NIH Genomic Data Sharing (GDS) Consent Checklist

PI: | **IRB #:**

Study Title:

Name of Institution that Approved this Consent Form and Name of Consent in iRIS:

Instructions: Submit this checklist to the UCSF IRB at the time of your request for a data submission certification letter. For multi-center research, 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 IRB must verify to the NIH that the submission of data and subsequent 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 to NIH GDS, the consent form must satisfy ***all*** of the following criteria.

Consent Form: Confirm that the consent form meets the following criteria by pasting in the wording from the consent document and the page number where it can be found. If the consent form does not meet one or more criterion, explain in the Comments field. ***Complete a checklist for each version of the consent, if there is more than one.***

	Required Elements	Wording from Consent Document	Page #
1	Allows for genetic research or analysis		
2	Allows for future use and broad sharing of the participant's coded phenotype and genotype data for research		
3	Allows for submission of the participant's coded phenotype and genotype data to a government health research database for broad sharing to		
4	Discusses risks of broad sharing of phenotype and genotype data		

5	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)		
6	Discusses the risks of computer security breaches relevant to maintaining data in an electronic format		
7	Discusses relevant risks to relatives or identifiable populations or groups		
8	Describes how individual privacy and data confidentiality will be protected		
9	Indicates that identifiers will not be provided to government database		
10	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		
11	Indicates either that research results will not be returned, or only returned in rare instances, and describe the conditions under which this could occur		

12	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 UCSF 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		
13	Allows or precludes commercial use of subject's phenotypic and genotypic data		
14	Please select what type of database the data will be submitted to.	Unrestricted ☐ Controlled Access ☐	
15	Does the consent form place a limit of use (e.g. data may only be used for research on a specific disease)?	Yes ☐ No ☐	

If yes, explain:

Comments:
