Institutional Certification

For data generated from cell lines created or clinical specimens collected before January 25, 2015, that lack consent

Date: [MM/DD/YYY] Name of GPA Genomic Program Administrator [, NIH, HHS 9000 Rockville Pike Bethesda, MD 20892-7395	
Re: Institutional Certification ofSubmission of the Dataset from	[ORIGINAL STUDY NAME ¹] for
Dear The submission of data to the NIH-designated data repository is being made w, along with appropriate institution as listed here: IIF APPLICABLE ENTER COLLABORATING SITE NAMES HERE AND CLICK 'ADD TO LIST]	nal approvals from collaborating sites,
The hereby assures that submentitled repository meets the following expectations, as defined in the <u>Genomic Dat</u> • The data submission is consistent, as appropriate, with applicable mand regulations as well as relevant institutional policies. ²	ta Sharing Policy:
Unless otherwise specified by	_ on page 2 of this search purposes without any

The data are to be made available through unrestricted² or controlled-access³ (If unrestricted access is marked, the data use limitation table on page 2 does not need to be completed.)

The National Center for Biotechnology Information is authorized to upload the display of variant alleles and/or frequencies from this study in public variation archives (i.e., dbSNP and dbVar)⁴.

^{*} Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide their own Institutional Certification.

Sample Institutional Certification for Data Derived From Clinical Specimens Collected or Cell Lines Created before January 25, 2015, that Lack Research Consent

For guidance on drafting data use limitations, please refer to the NIH Points to Consider in Drafting Effective Data Use Limitation Statements found at: <u>http://gds.nih.gov/pdf/nih_ptc_in_drafting_dul_statements.pdf</u>. Data use limitations are developed based on the original informed consent from the participant.

Data Use Limitations (will be used in dbGaP to create Consent Groups)

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the <u>dbGaP Collection</u> .
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Data Use Limitation Modifiers

IRB approval required	IRB	Requestor must provide documentation of local IRB approval.	
Publication required	PUB	Requestor agrees to make results of studies using the data available to the larger scientific community.	
Collaboration required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).	
Not-for-profit use only	NPU	Use of the data is limited to not-for-profit organizations.	
Methods	MDS	Use of the data includes methods development research (e.g., development of software or algorithms)	
Genetic studies only	GSO	Use of the data is limited to genetic studies only.	

Using the tables above, please indicate in the form below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	Data Use Limitation		Data Use Limitation Modifiers					
Eg: Cold Cohort Study	Health/Medical/Biomedical		IRB 🗌	PUB	COL	NPU 🗌	MDS	GSO 🗌
Eg: Cold Cohort Study	Disease Specific Research [_]	IRB 🔀	PUB 🗌	COL	NPU 🔀	MDS	GSO
			IRB	PUB	COL	NPU	MDS	GSO
			IRB	PUB	COL	NPU	MDS	GSO
			IRB	PUB	COL	NPU	MDS	GSO
			IRB	PUB	COL	NPU	MDS	GSO
			IRB	PUB	COL	NPU	MDS	GSO
			IRB	PUB	COL	NPU	MDS	GSO

Sincerely,	
Investigator:	
Name:	_ Title:
Signature:	
Authorized Institutional Official:5	
Name:	_ Title:
Signature:	_ Date:

¹Original Study Name should reflect the name of the original IRB-approved study (e.g. cohort or case-control study, clinical trial) under which participants provided informed consent and biospecimens were collected (e.g., Nurses' Health Study, Framingham Heart Study).

² Data made publicly available to anyone

³ Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

⁴ The Single Nucleotide Polymorphism Database (dbSNP) is a public archive for genetic variation (apparently neutral polymorphisms, polymorphisms corresponding to known phenotypes, and regions of no variation) within and across species. The Database of Genomic Structural Varian (dbVar) is a collection of genomic structural variation data, typically 50 nucleotides in length or longer, for different organisms. For more information, see: http://www.ncbi.nlm.nih.gov/variation/dbSNP_dbVar_FAQ/.

⁵ A senior official at an institution who is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who plans to submit data to NIH, e.g., Dean, Vice President for Research.