

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 |

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[FR Doc. 2018-01743 Filed 1-29-18; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Mother and Infant Home Visiting Program Evaluation (MIHOPE): Long-Term Follow-Up.

OMB No.: 0970-0402.

Description: The Administration for Children and Families (ACF), in partnership with the Health Resources and Services Administration (HRSA), both of the U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as

part of the Mother and Infant Home Visiting Program Evaluation Long-Term Follow-Up project (MIHOPE-LT). The purpose of MIHOPE-LT is to conduct follow-up studies that assess the long-term impact of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program. The design of MIHOPE-LT calls for multiple follow-up points including when the participating children are in kindergarten, 3rd grade, early adolescence, and late adolescence. This **Federal Register** Notice is specific to the first follow-up study. Data collected during the first follow-up study (when the children from the MIHOPE sample are of kindergarten age) will include the following: (1) A one-hour survey with

the child's primary caregiver (who will be the mother if she is available), (2) direct assessments of child development, (3) a semi-structured interview with the caregiver, (4) surveys with the child's teacher, (5) a direct assessment of the caregiver, and (6) 15 minutes of videotaped interactions between the caregiver and child. In addition to collecting these data, the MIHOPE-LT project will also maintain

up-to-date consent forms for the collection of administrative data. Future information collection requests and related **Federal Register** Notices will describe future data collection efforts for this project.

Data collected during the kindergarten follow-up study will be used to estimate the effects of MIECHV-funded programs on seven domains: (1) Maternal health; (2) child health; (3)

child development and school performance; (4) child maltreatment; (5) parenting; (6) crime or domestic violence; and (7) family economic self-sufficiency.

Respondents: The respondents in this follow-up study will include 4,115 families who participated in MIHOPE and 4,115 teachers of the focal children from those families.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|---|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| Survey of caregivers | 4115 | 1372 | 1 | 1 | 1372 |
| Direct assessments of children | 4115 | 1372 | 1 | 1.5 | 2058 |
| Semi-structured interview with caregivers | 100 | 33 | 1 | 2 | 66 |
| Survey of the focal children's teachers | 4115 | 1372 | 1 | 0.5 | 686 |
| Direct assessments of caregivers | 4115 | 1372 | 1 | 0.25 | 343 |
| Videotaped caregiver-child interactions | 8230 | 2743 | 1 | 0.25 | 686 |

Estimated Total Annual Burden Hours: 5,211.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Mary Jones,
ACF/OPRE Certifying Officer.
 [FR Doc. 2018-01683 Filed 1-29-18; 8:45 am]
BILLING CODE 4184-77-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting an Annual or Final Report to the Secretary

OMB No.: 0970-0409.
Description: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

The Administration for Children and Families, Office of Child Care, in

collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, has awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting discretionary grants support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively-mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

Tribal Home Visiting grantees have been notified that in every year of their grant, after the first year, they must comply with the requirement for submitting an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period and a final report to the Secretary during the final year of their grant. In order to assist grantees with meeting the requirements of the Annual and Final Report to the Secretary, ACF created guidance for grantees to use when writing their reports. The existing guidance (OMB Control No. 0970-0409, Expiration Date 10/31/18) provides sections where grantees must address the following:

- Update on Home Visiting Program Goals and Objectives
- Update on the Implementation of Home Visiting Program in Targeted Community(ies)