

Guidance – Department of Energy Requirements

General Description

Research that is regulated by federal agencies often times have agency-specific requirements. This guidance is the assist researchers and the IRB in identifying additional regulatory considerations.

When it applies / context

This guidance may be used by members of the UNLV Human Research Protection Program (HRPP), Researchers and the IRB. Researchers should review this guidance when conducting research supported by the Department of Energy (DOE). The IRB should use this guidance to review for agency-specific requirements in research supported by the DOE.

Considerations & Best Practices

Considerations

Research involving human participants also includes studies of the intentional modification of the human environment, generalizable includes the study of tracer chemical, particles or other materials to characterize airflow. Generalizable also includes studies in occupied homes or offices that:

- Manipulate the environment to achieve research aims.
- Test new materials.
- Involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
- Generalizable should be viewed in terms of the contribution to knowledge within the specific field of study.

DOE considers Human Terrain Mapping as Human Subject Research.

Additionally, DOE considers all personnel (i.e., former and current employees, contractors, and students) as vulnerable subjects with regards to projects conducted by their managers or co-workers.

Best Practices

UNLV Responsibilities: While following DOE requirements, UNLV will conduct self-assessments to ensure compliance with the HRPP procedures and other requirements.

IRB Responsibilities for Research Supported by the DOE:

- The IRB chair decides the level of review.
- The IRB assesses risks associated with the research and whether the individuals to be included in the research will be properly informed and protected.
- The chair sends a letter to the researcher indicating that the research has been approved in accordance with DOE expectations and will be monitored and tracked by the IRB.

Guidance – Department of Energy (DOE) Requirements

- The IRB or EC will review and approve the “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements” (Attached) submitted by the Researchers to verify compliance with the DOE requirements for the protection of personally identifiable information.
- Notify the DOE within 48 of notification by a researcher of any of the following:
 - Any significant adverse events, unanticipated risks; and complaints about the research
 - Any significant non-compliance with HRPP procedures or other requirements
- Notify the DOE **immediately** of:
 - Any suspension or termination of IRB approval
 - Any finding of suspected or confirmed data breach involving PII in printed or electronic form

Research Responsibilities for Research Supported by the DOE:

- Researchers are required to follow DOE requirements for the protection of personally identifiable information by completing and complying with the requirements of the “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements” (Attached).
- Researchers must promptly report the following to the Office of Research Integrity – Human Subjects:
 - 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.
 - The time frame for promptly is defined (no longer than within 30 days).
- Researchers must immediately report
 - Any compromise of personally identifiable information

Resources

DOE Order 443.1.B.

Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements

AAHRPP Elements I.1.A., I.5.A., II.2.D., II.3.E., III.2.C., III.2.D.

10 CFR 745, 45 CFR 46, DOE Order 443.1B Chg1, DOE Notice 443.1
(per <https://science.energy.gov/ber/human-subjects/about/>)

DOE Human Subjects Protection Program (HSPP) Education and Resources Special Research Categories

DOE Human Subjects Protection Program (HSPP) Regulations and Requirements DOE-Specific Requirements

“Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements” (developed from Attachment I DOE Institutional Review Board Template for Reviewing Human Subjects’ Research Protocols that Utilize Personally Identifiable Information (PII) from Central DOE Institutional Review Board-Classified (CDOEIRB-C)).

The following must be addressed in all protocols by Researchers, and evaluated by the IRB:

- Keeping PII confidential.
- Releasing PII only under a procedure approved by the responsible IRB(s) and DOE, where required.
- Using PII only for purposes of the Former Worker Medical Screening Program, assisting participants filing claims under the Energy Employees Occupational Illness Compensation Program (EEOICP), or with the consent of the participant.
- Handling and marking documents containing PII as “containing PII or PHI”.
- Establishing administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII.
- Making no further use or disclosure of the PII except when approved by the responsible IRB(s) and DOE, where applicable, and then only under the following circumstances:
 - in an emergency affecting the health or safety of any individual;
 - for use in another research project under these same conditions and with DOE written authorization;
 - for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project;
 - when required by law; or
 - with the consent of the participant.
- Protecting PII data stored on removable media (CD, DVD, USB flash drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2, *Security Requirements for Cryptographic Modules*, certified.
- Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements.
- Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped.
- Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.
- 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.
- Using FIPS 140-2 certified encryption methods for Web sites established for the submission of information that includes PII.
- Using two-factor authentication for logon access control for remote access to systems and databases that contain PII (two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2, *Electronic Verification Guide*, found at http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf).
- Reporting the loss or suspected loss of PII immediately upon discovery to (1) the DOE funding office program manager, and (2) the applicable IRBs (as designated by the DOE program manager); if the DOE program manager is unreachable, immediately notify the DOE-CIRC (1-866-941-2472, www.doecirc.energy.gov).