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|  | **SUPPLEMENT Department of Energy** |
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| **PURPOSE and INSTRUCTIONS** |

This supplement provides information and assurances necessary to fulfill the requirements of research that involves the Department of Energy (DoE) and the collection or use of Personally Identifiable Information (PII).

Upload the completed Supplement to your Zipline application on the **Study-Related Documents** SmartForm for multi-site studies or the **Local Site Documents** SmartForm for single-site studies.

**DoE involvement means: (1)** funded by any DoE program; and/or **(2)** conducted at DoE institutions or by DoE or DoE contract personnel (regardless of funding).

**Personally identifiable information (PII) means:** any information collected or maintained about an individual including but not limited to, education, financial transactions, medical history and criminal or employment history, and information that can be used to distinguish or trace an individual's identity sch as their name, Social Security number, date and place of birth, mother’s maiden name, biometric data, and including any other personal information that is linked or linkable to a specific individual.

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| **Study Title:** | Click or tap here to enter text. |

Department of Energy Privacy Requirements

These requirements are pulled from [this DoE webpage](https://science.osti.gov/ber/human-subjects/About/Researchers).

1. The IRB Protocol describes the methods you will use to keep personally identifiable information (PII) confidential.

**Confirmed**

1. You will release PII only under a procedure approved by the responsible IRB and DoE.

**Confirmed**

1. You will use PII for the purposes of this project only.

**Confirmed**

1. You will handle and mark all documents containing PII as, “containing PII or containing Protected Health Information (PHI)”.

**Confirmed**

1. You will establish and document reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII.

**Confirmed**

1. You will make no further use or disclosure of PII except when approved by the responsible IRB(s) and DoE, where applicable, and then only under the following circumstances:
   1. In an emergency affecting the health or safety of any individual;
   2. For use in another research project under these same conditions and DoE written authorization;
   3. For disclosure to a person authorized by the DoE program office for the purpose of an audit related to the project;
   4. When required by law; or
   5. With the consent of the participant/guardian.

**Confirmed**

1. You will protect PII, including PII stored on removable media (CD, DVD, USB Flash Drives, etc.), using encryption procedures that meet Federal Information Processing Standards ([FIPS 140-2](https://csrc.nist.gov/publications/detail/fips/140/2/final) certified).

**Confirmed**

1. You will use passwords to protect PII used in conjunction with [FIPS 140-3](https://csrc.nist.gov/publications/fips) certified encryption that meet the current DoE password requirements cited in [DoE Order 205.1C](https://science.osti.gov/Leaving-Office-of-Science?url=https%3a%2f%2fwww.directives.doe.gov%2fdirectives-documents%2f200-series%2f0205.1-BOrder-c%2f%40%40images%2ffile&external=true), [DoE Cyber Security Program](https://science.osti.gov/Leaving-Office-of-Science?url=https%3a%2f%2fwww.directives.doe.gov%2fdirectives-documents%2f200-series%2f0205.1-BOrder-c%2f%40%40images%2ffile&external=true), and [DoE Order 206.1](https://science.osti.gov/Leaving-Office-of-Science?url=https%3a%2f%2fwww.directives.doe.gov%2fdirectives-documents%2f200-series%2f0206.1-BOrder%2f%40%40images%2ffile&external=true), [DoE Privacy Program](https://science.osti.gov/Leaving-Office-of-Science?url=https%3a%2f%2fwww.directives.doe.gov%2fdirectives-documents%2f200-series%2f0206.1-BOrder%2f%40%40images%2ffile&external=true) (or current versions of these documents).

**Confirmed**

1. You will send removable media containing PII by express overnight service with signature and tracking capability and hard copy documents will be double-wrapped before shipping.

**Confirmed**

1. You will encrypt files containing PII that are being sent by email with FIPS 140-3 certified encryption products.

**Confirmed**

1. You will send passwords that are used to encrypt data files containing PII separately from the encrypted data file.

**Confirmed**

1. You will use FIPS 140-3 certified encryption methods for websites established for the submission of information that includes PII.

**Confirmed**

1. You will use two-factor authentication for logon access control for remote access to systems and databases that contain PII ([National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2](https://science.osti.gov/Leaving-Office-of-Science?url=http%3a%2f%2fcsrc.nist.gov%2fpublications%2fnistpubs%2f800-63%2fSP800-63V1_0_2.pdf&external=true)).

*Two-factor authentication is contained in the National Institutes of Standards and Technology (NIST) Special Publication 800-63 Version 2.*

**Confirmed**

1. You will report the loss or suspected loss of PII immediately upon discovery to:
   1. The DoE funding office Program Manager; **and**
   2. The applicable IRB as designated by the DoE Program Manager; **OR**
   3. If the Program Manager and/or IRB is unreachable, immediately notify the [DoE Joint Cybersecurity Coordination Center](http://energy.gov/cio/office-chief-information-officer/services/incident-management) (iJC3).

**Confirmed**

1. If you are not able to confirm any of the points above, provide an explanation in the text box below.

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| Click or tap here to enter text. |

**Keywords:** Federal agencies