

Rapid Acceleration of Diagnostics (RADxSM) 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](#)

☐ RADxSM 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

☐ RADxSM Data Hub

☐ ENA

Other (list all):

Sequence Read Archive (SRA)

GenBank

Array Express

GEO

ClinVar

MGI

dbGaP

Trace Archive

dbVar

dbSNP

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? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> 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	General Data Types <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Behavioral</td> <td style="width: 33%;">Genotyping</td> <td style="width: 33%;">Physical Activity</td> </tr> <tr> <td>Clinical</td> <td>Imaging</td> <td>Proteomic</td> </tr> <tr> <td>Cognitive</td> <td>Immunological</td> <td>Psychological</td> </tr> <tr> <td>Electronic Medical Records</td> <td>Individual Genotype</td> <td>Questionnaires/Surveys</td> </tr> <tr> <td>Environmental (Physical)</td> <td>Individual Phenotype</td> <td>Social</td> </tr> <tr> <td>Family History</td> <td>Individual Sequencing</td> <td>Supporting Documents</td> </tr> <tr> <td>Genomic</td> <td>Metabolomic</td> <td></td> </tr> <tr> <td></td> <td>Metagenomic</td> <td></td> </tr> <tr> <td colspan="3">Other (specify):</td> </tr> </table>			Behavioral	Genotyping	Physical Activity	Clinical	Imaging	Proteomic	Cognitive	Immunological	Psychological	Electronic Medical Records	Individual Genotype	Questionnaires/Surveys	Environmental (Physical)	Individual Phenotype	Social	Family History	Individual Sequencing	Supporting Documents	Genomic	Metabolomic			Metagenomic		Other (specify):		
Behavioral	Genotyping	Physical Activity																												
Clinical	Imaging	Proteomic																												
Cognitive	Immunological	Psychological																												
Electronic Medical Records	Individual Genotype	Questionnaires/Surveys																												
Environmental (Physical)	Individual Phenotype	Social																												
Family History	Individual Sequencing	Supporting Documents																												
Genomic	Metabolomic																													
	Metagenomic																													
Other (specify):																														
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):																														
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)
<i>Example:</i> [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: <input type="checkbox"/> Controlled Access Data <input type="checkbox"/> 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
<input type="checkbox"/> General Research Use	Use of the data is limited only by the terms of the Data Use Certification (DUC)
<input type="checkbox"/> IRB approval required	Requestor must provide documentation of local IRB approval
<input type="checkbox"/> Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community
<input type="checkbox"/> Collaboration required	Requestor must provide letter of collaboration with the primary study investigator(s)
<input type="checkbox"/> Not-for-profit use only	Use of the data is limited to not-for-profit organizations
<input type="checkbox"/> Health/Medical/Biomedical	Use of the data is limited to health/medical/biomedical purposes, does not include study of population origins or ancestry
<input type="checkbox"/> IRB approval required	Requestor must provide documentation of local IRB approval
<input type="checkbox"/> Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community
<input type="checkbox"/> Collaboration required	Requestor must provide letter of collaboration with the primary study investigator(s)
<input type="checkbox"/> Not-for-profit use only	Use of the data is limited to not-for-profit organizations
<input type="checkbox"/> Disease-Specific	Use of the data must be related to the specified disease
<input type="checkbox"/> IRB approval required	Requestor must provide documentation of local IRB approval
<input type="checkbox"/> Publication required	Requestor agrees to make results of studies using the data available to the larger scientific community
<input type="checkbox"/> Collaboration required	Requestor must provide letter of collaboration with the primary study investigator(s)
<input type="checkbox"/> Not-for-profit use only	Use of the data is limited to not-for-profit organizations
<input type="checkbox"/> Related conditions	Use of data includes disease XX and related conditions (Describe and include examples):
<input type="checkbox"/> Other (describe):	
dbGaP Collections (For Genomic Data Only)	
Is the aggregate-level genomic data appropriate for General Research Use? <input type="checkbox"/> Yes <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the individual-level data appropriate for General Research Use? <input type="checkbox"/> Yes <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> 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)