molecular techniques. This is also true with laboratory diagnoses of poxvirus infections. Precise and consistent identification of orthopoxviruses, in particular variola viruses, is now achievable using such molecular techniques as real-time Polymerase Chain Reaction (unlike earlier techniques that may have relied on direct virus isolation and identification).

Additionally, the U.S. Government supports the development of other medical products, including vaccines and drugs, for use within the U.S. upon verification of a smallpox case. The U.S. Government, through the Office of the Assistant Secretary for Preparedness and Response (ASPR), has successfully developed vaccine products, and is actively engaged in the development of several drug candidates for smallpox therapies which require access to the Variola virus to satisfy regulatory requirements for product approvals.

Period of Performance: September 30, 2014 to September 29, 2015.

FOR FURTHER INFORMATION CONTACT: The agency program contact is Julie Schafer, who can be contacted by phone at 202–205–1435or via email at *Julie.Schafer@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Sections 42 U.S.C. 241 and 247d–7e (Sections 301 and 319L of the Public Health Service Act); ASPR's Office of Biomedical Advanced Research and Development Authority (BARDA) is the program office for this award.

Justification: WHO is the only eligible applicant; it is the only organization that is allowed by international agreements to address the issues outlined in this proposal. WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats. States Parties to the U.N. have agreed to international standards on reporting public health incidents of concern under IHR (2005). Additionally, a majority of States Parties have also agreed to specific work-frames for pathogens such as smallpox under the Biological Weapons Convention.

Since May 1999, when the 52nd World Health Assembly (WHA) resolved to postpone the destruction of the Variola virus to allow for essential research (WHA 52.10), WHO has been charged with convening a group of experts to advise on the need for continuing such research, to review proposals for research involving viable Variola virus, to review the progress of such research, and to report to the WHA each year. The need to support the activities described in this project has not changed. In fact, WHO Member States continue to exert pressure for the WHO Secretariat to carry out this work.

The WHO Advisory Committee on Variola Virus Research (ACVVR) was established in 1999 to determine what essential research, if any, must be carried out with live Variola virus. The ACVVR monitored the research progress in order to reach global consensus on the timing for the destruction of existing Variola virus stocks. In 2007, the WHA requested the ACVVR undertake a thorough review of the approved research program with a report presented in 2010. The results were presented at the 64th WHA meeting in May of 2011. The ACVVR continues to serve a critically important function for global public health, and to oversee research requested specifically by the U.S. to complete its national strategic goals. This includes the development of new antiviral agents, safer vaccines, and better diagnostics, thus strengthening our national security.

Estimated amount of award: up to $662,500 USD.

HHS/ASPR/BARDA: $225,000
DOD: $250,000 (funds pending)
HHS/NIH/NIAID: $50,000
HHS/CDC: $87,500
HHS/OGA: $50,000

Procedures for Providing Public Input: All written comments must be received no later than 15 days after the posting of this announcement. Please submit comments via *asprgrants@hhs.gov.*

Date: August 4, 2014.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2014–18836 Filed 8–8–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–14AQA]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

The Enhanced STD surveillance Network (eSSuN)—New—Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Enhanced STD Surveillance Network (eSSuN) project is an active STD sentinel surveillance network comprised of 10 surveillance sites including Baltimore City Health Department, California Department of Public Health, Florida Department of Health, Massachusetts Department of Public Health, Minnesota Department of Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, and Washington State Department of Health.

The enhanced STD Surveillance Network is a sentinel surveillance initiative designed to collect longitudinal data of a magnitude sufficient to detect trends and changes over time in the clinical and demographic characteristics of persons presenting for care in STD and family planning/reproductive health clinical facilities and those being diagnosed and reported with gonorrhea in funded jurisdictions. Data collection activities will be ongoing and continuous and will take five years to complete to establish annual trends, allowing for accretion of a sufficient number of investigated cases or patient visits to detect statistically meaningful differences between population sub groups.

While routine STD surveillance activities are ongoing in all states and jurisdictions through the National Notifiable Disease Surveillance System, these data do not include the patient populations and specific clinical data elements and behavioral data proposed for collection in eSSuN. No other sources of information currently collected by, or available to, CDC answer the specific questions eSSuN is designed to answer.

A similar data collection infrastructure, the STD Surveillance Network (OMB No. 0920–0842), expires on September 30th, 2015. However, funding for this cooperative agreement ended in September 29th, 2013 and the protocols have been retired. The enhanced STD network is not a continuation of SSuN, instead, it is a new initiative to collect different kinds of data in different jurisdictions and to respond to different national objectives.

The objectives of the eSSuN Project are (1) provide a dataset of supplemental information on case reports of STDs of interest; (2) provide geographic information on case reports of STDs of interest for investigating social determinants of STDs; (3) monitor screening coverage for chlamydial infection among young women in sentinel clinical settings; (4) monitor STD screening, incidence, prevalence, epidemiologic and health care access trends in populations of interest such as men-who-have-sex-with men (MSM), young people and persons diagnosed with gonorrhea; (5) monitor STD treatment and prevention services practices; (6) monitor selected adverse health outcomes of STDs; (7) evaluate and enhance local and state STD surveillance capacity; (8) enhance local STD-specific health information technology and epidemiologic capacity, and, (9) establish a core of exemplary state, tribal, territorial, county and/or city health department STD surveillance programs employing innovative approaches to STD surveillance.

This project collects data using two surveillance strategies; (1) enhanced surveillance in participating STD and Family planning/reproductive health clinics and (2) enhanced gonorrhea surveillance on a random sample of persons diagnosed with gonorrhea in participating jurisdictions of these 10 local and state health departments.

For the clinic-based surveillance, participating sites have developed common protocols stipulating which data elements would be collected, including demographic, clinical, risk and sexual behaviors. The specified data elements are abstracted from existing electronic medical records for (1) all patient visits to participating STD clinics and (2) for all female patient visits aged 15–44 years of age to participating family planning/reproductive health clinics. Data are de-identified and recoded by health departments and then are transmitted to CDC through secure file transport mechanisms on an every two month basis. Each eSSuN site will spend 16 hours to transmit the data to CDC every two months. At CDC, data will be aggregated with data from all participating sites in a common language and formatted for analysis.

For the population-based surveillance, a random sample of individuals reported with gonorrhea residing within participating jurisdictions are interviewed using locally designed interview templates.

Enhanced data collection includes detailed information on demographic characteristics, behavioral risk factors and clinical history of persons with gonorrhea. Each of the 10 sites will interview a minimum of 250 persons or 2.5% of total morbidity if annual GC cases exceed 10,000 cases and each interview is expected to take about 10 minutes per person. Data for the population-based component will be collected through telephone-administered or in-person interviews conducted by trained interviewers in the 10 eSSuN sites.

The survey results will be entered into the existing information systems at each health department and sent to CDC through secure file transport mechanisms on an every two month basis.

This information is being collected to (1) enhance and improve STD surveillance data, (2) inform a more comprehensive understanding of tends and determinants of STDs of interest, (3) monitor public health program impact and (4) provide a more robust evidence base for directing public health action in the US.

Participation is voluntary. There is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Data manager at clinic (Electronic transmittal of clinical variables in clinic databases).	Record Abstraction	33	6	3	594
Data manager at each of the 10 local/state health department.	Record Abstraction	10	12	16	1920
Gonorrhea cases sampled	Telephone/in-person interview.	3,225	1	10/60	538
Total	.....	.....	.....	.....	3,050

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–18845 Filed 8–8–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–14ARJ]

Proposed Data Collections Submitted for Public Comment and Recommendations

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Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Clinic Context Matters Study–New–National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The daily use of specific antiretroviral medications by persons without HIV infection, but at high risk of sexual or injection exposure to HIV, has been shown to be a safe and effective HIV prevention method. The Food and Drug Administration approved the use of Truvada® for preexposure prophylaxis (PrEP) in July 2012 and CDC has issued Public Health Service clinical practice guidelines for its use. Because approximately 50,000 new HIV infections continue to occur each year, with rates of HIV infection increasing most rapidly for young MSM and because severe disparities in HIV infection continue among African-American men and women, incorporation of PrEP into HIV prevention is important. However, as a prevention tool in very early stages of introduction and use, there is much we need to learn about how to implement PrEP in a real-world setting.

CDC is requesting OMB approval to collect data over a 3-year period that will be used to conduct research among clinicians about their knowledge, attitudes, and practices related to a new intervention (PrEP) over the period of its initial introduction in their clinics. The knowledge gained will be used to refine measurement instruments and methods (for example, identify modifications to questions in the current surveys that are unclear to participants), develop training and educational resources and tools for use by CDC/DHAP (Division of HIV/AIDS Prevention)-funded partners, and other organizations supporting delivery of PrEP in clinical settings.

The project will be conducted in clinics in each of four cities (Houston, Newark, Chicago, and Philadelphia) where PrEP has recently become available through a local community health center.

Once per year for 3 years, CDC will conduct an online survey of clinicians at participating clinics to collect data on the demographics of the respondents and their knowledge, attitudes, practices, and organizational factors related to PrEP and its delivery in their clinics. Surveys will be administered through an online survey Web site.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden hours)
Clinician	Clinician Consent and Interview	175	1	30/60	88
Total					88

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–18940 Filed 8–8–14; 8:45 am]

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