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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-18CI]

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 "Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection" 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 January 30, 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

Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection – 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 National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention is requesting approval for 24 months of data collection entitled, "Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk for HIV Infection." The purpose of this study is to evaluate the efficacy of TLC, which provides combination (biomedical, behavioral and social/structural) HIV prevention and care services to adult transgender women at high risk for HIV infection, in a culturally specific and accessible environment. The information collected through this study will be used to evaluate whether the TLC intervention is an effective HIV-prevention strategy by assessing whether exposure to TLC services results in improvements in participants' health and HIV prevention behaviors. The trial will assess whether intervention participants' behaviors significantly change from baseline to 4- and 8-month follow-up periods.

This study will be carried out in Chicago, Illinois, where the TLC program is located. The study population will include 150 HIV-negative adult transgender women living in the Chicago metropolitan area. Participants will be at least 18 years of age; self-identify as transgender, transsexual, women and/or female who was assigned male sex at birth; and have a self-reported history of sex with men in the past four months. The study population will also include 10 TLC staff members. Staff members will be adults, involved in the delivery of TLC intervention services. Participation in this study is voluntary.

We anticipate enrollment of a diverse sample of transgender women comprised mainly of racial/ethnic minority participants under 35 years of age, consistent with the current TLC program and the epidemiology of HIV infection among transgender women. Intervention participants will be recruited to the study through a combination of approaches, including traditional print advertisement, referral, in-person outreach, and through word of mouth. TLC staff members will be randomly selected to participate in the evaluation.

A computer-assisted quantitative assessment will be used to collect information for this study, which will be delivered at the time of study enrollment and again at 4-month and 8-month follow-ups. The assessment will be used to measure changes in sexual risk behavior including condom use and pre-exposure

prophylaxis (PrEP) care engagement. Intervention mediators, including gender affirmation, collective self-esteem and social support, and intervention satisfaction will also be measured. Participants will complete the assessment at baseline and again at 4- and 8-month follow-ups after joining the TLC program. We will also examine intervention experiences through semi-structured interview with 20 of the 150 TLC participants and 10 TLC staff members involved in the delivery of services through the TLC intervention. The audio-recorded interviews will capture participants and staff views about the TLC implementation process, the process through which the TLC intervention influences HIV risk behavior, and the role of the intervention in addressing social determinates of health (housing, employment, legal issues, health care access).

It is expected that 50% of transgender women screened will meet study eligibility. We expect the initial screening to take approximately four minutes to complete and that providing contact information will take four minutes. The assessment will take 60 minutes (one hour) to complete and will be administered to 150 participants a total of three times. The interview will take 60 minutes (one hour) to complete and will be administered to 30 participants (20 intervention participants and 10 TLC staff) one time.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 255.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
General Public-Adults	Eligibility Screener	150	1	4/60
	Contact Information	75	1	4/60
	Baseline Assessment	75	1	1
	Follow Up Assessment	75	2	1
	Participant Interview	10	1	1
	Staff Interview	5	1	1

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