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| **Protocol Information** | | |
| **PI:** | | |
| **IRB #:**  **Title:** | | |
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| **Review Criteria** | | |
| **A. Prospective Studies** | | |
| Yes  No | | 1. The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46. |
| Yes  No | | 1. Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained (see Informed Consent points to consider below for guidance). |
| Yes  No | | 1. Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing. |
| Yes  No | | 1. To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing. |
| Yes  No | | 1. The investigator’s plan for de-identifying datasets is consistent with the standards outlined in the Genomic Data Sharing Policy. |
| **Comments**: | | |
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| **B. Retrospective Studies** | | |
| **1. Informed Consent Form (ICF) – Points to Consider**  **Is the initial consent under which the existing data/genetic material were obtained consistent with the submission of data to an NIH-designated repository and the sharing of that data in accord with Genomic Data Sharing Policy?** | | |
| **General** | | |
| Yes  No | 1. Does the consent form either allow or not preclude genetic research or analysis? | |
| Yes  No | 1. Does the consent form either allow or not preclude future use and broad sharing of the participant’s coded phenotype and genotype data for research? | |
| Yes  No | 1. Does the consent form either allow or not preclude the submission of the participant’s coded phenotype and genotype data to a government health research database for broad sharing to qualified investigators? | |
| Yes  No | 1. Does the consent form include any restrictions regarding the type of subsequent research using the participant’s phenotype and genotype data? | |
| Yes  No | 1. Does the consent form have any restrictions regarding the location of the research? | |
| Yes  No | 1. Does the consent form have any restrictions regarding the types of medical conditions or diseases studied? | |
| Yes  No | 1. Does the consent form have any restrictions re the duration of storage of the phenotype and genotype data? | |
| Yes  No | 1. Does the consent form have any limitations on who can use the participant’s phenotype and genotype data (e.g. only non-commercial researchers)? | |
| **Benefits** | | |
| Yes  No | 1. Does the consent form discuss that potential benefits may accrue broadly to the public through the advancement of science and understanding of health and disease, rather than resulting in direct benefits to individuals? | |

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| **Risks** | |
| Yes  No | 1. Does the consent form discuss risks of broad sharing of phenotype and genotype data? |
| Yes  No | 1. Does the consent form discuss privacy risks of sharing data (e.g. the possibility that the coded data may be released to members of the public, insurers, employers, and law enforcement agencies)? |
| Yes  No | 1. Does the consent form discuss the risks of computer security breaches relevant to maintaining data in an electronic format? |
| Yes  No | 1. Does the consent form discuss relevant risks to relatives or identifiable populations or groups? |
| **Return of Research Results** | |
| Yes  No | 1. Does the consent form discuss whether or not research results will be returned to the subjects, and under what conditions? |
| Yes  No | 1. Are those representations consistent with the GWAS policy that research results may only be returned in rare instances following established procedures at the contributing institutions? |
| **Privacy and Confidentiality Protections** | |
| Yes  No | 1. Does the consent form address how individual privacy and data confidentiality will be maintained? |
| Yes  No | 1. Is the manner in which privacy and data confidentiality measures are described consistent with the Genetic Data Sharing Policy policy (i.e. “Data submitted to the NIH-designated repository will be assigned a random, unique code”)? |
| **Withdrawal of consent** | |
| Yes  No | 1. Does the consent form address whether a subject can withdraw his/her phenotype and genotype data from research use? |
| Yes  No | 1. Is the language used consistent with the NIH Genetic Data Sharing Policy?  “*Submitting investigators and their institutions may request removal of data on individual participants from NIH-designated data repositories, in the event that a research participant withdraws or changes his or her consent. However, some data that have been distributed for approved research use cannot be retrieved.*” |
| **Commercial Use** | |
| Yes  No | 1. Does the consent form allow for or not preclude commercial use of the subject’s phenotypic and genotypic data? |
| **Comments**: | |
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| 1. **Study Protocol** | |
| Yes  No | 1. The phenotype and genotype data submitted were collected in a manner consistent with the requirements of 45 CFR 46? |
| Yes  No | 1. Is the investigator’s plan for coding data sets consistent with the Genetic Data Sharing Policy policy (i.e. “Data submitted to the NIH-designated repository will be assigned a random, unique code”)? |
| **Comments**: | |
| 1. **General IRB Considerations regarding the sharing of data/specimen with the repository/registry** | |
| Yes  No | 1. Are there any considerations to be addressed re the involvement of children or other vulnerable populations (e.g., when the child reaches legal age)? |
| Yes  No | 1. Are there any additional considerations to be addressed (e.g., the risks to individuals, their families, and groups or populations) associated with the data/specimen submitted to the repository/registry? |
| Yes  No | 1. Are there any cultural considerations or requirements to be considered (e.g., tribal consent from Native American populations)? |
| **Comments**: | |

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| **Summary plus Required and Recommended Stipulations (if any)** |
| **Additional Comments** |
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| **IRB Reviewer’s Stipulations** |
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| **Certification, Modification or Disapproval** | | |
| **Certification of Sharing Plan**  The data/specimen sharing plan is appropriate  The proposed sharing is consistent with the ICF  The data are to be made available through unrestricted access. | **Exclusions:**  The IRB-approved protocol/consent contain the following restrictions to the use of the data/specimen:  The IRB-approved protocol/consent limit future use to not-for-profit organizations.  The data are only to be made available through controlled-access. | |
| **Re-consent of Subject:**  Recommended  Not feasible or appropriate  Not necessary | Yes  No **Modifications Required?**  **Stipulations to be reviewed by:**  Review by Chair or Designee:  Full Board of the IRB | |
| **IRB Reviewer Name/Signature:** | | **Date:** |