

**Guidance: Additional Requirements for Research Supported by the
U.S. Department of Energy (DOE)
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1. Introduction

DOE has adopted the Common Rule at [10 CFR 745](#) and has published additional requirements for research it supports or conducts as described in [DOE Order DOE O 443.1B](#), Protection of Human Research Subjects and supplemented by [DOE memorandum from the DOE Institutional Official for Human Subjects Research to Laboratory Institutional Officials, April 25, 2013](#). Researchers are responsible for reviewing these documents to understand the applicable requirements and should check with their DOE Program Officer to ensure that all DOE requirements are met prior to beginning research.

2. Special Considerations for DOE-supported Research

2.1 Expansion of Definition of Research with Human Subjects for Research Involving Intentional Modification of the Human Environment

DOE has expanded the definition of human subjects research found at 45 CFR 46 as follows:

- a. Research involving human participants also includes studies that involve the intentional modification of the human environment; generalizable includes the study of tracer chemical, particles, or other materials to characterize airflow.
- b. Generalizable also includes studies in occupied homes or offices that:
 - Manipulate the environment to achieve research aims;
 - Test new materials;
 - 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.

For more information, see [DOE memorandum from the DOE Institutional Official for Human Subjects Research to Laboratory Institutional Officials, April 25, 2013](#).

2.2 IRB Review of Research Involving Expanded Definition

Even if the IRB does not view a project as meeting the literal definition of human subjects research as defined in 45 CFR Part 46, DOE requires initial review of the application and supporting materials by the IRB to determine whether the individuals included in the research will be **properly informed and protected**.

- a. The chair decides the level of review.
- b. The IRB assesses risks associated with the research and whether the individuals to be included in the research will be properly informed and protected.
- c. The chair sends a letter to the researcher indicating that the research has been approved in accordance with DOE expectations and will be monitored and tracked by the IRB.

For more information on this requirement, see [DOE Expectations Regarding Research Involving Intentional Modification of the Human Environment](#).

2.3 Research Involving Personally Identifiable Information (PII)

For research that involves PII, investigators must address the requirements outlined in [the DOE Checklist for Researchers Conducting Human Subjects Research that Utilizes Personally Identifiable Information](#), and the IRB must verify compliance with those requirements in its review of the project in accordance with the [DOE IRB Template for Reviewing Human Subjects Research Protocols that Utilize Personally Identifiable Information \(PII\)](#).

2.4 Notifications to the DOE Human Subjects Protection Manager (HSP)

- a. The HSP should be notified with 48 hours of any:
 - Significant adverse events, unanticipated problems or complaints about the research;
 - Study suspensions or terminations;
 - Significant noncompliance.
- b. The HSP should be immediately notified when there is a breach of PII
For more information, see [DOE O 443.1B, Attachment 1 \(Contractor Requirements Document\)](#).

2.5 Periodic HRPP Self-Assessment

DOE contractors are required to conduct periodic self-assessments to ensure compliance with DOE Human Subjects Protection Program requirements. For more information, see [DOE O 443.1B, Attachment 1 \(Contractor Requirements Document\)](#).

References

[10 CFR 745](#), Protection of Human Subjects

[DOE Order DOE O 443.1B](#), Protection of Human Research

[DOE memorandum from the DOE Institutional Official for Human Subjects Research to Laboratory Institutional Officials, April 25, 2013](#).

From the Department of Energy website: [DOE Expectations Regarding Research Involving Intentional Modification of the Human Environment](#).