

	INVESTIGATOR GUIDANCE: Additional DOE Obligations				
	NUMBER	DATE	Version No.	RESP. AUTHORITY	PAGE
	HRP-411	21SEP2022	001	Assistant/Associate Director, RI	1 of 3

1 PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting Department of Energy (DOE) research.

2 GUIDANCE

- 2.1. DOE-funded or DOE laboratory-managed or conducted projects involving intentional modification of an individual's or a group of individuals' environment must be managed as human subjects research and subject to the requirements of DOE Order 443.1B.

- 2.1.1. Where "generalizable" should be viewed in terms of contribution to knowledge within the specific field of study, this includes:
 - of outside air through new energy-saving ventilation systems.

- 2.1.1.2.2. Test new materials (e.g., sequentially changing the filter materials in the HVAC system while monitoring the effects on air quality and energy use).

- 2.1.1.2.3. 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.

- 2.1.2. Even if the IRB does not view a project as meeting the actual definition of human subjects research as defined in 45CFR46, DOE requires initial review by the IRB of the application and supporting materials to determine whether the individuals included in the research will be properly informed and protected. Adherence to each specific requirement of 45CFR46 is not required in such a case, but DOE does require that:
 - 2.1.2.1. An application and supporting materials be submitted to the IRB;
 - 2.1.2.2. a letter to the PI indicating that the project has been reviewed in accordance with DOE expectations and will be monitored and tracked by the IRB, which means that the PI will:
 - 2.1.2.4.1. Implement any IRB recommendations before the project begins;
 - 2.1.2.4.2. Notify the IRB of any proposed changes to the protocol in the future and ensure IRB review and

INVESTIGATOR GUIDANCE: Additional DOE Obligations				
NUMBER	DATE	Version No.	RESP. AUTHORITY	PAGE
HRP-411	21SEP2022	001	Assistant/Associate Director, RI	2 of 3

authorization to proceed before implementing these changes;

2.1.2.4.3.

Provide an annual update to the IRB; and

2.1.2.4.4.

Follow the notification and reporting requirements in DOE O 443.1B for reporting adverse events, annual update of the DOE HSRD, etc.

- 2.2. Within 48 hours of the following (or within 24 hours if private identifiable information is involved), provide a description of corrective actions taken immediately following the incident, as well as corrective actions to be taken for concurrence by the appropriate DOE HRPP Manager:
 - 2.2.1. Any significant adverse events, unanticipated problems, and complaints about the research,
 - 2.2.2. Any Suspension of IRB Approval or Termination of IRB Approval;
 - 2.2.3. Any significant Noncompliance with HRPP procedures or other requirements, which shall be reported to the IRB for evaluation for further action with the appropriate DOE Human Subject Protection Program Manager
- 2.3. In accordance with the DOE "Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements," your research protocol must include description of processes for:
 - 2.3.1.

INVESTIGATOR GUIDANCE: Additional DOE Obligations				
NUMBER	DATE	Version No.	RESP. AUTHORITY	PAGE
HRP-411	21SEP2022	001	Assistant/Associate Director, RI	3 of 3

the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf)

- 2.3.14. In addition to other reporting requirements, reporting the loss or suspected loss of PII immediately upon discovery to: 1) the DOE Project Officer and 2) the applicable IRBs.

3 REFERENCES

- 3.1. 10 CFR 745
- 3.2. DOE Order 443.1.B
- 3.3. Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements