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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[60Day-15-15JX]

Proposed Data Collections Submitted for
Public Comment and Recommendations

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 to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited 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) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 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, in Tampa, Florida; Washington, DC; Stony Brook, New York; Chicago, Illinois; Denver, Colorado; and Philadelphia, Pennsylvania.

Clinical data are abstracted on ongoing basis from the medical records of adult HIV-infected 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 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 anticipate that 450 new HOPS study participants will be recruited annually into the HOPS from a pool of HIV-infected individuals currently in HIV-care at the nine aforementioned clinics (50 patients per site). Patients are approached during one of their routine clinic visits to participate in the HOPS. Patients interested in participating in the 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 2,500 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. There is no cost to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
HOPS study Patients	Consent form	450	1	15/60	113
HOPS Study Patients	Behavioral survey	2,500	1	7/60	292
Total					405

Leroy A. Richardson
 Chief, Information Collection Review Office
 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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