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| **Name**: | | Degree: |
| Department: | E-mail: | Phone: |
| Additional Contact Person: | E-mail: | Phone: |
| Project Title: | | |
| Name of Genomic Program Administrator: | | Degree: |
| Institute and Center ([IC](https://gds.nih.gov/pdf/IC_GPAs.pdf)): | | |

***Details provided below should be consistent with the NIH grant or contract, the SLU IRB Protocol (or Human Subjects Research Determination Form), and the consent form(s).***

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| **Data/Specimen Information** | | | | | | | | | |
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| 1. From where were/will be these data/specimens (i.e. specimens from whom the data were derived) obtained? Please list the institution and location. | | | | | | | | | |
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| 1. If the data/specimens were/will be provided from an outside institution, how were/will they be provided? Please mark all that apply. | | | | | | | | | N/A |
|  |  | **Anonymous/De-identified:** data contain no identifiers, including code numbers that investigators can link to individual identities; | | | | | | | |
|  |  | **Coded:** data in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept separately from coded data; **AND/OR** | | | | | | | |
|  |  | **Identifiable:** data that includes personal identifiers (e.g., name, social security number), such that information could be readily connected to respective individuals. | | | | | | | |
| 1. Were these data/specimens obtained (or will they be obtained) under an IRB approved protocol? | | | | | | | | Yes  No | |
| If the specimens were obtained under an IRB approved protocol from another institution, please provide a copy of their IRB approval letter and consent form(s) **OR** their Genomic Data Institutional Certification Form. | | | | | | | | | |
| 1. Are there any existing Genomic Data Sharing Certifications for the subject group(s) or cohort(s) from which these data are derived? | | | | | | | | Yes  No | |
| If yes, please provide a copy of the GDS certification(s). | | | | | | | | | |
| 1. Were these data/specimens collected with consent? | | | | | | | Yes  No  N/A | | |
| 1. If consent was obtained, are there any restrictions on the use of the data/specimens? | | | | | | | Yes  No  N/A | | |
| If yes, please specify the restrictions:  Please select all that apply. | | | | | | | | | |
|  |  | Health/Medical/Biomedical – Use of data is limited to health/medical/biomedical purposes (excludes study of population origins or ancestry) | | | | | | | |
|  |  | Disease Specific – Use of the data must be related to the specified disease | | | | | | | |
|  |  | Other – Please explain below: | | | | | | | |
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| 1. If data are (or will be) from any specimens collected in another country or from a tribe, are there any additional laws that would prohibit future research and the broad sharing of the data through NIH repositories? | | | | | | | Yes  No  N/A | | |
| If yes, please list the countries/tribes and explain what the relevant international/tribal laws are and how they prohibit data sharing or limit data use. | | | | | | | | | |
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| 1. Will any data be from specimens collected before January 25, 2015? | | | | | | | | Yes  No | |
| If yes, please explain which data were from specimens collected before this date. | | | | | | | | | |
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| 1. If the research is a genome-wide association study, will any data be from specimens collected before January 25, 2008? | | | | | | | Yes  No  N/A | | |
| If yes, please explain which data were from specimens collected before this date. | | | | | | | | | |
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| 1. When was the grant/contract for this research submitted to/received by the NIH? | | | | | | | | | |
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| **Data Sharing** | | | | | | | | | |
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| Please describe the data that will be submitted to the NIH. | | | | | | | | | |
| 1. What are the data elements? | | | | | | | | | |
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| 1. What type of genomic data will be shared (e.g. sequence, transcriptomic, epigenomic, and/or gene expression)? | | | | | | | | | |
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| 1. Will the data be individual-level data, aggregate-level data, or both? | | | | | | | | | |
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| 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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| 1. Will data from children be included? | | | | | | | | Yes  No | |
| If yes, will they be given the opportunity to re-consent or withdraw their data from NIH repositories when they reach the age of maturity? | | | | | | | | Yes  No | |
| If no, please explain: | | | | | | | | | |
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| 1. Will data obtained with the consent of a legally authorized representative (LAR) be included? | | | | | | | | Yes  No | |
| If yes, will the subject later be provided with the opportunity to re-consent or withdraw data from NIH repositories? | | | | | | | | Yes  No | |
| If no, please explain: | | | | | | | | | |
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| 1. Will the data be shared through unrestricted-access repositories (i.e. data are made accessible to anyone via public website)?   *NOTE: Data may only be shared through unrestricted repositories if explicitly 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. To which [NIH Data Sharing Repositories](https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html) (e.g., dbGaP) will the data be shared? | | | | | | | | | |
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| 1. Do you plan to submit variant alleles or allele frequencies from this study for display in [public variation archives](https://www.ncbi.nlm.nih.gov/variation/dbSNP_dbVar_FAQ/) (dbSNP and dbVar)? | | | | | | | | Yes  No | |
| **Sharing of Results** | | | | | | | | | |
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| 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 the key is not retained.* | | | | | | | | Yes  No | |
| 1. Did/will the participants have the option to request the return of the results in the consent form? | | | | | | | | Yes  No | |
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| 1. In the rare circumstances when secondary research using the data submitted to the repositories 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 the NIH? | | | | | | | | Yes  No | |
| **Confidentiality** | | | | | | | | | |
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| 1. Please confirm that the following requirements are met by marking the boxes below: | | | | | | | | | |
|  |  | 1. The data will be coded or anonymous prior to submission to the NIH such that the identities of the 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 the specific individuals.* | | | | | | | |
|  |  | 1. The following identifiers enumerated at section 164.541(b)(2) of the HIPAA Privacy Rule are removed prior to data submission:    * Names    * Social Security numbers    * Telephone numbers    * All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is 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    * Fax numbers    * Electronic mail addresses    * Medical record 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 Locations (URLs)    * Internet Protocol (IP) address numbers    * Biometric identifiers, including finger and voice prints    * Full face photographic images and any comparable images    * Linkable code or any other unique identifying number or characteristic unless permitted by the Privacy Rule for re-identification *(NOTE: This does not mean the unique code assigned by the Investigator(s) to code the research data)* | | | | | | | |
| **Elements for Informed Consent Documents** | | | | | | | | | |
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| 1. Please confirm that the following requirements are met by marking at least one of the boxes (a-c) below: | | | | | | | | | |
|  |  | 1. SLU IRB template language for Genomic Data Sharing has been included in the consent document(s). Please see the [SLU Informed Consent Template](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/consent_biomedical_template.doc) for the template language. | | | | | | | |
|  |  | 1. The required Genomic Data Sharing elements have been included in the consent document(s). Please see below for the required elements. Please mark the applicable scenario. | | | | | | | |
|  | | | 1. NIH grant or contract submitted **on or after** January 25, 2015: | | | | | | |
|  | | | | Specimens were collected from subjects **on or after** January 25, 2015 | | | | | |
|  | | | |  | Consent was obtained for research with specimens *(NOTE: This consent requirement is limited to these elements and refers to any process that may or may not be the process described in 45 CFR 46)*   * Consent explicitly obtained for generating genomic and phenotypic data * Consent explicitly obtained for future research use * Consent explicitly obtained for broad sharing * Consent explicitly obtained for unrestricted access (when individual level data will be shared through unrestricted access as opposed to controlled access) | | | | |
|  | | | | Specimens were collected from subjects **before** January 25, 2015 | | | | | |
|  | | | |  | Specimens were de-identified when collected from subjects | | | | |
|  | | | | | | No consent requirements | | | |
|  | | | |  | Specimens were identifiable when collected from subjects | | | | |
|  | | | | | | Consent was obtained for research with specimens *(NOTE: This consent requirement is limited to these elements and refers to any process that may or may not be the process described in 45 CFR 46)*   * Consent is not inconsistent with generating genomic and phenotypic data * Consent is not inconsistent with future research use * Consent is not inconsistent with broad sharing * Consent is not inconsistent with unrestricted access (when individual level data will be shared through unrestricted access as opposed to controlled access) | | | |
|  | | | 1. NIH grant or contract submitted **on or after** January 25, 2008 but **before** January 25, 2015: | | | | | | |
|  | | | | Genome-wide association studies only | | | | | |
|  | | | |  | Specimens were de-identified when collected from subjects | | | | |
|  | | | | | | No consent requirements  *The NIH "GWAS policy" (NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) is silent on samples that are de-identified or anonymous at the time of collection.* | | | |
|  | | | |  | Specimens were identifiable when collected from subjects | | | | |
|  | | | | | | Consent was obtained for research with specimens *(NOTE: This consent requirement is limited to these elements and refers to any process that may or may not be the process described in 45 CFR 46)*   * Consent explicitly obtained for generating genomic and phenotypic data * Consent explicitly obtained for future research use * Consent explicitly obtained for broad sharing * Consent explicitly obtained for unrestricted access (when individual level data will be shared through unrestricted access as opposed to controlled access) | | | |
|  | | | | All other genomic data which may be shared broadly | | | | | |
|  | | | |  | Specimens were de-identified when collected from subjects | | | | |
|  | | | | | | No consent requirements | | | |
|  | | | |  | Specimens were identifiable when collected from subjects | | | | |
|  | | | | | | Consent was obtained for research with specimens *(NOTE: This consent requirement is limited to these elements and refers to any process that may or may not be the process described in 45 CFR 46)*   * Consent is not inconsistent with generating genomic and phenotypic data * Consent is not inconsistent with future research use * Consent is not inconsistent with broad sharing * Consent is not inconsistent with unrestricted access (when individual level data will be shared through unrestricted access as opposed to controlled access) | | | |
|  | | | 1. All other funding: | | | | | | |
|  | | | |  | Specimens were de-identified when collected from subjects | | | | |
|  | | | | | | No consent requirements | | | |
|  | | | |  | Specimens were identifiable when collected from subjects | | | | |
|  | | | | | | Consent was obtained for research with specimens *(NOTE: This consent requirement is limited to these elements and refers to any process that may or may not be the process described in 45 CFR 46)*   * Consent is not inconsistent with generating genomic and phenotypic data * Consent is not inconsistent with future research use * Consent is not inconsistent with broad sharing * Consent is not inconsistent with unrestricted access (when individual level data will be shared through unrestricted access as opposed to controlled access) | | | |
|  |  | 1. An exception to the consent requirements was granted as the conditions in the table below were met. Exceptions must be approved by the SLU IRB. | | | | | | | |
|  | | | * Any consent that was obtained was not inconsistent with:   + Generating genomic & phenotypic data   + Future research use of the specimens   + Broad sharing of data * There are compelling reasons why it is not possible to obtain consent. * There are compelling scientific reasons why genomic and phenotypic data should be collected, broadly shared, and used for future research. * The scientific benefits clearly outweigh any additional risks to subjects, families, and groups (after taking into account the protections that are in place) that are introduced by the absence of consent. | | | | | | |
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| **Investigator Assurances** | | | | |
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| I certify that:   * The information provided here is consistent with the approved protocol (or Human Subjects Research Determination Form) and all consent forms; * The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies; * Any limitations on the research use of the data/specimens, as expressed in the information consent documents, are delineated in the section titled “Restrictions and Data Use Limitations” above; * The identities of research participants will not be disclosed to the NIH-designated data repositories; * An update on progress will be made toward the genomic data sharing plan as part of the annual research reporting requirement;   *If data/specimens are being obtained from a controlled-access repository:*   * The data/specimens will be used only for the approved research; * The data confidentiality will be protected; * No attempt will be made to identify individual participants from whom the data/specimens were obtained; * The data/specimens from the NIH-designated data repositories will not be sold; * The data/specimens from the NIH-designated data repositories will not be shared with other individuals not listed on the project request; * A summary of approved research uses in dbGaP will be listed; * Violations of the GDS Policy will be reported, in real time, to the appropriate NIH Data Access Committee (DAC) and SLU Institutional Review Board; * Research progress using controlled-access datasets will be reported through annual access renewal requests or project close-out reports; * The use of the specific dataset or accession numbers and the repository will be acknowledged in all oral and written presentations;   *If data/specimens are being obtained from an unrestricted-access repository:*   * No attempt will be made to identify individual participants from whom the data/specimens were obtained; and * The use of the specific dataset or accession numbers and the repository will be acknowledged in all oral and written presentations. | | | | |
|  |  |  |  |  |
|  | Print Name of SLU Investigator |  | Date |  |
|  |  |  |  |  |
|  | Signature of SLU Investigator |  |  |  |