



INVESTIGATOR GUIDANCE: Additional DOE Obligations

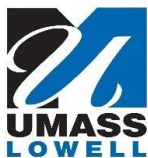
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1. PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting research supported or conducted by DOE.

2. GUIDANCE

- 2.1. No human participant research conducted with DOE funding at DOE institutions (Headquarters or sites/laboratories, regardless of funding source), or by DOE employees and contractor personnel (regardless of funding source or location conducted), and whether done domestically or in an international environment, including classified and proprietary research, shall be initiated without both a Federalwide Assurance and approval by the cognizant IRB in accordance with 10 CFR Part 745.103.
- 2.2. 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.
- 2.3. The IRB considers DOE workers (employees and contractors) to be vulnerable subjects.
- 2.4. Within 48 hours (or immediately upon discovery, if private identifiable information is involved), report to the IRB:
 - 2.4.1. Any significant adverse events, unanticipated problems, and complaints about the research,
 - 2.4.2. Any <Suspension of IRB Approval> <Termination of IRB Approval>;
 - 2.4.3. 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
- 2.5. In accordance with the DOE "Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements," the protocol must comply with the DOE requirements for protecting personally identifiable information (PII). Specifically, the protocol must include a description of processes for:
 - 2.5.1. Keeping private identifiable information confidential
 - 2.5.2. Releasing private identifiable information only under a procedure approved by the responsible IRB(s) and DOE, where required
 - 2.5.3. Using private identifiable information only for purposes of the DOE-approved research
 - 2.5.4. Handling and marking documents containing private identifiable information as "containing private identifiable information" or "containing protected health information"
 - 2.5.5. Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of private identifiable information
 - 2.5.6. Making no further use or disclosure of the private identifiable information except when approved by the responsible IRB and DOE, where applicable, and then only:
 - 2.5.6.1. In an emergency affecting the health or safety of any individual
 - 2.5.6.2. For use in another research project under these same conditions and with DOE written authorization
 - 2.5.6.3. For disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project or when required by law.
 - 2.5.7. Protecting private identifiable information data stored on removable media using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified



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- 2.5.8. Using FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1
- 2.5.9. Shipping removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped via express overnight service
- 2.5.10. Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products
- 2.5.11. Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter
- 2.5.12. Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII
 - 2.5.12.1. Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: https://www.gpo.gov/fdsysqpopages/pdfs/authentication/SP800-63V1_0_2.pdf)
 - 2.5.12.2. In addition to other reporting requirements, reporting the loss or suspected loss of PII immediately (within 5 business days) upon discovery to: 1) the DOE Project Officer and 2) the applicable IRBs.
- 2.5.13. For research conducted at a DOE facility, the DOE Institutional Official is responsible for:
 - 2.5.13.1. Ensuring the Central DOE Review Board and the Central DOE Institutional Review Board-Classified comply with applicable requirements.
 - 2.5.13.2. Formally appointing the chair, vice-chair, and other IRB members
 - 2.5.13.3. Approving classified research conducted with DOE funding at its sites/laboratories and by its employees and contractors after IRB approval and prior to initiation.
- 2.6. When conducting classified research:
 - 2.6.1. Requirements for human participant protections for classified research apply to all research conducted or supported by the DOE, including contracts, and including Human Terrain Mapping research.
 - 2.6.2. The following are prohibited:
 - 2.6.2.1. Use of exemptions
 - 2.6.2.2. Use of the expedited review procedure
 - 2.6.2.3. Waiver of the consent process
 - 2.6.2.4. Waiver of documentation of consent
 - 2.6.3. Any IRB member can appeal a vote to approve research to the Institutional Official, Secretary of Energy, and Director of the Office of Science and Technology, in that order.
 - 2.6.4. In accordance with the DOE "Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements," the protocol must comply with the DOE requirements for protecting personally identifiable information (PII). (see above)
 - 2.6.5. The IRB will determine if participants need access to classified information to make a valid consent decision.
 - 2.6.6. Consent documents must include additional DOE elements of disclosure:
 - 2.6.6.1. The identity of the sponsoring agency, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods; the research involves no more than minimal risk to



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participants; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.

- 2.6.6.2. When research is classified, consent documents must state the project is classified, and what it means for the purposes of the research project
- 2.7. For research conducted at a DOE facility, the DOE Institutional Official is responsible for:
 - 2.7.1. Ensuring the Central DOE Review Board and the Central DOE Institutional Review Board-Classified comply with applicable requirements.
 - 2.7.2. Formally appointing the chair, vice-chair, and other IRB members.
 - 2.7.3. Approving classified research conducted with DOE funding at its sites/laboratories and by its employees and contractors after IRB approval and prior to initiation.
- 2.8. For research conducted at a DOE facility, the DOE Human Subjects Protection Program Manager is responsible for:
 - 2.8.1. Developing procedures for the classified research program in consultation with the National Nuclear Safety Administration Human Subject Protection Program Manager.
 - 2.8.2. Conducting biennial performance reviews of all IRBs that review classified research involving human participants to assess compliance, in consultation with the National Nuclear Security Administration HRPP manager.
 - 2.8.3. Reviewing and approving local plans to correct noncompliance or mitigate adverse events and unanticipated problems involving risks to participants or others.
 - 2.8.4. Reviewing and approving statements of work for classified Human Terrain Mapping projects submitted by DOE's non-National Nuclear Security Administration sites or projects.
 - 2.8.5. Making recommendations to the Secretary after concurrence from the organizational Official, on a project by project basis, regarding exemptions from the requirements for classified research.
 - 2.8.6. Concurring on human participant provisions for classified research in interagency agreements, in consultation with the National Nuclear Security Administration, as appropriate.
 - 2.8.7. Maintaining an unclassified list of classified projects.
- 2.9. The organization periodically conducts self-assessments to ensure compliance with the HRPP procedures and other requirements.

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](#)