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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-15AEZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

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

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 primarily be disseminated 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 7 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 7 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 estimate 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 disease (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 ID number. Data will be stored on a secure server managed by the University of Washington Department of Medicine IT Services. The participation of respondents is voluntary. There is no cost to the respondents other than their time. The total annual burden hours are 2,110.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
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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Leroy A. Richardson,
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Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
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