



Data Sharing and Use Agreement
Between the Immunization Information Systems Support Branch
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
and
Virgin Islands Department of Health, Immunization Division

Purpose: This Data Sharing and Use Agreement (“Agreement”) between the **Centers for Disease Control and Prevention (CDC)**, **National Center for Immunization and Respiratory Diseases (NCIRD)**, **Immunization Services Division (“ISD”)**, having its primary offices at 1600 Clifton Road, Atlanta, GA 30333 and the **Virgin Islands Department of Health (“Jurisdiction”)**, through its **Immunization Division** having its primary offices at **1303 Hospital Ground, Suite #10, St. Thomas, VI 00802**, is to establish the basic terms and conditions concerning the access, sharing, protection, and use of data submitted by the Jurisdiction and received by ISD.

Background: Accurate vaccination data is critical for measuring vaccine uptake, monitoring trends during shortages, assessing compliance with recommendations, and informing decision makers. Multiple data sources are available for monitoring national vaccine administration, but IIS have shown to be a timely, accurate and complete source for these purposes. The Centers for Disease Control and Prevention (CDC) has previously used Immunization Information System (IIS) data to monitor vaccination coverage and evaluate vaccine usage within Jurisdictions and is seeking to support innovation leading toward broader usage of IIS data for monitoring national vaccination practices and for other public health purposes.

For example, IIS data can complement and improve national surveys and fill critical knowledge gaps. In addition, in order to support national vaccination monitoring, IIS data can be used to support the development and implementation of new approaches for assessing vaccination coverage.

To support these uses and critical public health purposes, CDC has developed an architecture to facilitate the secure transmission of IIS data from Jurisdiction to CDC. In addition, CDC has set forth herein a description of the requested vaccine administration data from Jurisdiction and the processes for submission to help ensure a comprehensive, timely and accurate understanding of vaccine administration, uptake, and coverage.

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CDC intends to use these data for purposes to include:

- Monitoring vaccination coverage; and
- Aiding in development of methods for estimating national vaccination coverage; and
- Conducting program evaluations; and
- Aiding in development of methods for assessing the quality (e.g., completeness, timeliness, accuracy) of IIS data; and
- Informing technical assistance provided to Jurisdictions.

Other U.S. Department of Health and Human Services (HHS) Operating Divisions will use these data for purposes to include:

- Evaluating vaccine effectiveness; and
- Conducting safety monitoring; and
- Supporting communication to patient populations to encourage vaccination.

To support the development and enhancement of Jurisdiction IIS, CDC funds Jurisdictions through various assistance mechanisms, such as Notice of Funding Opportunity (NOFO) CDC-RFA-IP19-1901. In part, those funds are intended to enable jurisdictions to advance the use of IIS systems and data for monitoring vaccination coverage and vaccine use. In addition, these assistance mechanisms may require, by their terms, Jurisdictions to 1) meet the requirements of CDC's Immunization Program Operations Manual (IPOM); 2) implement privacy-preserving record linkage (PPRL) by June 2023; and 3) sign this Agreement for data sharing and use. Where the assistance mechanism requires the signing of this Agreement and the collection of data elements collected under that mechanism, sharing of those data is governed by the terms of that assistance mechanism, including 45 CFR 75.322 and this Agreement. The terms of this Agreement are intended to be read to not conflict with the terms of the underlying assistance mechanism.

This Agreement is intended to apply to activities set out in the following assistance mechanism: CDC-RFA-IP19-1901.

Definitions: For purposes of this Agreement, the following definitions shall apply:

"Jurisdiction" means the local or state health jurisdiction operating under either statutory or regulatory authority to obtain and use health-related data for population health protection, including vaccine administration and other vaccine related data.

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“Immunization Information System” or “IIS” means any confidential, population-based, computerized database that records vaccine doses administered by participating healthcare providers to persons residing within a given geopolitical area. This term may be used interchangeably with Jurisdiction.

“Data” means the information that is being shared by the Jurisdiction with each relevant platform as further described in Appendices C, D, F, and G. CDC acknowledges that the data to which it will have access is the minimum amount of information necessary to accomplish its public health needs. A list of the requested elements for each dataset is provided in Appendices C, D, and F.

“Redacted” means the exclusion of direct identifiers of an individual, but with inclusion of specific elements related to vaccine administration management. Exact data elements, including instructions and value definitions, are outlined in the Data Dictionary (Appendices C and D).

“Privacy Preserving Record Linkage” or “PPRL” means the process whereby personally identifiable information (PII) is redacted from a patient/customer record using a one-way, irreversible encryption algorithm to create one or more unique tokens that replace PII elements and allow data systems to match patient/customer records.

“Party” means State or Local Jurisdiction or CDC; “Parties” means State or Local Jurisdiction and CDC.

Agreement Principles:

- 1) Quarterly Routine Vaccine Administration Data: Jurisdiction agrees to submit redacted record-level data for all ages (see Appendices C and D) to CDC quarterly. Submitted data should align with the calendar year; an example schedule is provided further herein. Each Jurisdiction should submit redacted record-level data at the end of the month for the period ending the prior quarter. For example, the quarterly data submission due January 30, 2023 should include all records in the IIS through December 31, 2022. Quarterly data submissions shall continue with the support of immunization funding for IIS provided under the CDC-RFA-IP19-1901 NOFO, with the final submission occurring for record-level data through June 30, 2024 on July 31, 2024. CDC will use submitted data to calculate vaccination coverage estimates for all those routinely administered vaccines listed in Appendices C and D.
- 2) Monthly Aggregate Seasonal Influenza Vaccine Data: Jurisdiction agrees to submit aggregate seasonal influenza data for all ages monthly on the 9th of each month, beginning on August 9, 2022, or as soon as this Agreement is in place. Each data submission should contain data from July 1 of the influenza season (October to February) through the end of 30-day period prior to the data submission (e.g., the October 9, 2022 submission should include aggregate influenza data for all ages from July 1, 2022 through the September 30, 2022). In addition, Jurisdiction shall provide an initial submission of aggregate monthly data for the previous two influenza seasons as baseline monitoring data. During influenza season (October



to February), Jurisdiction may be required to submit influenza data weekly. The Jurisdiction will be notified of this requirement within a reasonable time before weekly reporting should begin. Specific instructions for aggregate seasonal influenza reporting are included in Appendix B. CDC will use the submitted data to calculate vaccination coverage estimates for all administered seasonal influenza vaccines. Monthly data submissions shall continue, funded under CDC-RFA-IP19-1901 NOFO, through the final submission occurring for data through June 30, 2024 on July 31, 2024.

- 3) Emergency Response Vaccine Data: Should unforeseen events occur, such as pandemics, vaccine shortages, disease outbreaks, as determined by CDC, Jurisdiction agrees to submit, no-less than weekly, emergency-related vaccination data to CDC for all ages. CDC will notify Jurisdiction in writing of this requirement (including necessary data elements) and will work collaboratively with Jurisdiction to determine the quality and acceptability of submitted data for analysis, recognizing that completeness will vary between age groups. CDC intends to use these data submissions to monitor the particular emergency, shortage or outbreak. Analysis by the CDC during peak transmission season, including the influenza season, may result in a request by CDC of Jurisdiction for more frequent data submission from jurisdictions. In the event that increased frequency of reporting is required, specific submission schedules will be shared with Jurisdiction.
- 4) Jurisdiction agrees that record-level and aggregate vaccination data will be used by investigators for ad-hoc vaccination analyses in furtherance of public health purposes. CDC will determine the feasibility and appropriateness of IIS data for ad-hoc studies. Investigators will use the submitted data to monitor vaccination coverage as identified in the ad-hoc requests approved by ISD. The Jurisdiction will be notified of analyses utilizing IIS data within two weeks of analysis completion. Additional details about data access, use, and analysis are included in Appendix A.

CDC and other HHS Operating Divisions agree to a) use and disclose the data only in accordance with this Agreement, or as otherwise required by applicable federal law; b) limit access to these data only to those described and authorized in this Agreement, except as may be required by applicable federal law; c) use appropriate safeguards to prevent use or disclosure of the information other than as provided by this Agreement; d) ensure all investigators and data administrators are aware of and adhere to security and confidentiality requirements that may apply to these data; e) consistent with CDC and HHS policies and procedures, notify Jurisdiction of a use or disclosure of information that is not provided for by this Agreement; and f) make no attempt to identify or contact the individuals, providers, or health plans within the data, except as may be required by applicable federal law.



Examples of Data Submission Date Expectations

Submission Date	Data Type	Data to Submit
November 9, 2022	Influenza	July 1, 2022 – October 31, 2022
December 9, 2022	Influenza	July 1, 2022 – November 30, 2022
January 9, 2023	Influenza	July 1, 2022 – December 31, 2022
January 31, 2023	Routine	All records through December 31, 2022
February 9, 2023	Influenza	July 1, 2022 – January 31, 2023
March 9, 2023	Influenza	July 1, 2022 – February 28, 2023
April 10, 2023	Influenza	July 1, 2022 – March 31, 2023
April 30, 2023	Routine	All records through March 31, 2023

Dataset Description: For quarterly data submissions, ISD is requesting three tab-delimited files from the IIS, including 1) record-level demographic information for all ages in the Jurisdiction's geographic region at the time of file submission; 2) record-level vaccination information on all doses of all vaccine administered for each person who has at least one immunization record in the IIS at the time of file submission; and 3) a control file. The record-level demographic and vaccination datasets must be linked using a unique identifier (ID), provided by the IIS, which uniquely identifies each individual person in the dataset. This identifier can be the ID used by the IIS, or it can be a masked ID number. Jurisdictions utilizing PPRL will submit an additional file including the unique identifier to the PPRL engine for linking (details of PPRL submission are set out in Appendix E; PPRL data specifications are set out in Appendix F). Demographic datasets for any quarterly data submissions should include individuals of all ages in the IIS as of the period ending for the month of data submission (e.g., for December 31, 2022, data submitted on January 31, 2023).

For aggregate monthly seasonal influenza data submissions, each Jurisdiction must complete the monthly seasonal influenza template (Appendix B). This Excel document has two worksheets: 1) a table shell for the number of persons who receive 1+ doses of the flu vaccine by age group; and 2) a table shell for the number of persons in the IIS by age group (IIS denominator). For each table shell, CDC has provided the date range for the data that should be selected for inclusion in each month's report, as well as the birth date range for the specified age cohorts. Appendix B contains the table shell and instructions for aggregate monthly influenza data submission.

Since not all persons in an IIS will have vaccinations, it is possible for a demographic record to exist with no associated vaccination records. However, all vaccination records must be associated with a demographic record.

Data Elements: The specific control file data elements and instructions are listed in Attachments 2 and 3 (see Appendices C and D). The specific demographic and vaccination data elements requested are listed in the Data



Dictionary (Appendices C and D). IIS must include all variables in the submitted file in the same order as is listed in the Data Dictionary. In the event that values for a variable(s) are not routinely captured and stored in the IIS at the record-level (e.g., Vaccines for Children (VFC) eligibility), the IIS should not try to derive this information in order to complete the field prior to submitting data to CDC. More detailed information about each data element can be found in the respective Data Dictionaries. Columns should be present for all variables, including variables that are not populated. The Data Dictionary will be updated periodically to incorporate revisions to code sets, such as when new vaccines are introduced. Specific data elements requested for redaction via the PPRL engine are included in Appendix F.

File Name:

Data files submitted to ISD should be named using the following format:

IIS_Date of end of reporting period_Date of file submission_D (*for Demographic file*)

IIS_Date of end of reporting period_Date of file submission_V (*for Vaccination File*)

IIS_Date of end of reporting period_Date of file submission_C (*for Control file*)

The IIS code should be the three-letter code assigned to the program in User-Defined Table 0363 – Assigning Authority of the HL7 Version 2.5.1 Implementation Guide.

<https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-2011-08.pdf>.

All submitted dates should be in the yyymmdd format. For example, if Alaska submits a demographic dataset for December 31, 2022 on January 31, 2023, the file name should read
AKA_20221231_20230131_D.

The accompanying vaccination dataset file name should read AKA_20221231_20230131_V.

The accompanying control dataset file name should read AKA_20221231_20230131_C.

File Compression: Files should be compressed for transmission to CDC. Winzip is the preferred file compression software that CDC is supporting.

Data Confidentiality, Access, and Security

1. ***File Transmission:*** Data files will be submitted electronically to ISD using secured methods of file transmission that are approved for transporting moderate personally identifiable information (see Appendix G for data submission scenarios). Approved methods include, but are not limited to:

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- **CDC Immunization Gateway (IZ Gateway):** The IZ Gateway is a cloud-based message routing service intended to enable data exchange between IISs, other provider systems, and the IZ Data Lake. The IZ Gateway enables centralized data exchange and eliminates the need for multiple, individual, point-to-point connections. Secure FTP (below) will be utilized until a jurisdiction is onboarded to the IZ Gateway.
- **Secure FTP:** CDC's Secure FTP site meets the FIPS 140-2 requirements for encryption. An account and password are required to access this site. A third-party FTP client capable of FTP over Secure Shell (SSH) is required.
- Additional automated methods for file transmission may be considered by CDC. Any such option will be secured, encrypted, and deemed appropriately protected for moderate personally identifiable information.

2. Data De-Identification and Redaction: Approved methods include, but are not limited to:

- **PPRL:** Jurisdiction uses this secure and irreversible method of de-identification/redaction within the Jurisdiction's firewall before sharing data with CDC or another Jurisdiction. Additional instructions for data submission to the CDC-provided PPRL engine for de-identification are included in Appendix E.
- **Manual redaction:** Jurisdiction manually redacts identifiable data from vaccine administration and demographic files, specifications included in Appendices C and D.

3. Computing environments: IIS data will be housed and processed in CDC computing environments on CDC-approved platforms configured for the storage and processing of data that contains Personally Identifiable Information (PII). These include the Consolidated Statistical Platform (CSP), a CDC computing environment, and/or the Immunization Data Lake (IZDL), a secure, cloud-hosted environment. Limited HHS, CDC, and contract staff, listed below, have access to IIS data on these platforms. All HHS, CDC, and contract staff with access to IIS data on these platforms will be required to sign a data confidentiality agreement, consistent with CDC policies and procedures.

4. HHS, CDC, and Contract Staff Access to IIS Data: The following HHS, CDC, and contract staff will have access to IIS data in the CSP, IZDL; each staff member's primary duties are listed. Contract staff assigned to HHS and CDC in support of immunization data activities are held to the same security and confidentiality standards that apply to CDC/ISD federal staff. Each HHS, CDC, and contract staff person with access to the IIS data in the CSP or IZDL is required to sign a confidentiality agreement and adhere to the requirements therein.

- **ISD, NCIRD, CDC –** Oversees review and approval of requests for analyses using IIS data to determine feasibility and appropriateness of data use. Conducts vaccine-related assessments for programmatic and publication purposes.
- **Immunization Information Systems Support Branch (IISSB), NCIRD, CDC –** Participates in review and approval of requests for analyses using IIS data to determine feasibility and appropriateness of data use.



- CDC Analytics Project Lead, IISB, NCIRD, CDC – Serves as the primary point of contact for CDC Analytics operations, including system development, testing, and analyses.
- CDC Analytics IT Project Manager – Oversees CDC Analytics, including SAS code development and system testing for system accuracy and efficiency.
- Additional HHS and contract staff including developers, quality assurance specialists, business analysts, system architects, analysts, data modelers, data provisioners, basis administrators whose duties include support of programmatic and scientific activities.

Miscellaneous Provisions

1. ***Human Subjects:*** The data submitted under this Agreement have been designated by CDC as “Public Health: Non-Research” and are exempt from further human subjects review.
2. ***Ownership of Data.*** Jurisdiction shall retain ownership of the data it contributes to ISD under this Agreement. However, the Parties agree that the data provided under this Agreement and in the custody and control of CDC is subject to the laws applicable to the CDC.
3. ***Publication.*** Notwithstanding any other provision of this Agreement, CDC may release data provided to ISD or publish the results of any study or analysis conducted using that data, but only in forms that do not identify any individual, except as may be required by law.
4. ***Government Data Practices.*** Jurisdiction acknowledges that CDC is a federal agency subject to applicable federal laws. As such, with respect to data provided to CDC under this Agreement, CDC will protect the privacy and confidentiality of the data consistent, where applicable, with federal laws, including the Privacy Act of 1974 and the Freedom of Information Act (FOIA). Where other more specific federal laws apply to the data, CDC will comply with those laws, as well. CDC will seek to assert relevant exemptions to disclosure available under federal law, most critically, where applicable, for personal and/or private information, the disclosure of which would constitute an invasion of privacy; trade secret and commercial or financial information that is private and confidential; or information exempted from release by federal statute.
 - a. Consistent with applicable federal law, the CDC agrees to promptly notify Jurisdiction if it receives a legal request to release the data covered by this Agreement. CDC and Jurisdiction will confer concerning the release of the data to the requesting party before the data are released. Jurisdiction acknowledges that as a federal agency, CDC is subject to applicable federal law with respect to the disclosure of data in its custody and control.
 - b. CDC agrees, to the extent consistent with applicable federal law and this Agreement, to adhere to Jurisdiction’s Government Data Practices, as it applies to all data provided by Jurisdiction’s IIS to CDC under this Agreement.
5. ***Disposition of Records.*** ISD will dispose of data files received from Jurisdiction under this Agreement in accordance with the terms of the applicable Federal Records Act record control schedules (e.g., CDC Scientific and Research Project Records Control Schedule (N1-442-2009-1)).***Liability.*** Each party will be responsible for its own acts and behaviors and the results thereof. If any claim or cause of action is asserted against a party in connection with the performance of this Agreement, that party shall, consistent with applicable law, promptly notify the other party of the claim or cause of action. As may

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be permitted by applicable law, the parties shall cooperate with each other in the defense of claims and causes of action arising out of the performance of this Agreement.

- 6. Authorized Representatives.** CDC's Authorized Representative for purposes of this Agreement is Nicole Dowling, Associate Director for Science, 1600 Clifton Road, Atlanta, GA 30333, ncd5@cdc.gov.
- 7. Agreement.** This Agreement includes the following Appendices: Appendix A – Data Access, Analysis, and Publication; Appendix B – Monthly Influenza Reporting Template; Appendix C & D – Routine Data Submission Vaccine Administration and Demographic Data Dictionaries; Appendix E – Description of Privacy-Preserving Record Linkage (PPRL); Appendix F – Generic PPRL Specification; Appendix G – Jurisdiction Submission Scenarios.
- 8. Effective Period.** This Agreement shall become effective on the date all required signatures are obtained. This Agreement is intended to remain in place throughout the project period of NOFO CDC-RFA-IP19-1901 or until one or both Parties decide to terminate. The Parties acknowledge that termination of this Agreement may have an impact on the terms of the above-cited assistance mechanism.

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CDC Signatures

Nicole Dowling -S

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Date: 2023.02.15 11:13:36 -05'00'

Nicole Dowling, Associate Director for Science, ISD/CDC

Date

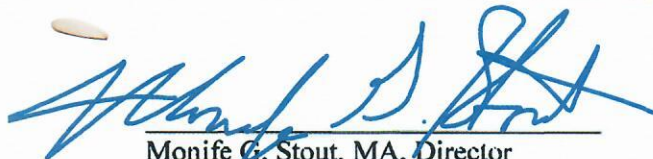
Georgina Peacock Goebel -S

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Date: 2023.02.15 11:04:36 -05'00'

Georgina Peacock, Division Director, ISD/CDC


Date

GOVERNMENT OF THE VIRGIN ISLANDS


Monife G. Stout, MA, Director
USVI Immunization Program

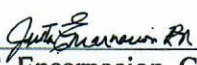
02/23/2023

Date


Annette Hobson, MBA
Immunization Registry Manager

2/23/2023

Date


Justa E. Encarnacion, Commissioner
Department of Health

3/28/2023

Date


Lisa M. Alejandro, Commissioner Nominee
Department of Property and Procurement

5/31/2023

Date

APPROVED AS TO LEGAL SUFFICIENCY
DEPARTMENT OF JUSTICE BY:


Assistant Attorney General

Date 5/30/2023

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