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| --- | --- |
| Date of Review: | IRB Number: |
| Researcher Name: |
| Department:  |
| Project Title:  |
| Consent Form(s) and Version Date(s): |
| Will this activity take place at an SSM facility?  | Yes [ ]   | No [ ]  |
| Certification: | Recommended [ ]   | Not Recommended [ ]  |

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| --- |
| **Level of Review:** |
| Full Committee | [ ]  | Expedited | [ ]  | Not Human Subjects Research | [ ]  | External IRB | [ ]  |
| **Main Criteria:** |
|  |
| All criteria below must be met for data to be certified for submission to NIH data repositories.  |
|  |
| 1. The data submission is consistent as appropriate with all applicable national, tribal, and state laws and regulations, as well as relevant institutional policies.
 | Yes [ ]  No [ ]  |
| 1. Any limitations on research use of the data, as expressed in the informed consent documents are delineated.
 | Yes [ ]  No [ ]  |
| 1. The identities of research participants will not be disclosed to NIH-designated data repositories.
 | Yes [ ]  No [ ]  |
| 1. An IRB has reviewed the proposal for data submission and assures that:
 |  |
| For research that has been or will be reviewed by the SLU IRB: |
| * + The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR, Part 46.
 | Yes [ ]  No [ ]  |
| * + The submission of data to NIH designated data repositories and subsequent sharing for research purposes are consistent with the informed consent of the study participants from whom the data were obtained. See [Genomic Data Sharing Form](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/genomic_data_sharing_form.docx).
 | Yes [ ]  No [ ]  |
| * + Consideration was given to risks to individual participants and their families associated with data submitted to NIH designated repositories and subsequent sharing.
 | Yes [ ]  No [ ]  |
| * + To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to the NIH-designated data repositories and subsequent sharing.
 | Yes [ ]  No [ ]  |
| * + The investigator's plan for de-identifying data sets is consistent with the standards outlined in the policy:
		1. The identities of data subjects cannot be readily ascertained or otherwise associated with the data by repository staff or secondary data users, **AND**
		2. The identifiers enumerated at section 164.514(b)(2) of the HIPAA Privacy Rule are removed.
 | Yes [ ]  No [ ]  |
|  |  |
| For sponsored research requesting confirmation from the SLU IRB: |  |
| * + The submission of data to NIH designated data repositories and subsequent sharing for research purposes are consistent with the informed consent of the study participants from whom the data were obtained. See [Genomic Data Sharing Form](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/genomic_data_sharing_form.docx).
 | Yes [ ]  No [ ]  |
|  |
| For research that has been or will be reviewed by an external IRB: |
| * + The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR, Part 46.
 | Yes [ ]  No [ ]  |
| * + The submission of data to NIH designated data repositories and subsequent sharing for research purposes are consistent with the informed consent of the study participants from whom the data were obtained. See Genomic Data Sharing Form.
 | Yes [ ]  No [ ]  |
| * + Consideration was given to risks to individual participants and their families associated with data submitted to NIH designated repositories and subsequent sharing.
 | Yes [ ]  No [ ]  |
| * + To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to the NIH-designated data repositories and subsequent sharing.
 | Yes [ ]  No [ ]  |
| * + The investigator's plan for de-identifying data sets is consistent with the standards outlined in the policy:
		1. The identities of data subjects cannot be readily ascertained or otherwise associated with the data by repository staff or secondary data users, **AND**
		2. The identifiers enumerated at section 164.514(b)(2) of the HIPAA Privacy Rule are removed.
 | Yes [ ]  No [ ]  |
|  **OR** |
|  |  |
| * + The external IRB for which Saint Louis University is relying on the IRB review has provided their Institutional Certification to cover all SLU study procedures.
 | Yes [ ]  No [ ]  |
|  |
| **Exception to Consent Expectations:** |
|  |
| 1. Has the IRB approved an exception to the GDS consent requirements for compelling scientific reasons?
 | Yes [ ]  No [ ]  |
| If yes, provide rationale below: |
|  |  |
|  |
| **Restrictions and Data Use Limitations:** |
|  |
| 1. Does the consent form include any restrictions that preclude submission of the data to NIH?
 | Yes [ ]  No [ ]  |
| If yes, **STOP**. The data cannot be certified. Explain below: |
|  |  |
|  |
| If no, continue. |
|  |
| 1. Identify the consent group specifications and data use limitations in the consent forms and document them in the table below:

*Check all that apply.* | Yes [ ]  No [ ]  |
|  |
|  | Participants have consented to the return of the results. | Yes [ ]  No [ ]  |
|  | The use of aggregate-level data for general research is consistent with the consent form. | Yes [ ]  No [ ]  |
|  | The data are to be made available through unrestricted[[1]](#endnote-1) access. | Yes [ ]  No [ ]  |
|  | The data are to be made available through controlled[[2]](#endnote-2) access. | Yes [ ]  No [ ]  |
|  | The National Center for Biotechnology Information is authorized to upload the display of variant alleles and/or frequencies from this study in public variation archives (i.e. dbSNP and dbVar).[[3]](#endnote-3) |  |
|  |
|  | General Research Use – Use of data for unspecified research is permitted. | Yes [ ]  No [ ]  |
|  |  | If yes, select all that apply:[ ]  IRB approval required – requestor must provide documentation of IRB approval[ ]  Publication required – requestor agrees to make results of studies using the data available to the larger scientific community[ ]  Collaboration required – requestor must provide a letter of collaboration with the primary study investigator(s)[ ]  Not-for-profit use only – use of the data is limited to not-for-profit organizations |
|  | Health/Medical/Biomedical – Use of data is limited to health/medical/biomedical purposes (excludes study of population origins or ancestry). | Yes [ ]  No [ ]  |
|  |  | If yes, select all that apply:[ ]  IRB approval required – requestor must provide documentation of IRB approval[ ]  Publication required – requestor agrees to make results of studies using the data available to the larger scientific community[ ]  Collaboration required – requestor must provide a letter of collaboration with the primary study investigator(s)[ ]  Not-for-profit use only – use of the data is limited to not-for-profit organizations[ ]  Methods – use of the data includes methods development research (e.g. development of software or algorithms)[ ]  Genetic studies only – use of the data is limited to genetic studies only |
|  | Disease Specific – Use of the data must be related to the specified disease. | Yes [ ]  No [ ]  |
|  |  | If yes, select all that apply:[ ]  IRB approval required – requestor must provide documentation of IRB approval[ ]  Publication required – requestor agrees to make results of studies using the data available to the larger scientific community[ ]  Collaboration required – requestor must provide a letter of collaboration with the primary study investigator(s)[ ]  Not-for-profit use only – use of the data is limited to not-for-profit organizations[ ]  Methods – use of the data includes methods development research (e.g. development of software or algorithms)[ ]  Genetic studies only – use of the data is limited to genetic studies only[ ]  Related disorders – use of the data is limited to genetic studies of the specified disease and related conditions, such as: |
|  | Other | Yes [ ]  No [ ]  |
|  |  | If yes, enter customized text: |
|  |  |  |
|  |

1. Data made publically available to anyone. [↑](#endnote-ref-1)
2. Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project. [↑](#endnote-ref-2)
3. The Single Nucleotide Polymorphism Database/ Database of Short Genetic Variations (dsSNP) is a public archive for genetic variation (apparently neutral polymorphisms, polymorphisms corresponding to known phenotypes, and regions of no variation) within and across species. The Database of Genomic Structural Variations (dbVar) is a collection of genomic structural variation data, typically 50 nucleotides in length or longer, for different organisms. For more information, see: https://www.ncbi.nlm.nih.gov/variation/dbSNP\_dbVar\_FAQ/. [↑](#endnote-ref-3)