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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-1100]

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 August 21, 2018 to obtain comments from the public and affected agencies. CDC received one (1) 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

Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT) (OMB No. 0920-1100, Exp. 2/28/2019) – Extension - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC requests a three-year OMB approval to continue information collection for "Project DETECT," an ongoing research study conducted by the University of Washington (UW). Study sites initiated information collection in 2016 and CDC is requesting OMB approval for three additional years (2019 – 2022). The study is designed to (1) identify behavioral and clinical predictors of early HIV infection, and (2) characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care (POC), relative to each other and to currently used gold standard, non-POC tests.

The primary study population is 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. In each year of the study, an average of 1,667 participants will be recruited from the Public Health – Seattle and King County (PHSKC) STD

Clinic, which serves as the primary study site, and an additional 200 persons will be enrolled from other clinics in the greater Seattle area. Information collection 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 sociodemographic characteristics, 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.

CDC will use findings to update guidelines for HIV testing and diagnosis in the United States. The guidelines will help HIV test providers choose which HIV tests to use, and target tests appropriately to persons at different levels of risk. Findings will also be disseminated through articles in peer-reviewed journals and the technical assistance provided by CDC to grantees that provide HIV testing and diagnostic services.

There are no changes to the previously approved information collection instruments or burden estimates. The participation of respondents is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden for the proposed project is 2,110 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Persons eligible for study	Phase 1 Consent	2,334	1	15/60
Enrolled participants	Phase 1 Enrollment Survey A	1,667	1	45/60
	Phase 1 Enrollment Survey B	200	1	60/60
	Phase 2 Consent	50	1	15/60

	Phase 2 HIV Symptom and Care survey	50	9	5/60
	Phase 2 Behavioral Survey	50	1	30/60

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