NHGRI Extramural Genomic Data Sharing Plan

(Basic Study Information)

Version 2019-12-10

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

Checklist of required documents:
☐Institutional Certifications
☐NHGRI Genomic Data Sharing Plan (this form)
☐Routing Sheet (see last page)

PART I – 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 II – 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 ☐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 Guidance for Data Submission and Data Release ☐ Yes ☐ No If **NO**, describe the data release timeline:
Target data delivery date: *(YYYY-MM-DD)*	Target public release date: *(YYYY-MM-DD)*
Estimated # of bytes of data to be deposited:	Estimated # of study participants:
The individual-level data are to be made available through: ☐ Unrestricted Access ☐ Controlled Access	
Are you requesting an Alternative Data Sharing Plan for samples that cannot be shared through a public database or repository**?** ☐ Yes ☐ No If **YES**, complete **PART VII - Request for an Alternative Data Sharing Plan** in its entirety**.** If **NO**, list all submission locations:	
☐ AnVIL ☐ dbGaP ☐ GenBank ☐ Model Organism ☐ Other (list all): ☐ Sequence Read Archive (SRA) ☐ ClinVar Database (specify): ☐ dbVar ☐ dbSNP ☐ GEO	

PART III – Study Description

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

Samples genotyped/sequenced (check all data types expected for this study).
Note that sufficient phenotypic information should be submitted to replicate the aims of the study.

Species ☐Human Data ☐Non-Human Data **Sample Collection** ☐Prospective Sample ☐Existing (Legacy) **Phenotype** ☐Individual-level Data ☐Aggregate Data ☐N/A- no human data	**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):
Genotypes ☐Array derived Genotypes ☐CNV calls from microarray ☐CNV calls derived from Sequencing ☐Genotype calls derived from Sequencing ☐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):	Describe other data that is anticipated to be shared:

Note: If you are not submitting human data, proceed to Part VIII - Extramural Routing Sheet

PART IV – Policy

Do you have an Institutional Certification(s) (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 of all the participants in the study.

If **Yes**, send the IC(s) to your NIH Program Officer along with this document.
If **NO**, obtain the IC from your Institutional Signing Official. dbGaP requires that the sponsoring NIH Institute/Center verifies that this certification has been met. A description of the requirements for the IC and an example may be found in the **Points to Consider for Institutions and Institutional Review Boards in Submission and Secondary Use of Human Genomic Data under the National Institutes of Health Genomic Data Sharing Policy** guide.

PART V – Acknowledgment Statement(s)

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

The suggested Acknowledgment Statement to accompany the dataset is (if needed, attached additional documentation):

PART VI - Request for an Exception for Samples Lacking Explicit Consent for Future Research Use and Broad Sharing

NHGRI expects all human data generated by NHGRI-supported research will be derived from specimens or cell lines for which explicit consent for future research use and broad sharing can be documented. NHGRI recognizes that not all studies are able to meet this expectation. For these studies an exception may be requested with strong justification.

Are you requesting an Exception for samples that lack explicit consent for future research use and broad data sharing? ☐ Yes ☐ No

If **NO**, proceed to Part VII.

If **YES**, complete the rest of this section. **You must include a written justification for the request in part 3 below.**

1. Name and Description of human specimen(s) or cell lines(s):
2. Rationale for the proposed use (choose one or more options below).
   - ☐ Specimens are from study populations that require limitations to broad data sharing and future research use (e.g., participants from recognized tribal nations) - request an **Alternative Data Sharing Plan (Part VII).**
   - ☐ Specimens or cell lines are highly studied, and this research will replace or augment existing data.
   - ☐ The research requires benchmarking of significantly improved, modified protocols generated using existing, standardized cell lines or specimens.
   - ☐ Other - you must provide a strong justification for the exception.
3. Justification for the reason selected above (limit to 1-2 paragraphs. If needed, attach additional documentation).
   Must include:
   i. An explanation as to why other existing resources or new biosamples with appropriate consent cannot be obtained or used.
   ii. An explanation as to why this biosample uniquely addresses the needs of the field.

New Section – Not Applicable to Studies initiated before January 25, 2021

PART VII – Request for an Alternative Data Sharing Plan

If you answered **Yes** to the question **"Are you Requesting an Alternative Data Sharing Plan"** in Part II, mark the reason(s) for the request and provide an explanation. Also describe the Alternative Data Sharing Plan below.

- ☐ 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 Request (If needed, please attach additional information to this document):

Alternative Data Sharing Plan

Describe how the data will be shared. See "Exceptions and Alternatives to the NHGRI Genomic Data Sharing Expectations", for examples of 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)

Director approval only if an Alternative Data Sharing Plan is requested

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

NHGRI Director (Signature)