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

DOE requirements apply to all research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research.

- When research involves contractors, DOE "Contractor Requirements Document" describing contractor responsibilities for protecting human research subjects must be included in contracts.
- Research that uses social media data must be submitted to the IRB for human subject research review and determination. (DOE O 443.1C, Section 4(a)(5))
- Research that involves the study of humans in a systematically modified environment must be submitted to the IRB for review and determination.
- Classified and unclassified human subject research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.
- UConn Health does not engage in Human Terrain Mapping (HTM) research.

When the institution receives funding from the Department of Energy, the institution must periodically conduct self-assessments to ensure compliance with the HSPP 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 they 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 HSPP 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.

Vulnerable Populations: DOE and DOE site contractors are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team), and that data collected about them is kept confidential. When research proposes to involve DOE employees or site contractors, the IRB will consider if additional protections are required for the research.

Multisite Research: Research involving human subjects involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, unless review by another appropriate IRB of record is authorized by the DOE and/or NNSA HSP Program Manager. If authorized by the DOE and/or NNSA HSP Program Manager, research may be reviewed by other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the human subject research and the organization responsible for IRB review.

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
- Informed consent may only be waived for classified research if the work meets one of the categories of the minimal risk human subject research addressed at 10 CFR Part 745.104.
- 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.

The Investigator will notify the HSP Program Manager at DOE or NNSA immediately upon learning of a serious adverse event. The HSP Program Manager(s) shall also be informed of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.

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 – HSPP Authority, Support and Evaluation

Basis –

Department of Energy 443.1B
Department of Energy – N 443.1

Document Attributes

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Reviewed and Approved By:

Richard H. Simon *11/01/2023*

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