



June 15, 2021

Dear RADx Project Officers, Program Officers, Science Officers, and Grants Management Officers:

As we pass the one-year mark of the RADx program, we write to express our gratitude for your efforts in making the launch of the RADx program a success, and to engage your support to ensure the rigor and reproducibility of this effort. Please extend our gratitude to all of your awardees.

NIH has adopted cooperative approaches to collect data in a common way across all programs and to make data, properly consented and de-identified, accessible to researchers in the future. Common data elements (CDEs) are preferred items and instruments, used across several projects that serve as indicators of biological processes or cognitive and behavioral concepts. Generally expressed as a question with associated acceptable responses, the use of Common Data Elements ensures data harmonization from the outset of a program. Every project engaging human participants, including members of tribal nations, is expected to collect a small but required set of data elements (the RADx Executive Committee Required CDEs), including demographics, disability status and health indicators. In addition, specific programs (e.g. RADx UP, RADx RAD) have added or may add additional common data elements that investigators are required to collect.

There is a process project staff or NIH staff to request exemptions to the CDE requirement. Minor modifications will be reviewed at the data coordinating center then communicated back to the PO who notifies the PI, the GMO if needed and the RADx Data Hub; major modifications, which require substantial justification and are expected to be rare, will be decided by the program officer. All communication and decisions by the PO must be documented and communicated to the PI, and the RADx Data Hub GMOs as needed.

The workspace for managing all common data elements, across the RADx programs, will be the newly developed [OD-RADx Common Data Elements Teams site](#). There are separate channels for each of the RADx programs, and one for the RADx Executive Committee materials. There you will find frequently asked questions regarding CDE exemptions, sample letters for GMOs to send to awardees, and other resources.

NIH is committed to learning all that we can from the pandemic response and the RADx program. All consented data collected in the RADx program will be de-identified and deposited into the RADx Data Hub. This resource will allow current and future researchers to interrogate the data and discover new patterns. We are instituting an accelerated data-deposit, curation, and access model. In this model, six months after the project has started and has enrolled the first participants, data will be submitted to the data coordination center. Thereafter the project will continue to submit data, on an ongoing three-month basis into the data coordinating center, which in turn will send it on to the RADx Data Hub every three months. Deposit of data that falls under the oversight of the tribal nations will be handled in

accordance with future negotiations. Data from the RADx Data Hub will be made available for general research use as soon as it has cleared the quality checks in place at the RADx Data Hub.

This rapid-cycle data deposit and access model will make it possible for RADx researchers to learn from the efforts of related projects. The use of common data elements will allow for easy integration of data across the over 100 projects now funded under the RADx program. Do not hesitate to contact your respective project officers if you have questions or suggestions.

We look forward to continuing to work with you on this important effort!

With best wishes, and thanks,

**Richard P.
Woychik -S**

Rick Woychik, PhD
Director, NIEHS

Digitally signed by Richard P.
Woychik -S
Date: 2021.06.25 07:59:27 -04'00'

**Lawrence
A. Tabak -S**

Digitally signed by
Lawrence A. Tabak -S
Date: 2021.06.26
15:14:06 -04'00'

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

Co-Chairs
RADx Executive Committee