STD Surveillance Network (SSuN)
Revision

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SUPPORTING STATEMENT A

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A. Justification

EXHIBITS

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- **Goal:** The STI Surveillance Network (SSuN) is a supplemental, sentinel surveillance project designed to: 1) provide critical supplemental information on case reports of sexually transmitted diseases (STIs); 2) monitor STI and HIV screening, incidence, prevalence, and health care access in populations seeking STI clinic services in STI specialty clinics; 3) provide timely surveillance and epidemiologic data on persons diagnosed with gonorrhea to direct public health STI prevention and control efforts; 4) provide information on syphilis cases not otherwise available through public health follow-up at the state/local level; 5) monitor STI treatment and prevention services practices, 6) monitor new and emergent STIs such as mpox, and 7) monitor selected adverse health outcomes of STIs.
- **Intended Use**: To better interpret trends in reported case incidence, assess burden of disease by key population and health equity characteristics, monitor and evaluate adherence to STI/HIV screening recommendations and treatment guidelines, capture patient-level outcomes of enhanced HIV prevention initiatives in STI clinical settings, monitor the emergence/re-emergence of novel STIs with the goal of enabling rapid public health response to issues such as syndemic co-morbidities, decreasing antibiotic susceptibility and re-emergence of vaccine preventable diseases such as mpox.
- **Methods**: SSuN activities utilize two distinct surveillance strategies to collect information: 1) sentinel surveillance of visit-level clinical care, diagnoses, laboratory and treatment data from all patients seeking care in selected STI clinics in the funded jurisdictions, and 2) enhanced case investigation (record searches, provider follow-up and patient interviews) for a random sample of patients diagnosed with gonorrhea and syphilis. Case investigations include HIV registry matching, treatment ascertainment, laboratory records and brief patient interviews to provide complete demographic and behavioral data.
- **Subpopulation:** Men and women seeking clinical care at STI specialty clinics; men and women diagnosed with gonorrhea or syphilis and reported to health authorities from any/all provider settings.
- **Analysis:** Descriptive statistics and multivariable analyses to assess STI prevalence and trends by patient characteristics, geography, social determinants, and provider characteristics. Data collected from the STI clinic component will be analyzed descriptively to evaluate STI/HIV testing, assess the burden of HIV co-infection, assess the incidence and prevalence of STDs by patient characteristics, and monitor prescribing of recommended treatments.

A. JUSTIFICATION

A. 1. Circumstances Making the Collection of Information Necessary

- The Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests a revision of the previously approved data collection entitled, “STI Surveillance Network (SSuN)”. SSuN is a sentinel surveillance system designed to provide information to better understand community burden of disease, identify populations at greatest risk for STIs, and to monitor long-term health consequences of STIs, including risk of HIV infection and provision of biomedical HIV countermeasures such as Pre-Exposure Prophylaxis (PrEP) to high-risk persons. Revisions to this submission include the modification of data elements intended for capturing information on patient sex to comply with Executive Order #14168 “*Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*”. . The following specific revisions are proposed to the currently approved project (OMB# 0920-1072). Restrict response options for secondary data elements abstracted from existing data systems (e.g. electronic medical record systems) indicating sex to “male”, “female”, “undetermined”, or missing value
- Restrict response options for primary data collection on patient sex and sex of their sex partners to “male” or “female”
- Remove data elements corresponding to capture of information on gender identity

Background

National STI case reporting through the National Notifiable Disease Surveillance System (NNDSS) is CDC’s primary source for reporting, analysis, and interpretation of trends in the incidence, prevalence and societal impact of chlamydia, gonorrhea, and syphilis infections in the United States and U.S. Territories. However, data derived from the national case reporting system are limited and increasingly incomplete as data systems and reporting formats have evolved toward greater complexity and the volume of reportable diseases reported solely through automated laboratory reporting has increased at the state and local level, reducing the proportion of cases with complete demographic, clinical and behavioral data available.

STI case report data received at CDC through NNDSS lack complete information on the race and Hispanic ethnicity of the patient. The proportion of cases missing these data in 2021 exceeded 25%, while other data needed to understand the epidemiology of STIs, such as sex of sexual partners, treatments prescribed, anatomic sites infected and health care seeking behaviors are not available at all in national reporting data. This limits the utility of case-level information received by CDC. Information critical to understanding disease trends is often not available or sufficiently timely to identify emergent issues and inform rapid disease control efforts. Moreover, routine case reporting does not provide comprehensive demographic information critical for understanding key health equity issues such as populations at highest risk and those most disproportionately impacted by STI morbidity or equitable access to STI preventive interventions. Sentinel and enhanced surveillance projects are specifically designed to address these shortcomings and are critical to characterize gaps in knowledge and identify opportunities in sexual health services to inform effective, timely response policy. These data also provide a wealth of information useful to equitably balance resource allocations and optimize public health disease control and prevention activities.

Ongoing enhanced and sentinel STI surveillance activities are also responsive to multiple priorities of the Division of STD Prevention (DSTDP), the National Center for HIV, Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP) and are fully aligned with CDC’s imperative to improve the nation’s overall disease surveillance portfolio. Specific priorities addressed by the STI Surveillance Network include the following:

(1) Focus on DSTDP programmatic priorities of population-level sexual health, adolescents and young adults, gonorrhea resistance, and preventing adverse consequences of STIs, including HIV infection, congenital syphilis and other maternal and reproductive health risks,
(2) Supports a syndemic, multi-strategy approach to surveillance and promotes service integration at the state and local level in support of STI/HIV prevention through healthcare initiatives, the National Strategy to End the HIV Epidemic (EHE) and;
(3) Addresses and successfully leverages changes in health IT infrastructure and emergent innovations in the healthcare delivery system to provide more timely, programmatically actionable information.

Limitations in national case reporting data, and the need to meet these longstanding division, center and agency goals led to the initial development and funding of the STI Surveillance Network in 2005. Through past and current funding cycles of the STI Surveillance Network, CDC has partnered with state and local health departments to obtain STI-related behavioral and clinical data from those persons diagnosed with STIs and all persons seeking care at selected STI clinics. Stakeholders for analysis and interpretation of data collected from the active surveillance programs funded by the STI Surveillance Network (SSuN) include national, state, and local STI program managers, public health personnel, health policy makers, health care providers, academic health departments and the general population. These data have proven invaluable for supporting the reporting of progress metrics the division provides to internal and external stakeholders, have directly contributed to STI prevention initiatives, and have contributed to numerous peer-reviewed manuscripts in clinical and STI-focused professional journals.

Collection of STI surveillance data is regulated by Title III – General Powers and Duties of Public Health Service, Section 301 (241.) (a) (**ATTACHMENT 1**).

A. 2. <u>Purpose and Use of Information Collection</u>

The primary objectives of SSuN are to, 1) enhance the quality, completeness, and timeliness of STI surveillance data to inform a more comprehensive understanding of epidemiologic trends and determinants of STIs of interest, and 2) to monitor public health program impact and provide a robust evidence base for directing current and future public health action. The explicit capacity to identify STI risk behaviors and clinical presentation among populations at risk – data which are otherwise unavailable from any other source – is a unique and defining feature of SSuN.

The large and geographically varied sample obtained through this project provides a valid and reliable data source for evaluating progress toward national public health goals, such as identifying priority populations for STI prevention activities, evaluating effectiveness of CDC published treatment guidelines and screening recommendations, providing the infrastructure for identifying emerging sequelae of STIs and for ascertaining behavioral characteristics among populations that contribute to significant syndemic co-morbidities, such as opioid use and HIV infection risk. Moreover, SSuN is one of the only sources of patient-level information for evaluating the uptake of important STI prevention interventions including expedited partner therapy (EPT), as well as HIV prevention interventions such as pre- and post-exposure prophylaxis (PrEP and PEP) among persons seeking care for – or diagnosed and reported with – STIs.

Data from sentinel surveillance in STI clinics collaborating in SSuN are also used to ascertain patient-level provision of recommended treatment and STI screenings, concurrent HIV testing and referral to HIV prevention interventions, and screening for STIs across all exposed anatomic sites. SSuN provides information on the characteristics of persons receiving STI and HIV prevention services and the types, frequency, and duration of services they are accessing. Planned revisions of SSuN also include data relevant to mpox incidence, mpox vaccination and risk. Mpox is an emergent disease of concern to populations at risk for STIs and recent large, global outbreaks indicate the need for more comprehensive surveillance activities. Information about access to, and use of, these clinical and preventive services is essential for evaluating and enhancing national, state, and local prevention services for people at risk for STIs.

Without the enhanced and sentinel surveillance data available through SSuN, behavioral data are constrained to, 1) national case surveillance, which collects a negligible amount of demographic and clinical information from case reports of persons diagnosed with STIs, or, 2) from small-scale, periodic, or ad hoc behavioral surveys conducted by community partners or in specific clinic populations. The latter efforts are not likely to have the large population size or geographic variance that SSuN provides. The absence of continuing, timely SSuN data would adversely affect the ability of CDC and the public health community to monitor emergent syndemic trends both locally and nationally.

This project utilizes two distinct surveillance methodologies that are conceptually grouped into two primary strategies, reflecting the core network functions: Strategy A includes sentinel surveillance in key clinical settings, and Strategy B enhances the utility of case-based surveillance through comprehensive investigations of a representative sample of reported cases. These investigations provide more complete, on-going case-based information such as patient demographics, clinical characteristics and treatments prescribed across the full range of healthcare settings. These data allow for reliably estimating the distribution of cases by characteristics routinely missing in national case reporting. These strategies are fully described in project protocols and are rigorously implemented across all collaborating health departments **(ATTACHMENT 4).**

Strategy A: Sentinel Surveillance in STI Clinics:

Strategy A includes sentinel facility-based surveillance in STI specialty clinics where visit-level clinical, diagnosis, laboratory, and treatment data **(ATTACHMENT 5)** are collected from patients attending participating clinics **(Table B.1.A)**. Specialty STI clinics, for the purposes of this project, are defined as clinical facilities whose main, advertised, and actual purpose is to provide STI and HIV-related sexual health services to all patients regardless of insurance status or ability to pay. Data collection is primarily accomplished through automated abstraction of information routinely collected during the clinical encounter from existing electronic medical records by clinic data managers. These data are securely transmitted to local/state health departments for HIV registry matching and, in some funded sites, for recoding into appropriate SSuN data structures. Data managers assure de-identification of records and secure transmission to CDC using specified data formats. Funding recipients are required by protocol to maintain rigorous procedures to assure the quality and validity of data before submitting to CDC. Recoding and compliance with strict data structure standards assures that data from multiple facilities can be seamlessly merged into national SSuN datasets at CDC for aggregate analysis and reporting. CDC supplies syntax and programming to local collaborators for data validation and appropriate quality assurance. Collaborating clinics/health departments apply these validation checks and correct record-level errors or issues prior to transmission to CDC.

In compliance with protocols, records transmitted to CDC do not include patient names, date of birth, phone numbers, mailing addresses, ZIP codes or medical record numbers. Patient records from STI clinics are assigned a non-name based unique patient identifier (patient ID) and a unique event number is assigned for each visit; CDC only receives the unique, non-name-based identifiers and does not have the ability to re-identify patients from information contained in these or any other ancillary records. Data are transmitted through CDCs secure data network (SAMS) using specified encryption methods monthly (alternating between Strategy A and B data files). CDC accepts, validates, and securely stores these data, which are accessible only to approved project staff on a need-to-know basis. Project data are not integrated into other datasets maintained by CDC and are stored on secure servers with fully restricted access.

Important healthcare services are provided at STI clinics that protect the reproductive and sexual health of men and women, prevent STI transmission in the community, prevent HIV transmission and monitor for emergent infections such as mpox. These services include STI testing and treatment, STI partner services, counseling, HIV testing and linkage to care for those who are HIV-infected, and to HIV prevention interventions such as PrEP. STI clinics also provide critical vaccination capacity for preventing and responding to mpox clusters. Previous studies have found that at-risk patients prefer to be treated at STI clinics for several reasons, including confidentiality concerns, the convenience of these venues and the availability of expert sexual health clinical care. As part of this project revision, capacity to incorporate additional clinic collaborators at modest burden in future cycles, many of which are independently funded to enhance HIV prevention activities through the nation End-the-HIV-Epidemic (EHE) initiative, is being proposed. SSuN Strategy A data will provide an additional resource for monitoring implementation and patient-level outcomes of these important HIV prevention efforts.

Strategy B, Case-based Enhanced STI Surveillance:

The case-based enhanced surveillance component of SSuN focuses on case investigations obtaining complete demographic, behavioral and clinical information on a probability sample of gonorrhea and syphilis cases. SSuN will expand active investigations to include a sample of early syphilis cases reported to participating health departments through routine case notifications. A minimum sample fraction of 7% of total gonorrhea morbidity and of early syphilis cases. A 2% overall effective sample (proportion of all reported cases with completed investigations) is the target for inclusion of a jurisdiction's data in national analytic datasets. Complete ascertainment of HIV co-infection and treatment status for all reported gonorrhea and syphilis cases **(ATTACHMENT 5, ATTACHMENT 8)** will also continue to provide robust monitoring of relevant syndemic co-infections.

Gonorrhea and syphilis cases must be reported within 60 days of specimen collection and must have resided in the jurisdiction at the time of the diagnosis to be eligible for sampling. Sampling methodologies are uniformly implemented across the funded health departments to assure a valid probability sample of cases for enhanced investigation. Health department staff review sampled records against existing health department disease and laboratory registries to determine if the sampled case (i.e., patient diagnosed and reported with gonorrhea or early syphilis) has previously been reported to the department of health for any notifiable disease of interest (STIs, HIV, TB, viral hepatitis, etc.), document recent history of STIs, and provide additional clinical information available locally through routine provider case reporting. Previous diagnoses occurring within 365 days of the specimen collection date/diagnosis date of their current diagnoses will be documented and included in the SSuN case record; this facilitates determining whether the record represents a 'duplicate record' (defined as a GC or syphilis diagnosis within 30 days of the specimen collection date/diagnosis date of a previously reported case record) or whether the current case indicates a potential treatment failure. The ability to identify treatment failures is critical for monitoring the emergence of antimicrobial resistance or for detecting patterns of inappropriate antimicrobial use in the provider community.

Patient-level investigations among sampled cases are conducted either by phone or, in limited circumstances, in person with at least 4 documented attempts to contact each sampled patient. Sites are encouraged to develop locally relevant materials and/or data collection instruments based on protocol patient interview templates provided by CDC (**ATTACHMENT 8)**. Moreover, all funded health departments are required to provide adequate training to local investigators conducting patient contact, and to address any applicable local human subject requirements. Where not otherwise formally required, informal verbal informed consent is obtained from patients prior to eliciting information in the same fashion as routine partner management activities conducted by the health department under local public health authorities; consent requirements are documented in local protocols.

In addition to enhanced surveillance for gonorrhea cases, all adult syphilis cases will also be extracted from the health department's existing STD surveillance system. While considerable public health follow-up is routinely conducted for all early syphilis cases, staff limitations at local public health agencies have led some jurisdictions to increasingly prioritize only specific categories of early syphilis cases for partner services and treatment assurance. SSuN collaborators will investigate all early syphilis cases in the random sample that are not prioritized for local follow-up and conduct case investigations. The purpose of these investigations is to replace significant epidemiologic information on the incidence of early syphilis that is lost because of a lack of other public health follow-up. Laboratory records associated with all reported cases of gonorrhea and syphilis are also obtained, allowing for documentation of testing across multiple anatomic sites and for validating staging of reported syphilis cases **(ATTACHMENT 5)**. Wherever available, negative laboratory results are also included in SSuN datasets to demonstrate provider adherence to recommended screening practices.

Both strategies of SSuN are designed to integrate with traditional case surveillance methods to produce high-quality, timely surveillance and epidemiologic data to direct public health STI prevention and control efforts, better understand community burden of disease, identify syndemic patterns and populations at greatest risk and monitor long-term health consequences of STIs. To assure comparability of activities and data across funded jurisdictions and maximize the potential utility of the network, recipients are required to follow common protocols (**ATTACHMENT 4)** in implementing Strategy A and B activities in their jurisdictions and at their facilities. This rigor assures that the project functions at the national level in a way that is consistent with the principles and attributes of all robust and reliable disease surveillance systems.

As with all other CDC surveillance activities, the revised information collection described in this request is funded through cooperative agreement with state and local health departments and clinical facilities. The five-year Notice of Funding Opportunity CDC-RFA-PS19-1907 was published February 15, 2019. Eleven (11) jurisdictions were competitively selected to participate in Cycle 4 of enhanced SSuN for the project period 9/30/2019 through 9/29/2024. See **ATTACHMENT 6** for a list of collaborators for the current cooperative agreement.

The usefulness of SSuN data has been, and continues to be, demonstrated by the amount of national media attention that SSuN analyses have received. Data from Strategy A and B of the current and previous SSuN cycles has been presented at international conferences and published in peer-reviewed journals demonstrating a significant and ongoing increase in the burden of gonorrhea among gay, bisexual, and other men who have sex with men (GBMSM). These data generated coverage from the general media in the U.S. as well as public health reporting from several international media outlets. Data from SSuN activities are also included in CDC's annual STD Surveillance Reports, which garner considerable domestic coverage, including findings related to the estimated proportion of gonorrhea cases attributable to GBMSM as well as heterosexual populations. Data from Strategy A, the STI facility component, has been used for analyses on incident HIV diagnoses among previously documented HIV-negative GBMSM who are repeatedly tested for HIV. Previous findings include an overall incidence of new HIV diagnosis approximately 25 times that observed in heterosexual men and women. Findings were also presented at the 2018, 2020,2022, and 2024 National STI Prevention Conferences showing that symptomatic case rates are increasing dramatically among GBMSM, providing evidence that gonorrhea incidence continues to increase among this group. See **ATTACHMENT 7** for additional bibliography of SSuN publications.

SSuN methods have been replicated by other non-funded jurisdictions, vetted by external and internal researchers, and have undergone internal validation by CDC colleagues as well as local and state health department collaborators. CDC and SSuN collaborators meet annually for a principal investigator’s meeting to discuss methodological issues and lessons learned in the preceding year; the current request for revisions is a direct result of changing national priorities and a full, collaborative assessment of SSuN methods and data outcomes.

A. 3. Use of Improved Information Technology and Burden Reduction

Interview and survey data are locally collected and managed using applications running on password-protected encrypted systems meeting the collaborating health department’s local health department security requirements. Interview and survey templates are provided for collaborators as a guide for developing local applications for data collection (See **ATTACHMENT 8**). Collaborating jurisdictions are encouraged to develop data collection tools and methods that maximize the efficiency of data collection and have developed a variety of technologies such as RedCap, Access and/or SQL to facilitate real-time capture of interview data. All patient interviews are conducted by locally trained staff using relevant public health standards for maintaining the security and confidentiality of all information collected. Future SSuN cycles plan to adopt modular technologies for patient interviews in Strategy B, allowing rapid rotation of domain-specific modules to reduce the burden on respondents by collecting some domains of information from a subset of sampled cases rather than from all respondents.

Local collaborators provide training that includes instructions on how to initiate patient contact, verify patient identity, establish rapport, conduct the interview, and manage all data generated. They also assign key project staff to provide supervision and monitor interviewers regularly. CDC conducts periodic site visits for quality assurance and to provide technical assistance as well as gather feedback on the interviewing and data collection processes. Since SSuN does not provide electronic applications or systems to funded entities and does not utilize web-based or other software for project activities at the national level, all data collected from clinic, case and patient interviews are validated and formatted into SAS datasets within the secure network environments available locally. CDC provides funded recipients with data structures, data formats and syntax for automating edit pre-checks to assure data quality prior to transmission to CDC. These measures, coupled with ongoing technical assistance, help reduce the burden on recipients conducting SSuN activities.

For the STI clinic-based component of SSuN, data managers at the STI clinics electronically abstract relevant data elements from their electronic medical records systems, recode, reformat into SAS structure files, and conduct data quality assurance before securely transmitting to CDC, either directly or through their local health department. Data managers at the clinics do not use paper forms, search any paper medical files, or conduct manual abstractions of medical charts to fulfil SSuN data requirements.

A. 4. Efforts to Identify Duplication and Use of Similar Information

CDC reviewed currently funded programs and did not identify areas of duplication. We are not aware of any department or agency that rigorously or systematically collects or maintains data on STI behavioral risk, treatment, clinical data, laboratory observations and treatment for patients diagnosed and reported with gonorrhea and/or adult syphilis from multiple jurisdictions or patient census data from multiple STI clinics.

Within CDC,the National Electronic Disease Surveillance System (NNDSS) contains some similar data elements as SSuN. However, the existing information collection system cannot be modified, used partially, nor fully satisfy the unique information needs that SSuN addresses. NNDSS collects minimal case information for persons diagnosed with gonorrhea and syphilis; limitations of the national case reporting infrastructure are a primary driver for the creation of the STD Surveillance Network.

A. 5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this data collection effort. County or city-level health departments and clinical facilities may be minimally impacted by data collection activities through contractual arrangements with state health departments participating in SSuN. Staff time and effort is reimbursed as routine disease investigation in these counties per pre-existing arrangements with their state health departments. Clinic-level data management staff in participating STD clinics are county health department employees, university employees (where the clinic has accreditation) or state-funded through other STI program funds; contractual agreements with collaborating health departments reimburse these entities for data extraction activities.

A. 6. Consequences of Collecting the Information Less Frequently

SSuN data collection activities are planned to continue through the end of the current cooperative agreement (ending on September 29, 2029) and into a new, competitive 5-year cooperative agreement cycle anticipated to be funded in 2029 for ongoing surveillance through 2034. Consistent with other infectious disease surveillance systems, SSuN depends on continuous, longitudinal data collection to monitor short and longer-term trends and allow for rapid identification of emergent changes in disease transmission. If these data are not available, CDC, state, and local health departments will lack an important tool needed to make evidence-based decisions regarding national prevention program planning, resource allocation and planning. SSuN data are transmitted to CDC monthly by funded collaborators, alternating between Strategy A and Strategy B in order to balance the need for timely information and to minimize data management burden on collaborating clinics and health departments.

A. 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Given the nature of how STD surveillance data is collected and compiled from various sources, the design of local surveillance systems at the health departments, and how data is to be reported and submitted from the health departments to CDC, surveillance systems at the health departments currently lack the ability to collect the granularity of sub-categories beyond the race/ethnicity categories included in this project. At this time, revising this component of data collection would pose significant financial and logistical burdens on the collaborating sites, while also significantly impacting CDC's ability to implement proper sentinel surveillance and ensure interoperability/comparability with other existing data systems. Many local health department collaborators and other Federal partners are in the process of updating their data collection standards, and will have capability to collect more reliable and valid race/ethnicity data from the populations we serve within the next 12-18 months. Accordingly, the next revision or extension of this data collection will be designed to achieve full compliance with the Office of Management and Budget's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, also known as Statistical Policy Directive 15 (SPD-15).

A. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Two comments were received from members of the public during the 60-day comment period. The first comment was supportive of the proposed information collection; no contact information was provided by the submitter and no response was considered necessary. The second comment was submitted anonymously and was unintelligible, unrelated test and machine code, was non-substantive and no response was considered necessary.

A. 9. Explanation of Any Payment or Gift to Respondents

No payments, honoraria or gifts are provided to respondents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act applies to this information collection. Personally identifiable information (PII) is routinely collected locally but never transmitted to CDC. A Privacy Impact Assessment was completed and approved in 2018 and is being extended for this submission **(ATTACHMENT 11)**. The applicable system of records notice (SORN) is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC.

Reporting of gonorrhea or syphilis case data is required under state laws and regulations for notifiable disease reporting. These data are reported without consent of the individual by health care providers and laboratories to state or local health departments or through abstraction of medical records by state/local health department personnel. Data are reported voluntarily by state and local health departments to CDC and these activities are supported through cooperative agreements. Although identifiable patient-level case report data are collected by local health departments, the case report data are de-identified before they are transmitted to CDC.

The personally identifiable information (PII) that is collected locally through routine patient care or disease reporting efforts includes the patient's name, contact information (including street address and phone number), sex, race/ethnicity, and date of birth to facilitate patient investigations. PII is used locally for 3 purposes: (1) the address is used to verify that the patient resides in the participating jurisdiction and to complete routine case investigations, (2) the name and date of birth are used to verify the patient's identity for consent for treatment, partner services, or SSuN investigations, and (3) the contact information, including telephone number is used to contact patients for interview as well as re-contacting the patient for any required follow-up. These PII are maintained independent of data collected through the course of SSuN activities. None of the patient identifiers, such as patient names, medical record numbers, home address or zip codes, or birthdates, are included in records transmitted to CDC as a core requirement of this project. Census tract information is used only in the aggregate to identify health disparities in treatment, clinical outcomes and access to care based on distance from resident census tract to provider location or based on population characteristics of place to identify social determinants of health. Information on sex, sexual orientation, age and race/ethnicity are collected (**ATTACHMENT 5**) and transmitted to CDC in national case reporting and through enhanced SSuN because STIs disproportionally impact segments of the population.

In the data sent to CDC, respondents are identified only by a unique patient ID code. This non-name-based unique person ID is assigned by either the state or local health department, or the sentinel facility, and is created solely for the purposes of surveillance and not used for any other purpose at the participating clinical facilities. The unique patient IDs for the STI clinic patients are assigned and maintained only by the participating facility for this surveillance project. CDC cannot use these IDs to re-identify any individual patients seeking care in these facilities. In the case-based component of enhanced SSuN, the unique person ID code is assigned by the local health department to each gonorrhea or syphilis case using data on case reports submitted by providers/ laboratories pursuant to local reporting regulations. These records can only be re-identified at the local level. Data is encrypted and transmitted via CDC's Secure Access Management System (SAMS). At CDC, SSuN data are maintained on secure servers. Password-protected access is required, and directory-specific user access rights are assigned by a CDC data steward. Restricted access to STI data is provided to DSTDP/CDC scientists, researchers, and program managers on a need-to-know basis.

Written informed consent is not required of patients at any of the STI clinics for the collection of de-identified electronic clinical data elements routinely maintained in archived databases at the clinics. This is considered minimal risk, and the data collection could not be conducted if written informed consent was separately required. CDC does not receive any information in the clinical data abstracts that could be readily used to personally identify any individuals whose health record information is abstracted for the STD Surveillance Network.

For the case-based STI surveillance activities in Strategy B, state and/or local health departments initiate contact with, 1) individuals diagnosed with gonorrhea or syphilis, and 2) diagnosing healthcare providers for relevant clinical information about the care cases received. State/local health departments conduct SSuN case investigations under existing local public health authority to conduct infectious disease investigations. Under no circumstances does CDC contact any providers or conduct interviews with patients. All case investigations are conducted by trained local health department staff following applicable local confidentiality procedures. Individuals being contacted for interview are verbally consented over the phone or in person prior to the administration of the interview, consistent with local public health disease investigation protocols. Participants are informed that they may decline to participate without penalty, or if they agree to participate, they may refuse to answer any of the interview questions. They are informed that their data are anonymously combined with other patient responses and analyzed to improve STI/HIV prevention services for persons at increased risk of STIs in their area and that only aggregated data is ever released in published reports. Similarly, clinic patients provided an anonymous survey at registration for their visit may decline to fill out any information without penalty or impact on the clinical services offered or received.

The Surveillance and Data Science Branch (SDSB/DSTDP/CDC) is charged with the responsibility of maintaining the privacy, security, and scientific integrity of SSuN data. The CDC project data managers are designated as custodians of the SSuN data files and are responsible for observance of all conditions of use, and for establishment and maintenance of security arrangements to prevent unauthorized use. Access to the data is strictly limited to key members of the SDSB who are formally recognized as officers or collaborators of the study in the performance of their assigned duties. The SSuN Project Officer(s) and/or SDSB data stewards are responsible for granting access to SSuN data by other CDC staff in DSTDP as needed. The SSuN principal collaborators are promptly notified of any CDC personnel changes that affect access to the data for the project. All CDC staff with data access have completed, and remain current with, the annual Health and Human Services Information Security Awareness Training. A record of the completion of security training for all CDC staff is maintained by the CDC Information Technology Services Office (ITSO). CDC may retain enhanced SSuN data as long as the data are protected as described herein. CDC will annually review the need for the data with SSuN principal collaborators and shall destroy all copies of the data if it is determined that no further analyses will be conducted.

A. 11. <u>Institutional Review Board (IRB) and Justification for Sensitive Questions</u>

The approved Project Determination Form (**ATTACHMENT 9**) indicates that because the project is a routine disease surveillance activity, the protocol is exempt from review by CDC's IRB.

The collection of information about sexual behavior is sensitive because of stigma that continues to be associated with STD/HIV infection **(ATTACHMENT 10).** In addition, the modes of transmission of STIs (through sexual contact with partners) and contributing risk factors necessitate the collection of sensitive data, including sexual practices, drug use, and HIV status. Other sensitive data are collected about specific behaviors, experiences or conditions that have been shown to be associated with STDs. For SSuN, this includes the collection of STD and HIV testing, diagnoses, sex, sexual orientation, demographics, and HIV status of most recent sexual partners. Collection of these data are used to understand barriers to STD care and treatment, and the impact of behaviors and health conditions on the clinical course of STD/HIV disease. These data are also used to enhance STD prevention programs designed to reduce high-risk behaviors in persons most likely to transmit/acquire STD/HIV, in understanding sexual network dynamics and for modeling STD transmission and prevention interventions. Data on health insurance status and type are also collected. However, no specific identifiers associated with insurance status/type is collected or transmitted. Census tract information is collected only for the purposes of aggregate spatial analysis to better understand the geographic distribution of disease and risk.

Although the information requested from STD clinic patients and interviewed participants is sensitive, the purposes of SSuN cannot be accomplished without their voluntary collection. Collection of the data are used to understand barriers to engaging in protective behaviors and to accessing STD prevention services. The public health follow-up context in which patients are contacted and interview questions are asked provides a confidential framing to the encounter and helps to overcome patient concerns about providing sensitive information. There are several steps taken in SSuN to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Questions allow for responses of “don’t know” or “refuse to answer.”
- Locally developed consent scripts make it clear that data collection is sponsored by CDC in collaboration with the local health department and that the information will be put to important public health uses.
- The interview questions are carefully organized to lead smoothly from one topic to another.
- Transitions are clear to respondents and the need for the information explained for many sensitive questions.
- Assurances about the privacy of the information provided are reiterated.

All interviews are conducted by trained local/state health department staff in a private location or by phone at times convenient to patients. Interviewers are trained to administer informal consent; all interview questions are administered by reading each item verbatim in compliance with protocols, ensuring that all respondents receive the same information with respect to each question. Interviews are not attempted without positive identification as the appropriate respondent and verbal consent is obtained to discuss health related information.

SSuN data collection also includes sensitive information relating to sex of sexual partners, HIV status, number and characteristics of recent sex partners, anatomic sites of exposure, and alcohol and drug use. This information is routinely collected as part of clinical care for the patients seen in STD clinics and is also collected by local health departments during routine partner services for persons diagnosed with STDs. All participants are assured that the information will be used only in the aggregate, only for the purposes of this project and will be kept private to the extent allowable by law.

A. 12. Estimates of Annualized Burden Hours and Costs

The estimate of annualized burden hours increases from 5,863 hours to 7,510 hours for revisions of the current project. The overall annual burden estimate primarily increases because of the expansion of project capacity to include additional STD clinics. Modest reductions in burden also result from the retirement of selected data elements and activities as well as revised burden estimates for data management and registry matching, and these are reflected in the overall burden estimate.

The current respondents for the facility-based strategy of the SSuN project currently include 15 facilities in 11 collaborating state or local health departments (**ATTACHMENT 6**). The number of STD clinic managers is projected to increase to up to a total of 40 in subsequent funding cycles and this additional burden is reflected in this revision. STD clinic managers are responsible for electronically abstracting STD clinic visit data (all patient visits of STD clinics) from their facilities medical record systems and providing those data queries to the project’s data manager at the local level. Since the data are transmitted every other month, this reflects a revised burden of 960 hours (40 respondents x 6 data transmissions annually x 4 hours for preparing each transmission). Minimal changes proposed to the previously approved medical record data elements are not expected to add substantively to this data management burden. However, the overall number of data elements does not affect project burden hours because the data are collected through automated processes that extract data from existing clinical databases.

The respondents for the case-based portion of SSuN are individuals identified by state or municipal health departments as having been diagnosed with gonorrhea or early syphilis and reported by a provider or laboratory as required by local reporting regulations. Because the number of respondents can vary depending on the number of cases diagnosed and reported within the jurisdiction, the annualized estimates of respondent burden provided below represents the number of cases reported for 2021. There were 211,791 gonorrhea case reports and 41,095 cases of early syphilis reported across the 11 participating SSuN jurisdictions. Each of the sites is expected to sample approximately 7% of gonorrhea cases and a similar proportion of syphilis cases not provided partner services. The average interview success rate has historically been close to 40%, therefore we expect to interview approximately 7,000 respondents annually. On average, SSuN patient interviews take approximately 10 minutes to complete; 1,167 burden hours are estimated for this activity.

Each of the 11 local/state health department data managers will be responsible for any recoding and/or data validation necessary to produce correctly formatted datasets. Every month, alternating between facility and population-based activities, the 11 collaborating jurisdictions provide clean, validated datasets to CDC (transmission to CDC via SAMS every two months), with cumulative data back to the beginning of each calendar year. That reflects 5,280 total burden hours (11 respondents x 12 data transmissions x 40 hours). Required HIV registry matching is incorporated into the total burden hours for overall data management.

A.12a. Estimated Annualized Burden Hours

Type of Respondents	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden (in hours)**
Data managers at sentinel STD clinics (**Table B.1.A**)	Electronic Clinical Record Abstraction (**ATT5**)	40	6	4	960
General Public – Adults (persons diagnosed with gonorrhea)	Patient interviews for a random sample of gonorrhea and syphilis cases (**ATT5, ATT8**)	7,000	1	10/60	1,167
Data Managers: local/state health departments (strategy A) (**ATT6**)	Data cleaning/ validation, HIV registry matching and data transmissions for all activity components (**ATT5**)	11	6	40	2,640
Data Managers: local/state health departments (strategy B) (**ATT6**)	Data cleaning/ validation, HIV registry matching and data transmissions for all activity components (**ATT5**)	11	6	40	2,640
General Public – Adults (persons presenting for care in STD Clinics)	Clinic waiting room surveys	1000	1	0.08	80
Total	…………	…………..	…………..	………….	7,487

Estimated Annualized Burden Hours and Costs

Table A.12.B Annualized Cost to Respondents

The table (A.12.B) below presents the estimated annualized burden costs. The data managers at the clinics have an average hourly wage of $29.88 and the database administrators at the health department have an hourly wage of $31.69. The majority of the patient respondents will be of lower socioeconomic status. If employed, the majority are likely to be in service-related industries or para-professionals with an estimated average hourly wage of $17.96.

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics: https://www.bls.gov/oes/current/oes191041.htm, https://www.dol.gov/whd/minwage/mw-consolidated.htm, https://www.bls.gov/news.release/empsit.t19.htm

Type of Respondent	No of Respondents	Total Burden	Hourly Wage	Total Respondent Cost

		Hours	Rate	
Clinic data managers	40	960	$29.88	$28,685
Data Administrator at health department (strategy A)	11	2,640	$31.69	$83,662
Data Administrator at health department (strategy B)	11	2,640	$31.69	$83,662
Patients diagnosed with gonorrhea and/or syphilis	7,000	1,167	$17.96	$20,956
Patients presenting to STD clinics	1,000	80	$17.96	1,437
Total				**$218,402**

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents associated with this proposed collection of information.

A.14. Annualized Cost to the Federal Government

The annualized cost to the government is $8,257,713. The cost of this project for the three years is estimated to be $24,773,139. The annualized cost is summarized in Exhibit 14.A.

A14a. Estimates of Annualized Costs to the Federal Government*

Expense Type	Expense Explanation			Annual Costs (dollars)
Direct Costs to the Federal Government*	SSuN – Personnel			
	Epidemiologist-14	2	100%	$319,556
	Epidemiologist-13	1	50%	$58,892
	Public Hlth Advisor-13	2	100%	$270,418
	Data Analyst-14	1	50%	$63,501
	Data Analyst-12	1	75%	$74,346
	Cooperative agreement funds to 30 project areas/40 clinics			$7,400,000
	Travel (site visits)			$70,000
	Meetings			$1,000
	TOTAL COST TO THE GOVERNMENT			$8,257,713

*Salary estimates were obtained from the US Office of Personnel Management salary scale at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2023/general-schedule/

The personnel related to the enhanced SSuN data collection include 1 Lead Science Officer (epidemiologist) and 1 medical officer/epidemiologist at the GS 14 level, 0.5 Health Scientist (epidemiologist) at the GS-13 level, 2 project officers (public health advisor) at the GS-13 level, and 1.25 GS-12 and GS-14 level data analysts. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that are held include the principal investigator’s meeting that will be held in government space with associated printed material costs.

The information collection described in this request are currently funded through cooperative agreements with state and local health departments (CDC-RFA-PS19-1907). CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments.

Data for Enhanced STI Surveillance Network are compiled by staff in local health departments and sent via a secure network (SAMS). Data managers at CDC receive data from the data managers at the local health departments, track the progress of the data, and distribute bimonthly monitoring reports to health department staff. CDC processes all data sent from local health departments to produce clean, final datasets for use by CDC and/or the health departments. SSuN epidemiologists have responsibility for analyzing the final data set and work with data analysts to create data tables to be displayed in STI surveillance reports and other data products.

A.15. Explanation for Program Changes or Adjustments

The total annualized burden will change from 5,863 hours to 7,510. Specifically, the changes in the estimates of burden are primarily accounted for by the following:
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- Future expansion to include up to 40 STD clinical facilities

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data from enhanced SSuN continues to inform STI prevention and to inform a more comprehensive understanding of trends and determinants of STIs of interest, monitor public health program impact and provide a more robust evidence base for directing public health action. CDC regularly publishes an annual STI surveillance report using SSuN data collected. For instance, the 2023 data collection cycle results were published in November 2024 (for example, see https://www.cdc.gov/std/statistics/2020/default.htm). Analyses of these data are also distributed to the participating jurisdictions through monthly reports as well as through presentations of annual summary data presented at the enhanced SSuN annual principal investigators meetings.

These data have also been distributed through presentation at local, national and international conferences, publication in peer-reviewed journals. Local communities will continue to be informed of enhanced SSuN findings through multiple conduits of information. National data results will be released through national publications (ATTACHMENT 7) and presentations at conferences. Local data results will be reported back to the communities through means such as local publications, presentations to local STI prevention and community planning bodies and at local conferences and workshops.

CDC analyses will focus on the following key objectives in our next 3-year OMB period:

- Enhanced syndemic understanding of HIV, mpox and other STDs.

- Assess uptake of PrEP (Pre-Exposure Prophylaxis- the use of anti-HIV medication that keeps HIV negative people from becoming infected) among all patients attending STD clinical facilities.
- Trends in the incidence of STIs among sexual, racial and ethnic minority populations.
- Use of appropriate antimicrobial regimens to treat gonorrhea and syphilis.
- Evaluation of PrEP and EPT (Expedited Partner Therapy- the practice of treating sex partners of patients diagnosed with gonorrhea by providing prescriptions or medications to the patient to take to his/her partner without the healthcare provider first examining the partner) among persons diagnosed and reported with gonorrhea or syphilis from all provider settings.
- Understanding barriers to care or prevention services among persons diagnosed and reported with gonorrhea or syphilis.
- Document drug use and sexual risks among persons diagnosed and reported with gonorrhea or syphilis.
- Document HIV co-infection status, trends and incidence among persons diagnosed and reported with gonorrhea and syphilis and among all persons presenting for care in STD clinical facilities.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.