

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.

Classified Research: The following additional criteria apply to classified research:

- Classified research shall not be implemented without IRB approval, followed by approval by the DOE Institutional Official (IO).
- Consent may not be waived.
- Research may not be exempt, nor may the expedited review process be used.
- The identity of the sponsoring Federal agency will be disclosed to subjects, 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 subjects; and the IRB determines that by not disclosing the identity the investigators will not adversely affect subjects.
- The informed consent will state that the research is classified and what that means for the purposes of that project

- The IRB must have a voting quorum of at least five members which must include a non-scientist and an unaffiliated member.
- The unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor.
- An IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, and Director of the Office of Science and Technology Policy (OSTP) in that order.
- The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision.

An IRB that believes that a project that is classified, in whole or in part, can be thoroughly reviewed in an unclassified manner, can submit a request for a waiver of the above requirements for the purposes of that study by submitting the DOE Request for Waiver form to the appropriate DOE or National Nuclear Security Administration HSP program Manager

Procedure

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

The IRB must review and approve Appendix I.

The IRB agenda and reviewer form instruct IRB staff/members to refer this policy to ensure additional criteria for classified research are met.

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 – HSP Authority, Support and Evaluation

Basis –

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Document Attributes

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Reviewed and Approved By:

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Date