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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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	Number of respondents	Number 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

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15AHO; Docket No. CDC–2015–0031]

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 efforts 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. This notice invites comment on a proposed information collection for a retrospective evaluation of the prevalence of acute flaccid myelitis with MRI grey matter findings among children aged ≤18 years.

DATES: Written comments must be received on or before July 13, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0031 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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.

Proposed Project

Retrospective evaluation of the prevalence of acute flaccid myelitis with MRI grey matter findings among children aged ≤18 years—NEW—National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Acute onset limb weakness, commonly referred to as acute flaccid paralysis (AFP), is a relatively uncommon syndrome among children. From August–October 2014, several clusters of AFP among children were reported from several states within the United States (U.S.) and an epidemiologic investigation was initiated to elucidate the possible causes of these cases.

CDC originally collected data under OMB Control Numbers 0920–1011 and 0920–0009. Cases were characterized by distinctive abnormalities on spinal magnetic resonance imaging (MRI), in which pathologic changes were largely restricted to the central grey matter of the spinal cord. Due to these findings and to differentiate this illness from other forms of AFP, CDC used the term 'acute flaccid myelitis' (AFM).

The main goal of this study is to obtain data in order to estimate the baseline rate of AFM that is accompanied by MRI changes confined to spinal grey matter among children ≤18 years of age that were seen at six pediatric medical centers in the United States. Data on spinal MRIs from years 2005–2014 will be collected from six sentinel medical centers. Physicians at these medical centers will examine the MRI reports and extract data on specific variables using a database developed by CDC.

Data will then be sent to CDC, where 2005–2013 data will be compared with 2014 data in order to assess if 2014 rates of AFM were higher than in previous years. Furthermore, this evaluation will provide important information regarding characteristics of patients presenting with AFM and grey matter changes, assist in determining the potential for surveillance focusing on MRI findings because AFM is not routinely conducted in the United States and identify possible risk factors.

The data will be used to estimate a baseline for the rate of AFM that occurs in the United States each year. This information has not been previously collected, since the U.S. does not collect routine surveillance for AFM/AFP.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. The