

# NHGRI Extramural Genomic Data Sharing Plan

## (Basic Study Information)

Version 2020-10-16

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? <span style="float: right;"><input type="checkbox"/> Yes   <input type="checkbox"/> No</span> If YES, go to the next field. If NO, register at <a href="https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp">https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp</a> .	
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? <span style="float: right;"><input type="checkbox"/> Yes   <input type="checkbox"/> No</span>	
<b>If YES, list participating sites:</b>	
Data will be submitted (choose one): <input type="checkbox"/> Within 3 months of last data generated or last clinical visit <input type="checkbox"/> 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 <a href="#">NHGRI Guidance for Data Submission and Data Release</a> <span style="float: right;">Yes   No</span>  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: <span style="float: right;"><input type="checkbox"/> Unrestricted Access   <input type="checkbox"/> Controlled Access</span>	
<b>Are you requesting an Alternative Data Sharing Plan</b> for samples that cannot be shared through a public database or repository? If YES, complete the <a href="#">Request for an Alternative Data Sharing Plan</a> in its entirety and attach it to this document. <span style="float: right;"><input type="checkbox"/> Yes   <input type="checkbox"/> No</span> If NO, list all submission locations:	
<input type="checkbox"/> AnVIL <input type="checkbox"/> dbGaP <input type="checkbox"/> GenBank <input type="checkbox"/> Model Organism <input type="checkbox"/> Other (list all): <input type="checkbox"/> GEO <input type="checkbox"/> dbSNP <input type="checkbox"/> ClinVar        Database (specify): <input type="checkbox"/> dbVar <input type="checkbox"/> Sequence Read Archive (SRA)	

**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.**

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

**Note: If you are not submitting human data, proceed to Part VII - 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 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 restrict or limit broad data sharing and future research use (e.g., participants from recognized tribal nations) - request an [Alternative Data Sharing Plan](#).
  - 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.

PART VII – 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)

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*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)