BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15AEZ; Docket No. CDC-2015-0028]

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 efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on the proposed information collection entitled *Identification of Behavioral and Clinical*

Predictors of Early HIV Infection (Project DETECT).

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0028 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted 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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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.

Proposed Project

Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT) - 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 Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for a new data collection called "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. CDC will use the HIV testing data collected for this project to update these guidance documents to reflect the latest available testing technologies, their performance characteristics, and considerations regarding their use. Specifically, CDC will describe the information on 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) because the majority of new HIV infections occur each year among this population. 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-POC tests, and 2) identify behavioral and clinical predictors of early HIV infection.

Project DETECT will enroll 1,667 persons annually at the primary study site clinic in Seattle, and an additional 200 persons will be enrolled from other clinics in the greater Seattle area. 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 the 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 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 up 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 that collects 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 electronic Computer Assisted Self-Interview (CASI) survey. Participants will complete the surveys on an encrypted computer, with the exception of the Phase 2 Symptom and Care survey, which will be administered by a research assistant and then electronically entered into the CASI system.

Data to be collected via CASI include questions on socio-demographics, medical care, HIV testing, pre-exposure prophylaxis, antiretroviral treatment, sexually transmitted diseases (STD) history, symptoms of early HIV infection, substance use and sexual behavior.

Data from the surveys will be merged with HIV test results and relevant clinical data using the unique identification (ID) number. Data will be stored on a secure server managed by the University of Washington Department of Medicine Information Technology (IT) Services.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. The total estimated annual burden hours for the proposed project are 2,111 hours.

Estimated Annualized Burden Hours

Type of Respondents	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Avg. Burden per Response (in hours)**	**Total Burden Hours**
Persons eligible for study	Phase 1 Consent	2,334	1	15/60	584
Enrolled participants	Phase 1 Enrollment Survey A	1,667	1	45/60	1,251
Enrolled participants	Phase 1 Enrollment Survey B	200	1	1	200

Enrolled participants	Phase 2 Consent	50	1	15/60	13
Enrolled participants	Phase 2 HIV Symptom and Care Survey	50	9	5/60	38
Enrolled participants	Phase 2 Behavioral Survey	50	1	30/60	25
Total					2,111

_____

Leroy A. 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. 2015-11511 Filed: 5/12/2015 08:45 am; Publication Date: 5/13/2015]