

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2014-031.0
Policy Title: Additional Requirements – Department of Energy (DOE)

Purpose

The purpose of this policy is to set forth additional requirements that are applicable to research supported by the Department of Energy.

Definitions

Policy

When the institution receives funding from the Department of Energy, the institution must periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements. This self-assessment is addressed through the Compliance Monitoring Program (Policy 2009-005.0 Monitoring of IRB Approved Studies) and the annual evaluation of the Human Subjects Protection Office (Policy 2011-025.0 HSPP Authority, Support and Evaluation).

The Principal Investigator must complete and submit, and the IRB must review and approve, Appendix I, the DOE Checklist for Investigators Conducting / IRBs Reviewing Human Subject Research that utilizes personally identifiable information). This form is used to verify that protocols are in compliance with DOE requirements.

The Principal investigator must also acknowledge on Appendix I that s/he will ensure compliance with the following reporting requirements:

- Prompt reporting (i.e. within 48 hours) of the following to the human subject research program manager and IRB:
 - Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
 - Any suspension or termination of IRB approval of research.
 - Any significant non-compliance with HRPP procedures or other requirements.
- Immediate reporting (i.e. within 24 hours) of any compromise of personally identifiable information to the human subject research program manager and IRB.

Procedure

The Principal investigator must complete and submit Appendix I which address DOE requirements.

The IRB must review and approve Appendix I.

Related Policies

2009-005.0 – Monitoring of IRB Approved Studies
2011-009.3 - Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board - Review by Convened Board
2011-009.12 – Institutional Review Board – Criteria for Approval
2011-025.0 – HSPP Authority, Support and Evaluation

Basis –

Department of Energy 443.1B

Document Attributes

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Reviewed and Approved By:

Richard H. Simon

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**Richard H. Simon, MD,
Director Human Subjects Protection Program**

Date