DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

From: Lawrence Tabak, Rick Woychik, Co-Chairs, RADx Executive Committee

As you are aware, 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. Recently NIH issued a clarifying letter that recognized the importance of Common data elements (CDEs) and the process by which researchers could request an exemption to the CDE requirements.

As we articulated in our June 15th letter*, 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 tointerrogate 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 thedata 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 forgeneral research use as soon as it has cleared the quality checks in place at the RADx Data Hub.*

This letter describes the criteria and process by which investigators can request an exemption for limited data sharing in order to protect data for intellectual property.

For the purposes here, intellectual property that deals with **Proprietary Data for the RADx program is define as:**

Data from RADx programs that may be exempt, for a limited time, from deposit into the RADx Data Hub are defined as proprietary data that report on the performance of a device with the intended purpose of supporting applications to obtain regulatory approvals, including but not limited to Emergency Use Authorization's (EUA), 510K applications, required post-market data, and PMA applications. In addition, propriety data obtained in support of intellectual property claims, including patent filings, trade secrets, trademarks, and copyrights would also be exempt. Clinical study data and data that conforms to and are responding to the required Common Data Elements (CDEs) are generally deemed, not exempt. However, these and other data such as program specific Common Data Elements, and the data that conforms to these CDEs, may be exempted for a limited time with strong

justifications.

NIH recognizes the need to protect sensitive proprietary data. Awardees who wish to request a time limited data sharing exemption should do so with a written request that provides substantial justification to their program officer. These exemptions are expected to be a rare occurrence. Requests should include both the justification for limited data sharing and the duration of the exemption. Industry standards for proprietary data sharing exemptions are typically 60-90 days. All communication and decisions by the program officer must be documented and will communicated to the PI, the staff of the appropriate RADX data coordinating center, the staff of the RADx Data Hub (for awareness only), and the GMOs.

While we expect that the rapid-cycle data deposit and access model will make it possible for RADx researchers to learn from the efforts of related projects, we recognize the potential for intellectual property protection for devices that are developed through the RADx program.

Do not hesitate to contact Susan Gregurick (gregurickssk@nih.gov) if you have questions or suggestions.

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

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