RADX-UP Data Sharing Policy

I. Introduction and Purpose

The National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. As part of this initiative, NIH developed the RADx-UP (RADx-Underserved Populations) program to understand disparities in COVID-19 morbidity and mortality and to help reduce disparities for those underserved and vulnerable populations who are disproportionately affected by, have the highest infection rates of, and/or are most at risk for complications or poor outcomes from the COVID-19 pandemic.

The RADx-UP Consortium will combine information from these studies to help researchers answer questions that the individual studies cannot answer alone. In support of that goal, the RADx-UP Coordination and Data Collection Center (RADx-UP CDCC) will create two highly secure databases, one with a limited data set and one containing direct participant identifiers that functions as a patient re-contact registry and a way to link other sources of data such as the Centers for Medicare & Medicaid Services (CMS), insurance claims data, and National Death Index. The RADx-UP CDCC will also share de-identified data with the NIH RADx Data Portal.

The RADx-UP Data Sharing Policy balances important goals: to acknowledge the concerns of vulnerable populations in research and the importance of community stakeholder expertise in developing appropriate practices, to respect and protect the confidentiality of RADx-UP projects' participants' data, and to maximize the value of the data generated by this program to the scientific and general community.

The RADx-UP Data Sharing Policy aims to promote wide and timely dissemination of data within the RADx-UP Consortium and its communities, the NIH, and the public to ensure their maximum utility and impact. The following principles guided the development of the policy:

- Sharing data in a timely manner is important for optimizing scientific progress, especially during the COVID-19 pandemic.

- This policy is consistent with the goals of the NIH data-sharing policy to make public access to digital scientific data the standard for all NIH-funded research. See "Draft NIH Policy for Data Management and Sharing."

- Combining and harmonizing data from multiple projects will increase power for addressing important research questions and facilitate addressing the heterogeneity of results and generalizability.

- Public funds support the data collected by the RADx-UP Program and, as such, the RADx-UP Data Platform should serve as an accessible resource helping to catalyze the research activities of scientists around the world, including those not directly supported by the RADx Program.

- It is important to strike a balance between making data broadly accessible to the scientific community and the legitimate interest RADx-UP investigators have in benefitting from their investment of time and effort to collect and harmonize data. The RADx-UP program will also acknowledge the desires of investigators to protect their relationships with their communities.

- The RADx-UP Program must protect the privacy and confidentiality of RADx-UP participants contributing data to the RADx-UP Data Platform.

II. Scope

This policy applies to all members of the RADx-UP Consortium. The NIH RADx-UP Program recognizes all laws and regulations concerning Tribal Sovereignty for American Indian and Alaska Natives. For Tribal Nations projects, individual Tribal Nations Data Sharing Agreements are reviewed and approved by all required Tribal IRBs or Indigenous health review boards before data are sent to the CDCC or to the NIH RADx Data Hub. Any specification in Tribal Nations Data Sharing Agreements that deviate from the contents of this policy will supersede the requirements laid out in this policy. The RADx-UP CDCC Data Stewardship Committee will review, revise, and approve this Data Sharing Policy on a regular basis (see section V).

III. Definitions

Item	Description
Information Security	
Confidentiality	Confidentiality applies to information already collected from a person and how a study protects or controls that information.
Privacy	Privacy applies to an individual and the gathering of an individual's information, particularly how access to that person and their information by the study team is controlled.
De-identified Data	The term "*de-identified data*" refers to a set of data where *protected health information (PHI)* is removed from data sets. De-identified data will be those for which all 18 designated HIPAA identifiers (as listed at https://privacyruleandresearch.nih.gov/pr_08.asp) have been deleted or altered to protect the privacy of participants.
Limited Data Set	A limited data set is a data set that contains health information but excludes direct identifiers as defined in HIPAA regulations (as listed at: https://privacyruleandresearch.nih.gov/pr_08.asp .) Indirect identifiers (city; state; zip code; all elements of dates; and other numbers, characteristics, or codes not listed as direct identifiers) may be included in a limited data set. Direct identifiers listed in HIPAA's provisions around what qualifies as an identifier and how limited data sets are defined apply not only to information about the individual, but also to information about the individual's relatives, employers, or household members.
PII	*Personal Identifiable Information (PII)* is defined as any information that can be used to uniquely identify a single individual or that can be used with other sources to uniquely identify a single individual.
FedRAMP	The Federal Risk and Authorization Management Program (FedRAMP) is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services. *FedRAMP* Low defines the set of security controls and

	procedures necessary to hold non-sensitive data. *FedRAMP* Moderate, which corresponds to FISMA moderate but in a cloud environment, specifies the controls and procedures necessary to store sensitive information like Personally identifiable information and Personal Health Information.
RADx-UP Program	
RADx-UP Coordination and Data Collection Center (CDCC)	The RADx-UP CDCC is responsible for developing the secure environment for accessing RADx-UP consortium data. It is responsible for managing receipt of *RADx-UP Consortium data* from RADx-UP projects, harmonization of *RADx-UP project data*, conducting analysis as needed, and providing access to the *RADx-UP project data* for querying, visualization, and analysis.
RADx-UP Consortium	Includes the RADx-UP CDCC, projects funded in the RADx-UP program, pilot project and community grants from the RADx-UP CDCC, principal investigators and key personnel of the referenced projects, NIH program staff, and project scientists.
RADx-UP Investigator	Any member of the *RADx-UP Consortium* who is supported by a RADx-UP grant, subcontract, or consultancy. Support is reflected by the designation as a Principal Investigator (PI), Multiple PI (MPI), or Co-Investigator (Co-I) with significant involvement in the grant or subsequent progress reports. Membership in the RADx-Up Consortium can continue beyond the funding end date of individual projects.
RADx-UP Data Platform	A data platform developed and maintained by the *RADX-UP CDCC* and consisting of two data repositories created from RADx-UP project data. The first repository includes de-identified essential (tier 1) and recommended (tier 2) common data elements as well as additional data provided from RADx-UP project awards. The second repository is highly secure and contains the patient re-contact registry and includes participant re-contact information for use by RADx-UP investigators who have approved studies requesting re-contacting of RADx-UP participants for future research studies.
RADx-UP Portal	A web portal located at https://myhome.radx-up.org maintained by the *RADx-UP CDCC* to ingest, host, and control access to data held in the RADx-UP data platform. The *RADx-UP Portal* provides secure access for consortium members with fully executed Data Use Agreements to the harmonized RADx-UP de-identified data set.
RADx-UP Project Data	RADx-UP projects will deposit existing or new data into the *RADx-UP Portal.* These data are ingested and harmonized with the RADx-UP Common Data Element specifications and contribute to the RADx-UP de-identified data set.
NIH RADx Data Hub	Central data center at NIH for the RADx Program.

RADx-UP Publications	
Partnering for Impact	Partnering for Impact is the process outlined in the RADx-UP CDCC Publications Policy that outlines the process for requesting cross-consortium data sets for cross-consortium analyses and publications.
Analysis Proposal	A formal request submitted by an investigator to use data from the RADx-UP Data Platform to answer a scientific question. The analysis proposal will be reviewed and considered for approval by the RADx-UP Publications & Dissemination Committee (see review criteria below and in Publications & Dissemination Committee Charter).

IV. Policy

A. RADx-UP Portal

RADx-UP Portal (https://myhome.radx-up.org) is a secure web portal through which designated individuals from each RADx-UP project can upload study data to the CDCC and view the data quality reports for each upload. These reports provide feedback on the conformance of the Project's file with the RADx-UP codebook/expected content and file structure. myRADx-UPhome also provides designated users from each project access to non-data related collaboration features such as resource libraries and project/user directories.

myRADx-UPhome supports federated authentication which allows users from projects to login with their organizational credentials. Organizations must be part of the InCommon Federation to be supported. For users from organizations that are not supported, Duke accounts are provisioned. Users are required to use two-factor authentication to access the environment. Their access and authorization to use specific functions is granted by the RADx-UP CDCC on an as-needed basis and is time-limited.

A subscription within the Duke owned/maintained Microsoft Azure tenant is dedicated to RADx-UP. Data uploaded by the projects is stored within this RADx-UP subscription and does not persist in the portal. The RADx-UP subscription is secured using Duke standard procedures in addition to using Microsoft's standard security blueprints that provide foundational security controls for the infrastructure. These security controls include RBAC settings at a management group, subscription and resource group level, the use of Azure Defender for SQL and Storage, the use of Azure Security Center and Azure Sentinel and the use of policy initiatives for HIPAA/HITRUST and NIST 800-171 and NIST 800-53.

B. Types of Data and Data Submission

The categories below describe the data collected and generated by the RADx-UP Projects. The RADX-UP investigators will share various types of data with the RADx-UP CDCC according to the policies described after each data type description.

1. RADX-UP Common Data Elements

The National Institutes of Health RADx-UP common data elements (NIH CDEs) are split into Tier 1 and Tier 2 data elements. The list of data elements in each tier can be found in the NIH RADx-UP CDCC CDE Data Dictionary at https://radx-up.org/learning-resources/cdes/.

All RADx-UP projects are required by the terms and conditions of their awards to submit a data set including all Tier 1 CDEs using the specifications found in both the RADx-UP NIH CDE code book and the data submission guidance (https://myhome.radx-up.org/RADx-UPDataSubmissionGuidance25MAR2022.pdf), unless granted an exception. There are two categories of exceptions:

1. Individual CDE exceptions for Tier 1 CDEs: This request is for a list of individual Tier 1 CDEs that a project will not collect at all, across any of their aims. This request can only be approved by the NIH and will be submitted via an official written request to the project's Grants Management Officer for Prior Approval for deviation to the terms and conditions of a project's award.
2. CDE Wording Change Request: This request is about any proposed wording changes a project has to the CDEs in either Tier 1 or Tier 2 for implementation in a study. This includes changes to the CDE questions or the answer choices. Changed answer choices should include a description of how to map the updated answer choices to the original CDE answer choices. The CDCC will review and approve Wording Change requests. Wording change requests will generally be approved so long as changes 1) do not change the meaning of the question and 2) changes to response options are able to be mapped to the original CDE responses. A CDCC Informaticist will work with a project to update wording changes if an issue with question meaning or mapping occurs.
    a. If a project requests a change to a CDE that changes the meaning of the questions or renders it unable to be mapped to the original CDE and does not want to edit the question to bring it into compliance, it is no longer considered a CDE and an individual CDE exception request must be made to the NIH via Prior Approval request for a deviation to the terms and conditions of their award, as above.

Tier 2 NIH CDEs are recommended to be collected, but not required. This specification is in alignment with the original expectations of the RADx-UP Notice of Award terms and conditions to leverage existing and new data. Tier 2 NIH CDEs that are collected by a project are also required to be submitted to the CDCC

C. RADx-UP Awardee Responsibilities

RADx-UP Project Awardees will:

1. Share Tier 1 and Tier 2 NIH CDEs for their projects with the ***RADx-UP CDCC on a quarterly basis***, with or without personal identifiers, depending on decisions of

authorized oversight committees/boards (e.g., the study's IRB, community advisory boards, etc.) and in alignment with any NIH CDE data sharing exceptions. Data must be shared on a quarterly basis, beginning the first day of data collection.

2. Share additional study data and documentation from their RADx-UP funded studies with the ***RADx-UP CDCC***
3. Ensure that their consent forms include language allowing for the General Research Use of deidentified copies of this data. This means that consent language states that any other researchers can use these data for any future research purposes.
4. Ensure that their project has submitted data elements in to the ***RADx-UP Portal*** consistent with their data use agreement, consent from participants, and terms with NIH.
5. Ensure that any data sets received by the project from the CDCC are not shared with any parties not authorized to hold that data. Authorizations for the sharing of data should be fully outlined in Data Use Agreements between the projects and the RADx-UP CDCC.
6. Ensure that any results reported in publications and presentations from RADx-UP Cross Consortia data sets that are received from the CDCC include suppression of cells containing a value of 1 through 10.

D. RADx-UP CDCC Responsibilities

1. The CDCC serves the larger NIH RADx initiatives by providing de-identified individual data to an NIH-based ***RADx Data Hub***. This functional requirement is in alignment with the original expectations of the RADx-UP Request for Application (RFA) and codified in the RADx-UP Notice of Award. No identifiable data provided to the RADx-UP CDCC will be shared with the NIH ***RADx Data Hub***.

2. The CDCC will ensure all data is hosted on a secure environment. Additionally, all HIPAA direct identifiers are hosted in a separate location on the RADx-UP secure Azure environment from the limited data set used for research purposes. Direct HIPAA identifiers will only be used for patient re-contact for future research where patients consented to such re-contact. Direct identifiers will not be transferred out of the CDCC for analysis.
3. The CDCC will harmonize NIH RADx-UP CDE data submitted by each of the projects before releasing for CDCC or RADx-UP Investigator use. Harmonization of the NIH RADx-UP CDE data will comprise of conformance analysis, working with each project to map their data to the CDEs and validate that each response code submitted is aligned with the CDE response values specified in the NIH CDE RADx-UP code set available at https://radx-up.org/learning-resources/cdes/
4. The CDCC will provide a secure dashboard for projects to review their data submissions and assess their level of conformance with the NIH RADx-UP CDEs. Additional secure dashboards will be accessible by projects to view aggregate data frequencies or

generate cross tabs to assess the capacity of data in the portal to answer their research question prior to requesting an analysis set.

5. Additionally, the CDCC serves the RADx-UP consortium by providing deidentified or limited data sets to consortium members for approved cross-consortial data analysis based on the needs of the analysis and the data sharing/use agreements in place.

6. The RADx-UP CDCC will ensure that all data transferred out of the CDCC is reviewed prior to transfer and abides by all data transfer agreements and policies, including those of Tribal Nations.

E. Data Access, Approval Requirements, and Terms of Access

1. Access to harmonized data within the RADx-UP Data Platform

All investigators follow a similar process to access and use RADx-UP Project Data for an approved Analysis Proposal. For more details, refer to the RADx-UP Publications Policy.

The RADx-UP CDCC will grant data access to project staff identified by an investigator who submits an Analysis Proposal requiring access to RADx-UP Project data once the RADx-UP Publications & Dissemination Committee approves the Analysis Proposal.

For ***Analysis Proposals*** that include data from a project involving a Tribal Nation, the Tribal Nation's data transfer and use agreement will govern both the approval for the use of and access to the data and will also require approval of analyses and presentation of the data in presentations and publications.

All investigators using RADx-UP data for any purpose will be required to abide by the RADx-UP Publications Policy.

2. Data Access Approval Requirements

Investigators and Consortium members seeking access to cross-consortia data to conduct analysis on individual-level data must first meet the following data access approval requirements. They are applicable to all ***RADx-UP*** investigators:

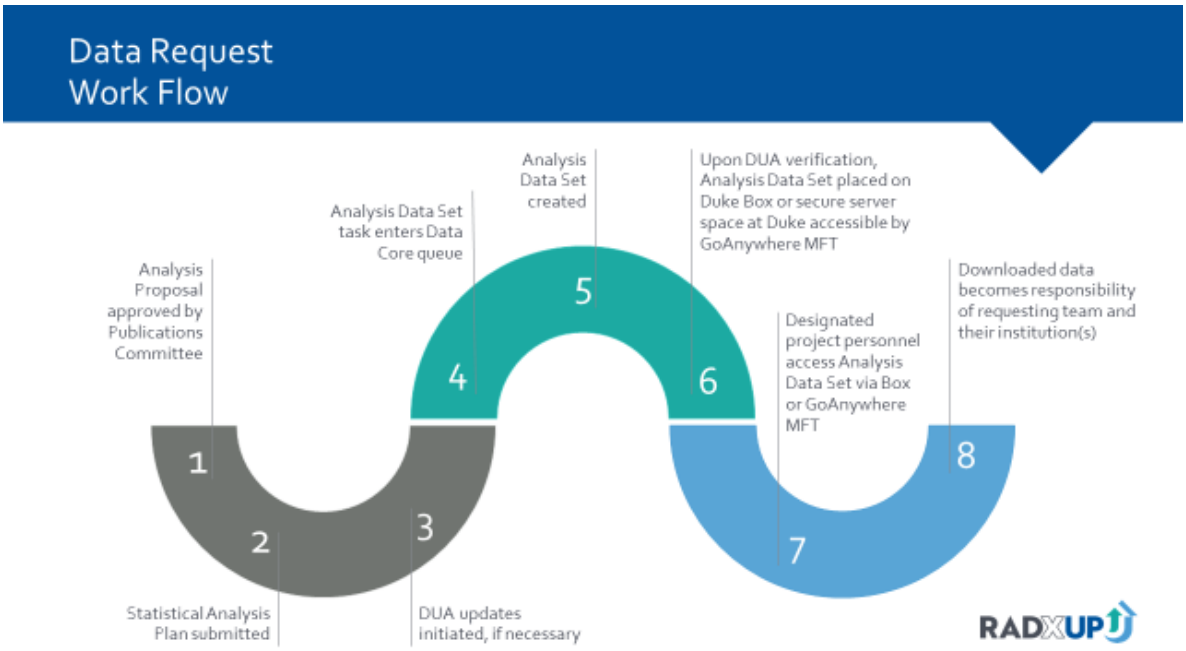
- Complete the Partnering for Impact process. Partnering for Impact is the process outlined in the RADx-UP CDCC Publications Policy that outlines the process for requesting cross-consortium data sets for cross-consortium analyses and publications.
- Investigators and Consortium members with a Publications & Dissemination Committee approved ***Analysis Proposal*** will have access only to those data needed for the approved ***Analysis Proposal***.

  The project will designate the individual or set of individuals on the analysis team who should receive the analysis data set. All parties receiving data must agree (via a data use agreement) to abide by all terms and conditions that protect the privacy and confidentiality of the dataset and the institutions involved attest to its ability to protect the dataset. The designated person or persons receiving the data

set will be able to log into a secure space and download the analysis data set created for their project. Once downloaded, the data set and all responsibilities regarding data privacy and confidentiality become the responsibility of the institutions receiving the data, including ensuring that data is secure and not shared with others outside of the specifications of the existing data use agreement, including members of the writing team who do not have appropriate DUAs in place.

- All investigators or Consortium members need IRB approval or an exemption letter prior to data access being granted.

RADx-UP Partnering for Impact - Data Access Process
This process is a subset of the Partnering for Impact process and only pertains to the data access portion of that process. For information on the full process, please see the RADx-UP Publications and Dissemination Policy: https://radx-up.org/resource-type/guide/radx-up-publications-policy/



3. Terms of Data Access

- For *all* ***analysis proposals***, investigators will have access to limited data sets or de-identified datasets only.
- Only analysts specified in the ***Analysis Proposal*** will receive access to de-identified or limited data sets of individual-level data via the secure portal, in accordance with the applicable data use or data sharing agreement.
- The ***RADx-UP CDCC*** will grant access only to data sets or data views required to implement the analyses specified in the approved ***Analysis Proposal***. The ***RADx-***

UP CDCC staff may provide consultation to determine the data needed for analysis.

- In alignment with the Publications Policy, time limitations on data access may apply. Generally, progress from ***Analysis Proposal*** approval to submission of the resulting manuscript to the publications committee for review (prior to submission for publication) should be one year or less unless otherwise designated by the Publications & Dissemination Committee within the Publications Policy. The RADx-UP Steering Committee will determine the consequences of failure to adhere to this timeline (e.g., suspension of access to data for a determined period).

F. Data Privacy Breach and Abuse and Penalties for Non-Compliance with Data Sharing Policy

The CDCC may monitor activities conducted on the computer system accessing the ***secure portal*** to facilitate protection against unauthorized access, and to verify security procedures, survivability, and operational security. During monitoring, the CDCC may examine, record, copy, and use information for authorized purposes. Unauthorized use or access are addressed in the data transfer and data use agreements in place with the CDCC, across the CDCC, and with NIH. If the CDCC or an individual outside the CDCC becomes aware of a suspected or actual privacy or information security incident, or a violation of the terms and conditions of data access, they must report the event to the RADx-UP CDCC immediately as it may impact confidentiality, integrity, or availability of ***RADx-UP Portal or other secure portal,*** data and resources. Whoever discovers such an event must report to appropriate institutional authorities, including their institutional IRB and Privacy Officers, in accordance with their institutional policies. The RADx-UP CDCC must report the incident to the Duke IRB, the affected projects, and the RADx-UP NIH Program Officers within 72 hours after receiving the report and will notify the RADx-UP Data Stewardship Committee. The report will include the following information as available:

- Type of data affected (e.g., ***PHI***, other)
- Approximate date and time of the incident
- Detailed description of the incident (e.g., amount of data involved, specific systems, servers, and IP addresses involved)
- Response taken to remediate the incident (e.g., notification of the data originator when ***PHI*** is involved) including notification of impacted projects.
- Identify a mechanism to prevent or minimize future risk

The ***RADx-UP CDCC*** will work with the RADx-UP Data Stewardship Committee, Steering Committee and the NIH Program Office to remedy any ongoing concerns, or revise processes to reduce the risk of a similar event recurring.

V. Review and Revision

The RADx-UP Data Stewardship Committee will review and approve updates to this policy annually.

VI. Supporting documents

A. RADx-UP Portal Data Access Request Form

B. Delegation of Authority

VII. References

A. RADx-UP NIH CDE Data Dictionary: https://radx-up.org/learning-resources/cdes/

B. RADx-UP Data Submission Guidance: https://myhome.radx-up.org/RADx-UPDataSubmissionGuidance25MAR2022.pdf

C. RADx-UP Publications and Dissemination Policy: https://radx-up.org/resource-type/guide/radx-up-publications-policy/

D. NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research: http://grants.nih.gov/grants/NIH-Public-Access-Plan.pdf

E. "Proposal for RADx[SM] (C)DCC Data Sharing with the RADx Data Hub

F. Frequently Asked Questions – RADx Exec Common Data Elements (CDEs), Patti Brennan, June 13, 2021

G. Letter to the POs, Drs Woychik and Tabak, June 17, 2021
Exceptions to data sharing for intellectual property concerns, Drs Woychik and Tabak, August 5, 2021.

VIII. History of Change Since Last Version

Section Affected	Changes Made
III	Added limited data set definition and updated definition of analysis proposal to conform to definition in pubs policy.
IV. C	Additions to project responsibilities.
IV.D.	Additions to CDCC responsibilities.
IV.E.	Minor grammatical edits and removal of reference to delivery of data via MyRADx-UPHome. Edits to data delivery process flow chart.
IV.E.	Edits to remove reference to delivery of data via MyRADx-UPHome.

Approval Page

Name/Title	Signature/Date
Approved by: Warren A. Kibbe, Ph.D, FACMI MPI, RADx-UP CDCC	 *Electronically signed by: Warren A. Kibbe* *Reason: Approved* *Date: Nov 22, 2022 17:05 EST*
	Date Vote Confirmed & Results
Approved by DSC Committee Vote	Vote confirmed on 11/13/2022 7 members voting, all voting in favor of ratification. Results of vote located here: https://duke.box.com/s/qhtvft3cdnd5z55osmlqta3uafzw60y1

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