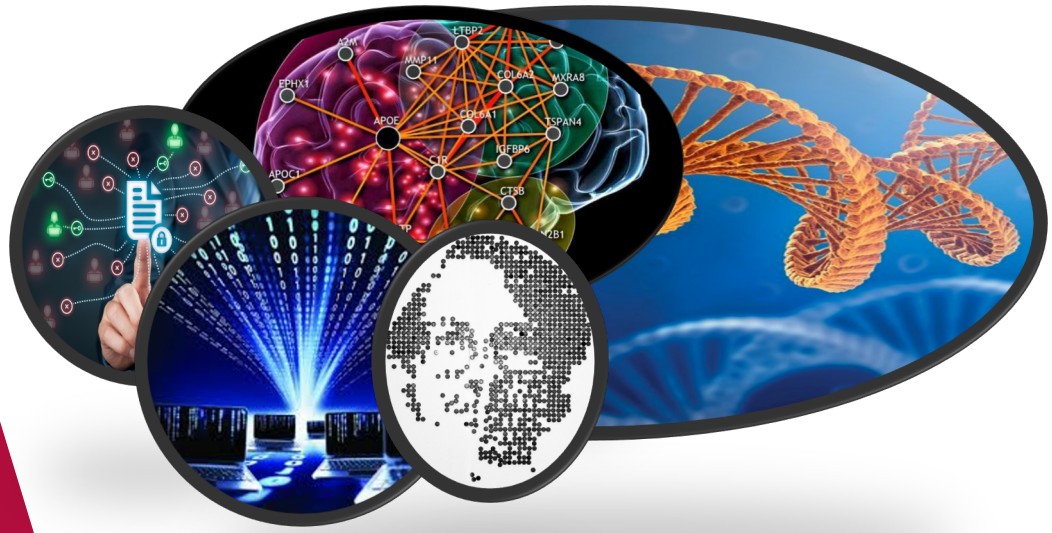
RADx Data Hub: Study Registration Processes

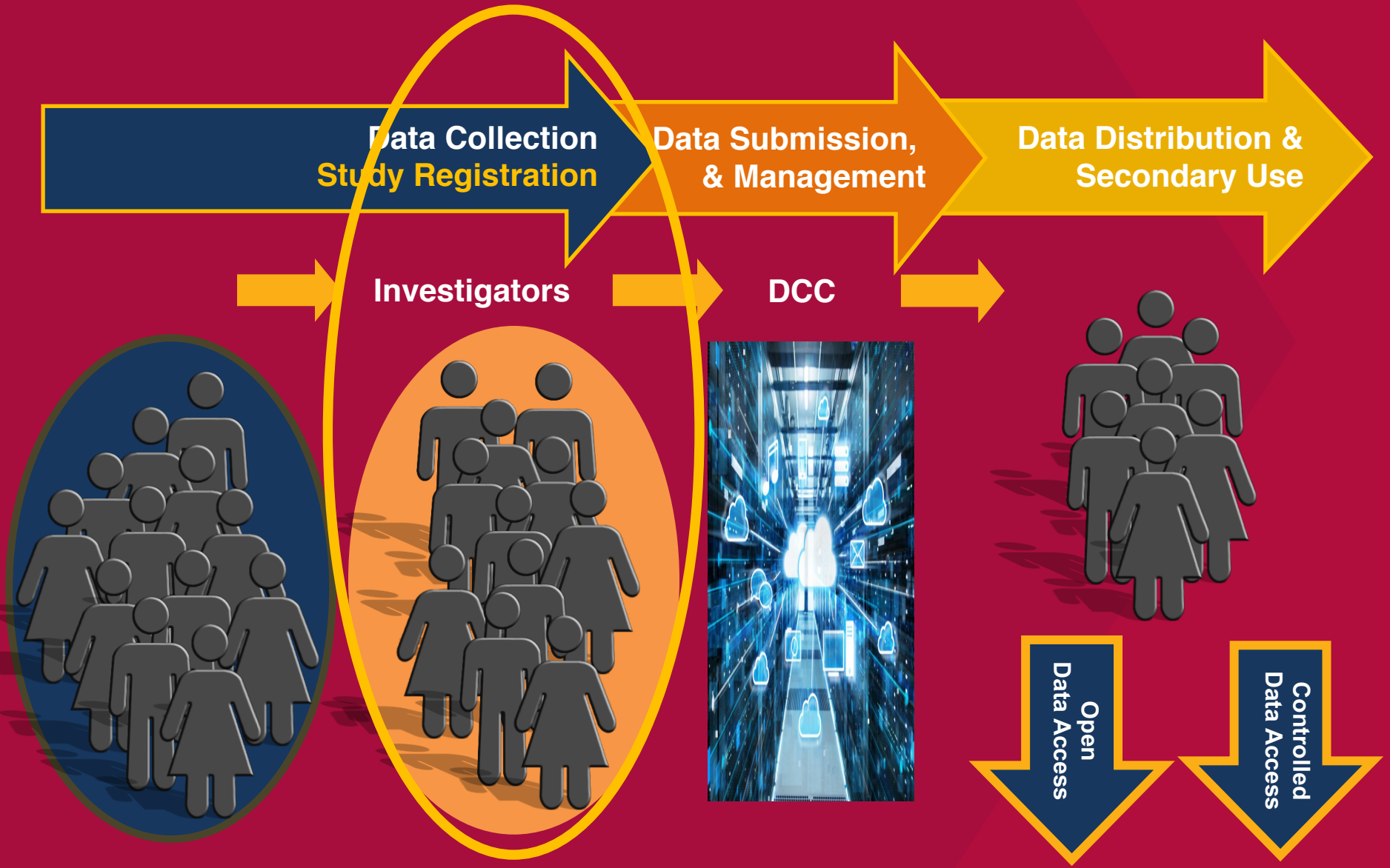


Vivian OTA WANG, Ph.D., CGC, FACMG

Deputy Director, Office of Data Sharing
Center for Biomedical Informatics & Information Technology (CBIIT)
National Cancer Institute-NIH
3 February, 2021

NIH NATIONAL CANCER INSTITUTE

RADx RAD Data Management Overview



RADx RAD Data Management Overview

WHO

- RESEARCH PARTICIPANTS PROTECTIONS

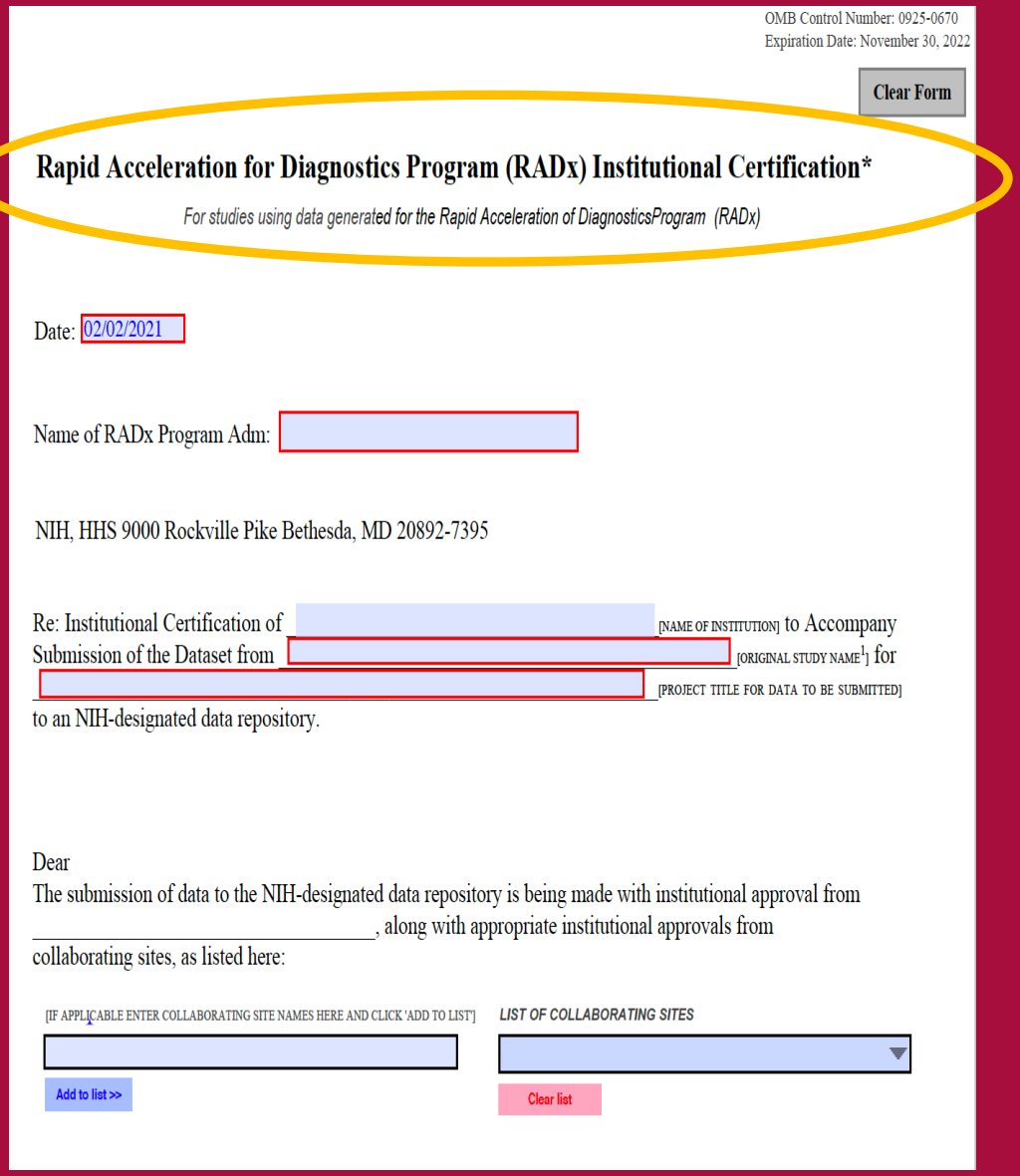
WHAT

- RESEARCH PARTICIPANT PROTECTIONS
- BROAD DATA SHARING

HOW

- STUDY REGISTRATION
  - *INSTITUTIONAL CERTIFICATION*
  - *DATA SHARING/ SUBMISSION INFORMATION*

INSTITUTIONAL CERTIFICATION



OMB Control Number: 0925-0670
Expiration Date: November 30, 2022

Clear Form

Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification*

For studies using data generated for the Rapid Acceleration of DiagnosticsProgram (RADx)

Date: 02/02/2021

Name of RADx Program Adm:

NIH, HHS 9000 Rockville Pike Bethesda, MD 20892-7395

Re: Institutional Certification of _____ [NAME OF INSTITUTION] to Accompany Submission of the Dataset from _____ [ORIGINAL STUDY NAME[1]] for _____ [PROJECT TITLE FOR DATA TO BE SUBMITTED] to an NIH-designated data repository.

Dear
The submission of data to the NIH-designated data repository is being made with institutional approval from _____, along with appropriate institutional approvals from collaborating sites, as listed here:

[IF APPLICABLE ENTER COLLABORATING SITE NAMES HERE AND CLICK 'ADD TO LIST']

LIST OF COLLABORATING SITES

Add to list >>

Clear list

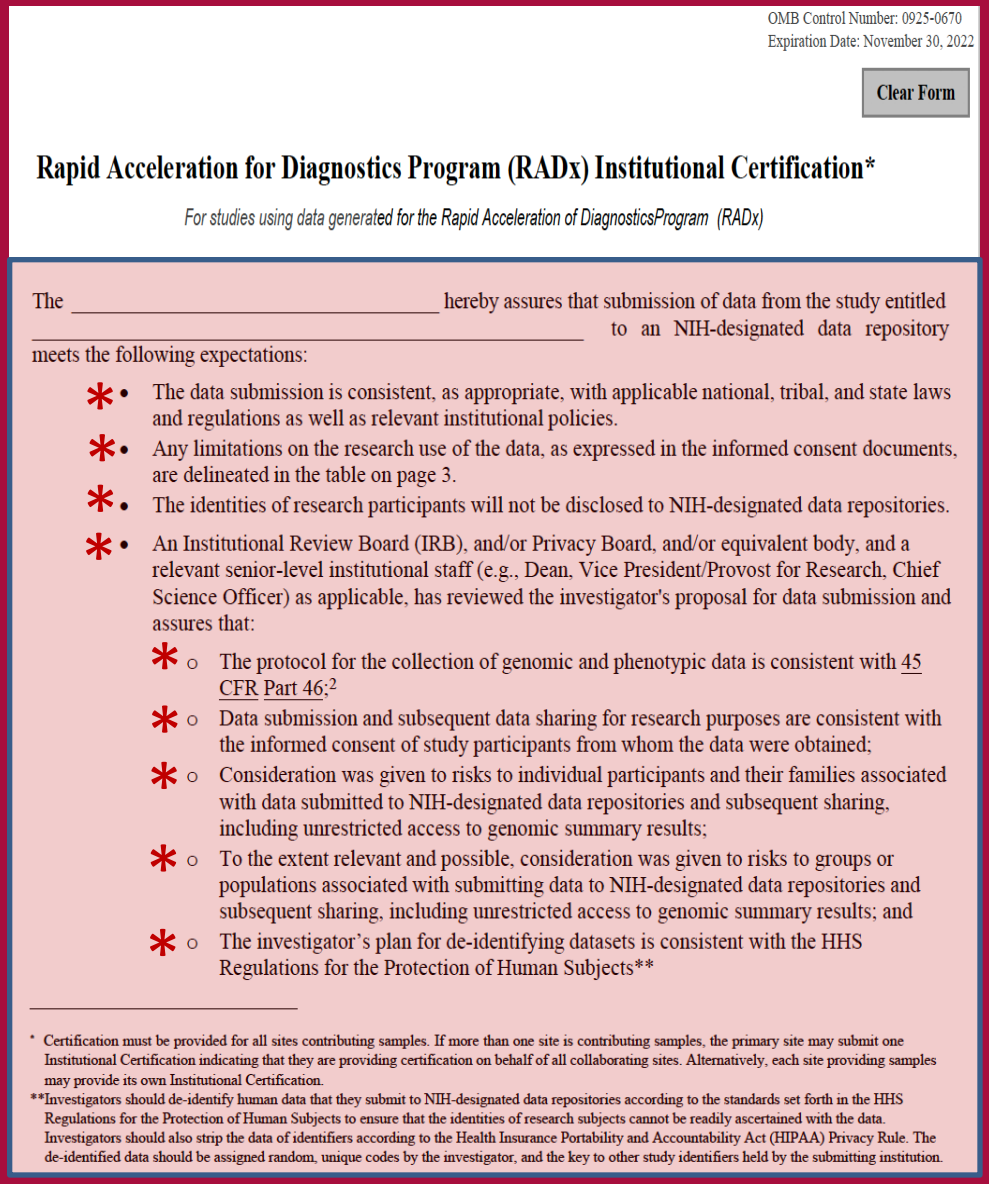
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- DATA
- ACKNOWLEDGEMENT STATEMENT
- STUDY DESCRIPTION

INSTITUTIONAL CERTIFICATION



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Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification*

For studies using data generated for the Rapid Acceleration of DiagnosticsProgram (RADx)

The _____ hereby assures that submission of data from the study entitled _____ to an NIH-designated data repository meets the following expectations:

- * The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
- * Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.
- * The identities of research participants will not be disclosed to NIH-designated data repositories.
- * An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, and a relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) as applicable, has reviewed the investigator's proposal for data submission and assures that:
  - * The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;[2]
  - * Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
  - * Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results;
  - * To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and
  - * The investigator's plan for de-identifying datasets is consistent with the HHS Regulations for the Protection of Human Subjects**

* Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide its own Institutional Certification.

**Investigators should de-identify human data that they submit to NIH-designated data repositories according to the standards set forth in the HHS Regulations for the Protection of Human Subjects to ensure that the identities of research subjects cannot be readily ascertained with the data. Investigators should also strip the data of identifiers according to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The de-identified data should be assigned random, unique codes by the investigator, and the key to other study identifiers held by the submitting institution.

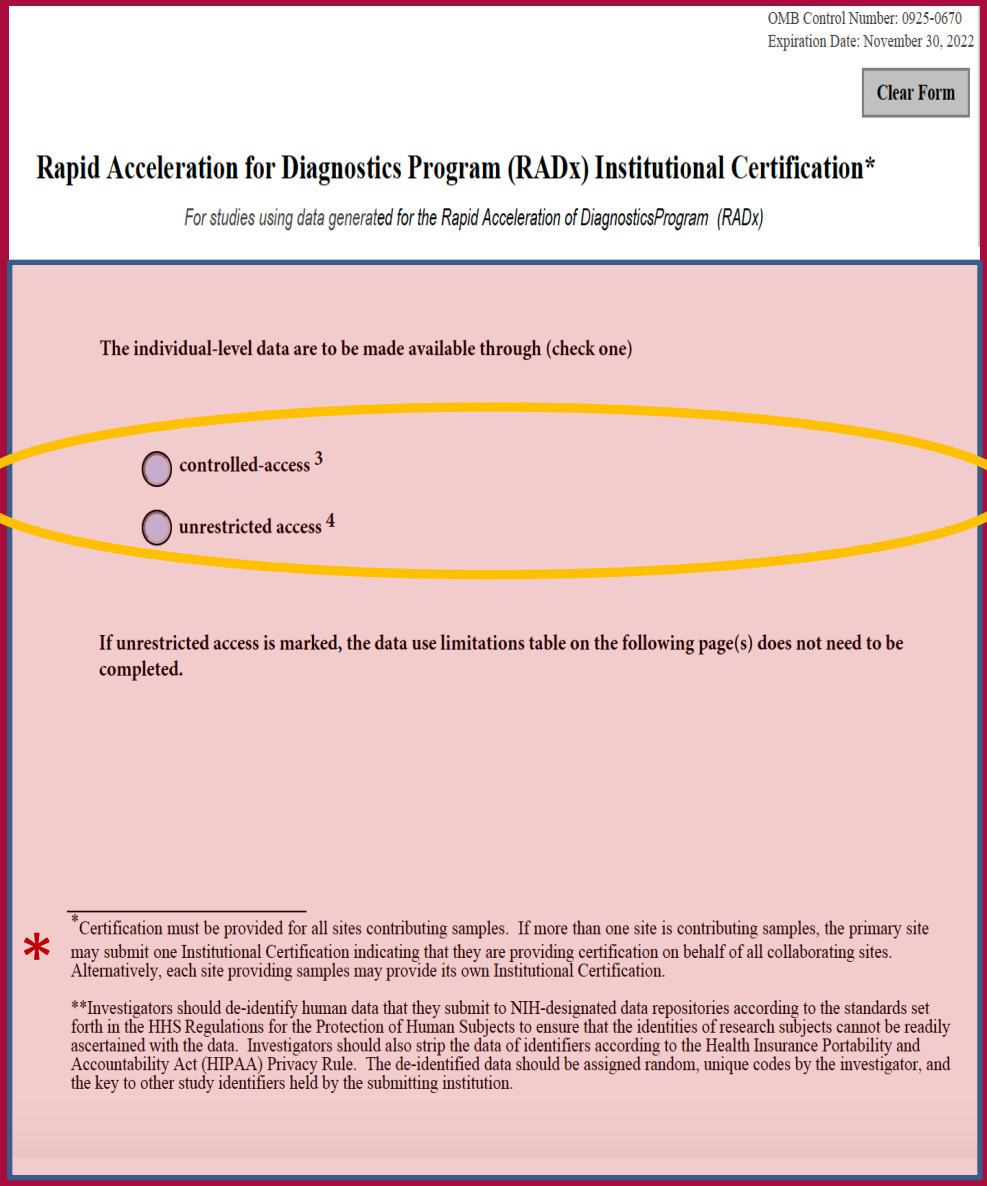
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- DATA
- ACKNOWLEDGEMENT STATEMENT
- STUDY DESCRIPTION

INSTITUTIONAL CERTIFICATION



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Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification*

For studies using data generated for the Rapid Acceleration of DiagnosticsProgram (RADx)

The individual-level data are to be made available through (check one)

- controlled-access [3]
- unrestricted access [4]

If unrestricted access is marked, the data use limitations table on the following page(s) does not need to be completed.

*Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide its own Institutional Certification.

**Investigators should de-identify human data that they submit to NIH-designated data repositories according to the standards set forth in the HHS Regulations for the Protection of Human Subjects to ensure that the identities of research subjects cannot be readily ascertained with the data. Investigators should also strip the data of identifiers according to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The de-identified data should be assigned random, unique codes by the investigator, and the key to other study identifiers held by the submitting institution.

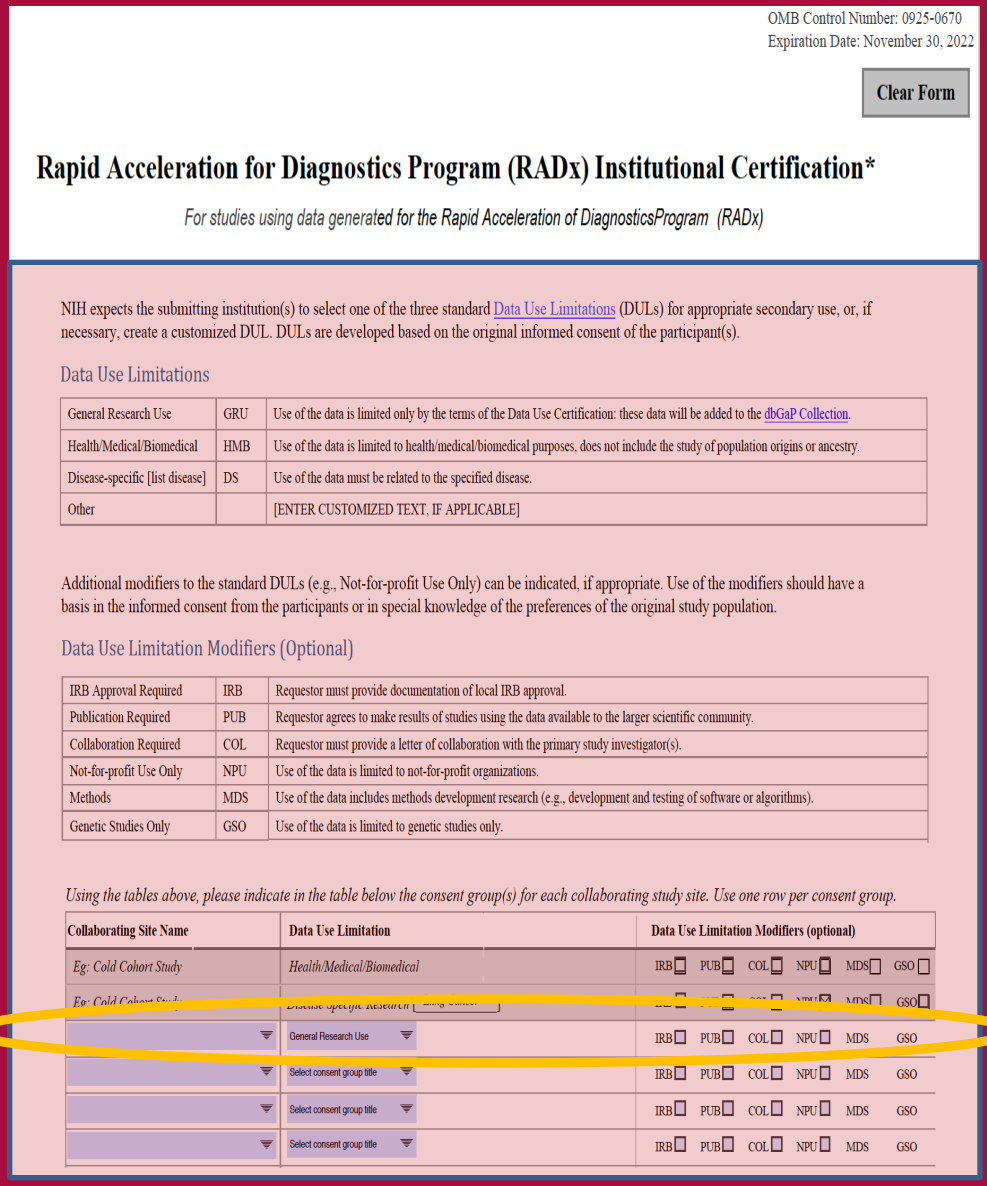
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- DATA
- ACKNOWLEDGEMENT STATEMENT
- STUDY DESCRIPTION

INSTITUTIONAL CERTIFICATION



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Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification*

For studies using data generated for the Rapid Acceleration of DiagnosticsProgram (RADx)

NIH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s).

Data Use Limitations

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

Data Use Limitation Modifiers (Optional)

IRB Approval Required	IRB	Requestor must provide documentation of local IRB approval.
Publication Required	PUB	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration Required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit Use Only	NPU	Use of the data is limited to not-for-profit organizations.
Methods	MDS	Use of the data includes methods development research (e.g., development and testing of software or algorithms).
Genetic Studies Only	GSO	Use of the data is limited to genetic studies only.

Using the tables above, please indicate in the table below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	Data Use Limitation	Data Use Limitation Modifiers (optional)
Eg: Cold Cohort Study	*Health/Medical/Biomedical*	IRB PUB COL NPU MDS GSO
Eg: Cold Cohort Study	*Disease Specific Research [ ]*	IRB PUB COL NPU MDS GSO
	General Research Use	IRB PUB COL NPU MDS GSO
	Select consent group title	IRB PUB COL NPU MDS GSO
	Select consent group title	IRB PUB COL NPU MDS GSO
	Select consent group title	IRB PUB COL NPU MDS GSO

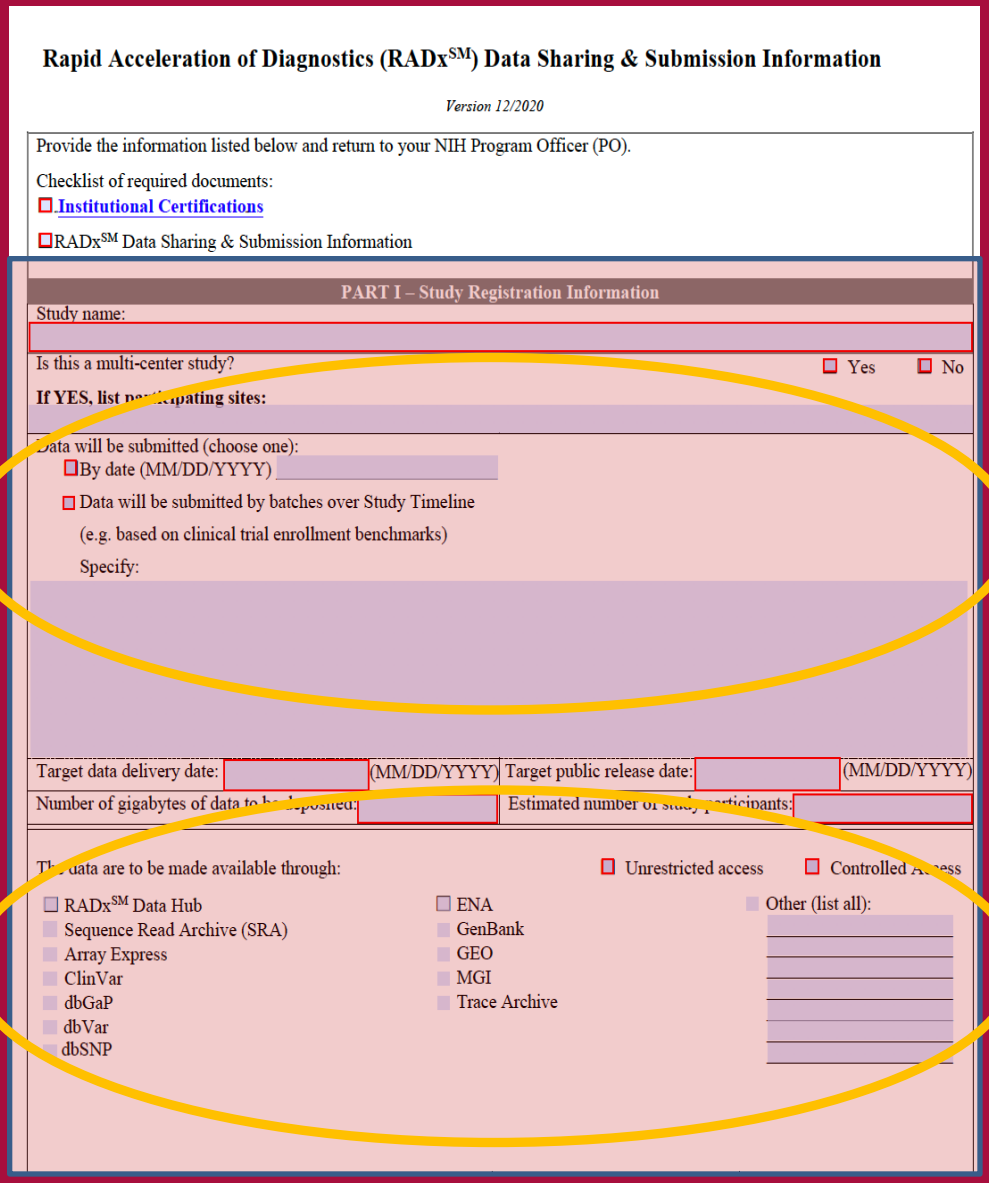
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- **GENERAL RESEARCH USE (GRU)**

DATA SHARING AND SUBMISSION INFORMATION

- DATA
- ACKNOWLEDGEMENT STATEMENT
- STUDY DESCRIPTION

DATA SUBMISSION INFORMATION



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):

INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- **DATA: *WHEN/WHERE***
- ACKNOWLEDGEMENT STATEMENT
- STUDY DESCRIPTION

DATA SUBMISSION INFORMATION

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):

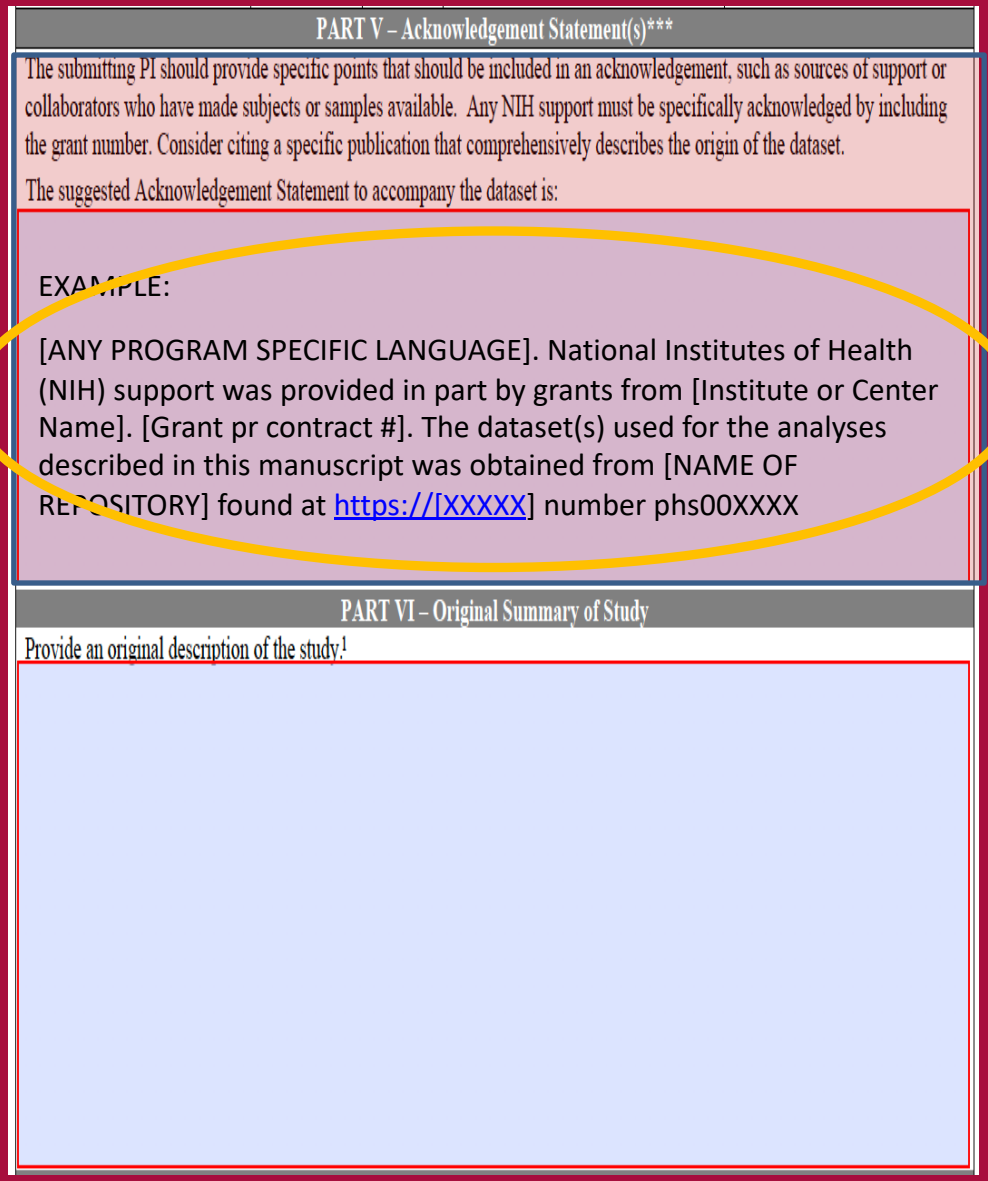
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- DATA: ***WHAT***
- ACKNOWLEDGEMENT STATEMENT
- STUDY DESCRIPTION

DATA SUBMISSION INFORMATION



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:

EXAMPLE:

[ANY PROGRAM SPECIFIC LANGUAGE]. National Institutes of Health (NIH) support was provided in part by grants from [Institute or Center Name]. [Grant pr contract #]. The dataset(s) used for the analyses described in this manuscript was obtained from [NAME OF REPOSITORY] found at https://[XXXXX] number phs00XXXX

PART VI – Original Summary of Study

Provide an original description of the study.[1]

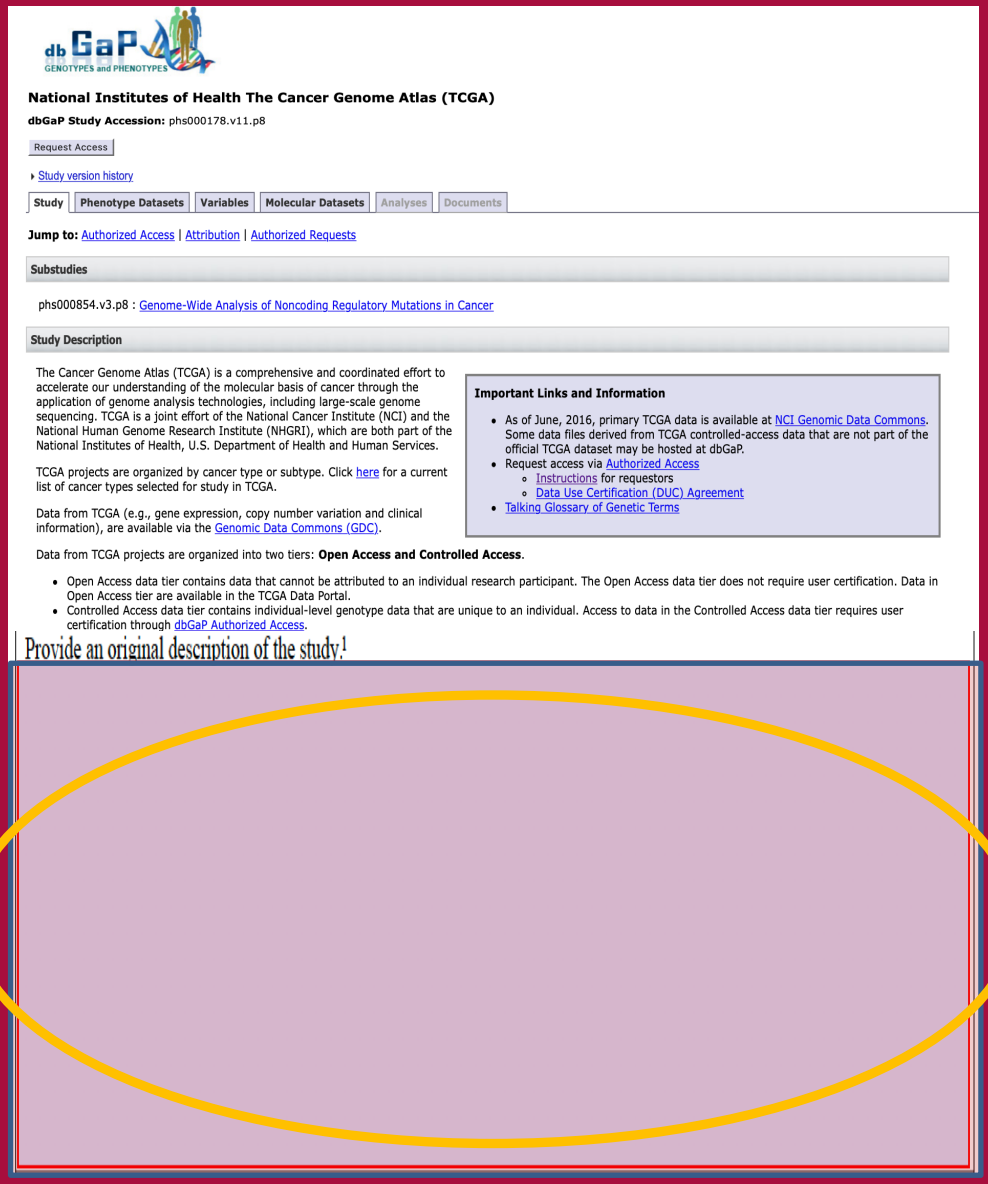
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- **DATA: *WHAT***
- **ACKNOWLEDGEMENT STATEMENT**
- STUDY DESCRIPTION

DATA SUBMISSION INFORMATION



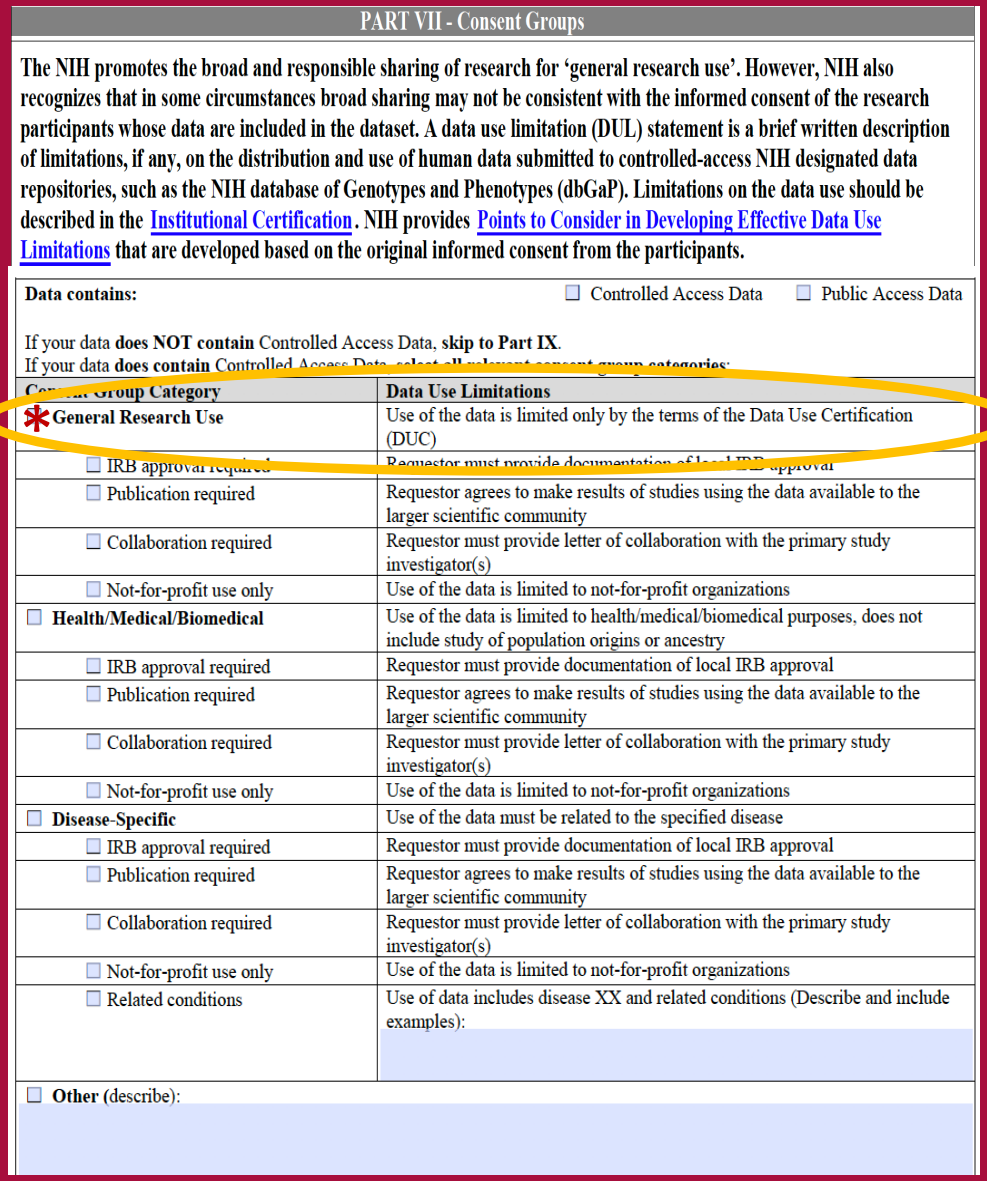
INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- DATA: *WHAT*
- ACKNOWLEDGEMENT STATEMENT
- **STUDY DESCRIPTION**

DATA SUBMISSION INFORMATION



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.

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):

INSTITUTIONAL CERTIFICATION

- RESEARCH PARTICIPANTS PROTECTIONS
- GENERAL RESEARCH USE (GRU)

DATA SHARING AND SUBMISSION INFORMATION

- DATA: ACKNOWLEDGEMENT STATEMENT
- **STUDY DESCRIPTION**

FOR RADx
STUDY REGISTRATION
AND
DATA ACCESS
QUESTIONS AND
ASSISTANCE

Vivian OTA WANG
E-mail: otawang@nih.gov

NIH NATIONAL CANCER INSTITUTE

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