

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
International panel physicians	TB Indicators Excel Spreadsheet	336	1	3	1,008
Total	1,008

Jeffery 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

[60Day-18-18AAE; Docket No. CDC-2018-0039]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National HIV Behavioral Surveillance among Transgender women (NHBS-Trans). CDC is requesting a new 2-year approval to pilot collecting standardized HIV-related behavioral data from transgender women at risk for HIV systematically selected from 9 Metropolitan Statistical Areas (MSAs) throughout the United States.

DATES: CDC must receive written comments on or before July 30, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0039 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

National HIV Behavioral Surveillance System—among Transgender women (NHBS-Trans)—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 purpose of this data collection is to monitor behaviors related to Human Immunodeficiency Virus (HIV) transmission and prevention in the United States of transgender women, who are known to be at high risk for HIV infection, and to assess barriers to, and best strategies for, conducting bio-behavioral surveys among minority transgender women in nine cities. This includes recruiting, interviewing and providing HIV testing and referral to services (as needed) following CDC protocol based on an existing HIV Behavioral Surveillance system. The proposed respondents are 200 adult minority transgender women in each of nine cities (1,800 interviews total) who will each respond one time over the course of the two year pilot. The information will be collected over a two year period beginning no later than two months after OMB approval.

NHBS-Trans provides information to help prevent HIV among transgender women. Preventing HIV, especially among high-risk groups, is an effective strategy for reducing individual, local, and national healthcare costs. The utility of this information is to provide CDC and local health department staff with data for evaluating progress towards local and national public health

goals, such as reducing new HIV infections, increasing the use of condoms, and targeting high risk groups by describing and monitoring the HIV risk behaviors, HIV seroprevalence and incidence, and HIV prevention experiences of persons at highest risk for HIV infection.

The Centers for Disease Control and Prevention request two year approval for a new information collection. Data will be collected through anonymous, in-person interviews conducted with persons systematically selected from nine Metropolitan Statistical Areas (MSAs) throughout the United States; these nine MSAs were chosen based on having high HIV prevalence. A brief screening interview will be used to determine eligibility for participation in the behavioral assessment. Participants will be recruited through respondent-driven sampling, a scientifically proven recruitment strategy for reaching hidden, hard-to-reach, or stigmatized populations. Interview data will be recorded on secure portable computers, without internet connections. Data will

be transferred to secure, encrypted data servers. Data will be stored at CDC and shared with local health departments in accordance with existing data use agreements and the Assurance of Confidentiality for HIV/AIDS Surveillance Data. Data will be disseminated in aggregate through academic and agency publications, presentations, and reports. All data collection and activities will be anonymous.

Personally identifiable information (PII) is not included in the data collection. The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. 552a. The Privacy Act is not applicable because PII is not being collected under this CDC funded activity. The NHBS-Trans formative interview and optional HIV testing are anonymous (neither names nor Social Security numbers are collected). Data that will be collected through NHBS-Trans, while sensitive, are not personally identifying.

The data from the behavioral assessment will provide estimates of (1)

behavior related to the risk of HIV and other sexually transmitted diseases, (2) prior testing for HIV, (3) and use of HIV prevention services. All persons interviewed will also be offered an HIV test, and will participate in a pre-test counseling session. No other federal agency systematically collects this type of information from persons at risk for HIV infection. These data have substantial impact on prevention program development and monitoring at the local, state, and national levels.

The Burden Table below shows the estimated annualized burden hours for the participants' time. Annually, 990 participants will complete an eligibility screener (an average of 5 minutes to complete), 900 participants will complete the Behavioral Assessment (an average of 40 minutes to complete), and 900 will complete the Recruiter Debriefing Form (an average of two minutes to complete). The estimated total annualized burden would be 713 hours. Participation of respondents is voluntary. There are no costs 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)	Total burden (in hours)
Persons Screened	Eligibility Screener	990	1	5/60	83
Eligible Participant	Behavioral Assessment	900	1	40/60	600
Peer Recruiters	Recruiter Debriefing	900	1	2/60	30
Total	713

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

Food and Drug Administration

[Docket No. FDA-2018-D-1468]

Registration of Food Facilities: What You Need To Know About the Food and Drug Administration Regulation; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled “Registration of Food Facilities: What You Need To Know About the FDA Regulation—Small Entity Compliance Guide.” The small entity compliance guide (SECG) is intended to help small entities comply with a final rule we issued in the **Federal Register** of July 14, 2016, entitled “Amendments to Registration of Food Facilities.” The final rule amends the registration of food facilities regulations.

DATES: The announcement of the guidance is published in the **Federal Register** on May 29, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the