DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-1080; Docket No. CDC-2023-0010]

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 the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled HIV Outpatient Study (HOPS). HOPS is a CDC data collection for standardized HIV clinical and behavioral data at private HIV care practices and university-based U.S. clinics participating in the HOPS program.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0010 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

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

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; 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 the 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;
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; and
5. Assess information collection costs.

Proposed Project

HIV Outpatient Study (HOPS) (OMB Control No. 0920-1080, Exp. 02/29/2024) – Extension - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests a three-year approval for the HIV Outpatient Study (HOPS) data collection. HOPS is a prospective longitudinal cohort of patients in HIV care at eight well established private HIV care practices and university-based U.S. clinics, in: Tampa, Florida; Washington, DC; Stony Brook, New York; Chicago, Illinois; Denver, Colorado; and Philadelphia, Pennsylvania. Clinical data are abstracted on an ongoing basis from the medical records of adult HOPS study participants, who also complete an optional telephone/web-based behavioral assessment as part of their annual clinic visit, which on average takes about seven minutes. Before enrolling in this study, all potential study participants will undergo an informed consent process (including signing of a written informed consent) which is estimated to take 15 minutes.

The core areas of HOPS research extending through the present HIV treatment era include: (i) monitoring death rates and causes of death; (ii) characterizing the optimal patient management strategies to reduce HIV related morbidity and mortality (*e.g.,* effectiveness of antiretroviral therapies and other clinical interventions); (iii) monitoring of sexual and drug use behaviors to inform prevention for persons living with HIV; and (iv) investigating disparities in the HIV care continuum by various demographic factors. In recent years, 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. 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.

Data will be collected through medical record abstraction by trained abstractors and by telephone or Internet-based, computer-assisted interviews at eight funded study sites in six U.S. cities. Collection of data abstracted from patient medical records provides 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+ Tlymphocyte (CD4+) cell counts, plasma HIV–RNA determinations, and genotype, phenotype, and trophile results. Data on visit frequency, AIDS, and death are acquired from the clinic chart. Data collected using a brief Telephone Audio-Computer Assisted Self- Interview (T–ACASI) survey or an identical Web-based Audio-Computer Assisted Self-Interview (ACASI) include: 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.

CDC anticipates that 450 new HOPS study participants will be recruited annually into HOPS from a pool of patients with HIV currently in HIV-care at the eight aforementioned clinics (50-60 patients per site). Patients are approached during one of their routine clinic visits to participate in HOPS. Patients interested in participating in HOPS are given detailed information about the nature of the study and provided with written informed consent that must be completed prior to enrollment. The 450 newly enrolled participants each year will be added to the database of existing participants such that approximately 2,700 participants will be seen in the HOPS each year. Medical record abstractions will be completed on all HOPS participants and impose no direct burden on HOPS study participants.

Participation of respondents is voluntary. CDC request OMB approval for an estimated 428 annual burden hours. There is no cost to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
HOPS Study Patients	Behavioral survey	2,700	1	7/60	315
HOPS Study Patients	Consent form	450	1	15/60	113
Total					428

Jeffrey M. Zirger,

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Centers for Disease Control and Prevention.

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