measured. Participants will complete the assessment at baseline and again at 4- and 8-month follow-ups after joining the TLC program.

We will also examine intervention experiences through semi-structured interview with 20 of the 150 TLC participants and 10 TLC staff members involved in the delivery of services through the TLC intervention. The audio-recorded interviews will capture participants and staff views about the TLC implementation process, the process through which the TLC intervention influences HIV risk behavior, and the role of the intervention in addressing social determinates of health (housing, employment, legal issues, health care access).

It is expected that 50% of transgender women screened will meet study eligibility. We expect the initial screening to take approximately four minutes to complete and that providing contact information will take four minutes. The assessment will take 60 minutes (one hour) to complete and will be administered to 150 participants a total of three times. The interview will take 60 minutes (one hour) to complete and will be administered to 30 participants (20 intervention participants and 10 TLC staff) one time.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 255.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public-Adults	Eligibility Screener	150	1	4/60
	Contact Information	75	1	4/60
	Baseline Assessment	75	1	1
	Follow Up Assessment	75	2	1
	Participant Interview	10	1	1
	Staff Interview	5	1	1

Jeffrey M. Zirger,

Acting 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–18MY]

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 Network Epidemiology of Syphilis Transmission (NEST) 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 03/05/2018 to obtain comments from the public and affected agencies. CDC received 1 (one) comment 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 or send an email to *omb@cdc.gov.* 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

Network Epidemiology of Syphilis Transmission (NEST)—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC, Division of STD Prevention (DSTDP), requests a 3-year approval for a new data collection entitled, Network Epidemiology of Syphilis Transmission (NEST). Study participants' sociodemographic, risk behavior, and insurance coverage information will be collected as part of study enrollment.

This study is funded by a cooperative agreement between CDC and three study grantees, two universities (Ohio State University and University of Illinois at Chicago) and one local health department (Baltimore City Health Department) in collaboration with a university (Johns Hopkins School of Medicine). The recruitment of study participants as well as the data collection activities will be carried out at university-affiliated sites including local health departments, community LGBT organizations, local STD clinics and HIV/AIDS care facilities.

The overall objective of NEST is to support the establishment of cohorts of MSM at high risk for syphilis and to prospectively collect behavioral, social, and sexual network data, and biological specimens. Study participants will attend study visits every three months for a period of up to 24 months. NEST is a multi-site study, with a target

enrollment of approximately 720 MSM aged 18 years and older from three geographic areas of the United States: (1) Chicago, Illinois, (2) Baltimore, Maryland, and (3) Columbus, Ohio.

At each study visit, study participants will be interviewed and biological specimens (blood and urine) will be collected to facilitate testing for syphilis, gonorrhea, chlamydia, and HIV, which are part of the routine clinical care at participating sites. All data will be collected using Form 1—Questionnaire and Data Elements (Attachment 3) and submitted electronically directly to the CDC NEST data manager. All personal identifying information (*e.g.,* name, address) collected on individual patients will be retained by the local NEST site, will not be collected on NEST data collection forms, and will not be transmitted to CDC.

The United States is currently experiencing an ongoing syphilis epidemic. MSM are disproportionately impacted by syphilis and the majority of incident syphilis cases in the United States occur among MSM. However, factors influencing syphilis transmission within this population, such as social and sexual network characteristics, sexual behaviors, and healthcare access and utilization, are poorly understood. In order to address these knowledge gaps, both individual-level and network-level data needs to be collected among this population. As such, we need to develop a better understanding of the feasibility of collecting complex sexual network data among this population. The collection of complex sexual network data—in addition to more traditional individual-level data, such as demographics and individual-level sexual and social behaviors—will help to collectively address some of the knowledge gaps in the transmission dynamics and epidemiology of syphilis among MSM in the United States and point towards effective public health interventions to slow the spread of syphilis.

The goal of NEST is to pilot the use of survey instruments to collect complex longitudinal sexual network data among MSM at high risk for syphilis in the United States. The feasibility of data collection on basic information about recent partners of persons diagnosed with syphilis is clear and is routinely performed by public health officials. However, the feasibility and optimal approaches for serial collection of complex sexual network data among populations that may have dynamic networks are not at all clear. Specifically, it is not clear what the optimal recruitment strategies are to recruit and enroll MSM at high risk for syphilis. The optimal approaches for retaining men as study participants for follow-up visits over a defined study period have not been well defined. Furthermore the best survey format for our proposed data collection activities has not been established. For example, it is not known whether study participants would prefer a survey that is completely self-administered and whether data collected using a self-administered survey will result in complete and valid data being collected or whether a survey administered by study staff would be a better format.

CDC is not engaged in research, and therefore not involved in data collection activities. The grantees are responsible for implementing the testing and collecting data and specimens from the participants.

Before starting any data collection activities a short eligibility screener (Attachment 4) will be administered to prospective study participants and if determined to be eligible consent from the participant will be obtained. Once consent is obtained data collection will begin and will include a baseline visit and follow-up visits every three months for a total follow-up period of 24 months. At each visit participants will provide biological specimens (blood and urine) to facilitate testing for syphilis, gonorrhea, chlamydia, and HIV. In addition to providing biological specimens, participants will complete a standardized survey which will be delivered electronically on a tablet or computer and will collect information on the participants' sexual network, individual behaviors, healthcare access and demographics (Attachment 3). The survey consists of 13 questionnaire modules with a range of 5 to 15 questions per module (Attachment 3). A small subset of sexual behavior questions will be delivered to the participant closer to real time using an open survey format and a weekly format (Attachment 5). The open survey format is a brief survey that participants can respond to at any to record a sexual encounter or other event. The weekly format will be sent on Sunday nights with a reminder on Monday evening, to address sexual behavior in the last week. These brief surveys will be delivered electronically to participants and each survey is expected to take 2 minutes or less. Data collected on electronic devices will be stored on a secure web-accessible local server at each site which will only be accessible with a user name and password. Study site investigators provided input (based on knowledge of relevant local communities) into development of the survey.

The total estimated annualized hourly burden anticipated for this study is 6,828 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Potential participants	Screener	900	1	2/60
Site data manager	Form 1—Questionnaire	3	5	10
Study participant	Form 1—Questionnaire	720	5	1.5
Study participant	Smartphone survey	720	52	2/60

Jeffrey M. Zirger,

Acting 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.

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