

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0706]

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 National Program of Cancer Registries Program Evaluation Instrument (NPCR–PEI) 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 March 26, 2021 to obtain comments from the public and affected agencies. CDC received two 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

National Program of Cancer Registries Program Evaluation Instrument (NPCR–PEI) (OMB Control No. 0920–0706, Exp. 02/28/2021)—Reinstatement—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is responsible for administering and monitoring the National Program of Cancer Registries (NPCR). The NPCR provides technical assistance and funding, and sets program standards to assure that complete local, state, regional, and national cancer incidence data are available for national and state cancer control and prevention activities and health planning activities. The Program Evaluation Instrument (PEI) has been used for 28 years to monitor the performance of NPCR grantees in meeting the required Program

Standards. CDC currently supports 50 population-based cancer registries (CCR) in 46 states, two territories, the District of Columbia, and the Pacific Islands. The National Cancer Institute supports the operations of CCRs in the four remaining states. The Program Evaluation Instrument (NCPR–PEI) includes questions about the following categories of registry operations: (1) Staffing, (2) legislation, (3) administration, (4) reporting completeness, (5) data exchange, (6) data content and format, (7) data quality assurance, (8) data use, (9) collaborative relationships, (10) advanced activities, and (11) survey feedback. Examples of information that can be obtained from various questions include, but are not limited to: (1) Number of filled staff full-time positions by position responsibility; (2) revision to cancer reporting legislation; (3) various data quality control activities; (4) data collection activities as they relate to achieving NPCR program standards for data completeness; and (5) whether registry data is being used for comprehensive cancer control programs, needs assessment/program planning, clinical studies, or incidence and mortality estimates.

The NPCR–PEI is needed to receive, process, evaluate, aggregate, and disseminate NPCR program information. The information is used by CDC and the NPCR-funded registries to monitor progress toward meeting established program standards, goals, and objectives; to evaluate various attributes of the registries funded by NPCR; and to respond to data inquiries made by CDC and other agencies of the federal government. CDC requests OMB approval for a period of three years to collect information in the winter of 2022 and 2024, and the new project period begins July 1, 2022. There are no costs to the respondents other than their time. CDC requests approval for an estimated 66 annualized burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
NPCR Awardees	PEI (Online)	30	1	2
NPCR Awardees	REI (Paper)	3	1	2

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-1100]

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 “Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT)” 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 July 12, 2021 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

Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT) (OMB Control No. 0920-1100, Exp. 1/31/2022)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV Prevention (DHP) requests a three-year Extension for an existing data collection titled “Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT).”

CDC provides guidelines for HIV testing and diagnosis for the United States, as well as technical guidance for its grantees. The purpose of this project is to assess characteristics of HIV testing technologies and to update these guidance documents to reflect the latest available testing technologies, their performance characteristics, and considerations regarding their use. Specifically, CDC will describe behavioral and clinical characteristics of persons with early infection to help HIV test providers (including CDC grantees) choose which HIV tests to use, and target tests appropriately to persons at different levels of risk. This information will be disseminated primarily through guidance documents and articles in peer-reviewed journals.

The primary study population will be persons at high risk for, or diagnosed with HIV infection, many of whom will be men who have sex with men (MSM), transgender women, minorities, and persons who inject drugs (PWIDs) because the majority of new HIV infections occur each year among these populations. The goals of the project are

to: (1) Characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care, relative to each other and to currently used gold standard, non-point-of-care (POC) tests, and (2) identify behavioral and clinical predictors of early HIV infection.

Project DETECT will enroll 1,867 persons annually from two study sites (Seattle and Baltimore). The study will be conducted in two phases.

Phase 1: After a clinic client consents to participate, he/she will be assigned a unique participant ID and will then undergo testing with up to seven new HIV tests under study. While awaiting test results, participants will undergo additional specimen collections and complete the Phase 1 Enrollment Survey.

Phase 2: All Phase 1 participants whose results on the seven tests under investigation are not in agreement with one another (“discordant”) will be considered to have a potential early HIV infection. Nucleic acid amplification testing that detects viral nucleic acids will be conducted to confirm an HIV diagnosis and rule out false positives. Study investigators expect that each year, 50 participants with discordant test results will be invited to participate in serial follow-up specimen collections to assess the time point at which all HIV test results resolve and become concordant positive (indicating enrollment during early infection) or concordant negative (indicating one or more false-positive test results in Phase 1).

The follow-up schedule will consist of up to nine visits scheduled at regular intervals over a 70-day period. At each follow-up visit, participants will be tested with the new HIV tests and additional oral fluid and blood specimens will also be collected for storage and use in future HIV test evaluations at CDC. Participants will be followed only to the point at which all their test results become concordant. At each time point, participants will be asked to complete the Phase 2 HIV Symptom and Care survey to collect information on symptoms associated with early HIV infection as well as access to HIV care and treatment since the last Phase 2 visit. When all tests become concordant (*i.e.*, at the last Phase 2 visit) participants will complete the Phase 2 Behavioral Survey to identify any behavioral changes during follow-up. Of the 50 Phase 2 participants; it is estimated that no more than 26, annually, will have early HIV infection.

All data for the proposed information collection will be collected via an