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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18CI; Docket No. CDC-2018-0009]

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 effort 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 project entitled "Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection." The collection is part of a research study designed to evaluate the efficacy of a locally developed and potentially effective intervention, TransLife Center (TLC), which provides combination

HIV prevention services to adult transgender women at high risk for HIV infection.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0009 by any of the following methods:

- Federal eRulemaking Portal: Regulations.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.

Please note: Submit all Federal comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, 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.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk for 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

CDC seeks to request a two-year OMB approval to collect data related to a project entitled "Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk for HIV Infection." With this study, CDC seeks 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 will help 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. In addition, CDC will assess whether intervention participants' behaviors significantly change from baseline to 4 and 8-month follow-up periods.

CDC will conduct the study in the TLC program's home base of Chicago, Illinois. 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 whom had 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.

CDC anticipates 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 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 randomly selected to participate in the evaluation.

CDC will use a quantitative assessment to collect information for this study. Researchers will deliver the assessment at the time of study enrollment and again at 4-month and 8-month follow-ups. CDC will use the assessment 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 measured. Participants will complete the assessment at baseline and again at 4- and 8-month follow-ups after joining the TLC program.

CDC 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 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).

CDC expects that 50% of transgender women screened will meet study eligibility and the initial screening to take approximately four minutes to complete. It will take respondents

one minute to provide contact information. On three occasions, CDC will administer the assessment to 150 participants. The assessment will take 60 minutes (1 hour) to complete. On a single occasion, CDC will administer the interview to 30 participants (20 intervention participants and 10 TLC staff). The interview will take 60 minutes (1 hour) to complete.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 252.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
General Public - Adults	Eligibility Screener	150	1	4/60	10
General Public - Adults	Contact Information	75	1	1/60	2
General Public - Adults	Assessment	75	3	1.0	225
General Public - Adults	Interview	15	1	1.0	15
Total					252

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.
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