



BERKELEY LAB

Bringing Science Solutions to the World



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
ENERGY
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

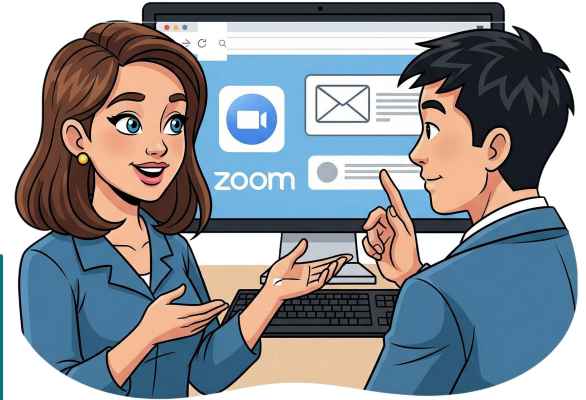
Research Compliance Office

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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INFORMAL

**ANSWERING YOUR
QUESTIONS!**

WHO

WHAT

WHERE

WHEN

WHY

WHY?



BERKELEY LAB

Bringing Science Solutions to the World



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

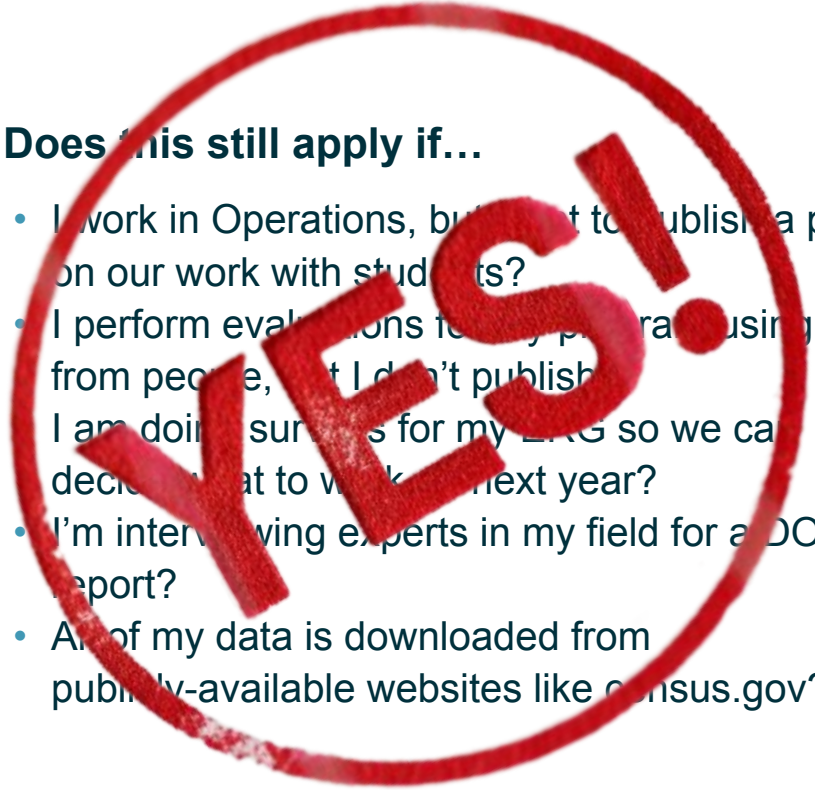
Research

with

Data from People!

Does this still apply if...

- I work in Operations, but I 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?
- All of my data is downloaded from publicly-available websites like census.gov?



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~~WHO~~ does this apply to?

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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>

WHERE IS THE FORM?!

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

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

Email HARC@lbl.gov with issues

Format for Today:

ANSWERING YOUR
QUESTIONS!

~~WHO~~ does this apply to?

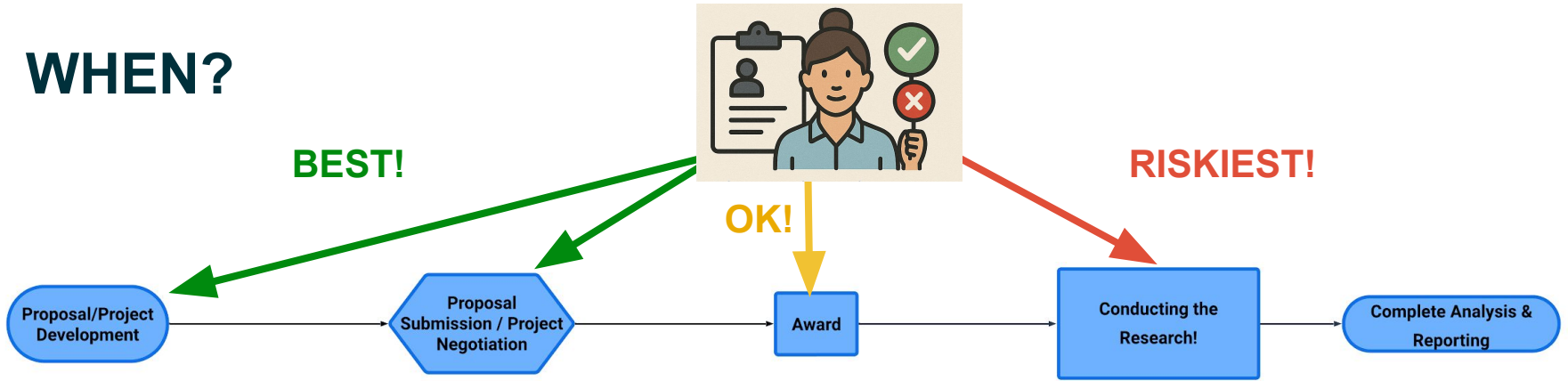
~~WHAT~~ do I do?

~~WHERE~~ do I go for help?

WHEN do I do this?

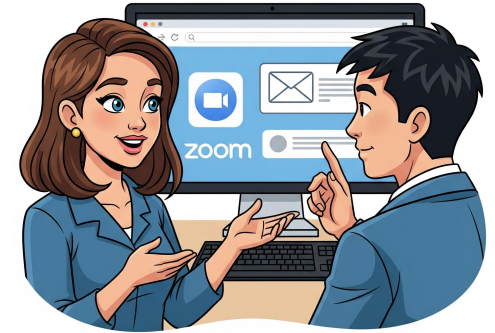
~~WHY~~ do I have to do it?

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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**What
Questions
Do You
Have?**