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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. 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:
    - 2.1.1.1. 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.
    - 2.1.1.2. Studies in occupied homes and/or offices that:
      - 2.1.1.2.1. Manipulate the environment to achieve research aims, e.g., increasing humidity and/or reducing influx 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 literal definition of human subjects research as defined in 45 CFR Part 46, 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 45 CFR Part 46 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. The Chair decide the level of review;
    - 2.1.2.3. During the review, the IRB assess risks associated with the research and whether the individuals to be included in such research will be properly informed and protected. SMEs should be used, as needed, in assessing risks and in determining whether risks have been mitigated to the extent practicable (to minimal risk).
    - 2.1.2.4. After the review, the Chair send 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

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- 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> <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. Keeping private identifiable information confidential
  - 2.3.2. Releasing private identifiable information only under a procedure approved by the responsible IRB(s) and DOE, where required
  - 2.3.3. Using private identifiable information only for purposes of the DOE-approved research
  - 2.3.4. Handling and marking documents containing private identifiable information as “containing private identifiable information” or “containing protected health information”
  - 2.3.5. Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of private identifiable information
  - 2.3.6. 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:
    - 2.3.6.1. In an emergency affecting the health or safety of any individual
    - 2.3.6.2. For use in another research project under these same conditions and with DOE written authorization
    - 2.3.6.3. 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.
  - 2.3.7. Protecting private identifiable information data stored on removable media using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified
  - 2.3.8. Using FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1
  - 2.3.9. 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
  - 2.3.10. Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products
  - 2.3.11. 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
  - 2.3.12. Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII
  - 2.3.13. Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in

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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](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 (within 5 business days) 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