

## **Data Use and Sharing Agreement: COVID-19 Emergency Response Jurisdiction Immunization and Vaccine Administration Data Agreement Q&A**

### **1. Can CDC provide more detailed information about breach notification protocols?**

Transmission of the Covered Data from the jurisdiction to CDC shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents. CDC will use all reasonable administrative, technical, and physical measures to safeguard the Covered Data and to protect the Covered Data from unauthorized access, disclosure, use, or modification. This includes setting permissions to access or edit Covered Data commensurate with the level of sensitivity of the Covered Data. Should there be a data breach and unauthorized disclosure of the Covered Data from the CDC controlled platform, a CDC representative shall contact the jurisdiction within 1 hour of the event occurring for personally identifiable information (PII) or protected health information (PHI) and 24 hours for non-PII/non-PHI to make the jurisdiction aware of the situation and provide the response plan.

### **2. Can CDC share more detailed information regarding what is meant by an “Authorized User”**

The current definition of “Authorized User” found on page 3 of the DUA states:

“For purposes of this DUA, means an individual who, as part of directly supporting the whole of government response efforts, has a need for data stored in the DCH, the IZ Data Lake, and/or the Tiberius platforms in furtherance of the purposes and uses set forth herein. Authorized Users will generally be employees, contractors, and/or other agents specified by jurisdictions or federal agencies engaged in the response for purposes of addressing critical public health and emergency response activities, including assessing infrastructure needs and resource allocation. Authorized Users must adhere to applicable federal law and to any applicable provisions set out in this DUA with respect to the data stored in the respective platforms, which are further defined herein and described in Appendices A–D.”

An Authorized User is an individual, employed by an entity of the government (e.g. CDC, HHS) or their contracted entities (e.g. Oracle for the purposes of the COVID-19 Data Clearinghouse) who is a participant in the COVID-19 response and whose duties require the use or access of vaccine administration data. Authorized users will be different for the different platforms since they each have different purposes and levels of data, as set out in the DUA and corresponding appendices. In addition, for each data platform, there may be Authorized Users who have incidental access to data in order to provide technical support services. For example, although CDC staff will not have access to the COVID-19 Data Clearinghouse, Oracle contractors may be designated as Authorized Users for technical support. For Authorized Users who may access data in order to support the COVID-19 response, through the creation of data analyses or aggregate data, their access would be limited to the IZ Data Lake.

The Authorized User must be authenticated as a participant in the COVID-19 response by their parent agencies (e.g. CDC, HHS), and upon the termination of the user’s time on the response, their access to data within data systems will be terminated. Examples of Authorized Users include, but are not limited to:

- CDC COVID-19 FTE Response Staff
- CDC contracted staff hired for specific duties and tasks related to the COVID-19 response
- CDC Fellows who have been deployed to the COVID-19 response
- HHS COVID-19 FTE and Contracted Response Staff

### **3. Will jurisdictions be notified when there is an update or change to an appendix?**

The appendices have been included to provide detailed information about each of the data platforms and the data elements that may be received. Because some of the technical details about the platforms may change, these appendices will continue to be living documents that may need to be updated. Before any modifications to an appendix are made, jurisdictions will be notified and provided an opportunity to comment. If any data elements are modified, the jurisdiction will have to agree to and execute the change in data provision. CDC and HHS will not have the technical capacity to change the scope of the data unilaterally. The language of the DUA, including the limitations set out by state law and the general data sharing structure described in it, will remain the same. Therefore, any changes to data elements that may be reported will have to occur through mutual agreement.

CDC has sought minimally necessary data elements for the public health purposes set out in the DUA. Those elements are set out in the appendices. CDC will not seek social security numbers, driver's license numbers, or passport numbers. As stated here, any changes to the data elements will be in consultation with the jurisdictions.

**4. CDC mentions “Federal Partners” within the DUA. Can CDC limit who the federal partners would be?**

As set out in the purpose of the background and purpose of the DUA, the use of vaccine administration data will be limited to completing work in furtherance of the public health response to COVID-19. Since data may only be used in furtherance of the public health COVID-19 response, data about individual vaccine recipients may not be used to market commercial services to individual patients or nonpatients, to assist in bill collection services, or for any civil or criminal prosecution or enforcement, including, but not limited to, immigration enforcement, against such individuals whose information is shared pursuant to this DUA.

The response to COVID-19 is a whole government effort and may include agencies who are not typically involved in public health work. For example, the Department of Defense is part of Operation Warp Speed, the program under which the vaccine is being distributed. Authorized Users may need to access different data systems to provide technical support. However, the DUA is set out so that information that is pulled for data analysis or review can only come from the IZ Data Lake or HHS Tiberius. Thus, Authorized Users who are not providing technical assistance to any of the platforms may only have access to the redacted data that comes from the IZ Data Lake or Tiberius.

**5. Will CDC notify jurisdictions when publishing any of its data?**

Given the emergent nature of the response, HHS and CDC will make all efforts possible to notify the jurisdiction of the publication of data from the jurisdiction but may not be able to inform the jurisdiction in all instances. For such publications CDC will coordinate as soon as possible and practicable, with the fullest intent of protecting the data from the jurisdictions while functioning in the role of a data steward. As appropriate, publications will acknowledge the jurisdiction as the source of the data in any such publication. Also, consistent with federal law and CDC publication processes, CDC protects the identity of individuals whose data is being used in publications.

**6. Will jurisdictions receive notice prior to judicial or other legal, e.g. FOIA, disclosures?**

When there is a legal request, such as a FOIA request or judicial subpoena, for confidential information provided pursuant to this DUA, CDC program staff will provide timely notice to the appropriate jurisdiction.

**7. What happens to data when the term of the DUA expires?**

When the DUA expires, access to the data provided through the DUA expires with it; however, there are two circumstances that require the data to be maintained after the expiration of the DUA. First, due to the Federal Records Act, an archival copy of the data will need to be maintained by HHS and CDC. All protections, including limitations, for the data will survive the termination of the DUA as noted on pg. 8. Second, because there may be publications that rely on the data, the data must also be maintained for research integrity purposes. Data will be maintained according to Federal Records Act record scheduled (CDC Scientific and Research Project Records Control Schedule (N1-442-2009-1)). Should the veracity of a publication come under question, the data must still be available for CDC or HHS to defend the conclusions made with the data.