Reviewer:	Principal Investigator:
Protocol #:	Submission ID:

COMIRB Reviewer Checklist: Additional Requirements for U.S. Department of Energy (DOE) Sponsored Research

1 **Human Subjects Research Determination.**

A human subjects research determination by COMIRB is required for DOE-supported or -conducted research involving humans through interaction, intervention, or use of their data or specimens, when the research may not constitute HSR per 10 CFR 745.102(e) and (l). In particular, research that involves the following activities must be formally reviewed by COMIRB for a HSR determination:

(a) 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; or
(b) The study of humans in a systematically modified environment, defined as modification of the human environment in this Order.

☐	This research constitutes human subjects research per 10 CFR 745.102(e) and (l).
☐	This research does not constitute human subjects research per 10 CFR 745.102(e) and (l).

2 **Protocols that Use PII. The protocol includes provisions for:**
(Check if **"Yes"**. All must be checked or completed.)

☐	Keeping PII/ PHI confidential. *Provide any supporting comments*:
☐	Protecting PII/PHI during storage and transmission. *Provide any supporting comments*:
☐	Releasing PII/PHI, where required, only under a procedure approved by the responsible IRB and DOE. *Provide any supporting comments*:
☐	Using PII/PHI only for purposes of this project. *Provide any supporting comments*:

☐	Handling and marking documents containing PII or PHI as “containing PII or PHI. *Provide any supporting comments*:
☐	Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI. *Provide any supporting comments*:
☐	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. *Provide any supporting comments*:
☐	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. *Provide any supporting comments*:
☐	Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the following current DOE password requirements[1]: • 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 *Provide any supporting comments*:
☐	Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped. *Provide any supporting comments*:
☐	Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products. *Provide any supporting comments*:
☐	Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer. *Provide any supporting comments*:
☐	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. *Provide any supporting comments*:

☐	Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII. *Provide any supporting comments*:
☐	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.) *Provide any supporting comments*:
☐	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-information-officer/services/incident-management/jc3-incident-reporting. *Provide any supporting comments*:
☐	Classified projects that use PII/PHI must also comply with all requirements for conducting classified research. *Provide any supporting comments*:

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 and classified and unclassified HSR funded through the Strategic Intelligence Partnership Program (SIPP).

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. DOE workers are considered vulnerable participants and shall be afforded additional protections as determined by the IRB.

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Reviewer Signature Date

Signature above verifies this checklist was used in the review of this protocol.