

## Proposal for RADx<sup>SM</sup> (C)DCC Data Sharing with the RADx Data Hub

*RADx<sup>SM</sup> DCC includes RADx-UP Coordination and Data Collection Center; RADx-RAD Data Coordination Center; RADx-TECH; Digital Health Platform Coordination Center*

### 1. Data Submissions

#### Periodicity

**Quarterly Data Submissions (every 3 months)** are expected for the RADx<sup>SM</sup> program. However, we expect some of the programs will not have new data at every quarterly upload cycle, due to how they structured their projects.

**Quarterly RADx<sup>SM</sup> EXEC Minimum Common Data Elements** (minimum CDEs) will allow the RADx Data Hub to enable understanding demographic and other characteristics of the study participants. Recruitment of candidates typically generates immediate minimum CDEs while other types of data may be collected at later quarterly time intervals (e.g., tests results, long-term symptom follow-up, etc.).

*We propose RADx<sup>SM</sup> Data Coordination Centers (RADx<sup>SM</sup> DCC) submit required by the RADx EXEC CDEs every 3 months. Data related to novel technology results are expected to be submitted by the RADx<sup>SM</sup> DCCs on a regularly scheduled basis and determined by the Program Officers (PO) and the awardees.*

The RADx<sup>SM</sup> DCCs are responsible for data submission and will managing communications with the awardees, especially when issues arise about expected and timely data submissions.

### 2. Data De-identification

**Zip codes.** The RADx<sup>SM</sup> DCC will send awardees software to de-identify zip code data consistent with Section 164.514(a) of the Health Information Portability and Accountability Act (HIPAA) Privacy Rule to ensure the coordination centers receive HIPAA de-identified zip code data.

*All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:*

- (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and*
- (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000<sup>1</sup>*

**Date shifting.** The RADx<sup>SM</sup> DCC will send the awardees software to de-identify dates by using a randomly selected, constant # of days (e.g., add 4 days to all dates) to ensure that date data submitted to the coordination centers are de-identified; awardees will keep a record of these data interval constants for each participant used for all data submissions.

The process for randomly choosing the number of offset days will be discussed among the RADx coordination centers to ensure consistency across RADx<sup>SM</sup> programs. Preliminary discussions suggested the time interval should be 10 days (e.g., if the interval is -5 to 5 days from day 0, the original date, one research participant may have all their dates shifted 3 days forward while another research participant may have their dates shifted 5 days back).

**Age.** For age, if a research participant is less than one year old, the submitted data will be listed as “0”; if a participant is 21 years old or above, the submitted age will be listed within +/- 2 years of the chronological age. In cases where the research participant is 90 years old or above, the submitted age element will be aggregated into a single number “90”. The RADx<sup>SM</sup> Data Hub will alert Awardees about these two age groups.

*Note: For projects that are generating data with no HIPAA-de-identifiers, awardees’ projects may require modifications to their IRB protocols (including consent form modifications), and require modifications to , Data Use and/or Data Transfer agreements, depending on the identifiers contained in the data. Additionally, a system for research participant notification of data breaches may be required depending on the identifier.*

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<sup>1</sup> Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (<https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>)