

HARC Town Hall

August 25, 2025



BERKELEY LAB

Bringing Science Solutions to the World



U.S. DEPARTMENT OF

ENERGY

Office of Science

Opening Statement

Agenda for Today

DOE Order 443.1C

Protection of Human Research Subjects

Updated November 2024

Full Compliance at LBNL

by February 2026

**BIG
CHANGE!**

NEW!

Improvements

CHANGES!

- ❑ **Introductions**
 - ❑ Who are we?
- ❑ **Why are you here?**
 - ❑ About the DOE Order
- ❑ **Required reviews**
 - ❑ What are these reviews for?
 - ❑ What exactly requires review?
 - ❑ Workflow Bonus!
- ❑ **What actually happens if my project is Human Subjects Research (HSR)?**
 - ❑ Clarifying the IRB Process
 - ❑ Order impact on the Research Lifecycle
- ❑ **Collaboration Opportunities**
 - ❑ A Foundation in Team Science
- ❑ **Ask Us Anything - Extended Q&A**
 - ❑ What other requirements are there for work with humans or their data?

Introductions

Who is Speaking Today

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 and Animal Regulatory Committees (HARC) Office
Program Manager, Kelsey S. Miller

Animal Care & Use Program
*Managed in collaboration with BSA
Animal Welfare & Research Committee (AWRC)
Dr. Suzanne Baker, Chair

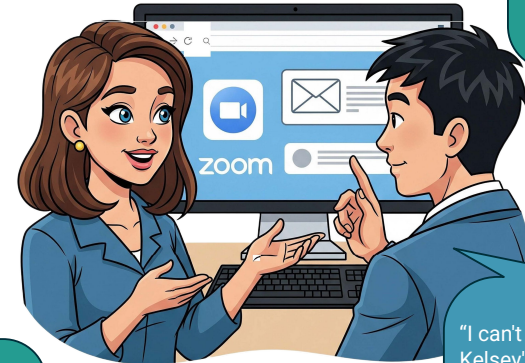
Human Subjects Protection Program (HSPP)
Human Subjects Committee (HSC)
i.e., Institutional Review Board (IRB)
Dr. Margaret Taylor, Chair



The Roles Played by the Human and Animal Regulatory Committees (HARC) Office

HARC

- ★ Assists with human data compliance
- ★ Implements DOE Order 443.1C requirements
- ★ Guides you throughout the research workflow
- ★ Helps to streamline research approvals



"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

"Having worked with many different IRBs, I can very strongly say that **the LBNL HSR experience is the most productive and efficient**. 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

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

Silvia Crivelli, CSA

"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

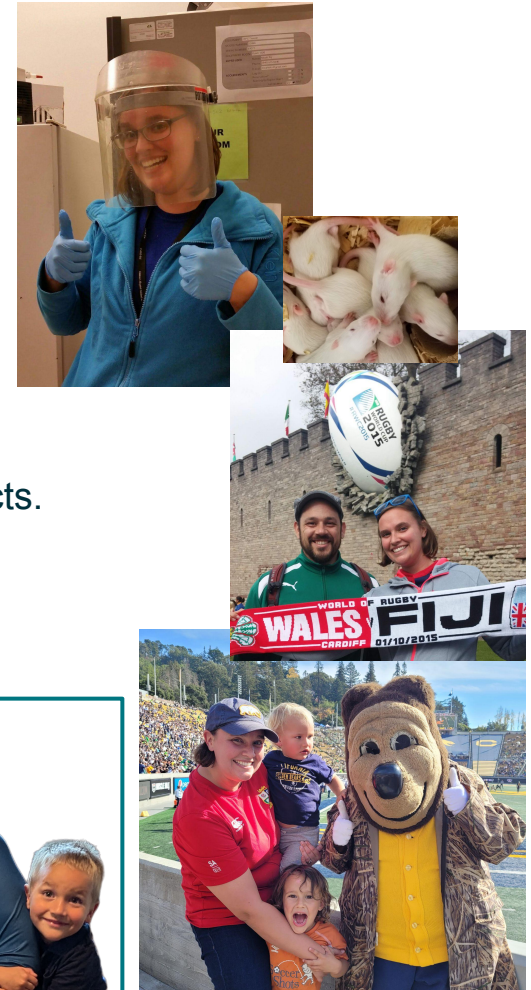
Human and Animal Regulatory Committees (HARC) Office
Program Manager, Kelsey S. Miller

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!

Office-wide Email: HARC@lbl.gov
Help Desk: HARC-Help@lbl.gov; [customer portal](#)
Phone: (510)486-6005
Office Hours: <https://calendar.app.google/3SwAgJ77mTiGNhm6>

Human and Animal Regulatory Committees (HARC) Office
Program Manager, Kelsey S. Miller



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

Why are You Here?

DOE Order 443.1C

Protection of Human Research Subjects

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by February 2026

1. **Big Change: Before** starting your research
 - *REQUIRED!* Only the HARC office can determine if your data from humans is technically “human subjects research”
2. **More Changes: During** your research
 - *REQUIRED!* Immediate Reporting to HARC of “reportable events”
 - Expanded reporting to DOE

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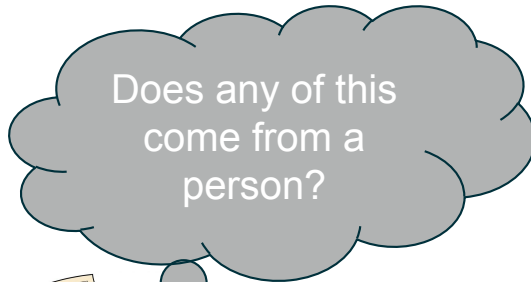
Improvements

CHANGES!

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Before you start Research:
Required Review

BIG CHANGE: All projects with data coming from people MUST be reviewed for human subjects determination



**Data from People
*Collected by Others***

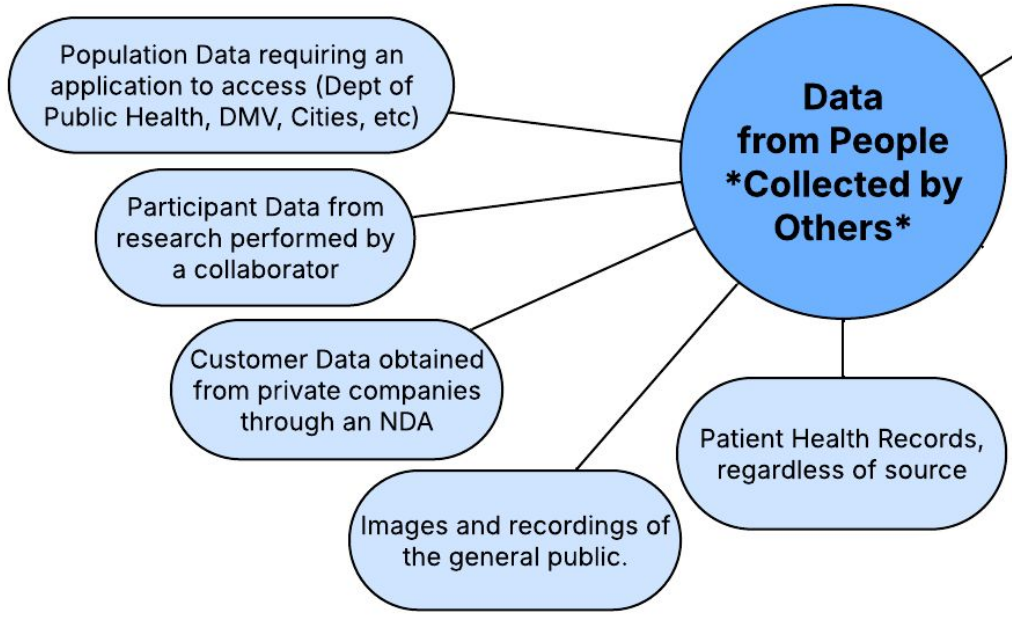
HUMAN SUBJECTS DETERMINATION



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.

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**Data from People
*Collected by Your Project***



HUMAN SUBJECTS DETERMINATION

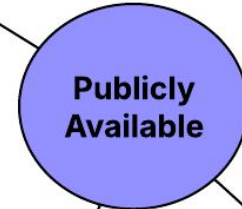
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NEW Order Requirement!

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



Anonymous Datasets with information about people (e.g., Census, data.gov, Gallup, etc.)

Human -omic data obtained through DBGap, Gnomad, etc.

Anonymized human samples from vendors or tissue banks

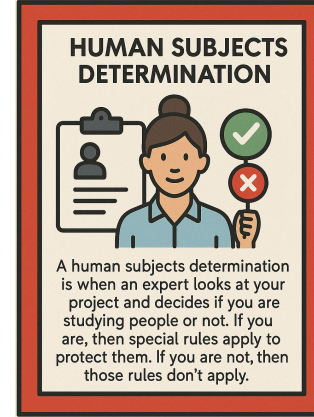
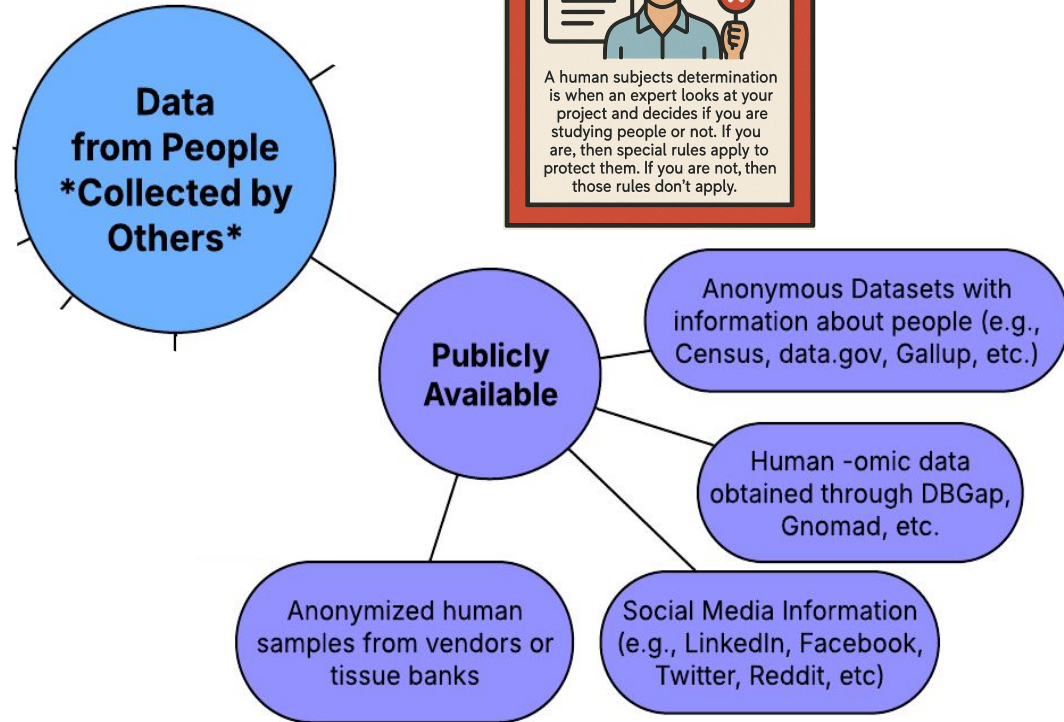
Social Media Information (e.g., LinkedIn, Facebook, Twitter, Reddit, etc)



Available Flexibility

- Central DOE HSPP has allowed a carve out using verified Not HSR (NHSR) sources to be established
- **Labs with their own IRBs (like LBNL)** are collaborating to curate and expand a shared list to make determinations faster

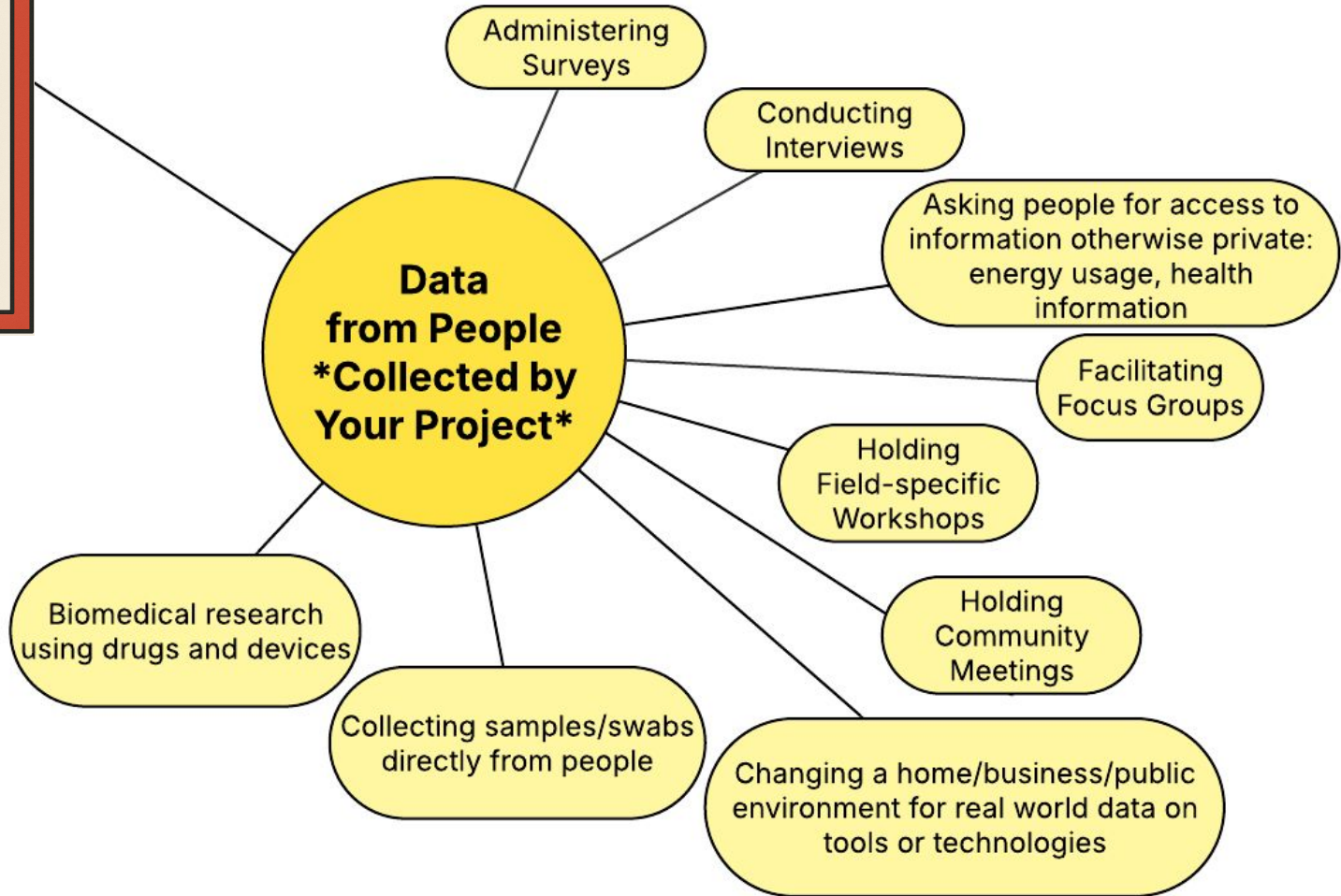
WE STILL NEED TO DO THE DETERMINATION!!



HUMAN SUBJECTS DETERMINATION




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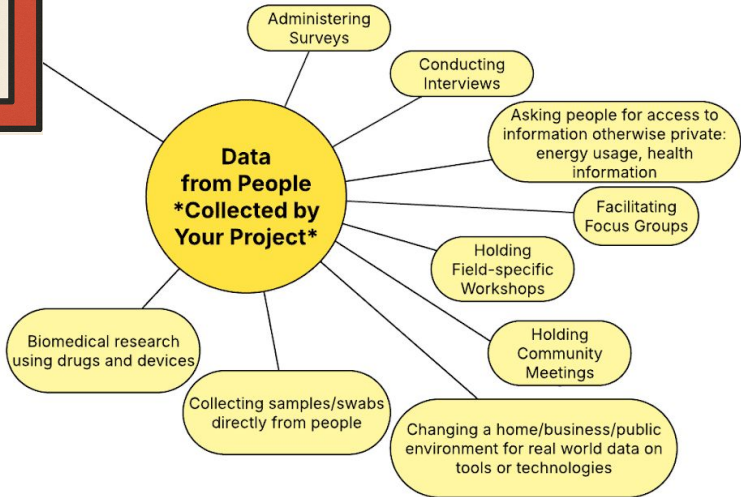
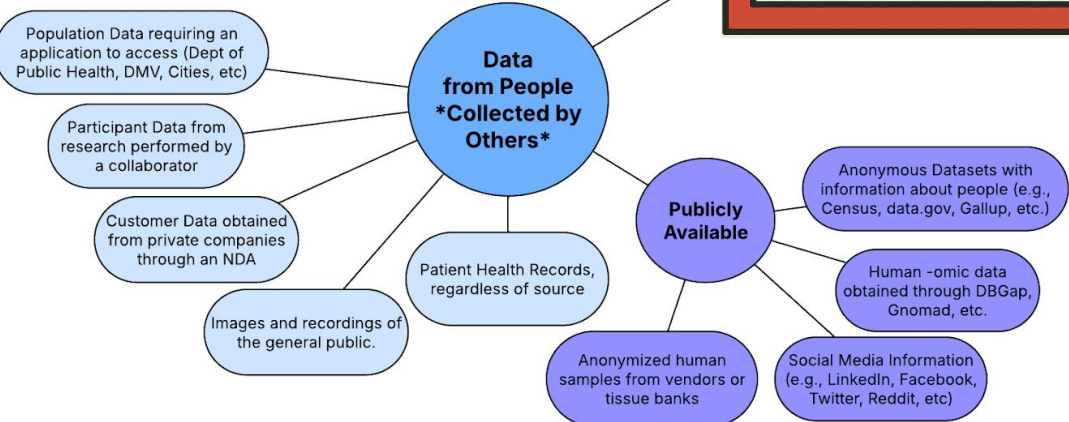
Many of your research projects will NOT be determined to be human subjects research.

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.

Some of your research projects WILL be determined to be human subjects research.

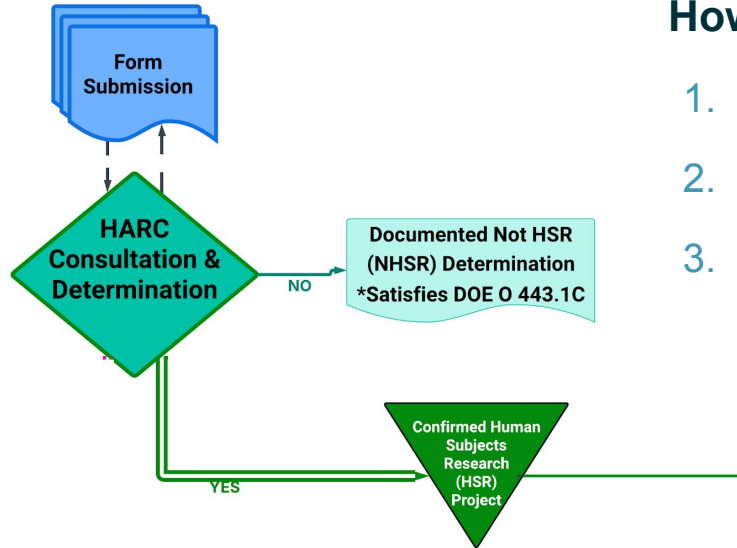


Some logistics



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

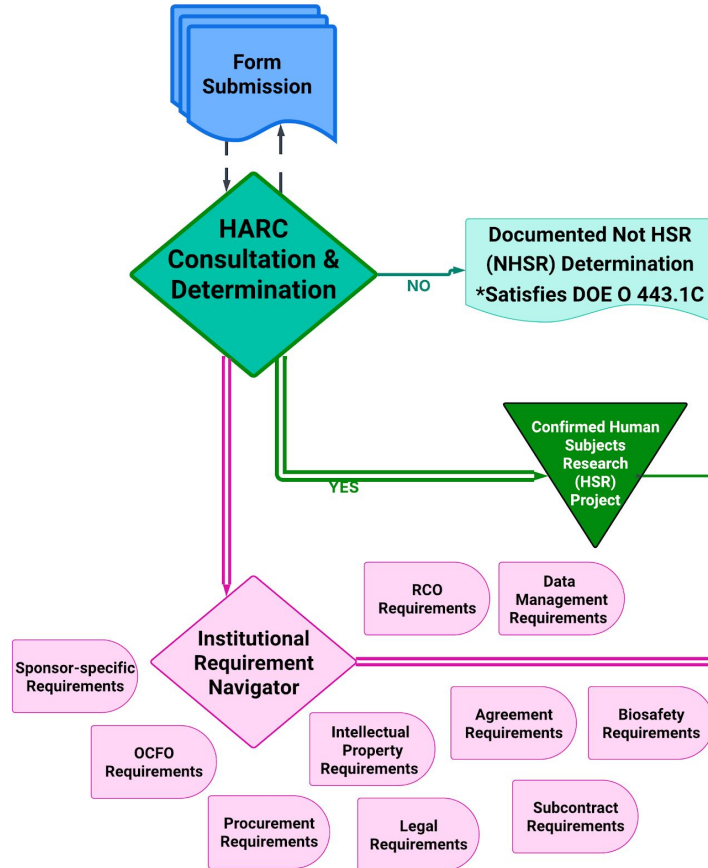


Some logistics



How do I get a determination?

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BONUS!!

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



Determinations - How?



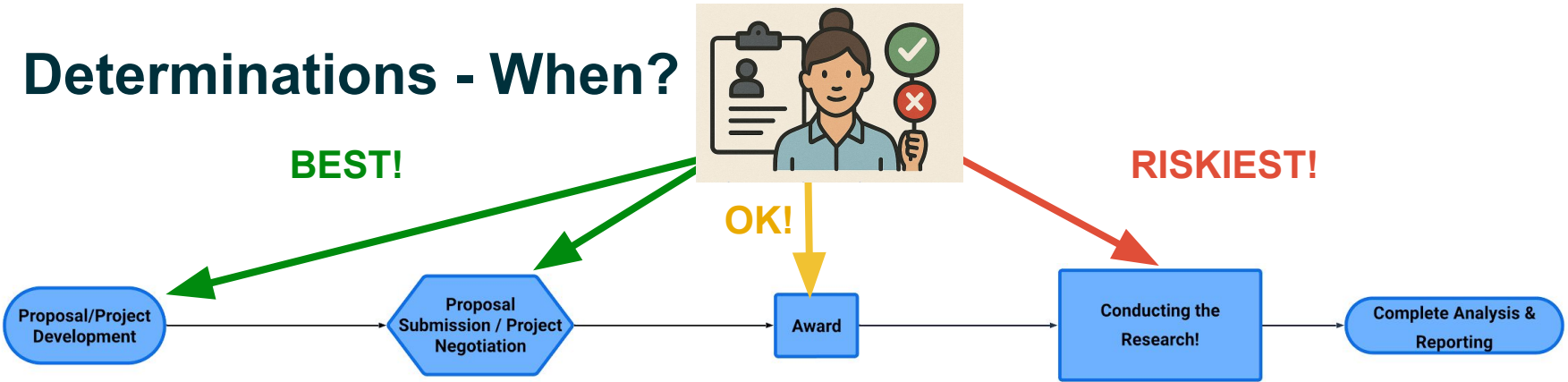
Submission Form is in Development

- Expected Release: Fall 2026
- Webinar will be held to introduce form
- JIRA or Smartsheet platform to facilitate tracking
- In-form feedback collection for continuous improvement
- Annual Reviews to find opportunities for streamlining

*****Required submissions by February to document compliance with DOE Order****

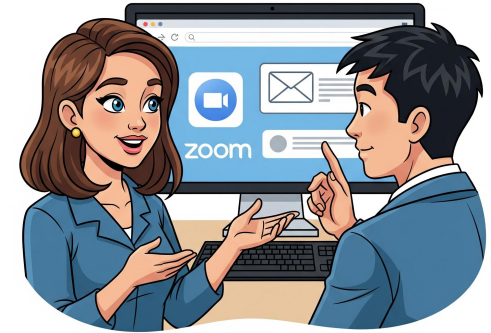


Determinations - When?



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

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**

- Released by the end of 2025

★ **BONUS!!**

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



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Q: I've received a "Human Subjects Research" determination – Now what?



A: What Researchers Need to Do

Before you start your research:

- Work with Kelsey to develop and submit a research plan (*i.e.* "protocol") for review and approval.

After you've started:

- Follow the approved plan
- Work with Kelsey and the Human Subjects Committee to process paperwork for:
 - 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.**

EXPEDITED



- **Minimal-risk** studies that are often discussed at the monthly HSC meeting.
- **Examples:** modifications to the human environment (e.g., lighting, airflow, energy use) or non-invasive measures (height, blood pressure).
- **Typical timeline after pre-review: 1–4 weeks.**

EXEMPT



- **Lowest-risk** studies that are not discussed at the HSC meeting, but reviewed by 1–2 people
- **Examples:** surveys or interviews without identifiable/sensitive information or use of publicly available datasets/specimens.
- **Typical timeline after pre-review: 1–3 weeks**

Q: When can I start my study?



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. The header includes the Berkeley Lab logo and the text 'BERKELEY LAB LAWRENCE BERKELEY NATIONAL LABORATORY'. A navigation menu on the left lists various protocol sections, with 'Data Safety & Monitoring' highlighted. The main content area displays the protocol details for 'Pro00023388', including the protocol file number (301NR007) and a list of sections with their respective descriptions and requirements. A large blue bracket on the left side of the screenshot connects the text on the left to the 'Data Safety & Monitoring' section in the interface.

Section ID	Section Name	Description	Notes
	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	This Title will be provided to satisfy annual report HSRD, which is a public-facing HSRD as required by DOE.
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).	This abstract will be provided to satisfy annual report HSRD, which is a public-facing HSRD, which is a public-facing HSRD as required by DOE.

UPCOMING IMPROVEMENTS!!



The Human & Animal Research Protocol (HARP) System

A screenshot of the Berkeley Lab HARP system interface. The header shows 'BERKELEY LAB LAWRENCE BERKELEY NATIONAL LABORATORY' and 'Hello, [user]'. The main content area is titled 'Reading: Pro00023388' and includes a 'Go to forms menu' button. A sidebar on the left lists various protocol sections, with 'Data Safety & Monitoring' highlighted. The main content area displays a table of protocol items with a red asterisk indicating required fields. A red arrow points from the 'Data Safety & Monitoring' section to the right, towards the Google Docs interface.

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

Q: My protocol was approved by the HSC and my study has started. What else do I need to know?

A: You need to keep us informed by submitting:



- **Amendments** – For any changes to your study plan
- **Reportable events** – For unexpected issues that could affect participants
- **Annual updates** – At the anniversary of approval for updates on study progress
- **Closeout materials** – Let us know when your project ends to close out the record

Q: What's a reportable event?

A: These include:



- **Data breach involving PII**
- **Adverse events** – Any unfavorable occurrence linked to research participation that meaningfully affects the participant(s)
- **Unanticipated problems** – Issues that are: (1) unexpected; (2) possibly related to the research; and (3) likely to increase risk to participants or others
- **Complaints about the research** – From participants or bystanders, whether resolved or not
- **Noncompliance** – Examples include protocol deviations, failure to report, or conducting human subjects research without approvals.

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We're here to help you with reporting!!!



- **It's always better to report.** Even if you're unsure, let us know. We can help figure out whether it meets reporting requirements.
- **We consult on the paperwork.** HARC can handle some of the regulatory and bureaucratic side for you, so you can stay focused on your research.
- **It's not unusual.** Unanticipated problems and complaints happen in many studies. Reporting them is part of responsible research, not a mark against you.
- **You're not alone.** Reporting shows you're protecting participants and the Lab, it doesn't make you a "bad" researcher.

Please help us help you!! The DOE Order requires IMMEDIATE reporting. For full compliance, we need to hear about events **WITHIN 1 BUSINESS DAY!**

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Q: I'm almost a year into my study. Is there anything I should plan for?

DOE Order 443.1C
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A: Yes, an annual check-in is a requirement in the DOE Order!



Protocol information must be reported to DOE at the end of each Fiscal Year

- Several fields are then posted on DOE's **central public-facing Human Subjects Research Database (HSRD)**

Starting FY26 we will use a Google Form not the HARP system for this! Benefits include:

- External partners performing the work can complete forms directly
- Fields shared to DOE's public HSRD will be clearly marked, for transparency

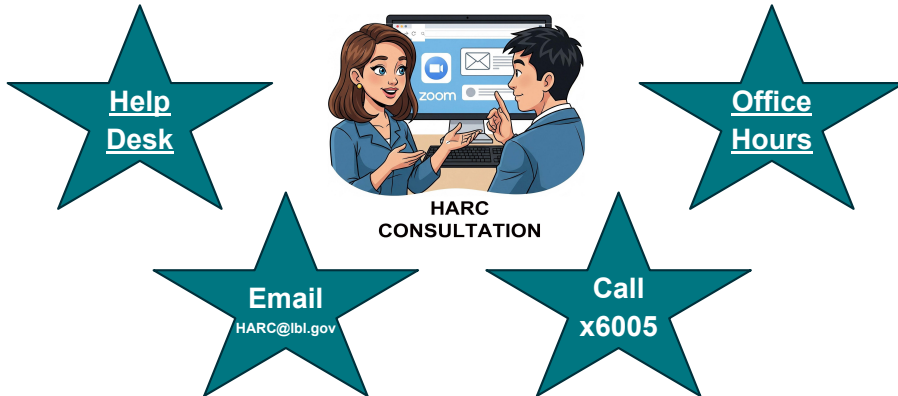


Please share your feedback to help us refine this form!

Key Takeaways

The IRB Process takes a new perspective on study design, and can be daunting at first.

HARC is here to help you be confident in your submissions, and get quick feedback on whether the HSC will need to review!



NEW BONUS - Google Workflows!

- ★ Easing burden where we have flexibilities
 - Annual Check-ins
 - Exempt Category HSR
- ★ FY26 Release

Conducting HSR requires upholding our stewardship values and ethical principles throughout the study.

- ★ **REQUIRED Immediate Reporting to HARC of Reportable Events**
- ★ **Additional Annual Reporting**

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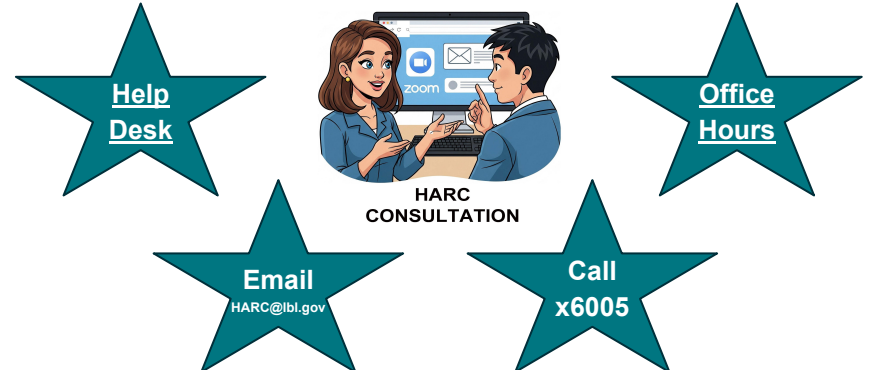
Collaboration Opportunities

Listening Sessions

- As new forms are released, sessions will be held to introduce and field questions
- Quarterly, HARC sessions will be held for collaborative problem solving and continuous improvement of processes, including
 - Determination Workflows
 - Google Doc Workflows
 - Understanding HSR Protocols
 - Human Subjects Research Best Practices

Feedback Forms

- [HARC Town Hall Feedback Form](#)
- [General Feedback Form](#)
- **In-form Feedback for new processes**
 - Determinations
 - Annual Check-ins



Contacts & Resources

Office-wide Email: HARC@lbl.gov

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

Phone: (510)486-6005

Websites:

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

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

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

Office Hours Appointments:

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

Individual Contacts

Program Manager:

Kelsey Miller, ksmiller@lbl.gov

HSC Chair:

Margaret Taylor, mtaylor@lbl.gov

PART II

Ask Us Anything

Extensive Q&A

ASK US ANYTHING!

HSR
Determinations

Other
Requirements
for Human Data
Use

Human Subjects
Research
Processes

Something Else?

Supplemental Slides

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



Office of Science

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”

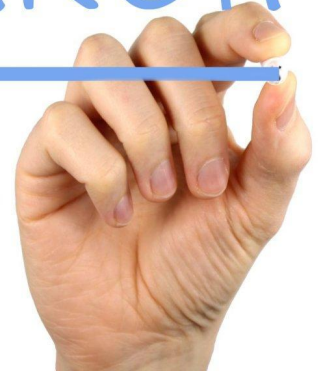
Regulatory Definition

“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

- 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 where to site monitoring equipment.

Modification of the Human Environment

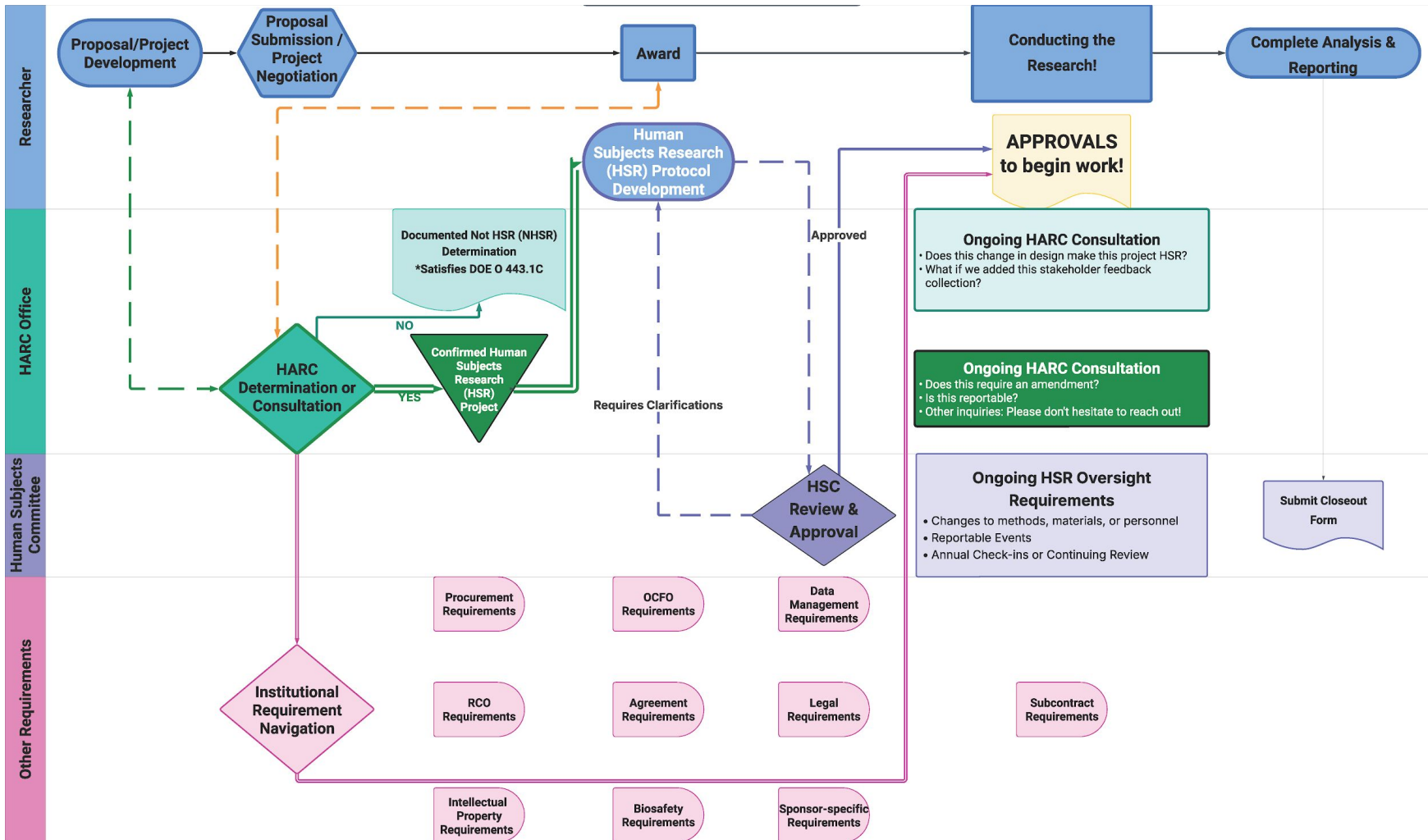
- Testing new technologies in homes and businesses to understand real world implementation barriers
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Identifiable Data Use

- Using identifiable private information to develop tools and resources, such as:
 - Mining health data to create tools for better evaluation of treatment needs or 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

The HSR Process - Simplified





HSC 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