National HIV Surveillance System (NHSS)

Attachment 7 (b)

HIV Surveillance Confidentiality Security Statement and Data Access Packet

CONFIDENTIALITY SECURITY STATEMENT

FOR THE NATIONAL HUMAN IMMUNODEFICIENCY VIRUS (HIV) SURVEILLANCE SYSTEM (NHSS) AND SURVEILLANCE-RELATED DATA (INCLUDING SURVEILLANCE INFORMATION, CASE INVESTIGATIONS, CLUSTER INVESTIGATIONS, SUPPLEMENTAL SURVEILLANCE PROJECTS, RESEARCH ACTIVITIES, AND EVALUATIONS)

July 2025

The HIV Surveillance Branch (HSB), the Behavioral and Clinical Surveillance Branch (BCSB), and the Detection and Response Branch (DRB), Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), have received approval for another extension of a 308(d) Assurance of Confidentiality protection for data collected through the National HIV Surveillance System (NHSS) and Surveillance-Related Data (including surveillance information, case investigations, cluster investigations, supplemental surveillance projects, research activities, and evaluations) conducted under cooperative agreements with state, city and territorial health departments. This extension is due to expire June 2028.

Because of this Assurance of Confidentiality, documents and files which contain patient-level information on persons with HIV or having been exposed to HIV, for example in the case of infants born to mothers with HIV, or individual-level data from surveillance surveys, case investigations, cluster investigations and evaluation studies, are considered confidential materials and must be safeguarded to the greatest extent possible. The confidentiality of HIV surveillance program data collected at the local and state levels is protected under state/territorial law, rule, or regulation. Although patient and physician names, street addresses, phone numbers, or other directly identifying information, are not routinely reported to CDC by health departments, HIV surveillance case reports and other surveillance-related data are highly sensitive and may have the potential to indirectly identify infected individuals. Therefore, these HIV surveillance and surveillance-related data have a need for 308(d) protection and require a high level of safeguards.

Protected Information

It is the professional, ethical and legal responsibility of all CDC authorized users of protected HIV surveillance and surveillance-related data, who participate in activities jointly approved by CDC and the sponsoring public health or academic institution, and the like, who are granted access to data from HIV surveillance program activities, to protect the confidentiality of data on all persons reported as having HIV or participating in CDC-sponsored surveys, investigations, or studies related to HIV surveillance. This document describes the procedures and practices that DHP intends to use to protect the confidentiality of the data collected as part of HIV surveillance program activities, including related laboratory and epidemiologic data collected for investigations, whether they are sponsored by HSB, BCSB, or DRB, or at the request of or in collaboration with health departments.

Portions of the data analysis and programming work supporting this project are performed under contract. Therefore, we have included reference to contractors in the Assurance of Confidentiality Statement and this Confidentiality Security Statement. The Office of Grants Services and Office of Acquisition Services should include appropriate reference to 308(d) Assurance of Confidentiality protection requirements in applicable cooperative agreements, grants and contracts that support this work. All contractor staff undergo limited background investigations prior to performing any work at CDC.

Authorized Users of Protected Information

The applicable HSB, BCSB, or DRB Branch Chief or their designee authorizes access and use of protected HIV surveillance and surveillance-related data. Authorized users of HIV surveillance and surveillance-related data include permanent employees of HSB, BCSB, DRB, LB, QSB, their contractors, other authorized staff (e.g., NCHHSTP staff involved in cluster investigations, staff who access or support servers with protected data, data management personnel) and other authorized agents. Other authorized agents include guest researchers, fellows, visiting scientists, authorized external collaborating researchers, interns and graduate students. Authorized users are required to maintain and protect at all times the confidentiality of records that may come into their presence or under their control. In particular, authorized users of protected information may not discuss, reveal, present, or confirm to external parties' information on, or characteristics of, individual cases, or small numbers of cases or clusters, in any manner that could directly or indirectly identify any individual on whom a record is maintained by an HIV surveillance program. In addition, authorized users of protected information must abide by the data re-release agreements between CDC, the Council of State and Territorial Epidemiologists (CSTE), and individual state/territorial health departments. To assure that authorized users of protected information are aware of this responsibility and the penalties for failing to comply, each person will be required to read and sign a Nondisclosure Agreement applicable to full-time equivalent staff members (FTEs), contractors, or guest researchers (See Attachments 2, 3, 4) assuring that all information in HIV surveillance program records and related files will be kept confidential and used only for public health purposes. Systems administrators for CDC IT infrastructure will complete Assurance of Confidentiality training and sign non-disclosure agreements at the agency level (which are not HIV specific).

Training and Oversight

Annual confidentiality training is mandatory for all authorized users of protected information. All staff working on surveillance program activities are required to take annual security and confidentiality training that includes review of the assurance of confidentiality, and security and confidentiality procedures. Authorized users of protected information shall be required to sign confidentiality agreements on an annual basis. It shall be the responsibility of the Technical and Business Stewards to provide for in-person and/or on-line training as needed and to obtain signed agreements from employees, contractors, and other authorized individuals who are granted access to HIV surveillance information.

The Business Steward has general responsibility for the operation and integrity of the system(s) and activities covered by this Assurance. The Business Steward for HIV surveillance program activities is the Chief, HSB, DHP (Dr. Angela L. Hernandez); alternate is the Deputy Chief, HSB, DHP (Nikiya Woodard). The Business Steward for Behavioral and Clinical Surveillance program activities is the Branch Chief, BCSB, DHP (Dr. Joseph Prejean); alternate is Deputy Branch Chief, BCSB, DHP (Melissa Cribbin). The Business Steward for Detection and Response program activities is the Branch Chief, Detection and Response Branch, DHP (Dr. Alexa Oster); alternate is the Deputy Branch Chief, DRB, DHP (Allison Mneimneh). The Technical Stewards are Patricia Sweeney, Senior Epidemiologist, HSB; Melissa Cribbin, Deputy Branch Chief, BCSB; Richard Terán, Senior Epidemiologist DRB; Dr. Cynthia Lyles, Branch Chief, QSB; and William M. Switzer, Lead, Molecular Epidemiology and Bioinformatics Team, LB. Technical stewards serve as points of contact for the Assurance and breach reporting, conduct training and track compliance and ensure implementation of standard operating procedures within each branch.

Nondisclosure and Data Release Restriction Agreements

Attachment 2 is the FTE Nondisclosure Agreement that all CDC employees participating in HIV surveillance program activities will sign. Attachment 3 is the Contractor Nondisclosure Agreement—Safeguards for Individuals and Establishments Against Invasions of Privacy. Contracts needed to support HIV surveillance program activities contain 308(d) clauses, and all contractor employees with access to the data are required to sign this agreement. Attachment 4 is the Non-CDC Employee 308(d) Pledge of Confidentiality for students, guest researchers and other non-FTEs. Attachment 5 is the HIV Surveillance and Surveillance-Related Data Release Policy. Attachment 6 is the Agreement to Abide by Restrictions on Release of HIV Surveillance and Surveillance–Related Data Collected and Maintained by DHP which must be signed by authorized staff granted access to records, files and databases containing HIV surveillance and surveillance-related information. The provisions of Attachment 5 and 6 have been negotiated between CDC, CSTE, and individual state/territorial health departments. Attachment 7 is the Request for Access to HIV Surveillance and Surveillance-Related Databases form. Originals of these documents will be retained by HSB, BCSB, DRB, QSB and LB who will be responsible for tracking completion of training and forms. Documentation of forms and training completion for other authorized staff (outside of those branches) will be maintained by HSB. Documentation of training and tracking of completion for CDC IT infrastructure System Administrators completing agency level Assurance of Confidentiality training will be maintained by the Office of Science, Office of Public Health Ethics and Regulations, Privacy and Confidentiality Unit staff. Compiled information on training compliance will be made available for review upon request by the Privacy and Confidentiality Unit. Documentation listing contractors will be maintained and should be made available to the DHP contract technical monitors by the Technical Stewards.

Restrictions on Use of Information and Safeguarding Measures

Information collected in the course of conducting HIV surveillance and surveillance-related program activities, including case investigations, cluster investigations, supplemental surveillance projects, research activities, evaluations and other activities as specified in the Description of Covered Activities (Attachment 1) will be used only for public health purposes. Surveillance information reported to CDC will be used primarily for public health statistical, epidemiologic, and analytic summaries and for public health evaluations in which no individual or institution on whom a record is maintained can be identified, and secondarily, for special public health research or investigations of the characteristics of populations suspected or confirmed to be at increased risk for HIV and of the natural history and epidemiology of HIV to inform public health activities and shall not otherwise be divulged or made known in any manner that could result in the direct or indirect identification of any individual on whom a record is maintained.

Except in rare and unusual circumstances, records or data containing names or other personally identifying information for individual patients will not be received by CDC on any records from HIV surveillance program activities. Although data collection forms that CDC provides to HIV surveillance cooperative agreement recipients to use in HIV case reporting or CDC-sponsored surveillance projects or activities may enable the collection of personal identifiers at the local, state, or territorial level, these identifiers will be removed before data are transmitted to CDC.

In unusual circumstances, such as investigations of cases involving rare or unusual modes of HIV transmission or potential threats to public health (e.g. unusual strains of HIV that may be undetected through routine screening of the blood supply, breakthrough infections in persons on HIV pre-exposure prophylaxis) in which expert CDC staff participate with local/state/territorial health department staff at their invitation, CDC staff may, with appropriate prior supervisory approval, retain records with information that identifies patients, physicians or other health care providers, laboratory personnel and other records necessary to the conduct of the epidemiologic investigation. Such records require additional physical and electronic protections; must be maintained in a locked file cabinet in a locked room which is secured by restricted access and if in electronic form, must be encrypted, retained in a secure environment, and stored using secure, CDC approved methods. Prior to downloading data from any other web accessed location, the user should verify where the data will be saved and ensure that it is a secure, approved location. Electronic data are transmitted via the Secure Access Management Services (SAMS) or other secure file transport mechanism implemented or approved by CDC. All data transmissions must be encrypted after deleting patient and physician identifiers. In all circumstances, only the minimum identifying information necessary to the conduct of the investigation shall be maintained. Disclosure of identifying information from such investigations is prohibited, except as provided in the Assurance of Confidentiality. In addition, confidential information related to investigations including laboratory test results and epidemiologic data may not be released without the authorization of the jurisdiction(s) involved in the investigation in accordance with data release policies.

Data collection forms will contain only assigned patient identification numbers and may contain computer-generated soundex codes from patient surnames, or other state-assigned codes. However, because these are 308(d) protected data, they will be transmitted to CDC in a secure and confidential manner. Hard copies of data collection forms may only be transmitted to CDC DHP staff if identifying information has been removed and records placed in sealed envelopes marked "confidential." Following data entry and verification, as soon as feasible, such hard copies should be shredded or destroyed.

Authorized users of protected information are responsible for protecting all confidential records containing information that could potentially identify, directly or indirectly, any person on whom a record is maintained from visual observation, from theft, or from accidental loss or misplacement due to carelessness. All reasonable precautions will be taken to protect confidential surveillance data.

All contractor personnel will receive project-specific training in confidentiality procedures, in addition to the training and background investigations they must receive/undergo prior to being hired by the contractor. All contractors must be located and their records maintained in a physically secure environment with appropriate oversight by the technical monitor. Contract personnel will access information on the CDC network through approved tools, may be limited in their ability to upload or download data from the network based on the tools used, and at a minimum will abide by the same rules for accessing the records as CDC employees.

If a local/state/territorial health department inadvertently fails to remove personal identifiers of individual patients, their family members or sexual or drug-using partners, or health care providers before forwarding hard copies or electronic files to CDC, or incorrectly enters such identifying data into comments fields, CDC staff will immediately delete the identifiers or delete the electronic file and all copies, remind health department personnel of the appropriate procedures to follow to delete such identifiers prior to transmitting records, forms, or electronic files to CDC, and report the incident to the technical steward, branch management, and the NCHHSTP Information Systems Security Officer (ISSO) as needed.

Except as needed for operational purposes, photocopies of confidential records are not to be made. If photocopies are necessary, care should be taken that all copies and originals are recovered from the copy machines and work areas. Correspondence or hard-copy files containing sensitive information, e.g., regarding an epidemiologic case investigation, shall be maintained in a locked file cabinet. All confidential paper records will be destroyed as soon as operational requirements and records retention schedule permits by shredding the documents using a cross-cutting shredder or secured shredding container service provided by CDC.

E-mail, electronic messages in collaboration platforms (such as, but not limited to, Microsoft Teams and SharePoint), memoranda, reports, publications, and presentations that contain data collected through HIV surveillance program activities shall not contain data or information that could directly or indirectly identify any person on whom a record is maintained by CDC. In particular, specific details of case investigations, including specific geographic identifying information are highly sensitive material, as are specific details of cluster investigations. It shall

be the responsibility of each authorized user of protected information who is granted access to sensitive surveillance information to safeguard such data. Only the minimum information necessary to conduct their duties will be made available to authorized users of protected information. Conversations via telephone or telecommunications application software with local/state/territorial health department personnel that include discussions of sensitive information shall be conducted discreetly, preferably in private, walled offices.

CDC is in compliance with applicable federal law requiring the protection of federal computer networks from cybersecurity risks like hacking, internet attacks, and other security weaknesses. Computer network experts working for, or on behalf, of the government, may intercept and review information sent through government networks for cyber threats if the information sent through the government network triggers a cyber threat indicator.

Enhanced Protection of Electronic Files

All data will be protected in confidential computer files. The following safeguards are implemented to protect HIV surveillance files so that the accuracy and the confidentiality of the data can be maintained:

Computer files containing programs, documents, or confidential data will be stored in computer systems that are protected from accidental alteration and unauthorized access. Computer files will be protected by password systems, access controls which can be audited, virus detection procedures, and routine backup procedures. Data stored at state and local health departments using CDC-supplied software designed to manage and analyze data for surveillance program activities are protected by security requirements that each recipient must certify it complies with before any cooperative agreements can be awarded; the software ensures that the data transmitted to CDC will be in a format that is compatible with the security and confidentiality requirements of the HIV surveillance databases maintained by CDC.

The data centers and cloud platforms maintained by OCIO and CDC contractors comply with federal policies, statutes, regulations, and other directives for the collection, maintenance, use, and dissemination of data, including the Department of Health and Human Services Automated Information Systems Security Program, the Computer Security Act of 1987 (Public Law 100-235), the E-Government Act of 2002 (Public Law 107-347), and the Federal Information Security Modernization Act of 2014 (FISMA 2014) (Public Law 113-283). Additionally, the data centers and cloud platforms also are in compliance with CDC's OCIO Security Architecture Design and Principles policy. The data centers and cloud platforms currently operate under Windows 2019 (or later) with Active Directory or Entra ID. Security features implemented include physical controls, user ID and password protection, multi-factor authentication, mandatory password changes, limited logins, user rights/file attribute restrictions and virus protection.

Use of encrypted CDC computers to support state and local cluster investigations must be implemented in accordance with standard operating procedures. Upon completion of the investigation, transfer of the data to state and local jurisdictions and deletion of all related data from CDC computers and sanitation are to be ensured.

HIV surveillance data will be entered into computer files by staff at state and local health departments and encrypted files will be transmitted electronically via SAMS or other agency approved secure file transport mechanism to DHP staff for uploading into the CDC in-network storage platforms, such as Multi-User Share Tool (MUST) drives. Data that fall within the scope of the Medical Monitoring Project (MMP) or National HIV Behavioral Surveillance (NHBS), and other behavioral surveillance related projects will be encrypted and transmitted electronically to CDC via secure transfer mechanisms operated by CDC or its contractor. Data submitted to CDC through CDC submittal mechanisms are protected by this Assurance from the time submitted, regardless of the CDC system or platform. DHP employees or contractors, and any OCIO or other CDC employees or contractors who service or maintain the systems or components necessary to support data management of HIV surveillance program files, will be granted access to the files only upon express written approval by a Business Steward (Chief, HSB, BCSB, or DRB) or their designee. Designated data stewards in HSB, BCSB, and DRB are authorized by the Business Stewards to provide access to data via MUST, or if CDC cloud platforms are being used, through the access control tools available in each cloud platform environment. Technical and Business Stewards will review the list of authorized users with data stewards on at least an annual basis to delete persons no longer needing access. The data steward(s) for HSB are John Gerstle, Baskaran Govindarajan, Anna Satcher Johnson and Patricia Sweeney; for BCSB, Pollyanna Chavez, Teresa Finlayson, and Ruth Gierke; for DRB, Anne Marie France, Nivedha Panneer, and Richard Terán.

Encrypted backup copies of data will be made by the data center's and cloud provider's backup procedures. Backup storage services are provided under separate CDC-wide contracts. Contractor facilities and staff are subject to the same federal policies, statutes, regulations, and other directives, as well as to departmental and CDC security policies, which apply to CDC data center servers and staff. Access to backups is restricted to OCIO and contract staff responsible for maintaining the backup procedures.

Dissemination of Data from HIV Surveillance Program Activities

State and local health departments receive confirmation of their transmittals of data to CDC. DHP HSB, BCSB, DRB, in collaboration with LB and QSB staff are responsible for timely dissemination of aggregate data at the national level, consistent with the data release policies described in Attachment 4. Data will generally be reported only in aggregate or summary form including restrictions on small cell sizes and geographic identifiers; such that data could not be used to indirectly identify an individual. Modes of disseminating data include reports, articles in the *MMWR*, peer-reviewed publications, public-use slide sets, and public use data sets. DHP HSB, BCSB, and DRB staff may provide aggregate HIV surveillance or surveillance-related data for public health purposes only, in response to special requests from Congress, the Department of HHS, other government agencies, and other programs within CDC on a priority basis with the approval of the Director, DHP or the Business Steward.

For public health purposes, data may also be analyzed and disseminated by external collaborators and their contracted agents with appropriate authorization and in collaboration with CDC DHP branches. External collaborators are those with whom DHP has existing cooperative agreements

or contracts involving the collection or analysis of the surveillance data. Requests for such access to the data and subsequent analysis and dissemination for public health purposes must be made according to the procedures outlined in Attachments 5 and 6 of the Confidentiality Security Statement.

In limited circumstances, restricted data sets could be made available to external researchers for public health related research with approval of the appropriate branch chief, and each relevant project area contributing data to the project. These requests would also be subject to the procedures outlined in Attachments 5 and 6 of the Confidentiality Security Statement.

Records Disposition for the National Archives and Records Administration

Records will be kept according to applicable CDC Records Retention Schedules. All CDC Records Control Schedules are media neutral and therefore are applicable to all records regardless of format. Records having met their records retention schedule should be disposed of appropriately. For example, paper records containing personal identifiable information (PII) should be shredded prior to recycling. Records may be kept longer for programmatic purposes. If 308(d) records for this project are sent to the Federal Records Center for temporary storage (in which CDC maintains control of the data), the SF 135 form will state: “This accession contains records protected by a confidentiality assurance under Section 308(d) of the PHS Act.” The SF 135 form will indicate that the records can be released only to authorized staff and indicate who is authorized to access the records (e.g., Branch Chief, Project Lead, staff from a specific office).

No records will be sent to the National Archives and Records Administration (NARA) for permanent storage unless a public use data set can be created. Otherwise, in accordance with the Assurance of Confidentiality (Public Health Service Act (PHSA) Section 308(d)) the data will be kept by CDC with applicable restrictions enforced.

Confidentiality Security Statement Attachment 1

DESCRIPTION OF COVERED ACTIVITIES

ASSURANCE OF CONFIDENTIALITY

FOR THE NATIONAL HUMAN IMMUNODEFICIENCY SYNDROME (HIV) SURVEILLANCE SYSTEM (NHSS) AND SURVEILLANCE-RELATED DATA (INCLUDING SURVEILLANCE INFORMATION, CASE INVESTIGATIONS, CLUSTER INVESTIGATIONS, SUPPLEMENTAL SURVEILLANCE PROJECTS, RESEARCH ACTIVITIES, AND EVALUATIONS)

July 2025

The National HIV Surveillance System (NHSS) provides important information about the epidemiology of HIV infection and is the scientific basis for prevention and control recommendations. Through the HIV Surveillance Branch (HSB) the Behavioral and Clinical Surveillance Branch (BCSB), and the Detection and Response Branch (DRB) of the Division of HIV Prevention (DHP), CDC provides financial support, technical consultation and analytic tools to state and local health departments for HIV surveillance and surveillance-related activities. These activities include designing, implementing, maintaining, and evaluating HIV surveillance programs at the state and local levels and investigating unusual reports and clusters of HIV transmission, surveillance-related activities that characterize behaviors and clinical outcomes among persons with HIV and behaviors among persons at risk for HIV in accordance with CDC guidelines and recommendations.

Data collected as part of the National HIV Surveillance System and surveillance-related data projects are used widely to monitor patterns of HIV infection and infection with other infectious disease pathogens (e.g., sexually transmitted infections, hepatitis viruses), and detect and respond to HIV clusters, identify individuals in need of engagement of or re-engagement to care, describe behaviors and clinical outcomes of persons with HIV or at risk for HIV, and target HIV prevention and care efforts. HIV surveillance, including adult/adolescent (persons aged ≥13 years) and pediatric case reports of persons diagnosed with HIV infection, together with clinical and laboratory data, provides information on the spectrum of HIV disease. HIV surveillance data including laboratory data on drug resistance and HIV-1 subtypes provide population-based data used to determine trends in transmission of drug resistance and the geographic distribution of subtypes in the United States. HIV nucleotide sequence and other data are used for identifying recent and ongoing HIV clusters to better focus prevention efforts. Surveillance data are also used to identify unusual or special cases requiring additional follow-up and to assess attributes of the performance of the surveillance system such as reporting completeness, timeliness, accuracy and validity. Supplemental data are also collected through related projects that extend and enhance the HIV case report data. Projects include follow-up investigations of persons with no identified risk (NIR), cases of public health importance (COPHI) such as cases with possible unusual transmission circumstances, and unusual clinical or laboratory test results. In addition, projects such as mortality studies, projects involving HIV-related opportunistic infections, HIV

bio-behavioral surveillance, surveillance evaluation studies, perinatal exposure surveillance, and other supplemental HIV surveillance including HIV clinical outcomes surveillance, evaluation of HIV testing, counseling and referral practices, and related research projects are also conducted. Research projects have IRB-approved protocols as required, and health departments are required to use uniform data collection methods, instruments and software to permit CDC to aggregate the data nationally.

A brief description of current surveillance program activities and research projects follows. In the future, other related data collection activities and projects may be added, and some activities may be discontinued, because all activities respond to the increasing knowledge base of HIV and the evolving need for data to plan for specific prevention and control interventions. Addition or deletion of activities will be done only with the express approval of the Chief, HIV Surveillance Branch (HSB), DHP, NCHHSTP, the Chief, Behavioral and Clinical Surveillance Branch (BCSB), or the Chief, Detection and Response Branch (DRB), DHP, NCHHSTP. Once data collection is completed, the protection for participants lasts in perpetuity and therefore remains throughout any ongoing or future data analyses.

Surveillance-related Activities: In addition to routine information provided by adult/adolescent (persons aged ≥13 years) and pediatric case reports, including molecular HIV data, these activities are done as part of follow-up of cases reported through NHSS including special investigations and evaluations.

Follow-up investigations of persons with no identified risk, unusual transmission, clinical or laboratory findings, and HIV clusters**.** CDC-developed protocols and criteria are used to conduct epidemiologic and laboratory investigations of cases that may have rare or previously unidentified modes of HIV transmission, unusual clinical manifestations, unusual laboratory test results, or that are involved in HIV clusters. These include, but are not limited to, transfusion and transplant-related cases, cases of HIV transmitted in occupational settings, cases of HIV-2 infection, cases transmitted through female-to-female sexual contact, cases with potentially unusual HIV strain variants, cases with clinical evidence of HIV infection but negative HIV test results, investigation of false positive clusters and discordant results, and breakthrough infections in the presence of pre-exposure prophylaxis. Investigations of HIV clusters identified using molecular HIV sequence or other data reported as part of HIV surveillance activities are also conducted to focus and assess HIV prevention efforts of state and local health departments.

Evaluation of the performance of the surveillance system. Evaluations include critical review of surveillance methodologies and redirection of resources to those case-finding methods that are the most productive. CDC assists states by providing matching and analysis tools necessary for state health departments in the conduct of routine intrastate and interstate de-duplication activities to improve accuracy of surveillance data. In addition, surveillance data are analyzed to discover possible under reporting and delays in reporting, monitor data quality, and assess completeness of reporting by comparing surveillance registries with alternate databases that are not routinely used for case finding (e.g., Medicaid databases). Surveillance programs routinely re-abstract demographic,

risk, laboratory, and clinical data from a representative sample of records to assess the quality and validity of information collected.

Perinatal HIV Exposure Reporting and Follow-up. HIV surveillance programs collect data on infants born to mothers with HIV because these infants are at risk for HIV and require early interventions to prevent HIV-related opportunistic infections. Data include maternal HIV test history, prenatal, intrapartum and neonatal antiretroviral therapy, and other variables relevant to the evaluation of recommended actions to prevent perinatal HIV transmission and to facilitate follow-up to identify perinatally acquired cases of HIV. Perinatal HIV Exposure Reporting (PHER) includes data collected on exposed infants as well as infants with HIV, and their mothers with HIV. In PHER, infants known to be HIV-exposed will be monitored after birth up to 18 months of age to determine the HIV infection status of the child and progression to HIV, stage 3 (AIDS). PHER, along with pediatric case surveillance will allow CDC and local health departments to better characterize perinatal HIV infections in the United States.

Supplemental Surveillance Projects: Using population-based methods of collecting data, these projects characterize persons at increased risk for HIV and persons with HIV to assess the impact of HIV within individual health jurisdictions and nationally. Supplemental Surveillance Projects include:

HIV-related Mortality Studies. Supplemental reviews of medical records of deaths among persons reported with HIV, routine reviews of death certificates to enhance case ascertainment and update vital status, and periodic matching of HIV surveillance databases to death registries are conducted to ensure that the HIV surveillance system provides data relevant to efforts to prevent premature death from HIV. As highly effective treatments for HIV become increasingly more available, efforts to prevent severe morbidity leading to death from HIV require additional efforts to understand factors associated with HIV-related deaths (e.g., late testing, lack of access to care, failing therapies, lack of adherence to treatment regimens).

Surveillance of HIV-Related Service Barriers Among Individuals with Early or Late HIV Diagnoses (SHIELD). Project SHIELD conducts enhanced surveillance among persons with early (at stage 0) and late (at stage 3 – AIDS) HIV diagnosis to understand systems- and individual-level factors associated with new infection and delayed testing. Using NHSS surveillance data, health departments will identify persons with a recent HIV diagnosis at stage 0 or at stage 3 in the United States to characterize barriers, gaps, and failures in existing HIV prevention and testing services and systems that contribute to people becoming infected or receiving a late diagnosis. Health departments will anonymously transfer identified persons to a CDC contractor who will conduct qualitative in-depth interviews and a standardized behavioral survey among eligible participants (no PII will be collected). CDC will conduct analysis of the collected data to identify actionable missed opportunities for early HIV diagnosis and prevention.

Project(s) for which data collection has ended and analysis is ongoing:

Monitoring of Perinatal HIV Prevention. Supplemental reviews of medical records of mother/infant pairs to assess counseling and testing, prenatal care, and treatment, longitudinal follow-up of infants with HIV to assess infection status, initiation of HIV-related care, and long-term outcomes. This includes but is not limited to enhanced perinatal surveillance (EPS) activities for which data collection ended in 2011 and analysis is ongoing. Similar data collection will continue with a reduced number of data elements collected on the Perinatal HIV Exposure Report form as part of PHER. We anticipate that over the next several years, data collection for PHER will become more integrated with routine HIV case surveillance. Therefore, we have combined description of these activities under Perinatal HIV Exposure Reporting under Surveillance-related activities.

HIV Clinical Outcomes Surveillance: Using population-based methods of collecting data, these projects characterize behaviors and clinical outcomes among persons with HIV within individual health jurisdictions and nationally. Clinical outcomes surveillance projects include:

Medical Monitoring Project (MMP). MMP is a population-based interview and medical record abstraction project designed to produce nationally representative data on people with diagnosed HIV in the United States. Project areas collect behavioral and clinical outcomes data through interviews and medical record abstraction to assess the met and unmet needs for treatment and other services. MMP data are electronically collected via portable computers and are submitted to and managed by CDC staff or a CDC-funded Data Coordinating Center (DCC). Data are weighted to represent the population of persons with diagnosed HIV and are both nationally and locally representative. MMP data on a national level are reported in annual surveillance summaries and other reports and national and local data are used to inform prevention and care planning groups, providers of HIV care, people with HIV and others to advocate for reducing the gaps in existing resources.

Project(s) for which data collection has ended and analysis is ongoing:

Case-Surveillance-Based Sampling (CSBS) Project. CSBS was a pilot of a nationally representative surveillance system for all HIV-diagnosed persons in the United States both in and out of HIV care conducted in 5 project jurisdictions. Data collection included linkage to case surveillance data and patient interview, and medical record abstraction regarding sensitive topics such as sexual behaviors, drug and alcohol use, and clinical outcomes. The CSBS Project was intended to evaluate a method of sampling participants for MMP to help guide the future direction of MMP and efforts to monitor progress toward the National HIV/AIDS Strategy objectives related to linkage to and retention in care. Data collection for this project ended in May 2015 and data analysis is ongoing.

Adult/Adolescent Spectrum of Disease (ASD) Project. The ASD project was conducted from 1990 until 2004 to describe the spectrum of HIV disease and subsequent mortality

among persons with different levels of immunosuppression and to monitor the use and effectiveness of recommended prophylactic interventions and antiretroviral and antimicrobial therapies. Results from the study have been useful in determining how best to expand the AIDS surveillance case definition, describing the rate of development of various opportunistic illnesses in persons with HIV, evaluating the effectiveness of prophylaxis for *Pneumocystis carinii* pneumonia and other interventions to delay or prevent the onset of HIV-related opportunistic illnesses, and guiding Public Health Service recommendations for the treatment of patients with HIV. Data collection for this project ended in June 2004 and data analysis is ongoing.

Survey of HIV Disease and Care. Changes in prophylactic and therapeutic interventions made it essential for CDC to provide representative supplemental clinical surveillance information so that health departments could use the information in concert with their core HIV/AIDS surveillance data to better describe changing trends in the epidemic and allocate resources accordingly. The project provided several states/territories with the ability to accurately estimate the met and unmet needs for treatment and other medical services in their communities. This project served as the pilot for the current Medical Monitoring Project. Data collection ended in January 2004 and data analysis is ongoing.

Supplement to HIV/AIDS Surveillance (SHAS) Project. SHAS was a facility-based (and in some cases a population-based) interview project conducted beginning in 1990 in 12 locations to collect additional data on persons reported through HIV/AIDS surveillance. During 2000, 3 additional areas were added to the project. Data from this project have been important for planning and evaluating prevention and care programs and in collecting behavioral surveillance data. Participating surveillance programs use a standardized questionnaire designed in collaboration with CDC to interview persons reported with HIV and AIDS through routine case surveillance. Data collection for this project ended in June 2004 and data analysis is ongoing.

Never in Care (NIC) Project. NIC identified, located and interviewed persons with diagnosed HIV who did not receive care within 3 months of their diagnosis. The interviews collected information on HIV testing history, health seeking behaviors, and access and barriers to health care. Blood samples were obtained and tested for CD4, HIV viral load and antiretroviral resistance to determine participants' care needs. Information collected has been used to understand reasons persons with HIV delay initiation of care and to assist in the development of appropriate interventions to get persons into care in a timely manner. Data collection ended in August 2010 and data analysis is ongoing.

HIV Behavioral Surveillance: HIV behavioral surveillance data may be collected from the general population, persons at high risk for HIV, and those with HIV. Examples of groups at high risk for infection include but are not limited to men who have sex with men, persons who inject drugs or use injectable drugs through alternate routes, and sexually active heterosexuals of low income living in jurisdictions with high prevalence of HIV. Behavioral surveillance data are used to monitor prevalence and trends in sexual behaviors, drug use, HIV testing, and use of HIV

prevention and care services. The types of data collected through behavioral surveillance include sensitive information about behaviors that are often highly stigmatized and, in some instances, criminal activities. Protecting the confidentiality and identity of participants is critical to the integrity of behavioral surveillance projects. These behavioral surveillance projects include:

National HIV Behavioral Surveillance System (NHBS). NHBS is CDC's comprehensive system for conducting behavioral surveillance among persons at highest risk for HIV in the United States. Interviews or brief quantitative or qualitative assessments, and biological testing including HIV testing, with, or without other testing (e.g., hepatitis or STD testing) are conducted among populations at high risk for HIV. These populations include but are not limited to: men who have sex with men, persons who inject drugs, and heterosexuals at increased risk for HIV living in Metropolitan Statistical Areas (MSAs) with the highest HIV prevalence, or in geographic areas identified as priorities for surveillance by funded states through a formal process based on needs assessment data and community partner input. Data on additional populations (e.g., young men who have sex with men, women who exchange sex) are collected in participating behavioral surveillance areas as funding permits. NHBS focuses on monitoring prevalence and trends in HIV risk behaviors, HIV testing, exposure to and use of prevention services, and other HIV-associated outcomes. NHBS data are electronically collected via portable computers and are submitted to and managed by CDC staff or a CDC-funded Data Coordinating Center (DCC). NHBS data on a national level are reported in annual surveillance summaries and other reports and are used to monitor national HIV prevention strategies. On a local level, NHBS data are used to prioritize and evaluate HIV-related prevention activities.

Needle Exchange Utilization Survey (NEXUS), formerly known as the Injection Drug Use Surveillance Project (IDU-SP). IDU-SP was a demonstration project that was completed in November 2023. NEXUS is a bio-behavioral activity conducted in collaboration with syringe services programs (SSPs) among people who inject drugs (PWID) and their peers who use drugs, and its purpose is to monitor risk practices, access and use of prevention services, prevalence of HIV and HCV, and prevalence of other health outcomes related to injection drug use. NEXUS will begin data collection in 2025 pending OMB approval.

Directly identifying information will not be shared with CDC. Data collected, both locally and at CDC, are stored and accessed by a survey identification number.

The data will be entered locally and transmitted without direct identifiers to CDC using the secure file transfer program (SFTP). Databases submitted through the SFTP will be encrypted before being sent to CDC and password protected with limited number of staff within CDC and at the collaborating site having access. Weekly meetings between the Contractor and CDC staff will maintain strict data protection for the data collected, transmitted, and stored with restricted access in accordance with procedures outlined in the Assurance of Confidentiality Security Statement. NEXUS data on a national level are

reported in annual surveillance summaries and other reports and are used to monitor national HIV prevention strategies related to PWID. On a local level, NEXUS data are used to prioritize and evaluate HIV-related prevention activities.

Project(s) for which data collection has ended and analysis is ongoing:

Web-based HIV Behavioral Surveillance (WHBS). WHBS involved internet-based interviews of men who have sex with men. WHBS data were collected electronically via a secure website managed by a CDC-funded contract. The goals for WHBS were to assess prevalence of and trends in risk behaviors for HIV, HIV testing behaviors, and exposure to, use of, and impact of HIV prevention services among internet using MSM in the 50 states and affiliated U.S. territories. Data from WHBS are used for tracking national trends in risk behaviors, HIV testing, and access to and utilization of HIV prevention services. Data collection for this project ended in August 2012 and data analysis is ongoing.

Behavioral Assessments and Rapid Testing (BART). The purpose of the Behavioral Assessment and Rapid Testing project was to implement event-based rapid testing and behavioral assessments as a strategy for reducing HIV transmission and increasing HIV prevention among 1) African Americans at large social events; 2) men who have sex with men (MSM) attending gay pride events in small- and medium-sized cities; 3) minority MSM attending gay pride events; and 4) young African Americans attending black spring break parties and festivals. Objectives included increasing awareness of HIV status among at-risk persons and characterizing the prevalence of unrecognized HIV. Behavioral and testing data have been used to inform HIV prevention services and policy at the local, state, and national levels. Data collection for this project ended in December 2010 and data analysis is ongoing.

HIV Testing Survey (HITS). HITS included interviews of persons at risk for HIV including STD clinic clients, out-of-treatment drug users, gay men in social venues, and other vulnerable at-risk populations. This study evaluated how well HIV case surveillance data represented the HIV-infected population and sought to identify the reasons that persons with HIV or at-risk for HIV may seek or defer HIV testing and HIV-related health care to improve the targeting of HIV prevention and testing messages, and the role HIV testing and reporting policies may play in those decisions. Data collection for this project ended in June 2003 and data analysis is ongoing.

Evaluation of HIV Testing, Counseling and Referral Practices: Evaluations of HIV testing, counseling, and referral practices are an integral part of HIV surveillance in the United States. These projects involve evaluating newly developed HIV testing methodologies and counseling practices. They also assist in providing data to help monitor the implementation of these new practices in different populations and settings. The evaluation projects take two main forms:

Evaluation of New HIV Testing Methods. These projects are used to evaluate the performance and application of diagnostic technologies to improve HIV testing practices

and incidence estimation in the United States and abroad. These projects include the evaluation of new HIV tests or combinations of tests, application of existing tests in different settings, methods to detect acute HIV infection, methods for confirmation of HIV infection, and the establishment of seroconversion panels for future HIV test evaluation.

Evaluation of the Implementation of New HIV Testing, Counseling and Referral Practices. These projects involve the demonstration and evaluation of new strategies for HIV testing, counseling, and referral practices. Data collected through these projects provide information on how new practices are implemented in different clinical and non-clinical settings. These evaluation projects will be used to develop effective models to extend new practices broadly throughout the United States.

Other HIV Surveillance-related Projects, Research Investigations, and Activities: Over time, our understanding of the natural history and epidemiology of HIV has increased. Effective prevention and treatment interventions have been demonstrated to reduce infection, disease and death from HIV. HIV surveillance data have guided the development of guidelines for disease control and prevention and are the basis for allocating resources for programs and services to prevent and treat HIV, and new testing, diagnostic and treatment methods continue to develop and change rapidly. The rapidly evolving nature of information about HIV requires the ability to add or delete variables from the case report forms and data collection instruments for supplemental surveillance projects, investigations, and research activities, and implement additional surveillance-related activities as new problems emerge, new epidemiologic questions arise, or new data are required to ensure that CDC and state and local health departments can mount an effective public health response. The addition or deletion of data collection activities is accomplished only under the express approval of the branch chief responsible for the activity, specifically either the Chief, HIV Surveillance Branch (HSB), the Chief, Behavioral and Clinical Surveillance Branch (BCSB), or the Chief, Detection and Response Branch (DRB), Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention.

Confidentiality Security Statement Attachment 2

FTE NONDISCLOSURE AGREEMENT

(*308(d) Assurance of Confidentiality for CDC Employees involved in HIV surveillance and surveillance-related activities*)

July 2025

The success of CDC's operations depends upon the voluntary cooperation of states and U.S. territories and freely associated states, of establishments, and of individuals who provide the information required by CDC programs under an assurance that such information will be kept confidential and be used only for epidemiological or statistical purposes.

When confidentiality is authorized, CDC operates under the restrictions of Section 308(d) of the Public Health Service Act which provides in summary that no information obtained in the course of its activities may be used for any purpose other than the purpose for which it was supplied, and that such information may not be published or released in a manner in which the establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented.

"I am aware that unauthorized disclosure of confidential information is punishable under Title 18, Section 1905 of the U.S. Code, which reads:

'Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment.'

"I understand that unauthorized disclosure of confidential information is also punishable under the Privacy Act of 1974, Subsection 552a (i) (1), which reads:

'Any officer or employee of any agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.'

“My signature below indicates that I have read, understood, and agreed to comply with the above statements.”

_____	_____	_____
Typed/Printed Name	Signature	Date

_____

National Center/Institute/Office/Branch

Rev. July 2025; based on CDC 0.979 (E) 10/2012

Confidentiality Security Statement Attachment 3

CONTRACTOR NONDISCLOSURE AGREEMENT

Safeguards for Individuals and Establishments Against Invasions of Privacy

July 2025

In accordance with Subsection (m) of the Privacy Act of 1974 (5 U.S.C. 552a) and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor is required to comply with the applicable provisions of the Privacy Act and to undertake other safeguards for individuals and establishments against invasions of privacy.

To provide these safeguards in performance of the contract, the contractor shall:

1. Be bound by the following assurance:

Assurance of Confidentiality

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor assures all respondents that the confidentiality of their responses to this information request will be maintained by the contractor and CDC and that no information obtained in the course of this activity will be disclosed in a manner in which the individual or establishment is identifiable, unless the individual or establishment has consented to such disclosure, to anyone other than authorized staff of CDC.

2. Maintain the following safeguards to assure that confidentiality is protected by contractor's employees and to provide for the physical security of the records:

    a. After having read the above assurance of confidentiality, each employee of the contractor participating in this project is to sign the following pledge of confidentiality:

        I have carefully read and understand the assurance which pertains to the confidential nature of all records to be handled in regard to this HIV surveillance or surveillance-related activity. As an employee of the contractor, I understand that I am prohibited by law from disclosing any such confidential information which has been obtained under the terms of this contract to anyone other than authorized staff of CDC. I understand that any willful and knowing disclosure in violation of the Privacy Act of 1974 is a misdemeanor and would subject the violator to a fine of up to $5,000.

    b. To preclude observation of confidential information by persons not employed on the project, the contractor shall maintain all confidential records that identify individuals or establishments or from which individuals or establishments could be identified under lock and key.

        Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals or establishments are to be kept in

locked containers when not in use by the contractor's employees. The keys or means of access to these containers are to be held by a limited number of the contractor's staff at each site. When confidential records are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and employed on this project. If at any time the contractor's employees are absent from the room, it is to be locked.

c. The contractor and his professional staff will take steps to ensure that the intent of the pledge of confidentiality is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic follow up procedures.

3. Print on the data collection form or questionnaire in a clearly visible location and in clearly visible letters the following notice of the confidential treatment to be accorded the information on the questionnaire by any individual who may see it:

Confidential Information

Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence by the contractor and CDC, will be used only for purposes stated in this project, and will not be disclosed or released to anyone other than authorized staff of CDC without the consent of the individual or the establishment in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

4. On a letter or other form that can be retained by the individual or the establishment, or on the questionnaire form itself if it is a self-administered questionnaire, inform in clear and simple terms each individual or establishment asked to supply information:

   a. That the collection of the information by CDC and its contractor is authorized by Sections 304 and 306 of the Public Health Service Act (42 U.S.C.242b and 242k);

   b. Of the purpose or purposes for which the information is intended to be used, clearly stating that the records will be used solely for epidemiological or statistical research and reporting purposes;

   c. Of the routine uses that may be made of the information, including all disclosures specified in the "Federal Register" for this system of records which may be applicable to this project;

   d. That participation is voluntary and there are no penalties for declining to participate in whole or in part; and

   e. That no information collected under the authority of Sections 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k) may be used for any purpose other than the purpose for which it was supplied, and such information may not be published or released in other form if the particular individual or establishment supplying the

information or described in it is identifiable to anyone other than authorized staff of CDC, unless the individual or establishment has consented to such release.

(The voluntary disclosure by the respondent of requested information after being informed of preceding paragraphs a through d is an acknowledgment of the uses and disclosures contained in paragraph c.)

5. Release no information from the data obtained or used under this contract to any person except authorized staff of CDC.

6. By a specified date, which may be no later than the date of completion of the contract, return all project data to CDC or destroy all such data, as specified by the contract.

_____

(Typed/printed Name)

_____

(Signature)

_____

(Date)

Confidentiality Security Statement Attachment 4

NON-EMPLOYEE 308(d) PLEDGE OF CONFIDENTIALITY

(308(d) Assurance of Confidentiality for Non-CDC employees)

July 2025

I, as a non-CDC Employee (e.g., Guest Researcher, Visiting Fellow, Student, Trainee, employee of a federal agency other than CDC, etc.) may be given access to personally identifiable data, preliminary data from other projects, proprietary data (for example, information from a manufacturer that is used to assess a cluster of adverse events), or pre-decisional information that is covered by Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). As a condition of this access, I am required to comply with the following safeguards for individuals and establishments against invasions of privacy.

1. I agree to be bound by the following assurance:

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), all respondents are assured that their responses will be kept confidential. No information obtained in the course of this activity will be disclosed in a manner in which the individual or establishment supplying the information or described in it is identifiable, unless the individual or establishment has consented to such disclosure, to anyone other than authorized staff of CDC or staff covered under this 308(d) Assurance. Additionally, data unrelated to specific patients that includes preliminary data from other projects, proprietary data, and pre-decisional data are to be kept confidential, unless CDC provides written authorization to release this information (i.e., CDC provides clearance to publish a scientific manuscript).

2. I agree to maintain the following safeguards to assure that confidentiality is protected and to provide for the physical security of the records:

To preclude observation of confidential information by persons not authorized to have access to the information on the project, I shall maintain all records that identify individuals or establishments or from which individuals or establishments could be identified in locked containers or protected computer files when not under immediate supervision by me or another authorized member of the project. The keys or means of access to these containers or files are not to be given to anyone other than CDC-authorized staff. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of individuals and establishments.

My signature below indicates that I have carefully read and understand this agreement and the assurance, which pertains to the confidential nature of the study records. As a(n) (_____) (e.g., visiting scientist, guest researcher, fellow, trainee, employee of a federal agency other than CDC), I understand that I am prohibited from disclosing any such confidential information that has been obtained under this project to anyone other than authorized staff of CDC or persons covered under this 308(d) Assurance. I understand that any disclosure in violation of this Confidentiality Pledge will lead to termination of my employment,

fellowship, training experience, or scientific collaboration with the HIV Surveillance Branch (HSB), the Behavioral and Clinical Surveillance Branch (BCSB), and the Detection and Response Branch (DRB), Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) as well as other penalties.

_____

(Typed/Printed Name)

_____

(Signature)

_____

(Date)

Confidentiality Security Statement Attachment 5

POLICY FOR RELEASE OF CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) HIV SURVEILLANCE AND SURVEILLANCE-RELATED DATA

July 2025

Description of the system

The National HIV Surveillance System (NHSS) is comprised of HIV case reports submitted on a voluntary basis to CDC by the 50 states, the District of Columbia, and U.S. territories and freely associated states (e.g., American Samoa, Guam, Northern Mariana Islands, Puerto Rico, the Republic of Palau, Republic of Marshall Islands, and the U.S. Virgin Islands).

National HIV Behavioral Surveillance (NHBS) collects behavioral and biological data on samples of persons at increased for HIV (men who have sex with men, persons who inject drugs, and heterosexual at increased risk) in U.S. cities with high HIV burden in rotating cycles. Participants are sampled using methods designed to reach hidden or stigmatized populations.

The Medical Monitoring Project (MMP) collects behavioral and clinical data on a nationally representative sample of persons with an HIV diagnosis through interviews and medical record abstraction.

Encrypted case reports and other surveillance-related data are received electronically using standardized reporting forms and software. The data from state and local health departments are decrypted and the CDC databases are updated on a regular basis to include all cases received and processed through the last day of the previous cycle. Personally identifying information on each case is deleted prior to transfer to CDC and cases are identified at the national level only by soundex code based on patient's surname, date of birth, and a state-assigned patient identification number.

The HIV Surveillance Branch (HSB), the Behavioral and Clinical Surveillance Branch (BCSB), the Detection and Response Branch (DRB), the Laboratory Branch (LB), and the Quantitative Sciences Branch (QSB) of the Division of HIV Prevention (DHP) maintain databases on individuals at risk for, or have received a diagnosis of, HIV infection. These databases include information from case reports, case investigations, cluster investigations, related surveillance databases, surveys, and data from medical records, laboratories or public health databases.

All surveillance and surveillance-related data collected and maintained by the DHP HSB, BCSB, DRB, LB, and QSB must be managed, presented, published and released in accordance with strict adherence to the standards for confidentiality and security consistent with the principles and guidelines for HIV case report data. These principles and guidelines must be strictly followed as geographic and small-cell data may be indirectly identifying when combined with detailed information contained in case reports, questionnaires, or from laboratory or medical records.

Restrictions on release of data

HIV surveillance data and data from surveillance-related projects, evaluation studies, and case investigations are collected under Sections 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k) and are protected at the national level by an Assurance of Confidentiality (Section 308(d) of the Public Health Service Act, 42 U.S.C. 242 m(d)), which prohibits disclosure of any information that could be used to directly or indirectly identify individuals whose records are contained in the NHSS and surveillance-related databases. This prohibition has led to the formulation of guidelines for data release. The guidelines reflected in this policy and related standard operating procedures represent a balance between the potential for inadvertent disclosure and the need for CDC/DHP to be responsive to information requests having legitimate public health application. The data re-release policies were developed jointly by CDC and the Council of State and Territorial Epidemiologists (CSTE). Each state or local HIV Surveillance Coordinator and state epidemiologist signed a data re-release agreement with CDC and selected the level of geographic specificity (e.g., state, county, size of metropolitan statistical area (MSA) or other geographic area) at which CDC may report data on HIV cases residing in that state. These principles and restrictions should also be applied to other surveillance or surveillance-related data and information collected and maintained by the DHP HSB, BCSB, DRB, or LB specific surveillance activities may have additional data-release requirements that are specified in their respective protocols. In the absence of project specific data release policies or agreements with project areas, these restrictions apply.

As a general rule, requests from the public, the media, and other government agencies for state/local data will be referred to the local area for reply. There are two reasons for this: 1) local health departments can release their HIV surveillance data in accordance with locally established policies and procedures, and 2) due to the delay between the date of diagnosis and report to CDC, the local health department data are more current than those contained in the NHSS database. However, CDC may release data to the public, for presentation in oral and written publications, and otherwise make data available for epidemiologic and public health purposes within the guidelines specified and described in the document "Agreement to Abide by Restrictions on Release of Surveillance Data..." When publishing or presenting state/local data, CDC staff should notify the local areas in advance whenever possible. Outside the bounds of these guidelines, CDC will not release, in any format, state, county, MSA, or U.S. territories and freely associated states area-specific data without the consent of the appropriate state or local health departments.

Access to the database

DHP HSB, BCSB, and DRB are charged with the responsibility of maintaining the security and confidentiality as well as the scientific integrity of CDC HIV surveillance and surveillance-related databases. Access to data beyond that available for public use is limited, through controlled-access groups, to members of the DHP HSB, BCSB, and DRB and selected members of the DHP QSB, LB, and their contractors and other authorized agents. In limited circumstances, CDC staff outside these groups or external project collaborators may be granted access on an as-needed basis, at the discretion of the appropriate branch chief. External

collaborators are those with whom DHP has existing cooperative agreements or contracts involving the collection or analysis of these surveillance data. To conduct analyses, staff must submit an analysis proposal which must be approved through the applicable branch management. Templates for analysis and manuscript proposals are available from BCSB and HSB for these requests. To obtain access and conduct analyses, others outside the CDC branches mentioned above must do the following:

1. Pose a specific research question.

2. Estimate the time required for their analysis/access.

3. Agree in writing to abide by DHP policies and procedures on data release and sign the "Nondisclosure Agreement," the "Request for Access...," and the "Agreement to Abide by Restrictions..." documents or other documents as required for specific projects that contain the policies and guidelines for use of HIV surveillance and related data. Completion of annual Assurance training is required if access to surveillance datasets is necessary, consistent with branch policies and procedures.

4. Provide an outline on their proposed methodology including names of variables to be used in the analysis.

5. Collaborate with staff of HSB, BCSB or DRB in analysis, presentation, and publication of the results of their analysis. In some cases, access to national data by collaborators may be designed as part of the project protocol and should be agreed to by all collaborators on the project.

6. Submit all reports, publications, and presentations to DHP clearance and cross-clearance channels.

Alternatives to access of NHSS or other surveillance-related data

To reduce the burden on HSB, BCSB, DRB, LB, and QSB staff, other CDC staff persons requesting HIV surveillance data are encouraged to use publicly available reports, slide sets, and the NCHHSTP AtlasPlus. CDC staff are also encouraged to use the CDC-internal DHP Dashboard for internal purposes (non-publication). CDC staff that use HIV surveillance data for policy development, resource allocation, research prioritization and other public health purposes are advised to consult with HSB, BCSB, or DRB staff to ensure appropriate interpretation of the data. CDC staff that present or publish HIV surveillance data should adhere to CDC policies for clearance and cross-clearance to ensure that data are presented and interpreted consistently and accurately.

1. The HIV Surveillance Report is published annually. The report is a collection of tables describing the characteristics of persons with diagnosed HIV in the United States and its territories and freely associated states. The report includes data on age, sex, race/ethnicity, and transmission category, and by state, region of residence, metropolitan statistical area (if greater than 500,000 population), and territory or freely associated state. This report is

updated annually to include data on diagnoses that have occurred through December 31 (of a given year) and reported to CDC through December 31 (of the following year).

2. DHP produces numerous supplemental reports, special reports, slides sets, fact sheets, MMWR articles, and peer-reviewed publications. These products conform to this data-release policy and criteria outlined in the re-release agreements. DHP surveillance publications can be accessed through the CDC website at https://www.cdc.gov/hiv-data/index.html or by contacting HSB at (404)-639-2050 or BCSB at (404) 639-2090.

3. The NCHHSTP AtlasPlus provides an interactive platform for accessing HIV surveillance data, allowing users to observe trends and patterns by creating detailed reports, maps, and other graphics. Currently, AtlasPlus provides interactive maps, graphs, tables, and figures showing geographic patterns and time trends of HIV diagnoses, stage 3 (AIDS) classifications, viral hepatitis, tuberculosis, chlamydia, gonorrhea, and primary and secondary syphilis surveillance data. Data are currently available at the national, regional, MSA, and county level as well as state/territory/freely associated state-area level. The NCHHSTP AtlasPlus can be accessed at https://www.cdc.gov/nchhstp/about/atlasplus.html.

4. State-specific data can also be accessed through state/local health department websites. DHP surveillance publications and the NCHHSTP AtlasPlus can be accessed through the CDC website at https://www.cdc.gov/hiv-data/index.html

5. The DHP HSB, BCSB, and DRB, wishing to be responsive to specific data requests having important public health application, will consider requests for data and complete analyses on data that cannot be retrieved using production materials. For requests requiring HSB, BCSB, DRB, or in some cases QSB or LB response, submission in written format must be submitted to assist in ensuring an appropriate response. Due to limited resources, processing requests for data is not guaranteed and data will be supplied only if their release does not conflict with current disclosure prohibitions. Initial requests may be taken verbally but requesters will be encouraged to submit their queries in writing to ensure an appropriate response.

   Consideration will be given to verbal requests from:

   - The Executive Branch; Members of Congress and their staffs; senior staff from other Federal agencies (HUD, HRSA, SAMHSA, National Institute of Allergy and Infectious Diseases [NIAID]); the states; associations serving the states (e.g., ASTHO, CSTE, NASTAD); other public institutions of CDC interest (e.g., The Red Cross and National Hemophilia Foundation); and selected CDC staff serving these constituencies.

   - The NCHHSTP, Program Planning & Policy Coordination Office or DHP Office of Policy, Planning and Communications.

   Other parties and individuals should submit requests in written format to the chief of either HSB, BCSB, DRB or one of their designees. Due to limited resources, processing of data requested cannot be guaranteed. Responses and request fulfillment are at the discretion of the branch chief.

Confidentiality Security Statement Attachment 6

AGREEMENT TO ABIDE BY RESTRICTIONS ON RELEASE OF HIV SURVEILLANCE AND SURVEILLANCE-RELATED DATA COLLECTED AND MAINTAINED BY THE DIVISION OF HIV PREVENTION (DHP)

July 2025

I, _____, understand that data collected by the Centers for Disease Control and Prevention (CDC) through the National HIV Surveillance System (NHSS) and related surveillance activities, projects, and case investigations under Sections 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k) are protected at the national level by an Assurance of Confidentiality (Section 308(d) of the Public Health Service Act, 42 U.S.C. 242m(d)), which prohibits disclosure of any information that could be used to directly or indirectly identify any individual on whom a record is maintained by CDC. This prohibition has led to the formulation of the following guidelines for release of HIV surveillance and surveillance-related data collected on such persons to which, in accepting access to data not considered public-use, I agree to adhere. These guidelines represent a balance between the potential for inadvertent disclosure and the need for CDC/DHP to be responsive to information requests having legitimate public health application, and reflect input from DHP subject matter experts, statisticians, and approval of state and local surveillance programs. In particular, variables that identify geographic units or facilities have the potential to indirectly identify individuals.

Therefore, I will not release, either inside or outside CDC, state/territorial, MSA, city, county, or other geographic area-specific data in any format (e.g., publications, presentations, slides, interviews) without the consent of the appropriate state or local agency, except as consistent with the format described in this document and related HSB, BCSB, and DRB standard operating procedures. Specifically, in accordance with the terms of written data re-release agreements between CDC, the Council of State and Territorial Epidemiologists (CSTE), and individual state/territorial health departments AND in accordance with the principles of the Assurance of Confidentiality for HIV surveillance and surveillance-related data authorized under Section 308(d) of the U.S. Public Health Service Act:

Levels of data release

National and regional level — I am permitted to release national and regional aggregate data without cell size or denominator restrictions. Data will include (but not be limited to) multiple cross tabulations by geographic level, sex, race/ethnicity (based on Office of Management and Budget (OMB) categories), age group, transmission category (or exposure category), and year. These include the variables outlined below and may include other variables reported to the National HIV Surveillance System, Medical Monitoring Project (MMP) or National HIV Behavioral Surveillance.

State level (including the District of Columbia and Puerto Rico) — For any state, the District of Columbia, and Puerto Rico. I am permitted to release one-way frequencies, two-way, three-way, and four-way stratifications of variables of interest (including sex, age group, race/ethnicity and transmission/exposure category) by location (i.e., states) and year with the denominator rule suppressing data for stratum-specific populations of size <100 according to the level of release specified in the state's data re-release agreement. I understand that the stratifications released may vary by jurisdiction and will review and release data according to each jurisdiction's agreed level of release. A summary listing of specified release levels for each state is available from the Data Analysis and Dissemination Team, HSB.

- No numerator suppression rule will be applied.
- For strata where a population size is not available in the U.S. Census (e.g., transmission/exposure category) the size of the underlying population that is *most similar to the group* will be checked before data are released. For example, for black men who have sex with men, the underlying population of black men will be checked for that geographic area.
- If the totals could inadvertently disclose a case through back-calculation by subtraction, secondary or complementary suppression will be done by either 1) combining two or more categories of data (e.g., aggregation of values within the stratification parameter) or 2) excluding all data in a subcategory (e.g., blocking disaggregation below a pre-selected value for the stratification parameter) across multiple states.
- Any requests for data beyond this data-release agreement will require permission by the applicable health department.

Geographic areas with ≥500,000 population — For areas with ≥500,000 population**, including MSAs, counties cities and other geographic areas,** I am permitted to release one-way frequencies, two-way, three-way, and four-way stratifications of variables of interest (including sex, age group, race/ethnicity and transmission/exposure category) by location (e.g., MSAs, counties cities and other geographic areas) and year with the denominator rule suppressing data for stratum-specific populations of size <100 according to the level of release specified in the state's data re-release agreement. I understand that the stratifications released may vary by jurisdiction and will review and release data according to each jurisdiction's agreed level of release. A summary listing of specified release levels for each state is available from the Data Analysis and Dissemination Team, HSB.

- No numerator suppression rule will be applied.
- For strata where a population size is not available in the U.S. Census (e.g., transmission category), the underlying population that is *most similar to the group* will be checked before release. For example, for black men who have sex with men, the underlying population of black men will be checked for that geographic area.

- If the totals could inadvertently disclose a case through back-calculation by subtraction, secondary or complimentary suppression will be done by either 1) combining two or more categories of data (e.g., aggregation of values within the stratification parameter) or 2) excluding all data in a subcategory (e.g., blocking disaggregation below a pre-selected value for the stratification parameter) across multiple areas.
- Any requests for data beyond this data release agreement will require permission by the applicable health department.
- **Geographic areas with 50,000 – 499,999 population —** I will review the data re-release agreements and most current standard operating procedures for applicable areas and restrictions in collaboration with the HSB, BCSB, or DRB Chief or the Data Analysis and Dissemination Team Leader, HSB before releasing any data for geographic areas with 50,000 – 499,999 population. I understand that the stratifications released may vary by jurisdiction and will review and release data according to each jurisdiction's agreed level of release. A summary listing of specified release levels for each state is available from the Data Analysis and Dissemination Team, HSB. A denominator rule of <100 will be applied for all frequencies and stratifications in areas with 50,000 – 499,000 population (i.e., when the stratum-specific population is <100 for a subgroup, count data will not be presented). In addition, data will be suppressed when numerators are 1 – 4 (i.e., cells with 1 – 4 will not be presented).
- For strata where a population size is not available in the U.S. Census (e.g., transmission category), the underlying population that is *most similar to the group* will be checked. For example, for black men who have sex with men, the underlying population of black men will be checked for that geographic area.
- Any requests for data beyond this data release agreement will require permission by the applicable health department.

Counties <50,000 population — Data will not be released for any area/location with <50,000 population other than counties. I will review the data re-release agreements and most current standard operating procedures for applicable areas and restrictions in collaboration with the HSB BCSB, or DRB Chief or the Data Analysis and Dissemination Team Leader, HSB before releasing any data for counties with <50,000 population. I understand that the stratifications released may vary by jurisdiction and will review and release data according to each jurisdiction's agreed level of release. A summary listing of specified release levels for each state is available from the Data Analysis and Dissemination Team, HSB.

- A denominator rule of <100 will be applied for all frequencies and stratifications in counties <50,000 (i.e., when the stratum-specific population size is <100 for a subgroup, count data will not be presented). In addition, data will be suppressed when numerators are 1 – 4 (i.e., cells with 1 – 4 will not be presented).

- For strata where a population size is not available in the U.S. Census (e.g., transmission category), the underlying population that is most similar to the group will be checked. For example, for black men who have sex with men, the underlying population of black men will be checked for that geographic area.
- Any requests for data beyond this data-release agreement will require permission by the applicable state health department.

U.S. territories and freely associated states of American Samoa, Guam, Northern Mariana Islands, the Republic of the Marshal Islands, the Republic of Palau and the U.S. Virgin Islands — I am only permitted to release and present data at the U.S. dependency level. The release of data below the U.S. dependency level or for additional territories and freely associated states other than the five areas listed above will require permission by the applicable health department(s).

- It is permissible to release totals (cumulative and annual) and one-way frequencies (cumulative only) of sex, age group, race/ethnicity or transmission by location (i.e., U.S. dependency). No suppression rules will be applied.

Data stability requirements for release of <u>all</u> data regardless of level of analysis — I will include a cautionary note on stability for all levels of analyses when numbers are less than 12 or rates are calculated based on numbers less than 12, or when trends or estimates are determined to be unstable or unreliable through other statistical methods (e.g., relative standard error).

<u>Variables permitted for release and stratification (examples)</u> — Any requests for variables other than those listed below will require approval by the HSB Chief or Data Analysis and Dissemination Team Leader, HSB, BCSB, or DRB Chief or Behavioral Surveillance or Clinical Outcomes Team Leaders, BCSB as appropriate**:**

<u>General</u>

- Location (United States, region, U.S. territories and freely associated states, state, MSA, county, city) based on standard definitions
- Year (report, diagnosis, death, prevalence, stage of disease, infection (incidence), perinatal exposure)

<u>Demographic/transmission</u>

- Sex
- Age group (using 5-year groups or larger for state-level and smaller geographic populations; at diagnosis, or calculated age at end of year for prevalence)
- Race/ethnicity (based on OMB classification)
- Transmission or exposure category

Stratifications (examples)

1-way

- Race/ethnicity
- Sex
- Age group
- Transmission category[1]

2-way

- Sex and age group
- Sex and race/ethnicity
- Age group and race/ethnicity
- Age group and transmission category
- Transmission category and race/ethnicity
- Transmission category and sex

3-way

- Transmission category by age group and race/ethnicity
- Transmission category by age group and sex
- Transmission category by sex
- Race/ethnicity by sex

4-way

- Transmission category by age group, race/ethnicity, and sex

Data release and publication

- I understand that release of data not specifically permitted by this agreement is prohibited unless written permission is first obtained from the appropriate branch chief (HSB, BCSB, or DRB), Division of HIV Prevention
- When presenting or publishing state-, city-, county-, MSA-, territory or freely associated state-specific data in accordance with the restrictions outlined above, I will inform the appropriate state(s) and local health department(s) in advance of the release of state or

[1]For the purpose of this agreement, we are considering stratifications at the variable level. Note that "male-to-male sexual contact" and the dual "male-to-male sexual contact *and* injection drug use" transmission categories include stratification by sex (i.e., include only men) but will be treated as a single variable for data releases.

local data, so as to afford them the opportunity to anticipate local queries and prepare their response.

- When presenting or publishing data from surveillance-related studies, investigations, or evaluations, I will adhere to the principles and guidelines outlined in this agreement and related HSB, BCSB, and DRB standard operating procedures.
- Publication of a manuscript in a journal or as part of conference proceedings requires a CDC clearance of that manuscript, even if an abstract for that manuscript was previously cleared.

Release of geocoded HIV surveillance data

- Any re-release of geocoded HIV surveillance data that identifies the geographic area below the state or U.S. territory or freely associated states level is subject to written approval of the applicable health department(s) (re-release of data can be in the form of peer and non-peer reviewed manuscripts, technical reports, manuals, and presentations).
- All publications using geocoded data must be cleared through DHP HSB clearance.

Data security

1. I agree to follow standard operating procedures for maintaining security and confidentiality of surveillance and surveillance-related data.
2. I will not give my access password to any person.
3. I will treat all data at my desk site confidentially and maintain in a locked file cabinet records that could directly or indirectly identify any individual on whom CDC maintains a record. Sensitive identifying information from special case investigations will only be maintained in a locked file cabinet in a locked room which has restricted access.
4. I will keep all hard copies of data runs containing small cells locked in a file cabinet when not in use, shredding them when they are no longer necessary to my analysis.
5. I will not produce a “back-up” data file of HIV case surveillance data or related databases maintained by DHP.
6. I will not remove electronic files, records or databases from the worksite, or access them remotely from home or other unofficial/unapproved off-worksite location.
7. I will not remove hard copies of case reports, survey instruments, laboratory reports, confidential communications, or any records containing sensitive data and information or the like from the worksite.
8. I will not remove from the worksite tabulations or data in any format that could directly or indirectly identify any individual.

9. I will maintain confidentiality of records on individuals in all discussions, communications, e-mails, tabulations, presentations, and publications (and the like) by using only the minimum information necessary to describe the individual case.
10. I will not release data to the press or media without pre-screening of the request by the NCHHSTP, Program Planning & Policy Coordination Office or the DHP Office of Policy, Planning and Communications.
11. I am responsible for obtaining IRB review of projects when appropriate.
12. I will abide by HSB, BCSB, and DRB telework/remote work policies and established secure procedures for accessing data remotely.

I have read this document, "Agreement to Abide by Restrictions on Release of HIV Surveillance and Surveillance-Related Data..." and the attached document "Policy for Release of Centers for Disease Control and Prevention (CDC) HIV Surveillance and Surveillance-related Data," and I agree to abide by them. Failure to comply with this agreement may result in disciplinary action, including possible termination of employment.

Signed: _____ Date: _____

(Requestor)

CIO, Division, Branch _____

Approved: _____ Date: _____

Chief, (HSB/BCSB/DRB), DHP, NCHHSTP or designee

Revised July 2025

Confidentiality Security Statement Attachment 7

REQUEST FOR ACCESS TO HIV SURVEILLANCE AND SURVEILLANCE-RELATED DATABASES MAINTAINED BY THE DIVISION OF HIV PREVENTION (DHP)

July 2025

Requests for access may be made using this form or by email. Please include the information below in any email request for access. All requests should be made by the appropriate team lead or will include information indicating supervisory approval.

Name: _____User ID: _____

Date of Request: _____ Branch: _____

List required data sets and access groups (if known):

Justification for Access:

Supervisory Certification:

I certify that it is a necessary part of the above staff member's official duties to have access to the National HIV Surveillance System and related surveillance databases. I have advised this employee of the confidentiality of these data and have attached a signed "Agreement to Abide by Restrictions on Release of Data."

_____
Supervisor's Signature

Approval:

_____
Chief, (HSB/BCSB), DHP or designee

- -

For HSB, BCSB, DRB or QSB Use Only (retain signed copies of "Request for Access..." and "Agreement to Abide by Restrictions..." forms and copies of MUST requests or emails to helpdesk.)

MUST action granting access submitted on _____ (date) by _____

MUST access deleting access submitted on _____ (date) by _____