Genomic Data Sharing (GDS) Consent Checklist

Mass General Brigham IRB Protocol #

PI:

Study Title:

If applicable to an I.O. Certification:

NIH Grant Title:

NIH Grant Number (R01XX12345):

Background: The IRB must certify that the submission of data and subsequent sharing for research **Instructions:** 1. At the time of your request for an Institutional Certification letter or submission of new cohorts for 2. Submit a copy of each consent form version used in the collection of samples that will be 3. In addition, highlight the language in each consent form version that supports the below genomic data sharing guidelines.

If there are multiple versions of the consent form, please confirm the following:
Title of Specimen Collection Protocol:

Protocol Number:

Consent Form Title:

Principal Investigator Listed on Consent Form:

Institution:

If the institution is not in the United States, provide city and country:

Date range of samples collected:

Consent Form: In order for the IRB to **c**onfirm the consent form(s) meet the NIH GDS criteria, please "copy and paste" the lanaguage 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.

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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 de-identified phenotype and genotype data for research.		
3	Allows for submission of the participant's de-identified phenotype and genotype data to a central repository (health research database) for broad sharing		
4	Discusses risks of broad sharing of phenotype and genotype data		
a.	Confidentiality risks		
b.	Familial risks (how this may affect relatives)		
c .	Population sensitivity (identifiable populations or groups)		
5	Describes how individual privacy and data confidentiality will be protected		
6	Includes language to describe the type of database Unrestricted (open access, i.e. GEO) or Controlled (closed access, i.e. dbGAP) the consent form describes submission of the data. Check all that apply:		
	☐ Unrestricted Access (openly posted data such as GEO)		
	☐ Controlled Access (limited to qualified investigators who apply such as dbGAP)		
	☐ Consent form does not specify.		

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7	Does the informed consent form or the IRB/EC prohibit any of the following? Check all that apply:	
	☐ Future use of data by commercial entities	
	☐ Methods research (analytic/software/technology development)	
	☐ Aggregate level data for general research use	
8	The display of variant alleles and/or frequencies from the study (e.g., study wide summary data on the frequency of particular genetic variants in the study population) in open access variation archives (i.e., dbSNP and dbVAR) is not inconsistent with the informed consent. [For more information about dbSNP and dbVar, visit: http://www.ncbi.nlm.nih.gov/variation/dbSNP_dbVar_FAQ.]	
	☐ Yes, display of variant alleles or frequencies is not inconsistent with the consent. (It is permitted)	
	☐ No, display of variant alleles or frequencies is inconsistent with the consent. (It is not permitted)	
9	If the consent form contains checkboxes specifying allowable types of future uses, has it been confirmed with the study team that there is a system to honor the subject's wishes?	
	☐ Yes	
	☐ No	
	If the answer is no, the most limiting choice must be applied. For example, data use is limited to a particular disease area or local use only. Complete the limitations in question 10.	
10	Permissible future uses of the data are as follows (check one):	
	The consent form limits use to the following disease areas:	
	☐ Future use is restricted to health/medical/biomedical research (does not include population origins or ancestry)	
	☐ No restrictions, general research use is permitted. The Partners IRB requires justification to allow for this:	
	Justification	
11	Other restrictions: (examples: IRB review needed for each future project, may only be used to study certain populations)	
12	Is there anything in the consent form that could preclude future sharing of data?	
	☐ No	
	☐ Yes	
	If yes, comment:	