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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-15JX]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

HIV Outpatient Study(HOPS) - New - National Center for HIV/AIDS, 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 requests a three-year approval for the HIV Outpatient Study data collection

activity. The HIV Outpatient Study (HOPS) is a prospective longitudinal cohort of HIV-infected outpatients at nine well-established private HIV care practices and university-based U.S. clinics. Clinical data are abstracted on ongoing basis from the medical records of adult HIV-infected HOPS study participants, who also complete an optional seven minute telephone/web-based behavioral assessment as part of their annual clinic visit.

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 with Positives, and (iv) 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.

Data will be collected through medical record abstraction by trained abstractors and by telephone or internet-based, computer-assisted interviews at nine 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); all laboratory values, including CD4+ T-lymphocyte (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.

We estimate consenting 450 new participants per year across all HOPS study sites (50 participants at each of the 9 sites). The consent process takes approximately 15 minutes to complete.

Medical record abstractions will be completed on all eligible participants. All eligible participants will be offered the opportunity to participate in an optional short survey that will take approximately seven minutes.

Participation of respondents is voluntary. There is no cost to the respondents other than their time. The estimated annual burden hours are 405.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
HOPS study Patients	Behavioral survey	2,500	1	7/60
HOPS Study Patients	Consent form	450	1	15/60

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Leroy A. Richardson,
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Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

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