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Human Subjects in Energy Technology and Policy Research

Symposium Report

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration

Human Subjects in Energy Technology and Policy Research Symposium

October 17 and 19, 2023

Convened by
U.S. Department of Energy/National Nuclear Security Administration
Human Subjects Protection Program

This report is available at
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Human Subjects in Energy Technology and Policy Research

Symposium Report

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Chapter 1

Introduction

The U.S. Department of Energy (DOE) has a unique and wide-ranging research portfolio. One focus of the department's research mission is to develop and promote the adoption of technologies that reduce greenhouse gas emissions and result in renewable and clean energy for the country. This research encompasses a surprisingly diverse array of studies, many of which involve the inclusion of human participants that go beyond traditional biomedical investigations. For example, individuals play an important role in DOE research on clean energy sources, development and testing of new energy-efficient technologies, and partnerships with local communities for equitable climate solutions (see Fig. 1.1, this page).

Fig. 1.1. Human Participants in Energy Research. The U.S. Department of Energy's (DOE) expansive and unique scope of research is becoming increasingly reliant on human subjects research (HSR) in the energy technology and policy field. DOE's portfolio includes a range of studies involving HSR, from seeking insight into users' experiences with new sources of clean and efficient energy to establishing community partnerships to develop equitable environmental solutions.

Fig. 1.2. Human Research Protections: A Framework of Shared Responsibilities. Active collaborations among funders, institutional review boards, researchers, and participants, along with guidance from regulations, encourage protection of research participants.

DOE research in energy technology and policy has previously focused on technical research elements and only minimally involved human subjects research (HSR). However, as energy research has evolved, it has become more diverse and reliant on interventions or interactions with individuals or use of their data. Many researchers and engineers are seeking insight into the impacts on and experiences of individuals who use new energy efficiency technologies, rather than relying solely on the technical expertise of those creating the technology. As a result, much of the work in this field now involves HSR and requires the oversight of the Human Subjects Protection Program (HSPP). DOE and its semi-autonomous National Nuclear Security Administration (NNSA) manage the HSPP together.

HSR in the energy technology and policy field is becoming an increasingly indispensable element of the field's pursuits to secure equitable and just adoption of future innovations in clean energy research. Indeed, HSR plays an integral role in finding solutions to some of humanity's most pressing energy challenges: discovering innovations in energy technology, making advances in renewable energy, and mitigating climate change. Protecting the valued participants in this research is of utmost importance and requires a shared framework of responsibilities among funders, researchers, institutional review board (IRB) professionals, and participants (see Fig. 1.2, this page).

To raise awareness about DOE-specific requirements for conducting research in this evolving field and to encourage collaboration between researchers, DOE sponsors, and IRB professionals, the DOE/NNSA HSPP hosted the inaugural "Human Subjects in Energy Technology and Policy Research Symposium" on October 17 and 19, 2023 (see Appendix A:

Symposium Agenda, p. 76). The primary goals of the symposium were to:

1. Increase awareness about what constitutes HSR in the energy technology and policy field and how to apply DOE-specific regulations consistently across agency-supported projects;
2. Promote best practices from the proposal stage through study completion; and
3. Foster a culture of collaboration to break down barriers and advance best practices specific to HSR in this field.

These goals should be considered in the context of historical and modern-day inequalities in energy infrastructure and DOE's efforts to ensure more equitable social and economic participation in the energy system. The following section, based on one of the symposium's plenary sessions (see Plenary Speaker, this page) highlights the importance of prioritizing the inclusion of marginalized communities in energy technology and policy research.

1.1 DOE's Commitment to Energy and Environmental Justice

Historically, disadvantaged and impoverished communities of color have faced disproportionate economic, energy, and environmental burdens that exacerbate inequality and inequity and create mistrust of government. Despite progress since the civil rights movement, these communities continue to experience systemic and structural barriers that prevent equal access to opportunities and benefits. The lived experiences of these communities are often not accurately represented in economic and energy research, at times being hidden by statistical averages. Safeguarding these communities from environmental and energy-related inequalities and inequities is a top priority for DOE, and DOE's Office of Energy Justice Policy and Analysis is focused on tackling the climate crisis through equity-centered solutions. Ethical and equitable engagement with communities for HSR depends on understanding the issues they face and developing research that incorporates their concerns and needs.

Plenary Speaker

Anjuli Jain Figueroa

Office of Energy Justice Policy and Analysis, U.S. Department of Energy

Plenary Topic:
Ensuring Ethical and Equitable Engagement

DOE's commitment to promoting ethical energy and economic policies began in response to the civil rights movement of the 1960s and the energy crisis during the 1970s. Throughout this time, Black activists showed that people of color faced disproportionate economic and energy burdens, such as discrimination in housing and employment and exposure to toxins left by industrialization (Schroeder 2023). One historical component that led to the unequal footing seen today is redlining, which is the discriminatory practice of classifying neighborhoods as "hazardous" to invest in the purpose of excluding certain groups from access to credit, loans, mortgages among others. Prior to the 1968 Fair Housing Act, mortgage lenders widely redlined core urban and Black-populated neighborhoods while the federal government played a key role in institutionalizing and encouraging redlining through the Federal Housing Administration (FHA). This discriminatory policy resulted in mistrust of the government among people of color. For many communities, redlining also reduced access to other opportunities that would lead to healthy lives, such as access to good schools, food, infrastructure, and even energy. As such, when conducting HSR that is tied to a government agency or affiliated with any part of the government (e.g., local, state, or federal), researchers must keep in mind that they are not necessarily starting a new relationship with a community. Instead, they are often building on a pre-existing relationship—and sometimes repairing a broken one—that was established long before.

Key Terms

- **Energy Insecurity:** an inability to meet basic household energy needs (Hernández 2016)
- **Energy Burden:** the percentage of income spent on energy costs

The Hidden Truth: Energy Poverty in the U.S.

Many of the overall measures used to evaluate **energy insecurity** inadequately represent the lived experience of low-income communities and communities of color and risk further reinforcement of the inequalities and inequities these communities face. The American Council for an Energy-Efficient Economy paints this picture in its 2020 assessment of national **energy burden**, or the percentage of income spent on energy costs. While the median statistics indicate low energy burden (defined as less than 6%) across the United States, low-income household energy burdens are 2.1 to 3 times higher than that overall median and 3.5 times higher than non-low-income households, surpassing that 6% threshold in every region. People of color also bear a higher energy burden, with Black households' median energy burden averaging 43% higher than that of white (non-Hispanic) households (ACEEE 2020).

Similarly, energy insecurity data from the U.S. Energy Information Administration's Residential Energy Consumption Survey in 2020 showed an overall reduction in energy insecurity from 2015 to 2020 (U.S. EIA 2020). However, closer examination of stratified social demographic data reveals that not everyone experienced this decline, with groups that already had high incidences of energy insecurity experiencing increased insecurity during this same time frame. The reality is that energy insecurity is highly correlated with specific demographics, occurring in higher incidences among Black, Hispanic, and low-income households as well as in households with older residents and children. Overall, energy insecurity is a significant issue for nearly one in four households in the United States, and one in five are forgoing basic necessities or falling behind on energy payments (U.S. EIA 2018). Taken together, these data spotlight the discrepancies in lived experiences of low-income communities and communities of color and the need to ensure proper representation of the gaps and barriers they experience.

Accurate representation of low-income and minority communities is even more important in the climate change space because extreme weather events, such as cold snaps and heat waves, can exacerbate inequities as households are required to use more energy to survive. Many low-income and minority communities, for example, lack the financial means or access to air conditioning, which prevents them from meeting additional heating and cooling demands (Whitely 2021; Popovich and Choi-Schagrin 2021; Khimm and Eaton 2021). These same communities also disproportionately bear the environmental burdens of the fossil fuel industry, with Black and Hispanic communities not only exposed to more pollution than they produce (Tessum et al. 2019), but also more limited access to clean energy. For example, low-income households are less likely to adopt solar power than higher-income households (Reames 2020), and even with a controlled income variable, households of color are slower to adopt solar technology than white-majority communities (Sunter et al. 2019). In the face of such inequities, the United States is confronted with a challenge to transform the energy system in such a way that no communities are left behind. This transformation must lead to an energy system that is more equitable and just for all Americans.

Implementing Energy Justice

Energy justice seeks to achieve equity in participation in the energy system through remediating the social, economic, and health burdens the energy system disproportionately places on frontline communities. Explicitly centering on these communities' concerns, energy justice aims to make energy more accessible, affordable, clean, and democratically managed for

Fig. 1.3. Pillars of Energy and Environmental Justice. Energy justice and environmental justice share the same core pillars of procedural, recognition, distributive, and restorative justice. Ultimately, DOE's work toward achieving energy justice must prioritize the involvement of disadvantaged communities and not only allow but also empower their active participation throughout all pillars of the energy justice process, from procedural justice to restorative justice.

all communities (IEJ 2019). Energy justice is tightly linked to the concepts of climate and environmental justice, both of which seek to implement "equal protection from burdens, meaningful involvement in decisions, and fair treatment in access to benefits" in at-risk communities (Jenkins 2018). However, the concept of energy justice provides a more focused means of tackling injustices and will have cumulative effects for the environmental and climate justice movements.

DOE strongly supports the energy and environmental justice movements and implemented the Justice40 Initiative to strengthen the core pillars of energy and environmental justice throughout the department (see Fig. 1.3, this page). This whole-of-government initiative creates a goal that 40% of the overall benefits of federal investments flow to disadvantaged communities. It provides a framework for priority outcomes that aim to remediate the inequities prevalent in frontline or disadvantaged communities. DOE's Justice40 Initiative aims to decrease environmental exposure and energy and environmental burdens in these communities while increasing the following:

- Parity in access to and adoption of clean energy technology (e.g., solar and storage).
- Access to low-cost capital.
- Clean energy enterprise creation and contracting for minority business enterprises.
- Clean energy jobs, job pipelines, and job training for individuals.
- Energy resiliency and democracy, including community ownership in disadvantaged communities.

DOE strives to meet its mission to ensure U.S. security and prosperity by addressing its energy, environmental, and nuclear challenges through transformative science and technology solutions. To do so, it must continue to prioritize the concerns of marginalized communities. Researchers conducting HSR in the energy technology and policy field can foster ethical and equitable engagement with research communities by understanding the issues they face, developing research that incorporates their concerns and needs, and encouraging active participation from community members throughout all phases of the research process.

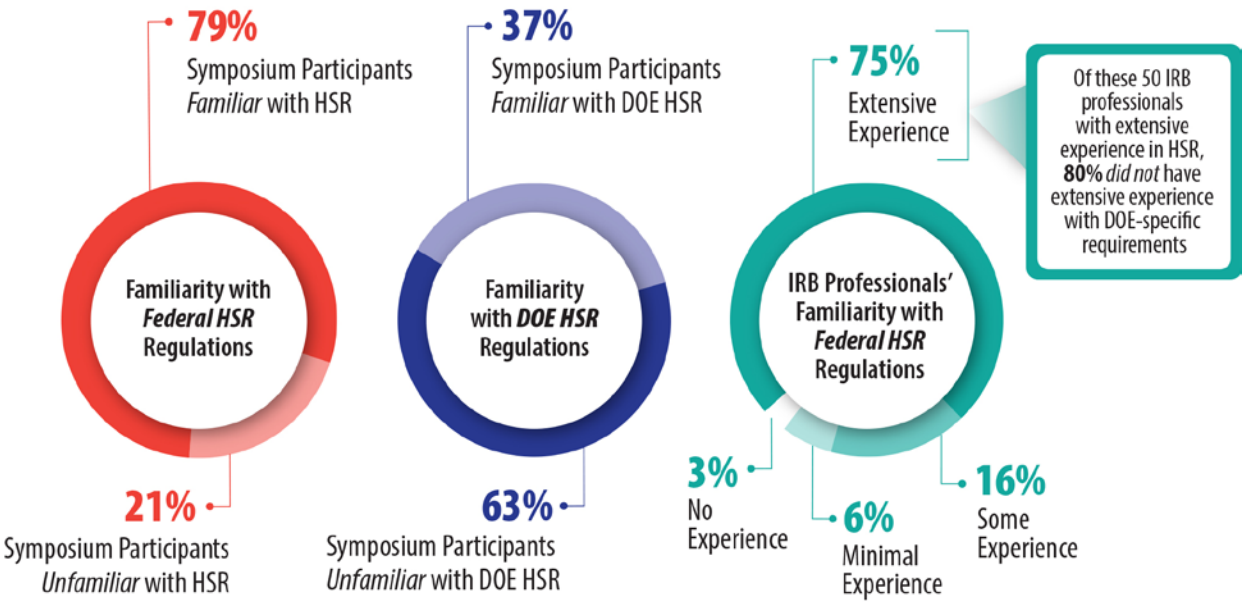

Fig. 1.4. Expanding Familiarity with DOE-Specific Human Subjects Research (HSR) Regulations. A pre-symposium poll asked registrants to rate their familiarity (e.g., no experience, minimal experience, some experience, and extensive experience) with federal and DOE HSR regulations. Of the 139 respondents, 110 (79%) reported having some to extensive experience with federal HSR regulations. However, respondents were considerably less familiar with DOE-specific regulations, with only 52 (37%) reporting that same level of familiarity. Moreover, of the 50 respondents who identified as IRB professionals having extensive experience with federal regulations, 40 (80%) did not have extensive experience with DOE regulations. These results highlight the opportunity for expanding outreach and educational activities on DOE-specific HSR regulations.

1.2 Human Subjects in Energy Technology and Policy Research Symposium

In preparation for the symposium, registrants were asked about their familiarity with HSR in general and with DOE-specific HSR requirements. More than three quarters of respondents (79%) had at least some experience in HSR. However, only 37% were familiar with DOE Order 443.1C, *Protection of Human Research Subjects*, which outlines DOE-specific requirements for ethical conduct of HSR in DOE-supported research (see Fig. 1.4, this page). Even among respondents who identified as IRB professionals, familiarity with the DOE requirements was low. These responses helped inform the workshop goals previously described.

The symposium featured presentations from DOE and NNSA leadership, the Office for Human Research Protections (OHRP), and experts in research and IRB administration. Attendees were provided interactive opportunities, some of which included:

- Workshops on best practices for HSR;
- Question and answer sessions about HSR in the energy technology and policy field; and
- Discussions of best practices of HSR projects both within and outside the DOE complex.

Presenters raised the issue of inconsistent implementation of HSR regulations in this field and stressed the need for collaboration and understanding across institutions. Ultimately, attendees acquired a greater level of awareness for what constitutes HSR, how to apply DOE IRB rules and regulations to their research, how to incorporate participants into their study design, and

when to seek guidance from IRB professionals at their institutions.

The following chapters summarize symposium sessions and key takeaways, identify lessons learned regarding what is and what is not HSR, and discuss potential directions and action items for future education and training events. Chapters also provide expert advice for encouraging collaboration among researchers, sponsors, and IRB professionals; perspectives and insights from and for IRB professionals and researchers regarding the IRB review process and designing IRB documents; and use cases highlighting how various DOE projects involved HSR and IRBs, identified challenges, and discovered best practices. Ultimately, this report aims to function as a resource for those supporting, reviewing, and conducting research to refer to when developing and deploying HSR in energy technology and policy.

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Chapter 2

Applying Human Subject Regulations to Energy Research

The primary goal of the "Human Subjects in Energy Technology and Policy Research Symposium" was to increase awareness about human subjects research (HSR) in the energy technology and policy field and how to apply DOE-specific regulations consistently across funded projects. Many symposium participants were familiar with human subjects research; according to a pre-symposium poll, 79% of participants responded that they had some experience to extensive experience. However, only 37% were familiar with DOE Order 443.1C, *Protection of Human Research Subjects*, which outlines DOE-specific requirements for ethical conduct of HSR (see Fig. 1.4, p. 6). As such, the first day of the symposium sought to (1) enhance symposium participants' understanding of human subjects in energy research and DOE's requirements and (2) improve symposium participants' knowledge of best practices. In the plenary session titled "Human Subjects and Energy Research: Applying the Regulations to this Field," speakers from the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) and DOE's Human Subjects Protection Program (HSPP) provided an overview of federal and DOE-specific human subjects regulations and addressed how to apply them to the field of energy transition research (see What Does OHRP Do?, this page).

What Does OHRP Do?

- *Operates within the U.S. Department of Health and Human Services (HHS) under the Office of the Assistant Secretary of Health*
- *Holds authority for 45 CFR 46, which includes the Common Rule*
- *Regulates all HHS nonexempt human subjects research*
- *Provides leadership for human research protections across all federal agencies and departments*

2.1 The Common Rule and Its Place in Energy Technology and Policy Research

Recognizing the Need for an Ethical Foundation in HSR

The purpose of research is to improve society by advancing scientific knowledge. Including human participants in a research study can introduce

Plenary Speakers

***Plenary Session:** "Human Subjects and Energy Research: Applying the Regulations to this Field"*

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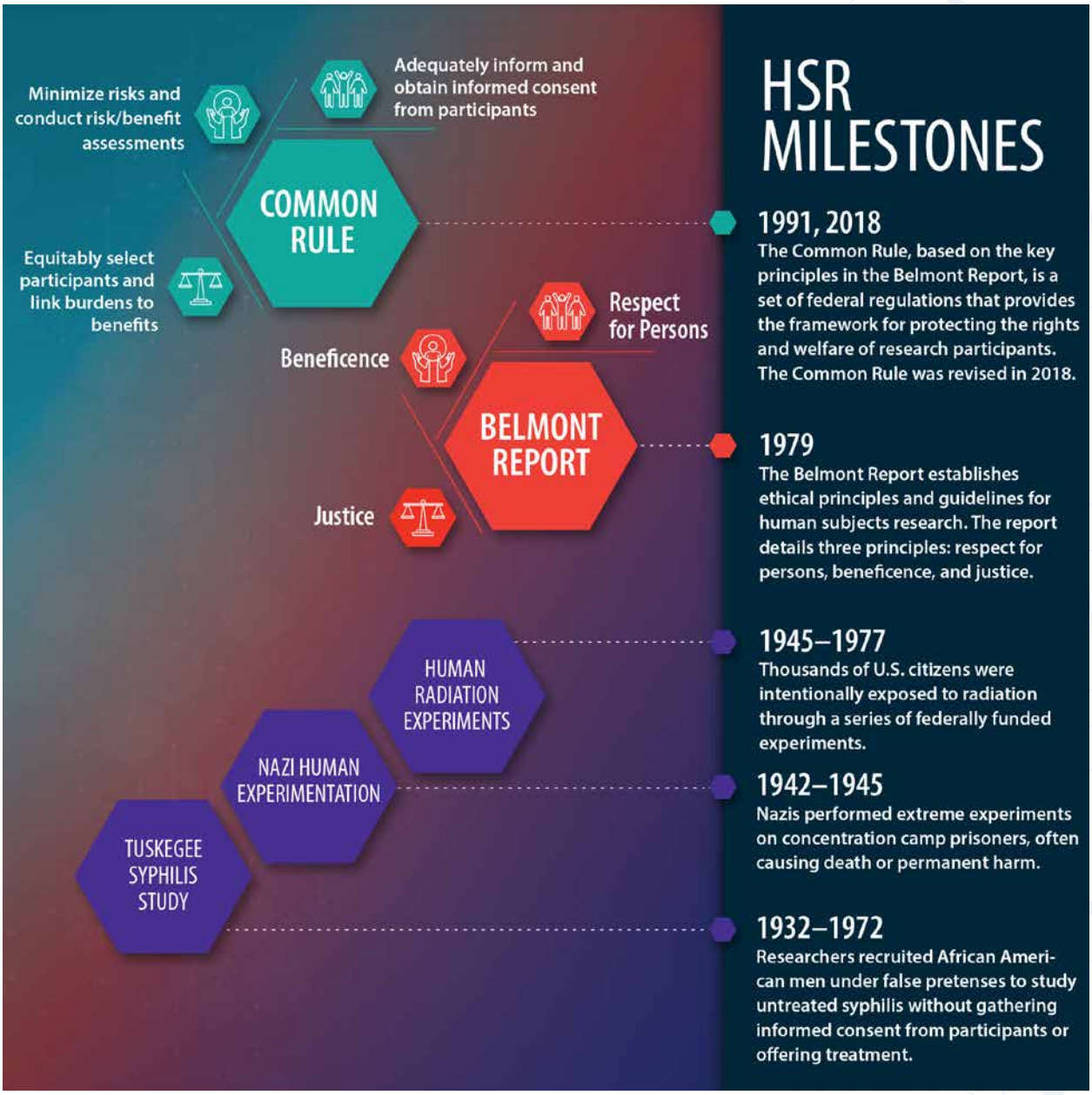

Fig. 2.1. Human Subjects Research Milestones. Research regulations and standards have evolved throughout history. Unethical treatment of research participants led to the ethical principles outlined in the Belmont Report. These principles underpin the federal regulations in the Common Rule that govern research practices today.

ethical tensions between advancing the research and protecting a participant's rights and welfare. Indeed, during the 19th and early 20th centuries, the poor, marginalized, and vulnerable were frequently subjected to unethical human experimentation. Historical examples include the U.S. Public Health Service's untreated syphilis study at Tuskegee and the Nazi concentration camp experiments on prisoners (see Fig. 2.1, this page). Examples of such studies also exist within DOE's history, including radiation experiments on humans and exposure to nuclear testing (U.S. EHSS 1995). In all of these examples, the individuals

involved were vulnerable to exploitation and coercion and were either unable or unwilling to provide consent. They were also singled out to bear the burden of research for the benefit of others or for the larger benefit of advancing scientific knowledge.

Implementing A Regulatory Framework for Protecting Research Participants

Public outrage about these exploitations prompted the federal government to establish an ethical foundation that would provide the needed protections for conducting research with human participants. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, more commonly referred to as the Commission, was created in 1974 by the National Research Act and charged with identifying the basic ethical principles for the conduct of research involving human participants and developing corresponding guidelines (Institute of Medicine 2007). In 1976, the Commission published the Belmont Report, which outlined and explained the following principles: (1) respect for persons, (2) beneficence, and (3) justice (U.S. HHS 1979). These principles underpin the federal regulations for the protection of human subjects in research, also known as the Common Rule, which was adopted in 1991 and updated in 2018 (see Fig. 2.1, p. 9).

While the Common Rule (45 CFR 46) provides the foundational framework for protecting the rights and welfare of research participants in federally conducted or supported research (see What's Common About the Common Rule?, this page), its regulatory requirements are only the baseline. Most institutions and agencies, including DOE, implement policies that incorporate additional protections for research participants (see Understanding DOE's Specific Requirements, p. 13).

Applying the Common Rule to Energy Research

The Common Rule regulatory requirements apply to any federally supported research that is considered nonexempt HSR. Making this determination involves asking and answering a series of three questions: (1) Does the activity involve **research**? (2) Does the research involve **human subjects**? (3) Is the human subjects research **exempt**? The definitions offered in "Key Terms" (see p. 11) should inform the decision process. If an institutional review board (IRB) determines that the answers to these questions are (1) yes, (2) yes, and (3) no, the research is nonexempt and requires review and approval by an IRB, compliance with the Common Rule, and informed consent from participants unless the IRB determines consent can be waived. The research must also follow any institutional and funding agency requirements.

The Common Rule regulatory requirements also necessitate that research falling into four of the eight exemption HSR categories (see 45 CFR 46.104) undergo a limited IRB review. This review, often conducted by the IRB chair or a member of the IRB, ensures that adequate provisions are in place to protect participants' privacy and maintain data confidentiality. Other Common Rule regulatory requirements do not typically apply when a project is considered exempt HSR; however, researchers may still need to adhere to other institutional or funding agency requirements.

To qualify for exemption, the entire project must meet the criteria for one or more of the eight exemption categories defined in the Common Rule (45 CFR 46.104). Under the DOE order, only an IRB or IRB office can determine whether a project meets the exemption criteria. Most importantly, regardless of the applicability of the regulatory requirements, ethical responsibilities for ensuring participants' rights and welfare still remain. Several agencies, including DOE, have their own additional requirements for exempt HSR in order to meet these ethical responsibilities.

What's Common About the Common Rule?

The set of regulations known as the Common Rule is followed by 20 U.S. federal departments and agencies for the HSR that they conduct or support. Each department or agency following the Common Rule is responsible for overseeing the research that falls under its purview.

*Key Terms**

- **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Human Subject:** A living individual about whom an investigator either **(1)** obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or **(2)** obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- **Intervention:** Physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment are performed for research purposes.
- **Interaction:** Communication or interpersonal contact between investigator and subject.
- **Private Information:** Any information about behavior that occurs when an individual can reasonably expect that no observation or recording is taking place. It also refers to information that an individual has provided for specific purposes and can reasonably expect will not be made public (e.g., a medical record).
- **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.
- **Identifiable Biospecimen:** A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Definitions adapted from Section 46.102 of the Common Rule.*

2.1: The Takeaway

The model for protecting human subjects in federally conducted or funded research includes a framework of shared responsibilities (see Fig. 1.2, p. 2). The regulations, based on ethical principles, provide baseline protections and guidelines for conducting HSR. Sponsors, such as DOE, take on the responsibility of funding research that promotes the common good but also respects individual research participants. Institutions conducting the research have the responsibilities of promoting ethical research, assuring regulatory compliance, and overseeing the protection of research participants. Researchers are tasked with respecting individuals' autonomy and protecting the rights and welfare of their research participants, and research participants volunteer to contribute through active engagement with researchers and to follow the procedures to ensure research integrity.

2.2 DOE HSR Regulations in Energy Technology and Policy Research

Identifying HSR at DOE

DOE's broad portfolio in HSR includes research conducted by multiple DOE sites, as well as universities and other outside organizations. DOE funds approximately half of this research portfolio while outside agencies or other institutions fund the other half.

Some examples of DOE-supported HSR in the energy technology and policy field are:

- Interacting with research participants through surveys, interviews, and focus groups.
- Partnering with research participants to evaluate environmental alterations such as testing energy-saving devices in buildings or homes.
- Generating identifiable information through the collection of homeowners' demographic data and energy use over time.
- Using existing identifiable information or samples collected for another purpose including, for example,

gathering information from social media chat rooms to use in a study on electric vehicle users.

DOE follows the same definitions for **research** and **human subjects** as outlined in the Common Rule (see Key Terms, p. 11) but additionally includes a definition of **generalizable** to aid in decisions of whether a study meets the definition of research (see Key Term, this page).

Key Term

Generalizable: Information or research findings that are intended to be applied to populations or situations beyond those studied that will have meaning and impact outside of the single immediate activity itself (U.S. DOE 2023).

Getting to Know the DOE/NNSA HSPP

A DOE-wide program, HSPP is overseen by DOE's institutional official for HSR and jointly managed by program managers within DOE's Office of Science and the National Nuclear Security Administration (NNSA). HSPP managers work closely with DOE headquarters and field organizations that fund and conduct HSR. The HSPP's primary responsibilities are outlined in Fig. 2.2, this page.

Identifying an Appropriate IRB for Your Project

Research involving human participants must be reviewed by an appropriate IRB. The information in Fig. 2.3, p. 13, can help researchers and sponsors pinpoint the appropriate IRB to review their study when funded or conducted by DOE.

When projects involve more than one collaborating institution, typically one IRB serves as the IRB of record. This involves developing a reliance agreement to be signed by all institutions collaborating on a study and the reviewing IRB. The reliance agreement outlines the IRB of record that organizations will rely on for a particular study or program. It also provides a list of any institution-specific requirements to ensure awareness and compliance of the reviewing IRB and researchers. DOE Order 443.1C should always be referenced in reliance agreements for DOE-funded or conducted HSR.

Fig. 2.2. Overview of the DOE/NNSA Human Subjects Protection Program's (HSPP) Primary Responsibilities. HSPP reviews, educates, guides, and partners with all DOE and NNSA sites conducting human subjects research to ultimately promote ethical research and protect participants.

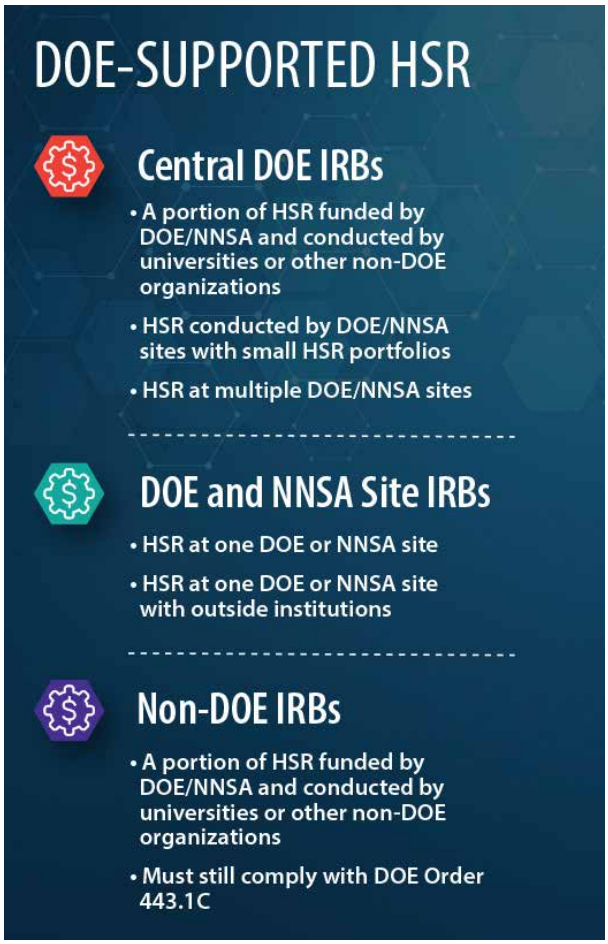

Fig. 2.3. Selecting an IRB. Human subjects research conducted or funded by DOE can be reviewed by three types of IRBs: central DOE IRBs, DOE and NNSA site IRBs, or non-DOE IRBs.

Protecting Research Participants

Research participants in energy and policy research studies play an integral role in finding solutions to some of humanity's most pressing challenges: discovering innovations in energy technology, making advances in renewable energy, and mitigating climate change. The IRB is an interdisciplinary ethics board with the primary goal of protecting these valued partners. Sponsors and researchers can play vital roles in this protection by partnering with the IRB and sharing responsibilities.

Partnering with IRBs

Partnering with IRBs helps sponsors and researchers ensure that (1) their proposed research is sound and justifies using human subjects or their data; (2) potential risks to human subjects have been minimized; (3) participation in the study is voluntary; and (4) potential participants receive clear and accurate information about the study, including participation benefits and risks, purpose and use of collected data, and safeguards for data protection (see Appendix C: Checklists for IRB Reviewers, p. 87).

Additionally, submitting any study that might be HSR to the IRB for review and approval helps to guarantee that sponsors and researchers can use the collected data, for example, in publications and funding requests. If a research project is not properly reviewed by an IRB ***before*** data is collected, sponsors and researchers run the risk of not being able to use or publish any information gathered during the study.

Sharing Responsibilities

Researchers, IRBs, sponsors, and the DOE/NNSA HSPP can work together to ensure that study participants are protected at every stage of the research process. These collaborative efforts and shared responsibilities are outlined in Fig. 2.4 (see p. 14).

Understanding DOE's HSR Requirements

Because the federal requirements included in the Common Rule are a starting point for protecting research participants, DOE has implemented policies that include additional protections for participants to ensure ethical conduct of HSR. These DOE-specific requirements, informed by the Belmont Report and the Common Rule, are outlined in DOE Order 443.1C, *Protection of Human Research Subjects*.

DOE-Specific Requirements

The designated IRB (or in some cases, the IRB office) is responsible for:

- Making determinations about what is and is not HSR, including exempt HSR. This includes research using potentially identifiable information collected from social media and other publicly available datasets.
- Reviewing and approving research studying humans in a systematically modified environment.

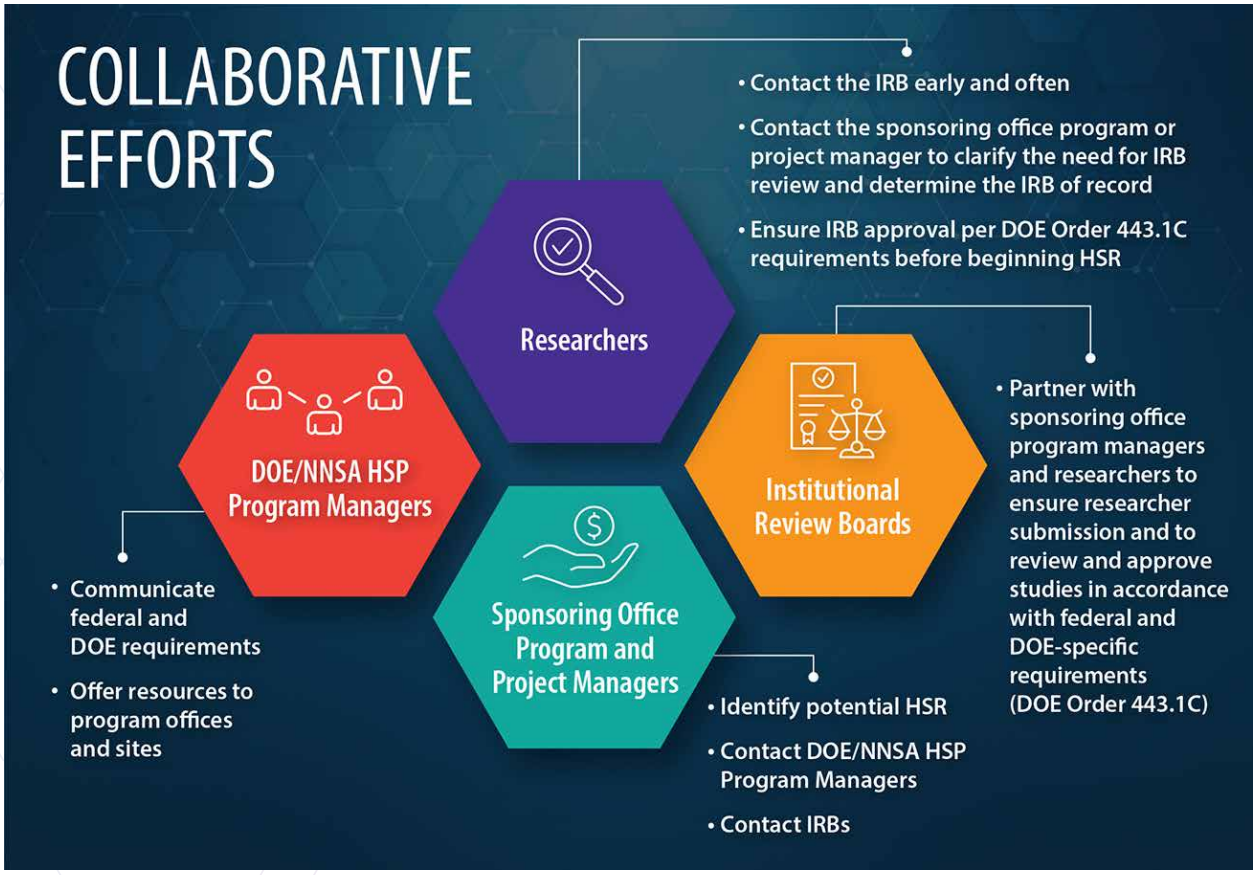

Fig. 2.4. Sharing Responsibilities. Though each entity involved in human subjects research has a unique role, they must collaborate in a framework of shared responsibilities to protect participants.

- Reviewing and approving HSR involving DOE/NNSA federal or contractor employees or their data. Unless otherwise approved, it is expected that the appropriate DOE/NNSA site or central IRB will conduct this review (see Appendix C: Checklists for IRB Reviewers; Protecting Employees Who Participate as Research Subjects, p. 97). Employees are considered a vulnerable population and must be protected from coercion or undue influence.

DOE-supported HSR, including exempt HSR, must report to the designated IRB and the DOE HSPP:

- When something goes wrong, such as an adverse event, a loss or breach of personally identifiable information, complaints about the research, or an incident of noncompliance.
- Annually to the Human Subjects Research Database (HSRD) unless a DOE/DOE site IRB is the research project's IRB of record. In that case, the information is already in the HSRD.
- All HSR, including exempt HSR, requires an annual check-in or continuing review application.

2.2: The Takeaway

The Belmont principles provide an ethical foundation for the conduct of HSR, and the Common Rule is a framework for implementing these principles. It outlines the basic provisions for IRBs, informed consent, and assurances of compliance. However, protections for research participants do not have to stop there. DOE builds on these protections in DOE Order 443.1C and provides resources and advice through the Human Subjects Protection Program (HSPP) as well as HSR review through the Central and site IRBs. Ultimately, the HSPP and the IRBs are always available to provide support and information at any stage of the review process. It is important to contact a local or DOE Headquarters Human Research Protections Program manager early to address HSR questions and concerns.

Chapter 2 References

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Chapter 3

Better Research Through Collaboration

Sponsors, researchers, and institutional review boards (IRBs) can have different purposes and obligations, which may appear to put them at odds with one another. For example, researchers prioritize scientific goals, while IRBs prioritize the rights and welfare of subjects. As a result, a prevailing belief is that the IRB impedes research by miring researchers and sponsors in the red tape of the compliance process. The "Human Subjects in Energy Technology and Policy Symposium" aimed to challenge this belief by showing how the IRB can be a partner to help sponsors and researchers achieve a common purpose of improving society by ethically advancing scientific knowledge. In the plenary session titled "Better Research Through Collaboration: A Partnership Among Sponsors, Researchers, and the IRB," speakers highlighted the importance of collaboration to efficiently and effectively advance energy technology and policy research and to better understand and meet the needs of communities served through this research. Speakers stressed the need for researchers and sponsors to understand the diverse priorities and perspectives of communities impacted by the research, maintain a collaborative mentality during research, and partner with the IRB throughout all stages of the research process. This chapter addresses the key points of two of the speakers, while Section 1.1 in Chapter 1, p. 3, addresses the session's broader background discussion of DOE's focus on energy and environmental justice.

3.1 A Partnership Among Communities, Sponsors, Researchers, and the IRB

Community-engaged research is increasingly performed in the field of energy technology and policy (Northwest Climate Adaptation Science Center n.d.; Wilmer et al. 2021; Jorgenson and Stephens 2022; Goolsby et al. 2023). This type of research requires an ongoing partnership among communities, sponsors, researchers, and IRBs. Interconnected feedback loops among these key roles foster an effective research environment (see Fig. 3.1, p. 17). This chapter focuses on this network of communication and cooperation and highlights various points throughout the research timeline when this partnership should be prioritized.

Making space for all relevant stakeholders during the initial study design phase and throughout the research process is important. Examples of stakeholders include (1) the targeted study population, (2) the wider impacted community, (3) sponsors and program managers, (4) researchers and research staff, (5) supporting institutions, and (6) IRB staff

Plenary Speakers

***Plenary Session:** "Better Research Through Collaboration: A Partnership Among Sponsors, Researchers, and the IRB"*

CHERYN METZGER
Researcher and IRB member, Pacific Northwest National Laboratory

ELIZABETH ELLIS
Central DOE IRB Vice Chair, U.S. Department of Energy

Fig. 3.1. Community-Engaged Research Stakeholder Network. The cycle of community-engaged human subjects research involves communities, sponsors, researchers, and IRBs working together to identify community-based energy and environmental issues and to search for solutions through ethical, effective research.

and board members. The best possible outcome for a research project occurs when all stakeholders are fully informed, committed to research excellence, and engaged in the process. By engaging stakeholders early, researchers can incorporate input from each perspective to formulate a more robust scope, timeline, and budget for the overall project design (see Fig. 3.2, p. 18).

When formulating research strategies, sponsor organizations can engage community voices to help identify research needs. Once a research need is identified to solve energy and environmental problems impacting communities, sponsors prepare and issue funding announcements for research proposals designed to address them. Early discussions with the IRB following funding can help sponsors and researchers think through when and how community engagement will occur. After funding a research project, the role of a sponsor's program manager may vary, but in many cases, they work closely with researchers to ensure requirements are met and to track research progress (U.S. GAO 2024).

The IRB similarly partners with researchers initially and throughout the project to help ensure that research is designed to gather input from a representative group of the impacted communities, complies with relevant regulations, and properly protects research participants (see Appendix C: Checklists for IRB Reviewers; Initial Application, p. 101). This partnership can also help researchers be better prepared to submit to the IRB, facilitating a more efficient review. The IRB submission

Fig. 3.2. Incorporating Stakeholder Input Facilitates Robust Project Design. Human subjects research requires a robust scope, timeline, and budget, which can be accomplished by being proactive and incorporating stakeholder input.

documents can guide researchers as they develop a study, helping to keep their research questions and participants in focus and provide complete information to the IRB.

For more information on writing an IRB protocol and incorporating survey and interview best practices, see Chapter 4: HSR in Energy Research: Building a Protocol Using Best Practices, p. 23. The following sections explore how researchers and program managers can most effectively include communities and IRBs throughout the research process.

3.2 Involving Communities Throughout Research

Community engagement can be an important component of energy technology and policy HSR. As efforts to implement energy justice increase, energy research is prioritizing the involvement of marginalized and underserved communities. An increasingly popular

Fig. 3.3. Minimizing Barriers to Research Participation. Community members may face various barriers to research participation, but taking steps to reduce these barriers helps ensure equitable selection of participants.

approach is to include these communities in all stages of the research process. For this type of research, one of the first steps researchers often take after receiving funding is to engage members of the target community. This step enables them to better understand the community's specific needs and concerns and to shape a research plan that builds community acceptance.

On average, white males with high socioeconomic status are most likely to respond to research participation requests (Scharff et al. 2010; Feldman et al. 2019; Mapes et al. 2020; Spector-Bagdady et al. 2021; Farooqi et al. 2022). Recruitment and communication strategies should be tailored to a wider variety of potential participants, with consideration given to the different professional and personal obligations that may prohibit someone from participating. Fig. 3.3, this page, offers advice for reducing barriers to participation and ensuring equitable selection of participants.

When planning a research project that aims to better understand the perspectives and behaviors of a marginalized community, researchers should contact community leaders to request their input on the proposed work. In some cases, explicit permission from community leaders will be needed. For example, before engaging in any kind of research involving tribal communities, researchers must connect with tribal leaders to inform them of the potential project and obtain approval to work with their community. Early interaction with community leaders can also foster a sense of goodwill between researchers and the community and improve recruitment efficacy. Above all, researchers should maintain cultural respect for the community throughout the project.

As a part of respecting these participating communities, study results should be shared with the community to facilitate discussions about the potential impacts of the findings and determine future research

Fig. 3.4. Belmont Report Core Principles. The Belmont Report outlines three core principles—respect for persons, beneficence, and justice—that IRBs use to evaluate human subjects research.

directions. These discussions demonstrate the iterative and ongoing nature of the research partnership with communities. While returning individual research results can sometimes introduce risk and should be discussed with the IRB, sharing the aggregated results with communities promotes trust in research and validates the community members' participation. At this stage, researchers should also consider the way results are shared, particularly among a lay population. Simply sending the scientific publication may not be enough, and using more impactful dissemination tools is recommended (VICTR n.d.; PCORI 2023; Sgro et al. 2023).

3.3 The IRB's Role in Ensuring Ethical Research

The Belmont Report informs the federal and DOE-specific requirements that the DOE Human Subjects Protection Program and its central and site IRBs apply when reviewing HSR (see Chapter 2: Applying Human Subjects Regulations to Energy Research, p. 8, for more information about the history and development of the Belmont Report, the Common Rule, and DOE-specific requirements). The three core principles outlined in the Belmont Report—respect for persons, beneficence, and justice—serve as a framework through which the IRB evaluates a research project (see Fig. 3.4, this page).

During IRB review, the Belmont principles directly relate to the following primary areas of concern: informed consent; risk/benefit assessment; equity, diversity, and inclusion; and privacy and confidentiality considerations (see Appendix C: Checklists for IRB Reviewers; Initial Application, p. 101).

Informed Consent

The respect for persons principle is most closely applied through the regulations mandating informed consent for research participation. The primary audience for the informed consent form is the

target research community; the IRB evaluates this document based on its appropriateness for that community.

Language should typically reflect a sixth- to eighth-grade reading level and provide a complete description of participant involvement to ensure that potential participants have all the necessary information to make an informed decision for themselves or as a legally authorized representative for a vulnerable subject. More detailed information about writing an informed consent form is provided in Chapter 4: HSR in Energy Research: Building a Protocol Using Best Practices, p. 23.

Risk/Benefit Assessment

IRBs apply the principle of beneficence while assessing whether a study protects individuals from harm and maximizes possible benefits while minimizing possible harms. In terms of benefits, while a direct benefit to participants isn't required, indirect benefits should exist beyond the participant population, such as benefits to society or scientific advancement. Researchers need to keep in mind that compensation is not a benefit and should not be listed as such.

The corresponding risks to participants and society are also weighed to ensure they are balanced. Even with low-risk research, the time and effort of participants should be worthwhile. For this reason, many IRBs also evaluate projects based on scientific merit (see Appendix C: Checklists for IRB Reviewers; Scientific or Scholarly Review, p. 99). Clear and detailed explanations about research questions, potential outcomes, and likely contributions to the discipline or field will help establish the project's sound design and methodology. A key aspect of the IRB's risk/benefit assessment involves ensuring that any participant burdens are minimized and likely to result in valuable contributions to research.

Diversity, Equity, and Inclusion

The IRB comprises members with a variety of backgrounds and expertise, both scientific and non-scientific, affiliated and unaffiliated, to ensure that the review conducted is inclusive of many perspectives. A diverse IRB is key to promoting the principle of justice by ensuring the cultural competence to evaluate research protocols' considerations of the target research community's culture, history, and language needs.

The IRB also evaluates protocols for potential instances of bias, both implicit and explicit, and equitable subject selection to prevent particular communities from bearing too much of the burden of research or from not experiencing the benefits of the research results. The historical context for this consideration is evident from examples of research being performed on vulnerable or minority populations for the benefit of more privileged groups.

Protecting Participants' Privacy and Maintaining Data Confidentiality

The evaluation of whether privacy and confidentiality are properly protected is important to the role of the IRB during review, especially in the age of "Big Data." All three of the Belmont Principles are key in this evaluation, which looks at the risk of data breaches, the ability of researchers to uphold guarantees to protect participants' privacy, mitigation steps to avoid inherent biases in available data, and maintaining data confidentiality through proper storage procedures.

Overall, the role of the IRB is to apply these principles not only during the initial study design but throughout the entire research process. The IRB can assist when processes need to be revised, helping researchers through modifications during the project (e.g., changing documents or implementing new measurement procedures or equipment). For many studies, continuous review or annual check-ins are performed as a part of regulatory requirements to track the project's progress. If researchers encounter any adverse events or unanticipated problems during the research, they must notify the IRB immediately, so the IRB can offer support and determine if further follow-up or regulatory reporting is required. While the first thought in approving HSR is ethical study design, ethical conduct throughout the research is prioritized through continued partnership with the IRB.

Chapter 3: The Takeaway

The partnership among communities, researchers, sponsors, and the IRB is important at all stages of research. The interconnectedness of stakeholders throughout the research process is a key component of ethical and effective community-engaged research. This engagement started in the healthcare field and is increasingly used in all fields of research (Vella et al. 2021; Wilmer et al. 2021; Jorgenson et al. 2022; Goolsby et al. 2023). To meet the needs of today's challenges through efficient and actionable research, all stakeholders should prioritize community engagement through this framework of partnership. There are many opportunities for collaboration to foster effective, ethical, and equitable research in the energy technology and policy field.

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Chapter 4

HSR in Energy Research: Building a Protocol Using Best Practices

As DOE research has diversified and incorporated human subjects research (HSR) elements into study designs, many energy technology researchers have found themselves in need of specialized training in HSR. To guide researchers through these challenges, the symposium offered two workshops focused on creating successful institutional review board (IRB) submissions and employing best practices for conducting HSR in the energy technology and policy fields. The "IRB Protocol Building Blocks" workshop held on October 17, helped researchers better understand what IRBs are looking for in a protocol. Subject matter experts (SMEs) explained basic protocol components, offered specific examples for difficult sections, and supplied tips for good protocol writing. The "Social Science Best Practices for HSR" workshop held on October 19, highlighted best practices for collecting meaningful data from real world settings. SMEs discussed matching data collection to research questions, obtaining meaningful research results, and making ethical considerations an integral part of study design. This chapter summarizes the two workshops, providing guidance and insights from SMEs, which will be helpful for both new and experienced researchers. This chapter can also serve as an essential reference for IRB professionals as they guide researchers through the IRB submission process.

4.1 Navigating the IRB Protocol

Understanding the Protocol Document and Its Basic Components

Researchers must have IRB approval before beginning research that involves human subjects. The proposed research is presented in a protocol, which is a written document describing the project procedures and study design with respect to compliance and ethical treatment of research participants. The goal is to provide the IRB with the information needed to make determinations about regulations, laws, and institutional policies. During review, the IRB takes each section into account but ultimately considers the document in its entirety, basing its determination on how well each part of the protocol fits into the larger context of the study's efforts to ensure compliance and ethical treatment of participants.

Protocols typically consist of: (1) background and aims, (2) local context, (3) recruitment and screening, (4) consent process, (5) study procedures, (6) risks, (7) benefits, (8) privacy, and (9) data management and

Workshop Speakers

***Session:** "IRB Protocol Building Blocks"*

CECILIA BROOKE CHOLKA
Human Research and Quality Assurance and Education Manager, Weill Cornell Medicine

BILL ECKMAN
Researcher, Oak Ridge National Laboratory

TRACY FUENTES
Researcher, Pacific Northwest National Laboratory

MARGARET TAYLOR
Researcher and IRB Member, Lawrence Berkeley National Laboratory

***Session:** "Social Science Best Practices for HSR"*

BEN HOEN
Researcher, Lawrence Berkeley National Laboratory

STEPHANIE L. KANE
Statistician and Researcher, Washington State University

BENJAMIN SIMS
Researcher, Los Alamos National Laboratory

confidentiality. Figure 4.1 provides a brief overview of each section (see p. 25). The following guidance explains these components and offers advice for dealing with potential challenges.

1. Background and Aims

This section of the protocol includes a literature review and provides context for the proposed research. This description is typically less than one page and gives the reasons for conducting the research in light of current knowledge.

Questions to Consider

- What is the problem or gap in the literature that research seeks to address? How will the research address the problem or gap?
- Why is the research necessary? How will it be relevant?

2. Local Context

When establishing the research context, consideration should be given to both the target participant pool and the necessary collaborators for a successful project. The location where the research is occurring can directly impact the study design, and the collaborating institutions may have specific requirements from an IRB perspective. Provide descriptions of these locations as applicable to the study, including any external sites conducting analytical procedures with project data. Each site's responsibilities should be documented as well as any site-specific regulations or customs affecting the research. The local scientific and ethical review structure should be noted. International research should include—in addition to the specific laws, regulations, and customs—descriptions of researcher safety; data and sample safety, storage, and transfer; and relationships with local communities.

Questions to Consider

- If the research involves multiple institutions, does it need an IRB reliance agreement?
- Is a letter of support authorizing use of a research site needed?

3. Recruitment and Screening

This section of the protocol includes the researchers' process for identifying potential participants. For instance, researchers might review databases, use commercial services, or locate organizations with access to relevant groups. This section also describes how researchers will contact potential participants and includes any recruitment materials researchers will use to solicit participation. Remember that all recruitment materials must be reviewed and approved with the IRB submission. This section should also justify the number of participants needed for the study and include any vulnerable populations that will be targeted during recruitment. The screening process describes how researchers will evaluate whether potential participants meet the study's inclusion and exclusion criteria (e.g., renter versus homeowner or experience with a particular topic or technology).

Questions to Consider

- How will the study be advertised to potential participants? What types of recruitment materials will be used (e.g., printed, verbal, or electronic solicitations)? How will the study recruit the necessary number of participants?
- How will the study confirm that potential participants meet the inclusion or exclusion criteria? What happens with screen failures (i.e., people who are not eligible to participate) and any data obtained from those failures?

4. Consent Process

The consent process should describe how researchers will ensure that potential participants are fully informed about the study before they decide whether to participate. To promote understanding and avoid peer pressure to consent, this process is usually best completed in individual settings, rather than consenting a group all at once. This section should include the steps researchers will take to minimize the possibility of coercion or undue influence, with special attention to additional protections for vulnerable populations. If applicable, researchers should:

- Describe who is authorized to provide consent on behalf of potential participants.
- Outline the assent process and explain how they will obtain parent permission if the research involves minors.

Fig. 4.1. IRB Protocol Components. The protocol helps the IRB determine if a study meets the regulatory criteria for approval, but it can also be a tool to help with research design. Working through the basic protocol components outlined here can help researchers think through and develop a project plan as well as anticipate and prepare for a variety of issues they may not have previously considered. [Graphic design adapted from Cecilia Brooke Cholka]

- Provide a justification for requesting a waiver of consent or waiver of consent documentation (see More About Consent, this page, for additional information about waivers).

This section should also describe the method for documenting consent and include the consent documents with the IRB submission (see Appendix C: Checklists for IRB Reviewers; Initial Application, p. 101).

Questions to Consider

- Where and when will the consent process occur? For more complex studies, should teach-back strategies be used to ensure that potential participants understand the research? This method involves the participant "teaching back" the information that the researcher has shared with them (for more information, see the discussion of teach-back techniques in Chapter 7: Frequently Asked Questions about HSR in the Energy Domain, p. 71).
- If the research will include individuals who may lack the capacity to consent, how will this be evaluated? If needed, how will the legally authorized representative for the potential participant be identified?

5. Study Procedures

This section of the protocol describes in detail all study procedures, interventions, assessments, and activities in sequential format, including how much time will be required to complete each procedure and the total time commitment. It should include any data collection documents (e.g., surveys and interviews), descriptions of how information will be captured (e.g., audio or video recordings, observations, and computer tasks) and any compensation or incentives, if offered. Keep in mind that the process of providing these financial considerations may require early communication with the institution's financial office.

6. Risks

This section of the protocol lists any possible harms and discomforts to participants. Harms can be physical, psychological, social, economic, legal, or informational. The potential risks listed in a protocol should be closely and reasonably paired to the research. Risks become meaningless when they are too far removed from the research (e.g., participants could get hit by a bus on the way to an interview) or too axiomatic (e.g., researchers are not trying to kill anyone). This section should also describe the likelihood and seriousness of harms and provide a plan for preventing or minimizing risks. Strategies include screening to ensure appropriate selection of participants, sound research design, appropriate project team training, prompt de-identification of data, and safety monitoring and reporting.

Questions to Consider

- Could any research procedures cause participants to become upset and require psychological or medical attention?
- Could research interventions physically harm participants?

More About Consent

Consent is the conversation researchers have with potential participants to explain what the research is and what they are being asked to do for the research. It is critical to write the accompanying consent document (e.g., informed consent form) in language that is clear and easy for participants to understand. Avoid using highly technical language and aim for the text to accommodate a sixth- to eighth-grade reading level. If the study includes non-English-speaking participants, the consent document should be translated into the appropriate language.

The informed consent form should outline the study's purpose, procedures, risks, benefits, data confidentiality, and voluntary nature. However, depending on the research, consent can be waived in some instances. For example, waivers are appropriate when they will not adversely affect participants' rights and welfare or when research involves minimal risks to participants or could not be carried out without a waiver. For more information about waivers, see 10 CFR 745.116(f)(3).

Insights from the Experts

Effective Risk Communication

Bill Eckman, Oak Ridge National Laboratory

As we were planning a new study, we realized that the installation process would require one participant group to temporarily move out of their homes. This forced us to think through the potential risks and benefits to this group and how to appropriately address these issues. A move-out would require us to cover temporary housing costs, daily living expenses, and so on. These costs quickly add up when considering the needs of a whole family and, in some cases, may have been more than the family income over the total duration of the study.

We wanted to be very careful about how we communicated that information in the consent process. We didn't want the reimbursement to be the reason people signed up for our study. We wanted to assure participants that their living expenses would be covered during the study without creating an apparent financial benefit that might unduly influence their choice to participate.

We worked closely with our IRB to determine the best way to convey this information, and their insights were incredibly helpful. They helped us create a communication plan that clearly described the study while minimizing any undue influence the compensation might have on participants' decision process.

- Could research participation cause participants potential harm in their surrounding social and political environments?
- Could participants experience economic burdens from research participation?
- Could a loss of data confidentiality occur? How serious would this loss of confidentiality be for a participant?

7. Benefits

This section of the protocol describes potential benefits that individual participants may experience from taking part in the research (e.g., acquiring energy-efficient technology or reduced energy costs) and should clearly indicate if there are no direct benefits to participation. Avoid an overly optimistic presentation of potential benefits, especially in the informed consent form. This section can also include anticipated societal benefits (e.g., new knowledge or technological innovations). Keep in mind that participation in the research itself and compensation for participating are not benefits, so avoid listing them as such.

8. Privacy

This section of the protocol describes the plans for safeguarding participants' privacy during the study. Privacy refers to an individual and their right to control how, when, and under what circumstances others can access their information (see Confidentiality Versus Privacy, p. 28). Individuals have greater concerns about privacy whenever the requested information is of a sensitive nature. Privacy considerations are relevant during the recruitment, informed consent, and data collection phases of the study. This section should also describe all the settings in which the participant will interact with the researcher.

Questions to Consider

- What procedures will best protect participants' privacy during the different phases of the study? Examples include access to private rooms, closed doors, and staying within research scope.
- Does the research setting undermine efforts to protect privacy (e.g., group settings or signage at the data collection location that discloses inclusion criteria)?

9. Data Management and Confidentiality

This section of the protocol should include the plans for handling and securing data through the life of the study. Data can take many forms (e.g., survey responses, humidity levels, and images) and can be recorded in many ways (e.g., paper forms, electronic documents, and audiovisual recordings). As such, this section should describe the type of data collected and

Insights from the Experts

Getting and Protecting Incentives

Margaret Taylor, Lawrence Berkeley National Laboratory

Getting approval to offer incentives for study participation can be challenging at a national laboratory. Your procurement office will help you understand the relevant concerns, such as shepherding taxpayer dollars, accountability for those dollars, and fraud mitigation. You also need to justify the amount of the incentive to your IRB. For example, we wanted to send Amazon gift cards to survey respondents in one of our studies. To justify the gift card value, we calculated the average salary of a typical respondent given salary rates in the region and estimated the amount of time to complete the survey. Once we had IRB approval, we provided this same justification to procurement and got their approval for the incentive.

When we started recruiting for participants, we encountered some unexpected challenges. We posted a link to our Qualtrics survey on X (formerly Twitter), including information about the gift card incentive, and our survey started to receive rapid attacks by bots. We immediately shut down the survey. We later reopened it but sent it through a commercially curated panel. After attending several Qualtrics conferences, we've learned that bots have also started to infiltrate these panels. The takeaway is that you have to be very careful about how you advertise surveys that offer financial incentives to potential participants.

how it will be recorded (see Appendix C: Checklists for IRB Reviewers; Reviewing Protocols that use PII, p. 94). Additionally, this section should include who will have access to the data and procedures for transferring data to collaborators, if applicable. If a study is greater than minimal risk, a data and safety monitoring plan is also required.

Questions to Consider

- Will physical records be locked in a secure location? Will electronic records be stored on password-protected or encrypted computers? (For protocols subject to DOE Order 443.1C, personally identifiable information collected or used during HSR projects must be protected in accordance with the requirements of DOE Order 206.1A, *Department of Energy Privacy Program*, or current version.)
- Will subject identifiers be stored separately from project data? Will a study code be used? If so, who has access to the code key?
- What will happen to data at the completion of the project? Will data be destroyed or permanently de-identified?

Writing a Successful Protocol

A partnership between researchers and IRB staff is critical for successful, compliant research, and protocol development is a particularly important stage of this partnership. When researchers and IRBs work together

Confidentiality Versus Privacy

Confidentiality and privacy are both information security issues; however, they address different aspects of information security. Confidentiality involves data—the information collected about and from participants—and how that data will be secured throughout a study's lifecycle. Privacy involves the interactions that researchers have with participants and their information—such as having difficult conversations or obtaining information that goes beyond the established research scope—and the ways in which researchers work to protect participants' interests and place limits on the personal information they provide.

Insights from the Experts

Considering Data at Every Stage

Tracy Fuentes, Pacific Northwest National Laboratory

Data underlies everything in the research process and is also deeply tied up into your protocol. The clearer you can be at every stage of your project in planning, gathering, and analyzing data, and in thinking about how you're going to protect your participants' identities, the more successful your protocol will be.

During recruitment, you need to ensure the data you'll be collecting will be representative of the populations you sample from. Designing surveys and interviews also requires data considerations. You not only have to think through how you will process the information you collect and translate it into something meaningful, but you also have to consider privacy and confidentiality measures. It's important that researchers are good data stewards.

Let's consider an example. If you photograph participants' homes, will the images include the house number, or the license plate on a car in the driveway, or geographic coordinates embedded in the images' metadata? If you want to use such images in presentations of your research, you need to remove these identifiable elements to protect subjects' privacy. It is also important that the consent form clearly states how you will use such images and keep the data confidential.

Protocol Dos and Don'ts

✓ DO ...	✗ DON'T ...
Make the IRB your intended audience and write with their needs in mind.	Write your protocol for your sponsor(s), research community, collaborators, or peers.
Tailor your writing to fit the exact requirements and to answer the specific questions for each protocol section.	Write one summary statement that you copy and paste into each protocol section.
Tell the entire story of your project by addressing the past, present, and future parts of your research.	Tell an imbalanced story by overly focusing on one part and neglecting another.
Contact your IRB early and often to clarify questions and minimize mistakes.	Wait until the last minute to reach out to your IRB with questions and concerns.
Fill out your protocol based on your current understanding of your research and its trajectory; if something changes, submit an amendment or modification for review by the IRB.	Try to anticipate everything that could happen over the duration of your research, especially if you are conducting a multiyear project.

to share their technical and regulatory expertise, the result is effective, well-designed research that advances science while protecting study participants. Researchers are encouraged to try the following:

Communicate Early and Often. Let the IRB know if a project involves special circumstances or deadlines or if the research is unique or complicated. IRB staff will work with the study team to address the relevant review requirements. Don't wait until the last minute.

Ask Questions. If the protocol writing process or review process is unclear, contact the IRB. Ask IRB staff as many questions as needed to ensure the

protocol includes all the information needed for IRB review.

Find Examples of Approved Protocols. Reviewing examples of approved protocols can be a great way to gain insight into what a successful protocol looks like. But keep in mind that what is appropriate and approvable for one study is not necessarily appropriate or approvable for another study.

Use the Right Templates. While the general components of a protocol are consistent across IRBs, each institution will have their own protocol template. Be sure to review, understand, and follow the guidelines and criteria for the study's specific IRB.

Build a Diverse Study Team. Designing HSR projects takes careful consideration and a different skill set than some researchers may be used to. Ensuring that the research team includes trained social scientists or has experienced consultants to help inform best practices in this area is highly recommended.

Enable Collaboration. Come up with a process that allows the study team to efficiently and effectively work together on the IRB protocol components. For example, using Google Docs allows the team to easily share the basic protocol text with others and enables collaboration.

Insights from the Experts

Beginning Where You Are

Cecilia Brooke Cholka, Weill Cornell Medicine

Research is an iterative process, and protocols should not be viewed as one-and-done. Rather, the IRB sees protocols as living documents that tend to evolve as the research process unfolds. Researchers are not expected to have a multiyear research project planned out in its entirety before the project even begins. Researchers can fill out their protocols based on their current understanding of the research and then amend that protocol at a future time if needed.

An amendment can change something in the protocol, such as increasing the number of participants, or add something new, such as a new method for data collection or an additional research site. Protocols can be amended at any time during the project's lifecycle to reflect changes in the research. But remember, it's important to get IRB approval for the changes before implementing them.

4.1: The Takeaway

The protocol is used by the IRB to determine if a study meets the regulatory criteria for approval, but it can also be a tool to help with research design. Working through the basic protocol components can help researchers think through and develop a plan for a variety of issues they may not have previously considered for their project. While writing the protocol, researchers need to consider multiple audiences; whether it's the IRB when researchers are writing the protocol or the target study population when they are writing the consent form, the needs of the audience should be at the forefront. Research and the associated protocol are iterative processes that require collaboration with colleagues, the IRB, and other stakeholders to get feedback on materials. Approaching the protocol with the tips described in this section will put researchers on the path to successful protocol writing.

4.2 Applying Social Science–Informed HSR Practices in the Energy Space

Matching Data Collection to Research Methods

Social science research methods help researchers and engineers gain insights into the opinions, attitudes, and experiences of individuals and communities that are vital to developing real-world solutions to pressing energy challenges. It is important for researchers to be explicit about the motivations for using these methods. For example, is the research motivated by a lack of knowledge that could not be gained through other techniques? Is the research needed to understand attitudes or preferences, and can this understanding be achieved only through an HSR approach? Or is there a need to better understand how consumers use a particular technology to find ways to increase adoption? Identifying the motivation will enable researchers to develop meaningful research questions and determine which data collection methods are best for their project.

Developing Research Questions

Crafting good research questions is essential for planning a successful HSR project (see Crafting Good Research Questions, this page). Good research questions focus the study team's efforts and operationalize key concepts. They also enable researchers to create better pitches to sponsors. Presenting the value of research in the form of questions can bolster understanding for those unfamiliar with social science research.

Selecting Data Collection Methods

Researchers need to choose collection methods that will allow them to obtain the data needed to answer their research questions. Table 4.1 breaks down three common data collection methods (see p. 32).

The specific community a researcher wants to target can also inform decisions about which data collection methods to use. For example, researchers looking to survey hard-to-reach populations, such as people living in rural areas, should consider what they can do to get adequate representation. If internet availability is an issue, distributing print surveys by mail may solicit more responses. If research areas include people whose first language might not be English, providing surveys in multiple languages would encourage participation.

Obtaining Meaningful Research Results

Effective research questions and appropriate data collection methods will set researchers on the path to meaningful results. Conducting quality checks before deploying a survey or engaging in an interview can also improve the validity of the results. Researchers can pretest and pilot test survey and interview questions to ensure that they are clear and understandable and will prompt the needed responses (see Key Terms, p. 33).

Connecting Research Questions, Study Design, and Analysis

Researchers can connect their data to their research questions and study design by identifying the subpopulation(s) they want to understand and making sure they are adequately represented in the study. For instance, researchers looking at a broad geographic region could include a mix of more densely populated and less densely populated areas in their sample population. Additionally, researchers investigating

Crafting Good Research Questions

- Start by thinking through potential questions that, if answered, will help solve the research problem.
- Consider making mockups of figures and graphs to help you envision the kinds of data you want to display, then fine-tune your research questions to help generate that data.
- Make sure that you can answer your research questions with the skills and resources that are available to you.
- Once funded, communicate early with members of communities you plan to recruit from to more clearly understand their needs and priorities. Community-informed research questions can provide value to the individuals or groups participating in your research.

Common Data Collection Methods At A Glance			
METHOD	**PURPOSE**	**ADVANTAGES**	**DISADVANTAGES**
Survey (paper, phone, online, or a combination of the three)	Learn about general trends and patterns in people's opinions, experiences, and behavior.	Appropriately designed and distributed surveys are useful for generating representative results of a population.	Participants can misunderstand questions, provide inaccurate responses, or skip questions.
Interview (face-to-face, phone, online)	Learn detailed information from specific people about their opinions, experiences, and behavior.	Interviews are useful for researchers wanting to explore a new subject or take a deeper dive into a subject. Structured and semi-structured interviews follow a set of predetermined questions that allow for comparison of responses across participants. Informal interviews are more casual and encourage open discussion.	Participants can veer off topic and engage in discussions that are not relevant to the research or that reveal personal or identifiable information.
Focus Groups (face-to-face, online)	Learn about a small group's opinions, experiences, and behavior, and gain insights into the population they represent.	Focus groups foster collaboration and advance thinking on a particular subject that would not occur through surveys or individual interviews.	Group think and dominant personality issues can hinder diversity of opinions in focus groups. Including moderators can help deal with these issues.

Table 4.1. Common Data Collection Methods. Collection methods should be informed by the study questions and research community.

new energy technologies or a particular policy could include historically underrepresented groups, such as Native Americans or low socioeconomic populations, to ensure that the impact of the technologies or policies is understood for a diverse cross-section of the broader population.

Once researchers are ready to analyze their data, they need to do so with their study design in mind. For example, if researchers collected complex survey data that exhibit stratification or clusters, their statistical analysis will need to account for this by determining the weighting procedure. Doing so will help ensure that the results can be aligned with the study design and can be scaled up to confidently posit what the overall results reveal about the population.

In any study, whether it includes social science data or not, researchers should ensure that the statistical model is appropriate for the data. Selecting the right model involves considering the type of data being collected (e.g., count versus continuous data); determining the measurement scale (e.g., nominal versus ordinal data); and accounting for model assumptions if using statistical tools to test results. Ultimately, it's good practice for researchers to carefully examine their data and the associated descriptive statistics before running a statistical model and then compare

Key Terms

- In a **pretest**, a researcher recruits a colleague to walk through each survey or interview question to get feedback about the question's clarity and comprehensibility. The process is slow, but it is invaluable in helping researchers identify which parts of a survey or interview might be confusing to participants. The results from pretests are not generally used in the analysis.
- In a **pilot test**, researchers distribute the near-final version of the survey or interview questions to a sample of their target cohort to give them the opportunity to provide feedback. If desired, researchers can include those results as part of their overall study (if they had IRB approval).

Insights from the Experts

Learning from Mistakes

Ben Hoen, Lawrence Berkeley National Laboratory

I learned my lesson as to when you should not survey people. One of the first large surveys we conducted was in the summer of 2016. That was also a presidential election year. As we were trying to get people to share their experiences and perceptions of wind projects near them, they were being inundated with calls, emails, and texts about the election. We found it was hard to get our response rate above where we needed it to be, and we spent a lot more money collecting those data than we expected to.

Mixing Methods

Stephanie L. Kane, Washington State University

I'm a big proponent of mixed methods. You don't have to pick just one method. Sometimes it's good to do focus groups or interviews to understand how people are thinking and then use those insights to design a well-thought-out study using survey methodology. Mixed methods are often a really good way to get both quantitative and qualitative information that can help researchers understand an issue in more depth.

Enhancing Data

Benjamin Sims, Los Alamos National Laboratory

Including a pre-existing body of data, such as chat rooms, forums, or social media posts, where people are leaving traces of how they interact with each other, can provide additional information that can inform data collected from surveys or interviews. For example, I'm talking to people on a computing project about how they interact with each other using GitHub, so being able to then pull data out of GitHub to show examples of those interactions will be really useful.

the outputs to ensure the model is returning meaningful results.

Anticipating Potential Limitations

No data collection method is perfect. Researchers should identify possible limitations, account for them during the analysis, and be honest and clear about limitations when writing about their research. Here are some common survey limitations that researchers could encounter:

Non-Responses. All surveys struggle with some kind of non-response. Researchers could have trouble reaching certain subpopulations or getting any responses at all. Evaluating the two response populations for key differences can sometimes identify systematic issues keeping particular groups from participating and prompt further outreach to resolve the discrepancy.

Measurement Errors. Measurement errors can arise from a variety of factors, such as ambiguous wording of survey questions or inappropriate response categories. Perhaps respondents didn't understand the question, or it was confusing to them. Indicators of a confusing question are when it is left blank or receives a large proportion of "I don't know" responses. Reaching out to experts or community members for insight can identify solutions.

Missing Data. Researchers might be missing data from certain variables. Options for addressing this include applying a statistical technique, such as imputation, to infer that information or dropping observations from their analyses if they are only missing data in a few places.

Mismatch Between Sample and Target Populations. To check for disparities between populations, compare the sample population's demographics to U.S. Census Bureau demographics to determine whether the study under- or overrepresented any kind of income bands, education level, race, or ethnicity. Approaches for dealing with mismatched populations vary among survey statisticians, from correcting for all factors to correcting for only key factors. Researchers should consider if the population discrepancies are relevant to their research questions and consult with their peers and other experts before deciding how far to go with their corrections.

Insights from the Experts

Inadequate Question Design

Benjamin Sims, Los Alamos National Laboratory

I see a lot of researchers making basic errors in how they pose survey or interview questions. For example, they may provide four categories for a response, but the categories are not mutually exclusive and participants are forced to choose just one. I've also seen surveys where the questions are phrased to ensure participants give the desired response. These types of errors can adversely affect the data you collect and create biases, so it's worth reaching out to your local social scientist or your IRB to get another set of eyes on your questions.

Question Design Advice

Ben Hoen, Lawrence Berkeley National Laboratory

Tip #1: Make sure you define the units you want respondents to use. We've made the mistake of not doing this when asking questions about money. Somebody might write a "1" for a question we were expecting to be responded to in 1000s. Did the respondent mean $1 or $1,000? All this to say, be careful about defining the units.

Tip #2: Find existing survey instruments that do some of what you want to do. For example, the U.S. Census Bureau has a well-established, well-vetted question battery related to demographics, so using these questions is a good starting point. You might be able to use survey instruments developed by other researchers in your field. Using previously established, vetted questions provides two advantages: (1) helping you write your survey without making too many mistakes and (2) comparing your results to the results of others, which can be particularly valuable.

Insights from the Experts

Ripple Effects of Poorly Collected Data

Stephanie L. Kane, Washington State University

Many ethical issues can exist in poorly designed studies that collect social science data. If questions were confusing or unclear and the information provided is not going to be helpful, you've wasted respondents' time and that in and of itself is an ethical concern. While there are no hard rules about this, I think you must weigh certain things when considering ethics in study design, such as:

- How much time are you taking from the respondents?
- How important is collecting representative information or that certain groups are represented?
- How are results going to be used? Could poorly collected information be used as a weapon in policy-making, potentially by a legislator, down the road?
- Are there differential impacts on certain populations?

As an example of differential impacts, say you have a large sample, and you have decent representation, but your project or the policy mostly impacts a small, historically marginalized group. Did you hear adequately from that population? All of these issues are tied together and can contribute to a poorly designed study, which has cascading ethical implications for how the study's data are going to be used.

Benefits of HSR Training

Ben Hoen, Lawrence Berkeley National Laboratory

In terms of ethics and study design, I found that taking Collaborative Institutional Training Initiative (CITI) training was useful as I was getting into this area. It opened my eyes to a number of potential risk areas that I never would have considered otherwise. And those risks might be unique to your research. So, I recommend that anyone doing this work—especially those who might be tangential to data collection but will participate in data analysis—get that training early in the survey development process. It's incredibly useful.

Prioritizing Ethical Considerations in Study Design

Social science researchers interact closely with participants, and every interaction influences data quality and the type of responses researchers will get; thus, ethical considerations are paramount and intersect with every aspect of the study design. If participants do not trust researchers or understand the consent process, their interactions with the researchers will change. Therefore, researchers need to think about ethical factors in the context of their proposed methodology.

Considering Informed Consent

Avoiding issues of coercion or undue influence during the consent process is critical, especially when researchers are working with vulnerable populations. For example, researchers working with DOE employees can encounter a vulnerability to defer to and respect authority (see Appendix D: DOE Templates for Researchers; Vulnerable Populations–Employees, p. 155). These participants tend to default to reserved professional courtesy, essentially tuning out of the consent process because they assume the researcher is knowledgeable. Researchers can push back against this tendency by making consent an engaged process that elicits active work from participants, such as having them answer questions to ensure they truly understand what they are being asked to consent to (see Appendix D: DOE Templates for Researchers; Consent Document, p. 120).

Ensuring Equitable Subject Selection

When identifying potential sample populations, qualitative researchers take cues from conversations with

interviewees. During these conversations, researchers might realize that different groups of people experience the research topic differently. For example, women and people of color can have very different experiences than white men. Researchers might subsequently prioritize including people from those groups in their study. Trying to fill gaps or needs in terms of responses can yield interesting and useful interactions with participants. Researchers must also ensure that risks and benefits are equally distributed across their participant communities.

Considering Privacy and Confidentiality

In some cases, a researcher might need to include identifying information to address the research question. Researchers should attempt to strike a balance between meeting research goals and the risks and benefits of including identifiable information. This can be achieved by minimizing the amount of identifiable information collected and establishing a plan for protecting that information that meets relevant regulatory requirements (e.g., protecting personally identifiable information in accordance with DOE Order 206.1A *Department of Energy Privacy Program*, or current version). This is especially important given the increasing ease of reidentification based on only a few data points.

4.2: The Takeaway

HSR studies in energy research are becoming an increasingly indispensable part of ensuring equitable adoption of future innovations in clean energy research. Researchers can better achieve their project goals by following best practices in social science research methods, such as developing robust research questions, selecting appropriate data collection methods, being honest and open during data analysis, and implementing ethical study design. Navigating an HSR approach can be intimidating for researchers without a social science background, but reaching out and seeking guidance from social science experts and IRB professionals can help them work through any stage of the research process.

Chapter 5

HSR in Energy Research: Standardizing IRB Processes and Promoting Collaboration at Every Stage

Human subjects research (HSR) is most commonly associated with clinical trials or behavioral studies in psychology or sociology. However, modern approaches in energy technology and policy research are increasingly expanding into human spaces. Such studies investigate participants' interactions with emerging technologies and seek their opinions on new energy policies in efforts to revolutionize energy conservation and innovation in energy equipment. This rapidly evolving research area can be unfamiliar to both researchers and institutional review boards (IRBs), but by working closely together, both groups can learn to navigate this new research frontier more efficiently and effectively. Collaboration is key; researchers are subject matter experts in energy sciences while IRB professionals have experience with HSR regulations applied to a variety of scientific disciplines.

To help standardize approaches for writing and reviewing this kind of study design, this chapter proposes best practices for IRB professionals and researchers and focuses on the crucial role that collaboration plays in new areas of research. Included are examples of energy-related HSR proposals, advice for potential pitfalls, and guidance for collaboration that both researchers and IRB professionals will find useful in their ongoing support, review, and conduct of HSR in energy research. These topics are illustrated with stories from IRB professionals who shared insights on how to address different challenges in HSR study design and regulation in the energy space. The examples and guidance derive from two workshops: "Reviewing Modification of the Human Environment Studies" and "Creating a Culture of Collaboration" held on October 17 and 19, respectively.

5.1 Modification of the Human Environment

Research that modifies the human environment using novel energy technologies poses unique challenges for IRB review (see Appendix C: Checklists for IRB Reviewers; Modification of the Human Environment, p. 91). In 2013, the Central DOE IRB reviewed a study proposing to modify the human environment that highlighted the need to create

Workshop Speakers

***Session:** "Reviewing Modification of the Human Environment Studies"*

STEVE RUPKEY
Biosafety and Human Research Subject Protection Programs Manager, Argonne National Laboratory

LINDSAY MOTZ
IRB Manager, Oak Ridge Associated Universities and Central DOE IRB

SUSAN VARNUM
Human Research Protections Program Manager, Pacific Northwest National Laboratory

JESSE WILLETT
IRB Chair, Pacific Northwest National Laboratory

BRETT C. SINGER
Former IRB Member and Human Subjects Researcher, Lawrence Berkeley National Laboratory

***Session:** "Creating a Culture of Collaboration"*

CECILIA BROOKE CHOLKA
Human Research Quality Assurance and Education Manager, Weill Cornell University

CINDY MAZUR
Ombuds, Los Alamos National Laboratory

JAMES E. MORRIS
IRB Chair and member, Central DOE IRB

PATRICIA GUNDERSON
Researcher, Pacific Northwest National Laboratory

specific guidance and regulations for this category of research (see Central DOE IRB Implements IRB Review/Oversight of Studies Involving Modification of the Human Environment, this page). Today, DOE Order 443.1C *Protection of Human Research Subjects* specifically incorporates considerations for this type of study design when reviewing HSR. The following two sections cover how to determine which regulatory categories apply to this research and important aspects to consider during IRB review.

What is Modification of the Human Environment?

Research in human environments can take place in almost any public or private location, including industrial complexes, commercial centers, transportation hubs, community centers, schools, and residential locations, such as shelters, apartments, and private homes. DOE studies involving modification of the human environment (MHE) typically fall into one of three categories (see Fig. 5.1, p. 39).

All of these studies implement MHE to observe how humans interact with new energy technology or react to energy policy changes under consideration. The purpose of such studies might be to gain knowledge that is generalizable to a larger population, such as characterizing airflow in an occupied space by adding nontoxic tracer chemicals. MHE studies could also seek to answer specific questions about real-world use of new technologies, such as testing a new energy-saving ventilation system by monitoring people's responses to changing humidity. Alternatively, MHE studies could simply involve understanding people's views on energy technology.

Key HSR Regulatory Considerations: Is It HSR? Which Category?

As described in the section titled, Applying the Common Rule to Energy Research in Chapter 2, p. 10, the Common Rule regulatory requirements apply to any activity that involves research and human subjects and is not exempt from the regulations. Once an activity has been determined to be non-exempt HSR, additional consideration must be given to whether the activity is eligible for expedited IRB review (45 CFR 46.110) or requires a full board review by the convened IRB. This same process applies when considering modifications to an IRB-approved study, as the

Central DOE IRB Implements IRB Review/Oversight of Studies Involving Modification of the Human Environment

In April 2013, the Central DOE IRB learned of a research project planning to modify the human environment after information about the study appeared in the *New York Times* (McGeehan 2013). The study sought to investigate urban air flow throughout the New York City subway system to better understand the risk posed by airborne contaminants, including chemical, biological, and radiological weapons, should they be dispersed in the subway system's atmosphere (BNL 2013).

Because this study was the first of its kind to be submitted to the Central DOE IRB, many questions arose during the review process. Ultimately, the IRB sought advice on how to properly review the proposed research from the DOE Human Subjects Protection program managers, in consultation with the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP). Learning more about the agents being used in the study—which were low concentrations of generally harmless gases known as perfluorocarbons (PFCs)—was a key component of the IRB's risk determination. Toxicologists were consulted regarding the specific PFCs to be used and the concentrations at the point of release. After ensuring that the proper protections were in place, the IRB approved the project.

In response, DOE issued a policy memo explaining the requirement for IRB review of studies involving intentional modification of an individual's or a group's environment. The requirement has since been added to DOE Order 443.1C. A DOE checklist for use in reviewing studies of this type has been provided to the DOE central and site IRBs (see Appendix C: Checklists for IRB Reviewers; Modification of the Human Environment, p. 91).

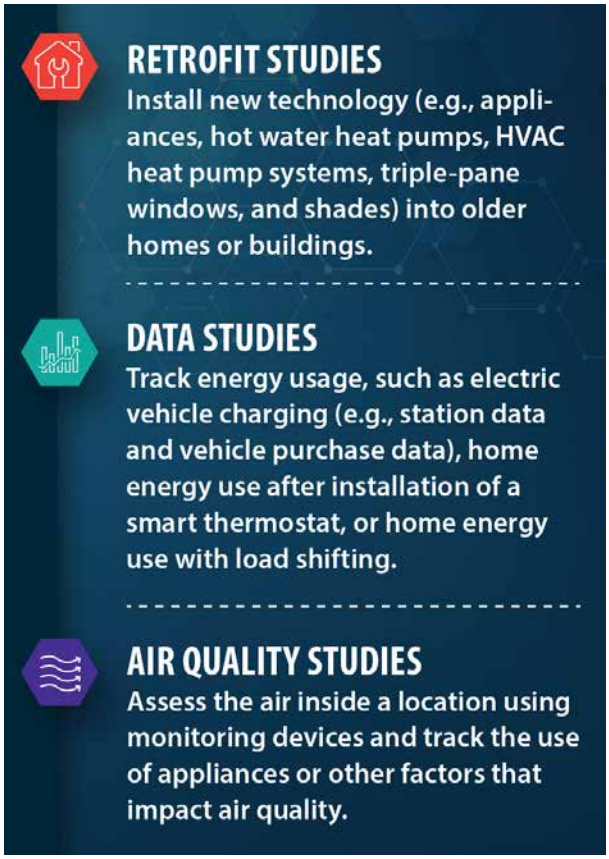

Fig. 5.1. Modification of the Human Environment (MHE) Studies. DOE researchers study interactions with energy technologies or policies through three categories of MHE studies: retrofit, data, and air quality.

changes could affect the study's eligibility for certain review categories. (Additional information about making changes to an IRB-reviewed study can be found in the discussion of amendments in Chapter 4, Insights from the Experts: Beginning Where You Are, p. 30). Note that DOE requires that determinations about whether a study is HSR and the appropriate category of review for this HSR (exempt, expedited, full board) be made by the IRB or IRB office.

The eight categories of research that are exempt from the Common Rule are defined in 45 CFR 46.104. The concept of exempt HSR has caused confusion at times, with some researchers interpreting it as complete exemption from review. However, the Office for Human Research Protections (OHRP) recommends that institutions implement exemption policies that address the local setting and programs of research and lead to accurate determinations. Additionally, DOE and other institutions require initial review and an annual check-in with the IRB, as well as reporting of incidents, for exempt HSR (see DOE-Specific Requirements, p. 13). Since most institutions require an IRB office to make exemption determinations, researchers should engage in early conversations with their IRB of record to determine if their study meets exemption criteria or if further review is required.

If an HSR study is not exempt from the Common Rule and involves no more than minimal risk to human participants, it can be considered for expedited review by the IRB. The nine expedited review categories are defined by OHRP under Expedited Review (45 CFR 46.110). Studies that meet the criteria for an expedited review may be reviewed by the IRB chair or by one or more experienced members of the IRB outside of a convened meeting. Any study that involves greater than minimal risk to participants—even if it meets criteria for one of the nine expedited review categories—must be reviewed by a convened IRB (see Risks Associated with Modifications to the Human Environment, p. 43, for definition of greater than minimal risk).

Most energy technology research, including MHE, is considered minimal risk HSR and does not require full board review, but initial risk determinations can be difficult to evaluate. Determining the category of research that an MHE study fits into may not be straightforward. The following four scenarios illustrate how an IRB might classify different MHE study proposals.

Hypothetical Study 1: Data Collection Only

MHE Study Type: Data Study

Purpose: A new hot water heat pump was previously installed in a home. The research team will collect temperature and humidity data directly from sensors placed in the home.

Questions to Consider

- Was the heat pump installed for the purpose of the research?
- Are sensors detecting temperature and humidity levels without modifying the homeowner's environment?

- Will data collection include any identifiable private information?

Regulatory Determination: Not HSR

Rationale: This study is most likely not HSR because (1) a previously installed heat pump requires no intervention or interaction with the homeowner, (2) sensors will not modify the homeowner's environment, and (3) no identifying or behavior-related data will be collected.

Hypothetical Study 2: Electric Vehicle Charging Patterns

MHE Study Type: Data and User Feedback Study

Purpose: Researchers want to gain insights into the use of public electric vehicle (EV) chargers, including general user patterns for EV and plug-in hybrid electric vehicle charging. The researchers will use automated collection methods to obtain data from the leading charging network provider and the leading vehicle data-logger provider. Remaining data will be obtained directly from vehicle owners through a questionnaire.

Questions to Consider

- Does data collection instrumentation need to be installed in vehicles?
- Does the study involve individuals or vehicle fleets, and who is the participant? Will the automated data collection include individually identifiable data points?

Regulatory Determination: HSR, Exempt Categories 2 and 4

Rationale: This study most likely meets the criteria for exempt HSR because it is limited to interactions via surveys and the collection of secondary data that will be shared with the researchers with all identifiable information removed.

Hypothetical Study 3: Smart Grid and Energy Load-Shifting Experiment

MHE Study Type: Data and Intervention Study

Purpose: Researchers want to collect real-world data on the impacts of automatic adjustments to household thermostats and hot water heaters for the purpose of optimizing grid resilience during peak energy use. Homeowners in a smart grid community agree to have their thermostat temperatures automatically adjusted by a few degrees during times of peak energy use on the electric grid. The timing of hot water heater operation will also be adjusted around times of peak energy use. Study participants provide researchers direct access to their utility usage information and their smart thermostat, as well as having remote sensors installed for additional monitoring of the environment.

Questions to Consider

- Do the research activities change the usual environmental conditions in the home?
- How long are the grid-flexing adjustments and the monitoring going to last?
- Is identifiable private information included as a part of data collection?

Regulatory Determination: HSR, Expedited Category 7

Rationale: In this study, the home is the environment that will be modified by the changes in the thermostat and hot water heater temperatures. This modification is not brief in duration as there will be multiple testing events spread out over the summer and winter seasons, so it does not fit Exempt Category 3. This study fits Expedited Category 7 because it employs human factors evaluation, which involves deploying products, systems, or processes and evaluating how people interact with them. In this case, the homeowner is interacting with the appliances in their home in response to the automatic adjustments, and their behavior is a key study result.

Hypothetical Study 4: New Energy-Efficient Technology Demonstrations

MHE Study Type: Data and Retrofit Study

Purpose: A research team will replace the homeowner's hot water heater with a new hot water heat pump and will collect and compare energy data (e.g., temperatures and water and power use) from the home

for a period of one year before and after the retrofit. Surveys will capture the homeowner's comfort and experience periodically throughout the study period.

Questions to Consider

- What are the short- and long-term risks associated with this retrofit?
- Does long-term monitoring overburden the participant?
- Does collecting utility data include identifiable private information?

Regulatory Determination: HSR, Expedited Category 7 or Full Board (dependent on risk assessment)

Rationale: This study fits Expedited Category 7 because it involves human factors evaluation (deploying products, systems, or processes and evaluating how people interact with them) and collects survey information. In this study, the home is being modified by the water heater replacement and the placement of monitoring sensors. The risks associated with the experimental equipment and retrofit may need to be thoroughly evaluated to determine if the study would qualify for expedited review.

Key Considerations During MHE Research Review

Because MHE research is rapidly evolving, the area can be new for both researchers and IRBs, posing unique challenges during review. Applying the HSR category criteria for these kinds of studies may not be straightforward. While making regulatory determinations ultimately involves looking at the whole study design, the IRB review process centers on several key considerations, including unique issues related to data collection procedures, technology demonstrations, and participant selection and protection (see Appendix C: Checklists for IRB Reviewers; Modification of the Human Environment, p. 91, and Criteria for Approval, p. 106). An important element for IRBs to remember during the review process is how participants' usual interaction with their environment or the technologies being studied will be changed for the purposes of the research. IRBs should consider the following factors for MHE research proposals during review.

Data Collection Methods

Because MHE research observes how humans interact with new energy technologies or react to energy-related changes, these studies may include the collection of identifiable private information. IRBs should ensure that proposals provide clear rationales to justify the need to obtain this data, the purpose it will serve in the study, and the safeguards that will be put in place to protect this data. For example, in a study about energy use in homes, the forms used to receive this information directly from utility companies frequently include significant amounts of identifiable private information. Having researchers explain their plan for using and handling participants' private information will confirm that it not only has a clear purpose in the study and is not being collected inadvertently but also will be protected and secured during the study. Detailed explanations of data collection methods will also ensure that researchers follow appropriate disposition plans at the time of study closure.

IRBs should also ensure that MHE researchers have a plan for how they will inform potential participants about the collection, purpose, and protection of their identifiable private information. Most individuals would expect that a study collecting information about their home or vehicle, such as energy usage or driving habits, should keep this behavioral information private (see Appendix C: Checklists for IRB Reviewers; Reviewing Protocols that Use PII, p. 94). While a temperature or mileage reading alone may not reach that threshold, additional data points (e.g., locations, speed, water usage, window use) lead to more comprehensive behavioral insights. Offering clear explanations to participants in the consent form and during the consent process about what information will be collected and why can help avoid potential confusion and help them make an informed decision about whether they want to participate.

Technology Demonstrations

An intervention is defined as modifying a person's environment for research purposes. While some MHE studies focus on the modification, such as installing a new hot water heater, others focus on obtaining more data from a modification that was made prior to the research study. However, the method of data collection and subsequent testing that impact a technology's function may

still qualify as an interaction or intervention and may generate identifiable private information. As such, IRBs should ensure that these studies are properly categorized and clearly explain to the researchers the regulatory determination and relevant DOE-specific requirements, when applicable.

Some MHE studies propose to provide new technologies to participants. In these instances, IRBs may need to consider additional terms and conditions from the manufacturer, the longevity of the appliance, or difficulties of operating novel user interfaces. Moreover, because many unknowns surround new technologies and their performance over time, MHE researchers may not be able to predict how new devices could pose future burdens for participants. IRBs can help researchers plan ways to address potential problems with new devices, such as replacement or removal of the new technology after study completion (for more information, see the section titled "Risks to Participants" in Chapter 7: Frequently Asked Questions about HSR in the Energy Domain, p. 65.) Furthermore, new technologies introduce the potential for novelty biases. The novelty of receiving new technology can influence participants' reactions to technology, both positively and negatively. To minimize such biases and preserve data integrity, IRBs and researchers can work together to ensure careful consideration of data to collect and questionnaire wording.

Certain technology demonstrations in MHE studies may consist of monitoring equipment use or tracking participant behaviors over time. However, long-term studies can experience changes in the use or occupancy of buildings or residences over the course of the study that may impact data quality. Moreover, the cost of providing technologies without gathering usable data can be a major concern for sponsors. In such cases, IRBs can help researchers anticipate potential use or occupancy changes and consider inclusion and exclusion criteria to limit them or provide alternative processes (e.g., consenting processes for new occupants) to mitigate their impact.

MHE research may also perform retrofits, which creates the potential for liability if something goes wrong. Liability in the context of retrofits is an important issue for IRBs to address in conjunction with institutional legal experts. Some considerations may include: Who is performing the work? Who is signing the contracts for the work to be performed (researchers or participants)? And how is the liability structured in those agreements? The issue of liability is further discussed in the section titled "Risks to Participants" in Chapter 7: Frequently Asked Questions about HSR in the Energy Domain, p. 65.

Additionally, IRBs should remember to ensure that researchers clearly describe subcontractor roles in the protocol. For example, if researchers plan to have subcontractors installing the equipment also collect data or conduct informed consent discussions, the contractors would become part of the research team and should be listed in the protocol. Their engagement in HSR would require additional training and either reliance agreements or their business obtaining a Federalwide Assurance. Thinking through these issues in advance is important for project timelines.

Participant Selection and Protection

Determining who meets the definition of "human subject" and would be required to give consent to participate can sometimes be difficult in MHE studies due to their complexity and involvement of multiple personnel. For example, studies may involve individual cars or vehicle fleets, owners or renters, private residences or public businesses. IRBs can help researchers focus on whose environment is being manipulated for the research, while also considering those with the legal right to agree to the changes and how the research may impact their relationship. In some cases, the IRB may need to ensure that renters are protected from landlords who may want to coerce participation or raise costs after upgrades are completed.

IRBs may also need to rethink what is considered key information to highlight in the beginning of the consent form. Because people's concerns vary, differences may exist in terms of what participants versus IRBs consider to be of greatest importance. For example, in the everyday life of a participant, the trip hazard or space taken up by monitoring equipment may seem more important than the IRB's concerns about the electrical hazards posed by equipment replacement. To help mitigate these differences of concern, IRBs could advise researchers to consider feedback they and other colleagues have received from participants involved in similar studies. Additionally, during study review IRBs can consider the local perspective and context by ensuring access to the appropriate expertise from IRB members and IRB consultants.

IRBs may also need to determine how wide-ranging study goals can be balanced with the corresponding burden the study places on participants. For example, participants should not be asked to provide additional contextual information about their home and household members unless such knowledge has the potential to yield valuable scientific insights.

MHE studies often involve additional household members other than the consenting participant. In these cases, one member of the household often takes the lead in working with researchers, but impacts to other household members occur and must not be overlooked. Proper disclosure is key to ensuring the entire household can comfortably complete the study. Therefore, IRBs should ensure that researchers have a plan for informing entire households about the research and for minimizing any impacts to all household members.

Risks Associated with Modifications to the Human Environment

Evaluating risks to participants involves assessing the magnitude and probability of potential psychological,

Evaluating Risk in Modifications of the Human Environment

Possible Risks During Installation

Equipment Risks

- Installation errors could result in a heat or power outage or faulty wiring that causes a short or an electrical fire.
- Difficult installation could inhibit the functionality of the heat pump or the control module, or it could require additional equipment that might be expensive or hard to obtain.

Home Risks

- Damage from the installation process could require repairs or affect the home's property value.
- Some homes may not have the electrical capacity necessary for the installation, leading to additional evaluations and installation work that can increase both cost to researchers and burden on participants.

Participant Risks

- The installation process could interrupt participants' daily lives, causing aggravation or frustration. For example, the installation noise could be disruptive to their daily activities, or taking time off for installation visits during the work week could lead to a loss of income. This should be offset with proper compensation for equitable accessibility.
- Technicians or researchers entering the home could cause participants to feel anxiety, embarrassment, or awkwardness.

Researcher and Technician Risks

- Difficult installations could affect the technicians' schedule or researchers' project timeline.
- Entering and exiting participants' homes could create problems, such as inadvertently allowing a pet to escape or a child to wander outside the house.
- Spending time inside participants' homes could expose technicians or researchers to potentially volatile situations, such as witnessing domestic abuse.

Possible Risks During Research Phase

Equipment Risks

- The control module or heat pump could experience reliability issues that result in the need for repairs and raise questions about financial responsibility. For example:
  - What happens if the unit breaks during the study?
  - Will participants have access to local service providers?
  - Will participants be financially responsible for any repairs?
  - Are participants stuck with the module at the end of the study?

Tenant Risks

- In a rental home, the landlord or property manager could try to coerce tenants to participate in

Continued on next page

Continued from previous page

the study. Improvements made during the study could also lead to unexpected increases in rent, which should be negotiated with the owner before participation.

Participant Risks

- Loss of control over the home environment could create discomfort.
- Lack of understanding about the control module's monitoring capabilities and limitations could create a concern that the module can monitor participants' behavior in the home without permission.
- Potential increases in heating and cooling bills could cost participants.
- The research team's use of the participants' Wi-Fi connection could have unanticipated impacts on participants, such as increased bandwidth usage and risk to private information.

Researcher and Technician Risks

- Participants may opt out of taking the post-study survey that is sometimes the most important data collection, potentially wasting time and money.

Risk Determination

While all possible risks should be considered by the IRB, it is important to remember that many of these risks could still be considered "ordinarily encountered in daily life." Evaluating them within that context is key, and engaging subject matter experts is frequently warranted to establish mitigation steps that are best practices.

5.1: The Takeaway

MHE studies have become a common type of HSR in energy research. These studies observe how humans interact with new energy technology or react to energy-related changes in efforts to understand benefits and challenges to real-world technology adoption. MHE studies can pose unique challenges to both researchers and IRB professionals, as the regulations do not always fit these types of studies well. Even applying the HSR category criteria for these kinds of studies may not be straightforward, so it is important to look at the whole study design when making these determinations. Additionally, standard IRB practices used for traditional biomedical or social-behavioral research can introduce confusion into the submission and review processes. Tailoring the submission and review processes to better fit MHE studies, providing informational and educational resources, and encouraging early communication and collaboration between researchers and IRB professionals can help mitigate the challenges these studies bring.

Thinking carefully through the study design with participants in mind not only helps protect participants but can also protect research integrity. Occasionally, the research team will need to talk with experts about their study design to minimize risks to the participants. While risks cannot be eliminated entirely, communicating as thoroughly as possible to participants about what they might experience is important so that they can make an informed decision.

physical, social, economic, or legal harms (see Appendix C: Checklists for IRB Reviewers; Modification of the Human Environment, p. 91). The researchers themselves are a key stakeholder to involve when trying to determine the potential impacts of risks and their likelihood. Studies fall into one of two risk categories:

- **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.
- **Greater than Minimal Risk**: The probability and magnitude of anticipated harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life.

Any actual or potential risks must be outlined in a consent form and shared with participants, so they can make an informed decision about whether they are willing to accept the risks and participate in the study (see Appendix C: Checklists for IRB Reviewers; Criteria for Approval, p. 106). The box titled "Evaluating Risk in Modifications of the Human Environment" (see p. 43) provides sample concerns for risk evaluation throughout an MHE research project.

5.2 Fostering a Collaborative Culture Between IRBs and Researchers

Researchers can perceive regulatory compliance as a bureaucratic hurdle leading to research delays. As a result, they may be reluctant to reach out to their IRB office, resulting in frustration for both study teams and IRB professionals. To counteract these perceptions, IRB professionals can take steps to create a collaborative environment that enhances the research process. Proactive partnerships with researchers can help ensure compliance, promote better study design, and foster productive working relationships. For HSR involving MHE studies in particular, early conversations between researchers and professionals from the IRB office can help both groups better understand study goals, identify complex risks, and ensure participant safety.

This section covers what collaboration means in the context of HSR oversight, focusing on partnerships among IRBs, IRB professionals, and researchers.

Insights from the Experts

Understanding Stakeholders

James E. Morris, Central DOE IRB

There are many stakeholders we have to consider: participants, communities, researchers, IRB members, the IRB office, institutional leadership, sponsors, and more, depending on the study. Remember that every stakeholder has an equally important mission, purpose, passion, obligation, and role. Each of us should make an effort to carefully listen to our partners so we can understand their needs in the context of a given study. One way that the Central DOE IRB tries to facilitate this listening is by requiring researchers and IRB members to read an implicit bias memorandum, which lays the groundwork for raising awareness of inherent biases and how they may affect the conduct and review of HSR.

Recognizing the Value of Partnership

Patricia Gunderson, Pacific Northwest National Laboratory

Prior to my role at PNNL, I was a researcher at a small private laboratory, and one of my projects was funded by the U.S. Department of Housing and Urban Development. We needed IRB review for the project and turned to a commercial IRB since we didn't have an in-house IRB. We experienced multiple challenges, many stemming from the fact that we had not anticipated needing an IRB review and thus had not factored it into the budget. We also found it difficult to communicate with the IRB we worked with and were frustrated by what we perceived as a lack of interest in our project on their part. Working with the IRB at PNNL has been a completely different experience. It is clear that they are committed to helping my research be successful and always offer their time and expertise to help me through the process. In turn, I feel comfortable asking them questions and finding ways to be flexible with research designs to ensure both the scientific and regulatory needs are met.

Insights from the Experts

Gaining First-Hand Experience

Cecilia Brooke Cholka, Weill Cornell Medicine

Many IRB professionals' relationship to research is limited to their IRB experience. A practical solution that improves understanding of how to cultivate collaboration is to join a research team. This experience can provide valuable insight into what it's like to recruit and consent participants and collect and handle data. This first-hand experience can help to better understand researchers' perspectives as they interact with the IRB.

Trusting IRB Staff

Patricia Gunderson, Pacific Northwest National Laboratory

Researchers should resist the urge to be overly protective of the various details of their study when working with the IRB. Most IRB staff are interested and ready to learn, and they want to help you find the best way for your research to meet its scientific objectives while also being compliant with regulations.

However, it is important to recognize that the HSR enterprise involves many stakeholders, each with their own mission (for more information about stakeholders and their responsibilities, see Fig. 1.2. Human Research Protections: A Framework of Shared Responsibilities, p. 2, and Fig. 2.4. Sharing Responsibilities, p. 14). Working to acknowledge, understand, and respect the importance of each mission is key to the overall success of a collaborative IRB.

Strategies for Creating a Collaborative Environment

Building a culture of collaboration between IRB professionals and researchers involves (1) facilitating trusting, proactive relationships; (2) communicating early and often; (3) developing and maintaining reasonable boundaries; (4) being thoughtful and flexible about IRB requirements; (5) engaging with the IRB at every step of the review process; and (6) avoiding assumptions. This section elaborates further on these six strategies and illustrates how a willingness to compromise when appropriate helps strengthen partnerships and ensure positive outcomes.

Facilitating Trusting, Proactive Relationships

Successful partnerships between IRB professionals and researchers are trusting and proactive. Both parties must be invested in having the open conversations needed throughout the IRB review process. For example, researchers should not shy away from asking direct questions; they can receive valuable, experienced input from the IRB office about HSR guidelines and study design. Additionally, researchers bring deep technical expertise and often have prior experience working with the study population, which can help IRBs better understand the team's proposal and more accurately identify potential risks as well as the most effective risk mitigations. This engaged partnership may initially require more time to have the conversations needed to reach a shared understanding, but it can ultimately improve the quality and value of the science and the treatment of participants.

Communicating Early and Often

Ideally, conversations should begin as early as possible so researchers can learn how the IRB can help as a partner, not as a gatekeeper. Professionals in the IRB office can be attentive to stakeholder needs for conducting a study by reading the materials researchers provide and responding with actionable suggestions to help them meet IRB requirements. Another important consideration is knowing who belongs in a conversation and who does not. For example, in the case of student research, it may not make sense to require the responsible faculty member to be present for all discussions. The student knows the details of their own study and can answer the IRB office's questions directly without a faculty go-between.

Insights from the Experts

Engaging Proactively

Cecilia Brooke Cholka, Weill Cornell Medicine

In a previous role, the institution I worked for received an NSF grant to support underrepresented faculty and research. In preparation, the institution held workshops where senior faculty could share their grant-funded research experience with junior faculty. Participating in this effort was a great opportunity for the IRB office to build new relationships with researchers who were at the start of their careers. Staff from the IRB office showed their willingness to be involved in the entire process and to offer assistance and guidance. This helped faculty to see the IRB staff as early partners rather than final gatekeepers and vastly improved the reputation and perception of the office. We followed a similar approach when the institution offered a workshop providing students with guidance on dissertation preparation. An IRB staff member presented a session on the IRB review process to make it less intimidating for students. These examples demonstrate how IRB offices can proactively engage new researchers and promote a better sense of collaboration and partnership.

Having Difficult Conversations

Cindy Mazur, Los Alamos National Laboratory

As an ombuds, I regularly help people have difficult conversations. We focus on enhancing communication and mitigating conflict. Here's an example: an IRB professional notices a problem with the risk disclosure language a researcher is proposing to include in the consent form to present to study participants. The conversation to address this problem can be broken down into several steps: (1) explain what you need, (2) invite the other person's perspective, (3) consider the other person's needs, and (4) gain buy-in by discussing whether a solution is reasonable or likely to succeed. IRB professionals and researchers can implement these steps when faced with tough conversations to not only build consistency and trust but also help people feel heard and understand the "why."

Developing and Maintaining Reasonable Boundaries

Trust enables each partner to feel comfortable developing and maintaining reasonable boundaries. The work of IRBs reflects an element of customer service: IRBs are charged with serving study participants and helping to ensure their rights and welfare. However, because the IRB office mostly interacts with researchers, some researchers may perceive themselves as the primary customers. Timely IRB support of successful research is crucial, but IRB staff must also be empowered to maintain healthy workplace boundaries. This might involve maintaining standard work hours even when a researcher makes a last-minute submission late on a Friday and wants their questions addressed immediately.

Being Thoughtful and Flexible About IRB Requirements

The IRB office can support successful research and build a culture of collaboration by approaching IRB requirements with thoughtfulness and flexibility. Anything the IRB requires of researchers should be supported by a reasonable, purposeful "why." The IRB mission is to protect the rights and welfare of participants; any processes or requirements that no

longer fit the mission should be eliminated. IRB staff should continuously reflect on what they are asking of researchers and be open to revising processes and procedures, which will help expedite research projects and make researchers feel heard. If a researcher struggles to understand an element of the review process, IRB staff can help break tasks or requirements down into smaller components or suggest revisions that a researcher can make to meet the necessary criteria, saving everyone time and frustration. Curating documents with a well-organized versioning system and review timeline can also reduce confusion about requirements and streamline the review process.

Engaging with the IRB at Every Step

For researchers, an effective strategy for building a culture of collaboration is to engage with the IRB office at every step of the process, from protocol development and troubleshooting to reviews and modifications. Researchers should share their basic project information, such as goals, expectations, work plan status, and technical and practical context. The benefits of a proactive partnership are realized when information and updates are shared early and often. Withholding pertinent information can create roadblocks; the importance of communication during the review process cannot be overstated.

Avoiding Assumptions

Finally, both researchers and professionals in the IRB office should avoid making assumptions. For researchers, this could mean avoiding the assumption that the IRB already knows the intricate details of the project and its challenges. For the IRB office, this could mean avoiding the assumption that researchers understand HSR regulations and IRB processes, even if they have previously submitted to the IRB at the same institution or elsewhere. To help facilitate understanding, the IRB office can provide researchers with sample forms containing examples of appropriate language from successful projects that demonstrate responsiveness to IRB needs and intentions. Ultimately, both researchers and IRB professionals can help create a strong foundation for a collaborative IRB experience through a willingness to be open-minded, learn and grow, and communicate clearly and consistently.

5.2: The Takeaway

To ensure that evolving methods in MHE HSR are properly protecting participants, a collaborative process for IRB review is critical. By communicating early and often, researchers can avoid time wasted on approaches that don't meet the criteria for IRB approval and can more efficiently address potential issues before they become problems. A collaborative approach can streamline the overall review process for IRB professionals as well, who will not have to spend additional time reviewing protocols that do not meet their expectations. By sharing knowledge, the IRB process can become more transparent, effective, and efficient; stakeholders are encouraged to ask questions and take advantage of each other's expertise.

Chapter 5 References

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Chapter 6

Use Cases

DOE research in energy technology and policy spans diverse institutions, projects, and fields. As energy research has evolved, human subjects research (HSR) has become an integral part of many projects, allowing research to include insights into the lived experiences of individuals who use new energy-efficient technologies.

As part of the symposium, a research showcase provided examples of DOE-funded projects conducting HSR in the energy technology and policy field. The showcase explored six unique projects and offered perspectives on how scientists, institutional review board (IRB) professionals, and DOE can work together in this era of collaboration to advance the energy infrastructure and establish future paths for HSR.

This chapter presents the projects as use cases to provide energy technology researchers and IRB professionals with examples to draw from when working on their own HSR-related projects. Use cases highlight how projects involved HSR and IRBs, identified challenges, and discovered best practices (see Summary of Challenges and Best Practices, p. 50). They are arranged topically among five overarching themes: (1) learning what constitutes HSR, (2) implementing equity in study design, (3) establishing trust and open communication, (4) understanding the importance of collaboration, and (5) calling for consistency across IRBs.

Use Cases and Themes

Summary of Challenges and Best Practices

Challenges

- Sponsors and researchers can lack knowledge about what constitutes HSR and applicable DOE requirements, leading to insufficient time, funding, and support for proper project review and conduct.
- Sponsors and researchers do not always incorporate community engagement during the research design phase, which can make including community feedback in later project stages difficult.
- IRB submission documents are frequently oriented toward medical, biotechnology, drug discovery, and clinical studies, leading to confusion among energy researchers.
- IRB policies can be inconsistently interpreted and applied across different institutions.

Best Practices

- Solicitations from DOE sponsors should include language regarding potential HSR and the corresponding requirements.
- Meeting with subject matter experts in HSR during the project design phase is key to avoiding working in HSR unknowingly and to incorporating best practices to conduct research ethically.
- Researchers, sponsors, and IRB professionals should work collaboratively throughout the project lifecycle.
- IRBs reviewing similar research should harmonize approaches by offering educational opportunities for IRB staff and sharing best practices.
- Sponsors and researchers can leverage and learn from colleagues with more experience with the IRB process by reviewing existing IRB-approved projects at their home institutions and sharing successful project templates.
- When projects have multiple phases, researchers and IRBs should support an iterative process for facilitating modifications over time.
- Researchers should take time to develop work plans in a thoughtful and detailed manner, including determining detailed roles and responsibilities for team members as well as clear plans for sharing information across institutions, researchers, and project teams upfront.
- Researchers should establish balance between research rigor and efficiency, as well as the IRB process.
- Sponsors, researchers, and IRBs should communicate time commitment expectations early.
- Ensuring that consent is informed and voluntary is critical.
- Researchers and IRBs should consider how consent changes in a multifamily context.
- A key consideration when designing studies is how to minimize participation risks.
- Researchers should engage participants as partners and establish trust.
- Researchers should offer participants appropriate and meaningful incentives.
- Researchers should normalize collecting all feedback, both positive and negative, from participants.
- Whether study equipment is commercial off-the-shelf or developed through research, sponsors and researchers should plan for the potential that equipment will fail.
- Researchers should always leave the building or home better than it was at the beginning of the project.
- In studies involving survey research, researchers should use consistent survey mechanisms across all participants.

Learning What Constitutes HSR

Use Case 1
EPIC and CalFlexHub

Project Overview

The California Energy Commission's Electric Program Investment Charge (EPIC) funds research, development, and demonstrations of clean energy technologies and approaches that will (1) benefit electricity ratepayers of California and (2) lead to technological advancement and breakthroughs to achieve the state's energy and environmental policy goals (CEC 2023). EPIC funds electricity research that includes, but is not limited to, investigating energy efficiency in buildings and industrial, agricultural, and water sectors; demand flexibility; and vehicle grid integration. Interest areas include heat pumps, charging electric vehicles, building automation, technology interoperability, and optimized load modification in response to prices for greenhouse gas signals.

The California Load Flexibility Research and Deployment Hub (CalFlexHub) is a high-visibility program within EPIC at Lawrence Berkeley National Laboratory (LBNL) with a portfolio of more than 16 laboratory-testing and field demonstration projects. These projects demonstrate the use of automated communication and control technologies to alter the load-consuming patterns of different distributed energy resources (DERs) and energy-consuming equipment in response to the CalFlexHub dynamic price signals. DERs and equipment studied includes heat pumps, air conditioners controlled by smart thermostats, energy storage, pool pumps, batteries, electric vehicle charging, and other technologies at varying scales.

HSR Involvement: Understanding DOE's HSR Requirements

EPIC and CalFlexHub require HSR to understand how people will use the energy technologies being studied and to gain information that will better inform product development and rate designs (see Sample EPIC Research Questions, p. 52). CalFlexHub research also has a strong equity component, with many field projects involving underserved communities.

When CalFlexHub began, project managers were unclear if the research would be considered HSR. To make this determination, a team was assembled that included division-level human subjects experts, project leads, and administrative staff. The team also worked directly with Kelsey Sharkey Miller, program administrator for LBNL's Human Subjects Committee (their IRB).

Project Leads

Matt Fung
Mechanical Engineer and Technical Lead, California Energy Commission

Jingjing Liu
Researcher, Lawrence Berkeley National Laboratory

"The human subjects process was a good friend to our team because it pushed us to think through many planning details in the beginning, instead of saying 'let's figure it out later.'"

— Jingjing Liu

Sample EPIC Research Questions

Crosscutting Questions

- Do customers want to participate in a demand flexibility research study?
- How much can customers shift their energy consumption to off-peak hours per day?
- How much can customers reduce their electricity costs by shifting their energy use to off-peak hours?

Smart Thermostat Examples

- How many thermostats successfully receive price signal over many events?
- How often would customers opt out of a load shed or shift event?
- How many degrees of cooling and heating setpoint adjustments are customers willing to change as a trade-off to utility bill savings?

Many researchers consider HSR to only include directly experimenting on human participants as in biomedical testing; CalFlexHub research does not involve direct testing on human participants. Instead, this project's research entails making modifications to living environments, such as adjusting thermostat settings at certain times of the day. Because projects involving modification of the human environment are typically interventions that fall under HSR (see Chapter 5: HSR in Energy Research: Standardizing IRB Processes and Promoting Collaboration at Every Stage, p. 37), the team determined that CalFlexHub research required IRB evaluation.

Additionally, CalFlexHub's research portfolio differs from many other LBNL HSR projects, which typically operate as single HSR studies focused on one technology or approach for multiple locations. In this case, each project in CalFlexHub's portfolio has differences (e.g., site types, technology impacts, collaborators, and incentive structures) that make a single protocol difficult. As a result, researchers determined that HSR protocols should be handled on a project-by-project basis. This approach ensures that protocols are best suited for each project's unique situation and attributes, allowing for the needed flexibility for each use case.

Best Practices

Throughout the research and IRB process, the team identified several best practices for HSR in the energy technology and policy field.

- **Consider HSR Early.** Considering HSR early in the project and including it in proposals, timelines, and budgets are essential steps for successful research. Communicating this information with partnering institutions early encourages collaboration and understanding and facilitates approval of protocols.
- **Plan Early and Communicate Expectations.** IRB protocols help manage participant expectations by providing explanations about why the research is needed, what the benefits are, and what actions will be performed in participant homes and to home devices. By law, participants can opt out of research at any time, but communicating clear expectations encourages participants to remain involved in the project.

  The IRB process also encourages teams to develop work plans in a thoughtful and detailed manner. People's natural tendency is to postpone thinking about details, but this goes against best practices for project management. The human subjects process prompts teams to consider details that could significantly impact research, such as recruitment, event sequences, roles and responsibilities, risk management, and data privacy.
- **Balance Rigor and Research Efficiency.** Finding a balance between rigor and research efficiency improves HSR. CalFlexHub achieved that balance by including administrative staff and human subjects experts in the process to lower costs associated with HSR. For labor-intensive work such as recruitment, subcontracting those efforts made the organization more efficient.

Learning What Constitutes HSR

Use Case 2
Urban Integrated Field Laboratories

Project Overview

Launched in fiscal year 2022 through DOE's Office of Science, the urban integrated field laboratories (UIFLs) are large, multidisciplinary, multi-institutional projects aiming to (1) understand the predictability of urban systems and their interactions with the climate system and (2) inform equitable climate and energy solutions that will strengthen community-scale resilience across urban landscapes (UIFL 2023). Focusing on Baltimore, Chicago, Southeast Texas, and an Arizona urban megaregion, the four UIFLs represent diverse demographic characteristics, differing climate-induced pressures on people and infrastructures, and unique geographic and climatic settings (see Fig. 6.1, p. 54).

HSR Involvement: Recognizing UIFL Research as DOE HSR

UIFL research projects, including elements that examine human interactions with the climate system, represented a new component of climate research within DOE's Biological and Environmental Research program's (BER) Earth and Environmental Systems Sciences portfolio. This expanded emphasis on the human dimension of climate research spurred questions among program managers about whether the research was HSR.

Discussions with DOE HSR staff and experts revealed that some UIFL research meets the federal and DOE criteria for HSR because the research involves interactions with stakeholder communities; use of surveys, interviews, and focus groups that ask individuals for their opinions; integration of health system records with environmental data; and educational and observational activities. Specific examples of these criteria in UIFL research include:

UIFL Program Manager

Sally McFarlane

Biological and Environmental Research Program Manager, U.S. Department of Energy

"UIFL project teams found the IRB process very useful to understand concerns and refine their research plans."

- **Interacting with Stakeholder Communities.** Several UIFLs engage local stakeholders to ensure that research is relevant to the involved communities. These projects conduct focus groups and hold stakeholder meetings to identify climate concerns and opportunities shared by residents.
- **Using Surveys and Interviews.** Projects conduct household surveys that include questions about demographics, individuals' climate concerns, and types of climate mitigation strategies that community members find suitable for their neighborhood and region. Some projects will use specific surveys to inform the future direction of their research activities. For example, the Arizona UIFL is exploring surveys on heat stress and the thermal security of residents. Another project will conduct a formal evaluation of its work through surveys and interviews with project participants.
- **Integrating Health and Environmental Data.** Some UIFLs are assessing transportation decisions and their impacts on air quality. One project is

Fig. 6.1. Science Underpinning Equitable Climate and Energy Solutions for Urban Regions. The Baltimore Social-Environmental Collaborative (BSEC) UIFL focuses on climate challenges that many midsized industrial cities must address (top left). Focused on the Chicago region, the Community Research on Climate and Urban Science (CROCUS) UIFL uses observational and modeling capabilities to address ways to mitigate climate change that will be useful to other major U.S. cities (top right). The Gulf Coast region has unique challenges and needs including acute-on-chronic hazards, along with long-term environmental, industrial, and social stressors, which the Southeast Texas (SETx) UIFL is working to address (bottom left). The Southwest Urban Corridor (SW-IFL) UIFL represents one of the fastest-growing urban corridors in the United States, including Tucson, Phoenix, and Flagstaff, Arizona (bottom right).

considering integrating health system records with environmental data.

- **Conducting Observational and Educational Activities.** One UIFL will work closely with stakeholders from city governments, which requires structured interviews with city officials and observing participants at city meetings. UIFLs also host educational activities, such as helping student communities make observations of local atmospheric and environmental conditions.

Best Practices and Lessons Learned

Researchers found the IRB process useful to identify concerns and refine research plans. They identified several best practices, including:

- Sharing information across institutions, with researchers, and with project teams;
- Working closely with social scientists on their team who have more experience with the IRB process;
- Developing templates that others can use; and
- Leveraging and learning from existing projects at their institutions with IRB approvals.

Program managers and principal investigators on many of the projects are physical scientists and thus unfamiliar with the IRB process (see Spotlight on CROCUS, p. 55). Identifying which research elements are considered HSR has been a learning curve. University team members accustomed to working with university IRBs are sometimes unclear about how to coordinate with the DOE process. Hosting a kickoff meeting focused on HSR-related expectations and requirements at the beginning of the project funding process may have helped mitigate these challenges.

Spotlight on CROCUS: Helping Physical Scientists Navigate HSR

What is CROCUS? The Community Research on Climate and Urban Science (CROCUS) UIFL studies urban climate change and its implications for environmental justice in the Chicago region. The CROCUS team conducts novel, multiscale observational science and creates highly accurate climate models. This information leads to new insights on current and future urban climate challenges and informs future actions for mitigating and adapting to climate change at the street, neighborhood, and regional levels (CROCUS 2023). The project engages local communities to define research questions relevant to them.

What challenges do CROCUS researchers face? Trained as physical scientists first, CROCUS researchers have minimal HSR experience. As a result, they have struggled to identify what constitutes HSR and to fill out IRB forms.

How does HSR factor into CROCUS research? CROCUS's community engagement work involves multiple categories of HSR.

- **Observations.** Most tasks under the scope of work do not encompass human behavior but instead rely on instruments to record atmospheric chemistry and quality, temperature, precipitation, and typical meteorological parameters. However, an IRB determination that this involves HSR is appropriate because the project plans to use these observations in part as a form of community engagement, making the work meaningful to communities when conducting street-level research.
- **Community meetings.** CROCUS will host periodic meetings with community groups to provide tutorials on the project's work and gather information and recommendations. For example, the community can recommend where to place sensors and provide historical information to help researchers understand sensor metadata and meta information. CROCUS will also poll community members, ask about their desired futures, and build scenarios with them. These responses and scenarios will then be incorporated into the project's models and observations. Researchers will also conduct debrief sessions on research results and surveys on project goals.

What could help CROCUS researchers better navigate HSR and the IRB process? Having more broad orientation and safety meetings with a component focused on expectations for tasks that may involve HSR at the project's beginning may have been beneficial for gathering ideas, tutorials, and research basics and avoiding potential pitfalls. Hosting orientation meetings could help projects design plans to avoid unknowingly working in HSR and establish boundaries to conduct research safely and ethically. Additionally, periodic meetings could work in parallel to help design planned and desired project outcomes and identify IRB review needs. Such meetings would help identify any potential concerns early in the design process to ensure that work can be conducted in a timely manner.

For large projects, submitting an individual application to the IRB for tasks that will be conducted early in the project and later submitting modification applications as additional research tasks or activities are identified would be beneficial. Such an approach could offer phased or tiered timelines for large projects that allow approval of smaller project segments instead of the entire project all at once. CROCUS has many different phases, aspects, and partners, but the IRB process requires managing various details and aspects of the project that are not yet developed. Focusing on one phase at a time would help include relevant partners at the right times and identify interdependencies. Identifying IRB best practices for large collaborative projects involving multiple institutions will be important for future research.

Ultimately, researchers need to face the unknown and explore the IRB process. They can learn quickly but would benefit from expanded context and a more tailored IRB form for physical science research.

Project Lead

Cristina Negri

Community Research on Climate and Urban Science (CROCUS) UIFL, Lead Principal Investigator, Argonne National Laboratory

"Hold our hands because we don't really know what we don't know. But we are eager to learn."

Implementing Equity in Study Design

Use Case 3

University of California–Davis Western Cooling Efficiency Center

Project Overview

The University of California–Davis Western Cooling Efficiency Center (WCEC) is an authoritative and objective research center at the UC Davis Energy and Efficiency Institute that accelerates the development and commercialization of efficient heating, cooling, ventilation, and energy distribution solutions (WCEC 2024). WCEC follows a dedicated list of seven principles when designing HSR studies to ensure ethical treatment of participants (see WCEC Human Subjects Research Principles, this page).

Best Practices: Principles for Ethical Study Design

The following list offers guidance for creating ethical study design. Ultimately, the IRB review process makes researchers consider and better plan for how they will address potential risks. All funded projects should be IRB reviewed to protect participants, contractors, and sponsors (see Appendix C: Checklists for IRB Reviewers, p. 87).

Ensure Consent is Informed and Voluntary

Provide detailed documentation for participants, including timelines, descriptions and photos of equipment, and explanations of expected impact. Write this information in terms that all participants can understand. Employ research-use agreements to convey equipment risks and inconveniences and confirm that participants have appropriate insurance. Fieldwork requires large amounts of effort upfront that can end up generating no results if participants withdraw during the study. Sharing all available information with participants at the projects' beginning through the informed consent process encourages long-term

Project Director

Sarah Outcault

Market Transformation Research Director, University of California–Davis, Western Cooling Efficiency Center

"The IRB review process is very helpful for making sure researchers think through and plan how to address many potential risks for participants. And by extension, protect those participants."

WCEC Human Subjects Research Principles

- Ensure consent is informed and voluntary.
- Consider how consent changes in a multifamily context.
- Minimize participation risks.
- Offer meaningful and appropriate incentives.
- Engage participants as partners.
- Plan for equipment failure.
- Leave the building better than it was at the beginning of the project.

participation by those who are truly interested in completing the study activities and prevents attrition by limiting surprises. Enrolling more participants than necessary also helps to ensure researchers can collect the data needed if some participants drop out.

Consider How Consent Changes in a Multifamily Context

Projects need to handle consent and privacy differently in multifamily contexts. Building owners agree to install equipment, but occupants (e.g., renters) consent to participate in research. No information about participants can be shared with building owners, including agreement to participate. Protecting this information can be difficult as owners may have access to details that would not usually be shared outside of the research team. However, projects should identify methods to act as a firewall between tenants and owners to protect privacy and safety. Research participants have shared concerns about retaliation from management if they report problems within their buildings, which demonstrates that privacy is a real concern.

Minimize Participation Risk

Potential risks include impacting vulnerable populations, sharing personal information, and influencing finances. Before conducting research, participants should be screened to determine vulnerabilities and possible impacts. For example, if an HVAC project is testing cooling equipment, populations who are vulnerable to heat, such as the elderly or children, should not be included as participants. Projects should remain conscious of always protecting participants' information. Consider all identifying information through the most sensitive-case scenario, such as a participant who is living in a secret location after escaping abuse. To minimize risk for all participants, personal information should not be shared in public, sponsor, or internal documents. Special care should be given to financial implications of research, particularly for low-income participants. Researchers should explain if equipment installation could increase participants' bills and be prepared to cover the difference for low-income participants for the expected useful life of the equipment since increasing operating costs would harm research participants.

Key Terms

- **Compensation:** Monetary support provided to participants for financial impacts, losses, or inconveniences occurring due to study participation.
- **Incentives:** Payment or items provided to participants to entice or encourage study participation.

Offer Meaningful Compensation and Incentives

Financial considerations should be generous enough to account for participants' effort and inconvenience, as well as compensate for expenses and time. Research participation can be a burden, and the costs are not always readily visible. Incentives help attract participants and keep them engaged. Compensation can be provided for a range of reasons including (1) participant expenses such as the need to hire childcare while they participate in an interview for the study, (2) the inconvenience of allowing people into their home, or (3) costs associated with alternative equipment or housing options in the event that the experimental technology does not perform adequately. These costs and discomforts should be considered when choosing compensation rates, as should participants' preferred form of incentives. Asking participants about their preferences ensures that incentives are meaningful to them.

Engage Participants as Partners

Participants should be treated and respected as partners. Designating one team member as a contact point encourages participants to stay in touch throughout the project. Participants are more likely to freely share questions and concerns with someone they know who has been involved in the recruitment process and communicates in plain language. Contacting participants after equipment installation to inquire about their experience also builds stronger relationships and goodwill. Make efforts to normalize negative feedback from participants, who may only share positive experiences

during interviews believing that is what researchers want to hear. Asking questions about what went wrong (i.e., What isn't working? How can we improve? How can we do better in installation or engagement? Help us troubleshoot.) encourages participants to share the full details of their experience. Remind them the purpose of the research is to test out the technology and improve it. Emphasize that the participants are the only ones who can share what it is like to live with and use the technology on a regular basis.

Plan for Equipment Failure

Technology does not always work as expected, so all projects should have a plan for equipment underperformance. Develop criteria and create contingency plans to meet participants' immediate needs. When issues arise, provide resources to offset burdens, such as hotel stays, food budgets, or backup equipment. Projects with a high rate of equipment failure may require procedures for pivoting or canceling demonstrations. These unexpected problems should also be immediately reported to the IRB to adjust the project's risk assessment and adequately adjust participant protections.

Leave the Building Better than It Was at the Beginning of the Project

Equipment cannot always remain after a project is complete, which requires budgeting to replace the equipment. New equipment should be equal to or better than what participants had before the study. Reinstall the equipment replaced by the project or purchase new equipment. Prioritize participants' preferences throughout the process, regardless of alignment with project goals. For example, a project testing electrification options may have to revert to gas equipment at the end of the project if that is the participant's preference.

Establishing Trust and Open Communication

Use Case 4
Interruption Cost Estimate Calculator 2.0

Project Overview

LBNL's Interruption Cost Estimate (ICE) represents the leading and only publicly available tool for estimating the cost of power interruptions in the United States. Since the tool launched in 2009, the ICE Calculator has continued to increase in popularity and usage. Today, it supports numerous internal utility reliability planning activities, provides a basis for discussing utility reliability investments with regulators, and allows for the assessment of economic impacts of past power outages.

The tool relies on a multitude of electric utility-sponsored customer surveys. Many of these surveys are more than 25 years old and do not statistically represent all U.S. regions. To improve representation, update statistical customer damage functions, and upgrade the ICE Calculator online tool, researchers are conducting a large survey initiative in two phases. In Phase I, 10 distinct surveys representing 21 distinct utility distribution service companies were conducted in 2023. Phase II is targeting 10 additional surveys, five of which have already been identified to be conducted in 2024. The new version of the tool is expected to be released in fall 2025.

HSR Involvement

Utility companies frequently conduct customer interruption cost surveys to elicit feedback from customers on the valuation of lost power. In this work, the research team has developed a consistent set of survey instruments to be administered in Qualtrics across the United States. The surveys present participants with a series of power interruption scenarios and ask residential customers to assess their willingness to pay to avoid an outage. Nonresidential customers are asked to estimate direct economic impacts, losses, or gains from the interruption.

The project's IRB protocol was approved under Exemption Category Two by the LBNL Human Subjects Committee under the explanation that the research involves surveys and interviews only. This effort was considered by the Human Subjects Committee under a single protocol that employs one primary survey model and allows for small changes in the content for each utility area involved. Through pre-meetings in the design phase, the administrator and study coordinator were able to develop an approach to streamline the IRB protocol so that each utility could be added through an amendment and only the minor

Project Lead

Kristina LaCommare

Electricity Markets and Policy Program Manager, Lawrence Berkeley National Laboratory

"Our sponsoring utilities are hypersensitive when it comes to protecting the privacy of their customers and appreciate the IRB protocol. Having it helped assure that we were thinking about the privacy of their customers and trying to mitigate any potential risks."

changes in the approved materials would be reviewed each time. This has resulted in an efficient process all around.

Challenges: Establishing Participants' Trust

One ongoing challenge is in establishing trust with participants who are recruited to take the survey. In particular, many nonresidential utility customers who are unfamiliar with LBNL may believe the survey request is coming from an untrusted source. Enlisting utility company account representatives and managers to contact customers for participation has been key in establishing the trustworthiness and credibility of surveys with these customers.

Best Practices

Overall, sponsoring utilities have appreciated the IRB protocol. Electric utilities are rightfully sensitive about protecting their customers' privacy. IRB protocols legitimize studies and ensure that projects always consider how to protect privacy and mitigate potential risks.

- **Early and Open Communication.** Start the communication process early to determine detailed project roles and responsibilities. Interviewing customers requires working with their providers' internal teams, such as marketing and communications, customer service, account representatives, and managers. Communication across teams requires significant coordination efforts; identifying roles early lightens the load, particularly as staff join and exit the company. Be open with participants about time commitment expectations to establish trust.
- **Consistent Use of Survey Instruments.** Using the same survey instrument across all utilities allows for consistent survey results that can be collectively assessed.

Understanding the Importance of Collaboration

Use Case 5

Community Engagement in Lithium and Geothermal Research

Project Overview

Electric vehicle sales and lithium demand for vehicle batteries are growing. Finding domestic and lower-impact sources of lithium is a high priority for the Biden administration. In the United States, lithium exists in geothermal brines near the Salton Sea in California. The technical pilot project "Characterizing the Geothermal Lithium Resource at the Salton Sea" aims (1) to determine how much lithium is available and recoverable from the brines and (2) to understand environmental impacts, including water use, waste generation, and air emission. A community engagement focus was added after the project proposal was funded, which created various challenges detailed in this use case.

HSR Involvement

Mineral extraction does not occur in a vacuum, and communities near the resource must be informed and involved in decision-making processes to be consistent with environmental justice principles. Communities near the lithium resource in the Salton Sea are some of the most disadvantaged in California in terms of exposure to environmental hazards, public health challenges, and socioeconomic indicators, such as linguistic isolation and unemployment.

The project incorporated community engagement after a direct request from DOE's Secretary of Energy, Jennifer Granholm, to address the community's concerns and make information accessible. The team faced feasibility issues with its initial plan of hosting focus groups throughout the study for feedback. As an alternative, the project analyzed public meeting minutes and comments to understand community members' questions and concerns. They also hosted an in-person workshop, where they used surveys to gather feedback on they study's relevance and communication quality. Surveys allowed the community to share questions, concerns, and priorities.

IRB submission and review went through LBNL to conduct surveys under Exempt Category 2, which helped with determining appropriate compensation for participation and designing the feedback mechanism. The project requested funding for participant compensation in recognition of people's time, feedback, and disadvantaged situations. The IRB process forced the project to prepare in advance and consider key details that might have been left out otherwise, such as determining eligibility criteria, planning recruitment, discerning justifiable compensation amounts, and translating materials. The IRB requires a high level of specificity and provides prompt, clear feedback and guidance throughout the process.

Project Lead

Meg Slattery

Master's and PhD Student, University of California–Davis

"Successful community engagement requires a good understanding of what it really takes to do it well and the time and work that is needed to do an effective job."

However, IRB protocol questions in some cases are not designed for research collecting feedback on technical areas, which made the process confusing for staff new to HSR.

Challenges: Collaborative and Communicative Pitfalls

Made up of a team of geoscientists, the project did not employ anyone with extensive background in the IRB process or social sciences. The research plan was also not created collaboratively, so effective communication was limited between the researcher responsible for community engagement and the rest of the team and led to a planning versus implementation gap that the project struggled to overcome. Additionally, the project was planned and funded before implementing community engagement. As a result, there was no clear mechanism for incorporating feedback from the community into other aspects of the project.

The project also struggled to gather support for engagement and implement work efficiently. While many researchers supported the concept, they did not understand the amount of time and effort required for effective community engagement. Communicating with research teams early and often is critical to ensure that they understand and are invested in the plan.

Lessons Learned

Benefits exist from advanced planning and early community involvement before creating a proposal; however, that coordination is difficult on current funding timelines and turnaround times. The HSR component of the project required IRB protocol approval before the corresponding subcontracted funds to the collaborating site could be approved, which required creating a proposal before the community engagement work could begin. This led to some timeline issues as the plan had to be developed before gathering input from the rest of the team or community partners. In the future, better coordination may be able to improve the process through more frequent amendments to allow the project to develop in tandem with other project components that do not engage participants.

Through this process, the team built a stronger network of local partners that will make future community engagement efforts more effective. The project has received further funds, including increased funding for community engagement. Plans for future research include improving the team's internal capacity for stakeholder-engaged research, establishing a community advisory board, hiring a local project intern, and dedicating more researcher time to community engagement.

Calling for Consistency Across IRBs

Use Case 6
Building America Program

Project Overview

To meet the Biden administration's goal of a clean economy by 2050, DOE is working to understand how to optimize energy efficiency for the country's 120 million homes. DOE's Building America program is working toward this goal by bridging the gap between emerging technology development, codes and standards, and full voluntary market adoption of advanced energy efficiency and home performance solutions (U.S. DOE 2016).

HSR Involvement

In both projects, Building America found that the IRB process significantly benefitted the program by minimizing the risks of causing harm and ensuring that projects received informed consent from participants and followed other HSR requirements and best practices.

- **New Home Ventilation and Indoor Air Quality Study.** This project began in 2017, was funded for 3 years, and recently finished due to pandemic delays. During this study, researchers entered homes to test ventilation systems and indoor air-quality sensors, which required frequent interactions with homeowners. Researchers had to receive homeowners' consent and minimize the impact of research on their daily lives.
- **Field Investigation of the Prevalence and Energy Impacts of Residential HVAC System Faults.** This ongoing project began in 2018. Researchers monitor hundreds of homes for heating, ventilation, and air conditioning system faults with a variety of measurement methods. The project requires interactions with homeowners as researchers enter homes to take measurements, monitor equipment, and more. While the study poses minimal risks to participants and offers potential benefits, IRB review is required because modification of the human environment is involved (see Appendix C: Checklists for IRB Reviewers; Modification of Human Environment, p. 91).

Project Director

Eric Werling

Building America National Director, Building Technologies Office, DOE Office of Energy Efficiency and Renewable Energy

"You never know what you don't know until you find out what the rules are."

Challenges

- **Inconsistent Application of IRB Policies.** IRB regulations can be inconsistently applied across organizations and at the individual project level over time with a single organization, which creates challenges for researchers. Not every organization has an IRB despite conducting research that would be categorized as HSR, and among organizations that do have IRBs, policies and implementation of requirements can vary. For example, one institution did not classify a Building America project as HSR and declined to review the study. However, the DOE IRB classified the study as HSR, showing an inconsistent application of IRB definitions and requirements.
- **Different Interpretations of IRB Policies.** IRB members on the same board can interpret policies differently. Collaborative education for all involved personnel may mitigate this challenge. Educating IRB members and staff on researchers' needs and researchers on IRB requirements encourages collaboration and equal application of all policies.

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Chapter 7

Frequently Asked Questions about HSR in the Energy Domain

Answers to commonly asked questions have been organized topically to serve as a resource and guide for researchers, IRB professionals, and sponsors of human subjects research (HSR) in the energy technology and policy field. For general questions about HSR as it relates to the Common Rule, visit the U.S. Department of Health and Human Services' Office for Human Research Protections website at hhs.gov/ohrp/index.html.

7.1 Defining HSR

When is research considered to be developing or contributing to generalizable knowledge versus research intended to inform internal federal decision-making and program direction?

Consult your IRB because the answer will depend on several factors. Questions the IRB may ask include: (1) how broadly the collected information will be disseminated and (2) whether the information-gathering effort is research or quality assurance aimed at program improvement. Relatedly, IRBs should not consider possible long-range effects of applying knowledge gained in the research, such as the possible effects of the research on public policy, when considering research risk [45 CFR 46.111(a)(2)]. For further discussion of generalizable knowledge, see Section 2.2 DOE HSR Regulations in Energy Technology and Policy Research, p. 11.

Would a study that collects images of people and license plates on a public road be considered HSR?

Assuming the study meets the regulatory definition of research, the next question is whether the research involves human subjects. To determine whether images of people and license plates meet this definition, an IRB might ask how the license plate information will be used, whether facial images of individuals in the car will be collected, and whether the license plate information and images will be intentionally collected and analyzed or immediately deleted if incidentally captured. For example, an IRB might determine that a study that collected these types of images but used software to blur faces and license plates was not HSR. A researcher should not make this determination for themselves but should consult with their IRB.

FAQ Topics

What is the difference between identifiable private information and personally identifiable information (PII)? How do these concepts impact HSR determinations?

Identifiable private information is a subcategory of PII. The Common Rule defines identifiable private information as that which can reasonably be considered private (i.e., not observed or recorded) or provided for a specific non-public purpose and for which the identity of the person may readily be ascertained by the investigator. A first name alone would not meet this definition. However, combining a first name with private information about the individual (e.g., behavior, opinions, opinions, and health information) could generate identifiable private information.

IRBs use the regulatory definition of identifiable private information as a component in determining if an activity is HSR. Once an activity is determined to be HSR, the IRB will consider whether adequate provisions exist for protecting privacy and maintaining confidentiality.

In contrast to identifiable private information, the definition of PII does not distinguish between whether the information is public or private. PII is the parent category that includes any information linked or linkable to a specific individual. This includes name, date and place of birth, mother's maiden name, education, financial transactions, criminal or employment history, and any other information that can distinguish or trace an individual's identity.

At a minimum, DOE follows the Health Insurance Portability and Accountability Act (HIPAA) and guidance issued by the National Institute of Standards and Technology (NIST) in determining identifiability. When collecting PII as a part of HSR, DOE requires compliance with DOE Order 206.1A (or current version). Individuals should always consult with the office responsible for data protection and privacy at their institution when establishing data protection procedures.

7.2 DOE Requirements

When do DOE Order 443.1C requirements apply?

The DOE Order applies whenever HSR is conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research.

When more than one DOE site is involved in a study, which IRB reviews the study: the Central DOE IRB or a site IRB?

This determination is typically study-specific. For example, while most HSR involving multiple DOE sites will be reviewed by the Central DOE IRB, DOE HSP program managers may determine it is acceptable for a DOE site IRB to be the IRB of record if that site already has an approved IRB protocol in place and is modifying the protocol to add research at other DOE sites.

How do university researchers conducting DOE-sponsored HSR determine which IRB should review their study?

This determination may be program- or study-specific. DOE frequently executes IRB authorization agreements with outside institutions, such as universities funded by DOE to conduct HSR, in which the university relies on a DOE IRB. This arrangement helps ensure compliance with DOE-specific requirements outlined in DOE Order 443.1C. In other instances, DOE may authorize the outside institution's IRB to conduct the review. In such cases, the IRB must follow DOE Order 443.1C during its review, and university researchers must follow the order throughout their project. Researchers are encouraged to contact both their institution's IRB and Central DOE IRB early to discuss which IRB will be the IRB of record.

Who is responsible for annual reporting to DOE's Human Subjects Research Database required by DOE Order 443.1C?

Researchers conducting DOE-supported research are required to provide summary information annually to DOE's Human Subject Research Database (science.osti.gov/HumanSubjects/Human-Subjects-Database/home). Different approaches can be used to upload and will depend on the preferences of the IRB of record or DOE program office. The specific process should be confirmed at the beginning of the study.

What is the obligation of DOE-funded laboratories and researchers under the Paperwork Reduction Act when it comes to HSR?

The Paperwork Reduction Act (PRA) mandates that all federal government agencies receive approval from the Office of Management and Budget (OMB) in the form of a "control number" before disseminating a paper form, website, survey, or electronic submission that will impose an information collection burden on the general public. DOE's current understanding is that if a federal agency directs an entity to perform a survey or gather information from the public as part of a funding opportunity, then the PRA may be invoked. However, if the funding opportunity does not specify how the information should be gathered from the public, the PRA does not need to be invoked. This is an evolving issue and may change in the future. The OMB issued helpful guidelines for how the PRA pertains to scientific research in a memo titled, "Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process" (U.S. OMB 2010).

7.3 Designing Research Protocols

How does the increased use of blended datasets affect the risk of participant re-identification?

Combining de-identified datasets from different sources to create a single rich dataset for analysis increases the risk of re-identification even when it is not the researcher's intention. Artificial intelligence methods increase this risk. Researchers must thoroughly consider how they will use and protect these datasets in their research. Some best practices to protect participants include:

- Minimize the amount of information shared in reports or otherwise made public.
- Consider the format of publicly released study information. For example, if zip codes need to be shared, consider using only three digits instead of all five.
- Eliminate demographic information from public datasets for categories containing only a few participants.
- Securely store all data that may contain PII.
- Create data assurance agreements between researchers and IRBs to further elaborate how study data will be used and protected during the research and what will be done with it after the study is complete. Such agreements may be needed even in the context of "Not HSR" determinations since the determination itself will depend on the way the data are used.
- Ensure that the only fields of data combined from the different datasets are those truly needed for the research, as opposed to combining entire datasets containing extraneous information.

When should differential privacy measures be applied?

When research data are sensitive, and confidentiality is critical, differential privacy measures can help protect participants. The differential privacy approach protects participant privacy by sharing observed group patterns but withholding individual information. This is achieved by adding small amounts of noise to the data to obscure an individual's identity without impacting the availability and quality of the aggregate information.

Do IRBs require a project to be peer-reviewed for scientific and technical merit before and during the study to refine research questions and data collection methods?

One criterion for earning IRB approval is to minimize risks to subjects using procedures consistent with sound research design [45 CFR 46.111(a)(1)(i)]. Some IRBs may require studies to be evaluated for scientific merit as part of the submission process, especially for research that has not undergone peer review (see Appendix C: Checklists for IRB Reviewers; Scientific or Scholarly Review, p. 99). A poorly designed study could subject participants to high risk for low benefit or harm them by drawing conclusions that misrepresent the population. It is therefore appropriate for IRBs to raise concerns and even refuse to approve studies lacking clear merit, and researchers are encouraged to be open to such input. IRBs can play a role in improving study design by counseling researchers on human subjects aspects of the methodology and best practices for capturing a representative sample.

How can researchers ensure that survey responses collected from the study sample are representative of the population being studied?

It is important to clearly identify the population of interest. For example, Census Bureau data or community-based organizations in the region can help provide insight about different populations or identify those that are difficult to reach and therefore underrepresented in the data. Such information can inform sampling design in terms of approach (e.g., stratified versus random sampling), means of contacting individuals (e.g., phone, email, mail, in person), and phrasing of questions (e.g., ensure the language meets the reading level of the target population, keeping in mind that eighth-grade reading level is appropriate for the average American participant). Using the Census Bureau surveys as a guide for phrasing demographic questions can help ensure comparability between study responses and the population as a whole. Initial responses from the survey should be reviewed to find responses that may indicate the population, sample, or questions should be refined.

Would it be appropriate to apply community-based participatory research (CBPR) to DOE research involving disadvantaged communities? Are there any successful examples?

CBPR, in which the community becomes equal partners in all phases of the research process, is occurring more frequently. This approach can be ideal in promoting justice by engaging the group that will benefit most directly. However, complexities can exist, particularly when a project includes multiple diverse communities across a wide region or the entire country. DOE's Urban Integrated Field Laboratories, for example, use the CBPR model to help inform equitable climate and energy solutions that can strengthen community-scale resilience across urban landscapes.

Should participants retain the freedom to override the study intervention when needed in Modification of the Human Environment (MHE) studies?

Some MHE studies shift energy loads in the home by modifying temperature setpoints or water heater's hours of operation, for example. While researchers may be tempted to collect information on the ideal performance of their technology by ensuring the settings are not changed during testing periods, the research conditions of restricting that control would not align with real-world adoption. As such, the results may not be as meaningful for the next stage of development. Researchers looking to eliminate a participants' ability to control their environment should provide sufficient justification for why that is necessary to meet the study's needs. Additional risk mitigation may also be needed, such as excluding homes where individuals living in the home have medical conditions that make them sensitive to temperature fluctuations.

7.4 Participant Recruitment and Compensation

How can incentives or payment be used to increase participation and extend participation to the full length of the study?

Incentives, such as gift cards, can be distributed over the course of the project and can be linked to survey completion and other milestones. Incentives provide a mechanism for researchers to thank participants for their participation in a study and compensate them for their time, effort, and any study-related expenses. Researchers should consider giving additional gift cards when problems arise, such as when an equipment service call is needed, to acknowledge the inconvenience. Avoid classist pay scales that pay "professional" participants more than those in "nonprofessional" positions.

What incentive dollar amount is appropriate?

A typical range for surveys and interviews is $25 to $50, depending on length. For long studies, spreading incentive payments across milestones (e.g., initial equipment installation or the end of baseline monitoring) is recommended. Milestone payments are typically $100 or more, with larger incentives provided for completion of the project. Such incentive payments are separate from any installed equipment that participants get to keep. Reimbursements for participants' time should be based on average hourly wages in the study area.

What are some obstacles to compensating participants for their time, and how can these be overcome?

Cash or physical gift cards are easily used by most participants, but an institution's process for issuing

them can be complex. They may need to be delivered in person by someone with IRB training and tracked through a chain of custody. Researchers should work with their research institution's financial office to find an allowable compensation method that suits all participants.

Compensating participants can be difficult at some institutions. Should it be avoided?

From the DOE perspective, compensation is appropriate and allowable in most cases but not mandated. Compensation helps to ensure fair process and a diverse participant pool. Institutions are encouraged to consider ways to streamline the approval process including utilizing a collaborating institution that may already have such a process in place.

What are some tips for increasing participation in modification of human environment studies?

- Offer incentives and compensation but think beyond gift cards to identify incentives that participants will really appreciate, such as a piece of equipment that offers new functionality to the living space or solves a problem.
- Provide regular opportunities for participants to receive compensation (e.g., reaching milestones) to keep them engaged with the project.
- Offer incentives to community members such as entry-level, resume-building opportunities (e.g., conducting door-to-door surveys, participating in an internship, or co-authoring a poster). A small, simple scoping study could help identify meaningful incentives specific to the study population.
- Leverage contacts that have existing relationships with the target population to help build rapport and encourage participation.
- Explain to participants the potential impact of the study, such as their important contribution to research by testing equipment that may improve comfort, convenience, and energy efficiency. Often, this societal benefit is meaningful enough to promote participation.
- Inform participants early of the potential impacts to their daily lives, such as people entering the home, challenges associated with equipment installation and operation, and time required to participate in surveys or interviews. This shows respect and reduces participant withdrawal from the study.
- Disseminate recruitment information through multiple channels (e.g., social media, in-person events, mail, newspaper ads, and physical community bulletin boards).
- Ask people who decline to participate in a study what factored into their decision. This information can help future recruitment efforts by identifying potential barriers to participation.

Is it ethical and allowable to recruit staff as study participants?

Recruiting staff and students can be allowed if certain protections are instituted to alleviate concerns of coercion and undue influence. Individuals should participate because they want to, not out of fear of reprisal. However, even with these protections, staff and students may inadequately represent the target population and may introduce biases due to prior knowledge of the research. Within DOE, IRBs generally will not approve a study where an employee is recruited or consented by a member of the research team who is also their direct supervisor. The IRB would typically encourage recruiting more broadly from separate groups within the organization. The Central DOE IRB provides a checklist of considerations regarding potential employee recruitment. These considerations include ensuring the potential participant was not chosen simply due to their ease of access, minimizing any potential coercion, and ensuring that the study could not be practically conducted with a different population (see Appendix C: Checklist for IRB Reviewers; Protecting Employees who Participate as Research Subjects, p. 97).

Can researchers participate as their own research subjects?

IRBs strongly discourage this practice due to the conflict of interest and the potential for researchers to self-impose greater risks. From a publishing and proof-of-concept perspective, such participation often produces datapoints perceived to be nonviable. Extremely rare examples exist, however, in which IRBs have approved testing of a new technology on a researcher. Researchers approaching an IRB with such proposals

must be able to justify why they believe the approach is necessary and how they plan to minimize risk. If the justification is legitimate, the IRB can potentially help work toward approval.

7.5 Diversity, Equity, Inclusion, and Accessibility

What benefits can a diverse IRB bring to research?

Diversity among IRB members produces three primary benefits: (1) diverse perspectives, (2) cultural competence, and (3) increased public trust. Diverse perspectives help reduce the likelihood of bias by ensuring that reviews reflect varying educational backgrounds, cultural perspectives, and life and professional experiences. Diversity can promote critical discussions about both obvious and lesser-known ethical implications of proposed methods. Cultural competence requires taking a step back and accepting personal limitations in understanding what it is like to live in another person's situation. An IRB with appropriate diversity and expertise therefore plays a critical role in capturing the real impact of research on participants. Increased public trust is an important area that is sometimes overlooked. The credibility and ultimate acceptance of research results depends upon earning public trust in the process, as well as in the data. Absent that level of trust, human subjects may be exposed to risk only to produce data that the public never accepts. This wastes resources and presents an unacceptable risk to participants. A diverse and vocal IRB can contribute all three of these primary benefits during the review process, resulting in immeasurable improvements to a research project.

What are some key considerations for working with potentially disadvantaged populations?

- Care should be taken to assess whether study compensation exerts undue influence on participants. Nonetheless, IRBs should keep in mind that low-income populations are not less deserving of receiving proper compensation for their time. In fact, payments may need to be increased if the population loses income while taking time to participate in study activities. See also the section on Participant Recruitment and Compensation, p. 68.
- A basic consideration is providing reimbursements to participants for expenses related to participating in the research (e.g., hiring childcare while participating in an interview).
- Scheduling study activities outside business hours for participants working full time can make the process more accessible.
- Researchers sometimes overlook the time burden, inconvenience, and intrusiveness of a research protocol, so it is important to check in regularly with participants to gauge their experience.
- When working with low-income populations, it is important to consider the lifetime of the new equipment being installed and tested and the likelihood of repair costs arising. Ask whether the equipment is new to the market and whether it has been reliably lab tested. If the equipment fails after the study period, the participant may be saddled with a maintenance or replacement bill they cannot afford. Studies likely to create an undue burden on participants in this regard should consider testing different equipment or budgeting for maintenance or replacement costs.
- Researchers should consider whether a technology or load-shifting protocol might in fact increase a participant's utility bill and either prepare to reimburse for the extra costs or alter the study protocol.
- To ensure equitable subject selection, researchers should consider whether the study design can include adaptations if insufficient infrastructure is encountered. For example, in large appliance retrofit studies, homes must have a certain level of electrical capacity, and lower-income housing may be less likely to have the necessary infrastructure to meet this requirement. Intentional study design adaptations will ensure that lower-income households are included in study populations.

7.6 Communication Among Participants, Researchers, and IRBs

Some researchers perceive HSR review as burdensome, with IRBs slowing down the research process. How can all parties ensure that the review process is efficient?

DOE program offices should clearly state in their funding announcements that research proposals

may include HSR as part of the study design and then outline any additional regulations that apply to HSR. By understanding these requirements ahead of time, researchers can avoid many barriers to approval by adjusting study design, timeline, and budget. Researchers should inform IRBs early in the funding proposal submission process of their intention to include HSR so that the IRBs and researchers can discuss what should be included in the submission and the process for timely review and approval. IRB review does not need to interfere with researchers receiving funding. Pre-HSR study tasks are typically conducted during the IRB submission and approval process. Groups and institutions that frequently conduct HSR can significantly smooth the review process for less experienced groups by sharing their knowledge and templates.

What are some tips for ensuring that a participant understands what they are consenting to?

- Use "teach-back" techniques to ensure understanding during the informed consent discussion (e.g., mrctcenter.org/health-literacy/tools/overview/interactive-techniques). Rather than asking only yes or no questions, this technique asks the potential participant to explain things back to the researcher so that it is clear they comprehend what is going to happen if they participate.
- Strike a balance between a consent form that is comprehensive and one that provides a brief overview. Information that is key for consideration can be presented at the beginning to ensure complete understanding.
- When reading through the consent form with the participant, pause after particularly important items to ask, "Does that make sense? Do you understand what that's about?"
- Cultural, educational, and language differences between participant and researcher can complicate communication, so focus on using simple language.
- Try to engage participants' attention by maintaining energy and enthusiasm or explaining the consent form in an interesting way. It is important to remember that the discussion is not simply reading the consent form to them but summarizing the key information in a way that is easily understood.
- Consider asking a project partner who is close to the community (e.g., property manager or community organization representative) to review draft recruitment materials, survey questions, and other communication materials. Also consider asking members of the project team who are less familiar with the project's technology and scientific methodology to review the materials for clarity.

How can researchers help community members describe their desires for the future state of their community, which the research project can then explore?

Working closely with communities helps researchers understand the population that their research intends to benefit and represent. One approach is to break the IRB protocol into steps or phases, with the first step potentially involving focus groups to gather initial input from community members. Community member input can then help refine study design to ensure the project addresses relevant problems. Projects that expand to include community members in the HSR itself are considered Community-Based Participatory Research (CBPR) projects. CBPRs are becoming increasingly common, and some consider them as providing the most equitable approach to enabling community decision-making power within a research context.

How do you ensure consistency in approach with IRB review across multiple studies funded under a program?

As it pertains to the IRB process, it is helpful to lay out expectations and rules of engagement up front. This may include the sponsor of the entire program dictating expectations for review, such as under the Central DOE IRB. When studies under an umbrella program are independently funded at different institutions, institutional policies may lead to differential IRB approaches. Research teams that are not subject to higher-level IRB review may not respect the principles or constraints imposed by the IRB process at other locations. For this reason, it is strongly recommended that all research teams be subject to the same IRB

review and human subjects protection requirements. Sponsors can also ensure clear communication among the study teams through a coordinator to harmonize the overall study approach.

Has there ever been a study where the researchers didn't tell the participants about the study intervention beforehand to ensure that knowledge didn't influence their response?

These types of studies, known as deception studies, are uncommon in modification of the human environment research because the participants need to be informed in order to agree to participate in something that changes their home. If a deception study is reviewed as Exempt Category 3 research, participants are required to provide prospective agreement to the deception so they know that they may be unaware or misled about the nature or purpose of the research. This prospective agreement to being deceived is not required if the research is reviewed and approved using an expedited or full-board procedure. Most IRBs require that participants be debriefed as to the true purpose of the research after participation is complete. As with many questions about what may be allowable, IRBs must weigh whether the deception is justified and worth the potential risks that are being introduced.

7.7 Risks to Participants

What risks arise from using a homeowner's Wi-Fi?

Homeowners risk exposure of their private and confidential information to researchers when their home network is used to transmit study data. If cell phone service is poor and does not support a cellular hotspot for internet access, the risks associated with using the homeowner's Wi-Fi must be stated in an informed consent. Protections guarding the Wi-Fi information should also be installed, such as adding a separate network to the router or creating a more secure password that can be changed at the study's end.

To address potential risks of reduced Wi-Fi performance and interrupted internet access, the consent form should clearly state the expected bandwidth impact. Researchers can also consider reimbursing participants for the commensurate cost of the portion of bandwidth required to transmit study data.

Is product liability covered in the consent, such as if a new technology fails and damages the home?

If a contractor is hired to install a new appliance, any problems are typically covered under the contractor's license and insurance. In the case of prototype appliances, researchers may opt for replacing it with a commercial model after study completion to avoid future problems. If removal is not practical, participants are asked to accept responsibility for product maintenance following the study as part of the consent form.

Can participants install equipment monitoring devices themselves?

While it is possible for the participant to install monitoring equipment, this should be limited to only electrically finger-safe, plug-and-play monitoring equipment specifically designed to be installed by a non-trained homeowner. Generally, it is best for either a trained researcher or a qualified professional to perform installations.

What happens if a participant is injured during installation or operation of monitoring equipment?

Liability can be a difficult area, so discuss this with the institution's legal team. Frequently, the determination comes down to whether there was clear negligence on the part of the research or installation team. Being very clear in the consent form regarding which risks the participant is accepting is an important way to mitigate potential issues during conduct of the study.

Does the homeowner face liability for injuries to the researcher, such as a fall or an animal attack?

Any injuries to the researcher are typically treated as a workplace safety issue and are addressed by the institution's environment, health, and safety department, which should train the researcher on how to deal with potential hazards in the home. If the home environment

is unsafe structurally or behaviorally, the home can be removed from the study. It is helpful to include this eventuality in the informed consent. It is impossible to map out every potential liability concern, but a good rule of thumb is to be very clear with participants about disclosing potential risks and work together to make the research/home environment safe for everyone involved.

7.8 Subcontractor Review and Agreements

Is a Data Use Agreement (DUA) or Data Transfer Agreement (DTA) the most appropriate way for a primary DOE contractor to share study data with subcontracted project partners? Is there a better protocol for providing such subcontractors access to study data that the primary contractor is not expressly authorized by DOE to manage?

In general, the primary contractor should always review its specific requirements for authorization to operate and pass those requirements along to any sub-contractors completing portions of the research. More specifically, IRBs often allow subcontractors to analyze data only when the data have been sufficiently de-identified and the subcontractor is not engaged in the primary contractor's HSR. IRBs will want to review any DUAs or DTAs regarding human subjects data to determine whether the subcontractor is engaged in the HSR.

Modification of the human environment studies frequently involve collaboration with private industries. When are they considered engaged in the research?

In its guidance on institutional engagement in HSR, the Office for Human Research Protections states, "In general, an institution is considered engaged in a particular… human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them, (2) identifiable private information about the subjects of the research, or (3) the informed consent of human subjects for the research." DOE also has a worksheet to assist with engagement determinations (see Appendix C: Checklists for IRB Reviewers: Engagement Determination, p. 87). It is important to remember that the entity that receives direct federal funding is also considered engaged, even if the funds are subcontracted to another site to conduct the HSR.

Chapter 7 References

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Chapter 8

The Future of HSR in Energy Research

The "Human Subjects in Energy Technology and Policy Research Symposium" set out to increase awareness about what constitutes human subjects research (HSR) in the energy technology and policy field and how to apply DOE-specific regulations consistently across agency-supported projects. This report has provided summaries of symposium sessions and key takeaways focused on promoting best practices from the proposal stage through study completion and fostering a culture of collaboration to break down barriers and advance best practices specific to HSR in energy research. Ultimately, this report is a resource that those supporting, reviewing, and conducting research can refer to when developing and deploying HSR in energy technology and policy. This final chapter outlines central themes that emerged from the symposium and discusses future directions to consider in the conduct and review of energy HSR.

8.1 Central Symposium Themes

Collaboration and Communication Among Stakeholders

Establishing Early Partnerships. HSR in energy technology and policy is a rapidly evolving research area that can be new for both researchers and institutional review board (IRB) professionals, but by working closely together, both groups can expect to navigate this new research frontier more efficiently and effectively. Collaboration is key; researchers bring subject matter expertise in energy sciences while IRB professionals bring vast experience with HSR applied in other scientific disciplines. When researchers and IRB professionals work together to share their technical and regulatory expertise, the result is effective, well-designed research that advances science while protecting study participants.

Involving Research Communities. Researchers and sponsors should engage early with their target research communities. Collaboration can foster ethical and equitable engagement with research communities by understanding the issues they face, developing research that incorporates their concerns and needs, and encouraging active participation from community members throughout all phases of the research process.

Communicating Regularly. Navigating this new research area can be intimidating, but communication among communities, researchers, sponsors, and the IRB can help create a strong foundation for a collaborative IRB experience. The submission process is iterative and requires clear and consistent communication between stakeholders to be successful.

Ethical Considerations for Research Participants

Sharing Responsibilities to Protect Research Participants. Protecting the valued participants in this research is of utmost importance and requires a shared framework of responsibilities (for more information about specific responsibilities, see Fig. 2.4 Sharing Responsibilities, p. 14). Researchers, sponsors, IRBs, and the DOE Human Subjects Protection Program can work together to ensure that study participants are protected at every stage of the research process. Partnering with IRBs helps sponsors and researchers ensure that potential risks to human subjects have been minimized; participation in the study is voluntary; and potential participants receive clear and accurate information about the study, including participation benefits and risks, purpose and use of collected data, and safeguards for data protection.

Engaging Marginalized Communities for Ethical, Equitable Research. As DOE strives to make energy more accessible, affordable, clean, and democratically managed for all communities, it must prioritize the concerns of marginalized communities.

Compensating Research Participants. Research participants should receive meaningful compensation and

incentives for their participation in a study. Financial considerations should be generous enough to account for participants' effort and inconvenience, as well as compensate for expenses and time. Research participation can be a burden, and the costs are not always readily visible. Compensation can be provided for a range of reasons including (1) participant expenses such as the need to hire childcare while they participate in an interview for the study, (2) the inconvenience of allowing people into their home, or (3) costs associated with alternative equipment or housing options if the experimental technology does not perform adequately. These costs and discomforts should be considered when choosing compensation rates, as should participants' preferred form of incentives. Incentives help attract participants and keep them engaged. Asking participants about their preferences ensures that incentives are meaningful to them.

8.2 Future Directions

In the coming months, the DOE Human Subjects Protection Program will continue its efforts to:

- Create and foster partnerships with organizations within and outside DOE that sponsor HSR in this space.
- Develop and make available user-friendly resources for program offices, contracting officials, IRBs and researchers, through the DOE Human Subjects Protection Program website.
- Coordinate and sponsor additional symposia and targeted training to continue to promote awareness of DOE/NNSA's diverse HSR portfolio, as well as best practices for researchers, IRBs, and sponsors.

Collective work by sponsors, researchers, and IRBs will support consistency in the IRB submission and review process. This will promote the ethical and just conduct of critical energy technology and policy research and better ensure impactful and equitable climate and energy research solutions that are so needed at this time.

Appendix A
Symposium Agenda

All times Eastern

Day 1: Tuesday, October 17

11:45 a.m. **Overview and Logistics, plus Opening Address by U.S. Department of Energy Leadership**

Speaker: Kelsey Sharkey Miller, Lawrence Berkeley National Laboratory

12:00 p.m. **Opening Address by U.S. Department of Energy**

Speaker: Gary Geernaert, U.S. Department of Energy

12:15 p.m. ***Plenary Session:*** **Human Subjects and Energy Research: Applying the Regulations to this Field**

45-minute presentation, 15 minutes Q&A

Moderator: Kelsey Sharkey Miller

Speakers: Marianna Azar, U.S. Department of Health and Human Services; Elizabeth White, U.S. Department of Energy; Cheri Hautala-Bateman, National Nuclear Security Administration

Session Description: This plenary session will walk attendees through the Common Rule regulatory requirements and explain basic terms, including research and human subject. It will then apply the regulatory requirements to energy technology and policy research and explain when to apply the DOE Order 443.1C requirements, when and which IRB to go to for a project, and how the IRB can help prevent complications during the research journey.

1:15 p.m. **Break**

1:30 p.m. **Workshop Sessions**

Split tracks with one-hour sessions consisting of interactive presentations

IRB Professionals Track: **Reviewing Modification of the Human Environment Studies**

Moderator: Steve Rupkey, Argonne National Laboratory

Speakers: Susan Varnum and Jesse Willett, Pacific Northwest National Laboratory; Lindsay Motz, Oak Ridge Associated Universities; Brett Singer, Lawrence Berkeley National Laboratory

Session Description: Technology demonstrations and monitoring of the human environment can bring a lot of confusion into the standard practices of a biomedical or social-behavioral IRB. This session will focus on how to make HSR determinations, how to categorize the work, and key elements of the review process that may be different from other types of studies.

Researcher Track: **IRB Protocol Building Blocks**

Moderator: Elizabeth Stelle, Los Alamos National Laboratory

Speakers: Cecilia Brooke Cholka, Weill Cornell Medicine; Bill Eckman, Oak Ridge National Laboratory; Tracy Fuentes, Pacific Northwest National Laboratory; Margaret Taylor, Lawrence Berkeley National Laboratory

Session Description: New to IRB submissions? Confused by the questions in the protocol? This session will focus on helping researchers understand what the IRB is looking for in a protocol, including real examples of protocol language, tips for explaining data privacy practices and risk/benefit evaluations, and time to answer questions.

2:30 p.m. **Break**

2:40 p.m. **Panel Discussion**

Moderator: Kelsey Sharkey Miller

Speakers: Elizabeth White, U.S. Department of Energy; Cheri Hautala-Bateman, National Nuclear Security Administration; Gary Geernaert, U.S. Department of Energy

Session Description: Join our experts for an 80-minute Q&A session all about HSR in these fields. Have a burning question? Get ready for an answer at this session, which will include subject matter experts on U.S. DOE regulations, IRB processes, and sponsor perspectives.

Day 2: Thursday, October 19

12:00 p.m. **Overview and Logistics**

Speaker: Kelsey Sharkey Miller

12:15 p.m. ***Plenary Session:*** **Better Research Through Collaboration: A Partnership Among Sponsors, IRBs, and Researchers**

45-minute presentation, 15 minutes Q&A

Moderator: Kelsey Sharkey Miller

Speakers: Anjuli Jain Figueroa, U.S. Department of Energy; Cheryn Metzger, Pacific Northwest National Laboratory; Elizabeth Ellis, U.S. Department of Energy

Session Description: Climate change is bringing the importance of this work to an all-time high. We have a responsibility to build the future energy infrastructure equitably and focus our efforts on creating a just system that works for all of our communities. Now is the opportunity to make a difference by applying ethical frameworks to all of our research, building public trust in our technologies, and including the diverse communities that are directly impacted by our results. Partnership between IRBs, sponsors, and researchers is needed to meet the urgency for mass adoption of these technologies, policies, and system improvements.

1:30 p.m. **Workshop Sessions**

Split tracks with one-hour sessions consisting of interactive presentations

IRB Professionals Track: **Creating a Culture of Collaboration**

Moderator: Elizabeth Stelle, Los Alamos National Laboratory

Speakers: Cecilia Brooke Cholka, Weill Cornell Medicine; Patricia Gunderson, Pacific Northwest National Laboratory; Cindy Mazur, Los Alamos National Laboratory; James E. Morris, U.S. Department of Energy

Session Description: Compliance is often a bad word among researchers; it equates to red tape and delays, leading to avoidance and frustration for both researcher and IRB professionals. This session will focus on the opportunities IRBs have to create a collaborative environment that enhances the research process. Proactive partnership with researchers can lead to better study design, optimal research results, and productive working relationships.

Researcher Track: **Social Science Best Practices for HSR**

Moderator: Jeffrey C. Joe, Idaho National Laboratory

Speakers: Stephanie L. Kane, Washington State University; Ben Hoen, Lawrence Berkeley National Laboratory; Benjamin Sims, Los Alamos National Laboratory

Session Description: At this stage in development, we need our brightest engineers and scientists to guide technology adoption, but for many, social science was not a part of their training. This lack of experience can make engaging with participants difficult. This session will highlight some of the most important best practices for collecting meaningful data from real-world settings. Subject matter experts will guide this

interactive session to share the importance of structuring qualitative data collection for robust results that are representative of your target research population.

2:30 p.m. **Break**

2:40 p.m. ***Specialty Session:*** **Human Subjects Research Showcase**

Moderator: Kelsey Sharkey Miller

Session Description: Engaging with human participants has proven to be a vital aspect of guiding adoption of new technologies and policies. This session will include a series of presentations about recent or ongoing research in this field from the perspective of program managers, in collaboration with their researchers. Sponsors will share the importance of this work in meeting organizational goals, as well as highlighting the HSR their office is supporting. These sessions are an opportunity to build on lessons learned for better research and fewer delays as we partner to create the future of our energy infrastructure.

Appendix B

Symposium Speaker Biographies

Moderators

Jeffrey C. Joe

Idaho National Laboratory

Jeffrey C. Joe has been chair of the Idaho National Laboratory (INL) IRB since December 2015 and a member of the INL IRB since 2004. He is also a distinguished research scientist in INL's Human Factors and Reliability Department. His research skills and expertise are in the areas of human factors research and development, human factors engineering, human performance improvement, human reliability analysis, safety culture, organizational development, public energy policy, and social and industrial/organizational psychology. He holds a master's degree in social psychology from the University of Utah and a bachelor's degree in psychology from the University of Colorado–Boulder.

Kelsey Sharkey Miller

Lawrence Berkeley National Laboratory

Kelsey Sharkey Miller has worked at Lawrence Berkeley National Laboratory (LBNL) since 2021, leading the Human and Animal Regulatory Committees office, which includes the Institutional Animal Care and Use Committee (IACUC), IRB, and Radioactive Drug Research committees. Miller works to apply the values of facilitating ethical research, supporting researchers in a collaborative approach to compliance, and promoting career growth opportunities across internal and external stakeholders. Her experiences in research bring perspective to the ethical questions of the compliance field. She leads a monthly virtual gathering of IRB professionals working in small human research protection programs across North America, participates in the Bay Area IACUC administrators group, and leads the Early Career Employee Resource Group at LBNL. Miller's previous compliance experience includes serving as IACUC administrator for a small research institute at the University of California–San Francisco Benioff Children's Hospital in Oakland, Calif. She graduated from the University of South Carolina with a bachelor's in exercise science and the University of California–Berkeley School of Public Health with a Master of Public Health focused on infectious disease and vaccinology.

Lindsay Motz

Oak Ridge Associated Universities

Lindsay Motz is the IRB administrator for the Central DOE IRB and the Oak Ridge site-wide IRB. During her time at Oak Ridge Associated Universities, Motz has worked on the Beryllium-Associated Worker Registry and the Human Subjects Research Database (HSRD). She began working with IRBs during her time as manager for the HSRD. Motz is responsible for daily operations of both boards, assists with the annual HSRD report,

and serves as a backup administrator to the other Central DOE IRB. She earned a bachelor's degree in public health from East Tennessee State University and a graduate certificate in bioethics from Washington State University. In 2014, Motz became a certified IRB professional.

Steve Rupkey

Argonne National Laboratory

Steve Rupkey is the Biosafety and Human Subjects Research Protection Programs manager at Argonne National Laboratory (ANL). While at ANL, he has served as worker safety and health programs manager and safety lead for the Joint Center for Energy Storage Research. Rupkey is a board-certified industrial hygienist with a background in occupational health and safety. His expertise extends to conducting comprehensive exposure assessments, designing programs, delivering training, and executing audits. He has also leveraged his acumen in safety and industrial hygiene within the realms of consulting and private industry, mitigating occupational injuries and illnesses by recognizing, evaluating, and controlling associated risks. Rupkey has a bachelor's degree in environmental health from Indiana University–Bloomington.

Elizabeth Stelle

Los Alamos National Laboratory

Elizabeth Stelle is the Los Alamos National Laboratory (LANL) Human Subjects Protection Program manager and a member of the LANL IRB. She works to develop clear policies and guidance that form an ethical foundation for researchers to conduct human subjects research. Prior to this role, Stelle worked in industry, supporting named entity coverage for text-to-speech and automatic speech recognition engines. She has also worked as a science communicator and outreach coordinator for a DOE nanoscience user facility. Stelle has a PhD in linguistics from the University of British Columbia, where her research focused on behavioral evidence for the multimodal nature of speech production and perception.

Speakers

Marianna Azar

U.S. Department of Health and Human Services

Marianna Azar is a program specialist with the Division of Education and Development at the Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services. Before joining OHRP, Azar served as director and chair of the IRBs for the New York City Department of Education. Prior to that, she was employed as a Human Research Protection Program manager at the City University of New York Graduate Center and an IRB specialist at Columbia University's Human Research Protection Office. Azar holds a bachelor's degree in philosophy from the State University of New York–Oswego, a Master of Arts in philosophy, and a graduate diploma in health services and policy research from York University. She is working on completing her PhD in bioethics at York University.

Josh Butzbaugh

Pacific Northwest National Laboratory

Josh Butzbaugh performs technology assessment with Pacific Northwest National Laboratory (PNNL), including acting as the principal investigator for multiple field studies involving human subjects research. Before joining PNNL, Butzbaugh worked on behalf of the California Energy Commission, where he provided strategic planning and technical expertise in support of appliance standards. Butzbaugh also spent six years working on behalf of the Energy Star program, where he led the development of the first Energy Star Residential Water Heater Program. He has a Master of Business Administration from the University of Colorado and a bachelor's degree in environmental policy and behavior from the University of Michigan.

Cecilia Brooke Cholka

Weill Cornell Medicine

Cecilia Brooke Cholka serves as a human research and quality assurance manager at Weill Cornell Medicine and is a consultant for the PEER (Performance, Excellence, and Efficiency in Research) Consulting Group. Cholka is a certified IRB professional and has 10 years of experience in research administration in both human and animal research, including as the head of the training and education components of a human research protections program. In this role, she helped the program achieve and maintain accreditation and a programmatic redesign. She is co-founder and co-facilitator of the Social, Behavioral, and Educational Research Network. Cholka has a PhD in health communication and nearly 20 years of research experience. Her research interests include human sexuality, health disparities, and health risk behaviors, particularly in Latinx communities. Research projects include early education experiences and their impact on health in later life with older American Indians using community-based participatory research methodologies and representations of mental health in communication research.

Bill Eckman

Oak Ridge National Laboratory

Bill Eckman leads the Weatherization Assistance Program efforts at Oak Ridge National Laboratory. This role continues his two decades of work in residential construction, including 14 years focused on weatherization and energy efficiency programs. Throughout his career, Eckman has worked on projects including zero-net energy new construction, in-field retrofit of historic homes to measurement, and verification of technically demanding retrofits. He currently leads a multistate field-based study involving modifications to the human environment. Eckman holds a bachelor's degree in economics from Hillsdale College.

Elizabeth Ellis

U.S. Department of Energy IRB

Elizabeth Ellis first became involved with protection of human subjects during her research as an occupational epidemiologist. She spent 43 years at the Oak Ridge Institute for Science and Education as a senior scientist studying the effects of occupational radiation on the DOE nuclear workforce. Since 1994, Ellis has served on local and Central DOE IRBs as a member, vice chair, and chair. She holds a bachelor's degree in zoology from Duke University, a Master of Science in epidemiology from Johns Hopkins Bloomberg School of Public Health, and a PhD in epidemiology from the University of North Carolina–Chapel Hill.

Anjuli Jain Figueroa

U.S. Department of Energy

Anjuli Jain Figueroa is chief of the Office of Energy Justice Analysis Division within the Office of Energy Justice Policy and Analysis. She works on the implementation of the Justice40 Initiative across DOE, which sets a goal that at least 40% of the benefits of federal investments flow to disadvantaged communities. Prior to her role at DOE, Jain Figueroa was associate director at GreenInfo Network, a nonprofit dedicated to geospatial data analysis. She earned her Bachelor of Science in civil and environmental engineering from the University of Michigan, a Master of Science in technology and policy, and a PhD in civil and environmental engineering from Massachusetts Institute of Technology. She has worked in the public, private, and nonprofit sectors and is particularly interested in how people find balance between built and natural environments.

Tracy Fuentes

Pacific Northwest National Laboratory

Tracy Fuentes is a terrestrial ecologist in the Risk and Environmental Assessment Group at Pacific Northwest National Laboratory (PNNL). Since joining PNNL in 2021, she has used quantitative and qualitative methods to explore decision-making regarding energy, environment, and infrastructure. Fuentes has broad technical expertise in environmental and regulatory analyses, infrastructure and land use planning, urban ecology, natural resource management, sample design, and household decision-making. She has a PhD in urban design and planning from the University of Washington, a Master of Science in plant biology from Arizona State University, and a Bachelor of Science in botany from the University of Washington.

Gary Geernaert

U.S. Department of Energy

Gary Geernaert is director of the Earth and Environmental Systems Sciences Division within DOE's Biological and Environmental Research program. In this capacity, he oversees DOE's investments in basic research involving environmental, atmospheric, and climate system sciences, including tools involving advanced data analytics. He also provides oversight of two national laboratory user facilities. He chairs, co-chairs, or represents DOE in several White House interagency coordination committees. Prior to joining DOE, Geernaert was director of the Institute of Geophysics and Planetary Physics at Los Alamos National Laboratory, department director at the Danish Environmental Research Institute, and a program manager at the U.S. Office of Naval Research. Geernaert holds a bachelor's degree from the University of California–Davis and a PhD from the University of Washington–Seattle. Over his career, he has published four books and more than 100 scientific articles.

Patricia Gunderson

Pacific Northwest National Laboratory

Patricia Gunderson joined Pacific Northwest National Laboratory in 2021 and supports several projects on the technology integration team in the building systems group. One of her strengths is collaborating with manufacturers, designers, builders, and trade industry professionals to understand and overcome barriers to adoption of optimized building technologies.

This work often includes field demonstrations involving human subjects. Gunderson most recently spent nearly six years at an independent research testing and certification lab in the Building Science Division, where she proposed, designed, and led research projects to study constructability, functionality, energy efficiency, and durability of buildings. Before that, she served as a mechanical engineer at an international architecture and engineering firm. In this role, Gunderson worked on numerous high-profile projects including embassies, medical centers, university law schools, and the flagship Net Zero Brock Environmental Center for the Chesapeake Bay Foundation. She has a Bachelor of Arts in music, literature, and philosophy and a Bachelor of Science in architectural engineering, both from the University of Wyoming.

Cheri Hautala-Bateman

National Nuclear Security Administration

Cheri Hautala-Bateman is the National Nuclear Security Administration (NNSA) Human Subjects Protection Program manager. She also serves as the program manager for the Strategic Partnership Projects at DOE NNSA. She is responsible for overseeing interagency work and nongovernment-sponsored work across the NNSA complex. Prior to assuming this role, Hautala-Bateman served as a senior test scientist at the U.S. Department of Homeland Security's Domestic Nuclear Detection Office. She has also served as a senior scientist at the Remote Sensing Laboratory at Andrews Air Force Base, where she was responsible for supporting nuclear and radiological emergency response efforts, as well as managing a support program with three remote offices. Hautala-Bateman earned a bachelor's degree in mathematics and physics from the University of Minnesota–Morris and a PhD in nuclear physics from Ohio University.

Ben Hoen

Lawrence Berkeley National Laboratory

Ben Hoen is a research scientist in the Electricity Markets and Policy Department at Lawrence Berkeley National Laboratory. Since joining the lab in 2006, he has conducted research and analysis on renewable energy including policy analysis and assistance; cost, benefit, and market analysis; and public acceptance and market barriers. Hoen leads the Community Impacts and Public Acceptance project area, which conducted past efforts such as the National Survey of Wind Project Neighbors, Community-Centered Solar Development, and multiple qualitative and quantitative studies of impacts and perceptions of renewable energy and communities that surround them. Hoen holds bachelor's degrees in finance and business from the University of Maryland and a master's degree in environmental policy from Bard College.

Stephanie L. Kane

Washington State University

Stephanie L. Kane is the interim executive director of institutional research in the Office of Strategy, Planning, and Analysis at Washington State University. Prior to her current role, she worked as a survey statistician in an academic survey unit at the University of Idaho, collaborating with many interdisciplinary teams to collect and analyze social science data using both quantitative and qualitative data to understand the human impact and public perception of policies and practices. Kane earned Master of Science degrees in biology and statistics from Washington State University. She is currently a doctoral student in the Individual Interdisciplinary Program at Washington State University where she is studying the impact of and remediation techniques for historical or structural bias in data used to train algorithms for educational or social contexts.

Cindy Mazur

Los Alamos National Laboratory

Cindy Mazur is the ombuds for Los Alamos National Laboratory. Prior to her current role, she was director of alternative dispute resolution at the Federal Emergency Management Agency for 20 years. She is a certified mediator and arbitrator and a professionally certified coach. Mazur earned a PhD in conflict resolution from the Institute for Conflict Analysis and Resolution at George Mason University, a Master of Laws in appellate advocacy from Georgetown University, a Master of Divinity from Princeton Theological Seminary, and a Juris Doctor from Syracuse University.

Cheryn Metzger

Pacific Northwest National Laboratory

Cheryn Metzger is the residential program manager and team leader for the Technology Integration Team at Pacific Northwest National Laboratory (PNNL). She has been supporting the Building Technologies Office at DOE since 2009. Metzger advises on a number of field validation, workforce, and market transformation projects and serves on PNNL's IRB. She has a master's in mechanical engineering from the University of Washington, is a professional engineer, and is a project management professional.

James E. Morris

U.S. Department of Energy

James E. Morris serves as the chair of the Central DOE IRB. His areas of training and expertise for research were immunology, immunochemistry, and microbiology. He joined Pacific Northwest National Laboratory (PNNL) in 1973 and continued his pursuit of basic research in the areas of immunotoxicology and applied diagnostics. His research activities ended in 2013 when he retired as a senior research scientist at PNNL. Morris has served as a member or chair of IRBs for more than 20 years including positions at PNNL as well as over 10 years as a member or chair of DOE IRBs. He is committed to seeking the protection of human subjects in research and ensuring that each stakeholder has an equal opportunity to contribute their expertise in this process. Morris earned a PhD from the University of Georgia.

Alan Rither

Pacific Northwest National Laboratory

Alan Rither came to Pacific Northwest National Laboratory (PNNL) in 1973, shortly after graduating from law school at the University of Washington. He started in the Contracts Department, managing two groups. He became a certified professional contracts manager in 1976 and was elected a fellow of the National Contract Management Association in 1997. In 1985, he transferred to PNNL's Office of General Counsel where he provides legal advice on contracting matters, serves as adviser to the laboratory Export Control Office, and provides advice on national security matters. Rither is co-founder and past national chair of the DOE Export Control Coordinators Organization. He is a member of PNNL's IRB for Human Subjects Research and is the past chair of the International Practice Section of the Washington State Bar Association. Additionally, Rither taught a course on government contract law for Columbia Basin College as an adjunct faculty member.

Benjamin Sims

Los Alamos National Laboratory

Benjamin Sims is a sociologist in the Statistical Sciences Group at Los Alamos National Laboratory (LANL). He has extensive experience in human subjects research as both an investigator and a member of the LANL IRB. In his over 23 years at LANL, Sims' work has encompassed risk assessment, knowledge management, infrastructure studies, and sociological studies of the weapons community and scientific computing teams. He is currently part of a multilaboratory team studying teamwork, collaboration, and developer productivity across DOE's Exascale Computing Project. He co-authored the book "Repairing Infrastructures: The Maintenance of Materiality and Power," which was published by MIT Press in 2020. He has a PhD in sociology and science studies from the University of California–San Diego.

Brett C. Singer

Lawrence Berkeley National Laboratory

Brett C. Singer is a senior scientist and department head of Sustainable Energy and Environmental Systems at Lawrence Berkeley National Laboratory (LBNL). He has over 25 years of experience conceiving, conducting, and leading research studies of air pollutant emissions and the physical-chemical processes and controls that impact exposures in varied building types. A focus of Singer's work in recent years has been quantifying the impacts of retrofits that decarbonize the building sector while improving energy performance, resilience, and indoor environmental conditions. His research also addresses low-energy systems for filtration, smart ventilation, and exposure mitigation. Singer earned a Bachelor of Science in mechanical engineering from Temple University and a Master of Science and PhD in civil and environmental engineering from the University of California–Berkeley. He served on LBNL's Human Subjects Committee from 2011 to 2017.

Margaret Taylor

Lawrence Berkeley National Laboratory

Margaret Taylor is a research scientist at Lawrence Berkeley National Laboratory and is affiliated with several units of the University of California–Berkeley, where she was a public policy faculty member for 10 years. Her work spans technology areas including solar power, electric vehicles (EVs), storage, household appliances, and commercial equipment. Recent research topics include: consumer behavior regarding the co-adoption of solar power, EVs, and storage; stakeholder and user issues related to price-responsive load flexibility technologies; equity considerations in the publicly funded EV infrastructure rollout; building operator and occupant preferences related to event-based demand response programs; soft costs reduction for rooftop solar; and workforce issues in the clean energy transition. Other appointments held by Taylor include a Fulbright Canada Research chair at the University of Ottawa and a position at Stanford University's Precourt Energy Efficiency Center. As part of the latter appointment, Taylor co-chaired the Behavior, Energy, and Climate Change Conference for six years. She holds a PhD in engineering and public policy from Carnegie Mellon University.

Susan Varnum

Pacific Northwest National Laboratory

Susan Varnum is the Pacific Northwest National Laboratory (PNNL) Human Research Protection Program manager. She is also a member and previous co-chair of the PNNL IRB. She served as a member on the Central DOE IRB from 2018–21. Prior to her current position, Varnum was a senior research scientist at PNNL working in molecular biosciences. Her research contributed to a variety of fields including the identification of biomarkers of disease, the development of protein microarrays, and the detection of bioweapon toxins. Varnum has a bachelor's degree in bacteriology from Iowa State University and a PhD in biology from Brandeis University.

Elizabeth White

U.S. Department of Energy

Elizabeth White is the DOE Human Subjects Protection Program manager. She is responsible for policy development and oversight of the protection of human subjects in DOE-funded and conducted research. She works closely with her counterpart in DOE's semi-autonomous National Nuclear Security Administration to implement a consistent program across all of DOE. White previously worked for 12 years in the DOE Office of Health and Safety, serving in several positions including director of the Office of Former Worker Screening Programs and program manager for international radiation health effects research. She has been a certified IRB professional since 2011 and earned a Master of Public Health from Johns Hopkins University and a Master of Business Administration from Northwestern University.

Jesse Willett

Pacific Northwest National Laboratory

Jesse Willett began his involvement with the Pacific Northwest National Laboratory IRB for human subjects research in 2003 as a researcher. He was invited to join the IRB in 2010. Willett has served as the board's chair since 2017. In addition to his IRB involvement, he has developed mechanical designs of integrated systems for challenging, real-world environments, such as radiation and dark matter detection, nuclear nonproliferation, and homeland security applications. Willett has demonstrated his project manager capabilities by developing crossdiscipline technical teams to address a variety of problems within the National Security and Energy and Environment directorates. He has a Master of Science in engineering and technology management from Washington State University and a Bachelor of Science in mechanical engineering from Walla Walla University.

Appendix C

Checklists for IRB Reviewers

HRP-311

WORKSHEET-Engagement Determination			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-311	06/19/2024	E. White/C. Hautala-Bateman	1 of 4
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this worksheet is to provide support for Designated Reviewers making engagement determinations when there is uncertainty regarding whether the organization is engaged in Human Research. For the purpose of this worksheet, "Engagement" means that the organization's human research protection program is responsible for the Human Research. For the purposes of being subject to requirements for DOE-supported HSR, engagement applies to exempt and non-exempt Human Research. This worksheet is to be used. It does not need to be completed or retained.

The organization is engaged in the research if the first item in section 1 is true regardless of whether the organization's involvement is limited to one or more of the items in section 2.

The organization is engaged in the research if any item other than the first item in section 1 is true except when the organization's involvement is limited to one or more of the items in section 2

1	**Conditions Under Which an Organization is Engaged**
☐	The organization receives an award through a grant, contract, or cooperative agreement directly from a federal agency for Human Subjects Research, even where all activities involving Human Subjects are carried out by employees or agents[1] of another organization.
☐	The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures or by manipulating the environment.
☐	The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by manipulating the environment.
☐	The organization's employees or agents interact for Research purposes with any Human Subject of the Research.
☐	The organization's employees or agents obtain the informed consent of Human Subjects for the Research.
☐	The organization's employees or agents obtain for Research purposes identifiable private information or identifiable biological specimens from any source for the Research. It is important to note that, in general, the organization's employees or agents obtain identifiable private information or identifiable specimens for Human Research are considered engaged in the

[1] An organization's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

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	Research, even if the organization's employees or agents do not directly interact or intervene with Human Subjects.
2	**Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 1 is Met**
☐	The organization's employees or agents perform commercial or other services for investigators provided that **ALL** of the following conditions also are met:
☐	☐ The services performed do not merit professional recognition or publication privileges.
	☐ The services performed are typically performed by those organizations for non-Research purposes.
	☐ The organization's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
☐	The organization is not selected as a Research site but its employees or agents provide clinical trial-related medical services that are dictated by the protocol that would typically be performed as part of routine clinical monitoring or follow-up of Human Subjects enrolled at a study site by clinical trial investigators provided that **ALL** of the following conditions also are met:
	☐ The organization's employees or agents do not administer the study interventions being tested or evaluated under the protocol.
	☐ The clinical trial-related medical services are typically provided by the organization for clinical purposes.
	☐ The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
	☐ When appropriate, investigators from an organization engaged in the Research retain responsibility for **ALL** of the following:
	☐ Overseeing protocol-related activities.
	☐ Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB(s)-approved protocol.
☐	The organization was not initially selected as a Research site but the organization's employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis where an investigator from an organization engaged in the Research determines that it would be in the Human Subject's best interest to receive the study interventions being tested or evaluated under the protocol and ALL of the following are true:

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	☐	The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
	☐	Investigators from the organization engaged in the Research retain responsibility for ALL of the following:
		☐ Overseeing protocol-related activities. Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
		☐ Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
		☐ Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
	☐	An IRB designated on the engaged organization's federalwide assurance (FWA) is informed that study interventions being tested or evaluated under the protocol have been administered at an organization not selected as a Research site.
☐	The organization is permitting use of its facilities for intervention or interaction with Human Subjects by investigators from another organization.	
☐	The organization's employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research.	
☐	The organization's employees or agents:	
	☐	Obtain coded private information or human biological specimens from another organization involved in the Research that retains a link to individually identifying information.
	☐	Are unable to readily ascertain the identity of the Human Subjects to whom the coded information or specimens pertain.
☐	The organization's employees or agents access or utilize individually identifiable private information only while visiting an organization that is engaged in the Research, provided their Research activities are overseen by the IRB of the organization that is engaged in the Research.	
☐	The organization's employees or agents access or review identifiable private information for purposes of study auditing.	
☐	The organization's employees or agents receive identifiable private information for purposes of satisfying FDA reporting requirements.	

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☐	The organization's employees or agents author a paper, journal article, or presentation describing a Human Research study.

HRP-421

CHECKLIST-Modification of the Human Environment			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-421	5/7/19	E. White/C. Hautala-Bateman	1 of 3
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314-WORKSHEET-Criteria for Approval when research involves modification of the human environment. For the IRB, this checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.

- For initial review using the expedited procedure and modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Designated Review" activity.
- For initial review using the convened IRB and for modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB complete the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB complete this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB uploads this checklist in the "Submit Committee Review" activity.

1 Applicability

Examples of Studies to Which this Checklist Applies:

- Generalizable studies in human environments (e.g., occupied homes and offices, classrooms, and transit centers like subway systems and airports) that use tracer chemicals, particles, and/or other materials, such as perfluorocarbons, to characterize airflow.
- Generalizable studies in occupied homes and/or offices that:
  - manipulate the environment to achieve research aims, e.g., increasing humidity and/or reducing influx of outside air, through new energy-saving ventilation systems.
  - involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy saving behaviors through surveys and focus groups. Some surveys may be online surveys administered through providers such as Amazon Mechanical Turk and Survey Monkey.

HRP-421

CHECKLIST-Modification of the Human Environment			
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See HRP-001 for definitions of applicable key terms and acronyms.			

What is DOE's philosophy regarding such studies?

In all research, potential risks must be evaluated and mitigated to the extent practicable. When:

a) people are included in research or experiments, voluntarily or involuntarily* and/or

b) people have their environment intentionally changed or manipulated for the purposes of the research, with or without their knowledge*, and/or

c) research can only be validly conducted with people present (other than those conducting the research), regardless of whether personally identifiable information is collected about them, the potential risks to those individuals must be considered by the appropriate IRB.

*Typically researchers conduct the research and do not participate in the research, but when they do, the potential risks to the researchers must also be considered by the IRB.

2 Research Involving Modification of the Human Environment
(Check if **"Yes"**. All must be checked or completed.)

☐	Is there is a compelling and credible case for anyone not on the research team to be present during the experiment? *Provide any supporting comments*:
☐	There are no other ways to achieve the research aims. *Provide any supporting comments*:
☐	All the risks and discomforts have been identified and considered. For example: • All chemicals/materials to be used have been evaluated for potential human health and safety effects; • All devices have had appropriate safety testing; • Other potential risks have been identified in the population group(s) to be exposed. *Provide any supporting comments*:
☐	Appropriate mitigations have been taken to minimize the risks, and risks are considered minimal for all involved. *Provide any supporting comments*:
☐	Those involved in the study, but not part of the research staff, will be informed of the research (unless the IRB waive consent). *Provide any supporting comments*:

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CHECKLIST-Modification of the Human Environment			
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☐	Subjects can "opt out" if they wish without any repercussions. *Provide any supporting comments*:
☐	The PI will monitor the research and measure outcomes. *Describe*:
How and from what sources will data be collected? Will characteristics of the subject population be determined and/or required for the research? *Provide any supporting comments*:	

HRP-490

CHECKLIST-Reviewing Protocols that Use PII		
NUMBER	Version Date	PAGE
HRP-490	09/09/2021	1 of 3
See HRP-001 for definitions of applicable key terms and acronyms.		

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314-WORKSHEET-Criteria for Approval when reviewing protocols that use PII or PHI. For the IRB, this checklist must be used for all initial approvals regardless of the type of review. Subsequently it must be used for major modifications and not used for any minor modifications.

Expedited Review

- For initial review, modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Designated Review" activity.

Convened IRB Review

- For initial review, modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB uploads this checklist in the "Submit Committee Review" activity.

Use a separate checklist for each waiver determination for a study.

1	**Protocols that Use PII. The protocol includes provisions for:** (Check if **"Yes"**. All must be checked or completed.)
☐	Keeping PII/ PHI confidential. *Provide any supporting comments* :
☐	Protecting PII/PHI during storage and transmission. *Provide any supporting comments*:
☐	Releasing PII/PHI, where required, only under a procedure approved by the responsible IRB. *Provide any supporting comments*:
☐	Using PII/PHI only for purposes of this study.

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	Provide any supporting comments:
☐	Handling and marking documents containing PII or PHI as containing PII or PHI. *Provide any supporting comments*:
☐	Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI. *Provide any supporting comments*:
☐	Making no further use or disclosure of the PII/PHI except when approved by the responsible IRB, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research study under these same conditions; (c) for disclosure to a person authorized by the IRB for the purpose of an audit related to the study (d) when required by law; or (e) with the consent of the subject/guardian. *Provide any supporting comments*:
☐	Protecting PII/PHI data stored on removable media (CD, DVD, USB Flash Drives, etc.), network drives, and stand-alone computers using encryption products that are FIPS 140-2 certified. *Provide any supporting comments*:
☐	Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the following current DOE password requirements[1]: • Minimum of twelve (12) non-blank characters • Must contain a lowercase letter • Must contain an uppercase letter • Must contain a number or special character • Must contain a nonnumeric in the first and last position • Must not contain the user ID

[1] The following are good practice guidelines to follow:

- Password does not include the user's own or, to the best of his/her knowledge, close friends' or relatives' names, employee serial number, Social Security number, birth date, phone number, or any information about him/her that the user believes could be readily learned or guessed;
- Password does not, to the best of the user's knowledge, include common words that would be in an English dictionary or from another language with which the user has familiarity;
- Password does not, to the best of the user's knowledge, employ commonly used proper names, including the name of any fictional character or place; and
- Password does not contain any simple pattern of letters or numbers, such as "qwertyxx" or "xyz123xx".

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	Provide any supporting comments:
☐	Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped. *Provide any supporting comments*:
☐	Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products. *Provide any supporting comments*:
☐	Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer. *Provide any supporting comments*:
☐	Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter. *Provide any supporting comments*:
☐	Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII. *Provide any supporting comments*:
☐	Using two-factor authentication for logon access control for remote access to systems and databases that contain PII/PHI. (Two-factor authentication is contained in the NIST Special Publication 800-63.) *Provide any supporting comments*:
☐	Reporting the loss or suspected loss of PII/PHI immediately upon discovery to: 1. The DOE funding office Program Manager or, if funded by a DOE laboratory, the DOE laboratory Program Manager; and 2. The DOE HSP Program Manager and the NNSA HSP Program Manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1-866-941-2472, by fax at 702-932-0189, or by e-mail at circ@jc3.doe.gov. For additional information, see: http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting. 3. The IRB Office, IRB Chair and related Institutional Officials. *Provide any supporting comments*:

HRP-423

CHECKLIST-Protecting Employees Who Participate as Research Subjects			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-423	11/2/21	E. White/C. Hautala-Bateman	1 of 2
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314-WORKSHEET-Criteria for Approval when research involves protecting employees who participate as research subjects. For the IRB, this checklist must be used for all initial approvals regardless of the type of review. Subsequently it must be used for major modifications and not used for any minor modifications.

Expedited Review

- For initial review, modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Designated Review" activity.

Convened IRB Review

- For initial review, modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB uploads this checklist in the "Submit Committee Review" activity.

Use a separate checklist for each waiver determination for a study.

Protocol Name:	

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CHECKLIST-Protecting Employees Who Participate as Research Subjects			
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Principal Investigator:	

DOCUMENTATION OF PROTECTING EMPLOYEES WHO PARTICIPATE AS SUBJECTS (Check if "Yes". All must be checked.)	
☐	Subject selection is not based solely on the subject's ready availability or malleability.
☐	The protocol explains that this is not a sample of convenience.
☐	The description of the use of the employees as subjects is included in the protocol summary and is necessary for the research.
☐	Advertisements recruiting subjects will be distributed across a broad base of employees, contractors, and students. If not, justification was provided.
☐	The use or disclosure of the employees' data involves no more than a minimal risk to the employee. If not, justification was provided.
☐	Recruitment materials includes how objectivity and validity of the data will be ensured.
☐	Specific steps should be included about how potential coercion will be minimized.
☐	The Principal Investigator (PI) is not including employees who are in the PI's supervisory purview. If not, justification was provided.
☐	Participation of direct reports to the research team should be avoided whenever possible. If not, justification was provided.
☐	If Unions exist at the site, the Union Leadership has been notified.
☐	Employees are informed about compensation for their time in the research (e.g. charge code, gift card). Any monetary compensation does not violate company policy.
☐	Employees covered under the laboratories' worker compensation coverage for any illness or accident during the study. If not, justification was provided.
☐	The research could **NOT** practicably be conducted without using this population.

If reviewing using the expedited review procedure, the designated reviewer signing below has determined that the above requirements are met, and are described in the protocol is necessary.	
Reviewer Signature:	
Date:	

HRP-320

WORKSHEET-Scientific or Scholarly Review			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-320	5/1/19	E. White/C. Hautala-Bateman	1 of 2
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this worksheet is to provide support for IRB members responsible for the scientific review of research. Use this worksheet to determine whether the research has scientific or scholarly validity. If a consultant is used he/she should complete this worksheet and provide it to IRB Administrator/staff who will retain it in the files.

	1 Overall Scientific and Scholarly Validity (Check if **"Yes"**. All must be checked.)
☐	Does the protocol accurately describe the research in a clear, detailed protocol in terms of? • Objectives • Background • Setting • Procedures • Data and safety monitoring plan • Risks • Potential benefits • Alternatives to participation
☐	Is there another way to do this research that would reduce risks to subjects and still answer the scientific question?
☐	Are there any monitoring procedures that would reduce risks to subjects and not affect the science?
☐	Is the research likely to answer its proposed question?
☐	Does the protocol fairly portray the knowledge expected to result?
	2 Clinical Trials **(If "No", select N/A. If the research is a clinical trial, all remaining boxes much be checked.)**
☐	N/A if not clinical trial research.
☐	The available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.
☐	The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
☐	The investigator has sufficient time to properly conduct and complete the trial within the agreed trial period.

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WORKSHEET-Scientific or Scholarly Review			
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☐	The investigator has available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
☐	The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
☐	A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, will be responsible for all trial-related medical (or dental) decisions.

Comment on the above:

HRP-492

CHECKLIST-Initial Application - Reviewer			
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HRP-492	11/14/21	E. White/C. Hautala-Bateman	1 of 5
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this checklist is to provide support for the reviewer in the review of continuing reviews. This checklist provides an outline for the presentation and discussion at a convened IRB meeting. This checklist is to be used in conjunction with HRP-314-Worksheet-Criteria for Approval.	
Project Title:	
Principal Investigator(s):	
CDOEIRB Primary Reviewer:	
CDOEIRB Secondary Reviewer:	

Evaluation of the Nature and Purpose of the Research		
What is the purpose/overall objectives of the research? *Provide any supporting comments:*		
☐ **Yes**	☐ **No**	Does the proposal contain sufficient background information regarding the results of previous studies, including animal or clinical studies? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Is the research controversial and could it potentially generate public concern? If so, should any special recommendations be implemented? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Are there any potential legal problems or increased investigator/institutional liability associated with the research? If so, should any special safeguards be suggested? *Provide any supporting comments:*

Evaluation of the Risk
What are the potential risks/discomforts/inconveniences associated with the research? *Provide any supporting comments:*
What is the overall risk classification: minimal or greater than minimal? *Provide any supporting comments:*

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What is the estimated probability, severity, average duration, and reversibility of any given harm? *Provide any supporting comments:*		
☐ **Yes**	☐ **No**	Have adequate safeguards been adopted to minimize to the greatest possible extent the probability of occurrence and the magnitude of the risks? *Provide any supporting comments:*
What steps will be taken to treat a subject who may suffer an injury? *Provide any supporting comments:*		
Evaluation of the Benefits		
What are the potential benefits to the subject? Are these potential benefits maximized to the greatest possible extent? *Provide any supporting comments:*		
What are the potential benefits to society (or some subset)? Are these potential benefits maximized to the greatest possible extent? *Provide any supporting comments:*		
Evaluation of the Risk/Benefit Relationship		
☐ **Yes**	☐ **No**	Is the potential risk to the subject outweighed or balanced by the potential benefit to the subject and/or by the potential benefit to society? *Provide any supporting comments:*
Evaluation of the Subject Populations		
What are the inclusion/exclusion criteria: sex, age, health status, number of subjects, clearance level, etc.? *Provide any supporting comments:*		
☐ **Yes**	☐ **No**	Is the proposed subject population appropriate for the goals of the study? *Provide any supporting comments:*

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☐ **Yes**	☐ **No**	Is the selection of subjects as equitable as possible given any restrictions imposed by justifiable inclusion/exclusion criteria? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Will any particular physiological, health, psychological, or sociological characteristics of the subject population pose special medical, ethical, or legal problems? Have appropriate steps been taken to minimize these potential problems? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Is the inclusion of a vulnerable subject population (employees) justified? *Provide any supporting comments:*
Evaluation of Subject Recruitment		
☐ **Yes**	☐ **No**	Is the method used to identify a particular subject population ethically and legally acceptable? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Is the process used to recruit potential subjects appropriate and free of coercion? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Are the advertisements used to recruit subjects acceptable? *Provide any supporting comments:*
Evaluation of the Process of Obtaining Informed Consent		
Who will solicit informed consent from the subject? *Provide any supporting comments:*		
☐ **Yes**	☐ **No**	Will the timing of and setting for the process of informed consent be conducive to rational and thoughtful decision-making by the subject without coercion? *Provide any supporting comments:*

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☐ **Yes**	☐ **No**	Should subjects be re-educated at periodic intervals and informed consent again solicited? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Will the nature of the research or other factors potentially inhibit a subject's desire/ability to withdraw from participation? If so, have appropriate steps been taken to minimize this problem? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Will the subjects be physically and mentally competent to give informed consent? If no, are the proposed proxy consent procedures acceptable? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Should a subject advocate or other individual be present during the consent process? *Provide any supporting comments:*
Evaluation of Research Data Processing and Storage		
How will be research data be stored and maintained? *Provide any supporting comments:*		
How sensitive will the research data be? *Provide any supporting comments:*		
☐ **Yes**	☐ **No**	If sponsor-provided operational data is to be used, has the researcher addressed whether the sponsor will be notified if the research team incidentally encounters information that they feel should be reported? *Provide any supporting comments:*

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☐ **Yes**	☐ **No**	Will the investigator provide information about subjects to other individual(s) and/or agencies? If so, is this ethically and legally acceptable? Will this be during or following the research? The protocol and consent form should specify this, as well as what will be included in the transfer agreement. Likewise, the protocol and consent form should specify that if data and/or specimens are to be used for any purpose other than the current research project, which should not occur until after the IRB reviews/approves. *Provide any supporting comments:*
To what extent would a breach of confidentiality or invasion of privacy constitute a harm to subjects? *Provide any supporting comments:*		
☐ **Yes**	☐ **No**	Are there adequate provisions to protect participants from the risks of breach of confidentiality and invasion of privacy? *Provide any supporting comments:*
☐ **Yes**	☐ **No**	Should a statutory shield against subpoena of research records be obtained? *Provide any supporting comments:*
Additional Monitoring		
☐ **Yes**	☐ **No**	Should the research be reviewed by the IRB more often than annually? If so, when and how should this review be accomplished? *Provide any supporting comments:*
Summary of Comments, Revisions and Recommendation for Approval *Provide any supporting comments:*		

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The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet is to be used. It does not need to be completed or retained.

1 General Considerations
(Check if **"Yes"**. All must be checked.)

☐	The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise. (NOTE: Designated Reviewer is N/A for classified research.)
☐	For initial review the principal investigator is not Restricted.
☐	Materials are complete.

***Provide any supporting comments (optional)**:*

2 Criteria for Approval of Research
(Check if **"Yes"** or **"N/A"**. All must be checked; applies to initial, continuing, modifications.)

☐	Risks to subjects are minimized by using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. ☐ **"N/A" if none.**
☐	Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.[1]

[1] In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

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☐	Selection of subjects is equitable and both explicit and implicit[2] biases have been addressed.[3] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) • Researcher provided sound justification for exclusion criteria. • Is the source used for subject categorization appropriate for the study population (e.g., US Census or similar) if applicable.
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. ☐ **"N/A" if ≤ Minimal Risk.**
☐	There are adequate provisions to protect the privacy of subjects.
☐	There are adequate provisions to maintain the confidentiality of data.
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. DOE considers Federal/contractor employees to be a vulnerable population. (DOE Report, Creating an Ethical Framework for Studies that Involve the Worker Community and HRP-423-CHECKLIST-Protecting Employees Who Participate as Research Subjects). Generally classified research should not involve pregnant women or any other vulnerable populations. ☐ **"N/A" if no vulnerable subjects.**

[2] As noted in the DOE HSPP "Implicit Bias Memoranda," implicit bias can be defined as having attitudes and/or stereotypes that implicitly affect our understanding, actions, and decisions in an automatic or involuntary, unconscious manner, those responses being without an individual's awareness or even intentional understanding or control. Examples of implicit bias are Affinity Bias, Ageism, Anchor Bias, Attribution Bias, Authority Bias, Beauty Bias, Confirmation Bias, Conformity Bias, Contrast Effect, Convenience Bias, Gender Bias, The Halo Effect/The Horns Effect, Height Bias, Language Bias, Name Bias, Nonverbal Bias, Overconfidence Bias, Political Bias, Race and Ethnicity Bias, Religious Bias, and Sexual Identity Bias.

[3] In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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☐	The informed consent process is appropriate.
	☐ Section 7: Consent Process ☐ HRP-410-CHECKLIST-Waiver or Alteration of Consent Process (Not for non-exempt classified research) ☐ Permanently closed to enrollment.
☐	The informed consent documentation is appropriate and at no more than an eighth-grade reading level. ☐ HRP-411-CHECKLIST-Waiver of Written Documentation of the Consent Process ☐ Permanently closed to enrollment. ☐ HRP-410-CHECKLIST-Waiver or Alteration of Consent Process (Not for non-exempt classified research)
☐	Additional applicable criteria[4] are met. ☐ **"N/A" if none.**
Provide any supporting comments (optional):	
3	**For Continuing Review of Research** (All should be checked.)
☐	The status report on the progress of the research includes:
	☐ Tracking of amendments or modifications (*except for the Former Worker Medical Screening Program, which is not research*).
	☐ Any relevant recent literature.
	☐ Any interim findings.
☐	The complete protocol, including any protocol modifications previously approved by the IRB were reviewed.
4	**Additional Considerations** (Check all that apply.)
☐	Does the research involve no more than Minimal Risk to subjects?
☐	Does the research require Continuing review? **(Note that for FDA or DOJ overseen research, research that is classified or is funded**

[4] Advertisements (HRP-315); Payments to Subjects (HRP-316); Additional Federal Criteria (HRP-318);

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	through the Strategic Intelligence Partnership Program, and research that falls under the requirements of the pre-2018 Common Rule, there is no option not to require Continuing review.) The research does not require Continuing review if it is approved under the 2018 Common Rule, and one of the following apply: ☐ The research is eligible for expedited review. **(See HRP-313-WORKSHEET-Expedited Review)** ☐ The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
☐	Should review take place more often than annually?[5] If so, specify period.
☐	Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[6] ☐ **"N/A" if initial.**
☐	Does information need to be provided to subjects because it may affect their willingness to continue participation? ☐ **"N/A" if initial.**
Provide any supporting comments (optional):	
5	**Additional Criteria for DOE Research** (Check if **"Yes"**.)
☐	Projects involving the **Manipulation of the Human Environment for Research Purposes**. At a minimum, the following key questions have been considered by the IRB: • Is there a compelling and credible case for anyone not on the research team to be present during the experiment? • Have all the risks and discomforts been identified and considered, e.g., have chemicals/materials been evaluated for human health effects, all devices had

[5] Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB's experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.

[6] Implement when the veracity of the information provided is questioned.

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	appropriate safety testing, and other potential risks been identified in the population group(s) to be exposed? • Have appropriate mitigations been taken to minimize risks, and are risks considered minimal for all involved? How will anyone who is involved in the study but not part of the research staff be informed of the research? Will consent forms be used? Are key elements of informed consent included or requirements for a waiver met? • Is there a way for people to opt out if they wish without repercussions? • How will the PI monitor the research and measure outcomes? • How and from what sources will data be collected?
☐	Keeping PII confidential. The protocol should address: • Releasing PII only under a procedure approved by the responsible IRB and DOE. • Using PII only for purposes of the IRB-approved project. • Handling and marking documents containing PII as "containing PII or containing Protected Health Information (PHI). • Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII. • Making no further use or disclosure of the PII except when approved by the responsible IRB(s) and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project; (d) when required by law; or (e) with the consent of the participant/guardian. • Protecting PII data stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified. • Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1. • Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped. • Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.

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	• Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e., separate e-mail, telephone call, separate letter. • Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII. • Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf. • Reporting the loss or suspected loss of PII immediately upon discovery to (1) the DOE funding office program manager, and (2) the applicable IRBs (as designated by the DOE program manager); if the DOE program manager is unreachable, immediately notify the DOE Joint Cybersecurity Coordination Center.
☐	**Evaluation of the Research Team** • Are the members of the research team properly identified regarding qualification(s) and role(s) within the research team? • Are there any unique/unusual characteristics about the culture and society at the sites where the study will occur? Does it describe how the research team is equipped to incorporate these considerations into their research? • Is the process that will be used to ensure that all persons on the research team are informed about protocol, procedures and their duties and functions, fully described? Does it describe how changes in the protocol and research procedures will be communicated to team members? • Are the members of the research equipped to offer support/guidance to non-English speaking subjects regarding questions, concerns, or other issues during the length of the study? ☐ **"N/A" if only using English speaking subjects.** • Are there any foreseeable implicit bias issues that could arise from the research team or its affiliations to funding, host institutions, and/or other stakeholders?
☐	**Classified Human Subjects Research** ☐ **"N/A" if NOT classified research.** For classified human subjects research (in whole or in part): • A waiver of informed consent is not granted for non-exempt research.

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	• Exemptions (as per 10 CFR Part 745.101(b)) and expedited review are not used. If the research meets a particular exemption or expedited category it may be noted, but full IRB review is required. • The identity of the sponsoring Federal agency will be disclosed to subjects, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods; the research involves no more than minimal risk to subjects; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the subjects. • The informed consent document will state that the project is classified, and what that means for the purposes of that project. • The IRB must have a voting quorum of at least five members, which must include a non-scientist and an unaffiliated member. The unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor. • Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, and Director of the Office of Science and Technology Policy (OSTP), in that order. • The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision. • Information on each project that is classified and reviewed during that fiscal year, as well as the number of human subjects in each project, must be submitted in accordance with the directions and schedules of the appropriate HSP program manager. • If the IRB believes that the project can be thoroughly reviewed in an unclassified manner, a request for a project-specific waiver from the requirements for classified research can be submitted. The waiver request must be signed by the IRB Chair and submitted to the appropriate HSP Program Manager for review and approval, using the appropriate form. A list of waiver requests and the actions taken will be provided monthly to the DOE IO. • After IRB approval, the DOE Institutional Official (IO) reviews and determines whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval
***Provide any supporting comments (optional)**:*	

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6	**Primary Reviewer Criteria for Initial Review** (Check if **"Yes"** or **"N/A"**. All must be checked; may be determined by a primary reviewer.)
☐	The research has the resources necessary to protect subjects (time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified and trained investigators and research staff; appropriate qualifications for international research) and ensure subject population has been selected in an unbiased manner and is representative of the population to which the research results will be applicable.
☐	The plan for communication among sites is adequate to protect subjects. ☐ **"N/A" if not a multi-center trial where PI is the lead or not initial.**
Provide any supporting comments (optional):	
Complete remaining items when applicable	
7	**Consent Process** (Check if **"Yes" or "N/A"**. All must be checked.)
☐	The investigator will obtain the legally effective informed consent of the subject or legally authorized representative (LAR). *Note that DOE does not allow subjects to participate in classified HSR if they cannot consent themselves.*
☐	The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
☐	The circumstances of consent minimize the possibility of coercion or undue influence.
☐	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
☐	The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
☐	Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
☐	Informed consent as a whole must present information in sufficient detail relating to the research. It must be organized and presented in a way that does not merely

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	provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.
☐	There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject's legal rights or releases or appears to release the investigator, the sponsor, the Institution, or its agents from liability from negligence.
☐	Are only English-speaking subjects included in your research population?
☐	Are non-English speaking subjects included in your research population? ☐ **"NA" if only using English speaking subjects.** If yes, ☐ Will the subject or LAR require a translator? ☐ If the subject requires a translator, does the subject have access to qualified language appropriate personnel during and beyond the consent process, to inquire about potential questions and concerns?
☐	Consent will disclose the elements in **Section 9: Elements of Consent Disclosure**
Provide any supporting comments (optional):	

8	**Consent Documentation** (Check if **"Yes"** or **"N/A"**. All must be checked.)
☐	The written consent document is accurate, complete, and consistent with the protocol.
☐	The written consent document embodies the elements in **Section 9: Elements of Consent Disclosure.**
☐	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐	The subject or LAR will sign and date the consent document.
☐	The person obtaining consent will sign and date the consent document.
☐	A copy of the signed and dated consent document will be given to the person signing the document.
☐	If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. ☐ **"N/A" if no signature line.**
☐	For non-English speaking subjects, are all communication materials (e.g., paper copies, digital sources, website materials, etc.), presented in the appropriate language?

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	☐ **"N/A" if only using English speaking subjects.**
☐	When a subject or LAR is unable to read, an impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. ☐ **"N/A" if all subjects are able to read.**
Provide any supporting comments (optional):	

9 Elements of Consent Disclosure
(Check if **"Yes".** All relevant sections must be reviewed and checked.)

Required
**Can be omitted if there are none.*

- ☐ The study involves research.
- ☐ The purposes of the research.
- ☐ The expected duration of the subject's participation.
- ☐ The procedures to be followed.
- ☐ Identification of any procedures, which are experimental.*
- ☐ Any reasonably foreseeable risks or discomforts to the subject.*
- ☐ Any benefits to the subject or to others, which may reasonably be expected from the research.*
- ☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
- ☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
- ☐ How to contact the research team for questions, concerns, or complaints about the research.
- ☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
- ☐ Whom to contact in the event of a research-related injury to the subject.
- ☐ Participation is voluntary.

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☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Required for More than Minimal Risk Research

☐ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.

☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

Required for Any Research That Involves the Collection of Identifiable Private Information or Identifiable Biospecimens

☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or

☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Required for classified research (in whole or in part)

☐ Identify the sponsoring Federal agency to subjects, unless determined not appropriate by the CDOEIRB-C, after required approvals.

☐ State that the project is classified, and what that means for the purposes of that project.

Required for Clinical Trials that Follow ICH-GCP

☐ The approval of the IRB.

☐ The probability for random assignment to each treatment.

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- ☐ The subject's responsibilities.
- ☐ When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- ☐ The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
- ☐ When there is no intended clinical benefit to the subject, a statement to this effect.
- ☐ The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
- ☐ If the results of the trial are published, the subject's identity will remain confidential.

Required for DOE Former Worker Medical Screening Program

- ☐ Disposition plan for de-identified data at the end of the project.
- ☐ Subject should be informed that no-cost screening is available through the National Supplemental Screening Program. If the participant does not live in close proximity to the medical clinic(s) used by the project, the participant should be referred accordingly.
- ☐ Subject should be provided the opportunity to opt in/opt out of providing his/her mailing address.

Required for DOD-funded Research

- ☐ A statement that DOD or a DOD institution is funding the study.
- ☐ A statement that representatives of the DOD are authorized to review the research records.
- ☐ The IRB must also determine that the disclosure/consent form includes language regarding research-related injury following the requirements of the DOD component.

Additional
(Include when appropriate)

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- ☐ The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
- ☐ If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- ☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- ☐ Any additional costs to the subject that may result from participation in the research.
- ☐ The consequences of a subject's decision to withdraw from the research.
- ☐ Procedures for orderly termination of participation by the subject.
- ☐ Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.
- ☐ Approximate number of subjects involved in the study.
- ☐ Amount and schedule of all payments.
- ☐ A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- ☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- ☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- ☐ Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.

Additional Comments (optional):

10 Additional Considerations for Electronic Consent
(Check if "Yes" or "N/A". All must be checked.)

☐	Electronic consent document includes all elements in **Section 9: Elements of Consent Disclosure.**

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☐	The date of the electronic signature will be captured. ☐ **"N/A" if waiver of documentation of consent is requested and justified.**
☐	Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.
☐	Electronic consent process includes age-appropriate materials to facilitate comprehension.
☐	Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.
☐	Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
☐	Measures are present to ensure that subjects have access to all the consent related materials, including hyperlinks or other external documents.
☐	Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.
☐	The informed consent process outlines in detail how any included documents will be utilized.
☐	Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.

Appendix D

DOE Templates for Researchers

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IRB-required template language is in black type and should not be changed.
Instructions are in blue italics type and should be deleted in final consent.
Items in red are not required elements of consent and can be deleted if not applicable.

Title of research study:
[Insert title of research study here with protocol number, if applicable.]

Investigator:
[Insert the name of the principal investigator, location, email address and telephone number plus a 24-hour telephone number if the study involves greater than minimal risk.]

KEY INFORMATION:

[Include paragraph here]

- *A Key Information paragraph is required for studies when the consent document is greater than 2,000 words. This information should include information that a reasonable person would want to know about participating in the study. This information may be repeated below but should be included up front for consideration by the participant. An example of Key Information could be that the participant would need to be in a lifelong treatment after entering the study or that they may be required to stay overnight for a 3- 4 day period. Any important factors that someone might want to give consideration to before participating should be included in this paragraph.*
- *The purpose of the Key Information paragraph: The revised Common Rule regulations on human subjects require that subjects be given a concise and focused presentation of key study information before being given other information.*
- *The goal of the Key Information paragraph is not simply to provide an abstract or executive summary of the rest of the consent form but to assist potential subjects with understanding the reasons why one might or might not want to voluntarily participate in the research.*

You are being invited to participate in a research study.

Why is this research being done?

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[Provide the potential subject with a short and simple explanation of the goals of the research in lay language consistent with the general population from which the subjects will be recruited and, if possible, at no greater than an eighth-grade reading level.

- *Include any experimental procedures or therapies and identify them as such.]*

What should I know about a research study?

- Whether you choose to participate in this research study is strictly up to you.
- You can always choose not to take part. Your participation is voluntary.
- You can ask and have answered all of the questions you want before you decide.
- You can agree to take part and later change your mind without giving any reason.
- Your decision will not be held against you, and there will be no penalty or loss of benefits.
- You do not waive any of your legal rights by signing this form.
- We expect about _____ people here will be in this research study out of _____ people in the entire study nationally *[or internationally]*.
- We expect this study will take _____ *[months, years]* and expect your participation will only take _____ *[days, months]*.
- This study is being sponsored by _____.
- You will get a signed copy of this consent form to keep. *[Remove if requesting a waiver of documentation of consent.]*

Is there any way being in this study could be bad for me? What are the predicted risks?

[In lay language no greater than an eighth-grade reading level, use this section of the consent form to identify the most important and reasonably foreseeable risks and/or discomforts, e.g., emotional distress resulting from a series of questions in a social-behavioral research project, headaches and nausea in a medical research project.]

What are the predicted benefits of the research? Is there any way being in this study could help me?

[*Include for a study with potential benefits to the subject and/or benefits to others, or alternatively, for a study that has no benefits to participation.]*

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We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. *[Describe any direct benefits to the subject, then any benefits to others.* ***Monetary reimbursement for participation is not a benefit****.]*

- *If benefits from participation may not continue after the research has ended, describe them here.*
- *Do not overemphasize the benefits.*
- *If you need to discuss benefits in additional detail, add an additional section later in the consent document.*

[Alternatively, include for a study with no benefits to participation.]

There will be no benefit to you from participating in this study. However, it is hoped that information gained in this study will help others by _____. *(Describe how the information gained in this study will help society, advance knowledge, etc.).*

What happens if I say "yes, I want to be in this research"?

[Explain to the potential subject in lay language no greater than an eighth-grade reading level what will happen to the participant or what s/he will be asked to do in the study. Be sure to include where, when and how the research will be done. Also include any data that will be collected about them. Whenever appropriate, include the following items:]

- *A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 step(s)/visit(s).*
- *The drugs or biologics that will be given to the subject.*
- *All devices that will be used.*
- *What data will be collected about them.*
    - *Note that the Department of Energy considers name, biometric identifiers, and some demographic information such as birthdate to be Personally Identifiable Information (PII).*
    - *When specifying what information will be collected, used, stored, and shared, it is important to specify exactly what individual-specific information you mean, e.g., name, birth date, gender, race/ethnicity, eye color, age, fingerprint images, facial images, etc.*
    - *You must also include how you will protect PII obtained from subjects and what steps, if any, will be taken if PII is erroneously disclosed or breached. At*

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a minimum, ensure that you comply with the requirements outlined in the protocol template.

- *Encryption should be in accordance with NIST 800-53, Privacy Controls for Federal Information Systems and Organizations.*

- *All hospitalizations, outpatient visits and telephone or written follow-up contacts.*
- *The length and duration of each visit and procedure.*
- *If blood will be drawn, indicate the amount in U.S. units and frequency.*
- *With whom the subject will interact.*
- *Where the research will be done.*
- *When the research will be done.*
- *How often procedures will be performed.*
- *How long the procedures will take.*
- *What is being performed as part of the research study.*
- *What is being performed as part of standard care.*
- *Whether the research will (if known) or might include whole genome sequencing, i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.*
- *When applicable, indicate whether the subject will be contacted for future research.*

If the research will include whole genome sequencing, include the following; if not, delete:

- *[If cell lines will be created, include this language.]* The blood or tissue collected in this research may be used to create a "cell line" that can be grown in the laboratory. A cell line can continue to grow and make more cells indefinitely. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. The researchers will use these cells to try to learn more about *[disease/condition]*.
- *[If induced Pluripotent Stem Cells (iPS cells) will be created, include this language.]* The researchers may use the cells taken from your *[specify the source of the cells]* to create a type of cell known as a pluripotent stem cell. This type of stem cell can be used to create other types of cells and tissue, including *[specify the type of cells]* cells. Your cells might be used to study genetic changes. The researchers will use your cells to try to learn more about *[disease/condition]*.

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- *[If whole exome or whole genome sequencing studies will be performed, include this language.]* The researchers [may/will] perform a *[whole genome/whole exome]* analysis on your sample. Some research involves studying only a few genes that are linked to a disease or condition. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of *[state here whether the sequencing data will be limited to the disease or condition under study and related disorders or "many diseases or conditions." If the research is subject to the NIH Genomic Data Sharing policy and submitted to a database like the database of Genotypes and Phenotypes (dbGaP), you must indicate "many diseases or conditions" and not limit uses.]*

[Include for a clinical trial that involves randomization. Otherwise delete.]
The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the researchers will choose what treatment you get. You will have a _____ *[equal/one in two/etc.]* chance of being given each treatment.

- *[If double-blinded research, add the following:]* Neither you nor the study doctor will know which treatment you are getting.
- *[Alternatively, if single blinded research, add the following:]* You will not be told which treatment you are getting; however, your study doctor will know.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at _____. *[Insert contact information for the research team.]*

This research has been reviewed and approved by the Central Department of Energy Institutional Review Board (CDOEIRB), an administrative group of people who oversee the rights and welfare of human-research subjects participating in research activities conducted under the auspices of U.S. Department of Energy.

- If you have any questions, concerns or complaints about the research study, or for any other reason, you may contact the CDOEIRB at (865) 574-4359 or at CDOEIRB@orau.org.
- You also may ask questions about your rights as a research subject, request to obtain information, or offer input.
- If you want to know more about the program, visit the Department of Energy Human Subjects Protection Program website at https://science.osti.gov/ber/human-subjects.

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Are there alternative procedures if I do not want to be in this research?

Participation in this research is completely voluntary. You can decide to participate or not to participate. Your decision will not be held against you, and there will be no penalty or loss of benefits.

[Include if there are alternatives other than participating.]

Instead of being in this research study, your choices may include: *[List alternative procedures. For clinical trials, describe the options that you would normally offer a subject. If applicable, include supportive care as an option.]*

[Include if there are no alternatives other than participating.]
Your alternative to participating in this research study is not to participate.

What happens to the information and data collected for the research?

Every effort will be made to protect the data and to limit the use and disclosure of your personal information, including research study and *(if applicable)* medical records, to the research team and others who have a need to review this information.

- *Describe what information and data will be collected. For instance, state whether identifying information will be collected or whether all data will be anonymous.*
- *Explain briefly how you will protect the confidentiality of the participant's identifiable personal information, e.g., subjects' names, biometric images, demographic information, other.*
- *If identifying data is collected, clarify whether any coding system will be used, and when and how it will be de-identified.*
- *State where the data will be stored. Provide details of how the data will be kept confidential, e.g., locked filing cabinet, password protected computer files, and how access will be controlled.*
- *State who will have access to the data both during the research and after the research is over, e.g., only the research team will have access to the identifying information. If any data is to be collected through Survey Monkey, Mechanical Turk, or similar services, clarify whether that organization will retain any data once the study is complete. Be specific.*

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- *State whether the data will be disposed of following the research and, if so, how. Proper destruction of PII must be carried out when it is no longer necessary to support the project.]*

[If known, describe the probability and magnitude of the risks of research data compromise/loss.]

When we share the results of this study [*insert details here, e.g., when published in scientific journals, professional publications and/or educational presentations*], we will not include your name *[insert other information that will not be disclosed and if data will be presented in aggregate form*].

The information that you provide in the study will be handled confidentially, and every effort will be made to protect the data and limit the use and disclosure of your personal information. However, there may be circumstances when this information must be released or shared as required by law. Other organizations that may have access to information from this study include the CDOEIRB, representative(s) of the Department of Energy Human Subjects Protection Program and its accrediting organization, other federal regulatory agencies, the sponsor of the study, and/or the following_____. *[Add other organizations that may have access to the subject's records during the study, for what purpose, and for how long.]*

Will my information (or biospecimens) be used for future research?
One of the following two statements is required if any identifiable personal information or biospecimens are collected:

- Information collected about you will NOT be used or shared for future research.

  OR

- All identifiable information, e.g., your name, date of birth, will be removed from the information and/or samples collected in this project. After we remove the identifiers, the information and/or samples may be used for future research or shared with other researchers without your additional consent.

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DETAILED INFORMATION: The following section of the consent is more detailed information about this study in addition to the information above. *[Investigators are advised to not complete any sections below that are inapplicable to the research for which you are proposing to use human participants.]*

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to _____.
[Describe any responsibilities of the subject, particularly to follow all of the instructions as well as to attend scheduled sessions with the research team.]

What happens if I say yes now but I change my mind later?

Your participation in this study is voluntary. You are free to withdraw your consent and leave the research at any time, and it will not be held against you. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you otherwise are entitled. *[Include, if the following applies*:] If you choose, you may request that the data collected about you to date be removed. *[If data already collected cannot be deleted, explain why their data will not/cannot be discarded if they make such a request but that no more data will be collected.]*

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete.]

If you decide to leave the research, *[describe the adverse consequences].* If you decide to leave the research, contact the principal investigator in writing [and provide the investigator's contact information] so that the investigator can _____. [*Describe the procedures for orderly termination by the subject, if any*.]

Describe what happens to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects but may agree to undergo follow-up procedures and data collection

If you sign the consent at the end, it means:

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- That you have read this form and have had all of your questions answered, and
- That you will allow the use and reporting of your data as described above.

Can I be removed from the research study without my consent?

[Include for research when this is a possibility. Delete this section if not applicable.]

The principal investigator and/or the sponsor can remove you from the research study without your approval. Possible reasons for removal include that you no longer meet the eligibility criteria, if it is in your best interest to do so, or if you do not follow study procedures. *[Describe any other reasons why the subject may be withdrawn if appropriate.]* You will be notified if you are removed from the research study.

Audio/and/or Photographic and/or Video Recording

If audio and/or photographic and/or video recording devices will be used, include the section below. Otherwise delete.] explain why the records are needed for the research and what will be done with them upon completion of the research, e.g., kept indefinitely, archived after transcription, destroyed after X years. For a photograph or video recording, explain if the face and/or identifying markings, e.g., tattoos, can/will be obscured. If audio and/or photographic and/or video recording will not be used, delete this section.

Please sign below if you are willing to have an interview recorded. You may still participate in this study if you are not willing to have the interview recorded.

☐ I do not want to have this interview recorded.

☐ I am willing to have this interview recorded.

Signed: _____

Date: _____

If you plan to take photographs or make audio, video, or other types of recordings, and you want to use the photographs/record for activities beyond research analysis, e.g., in publications, presentations, or other promotional purposes, include a section that does the following:

- *Informs the participant that you are making a [type(s) of media used] recording in which the person's name, likeness, image and/or voice will be included;*
- *Asks the participant to grant you the right to make and use recordings in whole or in part in media forms now known (such as film, slides, or digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;*

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- *Explains that the participant will not receive any financial compensation from commercial and/or non-commercial (as appropriate) uses of the images/recordings.*

The same signature line above may be used for this performance release information.

What else do I need to know?

[Include for research involving more than minimal risk. Otherwise delete.]

If you need medical care because of taking part in this research study, contact the principal investigator and medical care will be made available. Generally, this care will be billed to you, or to your insurance, or other third party. *[Insert the name of the institution]* has no program to pay for medical care for research related injuries. *[If available, describe any compensation available for research related injury. Otherwise delete.]*

[Include if subjects will be paid, and indicate the method, timing and amount of payment. Otherwise, state there is no payment for taking part in the study.]

If you agree to take part in this research study, we will pay you _____ *[amount]* for your time and effort. *[Compensation cannot be withheld until the participant completes the entire study. Payment should be provided after each study visit. Compensation can be prorated if participants do not complete all study visits.]* If you are paid $600 or more a year as a research subject, your earnings will be reported to government tax agencies. You also will have to fill out and submit a federal W-9 form to any institution that pays over $600.

[Include for Department of Defense (DOD) research that targets military personnel when subjects will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include when applicable. Otherwise delete.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *[or replace with plans when using identifiable information/samples]* to tell you, or to pay you, or to give any compensation to you and/or your family.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; include also for

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research involving biospecimens.] Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information and/or samples gives results that do have meaning for your health, the researchers __ will __will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor and/or get professional genetic counseling. You may have to pay for those additional services yourself.

[There are three signature pages attached to this template consent. Not all may be required. Use the signature page or pages appropriate for your study. *The CDOEIRB recommends that you make separate consent documents for each signature page to be used.]*

[Omit the signature page if there is no written documentation of consent.]

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[Add the following block if a witness will observe the consent process, e.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

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Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative — Date

Printed name of legally authorized representative

Signature of person obtaining consent — Date

Printed name of person obtaining consent

[Add the following block if you will document assent of the subject.]

Assent

☐ Obtained

☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject and that consent was freely given by the subject.

Signature of witness to consent process — Date

Printed name of person witnessing consent process

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Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

☐ Parent
☐ Individual legally authorized to consent to the child's general medical care (See note below.)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

☐ The CDOEIRB determined that the permission of one parent is sufficient. *[Delete if the CDOEIRB did not make this determination.]*
☐ Second parent is deceased
☐ Second parent is unknown
☐ Second parent is incompetent
☐ Second parent is not reasonably available
☐ Only one parent has legal responsibility for the care and custody of the child

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[Add the following block if you will document assent of children]

Assent
☐ Obtained
☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

[Add the following block to all consents]

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent _____

[Add the following block if a witness will observe the consent process, e.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject and that consent was freely given by the subject.

Signature of witness to consent process _____ Date _____

Printed name of person witnessing consent process _____

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Central Department of Energy Institutional Review Board (CDOEIRB)

FWA 00015568

Human Subjects Research Protocol Application

Note: if there is more than one DOE site involved in the research, contact the IRB Administrator before starting the IRB protocol application.

INSTRUCTIONS:

- **Add "Controlled Unclassified Information" as applicable. No classified information can be provided on this system.**
- Do NOT begin data collection prior to IRB approval.
- Do NOT leave a question blank; write "n/a" if a question does not apply to your application.
- If you leave any question blank, this protocol template will be returned to you to complete before any IRB review starts.
- For any items described in the sponsor's protocol, grant, contract, or other documents submitted with the application, you may reference the title and page numbers of those documents.
- When applicable, include copies of manual(s) specifying the use of any commercial off-the-shelf systems.
- If using services such as Survey Monkey, Prolific, or Mechanical Turk, attach copies of Terms of Use, Privacy Policies, etc., and clarify relevant details in the protocol and consent form as well as all surveys, scripts, and data collection forms.
- If intending to access datasets or specimens from external databanks or biorepositories, also attach relevant Terms of Use, Privacy Policies, Data Transfer Agreements, etc.
- Define any specific abbreviations/acronyms after first use in the study.
- See HRP-105-GENERAL-Implicit Bias Memorandum.
- If you need to make changes to the document already in the electronic system, click on the "Update button" next to the document. Do not upload a track-changed document. See screen shot below:

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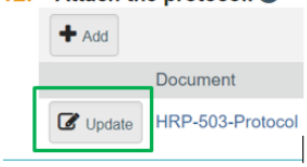
12. * Attach the protocol:



Documentation of human subjects training for all key project staff must be completed before this application will be approved.

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

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Protocol Title:

Include the full protocol title.

Principal Investigator:

Name
Department
Telephone Number
Email Address

1. Study Summary

1.1. Describe the purpose, specific aims, and objectives.

1.2. State the hypotheses to be tested.

1.3. Briefly describe any relevant background information (e.g., existing literature and knowledge gaps) that supports your research.

1.4. Is this research more than minimal risk? Yes ☐ No ☐

Note: minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1.5. Is this research medically related? Yes ☐ No ☐

1.6. Is this a multi-site study? Yes ☐ No ☐

1.7. Provide the Statement of Work (SOW) or grant application.

2. Study Procedures

2.1. Describe and explain the study design. In considering the study design, ensure that it will support recruitment of/participation by individuals representative of the entire population being studied.

2.2. Describe all research procedures being performed and the order in which they will be performed.

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2.3. Describe the locations where your research team will conduct the research.

2.4. Describe the steps to ensure location will be accessible to those individuals who are part of the intended population (e.g., Americans with Disability Act accessible).

2.5. Describe the data analysis plan, including statistical procedures, any power analysis, and how to ensure data analysis is sufficiently representative of the group(s) intended for study.

2.6. What is the plan to address identified biases?

2.7. Does the research involve drugs? Yes ☐ No ☐ or devices? Yes ☐ No ☐

If yes to either drugs or devices,

2.7.1. What are the plans to store, handle, and administer the drugs or devices so that they are:

- only used on participants?
- only administered by authorized investigators?

2.7.2. Is the drug investigational (has an IND) or is the device investigational (has an IDE) or claim a non-significant risk device? Yes ☐ No ☐

If yes,

- Who holds the IND/IDE/Abbreviated IDE?
- What procedures are followed to comply with sponsor requirements for FDA regulated research using the following table.

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	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Data transfer and use agreements should be entered into with any third party that will be receiving the data during or following the research.

2.8. Will data be collected during the study? Yes ☐ No ☐

If yes,

2.8.1. What data will be collected?

2.8.2. How will that data be obtained?

2.8.3. Will any data be obtained online or from another organization/source? Yes ☐ No ☐

If yes,

What social media, survey platforms, or other online sources will be used? *Include a copy of the terms of service agreements and privacy policies for data obtained online from any site including social media sites and survey platforms (e.g., Qualtrics, Survey Monkey). Include a copy of any data transfer and use agreement(s).*

2.8.3.1. Why was this data source(s) chosen for this research?

2.8.3.2. Are there other available data sources that might be appropriate for this research? Yes ☐ No ☐

If yes,

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Why were they excluded?

2.8.3.3. What is the potential for explicit or implicit bias to exist in the data?

2.8.3.4. What specific biases may exist?

2.8.3.5. Is there a way to mitigate any potential biases in the data?
Yes ☐ No ☐

If no,

How much and what kind of bias are you willing to accept in the data, model, or output, considering the impact of the research's potential uses?

2.8.3.6. Is the data representative of the population or domain that is the focus of the research? Yes ☐ No ☐

2.8.3.6.1. If the research is intended to develop a data tool or artificial intelligence method, is the data set representative of the data on which the tool or method will be used in operation?
Yes ☐ No ☐ N/A ☐

2.8.3.7. Does data over- or under- represent certain populations?
Yes ☐ No ☐

2.8.4. Where and how will data be stored during the study?

2.8.5. How long will the data be stored?

2.8.6. Who will have access to the data?

2.8.7. Will access to the data be restricted? Yes ☐ No ☐

If yes, how?

If no, why not?

2.8.8. Will data be shared with other organizations? Yes ☐ No ☐

If yes, what is the procedure for sharing? *Please attach a copy of the data transfer agreement to be used.*

- Will participants be informed of this on the consent form?

  Yes ☐ No ☐

2.8.9. Will data be stored for future use? Yes ☐ No ☐

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- If yes, will the data stored contain personal identifying information (PII)? Yes ☐ No ☐
- Will participants be informed of whether data will be stored for future use, and if so, whether it will contain PII, on the consent form?

  Yes ☐ No ☐

2.9. Attach the research materials that will be used to collect data about subjects. (*Attach all surveys, scripts, and data collection forms*).

2.10. Will specimens be collected? Yes ☐ No ☐

If yes,

2.10.1. What specimens will be collected?

2.10.2. Will PII be associated with the specimens? Yes ☐ No ☐

If yes, list the specific PII.

2.10.3. Where will specimens be stored during the study?

2.10.4. How long will the specimens be stored?

2.10.5. Who will have access to specimens?

2.10.6. Will access to specimens be restricted? Yes ☐ No ☐

If yes, what is the procedure?

If no, why not?

2.10.7. Will specimens be transported? Yes ☐ No ☐

If yes, what is the procedure?

2.10.8. Will specimens be released to a third party? Yes ☐ No ☐

If yes,

- Have participants been informed of this on the consent form?

  Yes ☐ No ☐

- What is the procedure for release of specimens? (*Attach any documents and data transfer agreements that will be used for this release*)?

2.10.9. Will specimens be stored for future use? Yes ☐ No ☐

- Have participants been informed of this on the consent form?

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Yes ☐ No ☐

2.11. Will you be collecting PII or PHI in the current study? Yes ☐ No ☐

Note that DOE considers name, biometric identifiers, and some demographic information such as birthdate to be personally identifiable information (PII). At a minimum, provide information to address all the requirements of HRP-490-CHECKLIST-Reviewing Protocols that use PII.

If yes,

2.11.1. How will you restrict access to PII and PHI?

2.11.2. How will PII and PHI be protected during storage?

2.11.3. How will PII/PHI be protected during transmission?

2.11.4. What administrative procedures will be used to prevent unauthorized use and disclosure of PII/PHI?

2.11.5. What technical procedures will be used to prevent unauthorized use and disclosure of PII/PHI?

2.11.6. What physical procedures will be used to prevent unauthorized use and disclosure of PII/PHI?

2.11.7. Are PII/PHI data stored and transported on media that use encryption products that are FIPS 140-2 certified? Yes ☐ No ☐

2.11.8. Do the passwords meet DOE requirements? Yes ☐ No ☐

2.12. Are there plans for long-term follow-up (once all research related procedures are complete)? Yes ☐ No ☐

If yes,

2.12.1. What data will be collected during this period?

2.12.2. What specimens will be collected?

2.12.3. How long will follow-up continue?

2.13. Describe the process that will be used to ensure that all research team members are informed about protocol, procedures, and their duties and functions.

2.14. How will changes in the protocol and research procedures be communicated to team members?

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3. Inclusion and Exclusion Criteria

3.1. Describe the study population.

3.2. What is your inclusion or exclusion criteria for your study population?

Indicate specifically whether you will include or exclude each of the following special populations.

Note, the first three groups below require special protections as they are considered vulnerable to coercion or undue influence. For these three vulnerable populations, there are additional forms listed below that you are required to fill out.

Special Population	Include	Exclude	Additional Form Required
Cognitively impaired adults	☐	☐	Template HRP-574
Children	☐	☐	Template HRP-575
DOE federal or contractor employees/students	☐	☐	Template HRP-576

Special Population	Include	Exclude
Pregnant women	☐	☐
Prisoners	☐	☐
Participants approached to participate during a stressful situation such as emergency room setting, childbirth (labor), etc.	☐	☐
Participants economically disadvantaged (i.e., income, housing, healthcare)	☐	☐
Participant has serious health condition for which there are no satisfactory standard treatment	☐	☐
Participants have a fear of negative consequences for not participating in	☐	☐

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the research (e.g., institutionalization, deportation, disclosure of stigmatizing behavior)		
Undervalued or disenfranchised social groups	☐	☐
Members of the military	☐	☐
Non-English speakers	☐	☐
Those unable to read (illiterate)	☐	☐
Employees of the researcher	☐	☐
Students of the researcher	☐	☐
Participants that are in any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research	☐	☐

3.3. What steps are being taken to avoid including populations for convenience reasons?

3.4. How will you make the research as accessible as possible to all potential participants to avoid over- or under- representation of your target population?

3.5. Are there any unique/unusual characteristics about the culture and society at the sites where the study will occur? Yes ☐ No ☐

If yes, describe the characteristics and how the research team is equipped to incorporate these considerations into their research.

4. Toxic or potentially harmful agents

4.1. Will you be using any toxic or potentially harmful agents? Yes ☐ No ☐

If yes,

4.1.1. Describe the expected exposure, including quantity, route, frequency, and duration.

4.1.2. Provide the dose calculations, including assumptions. When possible, include quantitative risk associated with the exposure.

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4.1.3. Describe whether these potentially toxic materials/harmful physical agents may negatively impact some individuals/groups in the intended population more than others and if so, how to mitigate and/or equalize those potential harms.

4.1.4. Independent Reviewer of Dose Calculation

4.1.4.1. Does the reviewer have any direct involvement in the research? Yes ☐ No ☐

4.1.4.2. Provide a brief summary (2-4 sentences) of the qualifications of the independent reviewer.

4.1.5. Include information about the safety of materials to be used (material safety datasheets, approval letters from biosafety or other laboratory committees).

Attach a copy of the independent validation in the IRB Electronic System.

5. Recruitment Methods

5.1. Describe the source of participants and address how you will ensure that the individuals being recruited are representative of those intended for the study.

5.2. What methods will be used to identify potential participants?

5.3. How will the participants be recruited?

5.4. Describe the materials that will be used to recruit participants, such as advertisements and recruiting scripts. Consider language, e.g., if recruiting in an area where Spanish is spoken by a subset of the intended population, provide both English and Spanish versions of the recruitment materials. (*Attach all recruitment materials*).

5.5. Will participants be paid or other type of compensation for their participation? Yes ☐ No ☐

If yes,

5.5.1. What is the maximum amount of payment? (*Ensure amount of payment or other type of compensation is appropriate and does not unduly influence potential participants/convince them to participate in research that is unreasonably against their interests. Also ensure that participants are informed that the Internal Revenue Service (IRS) requires study*

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participant payments aggregating $600 or more paid during a calendar year to be reported.)

5.5.2. At what point(s) in the study process will participants be paid and how much will they be paid at each point?

6. Consent Process

6.1. Will consent to participate be obtained? Yes ☐ No ☐

If consent will not be obtained or an alteration of the consent process will be used, you must fill out the Waiver or Alteration of Consent Process near the end of this section.

6.2. Where will the consent process take place?

6.3. Will there be a waiting period available between informing the prospective participant and obtaining consent?

6.4. How much time will be devoted to the consent discussion for the prospective participant, including time to consider the consent?

6.5. What is the waiting period between obtaining consent and starting the study?

6.6. What steps will be taken to minimize the possibility of coercion or undue influence?

6.7. What steps will be taken to evaluate the participant's grasp of the research?

6.8. Is your consent form written in clear plan language? Note that consent forms should typically be written at a 6th-8th grade reading level? Yes ☐ No ☐

If that is not your intention, why?

6.9. Are non-English speakers included in your research population? Yes ☐ No ☐

All consent forms and other materials given to participants should be in a language understandable to the participant in most circumstances.

If yes,

6.9.1. Will the subject or LAR require a translator? Yes ☐ No ☐

If yes,

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Does the subject have access to qualified language appropriate personnel during and beyond the consent process, to inquire about potential questions and concerns?

6.9.2. Will the consent form and other participant materials be translated into a language understandable to the participant? Yes ☐ No ☐

If no, explain why the materials will not be translated and how you made this determination.

6.9.3. List the language(s) (other than English) in which the research will be conducted.

6.9.4. How you will obtain translations of your study materials.

- How will you ensure the translations are accurate and appropriate?
- How you will provide interpretation during the consent process and throughout the study, including the qualifications of the interpreter(s)?

Waiver or Alteration of Consent Process: *if consent will not be obtained, required information will not be disclosed, or the research involves deception, complete the following Waiver or Alteration of Consent.*

In order to receive a waiver of some or all elements of consent the research must meet ALL of the following federal criteria:	**Yes**	**No**
The research involves no more than minimal risk to the participants	☐	☐
The waiver or alteration will not adversely affect the rights and welfare of the participants	☐	☐
The research could not practicably be carried out without the waiver or alteration	☐	☐
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	☐	☐

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Whenever appropriate, the participants will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information.	☐	☐
Provide the justification/rationale to explain why this study meets ALL the above criteria for waiving or altering consent:		

Waiver of Documentation of Consent Process: *if a consent form will be provided but the participant or LAR will not provide a signature, complete the following Waiver of Written Documentation Consent:*

Criteria to obtain waiver of documentation of consent: at least one criterion must be checked Yes.	**Yes**	**No**
Criteria 1: The only record linking the participant and the research would be the informed consent and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant or legally authorized representative will be asked whether the participant wants documentation linking the participant to the research and the participant's wishes will govern.	☐	☐
Criteria 2: The research presents no more than minimal risk of harm to the participants and involves no procedures for which written consent is normally required outside the research context;	☐	☐
Criteria 3: If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants and there is an appropriate alternative mechanism for documenting that informed consent was obtained.	☐	☐
Provide the justification/rationale to explain why this study meets ANY ONE of the above criteria for waiving or altering documentation of consent:		

7. Study Timelines

7.1. Describe the duration of an individual's participation in the study.

7.2. What is the expected length of time to enroll all study participants?

7.3. What is the estimated length of time to complete the study?

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8. Risks to Participants

8.1. What are the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participation in the research. Consider physical, psychological, social, legal, and economic risks and whether these risks are greater for some portions of the population being recruited than others.

8.2. How will risks be minimized, mitigated, and/or equalized?

8.3. Are there risks to others (third parties) who are not subjects? Yes ☐ No ☐

If yes,

8.3.1. What are the risks (e.g., loss of data, loss of privacy, genetic risk to subjects' families)?

8.3.2. How will the risk to others be addressed?

9. Benefits to Participants

Note that payment(s) and/or reimbursement of costs should not be listed as a benefit.

9.1. Are there any direct benefit(s) to the participant? Yes ☐ No ☐

If yes, what are the benefits? Consider physical, psychological, social, legal, and economic benefits.

9.2. Describe any potential benefit(s) to society that may be reasonably expected as a result from this study.

10. Compensation for Research-Related Injury

10.1. If the research involves more than Minimal Risk to participants, is compensation available in the event of research related injury.

☐ Yes

☐ No

☐ N/A

If yes,

10.1.1. Describe the compensation.

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10.1.2. Provide a copy of contract language relevant to compensation for research-related injury.

11. Study Endpoints

Definition: Study endpoint is a highly favorable or unfavorable result that requires the study to be suspended and re-evaluated as to whether the study can continue or should be terminated before its planned completion.

11.1. Describe all study endpoints.

11.2. Describe all safety endpoints.

12. Provisions to Monitor the Data to Ensure the Safety of Participants

Data monitoring is often used in biomedical and pharmaceutical studies for early detection of harm or benefit during the study period. It may be used for any study in which there are significant concerns about participant safety or well-being. Sponsors or IRBs may require data monitoring.

12.1. Will the study use data monitoring to ensure the safety of participants?

Yes ☐ No ☐

If yes,

12.1.1. What is the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe?

12.1.2. What data will be reviewed, including safety data, untoward events, and efficacy data?

12.1.3. How will the safety information be collected (e.g., with case report forms, at study visits, by telephone calls with participants)?

12.1.4. What will be the frequency of data collection, including when safety data collection starts?

12.1.5. Who will review the data?

12.1.6. What will be the frequency or periodicity of review of cumulative data?

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12.1.7. What statistical tests will be used to analyze the safety data to determine whether harm is occurring?

12.1.8. How will you ensure that those statistical tests sufficiently identify potential harms in the entire subject population rather than only a subset?

12.1.9. What conditions would trigger an immediate suspension of the research?

12.2. Is your Organization contracting or using a funding agreement with Sponsors or clinical research organizations? Yes ☐ No ☐

13. Withdrawal of Participants

13.1. Under what circumstances will participants be withdrawn from the research without their consent?

13.1.1. How will this be communicated to the participant?

13.2. What procedures will be followed when participants request to be withdrawn from research?

13.3. What will happen to the data that has already been collected about the participants?

14. Sharing of Results with Participants

14.1. Will results be shared with participants? Yes ☐ No ☐

If yes,

14.1.1. What results will be shared?

14.1.2. With whom will the results be shared?

14.1.3. How will the results be shared?

15. Data and Specimen Banking for Future Use

15.1. Will data be banked for future use? Yes ☐ No ☐

If yes,

15.1.1. What data will be stored?

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15.1.2. Where will they be stored?

15.1.3. How long they will be stored?

15.1.4. How will they be accessed?

15.1.5. Who will have access to the data?

15.1.6. Can the data be released to a third party? Yes ☐ No ☐

- Describe the procedures to release data, including:
  - What will be the process to request a release?
  - What approvals will be required for release?
  - Who can obtain data?

15.2. Will specimens be banked for future use? Yes ☐ No ☐

If yes,

15.2.1. What specimens will be stored?

15.2.2. What data will be associated with each specimen?

15.2.3. Where will they be stored?

15.2.4. How long they will be stored?

15.2.5. How will they be accessed?

15.2.6. Who will have access to the specimens?

15.2.7. Can the specimens be released to a third party? Yes ☐ No ☐

- Describe the procedures to release specimens, including:
  - What the process will be to request a release?
  - What approvals will be required for release?
  - Who can obtain specimens?
  - What data will be provided with each specimen?

16. Provisions to Protect the Privacy Interests of Participants

16.1. Describe the steps that will be taken to protect the participant's privacy interests. "Privacy interest" refers to a person's desire to restrict who they interact or to whom they provide personal information.

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16.2. Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.

16.3. Given the intended participant population, are there any cultural or other considerations that will impact your approach?

17. Multi-Site Research

17.1. Is this a Multi-site study? Yes ☐ No ☐

If yes,

17.1.1. List the name of each participating institution.

17.1.2. Describe the steps being taken at all participating sites to ensure that the population recruited is sufficiently representative of the population the research is intended to study.

17.1.3. Which institution will be the IRB of record?

17.1.4. Is an IRB Reliance Agreement in place?

17.1.5. Describe the communication plan between sites including:

- Unanticipated problems involving risks to participants or others,
- Interim results,
- Serious and/or continuing non-compliance, and
- Protocol modifications.

18. References

Provide a list of references for all citations included in the protocol.

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HRP-576

TEMPLATE-Vulnerable Populations - Employees			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-576	6/21/2024	E. White/C. Hautala-Bateman	1 of 3
See HRP-001 for definitions of applicable key terms and acronyms.			

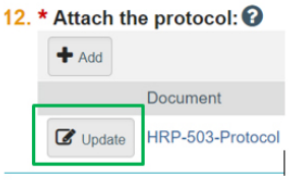
Central Department of Energy Institutional Review Board (CDOEIRB)

FWA 00015568

Human Subjects Research Protocol Application – Research Involving Employees as Participants

INSTRUCTIONS:

- **Add "Controlled Unclassified Information" as applicable. No classified information can be provided on this system.**
- Submit this document with the HPR-503-TEMPLATE-Protocol with Instructions.
- Do NOT leave a question blank; write "N/A" if a question does not apply to the application.
- If you need to make changes to the document already in the electronic system, click on the "Update button" next to the document. Do not upload a track-changed document. See screen shot below:



- Do **NOT** begin data collection prior to IRB approval.

Please fill out the Version number/date and history of a previously approved protocol.

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

IRB Approval Date

HRP-576

TEMPLATE-Vulnerable Populations - Employees			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-576	6/21/2024	E. White/C. Hautala-Bateman	2 of 3
See HRP-001 for definitions of applicable key terms and acronyms.			

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

Protocol Title:

Include the full protocol title.

Principal Investigator:

Name
Department
Telephone Number
Email Address

1. Study Summary

1.1 Why does the participant population include employees, contractors, and/or students? In your explanation be sure to include why other participants would not be suitable. If the researchers will also participate in the research, please address this here too.

1.2 How will participants be recruited from as broad a base of employees or students as possible?

1.3 Will advertisements recruiting participants be distributed across a broad base of employees, contractors, and students? Yes ☐ No ☐

1.4 If not, provide justification.

1.5 Does the use of employees and/or their data pose any risk to them or their employment?

1.6 How will the employee data be maintained?

1.7 How will potential coercion be minimized?

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See HRP-001 for definitions of applicable key terms and acronyms.			

1.8 Will employees who report directly to any member of the research team be eligible to participate in the research study? Yes ☐ No ☐
If yes,

1.8.1 Provide justification.

Note: *Participation of employees who report directly to the research team members should be avoided whenever possible*.

1.9 Will the employees be provided a charge code covering their time while participating in the study? Yes ☐ No ☐
If no,

1.9.1 Explain why.

1.9.2 Will they be covered under the laboratories' worker compensation coverage for any illness or accident during the study?

1.10 Will employees who are members of a union be asked to participate? Yes ☐ No ☐
If yes,

1.10.1 Has the study been discussed with the Union Leadership? Yes ☐ No ☐
If yes,

1.10.1.1 Has Union Leadership discussed with union workers? Yes ☐ No ☐

If yes,

1.10.1.1.1 Provide documentation of discussion with union workers if available.

If no,

1.10.1.2 Why not?

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Appendix E

Acronyms and Abbreviations

ANL	Argonne National Laboratory
BER	Biological and Environmental Research Program
BSEC	Baltimore Social-Environmental Collaborative UIFL
CalFlexHub	California Load Flexibility Research and Deployment Hub
CBPR	community-based participatory research
CITI	Collaborative Institutional Training Initiative
CROCUS	Community Research on Climate and Urban Science UIFL
DUA	data use agreement
DERs	distributed energy resources
DOE	U.S. Department of Energy
DTA	data transfer agreement
EPIC	Electric Program Investment Charge
EV	electric vehicle
FHA	Federal Housing Administration
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HSPP	Human Subjects Protection Program
HSR	human subjects research
HSRD	Human Subjects Research Database
HVAC	heating, ventilation, and air conditioning
ICE	Interruption Cost Estimate
INL	Idaho National Laboratory
IRB	institutional review board
LANL	Los Alamos National Laboratory
LBNL	Lawrence Berkeley National Laboratory
MHE	modifications of the human environment
NIST	National Institute of Standards and Technology
NNSA	National Nuclear Security Administration
NSF	National Science Foundation
OHRP	Office for Human Research Protections
OMB	U.S. Office of Management and Budget
ORNL	Oak Ridge National Laboratory
PFCs	perfluorocarbons
PII	personally identifiable information
PNNL	Pacific Northwest National Laboratory
PRA	Paperwork Reduction Act
SETx	Southeast Texas UIFL
SME	subject matter expert
SW-IFL	Southwest IFL
UIFL	urban integrated field laboratory
WCEC	University of California–Davis Western Cooling Efficiency Center