

type. Large schools will be given the option to invite a census of ninth grade students to participate in the study or to invite a subset of ninth grade students (in certain classes) to participate. Schools within a set of three will be matched on census versus subset selection of ninth graders to ensure that all schools in a set use the same selection process. Eighteen matched sets of three schools will be selected. One school from each matched set will be assigned randomly either to receive the Safe Dates program with teacher training and observation, to receive the Safe Dates program without teacher training and observation, or to serve as a control group.

Approximately 10,158 students at the 54 schools will complete a baseline effectiveness evaluation scannable survey. During the classroom-administered survey, information will be collected from students about how they feel about dating, communicating with a dating partner, and attitudes and behaviors related to violence, including violence between preteen and teen dating couples. Informed written

consent from parents for their child's participation and informed written assent from ninth graders for their own participation will be obtained. During Web surveys, school staff will be asked about implementation and costs of the Safe Dates program.

Effectiveness evaluation baseline data collection will span the period from October to November 2007, and follow-up data collection will occur during January and February 2009. Assuming an 80 percent response rate at follow-up, it is anticipated that a total of 8,126 students will complete follow-up effectiveness evaluation surveys.

To evaluate the implementation and implementation drivers of the program, principals and prevention coordinators at all 54 schools will be asked to complete a series of Web surveys from October 2007 to February 2009. Assuming a 91 percent response rate for all school staff surveys, it is anticipated that 48 principals and 48 prevention coordinators will complete baseline implementation questionnaires, 32 principals and 32 prevention coordinators at treatment schools will

complete mid-implementation questionnaires, 48 principals will complete end-of-school year implementation questionnaires, and 48 prevention coordinators will complete follow-up implementation questionnaires. In addition, 97 teachers at treatment schools will complete Web baseline implementation questionnaires, 48 teachers at treatment schools receiving training and observation will complete cost questionnaires, and 97 teachers at treatment schools will complete two mid-implementation questionnaires each. Students at treatment schools (n=5,417) will also complete two mid-implementation questionnaires each.

It is anticipated that study results will be used to determine the Safe Dates program's effectiveness, economic and time costs, cost-effectiveness, cost-utility, feasibility of implementation, dissemination facilitators, and needed improvements for implementation with fidelity.

There are no costs to respondents except their time to participate in the interview.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument name	Number of respondents	Responses/respondent	Hours/response	Total response burden (Hours)
Student effectiveness baseline survey .....	10,158	1	50/60	8,465
Principal baseline implementation survey .....	48	1	10/60	8
Prevention coordinator baseline implementation survey .....	48	1	10/60	8
Teacher baseline implementation survey .....	97	1	10/60	16
Principal mid-implementation survey .....	32	1	10/60	5
Prevention coordinator mid-implementation survey .....	32	1	15/60	8
Teacher cost survey .....	48	11	20/60	176
First teacher mid-implementation survey .....	97	2	15/60	48
Second teacher mid-implementation survey .....	97	2	15/60	48
First student mid-implementation survey .....	5,417	2	25/60	4,514
Second student mid-implementation survey .....	5,417	2	25/60	4,514
Principal end-of-school-year implementation survey .....	48	1	10/60	8
Student effectiveness follow-up survey .....	8,126	1	50/60	6,772
Prevention coordinator follow-up implementation survey .....	48	1	10/60	8
<b>Total .....</b>	<b>29,713</b>	<b>.....</b>	<b>.....</b>	<b>24,598</b>

Dated: January 11, 2007.

Joan F. Karr,

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**

**Review of Diagnostic Tests Available for the Detection of Tuberculosis in Imported Nonhuman Primates Undergoing Federal Quarantine**

**AGENCY:** Centers for Disease Control and Prevention, Department of Health and Human Services.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice announces a public meeting on the subject of tuberculosis detection in imported nonhuman primates. The purpose of the meeting is to review current Institute of Laboratory Animal Research recommendations and compare newer diagnostic tests available for tuberculosis testing in nonhuman primates.

**DATES:** The public meeting will be held February 16, 2007, from 12:30 p.m. to 4:30 p.m. in Atlanta, Georgia. Registration will begin at 11 a.m.

**ADDRESSES:** The public meeting will be held at the following location: Centers

for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333, Building 19 Auditorium A.

**FOR FURTHER INFORMATION, CONTACT:** Zoonoses Team, telephone 404-639-3441; [ggg0@cdc.gov](mailto:ggg0@cdc.gov); fax 404-639-4441; Division of Global Migration and Quarantine, CDC.

**SUPPLEMENTARY INFORMATION:**

**Participation at the Public Meeting**

Pre-registration is recommended. Because the meeting will be held at CDC's secure facility, non-U.S. citizens will be required to undergo a background check in order to attend. For individuals who are not U.S. citizens, the following information must be provided to the Zoonosis Team at least 15 days in advance:

Individual's Full Name (official):

Gender:

Date of Birth:

Place of Birth (city, province, state, country):

Country of Citizenship:

Passport Type and Number:

Date of Passport Issue:

Date of Passport Expiration:

Type of Visa and Expiration Date:

—If the visitor is a Permanent Resident of the U.S., provide Permanent Resident #

Visitor's Organization:

Visitor's Position/Title within the Organization:

Visitor's Organization Address:

Visitor's Organization Telephone Number:

**Background**

The presence of tuberculosis in nonhuman primates may pose a substantial health risk to caretakers and interfere with or interrupt research. Tuberculosis infections in nonhuman primates may have few outward symptoms, and testing of animals is usually needed to determine infection. Because of the public health risks associated with tuberculosis, nonhuman primates imported into the United States must be quarantined for a minimum of 31 days and have 3 negative tuberculosis skin tests performed at 2-week intervals in accordance with the Institute of Laboratory Animal Research (ILAR; formerly the Institute of Laboratory Animal Resources) guidelines that were published in 1980. The current accepted test for tuberculosis in nonhuman primates is the tuberculin skin test (TST) using Mammalian Old Tuberculin. The sensitivity and specificity of this test are not ideal. Since 1999, 1 to 54 cases of tuberculosis have been reported in imported nonhuman primates each year. In some cases, animals had multiple negative TSTs before a positive TST was noted. A few of the cases had negative TST results through the 31-day quarantine

period and then had a positive TST after release from quarantine, thus jeopardizing research or colonies into which the animals were introduced.

Since the publication of the 1980 ILAR guidelines, several alternative diagnostic tests have been developed. The purpose of this meeting is to discuss available alternatives to the TST; compare test results with alternative tuberculosis detection methods; and generate interest in a formal review of new diagnostics for tuberculosis testing of nonhuman primates.

**Public Meeting Procedures**

The following procedures will be in place for this meeting:

1. Admission and participation in the public meeting are free. The meeting will be open to all persons.

2. Representatives from the CDC will conduct the public meeting. Experts on nonhuman primate importation, tuberculosis diagnostic testing in nonhuman primates, and ILAR guidelines will give presentations.

3. The public meeting is intended as a forum to share information and answer questions concerning tuberculosis testing in nonhuman primates.

4. All interested parties will have the opportunity to ask questions or make short comments regarding diagnostic tests for tuberculosis in nonhuman primates.

5. Statements made by CDC personnel and other federal personnel are intended to facilitate discussion of the issues or to clarify issues. Such statements should not be interpreted as providing legal, professional, or other advice.

6. The meeting is designed to share information and solicit individual views from the public. The meeting will not operate in consensus fashion. The meeting will be conducted in an informal and non-adversarial manner.

Dated: January 16, 2007.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

[FR Doc. E7-794 Filed 1-19-07; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005D-0019]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of June 2, 2006 (71 FR 32101), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0594. The approval expires on September 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 16, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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