| U W  and H S D logo | **SUPPLEMENT Genomic Data Sharing** |
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PURPOSE and INSTRUCTIONS

This supplement should be used only when requesting certification for sending genetic data to a NIH database, and when you are asking UW to ensure consent forms can be certified for sending genetic data to a NIH database. Click or tap boxes to check them. To answer a text field question, make sure your cursor is in the gray text box before typing or pasting content.

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.

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| Click or tap here to enter text. |

**Study Title:**

1. DATA/SPECIMEN INFORMATION

* 1. Where have these data and specimens (i.e., the specimens from which the data were derived) been obtained from, or from where will they be obtained? List the institution and location.

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| Click or tap here to enter text. |

* 1. Are there any existing Genomic Data Sharing certifications for the subject group(s) or cohort(s) from which these data are derived?

[ ]  **No**

[ ]  **Yes** **→** If yes, provide a copy of the GDS certification(s)

* 1. Will any data be from specimens collected before January 25, 2015?

[ ]  **No**

[ ]  **Yes** **→** If yes, explain which data were from specimens collected before this date and whether specimens were identifiable or de-identified when collected from subjects.

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* 1. Which institution will certify the information for submission to an NIH database?

[ ]  **UW**

[ ]  **Other** **→** If other, list the institution, if known.

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| Click or tap here to enter text. |

* 1. Is this research funded by NIH?

[ ]  **No →** If you are asking UW to provide the certification, to which NIH database(s) will data be submitted?

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| Click or tap here to enter text. |

[ ]  **Yes** **→** When was the grant submitted and to which institute or center?

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| Click or tap here to enter text. |

* 1. List the appropriate name from the NIH [Genomic Program Administrators (GPAs) Contacts List](https://sharing.nih.gov/contacts-and-help#gds_support) that the certification letter should be addressed to.

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| Click or tap here to enter text. |

2. DATA SHARING

* 1. Describe the data that will be submitted to NIH.
		1. What are the data elements?

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| Click or tap here to enter text. |

* + 1. What type of genomic data will be shared (e.g., sequence, transcriptomic, epigenomic, and/or gene expression data)?

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| Click or tap here to enter text. |

* + 1. Will the data be individual-level data, aggregate-level data, or both?

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| Click or tap here to enter text. |

* + 1. Describe any other information that will be shared such as relevant associated data (e.g., phenotype or exposure data) and information necessary to interpret the data (e.g., study protocols, data collection instruments, survey tools).

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| Click or tap here to enter text. |

* 1. Will data from children be included?

[ ]  **Yes**

[ ]  **No**

* 1. If data from children will be included, will they be given the opportunity to re-consent or withdraw their data from NIH repositories when they reach age of majority?

[ ]  **Yes**

[ ]  **No** **→** If no, provide a justification below.

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| Click or tap here to enter text. |

* 1. Will data obtained with the consent of a legally authorized representative (LAR) be included?

[ ]  **Yes**

[ ]  **No**

* 1. If data obtained with LAR consent will be included, will the subject later be provided with the opportunity to re-consent or withdraw data from NIH repositories?

[ ]  **Yes**

[ ]  **No** **→** If no, provide a justification below.

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| Click or tap here to enter text. |

* 1. Will the individual level data be shared through unrestricted repositories (i.e., data are made accessible to anyone via a public website)? *NOTE: Data may only be shared through unrestricted repositories if explicit participant consent is given. Otherwise, data will be shared through controlled access repositories (i.e., data are available if certain stipulations are met).*

[ ]  **Yes**

[ ]  **No**

* 1. Are the [genomic summary results](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-023.html) “sensitive” in relation to individual privacy or potential for group harm (e.g., populations from isolated geographic regions, or with rare or potentially stigmatizing traits)? *NOTE: Genomic summary results are results from primary analyses if genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant. Genomic summary results with a ‘sensitive’ designation may only be shared through controlled access repositories.*

[ ]  **No**

[ ]  **Yes** **→** If yes, provide a brief explanation for the “sensitive” designation.

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| Click or tap here to enter text. |

3. SHARING RESULTS

* 1. Will you retain the key to the code that links the submitted data to identifiers? *(NOTE: This is permitted by NIH policy. It will not be possible to return results to participants if key is not retained.)*

[ ]  **Yes**

[ ]  **No**

* 1. In the very rare circumstances when secondary research using the data submitted to the repository generates results of clinical significance to the subject, will results be returned to participants even if it is years after the data are submitted to NIH?

[ ]  **Yes**

[ ]  **No**

1. CONFIDENTIALITY
	1. Confirm that the following requirements are met by checking the boxes below:

[ ] The data will be coded or anonymized prior to submission to NIH such that the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users. Note: the PI may retain the key to the code that would link to specific individuals.

[ ] The following identifiers enumerated at section 164.514(b)(2) of the HIPAA Privacy Rule are removed prior to data submission:

* Names
* All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code and their equivalent geographical codes except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census: (a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people. (b) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.
* All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
* Telephone numbers
* Facsimile numbers
* Electronic email addresses
* Social Security numbers
* Medical records numbers
* Health plan beneficiary numbers
* Account numbers
* Certificate/license numbers
* Vehicle identifiers and serial numbers, including license plate numbers
* Device identifiers and serial numbers
* Web universal resource locators (URLs)
* Internet protocol (IP) address numbers
* Biometric identifiers, including fingerprints and voiceprints
* Full-face photographic images and any comparable images
* Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
1. ELEMENTS for INFORMED CONSENT DOCUMENTS (PROSPECTIVE DATA COLLECTION)
2. Check the appropriate box below (you must choose one):

[ ]  HSD template language for Genomic Data Sharing has been included in the consent document(s). Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#sharing) for template language.

[ ]  Not using HSD template language but the required GDS elements have been included in the consent document(s). Review the worksheet, [Genomic Data Sharing Certification](https://www.washington.edu/research/forms-and-templates/worksheet-genomic-data-sharing-certification/) for required elements.

**Keywords:** Ancillary review; GDS; Results