Rapid Acceleration of Diagnostics (RADx[SM]) Data Sharing & Submission Information

Version 12/2020

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

Checklist of required documents:

☐ **Institutional Certifications**

☐ RADx[SM] Data Sharing & Submission Information

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):

☐ By date (MM/DD/YYYY) _____

☐ Data will be submitted by batches over Study Timeline

(e.g. based on clinical trial enrollment benchmarks)

Specify:

Target data delivery date: (MM/DD/YYYY)	Target public release date: (MM/DD/YYYY)
Number of gigabytes of data to be deposited:	Estimated number of study participants:

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

- ☐ RADx[SM] Data Hub
- ☐ Sequence Read Archive (SRA)
- ☐ Array Express
- ☐ ClinVar
- ☐ dbGaP
- ☐ dbVar
- ☐ dbSNP
- ☐ ENA
- ☐ GenBank
- ☐ GEO
- ☐ MGI
- ☐ Trace Archive
- ☐ Other (list all):
  _____
  _____
  _____
  _____
  _____
  _____
  _____

PART II – Principal Investigator (PI) and Funding Information

PI Name:	PI E-mail:
PI Institution:	
PI assistant/data submitter name:	PI assistant/data submitter e-mail:

Do you have an eRA Commons account? ☐ Yes ☐ No
If **YES**, go to the next field.
If **NO**, register at **https://public.era.nih.gov/commons/public/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 **Data Use Limitations (DUL)** are based on the informed consent given by each research participant. For every research participant, 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 IC verifies that this certification has been met.

PART IV – Study Description

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

Check all data types expected for this study:

Species
- ☐ Human Data
- ☐ Non-Human Data

Sample Collection
- ☐ Existing (Legacy)
- ☐ Prospective Sample

Genomic
- ☐ Aggregate Data
- ☐ Individual-level Data
- ☐ Non-human Data
- ☐ Other (specify):

Phenotype
- ☐ Aggregate Data
- ☐ Individual-level Data
- ☐ Non-human Data
- ☐ Other (specify):

Sample Types
- ☐ DNA ☐ From Repository
  Name: _____
- ☐ Germline ☐ Microbiome
- ☐ Mitochondria ☐ RNA
- ☐ Single Cell ☐ Tumor/Natural
- ☐ Other (specify):

General Data Types
- ☐ Behavioral
- ☐ Clinical
- ☐ Cognitive
- ☐ Electronic Medical Records
- ☐ Environmental (Physical)
- ☐ Family History
- ☐ Genomic
- ☐ Genotyping
- ☐ Imaging
- ☐ Immulogical
- ☐ Individual Genotype
- ☐ Individual Phenotype
- ☐ Individual Sequencing
- ☐ Metabolomic
- ☐ Metagenomic
- ☐ Physical Activity
- ☐ Proteomic
- ☐ Psychological
- ☐ Questionnaires/Surveys
- ☐ Social
- ☐ Supporting Documents
- ☐ Other (specify):

Genomic Data Types

Genotype
- ☐ Array CGH CNVs
- ☐ Array-derived Genotypes
- ☐ CNV calls derived from Sequencing
- ☐ CNV calls from microarray
- ☐ Genotype calls derived from Sequence
- ☐ Non-human data
- ☐ Somatic SNV (.MAF)
- ☐ Other (specify):

Sequencing
- ☐ 16S rRNA
- ☐ Epigenomic Marks
- ☐ Sanger
- ☐ Targeted Exome
- ☐ Targeted Genome
- ☐ Targeted Transcriptome
- ☐ Whole Exome
- ☐ Whole Genome
- ☐ Whole Transcriptome
- ☐ Other (specify):

Analyses
- ☐ Array-derived Expression
- ☐ Array-derived Methylation
- ☐ Association/Linkage Results
- ☐ RNA Seq derived Expression
- ☐ Other (specify):

Array Data
- ☐ Expression Array
- ☐ Methylation Array
- ☐ SNP Array
- ☐ Other (specify):

Genotype/Sequence Platform Information (If Applicable)				
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.[1]

PART VII - Consent Groups

The NIH promotes the broad and responsible sharing of 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 that are developed based on the original informed consent from the participants.

[1] If the submitting institution certifies that aggregate data from a project can be included in the Compilation, then a study description for the aggregate data should be provided in addition to a description for the individual data.

Data contains: ☐ Controlled Access Data ☐ Public Access Data

If your data **does NOT contain** Controlled Access Data, **skip to Part IX**.
If your data **does contain** Controlled Access Data, **select all relevant consent group categories**:

Consent Group Category	Data Use Limitations
☐ **General Research Use**	Use of the data is limited only by the terms of the Data Use Certification (DUC)
☐ IRB approval required	Requestor must provide documentation of local IRB approval
☐ Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community
☐ Collaboration required	Requestor must provide letter of collaboration with the primary study investigator(s)
☐ Not-for-profit use only	Use of the data is limited to not-for-profit organizations
☐ **Health/Medical/Biomedical**	Use of the data is limited to health/medical/biomedical purposes, does not include study of population origins or ancestry
☐ IRB approval required	Requestor must provide documentation of local IRB approval
☐ Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community
☐ Collaboration required	Requestor must provide letter of collaboration with the primary study investigator(s)
☐ Not-for-profit use only	Use of the data is limited to not-for-profit organizations
☐ **Disease-Specific**	Use of the data must be related to the specified disease
☐ IRB approval required	Requestor must provide documentation of local IRB approval
☐ Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community
☐ Collaboration required	Requestor must provide letter of collaboration with the primary study investigator(s)
☐ Not-for-profit use only	Use of the data is limited to not-for-profit organizations
☐ Related conditions	Use of data includes disease XX and related conditions (Describe and include examples):

☐ **Other (**describe):

dbGaP Collections (For Genomic Data Only)

Is the aggregate-level genomic data appropriate for General Research Use? ☐ Yes ☐ No

If **YES,** do you agree to add your aggregate-level data to the **Compilation of Aggregate Genomic Data for General Research Use**, a collection of analyses across many dbGaP studies that can be accessed with a single Data Access Request? **NOTE:** This should be consistent with the Institutional Certification ☐ Yes ☐ No

Is the individual-level data appropriate for General Research Use? ☐ Yes ☐ No

If **YES**, do you agree to add your individual-level data to the **dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use**, a collection of analyses across many dbGaP studies that can be accessed with a single Data Access Request? **NOTE:** This should be consistent with the Institutional Certification ☐ Yes ☐ No

PART IX – 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)

_____ _____

Program Officer (Print Name) **Date**

_____

Program Officer (Signature)