PI: **eProtocol #:**

Study Title:

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

Instructions: Submit this checklist and corresponding consent form(s) to the Stanford IRB at the time of your request for an Institutional Certification. For consents from multiple sites, submit a copy of this checklist for each different consent form used.

Background: The IRB must certify 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/specimens were obtained. For new studies proposing to send data to NIH-supported repositories, 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	Genomic and phenotypic data will be generated and may be used for future research (on any topic).		
2	Data will be shared broadly as consistent with consent		
3	Before submission to NIH/federal repository, data will be stripped of identifiers. Safeguards to protect the data will be implemented.		
4	Access to de-identified data will be controlled unless participant explicitly consents to allow unrestricted access and use of data for any purpose.		

Required Elements		**Wording from Consent Document**	**Page #**
5	Even if access is controlled and data security standards are met, confidentiality cannot be guaranteed. Re-identified data could potentially be used to discriminate against you or stigmatize participants, their families or groups.		
6	There may be unknown risks.		
7	No direct benefits to participants are expected for any secondary research that may be conducted.		
8	Consent may be withdrawn at any time without penalty or loss of benefits and will be removed from the repository. Data that is already distributed will not be retrieved.		
9	Name and contact information of individual affiliated with Stanford and familiar with the research who will be available to address participant questions.		
10	Please select what type of database the data will be submitted to.	Unrestricted ○ Controlled Access ○	
11	Does the consent form place a limit on use (e.g. data may only be used for research on a specific disease)?	Yes ○ No ○ **If yes, explain:**	

Comments: