



AAHRPP®

Association for the Accreditation of
Human Research Protection Programs, Inc.®

Department of Energy Revisions to
DOE O 443.1C

General Overview

This document lists the Standards and Elements where the US Department of Energy (DOE) requires additional protections. DOE requirements also apply to DOE's semi-autonomous National Nuclear Security Administration (NNSA).

DOE follows the Nuremberg Code, Belmont Report, and the Common Rule, including Subparts B, C, D, and E, except where noted below. Organizations following the Common Rule must meet all the Essential AAHRPP requirements and Common Rule requirements described under DHHS regulations in the Evaluation Instrument (except where DOE makes exceptions or has additional requirements, noted below).

The additional protections described below are focused on those most applicable to organizations engaged in research conducted with or supported by DOE, such as universities with DOE research funding. (Note: For DOE facilities there are additional requirements not described here.)

DOE also follows FDA regulations; FDA requirements are noted under FDA regulations described in the Evaluation Instrument.

This document summarizes DOE requirements based on:

- 10 CFR 745 (Common Rule)
- DOE O 443.1C Protection of Human Research Subjects (November 2019)
- Presidential Memorandum, Strengthened Protections for Human Subjects of Classified Research (March 27, 1997)
- Executive Order 12333 codified at 50 CFR Parts 2406 and 2511 (Regarding classified research involving human participants).

Underlined text indicates new requirements or revisions to requirements in the Evaluation Instrument.

~~Strikethrough~~ text indicates previously included information in the Evaluation Instrument that are no longer required under DOE O 443.1C or revised Common Rule (32 CFR 219).

Domain I: Organization

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program with appropriate leadership.

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.

- (4) When following DOE requirements (DOE O 443.1C Section (a):
(a) 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.

(i) When research involves contractors, DOE “Contractor Requirements Document” describing contractor responsibilities for protecting human research participants must be included in contracts.

(ii) Policies and procedures must specify whether the organization conducts classified research.

~~(a) Requirements for human participant protections for classified research apply to all research conducted or supported by the DOE, including contracts, and including Human Terrain Mapping research.~~

~~DOE workers are considered vulnerable subjects and shall be afforded additional protections as determined by the IRB. (Duplicate - moved to Element II.4.A.)~~

~~(b) Requirements for human participant protections and their accompanying Contractor Requirements Documents (CRDs) apply to all research conducted at DOE institutions regardless of funding source, or by DOE employees/contractor personnel regardless of funding source or location conducted, and whether done domestically or in an international environment, and including Human Terrain Mapping research.~~

(b) Research that uses social media data must be submitted to the appropriate IRB for human participant research review and determination. (DOE O 443.1C, Section 4(a)(5))

(c) Research that involves the study of humans in a systematically modified environment must be submitted to the appropriate IRB for HSR review and determination. (DOE O 443.1C, Section 4(a)(6))

(d) Classified and unclassified human participant research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified. (DOE O 443.1C, Section 4(a)(7))

(e) Human Terrain Mapping (HTM) is managed as research involving human participants. (DOE O 443.1C, Section 4(a)(12))

(i) Policies and procedures must specify whether the organization engages in DOE human terrain mapping research.

Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.

(2) When following DOE requirements (DOE O 443.1C Section (a):

(a) No human participant research conducted with DOE funding, at DOE institutions (Headquarters or sites/laboratories, regardless of funding source), or by DOE employees and or DOE contractor personnel (regardless of funding source or location conducted), and whether done domestically or in an international environment, including classified and proprietary research, shall may be initiated without both a Federalwide Assurance (FWA) or comparable

assurance (e.g., Department of Defense assurance) and approval by the cognizant IRB in accordance with 10 CFR Part 745.103.

~~(b) For research conducted at a DOE facility, the DOE Institutional Official is responsible for:~~

- ~~(i) Ensuring the Central DOE Review Board and the Central DOE Institutional Review Board Classified comply with applicable requirements.~~
- ~~(ii) Formally appointing the chair, vice chair, and other IRB members.~~
- ~~(iii) Approving classified research conducted with DOE funding at its sites/laboratories and by its employees and contractors after IRB approval and prior to initiation.~~

~~(c) For research conducted at a DOE facility, the DOE Human Subjects Protection Program Manager is responsible for:~~

- ~~(i) Developing procedures for the classified research program in consultation with the National Nuclear Security Administration Human Subject Protection Program Manager.~~
- ~~(ii) Conducting biennial performance reviews of all IRBs that review classified research involving human participants to assess compliance, in consultation with the National Nuclear Security Administration human participant protection program manager.~~
- ~~(iii) Reviewing and approving local plans to correct noncompliance or mitigate adverse events and unanticipated problems involving risks to participants or others.~~
- ~~(iv) Reviewing and approving statements of work for classified Human Terrain Mapping projects submitted by DOE's non-National Nuclear Security Administration sites or projects.~~
- ~~(v) Making recommendations to the Secretary after concurrence from the organizational Official, on a project by project basis, regarding exemptions from the requirements for classified research.~~
- ~~(vi) Concurring on human participant provisions for classified research in interagency agreements, in consultation with the National Nuclear Security Administration, as appropriate.~~
- ~~(vii) Maintaining an unclassified list of classified projects.~~

(b) The Human Subjects Protection (HSP) Program Manager (and when an NNSA element is involved, the NNSA HSP Program Manager) must be notified in writing prior to initiation of the HSR portion of a new project, even if it meets the regulatory definition of exempt HSR as outlined in 10 CFR Part 745.104, that involves (DOE 0 443.1C, section 4(d)):

- (i) An institution without an established IRB.
- (ii) A foreign country.
- (iii) A potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups).
- (iv) Research subjects in a protected class (prisoners, children, individuals with impaired decision making, or DOE/NNSA federal or

DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope.
(v) The generation or use of classified information.

Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

Element I.5.A. The Organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization makes improvements to increase compliance, when necessary.

~~(3) When following DOE requirements:~~

~~(a) The organization must periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements.~~

Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The Organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

(4) When following DOE requirements (DOE O 443.1C Section 4(d):

(a) The HSP Program Manager at DOE or NNSA must be notified within 48 hours, with a description of corrective actions taken, of any known or potential incidents of noncompliance.

Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization the rights and welfare of research participants are protected.

When following DOE requirements:

When serving as the IRB or EC for another organization:

(3) When following DOE requirements (DOE O 443.1C, section 4(a)(3, 4))

(a) Research involving human participants 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.

(b) 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 HSR and the organization responsible for IRB review.

Domain II: Institutional Review Board or Ethics Committee

Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.B. The IRB or EC has and follows written policies and procedures for addressing protection of participants in research that is exempt from applicable laws and regulations. These functions may be delegated to an entity other than the IRB or EC.

(3) When following DOE requirements (DOE O 443.1C Section 4(a)(14):

(a) When conducting or reviewing classified research, exemptions (as per 10 CFR Part 745.104) will not be used. The fact that research meets a particular exemption category may be noted, but review by a convened IRB is required.

Element II.2.D. The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.

~~(2) When following DOE requirements:~~

- ~~(a) When conducting classified research, the IRB must have a voting quorum of at least five members, which must include both a non-scientist and a non-affiliated member.~~
- ~~(b) The non-affiliated member must be a non-governmental member with the appropriate security clearances. This individual cannot be a current federal employee or contractor.~~
- ~~(c) Any IRB member can appeal a vote to approve research to the Institutional Official, Secretary of Energy, and Director of the Office of Science and Technology, in that order.~~

Element II.2.F.1. – Initial review

Element II.2.F.2. – Continuing review

Element II.2.F.3. – Review of proposed modifications to previously approved research

~~(6)(4) When following DOE requirements (DOE 443.1C, Section 4(a)(14):~~

~~(a) When conducting or reviewing classified research, the use of the expedited review procedure is prohibited. The fact that research meets a particular expedited category may be noted, but review by a convened IRB is required.~~

Element II.2.G. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.

- (4) When following DOE requirements (DOE O 443.1C Section 4(d)):
- (a) The HRP Program Manager at DOE or NNSA must be notified:
 - (i) 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
 - (ii) Within 48 hours, with a description of corrective actions taken, of:
 - (A) Unanticipated problems.
 - (B) Significant adverse events, and
 - (C) Complaints about the research.

Element II.2.H. The IRB or EC has and follows written policies and procedures for suspending or terminating IRB or EC approval of research, if warranted, and for reporting these actions, when appropriate.

- (4) When following DOE requirements (DOE O 443.1C Section 4(d)):
- (a) The HSP Program Manager at DOE or NNSA must be notified within 48 hours, with a description of corrective actions taken, of:
 - (i) Suspensions of IRB approval
 - (ii) Terminations of IRB approval

Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

Element II.3.D. The IRB or EC has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants, when appropriate, during their involvement in the research.

- (2) When following DOE requirements (DOE O 443.1C, section 4(a)(10) and (DOE O 443.1C Section 4(d)):
- (3)(a) Written materials require the IRB or EC to review and ensure that research protocols submitted to the IRB for review comply with the DOE requirements for protecting personally identifiable information (PII).
 - (a) Personally identifiable information collected and/or used during human participant research projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program.
 - (b) Any breach involving Personally Identifiable Information must be reported:
 - (i) Immediately upon a finding of a suspected or confirmed data breach involving Personally Identifiable Information (PII) in printed or electronic form, the incident must be reported to the DOE-Cyber Incident Response Capability in accordance with the requirements of DOE O 206.1.

(ii) Within 48 hours the DOE or NNSA HSP Program Manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.

Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.

(5) When following DOE requirements (DOE O 443.1C, section 4(a)(14)):

(a) When research is classified, consent documents must disclose:

(i) The identity of the sponsoring agency, unless the sponsor requests that it not be done. The only acceptable reason for non-disclosure is that disclosure could compromise intelligence sources or methods. Additionally, the research must be ~~because doing so could compromise intelligence sources or methods; the research involves~~ no more than minimal risk to participants; and the IRB must determine that ~~by not disclosing the identity the researchers will~~ not adversely affect the participants.

(ii) ~~Consent documents will state~~ That the project is classified, what it means for the purposes of the research project, and what part of the research that applies to.

(b) The IRB must determine if participants need access to classified information to make a valid consent decision.

(c) Consent documents must include additional DOE elements of disclosure. (See Table II.3.F.1.)

Element II.3.G. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

(4) When following DOE requirements (DOE O 443.1C, Section 4(a)(14)):

~~(7)(a) Policies and procedures specify that when conducting classified research, the IRB may not grant a waiver of the consent process or waiver of documentation of consent.~~

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

Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.

When following DOE requirements (DOE O 443.1C, Section 8):

~~(a) Policies must indicate that employees and contractors are considered vulnerable participants.~~

(a) DOE and DOE site employees 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.

(b) Policies must include direction for the IRB to consider if additional protections are required for research involving employees and contractors.

Domain III: Researcher and Research Staff

Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

Element III.2.D. Researchers and Research Staff follow reporting requirements in accordance with applicable laws, regulations, codes, and guidance; the organization's policies and procedures; and the IRB's or EC's requirements.

(4) When following DOE requirements: (DOE O 443.1C, Section 4(d)):

(a) Researchers must report the following within 48 hours to the HSP Program Manager:

- (i) Any significant adverse events, unanticipated problems, and complaints about the research, with a description of any corrective actions taken or to be taken.
- (ii) Any suspension or termination of IRB approval of research.
- (iii) Any significant noncompliance with HRPP procedures or other requirements.

(b) Researchers must report the following immediately to the Human Subject Protection Program Manager:

- (i) Any suspected or confirmed compromise of personally identifiable information, with a description of any corrective actions taken or to be taken. The incident must also be immediately reported to the DOE-Cyber Incident Response Capability.
- (ii) Any serious adverse event, with a description of any corrective actions taken or to be taken.