THE UNIVERSITY OF ARIZONA Research & Partnerships

Department of Energy (DOE) Research

Background

Human research conducted or funded by the Department of Energy (DOE), must be reviewed by the IRB under DOE-specific requirements outlined in DOE Order 443.1C and 10 CFR Part 745.

All human research conducted or funded by the DOE must comply with the standards outlined below:

1. Protocols must address DOE requirements regarding personally identifiable information (PII). PII collected and/or used during human participant research projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program.
2. Any breach involving PII must be reported **immediately** upon a finding of a suspected or confirmed data breach involving PII in printed, verbal, or electronic form, DOE employees will immediately (within one hour) report the incident to the Local Privacy Act Officers and/or Privacy Points of Contact AND the Integrated Joint Cybersecurity Coordination Center at 866-941-2472 (or via email to circ@jc3.doe.gov); OR through their Departmental Element in accordance with existing cyber incident reporting processes, which have been established in DOE Enterprise or Departmental Element Cybersecurity Program Plans as defined in to DOE O 205.1A, Department of Energy Cyber Security Program.
3. The investigator must report the following within **48 hours** to the Department of Energy human subject research program manager:
    a. Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
    b. Any suspension or termination of IRB approval of research.
    c. Any significant non-compliance with HSPP procedures or other requirements.
4. The DOE Human Subjects Protection (HSP) Program Manager or National Nuclear Security Administration (NNSA) must be notified within **48 hours**, with a description of corrective actions taken, of any known or potential incidents of noncompliance, suspected or confirmed data breach involving PII, suspension of IRB approval, or terminations of IRB approval.
5. The HSP Program Manager at DOE or NNSA must be notified:
    a. Immediately upon learning of a serious adverse event. The HSP Program Manager(s) shall also be informed of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.
    b. Within **48 hours**, with a description of corrective actions taken, of:
        - Unanticipated problems
        - Significant adverse events, and
        - Complaints about the research.
6. Requirements for human participant protections for classified research apply to all research conducted or supported by the DOE, including contracts, and Human Terrain Mapping research.
7. When conducting classified research, the use of exemptions is prohibited. The fact that research meets a particular exemption category may be noted, but review by a convened IRB is required.
8. Requirements for human participant protections and their accompanying Contractor Requirements Documents (CRDs) apply to all research conducted at DOE institutions regardless of funding source, or by DOE employees/contractor personnel regardless of

funding source or location conducted, and whether done domestically or in an international environment, and including Human Terrain Mapping research. DOE workers are considered vulnerable subjects and shall be afforded additional protections as determined by the IRB. Employees and contractors are considered vulnerable participants. A description of additional protections that must be considered by the IRB if additional protections are required for research involving employees and contractors.

9. Classified and unclassified human research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.

Resources

- DOE Human Subjects Protection Regulations: 10 CFR Part 745
- Protection of Human Research Subjects: DOE Order 443.1C
- DOE Privacy Program: DOE O 206.1A
- DOE Human Subjects Protection Website: https://science.osti.gov/ber/human-subjects