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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

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. Data will be stored on a secure server managed by the awardee's 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 1,594 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	1,867	1	30/60
	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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of Intent To Issue Two Replacement Awards To Provide Residential Services (Shelter)

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of Issuance of Two Replacement Awards to BCFS Health and Human Services (BCFS).

SUMMARY: ACF, ORR announces the intent to award two Replacement Awards in the amount of up to $77,496,593 to BCFS Health and Human Services in Los Fresnos, Texas. On September 17, 2021, Comprehensive Health Services, LLC (CHS) relinquished two federally funded discretionary grants. Per HHS policy, ORR identified the current recipient BCFS Health and Human Services to transfer the current permanent capacity to provide shelter for apprehensions of Unaccompanied Children (UC) at the Southwest Border. The continuation of permanent capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter and appropriate services for UC referred to its care by the Department of Homeland Security. The purpose of this award is to ensure the continuation of residential services for the capacity of 560 shelter beds for UC.

DATES: The proposed period of performance is December 1, 2021–September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Stephen Antkowiak, Office of Refugee Resettlement, Division of Unaccompanied Children Operations, 330 Street SW, Washington, DC 20447. Phone: 202–260–6165. Email: *stephen.antkowiak@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: ORR announces the intent to award the following replacement awards:

Original recipient	Recipient	Location (city, ST)	Award amount
CHS	BCFS Health and Human Services.	Los Fresnos, TX	up to $24,262,279.
CHS	BCFS Health and Human Services.	Los Fresnos, TX	Up to $53,234,314.

This award will prevent the disruption in residential services currently available at the two mentioned CHS locations and prevent children unnecessarily pending placement from Border Patrol. ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing if applicable, experience, and appropriate level of trained staff to meet those requirements.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of UC from the Commissioner of the former Immigration and Naturalization Service to the Director of ORR within HHS.

(B) The *Flores* Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the *Flores* Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996); pertinent regulations; and ORR policies and procedures.

Elizabeth Leo,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

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