

from that exposure. Biological measurements or biomarkers can detect effects of exposure long before a disease can be diagnosed. A questionnaire will be administered to determine confounders and other conditions that might affect exposure such as work history and work practices. This project

will recruit oncology nurses, pharmacists, and pharmacy technicians and will be conducted in collaboration with the University of Maryland, the University of North Carolina, and the M.D. Anderson Cancer Center.

By utilizing a battery of sensitive biomarkers, the effects of low-level chronic exposure to antineoplastic

agents can be determined. Using the results of the proposed study, exposures can be minimized or eliminated before adverse health effects occur. Ultimately, the study will contribute to the prevention of occupational disease from antineoplastic drug exposure. There are no costs to respondents.

| Survey | Number of respondents | Number of responses/respondent | Average burden/response (in hours) | Total burden (in hours) |
|------------------------------------------|-----------------------|--------------------------------|------------------------------------|-------------------------|
| Genotoxicity Immunotoxicity Study* | 150 | 1 | 1 | 150 |
| Reproductive Health Study† | 150 | 1 | 225/60 | 562.5 |
| Total | | | | 714.50 |

* This part of the study involves the participant, after informed consent, voluntarily providing blood and urine samples and responding to a questionnaire concerning medical history, work history, and work practices to identify study eligibility, past exposures, and confounders.

† In the reproductive health part of the study and after informed consent, women are being asked to voluntarily give a daily urine sample for approximately 45 days and keep track of their menstrual cycle by entries into a diary. In addition, a short questionnaire is given to each participant to determine eligibility for inclusion into the study and confounders of hormone analysis.

Dated: July 18, 2002.

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[FR Doc. 02-18781 Filed 7-24-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-02-71]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404)498-1210.

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; and (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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Adult and Pediatric HIV/AIDS Confidential Case Reports (CDC 50.42A, 50.42B)—New—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC). This data collection system was formerly included and approved under the National Disease Surveillance Program, OMB No. 0920-0009, National Center for Infectious Disease (NCID), CDC. CDC is seeking a 3-year OMB approval to continue data collection of the HIV/AIDS case reports, with revisions of the report forms to collect race and ethnicity data in adherence to OMB Statistical Policy Directive 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting.

The National Adult and Pediatric HIV/AIDS Confidential Case Reports are collected as part of the HIV/AIDS Surveillance System. CDC in collaboration with health departments in the states, territories, and the District of Columbia, conducts national surveillance for cases of human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS), the end-stage of disease caused by infection with HIV. HIV/AIDS surveillance data collection by CDC is authorized under sections 301 and 306 of the Public Health Service Act (42 U.S.C. 241 and 242k).

Currently, 55 states (areas/territories) mandate and collect AIDS surveillance

data. In addition, 35 areas mandate and collect surveillance data on HIV cases which have not progressed to AIDS in adults/adolescents and/or children using the HIV/AIDS case report forms. The purpose of HIV/AIDS surveillance data is to monitor trends in HIV/AIDS and describe the characteristics of infected persons (e.g., demographics, modes of exposure to HIV, manifestations of severe HIV disease, and deaths due to AIDS). Because HIV infection results in untimely death and most often infects younger adults in the prime years of life, large amounts of federal, state, and local government funding have been allocated to address all aspects of HIV infection, including prevention and treatment. HIV/AIDS surveillance data are widely used at all government levels to assess the impact of HIV infection on morbidity and mortality, to allocate medical care resources and services, and to guide prevention and disease control activities.

HIV/AIDS reports are sent to state/local health departments by laboratories, physicians, hospitals, clinics, and other health care providers using standard adult and pediatric case report forms. Areas use a microcomputer system developed by CDC (the HIV/AIDS Reporting System, HARS) to store and analyze data, as well as transmit encrypted data to CDC. An HIV program area module (PAM) for the National Electronic Disease Surveillance System (NEDSS) is in the early development stage and will replace HARS when it is complete.

In order to adhere to OMB Directive 15, the proposed data collection form will collect race and ethnicity separately, collect multiple races, and

disaggregate Asian/Pacific Islander into two categories: Asian and Native Hawaiian/Other Pacific Islander.

No other federal agency collects this type of national HIV/AIDS data. In addition to providing technical assistance for use of the case report

forms, CDC also provides reporting areas with technical support for the HARS software. There is no cost to respondents.

| Form | Number of respondents | Number of responses/re-spondent | Average burden/response/ (in hours) | Total burden (in hours) |
|-------------------------------|-----------------------|---------------------------------|-------------------------------------|-------------------------|
| Adult Case Report: AIDS | 55 | 782 | 10/60 | 7,168 |
| Adult Case Report: HIV | 35 | 1007 | 10/60 | 5,874 |
| Peds Case Report: AIDS | 55 | 3 | 10/60 | 28 |
| Peds Case Report: HIV | 35 | 16 | 10/60 | 93 |
| Total | | | | 13,163 |

Dated: July 19, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02-18818 Filed 7-24-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-39-02]

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) 498-1210. 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 Project: Report of Verified Case of Tuberculosis (RVCT) (CDC 72.9A, 72.9B, 72.9C) OMB No. 0920-0026—Revision—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention

(NCHSTP), Division of Tuberculosis Elimination (DTBE), proposes to continue data collection for the Report of Verified Case of Tuberculosis (RVCT) (CDC 72.9A, 72.9B, 72.9C), previously approved under OMB No. 0920-0026 in 1992, 1995, 1998, and 2001. This request is for a 3-year revision of OMB clearance approval beginning January 1, 2003 (current OMB No. 0920-0026 expiration date is December 31, 2002). CDC is requesting OMB clearance for revision of the RVCT which will change the race and ethnicity variables on the RVCT form to comply with the OMB “Standards for Maintaining, Collecting, and Processing Federal Data on Race and Ethnicity”.

To accomplish the CDC goal of eliminating tuberculosis (TB) in the United States, CDC maintains the national TB surveillance system. The system, initiated in 1953, has been modified several times to better monitor and respond to changes in TB morbidity. The most recent modification was implemented in 1993 when the RVCT was expanded in response to the TB epidemic of the late 1980s and early 1990s and incorporated into a CDC software for electronic reporting of TB case reports to CDC. The expanded system improved the ability of CDC to monitor important aspects of TB epidemiology in the United States, including drug resistance, TB risk factors, including HIV coinfection, and treatment. The timely system also enabled CDC to monitor the recovery of the nation from the resurgence and identify that current TB epidemiology supports the renewed national goal of elimination. To measure progress in

achieving this goal, as well as continue to monitor TB trends and potential TB outbreaks, identify high risk populations for TB, and gauge program performance, CDC proposes to extend use of the RVCT.

Data are collected by 60 Reporting Areas (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean) using the RVCT. An RVCT is completed for each reported TB case and contains demographic, clinical, and laboratory information. A comprehensive software package, the Tuberculosis Information Management System (TIMS) is used for RVCT data entry and electronic transmission of TB case reports to CDC. TIMS provides reports, query functions, and export functions to assist in analysis of the data. CDC publishes an annual report summarizing national TB statistics and also periodically conducts special analyses for publication in peer-reviewed scientific journals to further describe and interpret national TB data. These data assist public health officials and policy makers in program planning, evaluation, and resource allocation. Reporting Areas also review and analyze their RVCT data to monitor local TB trends, evaluate program success, and assist in focusing resources to eliminate TB.

No other federal agency collects this type of national TB data. In addition to providing technical assistance for use of the RVCT, CDC also provides Reporting Areas with technical support for the TIMS software. There annualized burden for this data collection is 8,338 hours.

| Respondents | Number of respondents | Responses per respondent | Average burden per response (in hours) |
|--------------------------------------|-----------------------|--------------------------|----------------------------------------|
| State/Local/Tribal Governments | 60 | 278 | 30/60 |