



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-1266]

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 "HIV prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention" 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 February 25, 2021 to obtain comments from the public and affected agencies. CDC received one 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. 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

HIV prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention (OMB Control No. 0920-1266, Exp. 6/30/2021) - Revision - 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 (NCHHSTP) is requesting approval for a two-year extension of a currently approved ICR (OMB Control No. 0920-1266), titled "HIV prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention." The goal of this study is to evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a locally developed and culturally congruent two-session Spanish-language small-group combination intervention, designed to promote consistent condom use, and access to, and participation in, pre-exposure prophylaxis (PrEP) and medically supervised hormone therapy by HIV seronegative Hispanic/Latina transgender women who have sex with men.

The information collected through this study will be used to evaluate whether the ChiCAS intervention is an effective HIV-prevention strategy by assessing whether exposure to the

intervention results in improvements in participants' health and HIV prevention behaviors. The study will compare pre- (baseline) and post-intervention (six-month) levels of HIV risk among participants who have received the intervention and participants who have not yet received the intervention (delayed-intervention group).

This study will be carried out in metropolitan areas in and around North Carolina, including Asheville, NC; Charlotte, NC; Research Triangle (metropolitan area of Greensboro, Winston-Salem and High Point NC); Raleigh, NC; Wilmington, NC; and Greenville, SC. The study population will include 140 HIV-negative Spanish-speaking transgender women. Participants will be adults, at least 18 years of age, self-identify as male-to-female transgender or report having been born male and identifying as female, and report having sex with at least one man in the past six months. We anticipate participants will be comprised mainly of racial/ethnic minority participants under 35 years of age, consistent with 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. A quantitative assessment will be used to collect information for this study, which will be delivered at the time of study enrollment, and again at a six-month follow up. The assessment will be used to measure differences in sexual risk

knowledge, perceptions and behaviors including condom use, PrEP use, and use of medically supervised hormone therapy.

Intervention mediators, including healthcare provider trust and communication skills, self-reported health status and healthcare access, community attachment and social support will also be measured. All participants will complete an assessment at baseline and again at a six-month follow-up, after enrolling in the study. The intervention group will participate in ChiCAS after completing the baseline assessment and the delayed intervention group will participate in ChiCAS after completing the six-month follow up assessment.

CDC will also examine intervention experiences through in-depth interviews with 30 intervention group participants. The interviews will capture participants' general experiences with the ChiCAS intervention, as well as their experiences and perceptions specific to the main study outcomes: PrEP knowledge, awareness, interest and use; condom skills and use; and hormone therapy knowledge, awareness, interest and use.

It is expected that 50% of transgender women screened will meet study eligibility. We expect the initial screening and contact information gathering to take approximately four minutes to complete. The baseline assessment will take 60 minutes to complete and will be administered to 140 participants. The follow up assessment will take 45 minutes to complete and will be administered to 140 participants one time. The interview will

take 90 minutes to complete and will be administered to 30 participants from the intervention group one time.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 155.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
General Public - Adults	Eligibility Screener	140	1	3/60
General Public - Adults	Contact Information	70	1	1/60
General Public - Adults	Baseline Assessment	70	1	60/60
General Public - Adults	Follow-up Assessment	70	1	45/60
General Public - Adults	Interview	15	1	90/60

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