STANFORD UNIVERSITY

# SLAC National Accelerator Laboratory

Operated by Stanford University for the U.S. Department of Energy

## DOE Order 443.1D, Protection of Human Research Subjects (08/05/2026)

**Site Compliance Plan** (11/02/2026)

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## Introduction

This Site Compliance Plan (SCP):

a) corresponds with the version of the DOE Directive listed in the Prime Contract,
b) states how the Laboratory complies with applicable requirements as tailored to the risks at the Laboratory, and
c) documents DOE-approved methods of compliance for applicable requirements and that there are no recurring deliverables*.

Impact on the Contract:
Under the SCP, sections of the CRD are incorporated into the Contract as-is, unless the SCP indicates that a section or portion thereof is inapplicable, or the section has been changed. Thus, for example, if "in compliance" is listed next to a CRD section, that section is incorporated into the Contract as-is. However, where an SCP indicates that a section or portion thereof is inapplicable, the section or portion thereof is excluded from the Contract. In addition, where a section or portion thereof is applicable, but changes to the section have been agreed by the Parties, the section, as modified by the Parties, shall be incorporated into the Contract.

This SCP also clarifies SLAC's interpretation of the requirements, memorializes the Parties' agreement on how SLAC will comply with sections of the CRD (whether or not modified) and identifies the Laboratory programs and processes established to fulfill the respective requirements.

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## Attachment 1 – Contractor Requirements Document

The table below identifies the applicable CRD requirements, compliance status, and SLAC's method of compliance.

| § | Requirements from Attachment 1 – CRD | Compliance Status | Method of Compliance |
|---|---|---|---|
| | Regardless of the performer of the work, the contractor is responsible for compliance with the requirements of this Contractor Requirements Document (CRD).<br>The contractor is responsible for flowing down the requirements of this CRD to subcontracts at any tier to the extent necessary to ensure the contractor's compliance with the requirements.<br>As directed by the contracting officer, the contractor must: | N/A | N/A; this is introductory verbiage with no contractor instruction. See below for specific methods of compliance. |
| 1 | Ensure that human subjects research (HSR),6 regardless of the source of funding, is conducted in accordance with the principles outlined in the Belmont Report and all applicable federal,7 DOE-specific, sponsor-specific, and other requirements, including 10 Code of Federal Regulations (CFR) 745, 45 CFR 46, and this CRD. | In Compliance by 12/21/2026 | SLAC-Stanford Policy Memorandum "SLAC Human Subjects Research Program" directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB). |
| 1.a | Maintain a valid Federal-wide Assurance (FWA) with the Office of Human Research Protections (OHRP), as described in 10 CFR 745.103. | In Compliance | SLAC National Accelerator Laboratory FWA 00026008 OMB number 0990-0278 Expires 04/23/2031 |
| 1.b | Ensure that HSR is only initiated after review and approval by an Institutional Review Board (IRB)8; or in the case of HSR meeting the categories of exemption at 10 CFR 745.104, has received a determination from an IRB, HSP office, or their designee. | In Compliance | SLAC-Stanford Policy Memorandum "SLAC Human Subjects Research Program" directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB). Addressed in Stanford University Human Research Protection Program Policy Manual, Chapter 3, Compliance Monitoring, Section 3.4 Exempt Research Determinations. |
| 1.c | Non-DOE-supported researchers who will conduct HSR at/using DOE/NNSA user facility capabilities must provide documentation of IRB or ethics board approval or exemption | In Compliance | Addressed in Internal Institutional Policy Memorandum And Compliance Plan |

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| | determination from their home institution. This HSR is not otherwise required to comply with the provisions of this Order, unless the DOE/NNSA site hosting the facility determines that such compliance is necessary. | | |
| 2 | For DOE-supported or -conducted research that involves humans through interaction, intervention, or use of their data or specimens, but may not constitute HSR per 10 CFR 745.102(e) and (l), the following requirements still apply. | Outlined in sections below | |
| 2.a | Institutions must adopt a process under which an IRB, HSP office or their designee determines whether proposed research constitutes HSR for the purposes of this Order and the applicability of 10 CFR 745 and 45 CFR 46. | In Compliance by 12/31/2026 | To comply with federal DOE requirements, all protocols affiliated with SLAC will complete a mandatory two-tier clearance process before initiating any research activities or data collection, as mentioned in the Internal Institutional Policy Memorandum And Compliance Plan document, 4.0. |
| 2.b | Determinations of whether a project constitutes HSR is required when research involves: | Outlined in sections below | |
| 2.b.(1) | The use of information or specimens for which the identity of the subject is or may readily be ascertained by the investigator or is linked or linkable to the information or specimens. | SLAC-Stanford Policy Memorandum “SLAC Human Subjects Research Program” directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB). | |
| 2.b.(2) | The study of humans in a systematically modified environment, defined as modification of the human environment in this Order. | SLAC-Stanford Policy Memorandum “SLAC Human Subjects Research Program” directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB). | |
| 2.b.(3) | Human Terrain Mapping (HTM) activities. Regardless of HSR determination, the following requirements apply to all HTM activities.<br>(a) At all DOE sites, HTM must be limited to only activities involving the analysis and modeling of de-identified data.<br>(b) Prior to initiation, statements of work for HTM projects must be submitted to the HSPP for DOE Headquarters review | N/A | N/A; Based on the definition of HTM in DOE O 443.1.C, Chg 1 (Ltd Chg), Protection of Human Research Subjects, this section is not applicable. |

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| | and approval. If the project is to be conducted by or for the intelligence community, such as through strategic partnership projects (SPPs) or SIPP, DOE-IN must also review and approve it prior to initiation. | | |
| 3 | DOE Site IRBs. DOE contractors with internal IRBs registered with OHRP must apply the following requirements, in addition to requiring compliance with this Order during IRB review of protocols. | In Compliance | Addressed in Internal Institutional Policy Memorandum And Compliance Plan |
| 3.a | An unaffiliated member must be among the voting IRB members present in order for a DOE Site IRB to conduct business requiring full board review. | In Compliance | Addressed in Stanford University Human Research Protection Program Policy Manual, Chapter 6, Structure and Composition of the IRB, |
| 3.b | Ensure HSR that includes engagement of three or more DOE sites as study team members is reviewed by the Central DOE IRB. | In Compliance by 06/30/2027 | SLAC-Stanford Policy Memorandum "SLAC Human Subjects Research Program" directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB). The Policy requires all HSR irrespective of whether other DOE entities are involved, must be reviewed by the SU IRB. |
| 3.c | Researchers who submit studies to the DOE site IRBs and members of these IRBs must complete initial and periodic refresher training in human subjects protection (HSP). | In Compliance | Addressed in Stanford University Human Research Protection Program Policy Manual, Chapter 6, Structure and Composition of the IRB, Section 6.3 IRB Composition and Membership.<br><br>Addressed in Stanford University Human Research Protection Program Policy Manual, Chapter 4, Knowledge of Human Research Protection Requirements, Section 4.2 Required Training in Human Research Protection.<br>Completion of Collaborative Institutional Training Initiative (CITI) training is compulsory for all individuals working with human subject protocols. |
| 3.d | IRB records must be maintained and managed in accordance with applicable NARA-approved records schedules. | In Compliance by 12/31/2026 | Addressed in Stanford University Human Research Protection Program Policy Manual, Chapter 6, Structure and Composition of the IRB, Section |

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| | | | 6.3 IRB Composition and Membership.<br><br>The SLAC Human Subjects Program Manager has access to the DOE Human Subject Research Database (HSRD) system allowing entry of SLAC protocols.<br>SLAC will include a step in the implementation process of the SLAC Human Subjects Research Program Policy to ensure protocols are reviewed with respect to HSRD entry criteria. |
| 4.a | Considerations for HSR.<br>DOE-affiliated personnel as subjects. Targeted inclusion of DOE-affiliated personnel (defined in this Order to include contractor personnel) as participants or the use of their data or specimens, in HSR requires additional consideration to protect potentially vulnerable subjects. Prior to initiation of HSR targeting DOE-affiliated personnel, researchers must obtain:<br>(1) Written approval from the DOE site being targeted for inclusion, or<br>(2) Review and approval by the Central DOE IRB when DOE federal employees or more than 1 DOE site are targeted for inclusion, unless an exemption is provided in writing by the DOE HSPP. | In Compliance | SLAC-Stanford Policy Memorandum "SLAC Human Subjects Research Program" directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB). Policy requires all HSR irrespective of whether DOE or Contractor Staff are involved, must be reviewed by the SU IRB. |
| 4.b | Personally Identifiable Information (PII). HSR that includes the collection and/or use of PII must adhere to all applicable requirements of DOE Order 206.1A, DOE Privacy Program, or current version. This includes safeguarding PII and reporting suspected or confirmed breaches, which are considered Unanticipated Problems, as defined in this Order. | In Compliance | Stanford University Human Research Protection Program Policy Manual, Chapter 11, Privacy and Confidentiality, addresses the protection of participant privacy and confidentiality. |
| 4.c | International HSR. Contractor conducted and supported HSR, | N/A | N/A; SLAC does not have a sponsored Exchange Visitor Program. |

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| | regardless of the location of the activity or participant, domestic or abroad, must adhere to the requirements of this CRD. This policy, however, does not preempt any foreign laws or regulations9 that may otherwise be applicable, as addressed in 10 CFR § 745.101(g). Where differences in applicable standards exist, the requirements that are most protective of human subjects should be applied. | | |
| 4.d | Classified HSR. Ensure that classified and unclassified intelligence and intelligence-related HSR, regardless of funding source (including studies funded through the Strategic Intelligence Partnership Program (SIPP), DOE Office of Intelligence and Counterintelligence (DOE-IN) or other DOE program offices using classified datasets), is reviewed and approved by the Central DOE IRB-Classified. | In Compliance | Per Stanford, https://irb.stanford.edu/for-researchers/irb-application-submission-guide/other-federal-agency-requirements, classified and unclassified human participant research funded through SIPP must be reviewed and approved by the Central DOE IRB-Classified. |
| 4.d.(1) | In addition to IRB approval, HSR that is classified, in whole or in part, must not be initiated without subsequent approval by the DOE IO. The DOE IO, in consultation with the HSPP, will determine whether to approve the project or brief the Secretary about the project prior to their decision. | N/A | N/A; SLAC does not perform classified research. |
| 4.d.(2) | Informed consent may only be waived for classified HSR if the project meets one or more of the categories of exemption at 10 CFR § 745.104. However, full IRB review will still be required, as categorical exemption from the requirements of 10 CFR 745 and 45 CFR 46 is prohibited for classified HSR. | N/A | N/A; SLAC does not perform classified research. |
| 4.d.(3) | The use of the expedited review process is prohibited. The fact that research meets a particular expedited category may be noted, however a full IRB review will be required. | N/A | N/A; SLAC does not perform classified research. |

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| 4.d.(4) | The identity of the sponsoring federal agency must be disclosed to subjects, unless the sponsor requests it not be done because it could compromise intelligence sources or methods. Additionally, the research must be no more than minimal risk, and the IRB must determine that not disclosing the identity will not adversely affect the subjects. | N/A | N/A; SLAC does not perform classified research. |
| 4.d.(5) | The informed consent document will state that the project is classified, what that means for the purposes of that project, and the part of the research to which it applies. The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision. | N/A | N/A; SLAC does not perform classified research. |
| 4.d.(6) | When reviewing classified HSR, the unaffiliated member of a DOE or DOE site IRB must be a non-governmental member (not currently a federal employee or a DOE site contractor employee) with appropriate security clearance. | N/A | N/A; SLAC does not perform classified research. |
| 4.d(7) | Any IRB member has the right to appeal the IRB's decision to approve a project to the DOE IO, and if not resolved to the IRB member's satisfaction, may advance to the Secretary of Energy. If still dissatisfied, the IRB member can appeal that approval decision to the Director of the Office of Science and Technology Policy (OSTP), or that Director's designee, or the Director of National Intelligence (ODNI), or that Director's designee. The Director of OSTP, or that Director's designee, or the ODNI, or that Director's designee, will review and approve or disapprove the research, or will convene or designate an IRB that is, to the extent possible, made up of unaffiliated members with the appropriate qualifications and clearance to approve or disapprove the research. | N/A | N/A; SLAC does not perform classified research. |

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| 4.d.(8) | All records related to IRB review/approval of classified HSR, as well as key researcher records must be maintained permanently. During and following the completion of classified research, copies of all signed classified consent forms must be stored in a separate but secure central location (e.g., Security Policy Officer or IRB office), other than the researchers' office, and participants of such research must be notified during the consenting process regarding how to access a copy of their individual signed classified consent forms should they want to in the future. | In Compliance by 12/31/2026 | The SLAC Human Subjects Program Manager has access to the DOE HSRD system allowing entry of SLAC protocols.<br>SLAC will include a step in the implementation process of the SLAC Human Subjects Research Program Policy to ensure protocols are reviewed with respect to HSRD entry criteria. |
| 5.a | Solicitations and Agreements<br>Ensure that contractor-issued solicitations or proposals for the conduct of research involving humans through interaction, intervention, or use of their data or specimens includes the requirements of this CRD. | In Compliance | SLAC-Stanford Policy Memorandum "SLAC Human Subjects Research Program" directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB).<br>In addition, this policy outlines that SLAC must also comply with DOE review and reporting requirements, namely: notification of the DOE SLAC Site Office, and annual reporting to the DOE's Human Subjects Research Database. |
| 5.b | Ensure that contracts, financial assistance agreements, and all other agreements issued for the conduct of research involving humans through interaction, intervention, or use of their data or specimens include the requirements of this CRD. | In Compliance | SLAC-Stanford Policy Memorandum "SLAC Human Subjects Research Program" directs all HSRR to be compliant with protocols issued by the Stanford University Human Subjects Institutional Review Board (IRB).<br>In addition, this policy outlines that SLAC must also comply with DOE review and reporting requirements, namely: notification of the DOE SLAC Site Office, and annual reporting to the DOE's Human Subjects Research Database. |
| 6.a | Required Reporting<br>(1) Prompt notification10 to the DOE HSPP is required when any of the following occur during performance of contractor | In Compliance by 12/31/2026 | Addressed in the Stanford University Human Research Protection Program Policy Manual, Chapter 3, Compliance Monitoring, and Chapter 11, Privacy and Confidentiality. While the requirement to notify SSO and DOE HSP is not currently included in the SLAC Human Subjects Research Program Policy or the SLAC Human Subjects Research Approval Process, SLAC will incorporate this notification step as part of the implementation of the Human |

| § | Requirements from Attachment 1 – CRD | Compliance Status | Method of Compliance |
|---|---|---|---|
| | conducted or supported HSR, including projects meeting the categories of exemption at 10 CFR 745.104. Contractors should send preliminary notification as soon as reasonably possible.<br><br>(2) Unanticipated Problems11 involving risks to subjects or others.<br><br>(3) Serious or continuing noncompliance with this Order, 10 CFR 745, 45 CFR 46, or the requirements or determinations of the IRB.<br><br>(4) Suspension or termination of IRB approval. | | Subjects Research Program Policy. |
| 6.b | Human Subjects Research Database (HSRD) Reporting. All contractor conducted and supported HSR, including those projects determined to meet a category of exemption at 10 CFR 745.104, and HSR that targets DOE-affiliated personnel, must be reported to the HSRD as follows.<br>(1) Project-specific information, as indicated by the HSPP, must be provided after initial IRB approval or determination of exemption has been obtained.<br>(2) Updated project-specific information must be provided every 3 years, or when substantive changes occur, such as any change impacting HSRD reporting categories, study objectives, or upon study completion. | In Compliance by 12/31/2026 | The SLAC Human Subjects Program Manager has access to the DOE HSRD system allowing entry of SLAC protocols.<br>SLAC will include a step in the implementation process of the SLAC Human Subjects Research Program Policy to ensure protocols are reviewed with respect to HSRD entry criteria. |
| 7 | Participate in DOE HSPP-led, quality assurance (QA) | In Compliance | This Site Compliance Plan (SCP) provides the site office with our |

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| | consultations at least once every 3 years. Collaborative QA consultations will be designed to provide recommendations for continuous improvement in contractor processes for HSP. | | conformance review of the HSR program between DOE O 443.1.D, Protection of Human Research Subjects, and Stanford's Human Research Protection Program. Assessments are captured in SLAC's tri-party integrated assessment schedule. |
| 8 | Requests for exemptions and equivalencies to the requirements of this Order must be submitted to the DOE HSPP. | In Compliance | Categories of Exempt Research are addressed in Stanford University Human Research Protection Program Policy Manual, Chapter 3, Compliance Monitoring, Section 3.4 Exempt Research Determinations.<br>Exemptions from the Order would need to go through the SLAC Site Office |

(End of CRD)

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## Site Compliance Plan (11/02/2026)

## Deliverables

| CRD § | Deliverable Item | Frequency | Due Date(s) | Recipient / Notes |
|---|---|---|---|---|
| 6.b | Provide updated project-specific information to HSRD. | Every 3 years | 9/30/2028 | DOE HSRD |

*Deliverables generally include data delivered to DOE or another external agency, such as recurring reports or external database entries.*

# DOE Order 443.1D, Protection of Human Research Subjects (08/05/2026)

## Site Compliance Plan (11/02/2026)

## Concurrence

| Name | Title | Signature |
|---|---|---|
| Ian Evans | Director, Environmental, Safety, and Health, SLAC | Ian Evans<br>Ian Evans (Nov 2, 2026 13:25:17 PST) |
| Risa Benwell | Safety Engineer, Operations, DOE-SSO | RISA BENWELL<br>Digitally signed by RISA BENWELL<br>Date: 2026.11.09 14:29:03 -08'00' |
| Ernest Maune | Director, Business Management, DOE-SSO | ERNEST MAUNE<br>Digitally signed by ERNEST MAUNE<br>Date: 2026.11.09 14:41:37 -08'00' |
| William W. Wheeler | Acting Manager, DOE-SSO | THOMAS RIZZI<br>Digitally signed by THOMAS RIZZI<br>Date: 2026.11.10 06:31:32 -08'00' |

## Revision History

| Revision | Revision Date | Summary of Change(s) |
|---|---|---|
| R0 | 09/16/2026 | Original release. |
| R1 | 11/02/2026 | Made minor adjustments to align the SCP with the published DOE Order due to discrepancies identified in the previously signed version. |