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| **or-logo-stacked** | **Institutional Review Board**[**Human Research Protections**](https://research.uci.edu/compliance/human-research-protections/index.html) **(HRP)**[**NIH Genomic Data Sharing (GDS) Policy**](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/)**: Consent Form Checklist****UPDATED!** *Version February 2021* |
| **INSTRUCTIONS:*** Submit a completed checklist to UCI IRB at the time of your request for an [Institutional Certification](https://osp.od.nih.gov/scientific-sharing/institutional-certifications/).
	+ For certification requirements that are included with the funding/award, please contact the following for signature:
		- NIH GDS Certification: Assigned [Sponsored Projects Officer](https://research.uci.edu/sponsored-projects/about/staff-dept-assignment.html)
		- NIH Database of Genotypes and Phenotype (dbGaP) Certification: Grace Park, Assistant Director, Sponsored Projects (parkgj@uci.edu)
	+ For certification requirements that are **not** included with funding/award, please submit a completed certification to the IRB. Choose from the various [NIH certification templates](https://osp.od.nih.gov/scientific-sharing/institutional-certifications/).
* For multi-site research where UCI is the IRB of Record, submit a copy of this checklist for each consent form, and also submit a copy of the consent form from the other site(s).

**BACKGROUND:** The UCI IRB must [verify to the NIH](http://gwas.nih.gov/08institutions.html) that the data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained. For new studies proposing to send data for NIH GDS, the consent form must satisfy ***all*** of the following criteria listed below.  |
| **HS#: Pending****(assigned by IRB)** | **Study Title: Type Here** |
| **Name of Institution that Approved the Consent Form:** **Type Here** |

1. **Consent Form:** Mark an “X” to confirm that the consent form meets each of the following criteria. If the consent form does not meet one or more criterion, explain in the Comments field below.
2. \_\_\_\_\_ Allows for genetic research or analysis
3. \_\_\_\_\_ Allows for future use and broad sharing of the participant’s coded phenotype and genotype data for research
4. \_\_\_\_\_ Allows for submission of the participant’s coded phenotype and genotype data to a government health research database for broad sharing to qualified investigators
5. \_\_\_\_\_ Discusses risks of broad sharing of phenotype and genotype data
6. \_\_\_\_\_ Discusses privacy risks of data sharing (e.g., the possibility that the coded data may be released to members of the public, insurers, employers, and law enforcement agencies)
7. \_\_\_\_\_ Discusses the risks of computer security breaches relevant to maintaining data in an electronic format
8. \_\_\_\_\_ Discusses relevant risks to relatives or identifiable populations or groups
9. \_\_\_\_\_ Describes how individual privacy and data confidentiality will be protected
10. \_\_\_\_\_ Indicates that identifiers will not be provided to government database
11. \_\_\_\_\_ Discusses 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
12. \_\_\_\_\_ Indicates either that research results will not be returned, or only returned in rare instances, and describe the conditions under which this could occur
13. \_\_\_\_\_ Indicates that a subject can withdraw his/her data from future research use. Instruct subject that if they decide to withdraw permission, to notify the UCI investigators in writing. Inform subject that in this case, their data will not be used for future research but that data that had already been distributed to researchers cannot be retracted
14. \_\_\_\_\_ Allows commercial use of subject’s phenotypic and genotypic data
15. Does the consent form place a limit on the use of the data (e.g. data may only be used for research on a specific disease, retained for a specific period of time)

 \_\_\_\_\_Yes \_\_\_\_\_No

*If yes, explain:*

1. **Comments Section:**