

1 **HRPP Document: GUI338**

2 **Effective Date: 3/10/10**

3 **Revision Dates:**

4 **Subject: DOE Guidance: Department of Energy (DOE) Requirements for DOE-**
5 **Sponsored Protocols**

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7 Regulations and directives that specifically address the protection of human subjects include 10 CFR
8 Part 745; 45 CFR Part 46, Subparts B, C, and D; Department of Health and Human Services Regulation on
9 Protection of Human Subjects; and DOE O 443.1A, Protection of Human Subjects, dated 12-20-07. The
10 requirements of all applicable regulations and directives must be met before any research involving human
11 subjects is initiated.

12 In addition to traditional biomedical and clinical studies, the DOE considers human subjects research
13 to include but is not limited to studies that:

- 14 • use humans to examine devices, products, or materials with the express purpose of investigating
15 human-machine interfaces or evaluating environmental alterations when humans are the subjects
16 being tested;
- 17 • use personally identifiable bodily materials such as cells, blood, tissues, urine, or hair, even if the
18 materials were collected previously for a purpose other than the current research;
- 19 • collect and use personally identifiable information such as genetic information or medical and
20 exposure records, even if the information was collected previously for a purpose other than the
21 current research;
- 22 • collect personally identifiable data, surveys, or questionnaires through direct intervention or
23 interaction with individuals; and
- 24 • search for generalizable knowledge about categories or classes of subjects (e.g., linking job
25 conditions of worker populations to hazardous or adverse health outcomes).

26 The DOE does not consider the following human subject research:

- 27 • studies to improve the safety or execution of procedures that apply to routine occupational
28 activities;
- 29 • occupational health surveillance of DOE Federal and contractor employees to determine apparent
30 departures from typical health status and not for the purpose of obtaining generalizable knowledge;
31 and
- 32 • employee surveys used as management tools to improve worker or contractor performance as long
33 as the identity of the participant is protected.

34 Research protocols must include a description of processes for:

- 35 • Keeping (Personally Identifiable Information) PII confidential;

- 36 • Releasing PII only under a procedure approved by the IRB and DOE, where required;
- 37 • Using PPII only for purposes of the DOE-approved research and/or EEOICPA;
- 38 • Handling and marking documents containing PII
- 39 • Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized
40 use or disclose of PII;
- 41 • Marking no further use or disclose of the PII except when approved by the IRB and DOE, where
42 applicable, and then only:
 - 43 ○ In an emergency affecting the health or safety of any individual;
 - 44 ○ For use in another research project under these same conditions and with (Department of
45 Energy) DOE written authorization;
 - 46 ○ For disclosure to a person authorized by the DOE program office for the purpose of an audit
47 related to the project; or
 - 48 ○ When required by law.
- 49 • Protecting PII data stored on removable media (CD, DVD, Flash Drives, etc.) using encryption
50 products that are Federal Information Processing Standards (FIPS) 140-2 certified;
- 51 • Using FIPS certified encryption that meet the current DOE password requirements cited in DOE
52 Guide 205.3-1;
- 53 • Shipping removable media containing PII, as required, by express overnight service with signature
54 and tracking capability, and shipping hard copy documents double wrapped via express overnight
55 service;
- 56 • Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified
57 encryption products;
- 58 • Sending passwords that are used to encrypt data files containing PII separately from the encrypted
59 data file, i.e. separate e-mail, telephone call, separate letter;
- 60 • Using FIPS certified encryption methods for web sites established for the submission of
61 information containing PII;
- 62 • Using two-factor authentication for logon access control for remote access to systems and database
63 that contain PII (http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf);
- 64 • Reporting the loss or suspected loss of PII immediately upon discovery to:
 - 65 ○ The DOE Project Officer; and
 - 66 ○ IRB

67 DOE Order 443.1A requires prompt reporting to the DOE HSR Program Manager, and coordination
68 with and approval from the HSR Program Managers in determining plans to correct the unanticipated
69 problem. While DOE 443.1A does not define “prompt,” they request that the HSR Program Manager(s) be
70 notified within 48 hours of learning of any unanticipated problem that does not involve personally
71 identifiable information (PII). However, if potential loss or compromise of personally identifiable

72 information is involved, the incident should be reported immediately (as soon as you learn about the
73 incident) to the Departmental Element; the DOE Cyber Incident Response Capability a
74 doecirc@doecirc.energy.gov or 8660941-2472 and to the DOE HSR Program Manager(s).

75 References:

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77 10 CFR 745 – “Protection of Human Subjects”

78 Checklist for IRBs to Use in Verifying that HS Research Protocols are in Compliance with DOE
79 Requirements

80 HQ Expectations of DOE Site IRBs- “Reporting Unanticipated Problems and Review/Approval of Projects
81 that Use Personally Identifiable Information” – May 7, 2009

82 DOE Order 443.1A