NHGRI Extramural Genomic Data Sharing Plan and dbGaP Submission Information

Version 2021-01-21

In order for the NIH National Human Genome Research Institute (NHGRI) to register your data into the dbGaP Submission System, please provide the information listed below and return to your NHGRI Program Officer (PO) or Genomic Program Administrator (GPA).

You may use the sample document or any other format.

PART I – Principal Investigator (PI) and Funding Information

PI name:	PI email:
PI institution:	
PI assistant/submitter name:	PI assistant/submitter email:
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**?** If **YES**, complete the Request for an Alternative Data Sharing Plan in its entirety and attach it to this document. ☐ Yes ☐ No

If **NO**, list all submission locations:

☐ AnVIL ☐ dbGaP ☐ GenBank ☐ Model Organism Database (specify):
☐ GEO ☐ dbSNP ☐ ClinVar
☐ dbVar ☐ Sequence Read Archive (SRA) ☐ Other (list all):

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 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)

Date registered in dbGaP:

(completed by GPA)

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)