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|  | **IRB INVESTIGATOR/IRB CHECKLIST FOR**  **Verification of Compliance with the Department of Energy (DOE) Requirements** | | |
| **Project Title** Enter text. | | **IRB#:** Enter text. | **Principal Investigator:** Enter text. |
| **I. Investigators conducting human subject research supported or regulated by the DOE and involving collection of PII or PHI, complete the following to address compliance with DOE requirements and include with IRB submission.** | | | |

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| The research protocol and/or IRB submission (i.e. research description) includes information on how the research team will keep PII/PHI confidential | |
| If you checked the above box, the study PI must agree to the following: | |
|  | release PII/PHI , where required, only under a procedure approved by the IRB and DOE; |
|  | use PII/PHI only for purposes of the study protocol; |
|  | handle and mark documents containing PII/PHI as “containing PII or PHI;” |
|  | establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI; |
|  | make no further use or disclosure of the PII/PHI except when approved by the IRB 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; |
|  | protect PII/PHI stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are [Federal Information Processing Standards](https://www.nist.gov/itl/itl-publications/federal-information-processing-standards-fips) (FIPS) 140-2 certified; |
|  | use passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in [DOE Guide 205.3-1](https://www.directives.doe.gov/directives/0205.03-CNotice/view); |
|  | send removable media containing PII/PHI , as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped; |
|  | encrypt data files containing PII/PHI that are being sent by e-mail with FIPS 140-2 certified encryption products; |
|  | send passwords that are used to encrypt data files containing PII/PHI separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter; |
|  | use FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII/PHI; |
|  | use 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 National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 [<https://csrc.nist.gov/publications/detail/sp/800-63/ver-102/archive/2006-04-30>]; |
|  | report the loss or suspected loss of PII/PHI immediately upon discovery, (as soon as aware of incident), to:  1) DOE Program manager or the DOE funding office HSP Program Manager or the DOE-CIRC (1-866-941-2472) if the DOE Program manager is unreachable; and 2) the IRB. |

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| **II. IRB Staff reviewing CLASSIFIED human subjects research (in whole or in part):** |

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|  | A waiver of informed consent shall not be granted. |
|  | Exemptions (as per 10 CFR Part 745.101(b)) and expedited review are not used. If the research meets a particular exemption category it may be noted, but full IRB review is required. |
|  | The identity of the sponsoring Federal agency will be disclosed to subjects, 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 subjects; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the subjects. |
|  | The informed consent document will state that the project is classified, and what that means for the purposes of that project. |
|  | The IRB must have a voting quorum of at least five members, which must include a non-scientist and an unaffiliated member. The unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor. |
|  | Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, and Director of the Office of Science and Technology Policy (OSTP), in that order. |
|  | The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision. |
|  | Information on each project that is classified and reviewed during that fiscal year, as well as the number of human subjects in each project, must be submitted annually by the responsible DOE IRB to the DOE and NNSA HSP Program Managers, following the end of the fiscal year and no later than October 15, using the appropriate form. |
|  | If the IRB believes that the project can be thoroughly reviewed in an unclassified manner, a request for a waiver from the requirements of this Notice can be submitted. The waiver request must be signed by the IRB Chair, and submitted to the appropriate HSP Program Manager for review and approval, using the appropriate form. A list of waiver requests and the actions taken will be provided monthly to the DOE IO. |
|  | **After IRB approval, the DOE Institutional Official (IO) reviews and determines whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval.** |

**By attaching this form with your submission, you are attesting that you will be complying with the Department of Energy’s requirements as stated above**