Dated: April 16, 1998.

Kathy Cahill,

Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–12–98]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

1. Follow-Up Study of Children With Developmental Disabilities—New—National Center for Environmental Health—In the mid-1980's, 10-year-old children were identified as having one or more of five developmental disabilities: mental retardation, cerebral palsy, epilepsy, hearing impairment, or vision impairment. These children were identified (mainly from special education records in the public schools) in the metro-Atlanta area as part of a study to develop surveillance methods for these conditions in school-age children. A follow-up study is proposed to trace, locate, and interview these children, who are now in their early twenties, to assess their status with regard to educational attainment, employment, living arrangements, services received, functional limitations, adaptive behavior, social participation, health, and quality of life. Previous studies (published mostly in the mid-1980's) on the post-secondary school experiences of former recipients of special education services were either limited to one type of impairment (e.g., mild mental retardation) or were restricted to a narrow range of outcomes (e.g., employment and education) or did not incorporate a comparison group of persons who were not in special education. The proposed study is a one-time, in-person interview and includes a contemporaneous comparison group of persons who, at age 10 years, were in regular education classes in the same schools as were the persons with developmental disabilities. A base of 1,608 identified children and 650 comparison persons will be used to find a total of 1,600 who will be interviewed. The data generated from this study will be used to estimate the burden of secondary health conditions, limited social participation, and economic disadvantage among young adults with long-standing developmental impairments. This information will be helpful to efforts aimed at the prevention of various secondary problems in this population. Total annual burden hours are 1,312.

Activity	Number of respondents	Number of responses/ respondent	Avg. burden/re-sponses (in hrs.)	Total burden (in hrs.)
Contacting/Scheduling call	1,290	1	0.166	215
Face-to-face Interview	1,097	1	1	1,097

2. Model Performance Evaluation Program for Retroviral and AIDS-Related Testing—(0920–0274)—Revision—Public Health Practice Program Office (PHPPO). The CDC Model Performance Evaluation Program (MPEP) currently assesses the performance of laboratories that test for human immunodeficiency virus type 1 (HIV–1) antibody, human T-lymphotropic virus types I and II (HTLV–I/II) antibody, perform CD4 T-cell testing or T-lymphocyte immunophenotyping (TLI) by flow cytometry or alternate methods, perform HIV–1 ribonucleic acid (RNA) determinations (viral load), and test for HIV–1 p24 antigen through the use of mailed sample panels. The CDC MPEP is proposing to use annual data collection documents to gain updated information on the characteristics of testing laboratories and their testing practices. Two data collection instruments, or survey questionnaires, will be used. The first data collection instrument will be concerned with laboratories that perform HIV–1 antibody (Ab) testing, HTLV–I/II Ab testing, HIV–1 viral RNA determinations, and HIV–1 p24 antigen (Ag) testing. Laboratories enrolled in the MPEP will be mailed a survey questionnaire and be asked to complete the sections pertinent to their laboratory's testing. The survey instrument will collect demographic information related to laboratory type, primary purpose for testing, types of specimens tested, minimum education requirements of testing personnel, laboratory director, and laboratory supervisor, and training required of testing personnel. The demographic section will be followed by more specific sections related directly to HIV–1 Ab testing, HTLV–/II Ab testing, HIV–1 RNA, and HIV–1 p24 Ag testing. Included in the latter sections will be questions related to the types of tests performed, the algorithm of testing, how test results are interpreted, how results are reported, how specimens may be rejected for testing, if some testing is referred to other laboratories, and what quality control and quality assurance procedures are conducted by the laboratory. Similarly, the TLI survey questionnaire will also collect demographic information about each laboratory, as well as the type(s) of flow cytometer used, educational and training requirements of testing personnel, the types of monoclonal antibodies used in testing, how specimens are received, prepared, and stored, how test results are recorded and reported to the test requestor, and what quality control and quality assurance procedures are practiced. Information collected through the use of these instruments will enable CDC to determine if laboratories are conforming to published recommendations and guidelines, whether education and training requirements of testing personnel are conforming to current legislative requirements, and whether problems in testing can be identified through the collection of information. Information collected through the survey instruments will then be compared statistically with the performance evaluation results reported by the enrolled laboratories to determine if characteristics of laboratories that perform well can be distinguished from laboratories not performing as well. Upon enrolling in the MPEP, participants are assigned an

MPEP number used to report testing results and survey questionnaire responses, allowing the individual responses of each laboratory participant to be treated in confidence. When participants respond to the surveys by sending CDC completed questionnaires, the collected information is developed into aggregate reports. A copy of the completed report is provided to each participating laboratory. Total annual burden hours are 668.

Type of respondents	Number of respondents	Number of respondents/ response	Average burden/response (in hrs)	Total burden (in hrs)
Enrollments (new)	100	1	0.05	5
Retroviral Survey	1,000	1	0.5	500
TLI Survey	350	1	0.5	163

3. Evaluation of Educational Brochures on Opportunistic Infections Affecting People with HIV/AIDS—New—The National Center for HIV, STD and TB Prevention, Division of HIV/AIDS Prevention, Intervention Research and Support proposes to conduct research to assure that intended audiences (persons living with HIV/AIDS) find the brochures clear, informative and useful. Specifically, the research will examine perceptions of the appearance, quality, value, readability, and clarity of the information provided. Attention will be focused on identifying information, language and/or formatting issues which are confusing or unclear. Further, although the intended audience of the brochure series is all persons living with HIV/AIDS, we propose to use the limited resources available to target those who are lower income. This is warranted given their often more restricted access to reliable information sources, making the brochures a more valuable resource for them. In addition, the correlations between low socio-economic status (SES) and low literacy warrant attention to assuring the readability and comprehension of the materials among this group.

The information generated from this research will enable NCHSTP to tailor materials to the needs, wants and preferences of individuals living with HIV/AIDS. Additionally, the center is committed to developing a standardized process for including such audience testing in subsequent materials development projects. The proposed process will provide the foundation for establishing a standardized process for such assessment. Total annual burden hours are 275.

Form name	Number of respondents	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Form A [1]	550	1	0.5	275

[1] Estimated time includes 10–15 minutes for reading one of the 11 information brochures and 10–15 minutes to complete the survey which will be administered orally.

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Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Vaccine Advisory Committee, Subcommittee on Future Vaccines, Subcommittee on Immunization Coverage, and Subcommittee on Vaccine Safety: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Federal advisory committee meetings.

Name: National Vaccine Advisory Committee (NVAC).

Times and Dates: 9 a.m.–2 p.m., May 7, 1998. 8:30 a.m.–1:30 p.m., May 8, 1998.

Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each day either between 8 and 8:30 a.m. or 12:30 and 1 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured.

Purpose: This committee advises and makes recommendations to the Director of the National Vaccine Program on matters related to the Program responsibilities.

Matters To Be Discussed: Agenda items include updates on the National Vaccine Program Office (NVPO) activities and non-traditional sites for adult immunization: NVAC recommendations and guidelines and a presentation on a model system in San Antonio, Texas. David Satcher, M.D., Ph.D., the Assistant Secretary for Health and Surgeon General, will discuss his new role and immunization as a key component in enhancing the health of the Nation. Committee discussions on the following: initiatives in vaccine communication, strategies for promoting travel vaccines, the impact and effects of welfare reform on immunization, vaccines as a response to bioterrorism, the status of influenza pandemic preparedness, joint vaccine acquisition program—limited use vaccines; reports from the Immunization Registries Workgroup, Subcommittee on Immunization Coverage, Subcommittee on Future Vaccines, and Subcommittee on Vaccine Safety; and a review of fiscal year 98 unmet needs.

Name: Subcommittee on Immunization Coverage.

Time and Date: 2 p.m.–5 p.m., May 7, 1998.

Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee identifies and proposes solutions that provide a multifaceted and holistic approach to reducing barriers that result in low immunization coverage for children.

Matters To Be Discussed: Agenda items include a review of recommendations from the document, ''Strategies to Sustain Immunization Coverage,'' and how to sustain immunization coverage rates in children.

Name: Subcommittee on Future Vaccines.

Time and Date: 2 p.m.–5 p.m., May 7, 1998.