UNLV Office of RESEARCH INTEGRITY RESEARCH PROTECTIONS

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.

- 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
- 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.
- Any breach involving Personally Identifiable Information must be reported:
    - 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.
    - 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.

Additional consent requirements for DOE research:

- The identity of the sponsoring agency, 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 participants; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.
- When the research is classified, the IRB must determine if participants need access to classified information to make a valid consent decision.
- When research is classified, consent documents must state the project is classified, and what it means for the purposes of the research project.
- When conducting classified research, the IRB may not grant a waiver of the consent process or waiver of documentation of consent. 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.
- For classified human subjects research (in whole or in part):

Exemptions (as per 10 CFR §745.104) and expedited review cannot be used. If the research meets a particular exemption or expedited category it may be noted, but full IRB/EC review is required.

- A waiver of informed consent may only be granted by the convened IRB/EC for minimal risk research that qualifies for exemption under 10 CFR §745.104.

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