

with the RAC Chair and one or more RAC members as needed. This consultation is complete. However, in the interest of soliciting broad public input, OBA is submitting this action for public comment and will finalize the changes after reviewing any comments.

**DATES:** The public is encouraged to submit written comments on this minor action. Comments may be submitted to the OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION CONTACT**. The NIH will consider all comments submitted by September 9, 2011. All written comments received in response to this notice will be available for public inspection at the NIH OBA office, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20817-7985, weekdays between the hours of 8:30 a.m. and 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** If you have questions, or require additional information about these changes, please contact OBA by e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov), telephone (301-496-9838), or mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985.

**Background:** Appendix B of the *NIH Guidelines* is a list of biological agents that are classified into risk groups on the basis of their ability to cause disease in healthy adults and the availability of preventive or therapeutic interventions. Agents listed in Appendix B have been classified into one of four risk groups:

- RG1 agents are those that are not associated with disease in healthy adult humans;
- RG2 agents are those that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available;
- RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available; and
- RG4 agents are those that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

For the most part, the agents listed in Appendix B are wild-type, fully pathogenic strains. However, laboratory research that is subject to the *NIH Guidelines* frequently employs strains that are attenuated. An attenuated strain is not necessarily avirulent but generally is less pathogenic than the wild-type strain, and therefore the biosafety risk posed by research with an attenuated strain is not necessarily equivalent to

that posed by the wild-type strain. As the RG of an agent is the starting point for the risk assessment to determine containment for research with that agent, OBA is amending Appendix B to provide more specific guidance for these attenuated strains.

In addition to designating RGs for several attenuated strains, four additional changes will be made to Appendix B. The classification of attenuated strains of Vesicular stomatitis virus will be clarified. West Nile Virus (WNV) and Chikungunya virus are currently not specifically listed in the RG classification. WNV will now be listed as a RG3 Flavivirus and Chikungunya virus will be listed as a RG3 Togavirus. In addition, the coronavirus that is the causative agent of severe acute respiratory syndrome (SARS) will be listed as a RG3 coronavirus. All coronaviruses are currently RG2 viruses. The BMBL currently recommends BL3 containment for research with these three viruses.

The following additions will be made to Appendix B—II—A. Risk Group 2 (RG2)—Bacterial Agents Including Chlamydia:

*Coxiella burnetii*, Nine Mile strain, plaque purified, clone 4

\**Francisella tularensis* subspecies *novicida* (also referred to as *Francisella novicida*) strain, Utah112

\**Francisella tularensis* subspecies *holartica* LVS

\**Francisella tularensis* biovar *tularensis* strain ATCC 6223 (also known as strain B38)

*Yersinia pestis* *pgm*<sup>(-)</sup> (lacking the 102 kb pigmentation locus)

*Yersinia pestis* *lcr*<sup>(-)</sup> (lacking the LCR plasmid).

The following footnote will be added regarding research with attenuated strains of *Francisella*:

\*For research involving high concentrations, BL3 practices should be considered (See Appendix G—II—C—2).

The following changes/additions will be made to Appendix B—II—D (RG2 Viruses) of the *NIH Guidelines*:

Alphaviruses (Togaviruses)—Group A Arboviruses.

“Venezuelan equine encephalomyelitis vaccine strain TC-83” will be changed to:

Venezuelan equine encephalomyelitis vaccine strains TC-83 and V3526.

The following will be added to Appendix B—II—D:

Alphaviruses (Togaviruses)—Group A Arboviruses.

Add: Chikungunya vaccine strain 181/25.

Arenaviruses.

Add: Junin virus candid #1 vaccine strain.

Flaviviruses (Togaviruses)—Group B Arboviruses.

Add: Japanese encephalitis virus strain SA 14-14-2.

Rhabdoviruses.

“Vesicular stomatitis virus—laboratory adapted strains including VSV—Indiana, San Juan, and Glasgow” will be changed to:

Vesicular stomatitis virus non-exotic strains: VSV—Indiana 1 serotype strains (e.g. Glasgow, Mudd-Summers, Orsay, San Juan) and VSV—New Jersey serotype strains (e.g. Ogden, Hazelhurst).

The following additions will be made to Appendix B—III—D (RG3 Viruses and Prions) of the *NIH Guidelines*:

Add: Coronaviruses.

Add: SARS-associated coronavirus (SARS-CoV).

Alphaviruses (Togaviruses)—Group A Arboviruses.

Add: Chikungunya.

Flaviviruses (Togaviruses)—Group B Arboviruses.

Add: West Nile Virus (WNV).

Dated: July 18, 2011.

**Jacqueline Corrigan-Curay,**

*Acting Director, Office of Biotechnology Activities, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

#### Project: The Safe Schools/Healthy Students (SS/HS) Initiative National Evaluation (OMB No. 0930-0297)—Revision

SAMHSA's Center for Mental Health Services (CMHS) will conduct a study to evaluate the relationships between different grantee characteristics and implementation strategies to outcomes at the project, school, and student level. Data collected by this study will facilitate an examination of contextual

factors and inform those who hope to improve the effectiveness of partnerships and implementation efforts under the grant and lead to improved outcomes for communities, schools, and students. The three agencies sponsoring the SS/HS Initiative (the U.S. Department of Health and Human Services, the U.S. Department of Education, and the U.S. Department of Justice) may also choose to incorporate aggregate results from collected data in journal articles, scholarly presentations, and congressional testimony referring to

the outcomes of the SS/HS grant program. Data collection activities involve the administration of four separate surveys (a Baseline Assessment Survey, a Project-Level Survey, a School-Level Survey, and a Staff School Climate Survey) and a Site Visit Protocol for individuals involved with the SS/HS Initiative at the local grantee level. Respondents will submit their responses for all surveys via Qualtrics, a third-party, online Web-based survey platform, except for the Site Visit

Protocol, which will be administered on site with grantees. The estimated burden for data collection is 5,732 hours across a total of 28,125 participants. Using median hourly wage estimates reported by the Bureau of Labor Statistics, May 2009 National Occupational Employment and Wage Estimates, and a loading rate of 25%, the estimated total cost to respondents is \$207,343. A breakdown of these estimates is presented in Table 1 below.

TABLE 1—ELEMENTS OF ANNUALIZED HOUR-COST BURDEN OF DATA COLLECTION \*

Instrument description	Anticipated number of respondents	Responses per respondent	Average hours per response	Total annual hour burden
Site Visit Protocol .....	100	1	9	900
Baseline Assessment Survey .....	25	1	.67	17
Partnership Inventory .....	400	1	0.25	100
Project-Level Survey .....	100	1	0.42	42
School-Level Survey .....	2,300	1	0.45	1,725
Staff School Climate Survey .....	25,200	1	0.117	2,948
<b>Total .....</b>	<b>28,125</b>	<b>.....</b>	<b>.....</b>	<b>5,732</b>

\* Number of respondents based on an estimated annual average of 100 grantees. Baseline Assessment Survey administered only to grantees in the 2011–2013 cohorts. School-Level Survey estimates based on an average of 23 schools per grant. Staff School Climate Survey estimates based on 252 respondents per grantee. Average hours per response based on previous evaluation and pilot tests.

Written comments and recommendations concerning the proposed information collection should be sent by August 24, 2011 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–7285.

Dated: July 18, 2011.

**Elaine Parry,**

*Director, Office of Management, Technology and Operations.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

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Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Assessment of the Underage Drinking Prevention Education Initiatives State/Territory Videos Project—New**

The Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Prevention (SAMHSA/CSAP) is requesting Office of Management and Budget (OMB) approval of three new data collection instruments—

- State/Territory Video Contacts Interview Form
- State/Territory Videos Project—Dissemination Update Form
- Video Viewers Feedback Form

This new information collection is for a process assessment of the Underage Drinking Prevention Education Initiatives State/Territory Videos project to be conducted from 2011 through 2014. In 2007, four States participated in a pilot study to produce videos highlighting the underage drinking (UAD) prevention efforts of the States. Based upon the success of those videos in showcasing the States' UAD prevention activities, 10 additional States and 1 Territory were provided funds to produce UAD prevention videos in 2009. SAMHSA/CSAP intends to support the production of the State/

Territory UAD prevention videos annually. Therefore, from 2010 through 2013, SAMHSA/CSAP will invite approximately 45 additional States/Territories to produce their own UAD prevention video.

The information collected for the assessment will be used by SAMHSA/CSAP to (1) Ascertain whether the videos produced under the State/Territory Videos project are assisting States and Territories in communicating effectively about their underage drinking prevention initiatives, goals, and objectives; (2) document the dissemination efforts of the videos; and (3) enhance the technical assistance (TA) that is provided by the video production team in producing the videos. This information collection is being implemented under authority of Section 501(d)(4) of the Public Health Service Act (42 U.S.C. 290aa).

There are three phases to the process assessment of the State/Territory Videos project—(1) State/Territory video contacts interviews, (2) dissemination updates, and (3) video viewers feedback.

*Phase I—State/Territory Video Contacts Interviews*—A member of the assessment team will contact the designated State/Territory point of contact once the video is finalized. The focus of the interview will be around the State's/Territory's experience in producing the UAD prevention video,