



March 25, 2021

Dear RADx Committee Chairs, Program Staff, Project Officers and Scientific Officers:

The RADx program represents an unprecedented investment by the NIH to mitigate the COVID-19 pandemic by accelerating access to testing. There is much to be learned, both in the present as well as over time. To glean the maximum value from the data generated through RADx, all studies involving human participants are required to collect information on 12 key data elements, referred to as common data elements (CDEs).

The attachment enumerates these data elements, including the stimulus and acceptable response. Deidentified data from the RADx projects will be available for researchers in the future through the RADx data hub. In addition to the 12 required data elements, groups of projects or entire RADx programs may specify additional data to be collected in a common way across projects.

We recognize that this is a new model of research, and that some investigators have raised concerns about the relevance, acceptability, or feasibility of collecting these data elements. *Therefore, we seek your help in addressing these concerns and ensuring that all projects collect these data elements in a consistent manner.* We believe that embracing these common data elements will help ensure that the data being collected across the various RADx projects can be seamlessly integrated into a comprehensive data resource.

As part of their role in ensuring that the terms and conditions of an award are met, program officers are responsible for reviewing data collection strategies to ensure that CDEs are being collected in a consistent manner. Minor modifications that will allow harmonization of a project's data with all other data (e.g., collecting racial and ethnic data with greater specificity; using age instead of date of birth) can be approved by the relevant RADx program's data coordination center. More significant modifications, such as collapsing all disability items into a single item indicator, should be communicated to the program official. These will require written approval from the NIH Institute and Center Grants Management Official in advance of the change, as specified in the [NIH Grants Policy Statement \(8.1.2\)](#). We expect that approval of these modifications will be rare and done in consultation with the specific RADx Committee Chairs and the RADx Executive Committee.

Please contact Patti Brennan as your liaison to the RADx Executive Committee ([patti.brennan@nih.com](mailto:patti.brennan@nih.com)) with any questions.

We thank you for all of your efforts to make this program a success. This program would not exist or be where it is without your hard work and dedication.

Sincerely,

Tara A. Schwetz, PhD  
Rick Woychik, PhD  
RADx Executive Committee Co-chairs