



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-1080]

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 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 September 14, 2020 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.

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. 9/30/2021) - Extension - National Center for HIV/AIDS,

Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention requests OMB approval to continue collecting information for HIV Outpatient Study (HOPS). The study is based on a prospective longitudinal cohort of adults living 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 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 (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 multiyear 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 will increase from 2,500 respondents to 2,700 respondents, resulting in an increase of 23 burden hours. 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	Behavioral	2,700	1	7/60

Patients	survey			
HOPS Study Patients	Consent form	450	1	15/60

Jeffrey M. Zirger,
Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2021-00003 Filed: 1/6/2021 8:45 am; Publication Date: 1/7/2021]