WHAT IS AN INSTITUTIONAL REVIEW BOARD?

An IRB is an interdisciplinary ethics board responsible for ensuring that:

- The proposed research is sound and justifies the use of human subjects;
- The potential risks to human subjects have been minimized;
- Participation is voluntary; and
- Clear and accurate information about the study, the benefits and risks of participating, and how individuals' data will be protected/used, is provided to potential participants for their use in determining whether or not to participate.

You must have IRB approval before beginning any research involving human subjects. If the research continues, you must submit an annual update or continuing review application to the IRB at least once a year.

Any proposed changes to an approved protocol must be reviewed and approved by the IRB before they can be implemented.

If unanticipated problems or adverse events occur, including any harm, physical injury, or economic loss to research subjects, or improper disclosure of private information, or any other harmful or potentially harmful occurrence—you must notify the IRB.

HOW LONG WILL IRB REVIEW TAKE?

Turn-around time is dependent on the type of review, level of risk, and how quickly you get your paperwork and any requested edits completed.

WHAT RULES APPLY?

Federal regulations and U.S. Department of Energy (DOE) directives to protect human subjects apply if your research is conducted using DOE funding, facilities, or personnel, or if your research includes as participants DOE employees or contractors or their identified information.

The DOE Under Secretary for Science and Innovation, in consultation with the National Nuclear Security Administration (NNSA), monitors implementation of 10 CFR 745 within DOE, in accordance with DOE Order 443.1C.

Together, these organizations determine what constitutes DOE-related human subject research.

As defined in 10 CFR Part 745, "research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. "Human Subject" means a living individual about whom an investigator conducting research

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.

DOE O 443.1C defines "generalizable" to mean: "Information/research findings that are intended to be applied to populations or situations beyond that studied/will have meaning and impact outside of the single immediate activity itself."

Department of Energy
Human Subjects Protection Program
1000 Independence Ave SW Washington, DC 20585
301.903.7693 / 202.586.1444
DL-DOEHSPP@hq.doe.gov
https://science.osti.gov/ber/human-subjects

National Nuclear Security Administration

PROTECTING HUMAN SUBJECTS

WILL YOUR STUDY INVOLVE HUMAN SUBJECTS RESEARCH?

It's more than you think!

Version Date - April 16, 2024

WHAT IS HUMAN SUBJECTS RESEARCH (HSR)?

Just because you aren't performing medical research doesn't mean it isn't HSR. The DOE and federal requirements to protect human subjects apply to a broad range of work. If your research involves:

- An individual's personal information, even if the information was not collected specifically for the study in question;
- Use of datasets obtained from social media sites or elsewhere on the internet;
- Generalizable information, when collected through intervention or interaction (including surveys) with individuals;
- Tissue, specimens, or bodily materials (e.g., hair & fingernail clippings, or a single blood drop);
- Use of humans in the testing of energy technologies, devices, products, or materials developed through research; or to investigate human-machine interaction or evaluate environmental alterations;
- Use of humans or their data to investigate Artificial Intelligence, Machine Learning, or other tools or techniques developed through research (e.g., virtual reality or biometric identification techniques).

Contact Your HSR Office or Institutional Review Board (IRB) Representative to discuss planned research.

ENGAGING WITH HUMAN SUBJECTS

The human subjects in your project should only participate if they are doing so willingly, having been adequately informed about the research. They are volunteers. Vulnerable popula-tions, such as prisoners or children, require special protections. DOE O 443.1C requires protections for DOE/NNSA federal and/or contractor employees who become human subjects of research as they may be subject to coercion or undue influence.

For more information on vulnerable populations, consult the Office of Human Research Protection (OHRP) web page on "vulnerable populations."

Ensure the populations you are recruiting from are representative of those whom the study is intended to impact and that your recruitment materials and processes are appropriate for those populations. Similarly, the consent documents and processes should be designed so that they are easily understandable.

To locate IRB contacts for your DOE Institution…
Visit https://science.osti.gov/ber/human-subjects/IRBs.

If your DOE Institution has no IRB...
Contact the DOE Human Subjects Protection Program for guidance and direction (DL-DOEHSPP@hq.doe.gov).

ESSENTIALS OF INFORMED CONSENT

Voluntary participation means that subjects have enough information to give true informed consent. This includes:

- Purpose of the research.
- All foreseeable risks or discomforts to the subject. Note that these include not only physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- Benefits of the research to the individual subject and/or to society
- Length of time subject is expected to participate.
- Person to contact for answers to questions, or in the event of a research-related injury or emergency.
- Statement that participation is voluntary and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.
- Subjects' right to withdraw from the study at anytime without consequence.
- Payment for participation should be considered (dependent on the research project).