

Summary of Requirements for Department of Energy (DOE) Supported or Regulated Human Research

Human Research supported by the DOE is subject to additional requirements set forth in [10 CFR 745.103](#), DOE Directive [DOE O 443.1C](#) and ethical standards outlined in the Human Subjects Protection (HSP) Resource Book – [https://science.osti.gov/-/media/ber/human-subjects/pdf/education-and-resources/doe-resources/DOE_HSR_Resource_Book_2012_Update.pdf], and the DOE Requirements for Protecting Personally Identifiable Information [<https://science.energy.gov/ber/human-subjects/regulations-and-requirements/>] M 471.3-1; and DOE M 205.1-8).

As described in the DOE HSP Resource Book, DOE supported research protocols encompass a broad range of medical and scientific technologies from nuclear fission to human biology. Studies may include device testing, tissue testing, medical or exposure records, and categories of subjects such as worker subgroups.

The Principal Investigator (PI) and IRB may refer to the DOE Directive O 443/1C for interpretation of what meets the definition of human subject research relative to DOE sponsored research. In 2013, the DOE issued a memorandum defining when activities that intentionally modify or manipulate human occupied environments require IRB review. This memo applies to the following studies:

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

*Generalizable should be viewed in terms of contribution to knowledge within the field of study.

The PI is responsible for working with designated officials at the DOE such as a Human Subject Protection (HSP) Program manager.

The IRB, when conducting its review, assesses risks associated with the research and whether the individuals to be included in the research will be properly informed and protected. Employees and contractors may be entitled to additional protections as vulnerable subjects. The IRB determines the level of review and notifies the investigator that the research has been approved in accordance with DOE expectations and will be monitored by the IRB.

General DOE Requirements

1. Confidentiality and Data Security

- For DOE supported research utilizing or collecting personally identifiable information (PII) or protected health information (PHI), the investigator completes the [Investigator Checklist for Verification of Compliance with the Department of Energy \(DOE\) Requirements for the Protection of PII/PHI](#). The investigator signs the checklist to indicate understanding and intent to comply with the technical requirements. In general, the IRB uses the information to verify that the investigator has a clear and detailed plan for:
 - protecting PII/PHI including reasonable safeguards to prevent unauthorized use or disclosure;
 - immediate notification of any incident involving potential compromise or loss of PII data;
 - making no further use or disclosure except when approved by the IRB and DOE; and
 - encryption of any data to be transferred.

- PII/PHI transferred from one organization to another as part of a human research project (*when/as authorized by the approving IRBs, the responsible DOE Program Office, and the research/screening participant*) must first be encrypted consistent with PII protection requirements stated in DOE M 205.1-7 using a program as directed by DOE.

- For assistance in complying with technical requirements, the PI may consult departmental Information Technology (IT) personnel or University of Kentucky IT Security personnel [\[https://www.uky.edu/its/it-security-policy\]](https://www.uky.edu/its/it-security-policy).

2. Reporting

- The DOE reporting requirements are more stringent than the University of Kentucky (UK) requirements relative to reporting timelines. In addition to reporting to the UK IRB (using UK reporting forms), the investigator notifies the DOE as follows.

- The notification period for reporting unanticipated problems for loss or compromising of data differs, depending on whether PII/PHI is involved.
 - The investigator notifies the DOE HSP Program Manager immediately, (upon discovery), of a suspected or confirmed data breach involving PII or PHI in printed or electronic form and reported to the DOE-Cyber Incident Response Capability in accordance with the requirements of [DOE O 206.1](#).
 - The investigator informs the DOE HSP Program Manager regarding any corrective actions planned or taken.

- The DOE requires prompt reporting, (within 48 hours), and coordination with, and approval from the HSR Program Manager in determining plans to correct any noncompliance or to deal with unanticipated problems.
 - The investigator notifies the DOE HSP Program Manager in writing within 48 hours, with a description of corrective actions taken, and shall concur on the plan for any remaining corrective actions, following:

- a) significant adverse events, unanticipated problems, and complaints about the research, suspension or termination of IRB approval of research;
 - b) known or potential incidents of noncompliance with requirements of this Order, 10 CFR Part 745, 45 CFR Part 46.
- The PI is also responsible for implementing any IRB or DOE required corrective action.

3. Classified Research

- When conducting classified research, the use of exempt and expedited review is prohibited. The Fact that research meets a particular exemption or expedited category may be noted, but review by a convened IRB is required.
 - When conducting classified research the IRB must have a voting quorum of at least five members, which must include both a non-scientist and a non-affiliated member.
 - The non-affiliated member cannot be a current federal employee or contractor.
 - An IRB member may appeal a vote to approve research to the institutional Official, Secretary of Energy, and Director of the Office of Science and Technology.
- When the research is classified, the IRB must determine if participants need access to classified information to make a valid consent decision.
- Consent documents must include additional DoE elements of disclosure.
 - The identity of the sponsoring agency, unless the sponsor requests that it be done, because doing so could compromise intelligence sources or methods; the research involves no more than minimal risk to participants; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.
 - When research is classified, consent documents must state the project is classified, and what it means for the purposes of the research project.
- When conducting classified research that the IRB may not grant a waiver of consent process or waiver of documentation of consent.

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