**STD Surveillance Network (SSuN)**

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**Title**

**Table of Contents**

**LIST OF ATTACHMENTS**

**Attachment 1** Legislative authority

**Attachment 2** 60 day Federal Register notice.

**Attachment 3.**

3.A Clinic-based surveillance: data elements

3.B Population based surveillance: data elements

**Attachment 4** List of Collaborators

**Attachment 5** IRB exemption—Determination of non-research

**Supporting Statement**

**Section**
**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection system called the STD Surveillance Network (SSuN) for 3 years. **Background**

The SSuN Project is an active Sexually Transmitted Disease (STD) sentinel surveillance network comprised of 12 surveillance sites around the United States. The purpose of SSuN is to improve the capacity of national, state, and local STD programs to detect, monitor, and respond rapidly to trends in STDs through active surveillance collection, reporting, analysis, visualization (e.g., mapping) and interpretation of disease information.

SSuN addresses the weaknesses in the current passive STD surveillance systems that do not associate risk behaviors with STD nor detect persons dually infected with STD and HIV.

The national passive STD surveillance system administered through the National Electronic telecommunication Surveillance System (NETSS) includes a limited number of demographic data elements (e.g. age, race/ethnicity, sex, and county) collected from all states for a limited number

of sexually transmitted diseases. The Gonococcal Isolate Surveillance Project (GISP) enhances the overall surveillance for gonorrhea susceptibility patterns and trends in the U.S. GISP is not designed to understand the clinical and behavioral characteristics of a broader population of patients with gonorrhea outside the STD clinic setting, nor does it inform CDC of any other diseases. While congenital syphilis is a critical problem when it occurs, it accounts for only a small percentage of all syphilis cases in the U.S., and case information gathered through the Congenital Syphilis Case Investigation and Report Form will not inform CDC about the broader population of patients with syphilis in the U.S. The Congenital Syphilis Case Investigation and Report Form is used by several U.S. reporting areas as a mechanism for providing CDC with morbidity data on congenital infections only. National-level data on HIV-STD co-infection in the U.S. from providers other than sexually transmitted disease (STD) clinics is largely unavailable for all sexually transmitted infections including *Chlamydia trachomatis, Trichomonas vaginalis,* primary and secondary syphilis, herpes, and others.

SSuN will address the needs of four of DSTDP's seven goals outlined in the division's 2009 Strategic Plan: (1) Prevent

STI-related cancers, (2) Prevent STI-related HIV transmission, (3) Strengthen STD prevention capacity and infrastructure, and (4) Reduce STD health disparities across and within communities and populations.

Stakeholders for data collected from the active surveillance programs funded by SSuN include STD program managers and other public health personnel, policy makers, health care providers, and the general population.

This activity is authorized under Section 301 [241] (a) of the Public Health Service Act (Attachment 1) and does not respond to any specific Congressional mandates.

Privacy Impact Assessment

Overview of the data collection system

SSuN will utilize two distinct surveillance strategies to collect information. The first is clinic-based STD surveillance which will abstract data from existing electronic medical records for all patient visits to participating STD clinics during the 3 year OMB time period in a standardized way from each of the 12 SSuN sentinel surveillance sites. The second strategy is population-based STD surveillance where interviews will be conducted, using locally designed templates, on 240 persons per site who are

randomly selected out of the total number of gonorrhea case reports received by each state.

Items of Information to be collected

Attachments 3a and 3b are comprehensive lists of all items of information to be collected by the CDC for SSuN clinic-based and population-based county surveillance activities. For clinic-based STD surveillance, the specified data elements will be abstracted on a quarterly basis from existing electronic medical records for all patient visits to participating clinics (Attachment 3a). Data in the electronic medical record may have been collected at time of registration, during the clinic encounter, or through laboratory testing. SSuN does not require modification of underlying electronic medical record systems for participation; each clinic's electronic medical record conforms to local data collection systems and needs.

SSuN sites will abstract data elements listed in Attachment 3a from the clinic's electronic medical record for transmission to CDC. These data elements that have been collaboratively defined and agreed upon by SSuN collaborators (both CDC and site participants) will be sent to CDC. Core data elements are those items of information

that should be transmitted for all patient visits every quarter. Core data elements include basic demographic, behavioral, and clinical information collaboratively identified as being necessary for routine SSuN monitoring activities (Attachment 3a). In addition, SSuN sites have collaboratively defined a set of standardized data elements that will only be sent to CDC when a specific analysis has been identified as being of public health importance. Both the core and standardized data elements will be transmitted to CDC in the collaboratively-defined, common SSuN format. All SSuN sites will also be conducting population-based STD surveillance in which a random sample of patients reported with gonorrhea in the counties participating in SSuN are contacted for interview by phone or in person. Each site is expected to obtain a common set of items of information on 240 patients reported with gonorrhea each year. Items of information to be elicited from these patients include demographic, risk behavior, and clinical information related to infection with gonorrhea. The complete list of items of information are listed in Attachment 3b. Although SSuN collaborators (both CDC and participating sites) have agreed upon the formats in which the information will be transmitted to CDC, each site has developed or adapted site-

specific data instruments to conform to public health program needs.

For both clinic-based and population-based STD surveillance activities, data will be collected and edit-checked on a quarterly basis by the participating SSuN state or local health department prior to transmission to CDC. Although information in identifiable form (IIF) is collected by these clinics as a routine part of providing clinical care, all potentially identifiable information (e.g., name, date of birth, medical record number, social security number) will be removed prior to transmission to CDC; thus, CDC will receive no sensitive information that can be linked back to any individual. All SSuN records will contain a non-identifiable unique identification number (for each patient) as well as a unique event identification number (for each visit).

CDC will provide edit check statistical algorithms programmed in the Statistical Analysis System (SAS), to assist with local data cleaning. All data will be transmitted to CDC as a SAS file in the collaboratively defined SSuN format, encrypted using SEAL or PGP, via the Secure Data Network (SDN). Sites may use the Secure File Transfer Protocol (FTP) established by CDC to transmit non-data information. All data will be transmitted to CDC

through a single agreed-upon point of contact from each SSuN site.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.

SSuN does not have a website and SSuN data will not be posted on the internet.

**2. Purpose of Use of the Information Collection**

SSuN will be an active surveillance system for dual infections of HIV and STDs. Clinical and behavioral data on persons infected with notifiable STDs are essential elements to guide local interventions to prevent STDs and their complications.

CDC envisions that the 12 sentinel sites will continue to serve with enhanced capacity for applied epidemiology and timely response. Associating STDs with clinical, demographic, and behavioral information at the local level reveals 'hot-spots' of health disparities and enables prevention strategies that are tailored to specific populations.

Privacy Impact Assessment Information

SSuN will collect sensitive information on sexual and drug-using behaviors associated with the case-patient identified only as a case identification number. Participating clinics

collect patient information in identifiable form (IIF) as a routine part of providing clinical care. This information will continue to exist locally and never be accessed directly by CDC. No IIF will be included in the data sets transmitted to CDC. The proposed data collection will have no effect on the respondent's privacy. Social Security numbers will never be collected.

A unique project identification number will be assigned to each case. All IIF (e.g., name, date of birth, local medical record number) will be stripped and de-linked before data are sent to CDC via CDC's Secure Data Network (SDN) as an encrypted file. The key to link data will only be available at the local level. At CDC, SSuN data will be maintained on secure servers behind the CDC firewall. Password-protected access will be required and directory-specific user access rights will be assigned by a CDC data steward. Restricted access to STD data is provided to DSTDP/CDC scientists, researchers, and program managers.

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

*Clinic-based STD Surveillance*

Data will be abstracted from routine, pre-existing electronic and/or hard-copy STD clinic medical records and sent to CDC in a common SAS format. STD clinic data to be transmitted to CDC for SSuN will be periodically edited by trained personnel using a CDC-designed edit check program. Data will be uploaded on a quarterly basis by trained data managers at collaborating sites to the SDN. Data will be downloaded from the SDN, stored, and maintained at CDC by a data manager in the Statistics and Data Management Branch of the National Center for HIV, Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC on at least a quarterly basis. Site visits, regular communication with CDC, and data quality checks will provide opportunity for evaluation and troubleshooting of these processes.

*Population-based STD Surveillance*

Results of interviews will either be entered directly into a Microsoft Access database during the interview or will be transcribed from interview notes into the Microsoft Access database, depending on local protocols. Interview notes will remain confidential and secure based on local protocol. As with clinic-based STD surveillance, data will be periodically edited by trained personnel using a CDC-

designed edit check program. Data will be uploaded by trained data managers at collaborating sites to the SDN on a quarterly basis. Data will be downloaded from the SDN, stored, and maintained at CDC by a data manager in the Statistics and Data Management Branch of the National Center for HIV, Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC on a quarterly basis. Site visits, regular communication with CDC, and data quality checks will provide opportunity for evaluation and troubleshooting of these processes.

**4. Efforts to Identify the Duplication and Use of Similar Information**

CDC is the only agency that conducts national STD surveillance through the funded assistance of state and local health departments. There is no known federal Department or Agency which describes the national and regional distribution of STD morbidity by clinical exam findings, nor is this information available from other sources within our Department. CDC has also verified through the Council of State and Territorial Epidemiologists (CSTE), state and local STD prevention programs and, the National Coalition of STD Directors, that there is no other nationwide collection of STD-specific morbidity information.

CDC has also confirmed the absence of duplicate information systems in the U.S. through literature searches and communication with other health professionals and organizations. Program reviews were conducted to identify potential areas of duplication; however, none were found. The Program Evaluation and Monitoring System (PEMS) of the Division of HIV/AIDS Prevention collects HIV-related information at STD clinics using their standardized case report form. However, the PEMS form collects only HIV testing and counseling information and not STD information.

STD morbidity surveillance does collect demographic, clinical, and laboratory data but is a passive surveillance system and does not combine clinical findings data, drug use data, and random population-based sampling of gonorrhea patients as SSuN does.

**5. Impact on Small Business or Other Small Entities**

No small businesses will be involved in this data collection.

**6. Consequences of Collecting the Information less Frequently**

STD control is dependent upon the rapid identification of changes in disease transmission. SSuN data will be reported to the CDC on a quarterly basis which is required to allow for the early detection of potential STD outbreaks. Earlier detection should support earlier implementation of prevention and control efforts resulting in prevention of additional STD transmission. If these data are not available, CDC, state, and local health departments will not have the necessary tools to make data-based decisions regarding national prevention program planning and resource allocation.

Information for the SSuN project will be collected on a quarterly basis in order to balance the need for timely information and the need to minimize burden on collaborating clinics and departments of health.

**7. Special Circumstances relating to the Guidelines of 5 CFR1320.5**

This request fully complies with the guidelines of 5CFR 1320.5.

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

A 60-day Federal Register Notice was published on February 20, 2009 in Vol 74, No 33 of the Federal Register. No comments from the public were received.

From September 2008 to March 2009, weekly SSuN collaborative conference calls were held with participating collaborators from all SSuN sites to determine the availability of data, reasonable frequency of data collection, the clarity of instructions and record keeping, and data elements to be recorded, disclosed, and reported. From December 2-4, 2008, a SSuN collaborators' meeting in Atlanta, GA included discussions on the frequency of data collection and the data elements to be collected, disclosed, and reported given the importance of minimizing the burden on collaborating clinics and departments of health. All sites have confirmed that the data are available and that they will send them to CDC on a quarterly basis.

A list of collaborators can be found in Attachment 4.

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

No payments or gifts are provided to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

The Information Collection Review officer has decided that the Privacy Act does not apply to this request.

To protect the confidentiality of persons attending STD clinics and reported with STDs, state and local surveillance program staff shall not send any IIF to CDC. The census tract of the patient's residence will be used to identify health disparities in treatment, clinical outcomes and access to care based on distance from resident census tract. SSuN data will be accessible only to the 12 sentinel sites and CDC staff. No public use data sets are envisioned. Census tract data may be used to link SSuN data to US census data and other complementary data sources, and any resultant datasets will also be stored on a secure server with restricted access.

CDC will receive only a SSuN site-assigned case number that does not include any IIF. Respondents will be STD clinic patients, and the unique Case ID assigned by the State is not a number that in and of itself can lead to the identification of an individual.

*Clinic-based STD surveillance*

All SSuN participating sites are public health departments, covered entities under HIPAA regulation: (HIPAA Privacy

Rule, Disclosures for Public Health Activities, 45 CFR 164.512 (b)). Data sent to CDC will contain no personal identifiers such as name, social security number, date of birth, street address, or medical record number.

*Population-based STD surveillance*

State and/or local health departments will contact individuals for interviews. CDC will not have access to IIF or conduct any interviews with patients. Verbal consent will be obtained prior to the administration of the telephone survey. Individuals being contacted for interviews will offer verbal consent over the phone or in person prior to the administration of the survey.

The NCHHSTP Associate Director of Science has determined that this project is not research and does not involve human subjects.

**Privacy Impact Assessment Information**

This project is not subject to the Privacy Act.

The state or local health department will encrypt data prior to transmission using either Software Encryption Algorithm (SEAL) or Pretty Good Privacy (PGP, data encryption software). Sites will send encrypted SSuN data to CDC through the SDN. CDC agrees to accept and securely store these data at headquarters in Atlanta. SSuN data will not

be integrated into NETSS datasets by CDC, but will be stored separately on a secure server with restricted access.

The Division of STD Prevention, Statistics and Data Management Branch, is charged with the responsibility of maintaining the security and confidentiality as well as the scientific integrity of all SSuN databases. Darlene Davis and Jim Braxton (Project Data Managers) will be designated as custodians of the SSuN data files, and will be responsible for observance of all conditions of use, and for establishment and maintenance of security arrangements to prevent unauthorized use. Access to the data shall be limited to key members of the Division of STD Prevention who are integral officers and collaborators of the study in the performance of their assigned duties. The SSuN Project Officer will be responsible for granting access to SSuN data by other CDC staff in the Division of STD Prevention as needed. The SSuN Principal Collaborators will be promptly notified of any CDC personnel changes that affect access to the data for this project. All CDC staff with data access have completed, and will 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 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 analysis will be conducted.

**11. Justification for Sensitive Questions**

Sensitive information elements reported to CDC as part of the SSuN study are limited to sexual and drug-using behaviors associated with the STD case report (Attachment 3b). Sexual and drug-use behaviors impact STD distribution and epidemiology. These sensitive elements are essential to better understand the sexual practices that increase the risk of transmission or acquisition of the STDs. This information will help CDC formulate more efficient intervention strategies and evaluate the impact of ongoing control efforts. For clinic-based STD surveillance, these questions will be asked as part of routine health care interviews for patients seeking health care. For population-based STD surveillance, these questions will be

asked as part of the follow-up interview with patients identified as having gonorrhea.

In the U.S., racial and ethnic minorities are disproportionately affected by STDs and HIV, and one of CDC's Division of STD Prevention's major goals is to reduce STD health disparities across and within populations and communities. It is essential to collect the race and ethnicity of each respondent in order to provide useful information to guide interventions to reduce health disparities from STDs and their complications.

**12. Estimates of Annualized Burden Hours and Costs**.

The respondents for the clinic-based portion of the SSuN project are the 12 SSuN collaborating state or local health departments (=sites (Exhibit B.1.A)) There are a total of 42 STD clinics that report to the 12 health jurisdictions. Each health department will abstract line-listed clinic data on all patient visits entered into their STD clinic database. On a quarterly basis, the 12 collaborating sites will consolidate the data for the previous quarter, encrypt and transmit the dataset to CDC via the SDN.

The respondents for the population-based portion of the SSuN project are members of the general public identified by state or municipal health departments as having a gonorrhea

case report. In 2007 there were 72,642 such case reports (Exhibit B.1.B). Each of the 12 collaborating SSuN sites will interview 240 people who have a gonorrhea case report per year for a total of 2880 persons with STD case reports interviewed by all 12 sites.

Exhibit A.12.A

| Type of Respondent | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|
| SSuN site | 12 | 4 | 2 | 96 |
| Gonorrhea Case | 2880 | 1 | 7/60 | 336 |
| Total | | | | 432 |

B. Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B for both the STD Clinic and the population-based surveillance. The hourly wage rate for Clinic portion is based on the average rate reported by the US Office of Personnel Management, 2009 General Schedule (GS) Locality Pay Tables (http://www.opm.gov/oca/09tables/indexGS.asp). We estimated the hourly wage for cases of gonorrhea to be minimum wage ($7.25/hour) as outlined by the US Department of Labor (http://www.dol.gov/esa/whd/flsa/#min).

Exhibit A.12.B: Estimated Annualized Burden Costs

| Type of Respondent | Total Burden hours | Hourly Wage Rate | Total Respondent Cost |
|---|---|---|---|
| SSuN site | 96 | $15.00 | $1,440.00 |
| Gonorrhea Case | 336 | $7.25 | $2,436.00 |
| **Total** | **432** | | **$3,876.00** |

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

There are no costs to respondents other than their time.

## 14. Annualized Cost to the Federal Government

The cost of the project for the 3 years is estimated to be $5,319,000, or $1,773,000 annually. The annual cost is summarized in Exhibit A.14.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government.

| Expense Type | Expense Explanation | Annual Costs (dollars) |
|---|---|---|
| Direct Costs to the Federal Government | CDC Project Officer (O-5, .5 FTE) | $95,000 |
| | CDC Co-Project Officer (0-4, .25 FTE) | $45,000 |
| | CDC Medical Epidemiologist (0-4, .25 FTE) | $45,000 |
| | CDC Co-Principal Investigator (GS-13, .25 FTE) | $31,000 |

| | | |
|---|---|---|
| | CDC Computer Programmer (GS-13, 0.25%) | $35,000 |
| | CDC Data Management (GS-12, .25 FTE) | $25,000 |
| Operational | Travel (site visits) | $5,000 |
| | Meeting expenses | $3,000 |
| | Subtotal, Direct Costs to the Government | $253,000 |
| Contractor and Other Expenses | Public Health Analyst I (contractor, .4 FTE) | $20,000 |
| | Alabama Site Cost | $125,000 |
| | Baltimore Site Cost | $125,000 |
| | Chicago Site Cost | $125,000 |
| | Colorado Site Cost | $125,000 |
| | Connecticut Site Cost | $125,000 |
| | Los Angeles Site Cost | $125,000 |
| | Louisiana Site Cost | $125,000 |
| | New York City Site Cost | $125,000 |
| | Philadelphia Site Cost | $125,000 |
| | San Francisco Site Cost | $125,000 |
| | Virginia Site Cost | $125,000 |
| | Washington Site Cost | $125,000 |
| | Subtotal, Contracted Services | $1,520,000 |
| | TOTAL COST TO THE GOVERNMENT | $1,773,000 |

*Salary estimates were obtained from CDC Financial Management Office.*

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

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

**Exhibit A.16: Project Time Schedule**

| Activity | Time Schedule |
|---|---|
| Beginning of data collection | At the time of OMB approval |
| Beginning of data analysis | 4 months after OMB approval |
| Development of data report | 4 months after OMB approval |

The processes of collection and analysis will continue for the duration of the project, and the development and distribution of data reports will be repeated on a quarterly basis throughout the duration of the project.

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

No paper-based data collection form supports the collection of the STD morbidity case report variables. Collaborating partners abstract relevant data from their own information systems into the record format for reporting to CDC. Therefore, there is no physical form on which to display an OMB expiration date and no such exception is requested.

**18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)**

There are no exceptions to the certification.