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']

Add to list >>

LIST OF COLLABORATING SITES

Clear list

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**

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

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* [*Lung Cancer*]	IRB ☐ PUB ☐ COL ☐ NPU ☒ MDS ☐ GSO ☐
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
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Eg: Cold Cohort Study	*Disease Specific Research* [*Lung Cancer*]	IRB ☐ PUB ☐ COL ☐ NPU ☒ MDS ☐ GSO ☐
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
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	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO

Sincerely,

Investigator:

Name: _____ Title:_____

Signature: _____ Date: 02/02/2021

Institutional Signing Official:[6]

By signing below, I certify on behalf of
that, in addition to myself, an IRB or Privacy Board or equivalent body, as applicable, and other relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) who has the legal authority to bind their institution to this certification and has reviewed the requirements in this certification and agree that the submission meets them.

Name: _____ Title:_____

Signature: _____ Date: 02/02/2021

References

1. Original Study Name should reflect the name of the original IRB-approved study (e.g., cohort or case-control study, clinical trial) under which participants provided informed consent and biospecimens were collected (e.g., Nurses' Health Study, Framingham Heart Study).

2. 45 CFR Part 46. Protection of Human Subjects. See https://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013-title45-vol1-part46.xml.

3. Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

4. Data made publicly available to anyone.

5. Genomic summary results are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies; allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values).

6. Under the NIH Genomic Data Sharing Policy, an Institutional Signing Official is generally a senior official at an institution who is credentialed through the NIH eRA Common system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH.

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Expiration Date: November 30, 2022. Public reporting burden for this collection of information is estimated to vary from 15 to 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0670). Do not return the completed form to this address.