

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-04-60]

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 or send an email 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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov. Written comments should be received within 60 days of this notice.

Proposed Project

Control of Communicable Diseases: Restrictions on African Rodents, Prairie Dogs, and certain other Animals (OMB 0920-0615)—Reinstatement—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Section 361 of the Public Health Service (PHS) Act, [42 U.S.C. 264],

authorizes the Secretary of Health and Human Services to make regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Existing regulations governing quarantine activities [42 CFR 71.54] provide for the issuance of permits by the Director, Centers for Disease Control and Prevention (CDC), for the importation of any animal host or vector of human disease, or any other animal capable of being a host or vector of human disease, contingent upon the importers meeting certain application and disease control requirements, to be established by the Director (OMB# 0920-0199).

In 2003, individuals in the United States began contracting monkeypox, and very likely as a result of contact with prairie dogs that had contracted monkeypox from diseased African rodents. Investigations indicated that a Texas animal distributor imported a shipment of approximately 800 small mammals from Ghana on April 9, 2003, and that shipment contained 762 African rodents, including rope squirrels (*Funisciurus* sp.), tree squirrels (*Heliosciurus* sp.), Gambian giant rats (*Cricetomys* sp.), brushtail porcupines (*Atherurus* sp.), dormice (*Graphiurus* sp.), and striped mice (*Hybomys* sp.). Some animals were infected with monkeypox, and CDC laboratory testing confirmed the presence of monkeypox in several rodent species.

On June 11, 2003, the Director of CDC and the Commissioner of the Food and Drug Administration (FDA) issued a joint order prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of:

- Prairie dogs (*Cynomys* sp.);
- Tree squirrels (*Heliosciurus* sp.);
- Rope squirrels (*Funisciurus* sp.);
- Dormice (*Graphiurus* sp.);
- Gambian giant pouched rats (*Cricetomys* sp.);
- Brush-tailed porcupines (*Atherurus* sp.), and
- Striped mice (*Hybomys* sp.).

In addition, CDC implemented an immediate embargo on the importation of all rodents from Africa (order *Rodentia*). On Nov. 4, 2003, the Department of Health and Human Services (the Food and Drug Administration (FDA) and CDC) promulgated an Interim Final Rule (IFR) restricting the importation of African rodents (42 CFR 71.56) and restricting domestic trade in certain African rodents and domestic prairie dogs (21 CFR 1240.63) (see 68 FR 62353). This interim final rule supersedes the June 11, 2003, order.

Under § 71.56(a) (2), prospective importers must submit a proposed import plan to CDC if they wish to import the specific rodents and rodent products covered by this rule. The plan must address disease prevention procedures to be carried out in every step of the chain of custody of such rodents, from embarkation in the country of origin to release from quarantine (if required). Information such as species, origin and intended use for the rodents and/or rodent products, transit information, isolation and quarantine (if required) procedures, and procedures for testing of quarantined animals is necessary for CDC to make public health decisions. This information enables CDC to evaluate compliance with the standards and determine whether the measures being taken to prevent exposure of persons and animals during importation are adequate.

The burden imposed by this permit application is based on the estimated amount of time needed to perform the requirement multiplied by the number of responses. Five (5) respondents are estimated to submit an average of 2 responses each. Respondents operating with established permits would normally need less time to make submissions (30 minutes per response); new permit holders, estimated to be 7 in number, would each make no more than 1 full submission. All remaining submissions would be itinerary and/or change information only (10 minutes per response). The estimated total annual burden is 10 hours. There is no cost to respondents.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hours)	Total burden in hours
Individuals	2	1	30/60	1
Businesses	5	1	30/60	3
Organizations—initial request	5	1	1	5
Organizations—subsequent request	5	1	10/60	1
Total	12	10

Dated: May 27, 2004.

Alvin Hall,

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Office, Centers for Disease Control and
Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Simplified Procedures for Routine HIV Screening in Acute Care Settings

Announcement Type: New.

Funding Opportunity Number: 04156.

Catalog of Federal Domestic

Assistance Number: 93.943.

Key Dates: Application Deadline:
August 2, 2004.

Executive Summary

Approximately 250,000 people living with HIV in the United States are undiagnosed. Many persons with AIDS made multiple visits to hospitals, acute care clinics and managed-care organizations before their AIDS diagnosis, but were never tested for HIV. These encounters are missed opportunities for earlier detection of HIV infection. When HIV testing has been offered on a routine basis (independent of risk factors or symptoms suggestive of HIV) to patients in high-prevalence, high-volume acute care settings, many HIV-infected patients have been identified and the proportion of positive tests has often been equal to or greater than among publicly funded HIV counseling and testing sites and sexually transmitted disease (STD) clinics. Such findings suggest that broader implementation of routine HIV screening in high-prevalence health care settings is an important component of our national strategy aimed at identifying persons with undiagnosed HIV infection.

Many patients in high volume, high HIV prevalence acute care facilities that have implemented routine rapid HIV testing have not been offered HIV testing because of the limitations imposed by the required procedures and staffing. Many providers perceive pre-test discussions as too time-consuming. In addition, it may not be practical to commit sufficient staff to approach all patients to offer HIV testing and provide prior counseling during peak time periods. Prevention counseling may not be appropriate or feasible during many episodic or acute care visits. Thus, mandatory individual pretest counseling may be a barrier to offering

HIV testing in these settings. Written brochures, when used to replace formal verbal pretest discussions, have been shown to increase the numbers of patients who can be offered HIV testing. In order to be successful in implementing routine HIV testing programs, pre-test procedures must be simplified to ensure that large numbers of patients can be screened for HIV in busy clinical settings.

The goal of this program is to examine changes in pre-test screening and education procedures which may increase the number of patients who test for HIV and who receive their results. The objectives of this program are to modify procedures and materials for providing pre-test information and to evaluate the feasibility, acceptability, and success of these simplified procedures at the participating site(s).

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act, sections 301, 311, and 317 (42 U.S.C sections 241, 243 and 247(b)), as amended.

Purpose: The purpose of the program is to develop and evaluate simplified procedures and materials to improve the programmatic success of existing routine HIV screening projects in acute care settings. Simplified procedures are necessary to ensure that large numbers of patients can be screened for HIV in busy clinical settings. This program addresses the "Healthy People 2010" focus area(s) of HIV. Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for HIV, STD and TB Prevention (NCHSTP): Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs. In addition, this program addresses the Division of HIV/AIDS Prevention priorities: Develop new methods for diagnosing HIV infection.

Activities

Awardee activities for this program are as follows:

- Modify the facility's existing procedures for HIV pre-test education and recruitment in order to increase the number of patients tested and who receive their results, by developing materials or procedures such as brochures, posters, videos, or group waiting room activities to promote routine HIV screening and provide pre-test information.
- Continue to routinely offer rapid HIV testing to patients in the acute care

center with the modified pre-test procedures.

- Assess the programmatic outcomes of the modified procedures (e.g., number of patients offered testing, number of patients accepting testing, number of patients tested, number of newly diagnosed HIV infections, seropositivity rate among persons tested). Periodically provide CDC with these data.

- Assess patient and provider satisfaction with the modified procedures.

- Assess patient comprehension of pre-test messages delivered through modified materials relative to existing procedures.

- Utilize program data to revise the procedures to improve the project's effectiveness.

- Participate in conference calls, meetings, and site visits.

- Collaborate with CDC to disseminate the findings and details on modified procedures and materials.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Assist in the development and review of the modified pre-test counseling procedures, activities, and printed materials.
- Provide guidance and assistance in the development of data collection instruments as well as data management systems and procedures.
- Facilitate conference calls, grantee meetings, and site visits.
- Assist in the analysis and dissemination of findings.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$120,000.

Approximate Number of Awards: One-Two.

Approximate Average Award: \$60,000-\$120,000 (This amount includes both direct and indirect costs).

Floor of Award Range: \$60,000.

Ceiling of Award Range: \$120,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: one year.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as