave this for completion by an IRB/HSC administrator):
2.0	Protocol Title: Business Models for Demand Flexibility
3.0	Protocol Description: * This protocol is for an interview study of organizations that are parties to California's Demand Flexibility Rulemaking (R.22-07-005) or have played other roles in shaping this proceeding (e.g., through working group participation). The purpose of these interviews is to understand the approaches these organizations are taking to monetize demand flexibility, given the emergence of dynamic tariffs in California in 2027. This work should benefit California and other U.S. States that are interested in incentivizing continuous load flexibility as a way to support grid needs (e.g., through highly dynamic prices).
3.1	Abstract for Public-Facing Human Subjects Research Database (HSRD): This protocol is for an interview study of organizations that are parties to California's Demand Flexibility Rulemaking (R.22-07-005) or have played other roles in shaping this proceeding (e.g., through working group participation). The purpose of these interviews is to understand the approaches these organizations are taking to monetize demand flexibility, given the emergence of dynamic tariffs in California in 2027. This work should benefit California and other U.S. States that are interested in incentivizing continuous load flexibility as a way to support grid needs (e.g., through highly dynamic prices).



Starting in FY26: Google Workspace Workflow for Exempt Protocols

- ★ **Easy to use:** Works like other Google Docs with familiar sharing and editing
- ★ **Collaborator-friendly:** Can include external partners without firewall barriers
- ★ **Flexible & responsive:** Easier for us to update wording and clarify questions as we roll this out

Other Compliance Requirements

Conflict of Interest

- Must disclose any related financial interest on human subjects COI forms Research Data
- This includes COIs that have already been addressed by the COI committee!

Vulnerable Subjects

- LBNL/DOE Employees
- Disadvantaged Populations
- Tribal Populations
- Children

DATA Retention

- Records Retention Requirements
 - Raw data - kept for 10 years, earlier destruction *may be* appropriate for sensitive data.

SAFETY

- Work performed in homes/businesses
 - WPC - by Lab employees/affiliates
 - SJHA - by subcontractors
- Controlled Substances Program
- Institutional Biosafety Committee
- BBP/sample collection/sharps safety
- Transport of materials/shipping
- Disposal

	PRIVACY
	<ul style="list-style-type: none">● Lab Privacy Policies (Controlled/Sensitive PII versus Prudent-to-Protect PII versus Unrestricted PII. Examples:<ul style="list-style-type: none">○ SSN = Controlled/Sensitive PII (protected by law),○ Contact information = Prudent-to-Protect PII (not protected by law but should be protected)○ Work title, email etc is Unrestricted PII.● More on this here: https://it.lbl.gov/itpolicy/privacy/

	NIH
	<ul style="list-style-type: none">● Data Management & Sharing● Genomic Data Sharing Policy● Public Access Policy (Applies to DOE as well)● Recombinant DNA experiments

	Agreements
	<ul style="list-style-type: none">● All requests must come from a Berkeley Lab researcher with complete information—not from an external party● Can I just sign this NDA? NO, you absolutely cannot

	Foreign Collaborations
	<ul style="list-style-type: none">● Export Control<ul style="list-style-type: none">○ https://exportcontrol.lbl.gov/● Research Security<ul style="list-style-type: none">○ https://rco.lbl.gov/research-security

LEGAL

- Privacy Laws (State & International)
 - Highly complex landscape!
 - Specific to where information is collected
- Restrictions on lotteries
- Contracts - liability/indemnification
- HIPAA, FDA, other applicable laws

Subcontracts

- Subcontracts
 - Insurance & Data privacy clauses
 - SJHA process
 - FWAs and IRB Agreements
 - Customer Guides:
 - Guide on [Human Subjects Research](#)
 - Guide on [Incentive Payments](#)

DATA Protection

- Data Management Plans
 - All research projects or programs (regardless of funding source) require a data management plan (DMP) that covers the research performed.

Reliances

- Federalwide Assurance (FWA)
 - IRB Authorization Agreements
 - Individual Investigator Agreements
- Other considerations

HSR Specific



BERKELEY LAB

Bringing Science Solutions to the World



What is Human Subjects Research (HSR)?

Activities conducted for Research purposes, with **Interactions** or **Interventions** with living people to collect data about them or specimens from them, or using their **Identifiable Private Information**

“for Research purposes”

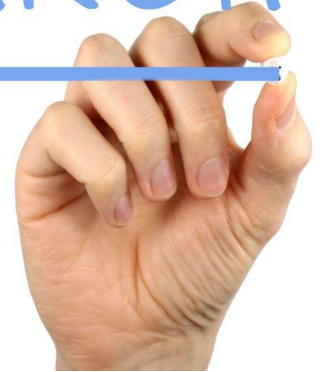
Regulatory Definition

“A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.”

DOE definition of generalizable

“Information/research findings that are intended to be applied to populations or situations beyond that studied/will have meaning and impact outside of the single immediate activity itself.”

RESEARCH



Human Subjects Research @ Berkeley Lab

Surveys/Interviews

- Collecting public opinion on energy or environmental technologies and policies through surveys or workshops
- Interviewing experts or communities to understand the challenges and opportunities in their field or in their towns.
- Collecting feedback on a model's usefulness, an environmental solution, or on where to site monitoring equipment.

Interactions:

Communication or interpersonal contact between investigator and subject.

- “Social Science” - Surveys, Interviews, Focus Groups, Workshops for research purposes
- Systematically collecting stakeholder feedback or conducting social impact assessments on attitudes, opinions, or behaviors.

Human Subjects Research @ Berkeley Lab

Interventions:

Physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment performed for research purposes.

- Changing environmental exposures to assess the impact on people
- Installing new technologies in public or private spaces that change the usual look and feel or functionality of the space
 - Determinations are largely based on the *impact* on people, not only the information collected

Modification of the Human Environment

- Testing new technologies in homes and businesses to understand real world implementation barriers
- Monitoring indoor air quality to identify hazards & develop interventions
- Assessing the way that people interface with technologies in their everyday lives

Human Subjects Research @ Berkeley Lab

Identifiable Data Use

- Using identifiable private information to develop tools and resources, such as:
 - Mining health data to create tools for better evaluation of exposure risks
 - Using videos/images of people to understand behavior and innovate solutions to public concerns
 - Examining consumer activities to inform policy decisions and identify trends

Identifiable Private Information:

*Private information for which the identity of the subject is or **may readily be ascertained** by the investigator or associated with the information.*

- Consumer/Customer data
- Health record information
- Videos and images of people or public spaces

****DOE Order 443.1C(chg1)** specifies that social media data and publicly available data about people still require review by the HARC Office!

Human Subjects Research Examples @ Berkeley Lab

Biomedical Research

- Using/creating radiotracers to visualize things in the brain that impact cognitive ability using PET Scans
- Developing a device to diagnose Alzheimer's Disease using blood samples
- Using de-identified samples from people for any device or drug development intended to diagnose, prevent, or treat diseases/conditions

Surveys/Interviews

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- Interviewing experts or communities to understand the challenges and opportunities in their field or in their towns.
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HARC Reportable Event Requirements

Significant Adverse Events

Any unfavorable occurrence associated with research participation, and substantively impacting the participant(s)

Unanticipated Problems

- 1) Unexpected
- 2) Possibly Related to the research
- 3) Likely to increase risk to subjects or others

Complaints about the Research

Regardless of whether from participants or bystanders, and whether it was resolved

Noncompliance

Ex. protocol deviations, failure to report, conducting Human Subjects Research without approvals

Report to the HARC Office
immediately upon learning of the event

Call: 510-486-6005

Email: HARC@lbl.gov

Data Breaches and/or Loss of PII

DOE Order 206.1 - *Immediate* Reporting to DOE-Cyber Incident Response Capability

DOE Order 443.1C - *Immediate* Reporting to HARC/DOE HSPP

APPLICABILITY

All Study Team Members
Share Responsibility for Reporting, not only the PLI or LBNL employees

Failure to meet these requirements will result in noncompliance

If you're unsure,
****REPORT ANYWAY****
HARC can help