NHGRI Extramural Genomic Data Sharing Plan

(Basic Study Information Form)

Version 2019-07-23

Provide the information listed below and return to your NIH Program Officer (PO).

Checklist of required documents:

☐ Institutional Certifications

☐ NHGRI Genomic Data Sharing & Submission Information

☐ Routing Sheet (see last page)

PART I – Study Registration Information

Study name:

Is this a multi-center study? ☐ Yes ☐ No

If YES, list participating sites:

Data will be submitted (choose one): ☐ Within 3 months of last data generated or last clinical visit ☐ By the time of initial publication *(non-human data ONLY)* ☐ Data will be submitted by batches over Study Timeline (e.g. based on clinical trial enrollment benchmarks) Specify:	Data to be released will meet the timeframes specified in the **NHGRI Genomic Data Sharing (GDS) Policy: Data Standards** ☐ Yes ☐ No If **NO**, describe the data release timeline:
Target data delivery date: *(YYYY-MM-DD)*	Target public release date: *(YYYY-MM-DD)*
Number of bytes of data to be deposited:	Estimated number of study participants:

Are you requesting for an exception to data deposition? ☐ Yes ☐ No

If **YES**, complete **PART VIII- Request for an Exception to Data Deposition** in its entirety**.**
If **NO**, list all submission locations:

The individual-level data are to be made available through: ☐ Unrestricted access ☐ Controlled Access

If **UNRESTRICTED ACCESS**, Part VII does not need to be completed.

☐ Sequence Read Archive (SRA)	☐ ENA	☐ Other (list all):
☐ Trusted Partner (e.g. Bionimbus, GDC)	☐ GenBank	_____
☐ Array Express	☐ GEO	_____
☐ ClinVar	☐ MGI	_____
☐ dbGaP	☐ Trace Archive	_____
☐ dbVar	☐ WormBase	_____
☐ dbSNP	☐ ZFIN	_____

PART II – Principal Investigator (PI) and Funding Information

PI name:	PI e-mail:
PI institution:	
PI assistant/submitter name:	PI assistant/submitter e-mail:

Do you have an eRA Commons account? ☐ Yes ☐ No If **YES**, go to the next field. If **NO**, register at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.	
NIH Grant or Contract Number:	NIH Program Officer:
NIH Institutes/Centers supporting the study:	

PART III – Policy

Do you have Institutional Certifications (IC) to submit these data? ☐ Yes ☐ No

The IC will include the **Data Use Limitations (DUL)**, which are based on the informed consent given by each research subject. For every research subject, his/her corresponding data will be tagged with the appropriate DUL. Each study may have multiple DULs, based on the informed consent in the study.

If **YES**, send Institutional Certification(s) to the NIH Program Officer, along with this document.
If **NO**, obtain the Institutional Certification from your Institutional Official. dbGaP requires that the sponsoring NIH Institute/Center verifies that this certification has been met. A description of the requirements for the Institutional Certification and an example may be found in the accompanying **Submission into the NIH Database of Genotypes and Phenotypes (dbGaP)** guide.

PART IV – Study Description

Study type(s) (e.g. longitudinal, case-control, case set, control set, parent-offspring trios, cohort):

Samples genotyped/sequenced:

Check all data types expected for this study:	**General** ☐Individual Phenotype ☐Individual Genotype ☐Individual Sequencing ☐Supporting Documents ☐Metagenomic ☐Proteomic/Metabolomic ☐Images ☐Other (specify):	**Sample Types** ☐Germline ☐Tumor/Normal ☐DNA ☐RNA ☐Mitochondria ☐Microbiome ☐From Repository ☐Other (specify):	**Array Data** ☐SNP Array ☐Expression Array ☐Methylation Array ☐Other (specify):
Species ☐Human Data ☐Non-Human Data **Phenotype** ☐Individual-level Data ☐Aggregate Data ☐N/A- no human data			
Genotypes ☐Array derived Genotypes ☐CNV calls from microarray ☐CNV calls derived from Sequencing ☐Genotype calls derived from Sequence ☐Somatic SNV (.MAF) ☐Array CGH CNVs ☐Other (specify):	**Sequencing** ☐Whole Genome ☐Whole Exome ☐Targeted Genome ☐Targeted Exome ☐Whole Transcriptome ☐Targeted Transcriptome ☐Epigenomic Marks ☐Sanger ☐16S rRNA ☐Other (specify):	**Analyses** ☐Association/Linkage Results ☐Array derived Expression ☐RNA Seq derived Expression ☐Array derived Methylation ☐Other (specify):	**Sample Collection** ☐Prospective Sample ☐Existing (Legacy) Describe other data that is anticipated to be shared (e.g. phenotype):

Genotype/Sequence platform information				
Name and version	**Vendor**	**# Probes**	**URL**	**Description (optional)**
Example: [GenomeWideSNP_6] Affymetrix Genome-Wide Human SNP 6.0 Array	*Affymetrix*	*1880794*	*http://www.ncbi.nlm.nih.gov/geo/query/acc.cgi?acc=GPL6801*	

PART V – Acknowledgement Statement(s)

The submitting PI should provide specific points that should be included in an acknowledgement, such as sources of support or collaborators who have made subjects or samples available. Any NIH support must be specifically acknowledged by including the grant number. Consider citing a specific publication that comprehensively describes the origin of the dataset.

The suggested Acknowledgement Statement to accompany the dataset is:

PART VI – Original Summary of Study

Provide an original description of the study.

PART VII – Request for an Exception to Data Deposition

Are you requesting for an exception to data deposition for broad data sharing? ☐ Yes ☐ No

If **NO**, skip the rest of Part VIII, including the Alternative Data Sharing Plan. Proceed to Part IX.

If **YES**, mark the reason(s) for requesting an exception, then describe and explain the reason(s).

- ☐ Legal restrictions
- ☐ Informed consent processes are inadequate to support data sharing through dbGaP for the following reason(s) (NOTE: IRB must concur)
  - ☐ The consent forms are unavailable or non-existent for samples collected after January 25, 2015
  - ☐ The consent process did not explicitly address future use or broad data sharing for samples collected after January 25, 2015
  - ☐ The consent process inadequately addressed risks related to future use or broad data sharing for samples collected after January 25, 2015
  - ☐ The consent process specifically precludes future use or broad sharing (including a statement that use of data will be limited to the original researchers)
  - ☐ Other informed consent limitations or concerns
- ☐ Other

Explanation for Exception Request (If needed, please attach additional information to this document):

Alternative Data Sharing Plan

Describe how access to the data will be provided. See "**Exceptions and Alternatives to the NHGRI Genomic Data Sharing Expectations**" for basic criteria that NHGRI will use to assess Alternative Data Sharing Plans.
(If needed, please attach additional information to this document)

PART VIII – Extramural Routing Sheet

If filled out electronically, the "Fill and Sign" tool can be used to electronically sign this document.

_____ _____
Principal Investigator (Print Name) **Date**

_____
Principal Investigator (Signature)

_____ _____
Institutional Signing Official (Print Name) **Date**

_____
Institutional Signing Official (Signature)

_____ _____
Program Officer (Print Name) **Date**

_____
Program Officer (Signature)

_____ _____
Genomic Data Sharing Program Administrator (GPA) (Print Name) **Date**

_____
Genomic Data Sharing Program Administrator (GPA) (Concurrence/Signature)

For Genomic Data Sharing Program Administrator only if exception requested

Eric D. Green, M.D., Ph.D. _____
NHGRI Director (Print Name) **Date**

_____
NHGRI Director (Signature)