NCI GENOMIC DATA SHARING PLAN TEMPLATE

Data produced through this award will be shared in a manner consistent with data-sharing under the *NIH Genomic Data Sharing Policy* (NOT-OD-14-124).

Intramural Project (Z01), Grant, or Contract number (if available): _____

Project Title: _____

Principal Investigator: _____

Investigators Affiliation (Institution/Division/Program/Branch): _____

1. Data to be Shared (mark all that apply):

Species:	☐Human	☐Rat	
	☐Mouse	☐C. elegans	
	☐Drosophila	☐Yeast (Species:_____)	
	☐Bacteria (Species:_____)	☐Other (Species:_____)	
Sample Type:	☐Tumor Tissue	☐Normal Tissue	☐Blood
	☐Buccal	☐Urine	☐Other (Sample type:_____)
Analyte Type	☐DNA	☐RNA	☐Other (Analyte type:_____)

Genomic data (See NCI GDS framework for data sharing thresholds for each data type):

☐	SNP array data from >500K single nucleotide polymorphisms (SNPS) *e.g., GWAS data*	# of Samples:
☐	DNA sequence data from < 100 genes or regions of interest *e.g., targeted sequencing*	# of Samples:
☐	DNA sequence data from ≥ 100 genes or regions of interest *e.g., targeted sequencing, whole exome sequencing, whole genome sequencing*	# of Samples:
☐	Genome-wide RNA sequencing (RNA-seq) data *e.g., transcriptomic data*	# of Samples:
☐	Genome-wide DNA methylation data *e.g., Illumina 450k or other platforms, bisulfite sequencing data*	# of Samples:
☐	Genome-wide chromatin immunoprecipitation sequencing (ChIP-seq) data *e.g. transcription factor ChIP-seq, histone modification ChIP-seq*	# of Samples:
☐	Metagenome (or microbiome) sequencing data *e.g., 16S rRNA sequencing, shotgun metagenomics, whole-genome microbial sequencing*	# of Samples:
☐	Metatranscriptome sequencing data *e.g., microbial/microbiome transcriptomics*	# of Samples:
☐	Other:	# of Samples:

Phenotype data:

Data pertinent to the interpretation of genomic data, including the minimal phenotype information needed to reproduce the primary analysis —such as associated phenotype data (e.g., clinical information), exposure data, relevant metadata, and descriptive information (e.g., protocols or methodologies used)—will be shared. Individual-level Phenotype data will include, at minimum:

_____

2. Data Repository:
Identify the data repositories to which the data will be submitted, and for human data, whether the data will be available through unrestricted[1] or controlled-access[2]. A list of relevant databases can be found at: https://osp.od.nih.gov/scientific-sharing/data-repositories-and-trusted-partners/.

Repository: _____

Repository Accession Number (if known): _____

If human data, how will be data be made available?
☐ Unrestricted-Access ☐ Controlled-Access

3. Data Submission Timeline:
We will submit the genotype/sequencing and phenotype data after the genotyping/sequencing data have been cleaned (i.e. once the QA/QC is complete and the analytical dataset is finalized).

We understand that following data submission, the data may be held for a period not to exceed six months. Following this period of exclusivity, or at the time of publication (whichever comes first), the data will be available for secondary research access without restrictions on publication (i.e. there will be no publication embargo).

Date submission is expected (approximate): _____

4. IRB Assurance of the Genomic Data Sharing Plan:
Has an IRB or analogous review body reviewed the genomic data sharing aspects of your project? If not, provide a timeline for such review.

☐ Yes
☐ Not Yet (Enter date of expected review: _____)
☐ Not Applicable (e.g. no human data)

5. Appropriate Uses of the Data:
The NIH promotes the broad and responsible sharing of genomic research for 'general research use'. However, NIH also recognizes that in some circumstances broad sharing may not be consistent with the informed consent of the research participants whose data are included in the dataset. A data use limitation (DUL) statement is a brief written description of limitations, if any, on the distribution and use of human data submitted to controlled-access NIH designated data repositories, such as the NIH database of Genotypes and Phenotypes (dbGaP). Limitations on the data use should be described in the Institutional Certification. NIH provides *Points to Consider in Developing Effective Data Use Limitations*.

How will data be shared?

☐ Data will be made available for general research use
☐ Data will be made available with the following limitation(s): _____
☐ Data sharing is not appropriate, an exception is being requested (If selected complete 5a and 5b)

[1] Data publically available to anyone
[2] Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project

Exceptions to Submission:
Submission of genomic data to an NIH data repository (e.g. dbGaP) may be precluded by various factors, such as international laws, limitations in the original informed consents, concerns about harms to individuals or groups, or other cases where expectations for data submission cannot be met. The Institute recognizes that open or controlled access data sharing may not always be appropriate. In such **rare cases**, NCI will consider requests for an exception to usual data submission expectations. For more information about data sharing exceptions, please go to: https://www.cancer.gov/grants-training/grants-management/nci-policies/genomic-data/about-policy#exceptions

5a. If submission of human data generated in the study would be not be appropriate because the Institutional Certification criteria cannot be met, the investigator should explain why (explanation subject to NIH review):

_____

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5b. Describe an alternative mechanism for data sharing. If the NCI grants an exception to submission, the research will be registered in dbGaP and the reason for the exception and the alternative sharing plan will be described:

_____

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6. Approvals

Investigator: _____ Date: _____

Scientific Director, or designee
(Intramural only): _____ Date: _____