



Additional Requirements Involving Human Subject Research Protections Specific to Some Federal Sponsors

Department of Defense (DoD)

1. **DoD Component Review:** *Research conducted or supported by the DoD must undergo review by the Institutional Review Board (IRB) of the DoD component involved. The IRB ensures that the research adheres to ethical standards and protects the rights and welfare of human subjects.*
 - a. Contracts and other agreements must restrict the performance of prospective DoD-supported HSR before IRB review of the DoD component is completed
2. **Informed Consent:** *Like the Common Rule, DoD policy emphasizes the importance of obtaining informed consent from research participants. Informed consent must be documented, and participants must be fully informed about the nature of the research, potential risks and benefits, and their right to withdraw from the study at any time.*
 - a. There are three (3) additional (aside from those in the 2018 Requirements) criteria for granting waiver of consent:
 - (1) The research is to advance the development of a medical product necessary to the DoD.
 - (2) The research may directly benefit the individual experimental subject.
 - (3) The research is conducted in compliance with all other applicable laws and regulations.
3. **Data Security:** *The DoD places a strong emphasis on data security and confidentiality. Researchers are required to implement measures to protect the privacy and security of research data, especially when dealing with sensitive or classified information.*
4. **Military Research Considerations:** *When conducting research involving military personnel, the DoD may have additional considerations, given the unique context and potential impact on military operations. Researchers must take into account the mission requirements, unit readiness, and the well-being of military personnel.*
5. **Compliance and Monitoring:** *The DoD emphasizes ongoing compliance monitoring to ensure that research projects adhere to ethical standards. This includes the responsibility of DoD Components to report any adverse events or non-compliance with regulations.*
6. **Research-related injury:** *treatment may be provided by a DoD medical facility.*

References:

<https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-219?toc=1> <https://irb.ucsf.edu/department-of-defense-research#>



Department of Energy (DOE)

1. **Definition of “research”** is broader than the 2018 Requirements; includes intentional modification of the human env’t ,study of tracer chemicals, particles, and/or other materials to characterize airflow, collecting information on occupants’ views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups
2. **Vulnerable subjects:** DOE employees and contractors are considered vulnerable subjects
3. **Reporting:**
 - a. Report within 48 hours:
 - i. any significant adverse events (AEs), unanticipated problems (UPs), or complaints about the research with a description of any corrective actions
 - ii. Study suspension/termination
 - iii. Significant noncompliance
 - b. Report immediately – breach of PII
4. **Use of Private Identifiable Information (PII):** IRB review should include:
 - a. Protection of PII during storage and transmission
 - b. Procedure for release of PII
 - c. Confirmation that documents containing PII or PHI are marked as such (e.g., “containing PII or PHI”)
 - d. Confirmation that reasonable administrative, technical, and physical safeguards are in place to prevent unauthorized use or disclosure of PII/PHI
 - e. Making no further use or disclosure of the PII/PHI except when approved by the responsible IRB and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project, as required by Office of Management and Budget Circular No. A-133; (d) when required by law; or (e) with the consent of the participant/guardian’
 - f. Protecting PII/PHI data stored on removable media (CD, DVD, USB Flash Drives, etc.), network drives, and stand-alone computers using encryption products that are FIPS 140-2 certified.
 - g. Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the following current DOE password requirements:
 - Minimum of twelve (12) non-blank characters
 - Must contain a lowercase letter
 - Must contain an uppercase letter
 - Must contain a number or special character
 - Must contain a nonnumeric in the first and last position
 - Must not contain the user ID



- h. *Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products*
- i. *Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer.*
- j. *Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter.*
- k. *Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII.*
- l. *Using two-factor authentication for logon access control for remote access to systems and databases that contain PII/PHI. (Two-factor authentication is contained in the NIST Special Publication 800-63.)*
- m. *Reporting the loss or suspected loss of PII/PHI immediately upon discovery to:*
 - 1. *The DOE funding office Program Manager or, if funded by a DOE laboratory, the DOE laboratory Program Manager; and*
 - 2. *The DOE HSP Program Manager and the NNSA HSP Program Manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1- 866-941-2472, by fax at 702-932-0189, or by e-mail at circ@jc3.doe.gov. For additional information, see: <http://energy.gov/cio/office-chief-informationofficer/services/incident-management/jc3-incident-reporting>*

References:

https://research-compliance.umich.edu/sites/default/files/resource-download/doe_guidance_v1.pdf
<https://www.directives.doe.gov/directives-documents/400-series/0443.1-BOrder-c/@@images/file>
<https://science.osti.gov/ber/human-subjects/Regulations-and-Requirements/DOE-Specific-Requirements>

Environmental Protection Agency (EPA)

- 1. The EPA Does not support studies involving intentional exposure of pregnant women, nursing women, or children.
- 2. Multiple levels of approval are needed.
 - a. *The specific path for review differs slightly depending on the origin of the research, but all human subjects research projects must be approved by the Human Subjects Research Review Official (HSRRO) before any work involving human subjects can begin.*
 - b. *EPA's approval process guidelines exceed what is generally accepted and required by universities, industry, and other government agencies. In those organizations, human subjects research is often proposed by an investigator, reviewed by a supervisor, and finally, reviewed by an Institutional Review Board (IRB). Research conducted or supported by EPA, on the other hand, has additional levels of oversight. For example, projects that are conducted or funded by the EPA are reviewed by the Program, Office, or Region's Human Subjects Officer (HSO) prior to submission to the HSRRO for their review. HSRRO. Controlled human exposure studies conducted at EPA's Office or Research and Development (ORD) undergo multiple levels of both internal and external review.*



Department of Education

1. *Adopted Subparts A and D of the 2018 requirements*
2. *For research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must have at least one person primarily concerned with the welfare of these research subjects.*

Reference: <https://www2.ed.gov/about/offices/list/ocfo/humansub.html>

Department of Justice (DOJ)

The DOJ has not incorporated the 2018 Requirements but continues to implement the pre-2018 Requirements subpart A of 45 CFR 46 as part of 28 CFR 46.

Reference: <https://nij.ojp.gov/funding/human-subjects-protection>

National Institutes of Health (NIH)

Per [Final NIH Policy o the Use of a Single IRB for Multi-Site Research \(NOT-OD-16-094\)](#), all sites participating in multi-site studies involving non-exempt (i.e., expedited review, or full board review studies) human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.

Such policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy. This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017.

Reference: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

Revision history:

29Mar2024 – the NIH was added to this compilation.

13Dec2023 - The IRB administrators put together the first version of this compilation.