1. PURPOSE
   1. This guidance outlines the additional obligations of investigators conducting DOE research.
2. GUIDANCE
   1. 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:
      1. Any significant adverse events, unanticipated problems, and complaints about the research,
      2. Any Suspension of IRB Approval Termination of IRB Approval;
      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. 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:
      1. Keeping private identifiable information confidential
      2. Releasing private identifiable information only under a procedure approved by the responsible IRB(s) and DOE, where required
      3. Using private identifiable information only for purposes of the DOE-approved research
      4. Handling and marking documents containing private identifiable information as “containing private identifiable information” or “containing protected health information”
      5. Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of private identifiable information
      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:
         1. In an emergency affecting the health or safety of any individual
         2. For use in another research project under these same conditions and with DOE written authorization
         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.
      7. Protecting private identifiable information data stored on removable media using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified
      8. Using FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1
      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
      10. Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products
      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
      12. Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII
      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 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>)
      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
   1. 10 CFR 745
   2. DOE Order 443.1.B
   3. Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements