

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International TB Manifest Template	51	1	360/60
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International Non-TB Manifest Template	249	1	360/60
International Passengers (3rd party disclosure).	No Form	110,000,000	1	.5/60
Airline staff	No Form	110,000,000	1	.5/60

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-20-1072]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “The Enhanced STD surveillance Network (SSuN)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on Friday, October 25, 2019, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Enhanced STD surveillance Network (SSuN), (OMB Control No. 0920-1072 Exp. 09/30/2021)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) is requesting revision of the information collection entitled “Enhanced STD Surveillance Network (SSuN)”. Revisions to this submission include adding reported adult syphilis cases to enhanced case-based surveillance records, addition of 87 new data elements, removal of 115 data elements associated with a discontinued neurosyphilis surveillance activity and revision of methods to include Health

Department surveillance HIV registry matching activities for patients presenting for care in STD clinical facilities. This revision also includes changes to the number and identity of collaborating jurisdictions from 10 to 11 sites as a result of a recent notice of funding opportunity. The estimate of annualized burden hours for this data collection increases modestly from 4,134 hours to 6,303 hours for the revised project as a result of revisions and expanding the project from 10 to 11 awardees for the current data collection cycle.

The purpose of this project is to enhance capacity for STD surveillance and better meet CDC’s disease surveillance mandate by; (1) providing more comprehensive information on reported cases of notifiable STDs to enhance the ability of public health authorities to interpret trends in case incidence, assess inequalities in the burden of disease by population characteristics and to monitor STD treatment and selected adverse health outcomes of STDs, and, (2) to monitor STD and HIV co-infection, screening, uptake of high-impact HIV prevention and health care access trends among patients seeking care and those diagnosed with STDs in specific clinical settings.

Routine STD surveillance activities are ongoing in all US states and jurisdictions, and cases are reported to CDC through the National Notifiable Disease Surveillance System (NNDSS). However, case reports are often missing critical patient demographics and are of limited scope with respect to risk behavior, provider and clinical information, treatment, co-infection and partner characteristics—data that are needed to appropriately direct disease control activities. Enhanced SSuN is the only current surveillance infrastructure providing information on patient and partner characteristics, clinical presentation, screening and uptake of HIV testing, treatment patterns, provider compliance with treatment recommendations, HIV co-infection among persons diagnosed with STDs

and use of high impact STD-related HIV prevention interventions such as pre-exposure prophylaxis.

The precursor to Enhanced SSuN was the STD Surveillance Network (SSuN), which was established in 2005 as a network of six collaborating state and local public health agencies providing more comprehensive STD case-level and clinical facility information. In 2008, SSuN was expanded to 12 awardees to add important geographic diversity and to include visit-level data on a full census of patients being seen in categorical STD clinics. Activities of the previously funded SSuN were subsumed under the network’s scope in establishing enhanced SSuN in 2013, which funded 10 awardees to conduct core data collection activities.

The revised project, SSuN Cycle 4, comprises 11 U.S. local/state health departments, including Baltimore City Health Department, California Department of Public Health, City of Columbus Public Health Department, Florida Department of Health, Indiana Department of Public Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, Utah Department of Public Health and Washington State Department of Health.

Subsequent to reinstatement of OMB approval in 2018, enhanced SSuN continues to provide ongoing data addressing CDC’s Division of Sexually Transmitted Disease and Prevention priorities (DSTDp), including contributing to CDC’s annual STD surveillance report, CDC’s quarterly and annual progress indicators, and has informed policy discussions on expedited partner therapy, pre-exposure prophylaxis to prevent HIV infection (PrEP), documented critical clinical services provided by categorical STD clinics, and provided information on the proportion of cases treated with appropriate antimicrobial regimens, which is an essential indicator of compliance with CDC treatment recommendations and critical for addressing the emergence of antimicrobial resistance. The major data collection components of the network are grouped into two primary strategies,

reflecting different sentinel and enhanced population-based surveillance methods.

The first, Strategy A, includes sentinel surveillance in STD clinics to monitor patient care, screening and diagnostic practices, HIV co-infection, treatment and assess the delivery of high impact, STD-related HIV prevention services. Participating local/state health departments are implementing common protocols to abstract demographic, clinical, risk behaviors from existing health records for patients presenting for care in 15 selected local STD Clinics. Data for this strategy is abstracted from existing electronic medical records at the participating STD clinics, leveraging information that is routinely collected in the provision of clinical care. A brief 10-item de-identified survey will be administered at registration to 350 patients presenting consecutively to the clinics once annually to assess demographics not collected in the course of routine patient care. All survey and medical records are fully de-identified by collaborating health departments and transmitted to CDC through secure file transport mechanisms six times annually (every two months). The estimated time for the STD clinic data managers to abstract data from electronic health records and process patient surveys is four hours every two months.

The second surveillance activity in SSuN Cycle 4, Strategy B, includes abstraction of all reported gonorrhea and adult syphilis cases from the jurisdiction’s routine STD surveillance data management system, recoding case data to conform with common protocols and performance of a registry match with the jurisdictions HIV case surveillance system. A random sample of gonorrhea cases is selected, and enhanced investigations conducted on the gonorrhea cases selected in the random sample. Enhanced investigations include clinical data collection from reporting providers, searching existing health department disease and laboratory registries for additional diagnostic and laboratory data and attempting to obtain brief patient behavioral and demographic interviews on patients selected in the random sample. Estimated time for

patients to complete these interviews is 10 minutes or less depending on skip patterns. For these activities, jurisdictions follow consensus protocols for all data collection to provide uniformly coded data on demographic characteristics, behavioral risk factors, clinical care, laboratory data and health care seeking behaviors. There were 164,177 cases of gonorrhea diagnosed and reported across the 10 participating enhanced SSuN jurisdictions funded in 2018. Approximately 10.6%, or 17,512 cases were randomly sampled for enhanced investigation and full enhanced investigations were completed for 7,132 (40.7%). The remaining cases were lost to follow-up due to insufficient contact information, or the patient failed to respond to multiple contact attempts. Similar performance is anticipated in the revised project, which includes 11 jurisdictions which reported 173,605 gonorrhea cases in 2017. Approximately 17,360 cases will be sampled and 7,380 completed patient investigations are anticipated.

Data managers at each of the 11 local/state health departments are responsible for transmitting validated datasets to CDC every month, alternating between strategies A and B each month. This reflects 3,168 burden hours for data management (11 respondents × 12 data transmissions × 24 hours). Data managers will also be responsible for conducting HIV registry matching bimonthly; registry matches are estimated to take 20 hours for matching, cleaning and recoding records into approved data formats. Across all 11 jurisdictions, this represents an additional data management burden of 1,320 hours (11 sites × 6 annual matches × 20 hours).

The total estimated annual burden hours for data management staff in funded jurisdiction is 4,488 hours (3,168 + 1,320) for the revised information collection. Respondents from local/state health departments receive federal funds to participate in this project. Participation of patients and of facility staff is voluntary. There are no additional costs or benefits accrued to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Data managers at sentinel STD clinics	Electronic Clinical Record Abstraction	11	6	4

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public—Adults (persons diagnosed with gonorrhea).	Patient interviews for a random sample of gonorrhea cases.	7,380	1	10/60
Data Managers: 11 local/state health department.	Data cleaning/validation, HIV registry matching and data transmission for Strategy A and Strategy B.	11	12	44
General Public—Adults (persons visiting STD clinics and participating in the clinic survey).	Clinic Survey	3,850	1	5/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2020-0035; NIOSH-334]

World Trade Center Health Program Research Agenda; Request for Information

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), is opening a docket to solicit public comment on the scope of upcoming funding announcements for the World Trade Center (WTC) Health Program research funding cycle for FY2021. The WTC Health Program's research program helps answer critical questions about potential 9/11-related physical and mental health conditions as well as diagnosing and treating health conditions on the List of WTC-Related Health Conditions.

DATES: Comments must be received by June 1, 2020.

ADDRESSES: Comments may be submitted through either of the following two methods:

• *Federal eRulemaking Portal:* <http://www.regulations.gov> (follow the instructions for submitting comments), or

• *By Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS C-34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226-1998.

Instructions: All written submissions received in response to this notice must

include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2020-0035; NIOSH-334) for this action. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION: Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113 and Pub. L. 116-59), added Title XXXIII to the Public Health Service (PHS) Act,¹ establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits for health conditions on the List of WTC-Related Health Conditions (List)² to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders). The Program also provides benefits to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

² The List of WTC-Related Health Conditions is established in 42 U.S.C. 300mm-22(a)(3)-(4) and 300mm-32(b); additional conditions may be added through rulemaking and the complete list is provided in WTC Health Program regulations at 42 CFR 88.15.

The Zadroga Act also requires that the Program establish a research program on health conditions resulting from the September 11, 2001, terrorist attacks, addressing the following topics:

- Physical and mental health conditions that may be related to the September 11, 2001, terrorist attacks;
- Diagnosing WTC-related health conditions for which there have been diagnostic uncertainty; and
- Treating WTC-related health conditions for which there have been treatment uncertainty.

Request for Information

To establish the scope of the next 5-year research project funding cycle of the WTC Health Program, NIOSH is soliciting public comments from any interested party. Specifically, NIOSH seeks input on research priorities involving the WTC Health Program population of responders and survivors on the following questions:

(1) What are the most important research gaps that need to be addressed within the scope of the research solicitation?

(2) What are the most important areas of diagnostic and treatment uncertainty that could most benefit from intervention research (information that bridges the gap between science and practice, care, or treatment by addressing the barriers, challenges, and needs to advance implementation of new or improved treatment, care, or practices)?

(3) What are the primary research needs of responders and survivors?

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

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