

Dated: August 11, 2005.

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Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-05-0680]

Proposed Data Collections Submitted for Public Comment and Recommendations

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) 371-5983 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Model Performance Evaluation Program (MPEP), Severe Acute Respiratory Syndrome (SARS) MPEP

OMB No. 0920-0680—Revision—Division of Laboratory Systems, Center for Health Information and Services (CoCHIS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

To support our mission of improving public health and preventing disease through continuously improving laboratory practices, the Model Performance Evaluation Program (MPEP), Division of Public Health Partnerships, Coordinating Center for Health Information and Services, in collaboration with the Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, intends to provide a new SARS-associated Coronavirus testing Model Performance Evaluation Program (SARS MPEP). This program will offer external performance evaluation (PE) for SARS antibody (Ab) testing and SARS Ribonucleic Acid (RNA) Reverse Transcriptase—Polymerase Chain Reaction (RT-PCR) testing. A SARS outbreak or epidemic could recur at any time. Therefore, it is imperative that the CDC ensure all state public health department laboratories, Laboratory Response Network laboratories and other laboratories designated by CDC remain proficient in performing SARS testing. For this reason, it is of critical public health importance at this time, that the CDC develop and maintain a performance evaluation program for SARS. Participation in PE programs is

expected to lead to improved SARS testing performance because participants have the opportunity to identify areas for improvement which will help to ensure accurate testing as a basis for development of SARS prevention and intervention strategies.

This external quality assessment program will be made available at *no cost* (for receipt of sample panels) to 54 state laboratories. This program will offer laboratories/testing sites opportunities for:

- (1) assuring that the laboratories/testing sites are providing accurate tests through external quality assessment,
- (2) improving testing quality through self-evaluation in a nonregulatory environment,
- (3) testing well characterized samples from a source outside the test kit manufacturer,
- (4) discovering potential testing problems so that laboratories/testing sites can adjust procedures to eliminate them,
- (5) comparing individual laboratory/testing site results to others at state level, and
- (6) consulting with CDC staff to discuss testing issues.

Participants in the MPEP SARS will be required to submit results twice a year after testing mailed performance evaluation samples.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 18.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	No. of respondents	Frequency of responses	Average burden per response (in hours)
SARS Testing Results Booklet	54	2	10/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-05-05CS]

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 404-371-5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

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. Written comments should be received within 60 days of this notice.

Proposed Project

Nurse-Delivered Risk Reduction Intervention for HIV-Infected Women-New-National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: CDC is requesting a 3-year approval from the Office of Management and Budget (OMB) to administer a questionnaire and a one-on-one qualitative interview to HIV-infected women in the southern United States who are at risk for further transmission of the disease. This study is designed to adapt and evaluate an HIV transmission prevention intervention for the growing population of HIV-infected women in the South and to study factors associated with risk among women. The primary outcome will be a reduction in

sexual risk behavior as a result of a brief, nurse-delivered prevention intervention adapted for use with HIV-infected women in the South. The project will also conduct in-depth qualitative interviews of young, recently HIV-infected women to assess social and environmental factors that contribute to behavioral risk for HIV infection. The project addresses goals of the *CDC HIV Prevention Strategic Plan*, specifically the goal of increasing the number of HIV-infected persons who are linked to appropriate prevention, care, and treatment services. In addition, information from this research will inform future prevention interventions that encompass individual and contextual factors.

Approximately 550 women will be screened for eligibility to participate in the study, and a minimum of 330 women from one or two sites will be recruited and administered baseline and follow-up behavioral risk assessments in a randomized wait-list comparison design with a 6-month follow-up period. That is, the intervention and comparison group will complete an assessment at the baseline and in 6

months a follow-up assessment will be conducted to compare behavior change. Six months after the intervention group has been provided the intervention and follow-up, women in the comparison group will receive the intervention. The assessments will capture information on demographics, risk behaviors, attitudes, and knowledge related to HIV/STD transmission and prevention. Semi-structured qualitative interviews will be conducted with a subgroup of 25–30 young, recently-diagnosed participants following their participation in the intervention study. These interviews will explore behavioral, social, and contextual conditions that may have contributed to the women’s risk for HIV infection and ideas about preventing other women from becoming infected. The two behavioral assessments will take about 1 hour each to complete, the nurse-delivered intervention will take about 1 hour to complete, and the qualitative interviews will take about 2 hours to complete. The screening interview will take about 10 minutes to complete. There is no cost to respondents other than the time it takes them to participate.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Burden per response (in hours)	Total burden (in hours)
Women—screening interview	550	1	10/60	92
Women—assessment interviews	330	2	1	660
Women—intervention	330	1	1	330
Women—qualitative interviews	30	1	2	60
Total				1142

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0573]

Proposed Data Collections Submitted for Public Comment and Recommendations

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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 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

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. Written comments should be received within 60 days of this notice.

Proposed Project

Adult and Pediatric HIV/AIDS Confidential Case Reports (OMB Control No. 0920–0573)—Revision-National Center for HIV, STD, and TB Prevention (NCHSTP), Divisions of HIV/AIDS Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking a 3-year approval from the Office of Management and Budget (OMB) to continue data collection of the HIV/AIDS case reports. CDC is proposing to collect additional data on testing history for improved monitoring of HIV incidence (HIV testing history pre-test and post-test data collection forms), on specimen quality and