DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1301]

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 ''Templates for Extramural Data Management Plans'' 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 November 4, 2022 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.

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.

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.

Proposed Project

Templates for Extramural Data Management Plans (OMB Control No. 0920–1301, Exp. 6/30/2023)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This Information Collection Request (ICR) seeks continued approval for Data Management Plan (DMP) templates. DMPs are required annually of entities using CDC funds to collect or generate public health data. They are submitted to CDC by grant and cooperative agreement applicants and awardees for assessment to verify that they are compliant with CDC's data sharing policy. Having templates makes it easier for CDC awardees to create complete and compliant DMPs and easier for CDC project officers to assess them. Several CDC Centers have created customized templates. For this proposed Extension, some of the templates will undergo minor changes to increase utility and ease of use and the annual burden hour estimate has been updated based on the experience of the past three years and planned future use.

CDC requests OMB approval for an estimated from 1450 annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Applicants and Award Recipients	DMP Template	1450	1	60/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1080]

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 Outpatient Study (HOPS)'' 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 17, 2023 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 Outpatient Study (HOPS) (OMB Control No. 0920–1080, Exp. 2/29/2024)—Extension—National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests OMB approval to continue collecting information for HIV Outpatient Study (HOPS). The study is based on a prospective longitudinal cohort of adults with HIV in outpatient care at eight well-established private HIV care practices and university-based clinics in the U.S. The HOPS study sites are located in six cities: Tampa, Florida; Washington, DC; Stony Brook, New York; Chicago, Illinois; Denver, Colorado; and Philadelphia, Pennsylvania. The study currently collects information on a maximum of 2,700 outpatients per year. A portion of HOPS participants are lost to follow-up each year (most due to transferring out of the HOPS clinics), and our target goal is to enroll up to 450 new participants (50–60 per site) annually. Patients are approached during one of their routine clinic visits and invited to participate in the HOPS.

There are two sources of information for the HOPS. First, clinical data are abstracted on an ongoing basis from the medical records of study participants. Medical records provide data in five general categories: demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions (definitive and presumptive); medications prescribed (including dose, duration, and reasons for stopping); and all laboratory values, including CD4+ T lymphocyte (CD4+) cell counts, plasma HIV–RNA determinations, and genotype, phenotype, and trophile results. Clinic charts also provide data about visit frequency, AIDS, and death. Medical records abstraction is conducted by trained study staff and does not impose ongoing burden on HOPS participants. However, CDC does account for burden associated with the initial study consent and orientation process. The estimated burden per response is 15 minutes.

The second source of HOPS information is the annual behavioral assessment, an optional activity scheduled in conjunction with the participant's annual clinic visit. For convenience, the behavioral assessment can be completed in either of two modes: a brief Telephone Audio-Computer Assisted Self-Interview (T–ACASI) survey or an identical Web-based Audio-Computer Assisted Self-Interview (W–ACASI). Data collection includes: age, sex at birth, use of alcohol and drugs, cigarette smoking, adherence to antiretroviral medications, types of sexual intercourse, condom use, and disclosure of HIV status to partners. The estimated burden per response is seven minutes.

The core areas of HOPS research extending through the present HIV treatment era include: (i) investigating and characterizing (new) problems associated with long-term HIV infection and its treatments using the longitudinal cohort data; (ii) monitoring death rates and causes of death; (iii) characterizing the optimal patient management strategies to reduce HIV related morbidity and mortality (*e.g.,* effectiveness of antiretroviral therapies and other clinical interventions); (iv) assessing sexual and drug use behaviors and other patient reported outcomes that supplement data from chart abstraction; and (v) investigating disparities in the HIV care continuum by various demographic factors. In recent years, the HOPS has been instrumental in bringing attention to emerging issues in chronic HIV infection with actionable opportunities for prevention, including cardiovascular disease, fragility fractures, renal and hepatic disease, and cancers. The HOPS remains an important source for multi-year trend data concerning conditions and behaviors for which data are not readily available elsewhere, including: rates of opportunistic illnesses, rates of comorbid conditions (*e.g.,* hypertension, obesity, diabetes) and antiretroviral drug resistance.

OMB approval is requested for three years. The estimated number of participants in the annual behavioral assessment is 2,700 respondents. There are no changes to the information collection forms or methods. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 428 hours.

Estimated Annualized Burden Hours

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
HOPS Study Patients	Behavioral survey	2,700	1	7/60
HOPS Study Patients	Consent form	450	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–23AP]

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 ''TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic'' 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 November 16, 2022 to obtain comments from the public and affected agencies. CDC received three 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

TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic—New—National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC requesting public comment and OMB approval on a New information collection request (ICR) for the demonstration project titled ''TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic.''

Transgender (TG) persons, especially transgender women (TGW), have a high prevalence of HIV and lifetime risk of acquiring HIV. In the 2019–2020 National HIV Behavioral Surveillance Trans cycle, 42% of TGW tested positive for HIV. Racial/ethnic disparities were also found, with HIV positivity rates of 62% among Black/African American TGW and 35% among Hispanic/Latina TGW compared to 17% among White TGW. Despite the disproportionate burden of HIV among TGW, receipt of HIV prevention and care services have been suboptimal. Many TG persons experience poverty, homelessness, abuse, and have substance use or mental health disorders, which impact access to and utilization of HIV prevention and care services. Many TG persons seek gender-affirming care, including hormone therapy, at transgender health care organizations (TG clinics), and these encounters provide opportunities for HIV testing and status-neutral HIV services.

In the proposed demonstration project, TG clinics and transgender-serving community-based organizations (CBOs) will work collaboratively to evaluate community-to-clinic models to provide integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary healthcare, as well as to ensure access to mental health, substance use, and social support services. All services will be culturally and linguistically responsive for TG persons to ensure that they feel welcomed, heard, and cared for. The recipients will also participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons.

This collection of data, which involves creation of a unique identifier so that CDC does not receive any personally identifiable information (PII), will allow CDC to assist TG clinics and CBOs in monitoring and evaluating their programs providing status-neutral HIV services and comprehensive healthcare for TG persons and for community-to-clinic models of service provision. Longitudinal person-level data collection will occur through the clinics' electronic health record (EHR Data Form) and the Client Intake Form, and additional program evaluation data will be collected through client surveys (Client Satisfaction Survey).

The clients will complete the Client Intake Form once when they first join the program, with expected 800 clients per year for a total burden of 107 hours annually. A sample of 100 clients per site (400 total) will respond to the Client Satisfaction Survey once per year, for a total burden of 100 hours annually. The four data managers will extract data from the EHR, perform quality checks, code the data with a unique identifier, and transmit the deidentified data to CDC two times per year, for a total of 64 hours per year. The four data managers will also compile, link, deidentify, and report data from the Client Intake Forms two times per year, with an estimated burden of 16 hours annually. The four data managers will compile and report data from the Satisfaction Survey once per year, with an estimated burden of eight hours annually.

OMB approval is requested for three years. Participation of the funded recipients' data managers is required, and participation from the clients is voluntary. There is no cost to participants other than their time. The total estimated annualized burden is 295 hours.