

# **Enhanced STD Surveillance Network (eSSuN)**

**OMB No. 0920-new**

## **SUPPORTING STATEMENT A**

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## **A. JUSTIFICATION**

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

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests a 3-year approval for a new data collection entitled, “Enhanced STD Surveillance Network (eSSuN)” as part of a sentinel surveillance system to better understand community burden of disease, identify syndemic patterns and populations at greatest risk, assess relevant clinical services and monitor long-term health consequences of STDs. This surveillance activity is funded by CDC and will be conducted at ten (10) state and local health departments in the United States. This research is authorized under Section 301 (Sec. 241) of the Public Health Service Act (**Attachment 1A**).

National STD case reporting data is the primary source for reporting, analysis, and interpretation of trends in the incidence, prevalence and societal impact of chlamydial infection, gonorrhea and syphilis in the United States and U.S. Territories. However, data derived from the national case reporting system are limited, incomplete and insufficiently timely. For example, case report data often lack complete information on the race and Hispanic ethnicity, gender of sex partners, and other essential epidemiologic and health care information on persons diagnosed with STDs. STD case reporting is also subject to significant reporting and analysis delays at the national level; identification and understanding of important, emergent disease trends may not be available in a timely manner through routine case reporting data. Moreover, case reporting data provide little information for understanding key populations at risk, especially sexual minorities such as men-who-have-sex-with-men (MSM), transgendered individuals and racial/ethnic minorities. Information needed to better understand gaps and opportunities in sexual health services, such as STD screening, is not provided at all through case reporting at the national level. Additionally, the Enhanced STD Surveillance Network will address the impact of innovations in health information technology and provide unique opportunities for modernizing STD surveillance practice.

The Enhanced STD Surveillance Network is comprised of 10 surveillance sites around the United States. The purpose of eSSuN is to be a robust platform for the timely identification of STD trends, monitoring of STD epidemiology and evaluating the effectiveness of public health interventions through active surveillance, reporting, analysis, visualization (e.g., mapping) and interpretation of disease and STD-related clinical information.

The Enhanced STD Surveillance Network is aligned with priorities of the Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and Tuberculosis Prevention as well as CDC-wide priorities. They include the following:

- (1) Focus on DSTDP programmatic priorities of men who have sex with other men (MSM), sexual health, adolescents and young adults and gonorrhea resistance, and,

- (2) Support program collaboration and service integration and prevention through healthcare initiatives, and,
- (3) CDC-wide priority of strengthening surveillance systems.

## **A. 2. Purpose and Use of Information Collection**

The purpose of the information collection is to improve national capacity to detect, monitor, and respond to emerging trends in STDs and related behaviors. The goals of this activity are to inform a more comprehensive understanding of trends and determinants of STDs of national interest, monitor public health program impact and provide a robust evidence base for directing public health action.

These surveillance activities will be conducted in the following state and local health departments: (1) California Department of Public Health, (2) Washington Department of Public Health, (3) Massachusetts Department of Public Health, (4) New York City, (5) Philadelphia, (6) San Francisco Department of Public Health, (7) Baltimore, (8) Minnesota, (9) Multnomah County (Oregon), (10) Florida Department of Health. These 10 sites were among 26 sites that competed for this cooperative agreement and were selected for funding as a result of an objective review process conducted in June 2013.

This project will utilize two distinct strategies to collect the required surveillance information. The first strategy employs facility-based sentinel surveillance, which will abstract standardized data from existing electronic medical records for all patient visits to participating STD clinics and female patients aged 15-44 years of age visiting participating family planning/reproductive health clinics (or other facilities such as school-based clinics and federally qualified healthcare centers) during the project period. The second strategy is population-based STD surveillance among a random sample of reported gonorrhea cases. Sampled cases will be contacted for standardized interview and additional information will be obtained from health department case investigations. The sample size will be 250 completed enhanced case investigations and interviews in lower morbidity jurisdictions or 2.5% of total gonorrhea morbidity if annual cases exceed 10,000 in the participating jurisdiction. The sample will be selected from the universe of all records indicating gonorrhea infection received through routine public health case reporting by the collaborating health department.

The primary outcomes are:

- Information addressing gaps in national case reporting data and epidemiologic questions relevant to notifiable STDs through case sampling for enhanced population-based surveillance
- Sentinel surveillance in provider settings serving specific populations of importance to STD transmission such as men-who-have-sex-with-men(MSM) and women

### **Proposed Data Collection**

The proposed data collection is necessary for effectively implementing sentinel and population-based surveillance activities constituting the core functions of the network. Data obtained

through these methods has significant utility to the government, the state and local STD programs participating in the project, as well as other STD prevention partners and stakeholders.

The proposed data collection with frequency of administration for both components of the project will include:

Activity	Attachment number
<b>Sentinel surveillance in clinics:</b>	
Electronic transmission of clinical variables routinely collected as standard of care by the facilities/networks (STD clinics, FP/RH, federally qualified healthcare centers, and school-based clinics) and available clinic’s medical records systems (electronic transmittals once every 2 months); this activity will occur for 3 years in clinics participating in the network).	3B
<b>Population-based surveillance among gonorrhea cases:</b>	
Matching of sampled gonorrhea cases to existing disease and laboratory registries within the health department to document recent history of notifiable disease of interest (STDs, HIV, TB, viral hepatitis, etc.), rule out duplicate records, and document multiple tests across multiple anatomic sites. This activity will occur for 3 years in state/local health departments participating in the network. Electronic transmittals of data to CDC will occur once every 2 months, alternating with the sentinel surveillance activity.	3C
Ascertainment of additional clinical characteristics of the sampled cases, (information will be obtained from all available data sources). This activity will occur for 3 years in state/local health departments participating in the network. Electronic transmittals of data to CDC will occur once every 2 months, alternating with the sentinel surveillance activity.	3C
Interviews to obtain behavioral and demographic information with gonorrhea patients in the random sample of cases; this activity will occur for 3 years in state/local health departments participating in the network. Electronic transmittals of data to CDC will occur once every 2 months, alternating with the sentinel surveillance activity.	3D

The data collection activities are described in full detail in Attachments 3A and 3B.

Sentinel surveillance in clinical settings

The clinic data managers will electronically transmit de-identified clinical variables routinely collected as part of clinical care to funded staff at state and local health jurisdictions. Data are de-identified and recoded by local and or state health departments and then transmitted to CDC through secure file transport mechanisms every two months (alternating with eSSuN’s population component).

The following data elements for clinic patients (all STD clinic attendees and women aged 15-44 years attending FP/RH and other clinics) will be electronically transmitted to CDC (for a three-year period beginning on the date of OMB approval).

- Demographics (biological sex, race/ethnicity, age)
- Insurance status (e.g., Private, Public, Uninsured, Unknown)
- Type of clinic visit, primary reason for encounter, self-reported pregnancy status
- Contraception (FP/RH only)
- Contact to STD
- Pelvic exam
- Date first tested HIV positive
- Gender of sex partners and sexuality (STD clinics only)
- New sex partners
- Anatomic sites of exposure
- Expedited Partner Therapy
- STD and HIV history
- Recent antibiotic use and travel
- Symptoms and clinical signs
- Diagnosis, laboratory and treatment information

#### Population-based surveillance among a representative sample of gonorrhea cases

Staff at state and local health jurisdictions collaborating in eSSuN will select a probability sample of gonorrhea cases reported to their health department. Sampled records will be matched with existing disease and laboratory registries within the health department to determine if the patient has previously been reported for any notifiable disease of interest (STDs, HIV, TB, viral hepatitis, etc.) and to document the patient's recent history of STDs. Laboratory data associated with the patient and the specific episode of disease/infection will be obtained and documented to capture tests and infections across multiple anatomic sites. For each sampled record, additional information about the case's clinical characteristics and the specific care setting where the patient was diagnosed, that were not present in the original case or laboratory report, will be collected through direct contact with providers or through other existing supplemental health department data sources. Patient interviews will be conducted for the sampled cases, either by phone or in-person, to obtain critical behavioral information about disease exposure, diagnostic care and treatment received and to complete or confirm patient demographics. At least 3 documented attempts will be made to contact sampled patients to complete the interview. Sites will develop locally focused protocols and/or data collection instruments (paper and/or electronic) and will provide comprehensive interviewer training. Sites are also required to address local human subject's requirements before data collection begins. Where not otherwise formally specified, verbal informed consent will be obtained from patients prior to eliciting information; local consent requirements and compliance will be documented in local protocols.

The following data domains will be collected for all sampled cases, in addition to core report information routinely reported for all cases. Data will be securely transmitted to CDC (for a three-year period beginning on the date of OMB approval).

- Sample status, sample date, date record received at department of health
- Previous patient information (match of HIV registry, prior history of STDs)
- Unique identifier of diagnosing facility/provider
- Demographics (sex, race/ethnicity, age, county of patient residence, census tract of residential address)

- Clinical (diagnosis date, anatomic site of infection)
- Provider name, provider address, facility type
- Date of visit, provider type
- Insurance status
- Clinical signs
- Anatomic site tested and anatomic sites positive
- HIV testing
- Gender of sex partners
- Treatment (treatment status, medication prescribed)
- Expedited Partner Therapy
- Prevention counseling and/or referrals
- Patient ID and contact attempts/dates, interview disposition
- Demographics (age at diagnosis, county FIPS code, and race/ethnicity)
- Insurance type, out of pocket expense, medical home, proximity of patient to provider
- Date of last visit
- Symptomatic status, length of symptoms, contact exposure
- Reason for going to specific doctor
- Patient counseling for avoiding re-infection, partner tested/treated, abstain from sex until Treatment complete
- Expedited partner therapy (offered, fill prescriptions for partners,)
- HIV testing (offered, current and previous testing, results, date of testing)
- Gender of sex partners and self-report sexual orientation
- Risk behavior (exchange sex/drugs for sex, date of last sex episode,

For both facility-based and population-based STD surveillance activities, funded jurisdictions are required to institute rigorous procedures to assure the quality and validity of data before submitting to CDC. In collaboration with data managers in each jurisdiction, CDC will prepare protocols for data validation that will provide for appropriate quality assurance. No eSSuN data received at CDC will ever include patient names, social security numbers, email addresses, home addresses, zip code, telephone numbers or medical record numbers. All records will be assigned a unique event identification number (for each visit) as well as a unique patient identification number by the corresponding state/local health department. CDC will only receive these de-identified codes and will not have the ability to link IDs to medical record numbers or any other patient identifying information. Sites will send data through CDC's Secure Access Management System (SAMS) using RSA-standard encryption methods. CDC will accept and securely store these data, accessible only to the eSSuN project staff. Enhanced STD Surveillance Network data will not be integrated into other datasets maintained by CDC and will at all times be stored on secure servers with fully restricted access.

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

#### *Facility-based Sentinel STD Surveillance*

Data will be abstracted from pre-existing electronic medical records in collaborating clinical facilities and sent to CDC through state/local health departments in standardized SAS data formats. Data will be uploaded every two months by trained data managers at collaborating sites. Data will be received, stored, and maintained at CDC by a data manager in the Surveillance and

Data Management Branch of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data will be monitored by CDC for every data transmission. Site visits, regular communications with collaborating health departments, and data quality checks will provide opportunities for evaluation and troubleshooting of these processes. Automation of processes wherever possible will be required at the local level to significantly lessen the burden on collaborating health department staff.

#### *Population-based STD Surveillance*

Data obtained for the population component will come from numerous sources within the health department and will be locally merged, recoded and appropriately structured to facilitate appending into the national Enhanced STD Surveillance Network datasets. CDC will provide standardized SAS data structures with variable names, lengths and types defined for all requested datasets. Funded jurisdictions will complete data verification and validity checks on datasets prior to transmission to CDC. In collaboration with data managers in each jurisdiction, CDC will require protocols for data validation that will provide for appropriate quality assurance. Jurisdictions will assure validity of the data prior to transmission. Record-level data will be transmitted to CDC through SAMS every 2 months, alternating with the facility component data transmissions. Datasets received at CDC will be validated and appended to the national Enhanced STD Surveillance Network database within two weeks of receipt. Automation of processes wherever possible will be required at the local level to significantly lessen the burden on collaborating health department staff.

#### **A. 4. Efforts to Identify 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 other federal agency or department with responsibility for monitoring the national and regional distribution of STD morbidity by clinical exam findings and other behavioral information, nor is this information available from other sources within CDC. 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 such as proposed for eSSuN. Efforts have been made to prevent duplication of effort, including conducting extensive, systematic searches of electronic databases of published articles and abstracts, attending local and national conferences relevant to the topic, communication with non-federal colleagues at state and local health departments as well as colleagues within the government. Apart from the proposed project, this type of surveillance activity and data collection are not currently being conducted specific to nationally notifiable STDs.

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

No small businesses will be involved in this study. Further, the study will not impact small businesses, including health departments, non-profit organizations, dentist or physicians' offices, or CBOs.

#### **A. 6. Consequences of Collecting the Information Less Frequently**

Sexually transmitted disease control is critically dependent upon the rapid identification of changes in disease transmission. Enhanced STD Surveillance Network data will be reported to the CDC on a monthly basis (alternating between facility and population component datasets). Earlier detection of trends and emergent issues will support timelier 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 information to make evidence-based decisions regarding STD prevention program planning and resource allocation.

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

There are no special circumstances relating to the guidelines of CFR 1320.5.

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

A 60 day federal register notice (**Attachment 2A**) to solicit public comments was published in the Federal Register on 08/11/2014, Volume 79, and Page number 46825-46827. One non-substantive comment was received in response to the 60-day Federal Register notice and the standard CDC acknowledgement was forwarded (**Attachment 2B**).

The development of the project, including the protocol and data collection instrument, has been a collaborative effort among investigators at CDC, and the ten participating state/local health departments. From September 2013 to November 2014, monthly Enhanced STD Surveillance Network collaborative conference calls were held with participating collaborators from all sites to determine the availability of data, reasonable frequency of data collection, the clarity of instructions and record keeping data management processes and data elements to be collected and reported. On February 4-5, 2014, the Enhanced STD Surveillance Network collaborators' met in Atlanta, GA. Comprehensive discussions on the frequency of data collection and the data elements to be collected and reported were held with consideration given to 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 every month (alternating months between facility and population component). A list of collaborators can be found in **Attachment 4A**.

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

No payments or gifts are provided to respondents.

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

The Privacy Act does not apply to this data collection.

##### **A.10.1 Privacy Impact Assessment Information**

The Privacy Act does not apply to this data collection. No personally identifiable information

will be received by CDC. CDC will not collect, or have access to, patient names, social security numbers, medical record numbers, home address, zip codes, email address or dates-of-birth. In the data sent to CDC, patients will be identified only by a unique patient identification number. The unique patient identification number, assigned by the state or local health department, cannot be used to identify any individual patients. CDC will not have the ability to link these patient identification numbers to a medical record number or any other potentially identifiable data.

*Facility-based activity:*

Written informed consent was not required at any of the facilities for the collection of de-identified electronic clinical data elements maintained in databases at the clinical facility. There is minimal, or no, risk to the patient; data collection could not practicably be conducted if written consent is required.

The data transmittals will not contain any personal identifiers (patient name, initials, social security number, or medical record number). Patients will be identified in the database by a unique patient identification number and CDC will not receive any information that could be used to personally identify any data records.

*Population-based activity:*

State and/or local health departments will have access to identifying information to contact individuals for interview. This is consistent with their existing authority to investigate reports of notifiable diseases for routine surveillance purposes. However, under no circumstances will CDC have access to personal identifiers or direct contact with patients. Verbal consent will be obtained by state and local health departments prior to the administration of interviews consistent with local, routine procedures for patient contact. Participants are informed that participation in the interview is voluntary and refusal to participate is at no risk or harm to them. Data collected will include information on patient demographics, clinical and treatment history, behavioral and risk factors, previous STD/HIV history, provider type and insurance status. In records sent to CDC, unique persons with gonorrhea will be identified by a non-name-based patient identification number.

With respect to assurance of privacy, none of the data received by CDC will be identifiable, and no information will be used for purposes other than those explicitly defined in protocols for the current surveillance project. Patients at all sites retain their right to refuse participation in the interview portion of the investigation.

*Data Transmittals and Safeguards*

Data transmission from sites to CDC will be restricted to CDC's Secure Access Management Services (SAMS). SAMS is an approved federal information technology system that provides authorized, validated users secure, encrypted access to CDC file transfer applications. The encrypted data will be stored in a secure CDC server with strictly controlled and restricted access rights.

The Division of STD Prevention, Surveillance and Data Management Branch, is charged with

the responsibility of maintaining the privacy, security, and scientific integrity of all eSSuN databases. The Data Managers will be designated as custodians of the eSSuN data files and will be responsible for assuring all conditions of use and for security arrangements to prevent unauthorized use of, or access to eSSuN data. Access to the data shall be limited to specific eSSuN staff members of the Division of STD Prevention and designated collaborators of the study in the performance of their assigned duties.

The eSSuN Project Officer(s) will be responsible for granting access to eSSuN data by other CDC staff in the Division of STD Prevention as needed. The eSSuN Principal Collaborators will be promptly notified of any CDC personnel changes that affect access to the data for this project. All CDC personnel 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). State and local surveillance program personnel agree to abide by the Data Security and Confidentiality Guidelines for NCHHSTP. These guidelines can be accessed at the following link: (<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>) and will be required to document compliance as part of annual project reporting.

#### *Institutional Review Board (IRB) Approvals*

This project has received a determination of non-research (as a routine disease surveillance activity) by the NCHHSTP Associate Director of Science, waiving the necessity for review by CDC's Institutional Review Board. State and local collaborators are required to obtain waiver or IRB approval as appropriate for conducting project activities in their jurisdictions.

Informed Consent: Not required for eSSuN activities.

Local collaborators retain full control of and rights to analysis, research, and publication of their locally collected data, regardless of whether these data are also provided to CDC as part of SSuN activities. Principal Collaborators may request and receive multi-site SSuN dataset for specific analytic purposes provided the SSuN Project Officer and the Principal Collaborator (or designated representative) of sites contributing data have reviewed and approved the analysis proposal. Proposals for such analyses must include all of the information required in SSuN protocols prior to consideration for approval. Analyses and dissemination of SSuN multi-site data, used for peer and non-peer reviewed manuscripts, technical reports, manuals, and presentations will require the written approval of CDC and every SSuN site that has contributed data for that analysis. All publications with a CDC author must be cleared through DSTDP/NCHHSTP/CDC clearance. Analyses will only present data in aggregate; no record level data will be released or published.

CDC may retain eSSuN data for appropriate analytic purposes as long as the data are protected as described herein. CDC will annually review the need for the data with eSSuN Principal Collaborators and shall destroy all copies of the data if it is determined that no further analysis will be conducted. No name-based records are received through the Enhanced STD Surveillance Network; no system of records is being created.

#### **A. 11. Justification for Sensitive Questions**

A subset of data collected in both the clinic and the population components of eSSuN (**Attachment 3B, 3C, 3D**) are of a sensitive nature, including questions related to patient's insurance status/ out-of-pocket expenses for clinic visit, gender of sex partners, anatomic sites of exposure and behavioral risk behaviors.

Information on the proportion of patients with insurance or costs for out-of-pocket expenses for routine preventive screening must be monitored over time to assess cost as a potential barrier to STD screening and integration of STD services into primary care. This measurement may be important for planning safety-net services for un- or underinsured citizens.

Data on behavioral risk factors (sexual activity, MSM, characteristics of recent sex partners) is essential for understanding the epidemiology of gonorrhea and understanding sexual network dynamics needed for modeling gonorrhea incidence and transmission. These data are not available from any other surveillance system at the national level for persons reported with gonorrhea.

All participants will be fully informed of the voluntary nature of the data collected and assured that only de-identified, aggregate information will be used for surveillance purposes and that these data will be kept private to the fullest extent allowable by law.

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

The respondents for the Enhanced STD Surveillance Network include (1) the clinic data managers at the facilities/networks, (2) members of the general public identified by state or municipal health departments as having a gonorrhea case report who were randomly selected for an interview, and, (3) the data managers at the 10 eSSuN collaborating sentinel surveillance sites (Table B.1.A).

##### Facility-based activity:

There are a total of 132 facilities (30 STD clinics, 65 family planning/reproductive health clinics and 37 other types (school based, community health centers, FQHC) that report data to the 10 health jurisdictions. Although there are 137 facilities, some of these facilities are part of larger networks of clinics with centralized medical record systems. Consequently, there are a total of only 22 unique clinic data managers that will be abstracting facility data to transmit to the corresponding health jurisdictions. Each of the 22 clinic data managers will abstract line-listed clinic visit data (all patient visits of STD clinics and all females aged 15-44 years in FP/RH clinics) from the facility or network medical records system. Every two months, the 10 collaborating sites will provide clean, validated facility-based datasets to CDC (transmission to CDC via the SAMS); including cumulative data from the beginning of each calendar year. The final, validated annual datasets will be archived and become the primary repository of that site's annual reporting.

##### Population-based activity:

In 2012 there were 92,255 gonorrhea case reports from the participating eSSuN jurisdictions. Each of the sites will interview 250 randomly selected persons (or 2.5% of total morbidity if annual GC cases exceed 10,000 cases/ year) who have a gonorrhea case report per year. Thus, the annual number of respondents will be 3,225. The 3,225 respondents will provide 1 response each that will take approximately 10 minutes for a total of 538 burden hours.

Health department data managers will perform the following tasks on the data from both activities:

- (1) merge, recode and appropriately structure the population and facility data to facilitate merging into the national SSuN datasets, and,
- (2) complete data verification and validity checks on datasets prior to transmission to CDC, and,
- (3) transmit data files through secure file transport mechanisms.

The burden table below reflects the total estimated annualized respondent burden hours for the project.

A12a. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Clinic Data manager at clinic	N/A	22	6	3	396
Gonorrhea Patients sampled and interviewed	Patient Interview	3225	1	10/60	538
Health Department Data Manager	N/A	10	12	16	1920
<b>Total</b>					<b>2854</b>

The table below (Exhibit A.12.B) presents the estimated burden costs. The annualized burden cost is \$93,234. The mean hourly wage of a data manager is \$35.32. Estimates of hourly wage rates are based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the United States (May 2013). We do not know what the wage rate category will be for the randomly selected participants for interview (or even whether they will be employed). We used \$22.33 per hour as an estimate of average hourly wage rate across the country for the general public (United States Department of Labor, Bureau of Labor Statistics May 2013, [http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000)). The estimated annual cost to participants for the collection of information will be \$12,014.

A12 b. Estimated Annualized Burden Costs

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

There are no costs to respondents other than their time.

**A.14. Annualized Cost to the Federal Government**

The cost of the project for the 3 years is estimated to \$8,085,060 or \$2,695,020 annually. The annual cost is summarized in Exhibit A 14a.

A14a. Estimates of Annualized Costs to the Federal Government\*

Expense Type	Expense Explanation	Annual Costs (dollars)	
Direct Costs to the Federal Government	CDC Co-Project Officer/Epidemiologist (GS-14, 1.0 FTE)	\$107,770	
	CDC Co-Project Officer/Epidemiologist-E-04 (1.0 FTE)	\$91,200	
	CDC Co-Project Officer (GS-13, 0.25 FTE)	\$22,800	
	CDC Data Management (GS-13, 0.75 FTE)	\$60,300	
	CDC Data Management (GS-12, 0.25 FTE)	\$20,000	
	CDC Data Management (GS-12, 0.25 FTE)	\$20,000	
Operational	Travel (site visits)	\$12,000	
	Subtotal, Direct Costs to the Government	\$334,070	
Contractor and Other Expenses	Public Health Analyst I (contractor, 0.5 FTE)	\$35,950	
	Baltimore Site Cost	\$160,000	
	California Site Cost	\$300,000	
	Florida Site Cost	\$300,000	
	Massachusetts Site Cost	\$300,000	
	Minnesota Site Cost	\$300,000	
	Multnomah County Site Cost	\$150,000	
	New York City Site Cost	\$180,000	
	Philadelphia Site Cost	\$160,000	
	San Francisco Site Cost	\$150,000	
	Washington Site Cost	\$300,000	
	Subtotal, Contracted Services	\$2,325,000	
	TOTAL COST TO THE GOVERNMENT		\$2,695,020

\*Salary estimates were obtained from the US Office of Personnel Management salary scale at <http://www.opm.gov/oca/11TABLES/>.

The personnel related to the Enhanced STD Surveillance Network data collection include project officers (epidemiologists) at the GS-13 and 14 levels, GS-11 level public health analyst, and data managers/analysts. Travel is related to providing technical assistance and conducting site visits

to monitor performance.

The information collection described in this request will be funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments).

Data for the Enhanced STD Surveillance Network are compiled by staff in local health departments and sent to CDC via a secure network (SAMS). Data managers at CDC will receive data from the data managers at the local health departments, track the progress of the data, and distribute monthly monitoring reports to health department staff. CDC will process all data sent from local health departments and produce a clean, final data set for use by CDC and/or the health departments.

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

This is a new data collection.

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

A16a. Project Time Schedule

Activity	Time Schedule
Beginning of data collection	At the time of OMB approval
Beginning of data analysis	4-6 months after OMB approval
Development of data report	4-6 months after OMB approval

Once OMB approval has been granted and local approval processes completed, sites will begin data collection and contacting patients for GC interviews. Most of the results are expected to be useful at the local level, while other results will be more meaningful aggregated across sites. Local data will be reported back to the community through quarterly data reports. These data will be distributed through national publications and presentation at national conferences.

**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.