

ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 22, 2010.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 2010-10199 Filed 4-30-10; 8:45 am]

**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "National Hospital Adverse Event Reporting System: Questionnaire Redesign and Testing." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520. AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by July 2, 2010.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### Proposed Project

#### *National Hospital Adverse Event Reporting System: Questionnaire Redesign and Testing*

As provider of operational support to the chair of the Quality Interagency Task Force (QuIC), AHRQ coordinated the Federal response to the Institute of Medicine's (IOM) 1999 report on medical errors and outlined specific initiatives the QuIC agencies will take. The Errors Workgroup within the QuIC identified the need for measures to evaluate the use of adverse medical event reporting for managing and improving patient safety within healthcare institutions. In response, AHRQ created the Hospital Adverse Event Reporting Survey to Provide national estimates. This survey has been fielded twice, first in 2005 and again in 2008.

Revisions to the questionnaire and sample selection are now necessary in response to the Patient Safety and Quality Improvement Rule (Patient Safety Rule), 42 CFR Part 3, issued by the United States Department of Health and Human Services, which implements the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), 42 U.S.C. 299b-21 through 299b-26. The Patient Safety Rule and Patient Safety Act authorize the creation of Patient Safety Organizations (PSO) to enhance quality and safety by collecting patient safety reports of adverse events. AHRQ started listing PSOs in late 2008 pursuant to the Patient Safety Act. These organizations have begun working with hospitals and other providers to monitor patient safety events according to common reporting formats, and to improve patient safety. This revised survey will be used for the third round of data collection in 2011, under a separate OMB clearance, to assess the impact of the PSOs and the Patient Safety Act on the use of adverse event reporting systems and will incorporate questions about reporting using the AHRQ Common Formats, and reporting information to a Patient Safety Organization.

This project is being conducted by AHRQ's contractor, Westat, pursuant to AHRQ's statutory mandates to (1) promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality (42 U.S.C. 299(b)(1)(F)) and (2) conduct and support research on health care and on systems for the delivery of such care, including activities with respect to

quality measurement and improvement (42 U.S.C. 299a(a)(2)).

### Method of Collection

This project will include the following data collections:

(1) Semi-structured interviews will be conducted with one risk manager or other representative responsible for adverse event reporting from 7 participating hospitals and with one person from the two participating PSOs. These interviews will be conducted to learn more about the current hospital adverse event reporting environment and to understand how adverse event reporting may have changed in response to the Patient Safety Act. Survey developers will use the information from these interviews to develop questions for the revised questionnaire.

(2) Cognitive interviews will be conducted with one risk manager or other representative responsible for adverse event reporting in 30 participating hospitals. The purpose of these cognitive interviews is to test and refine the revised questionnaire. The questionnaire will be tested among respondents in hospitals with no reporting affiliation with a PSO, with reporting affiliations with one PSO, and with reporting affiliations with more than one PSO.

Results from these interviews will help inform actions by AHRQ to encourage effective adverse event reporting by hospitals, as part of its patient safety initiative, including standardization of reporting so that consistent concepts, information, and terminology are used in the patient safety arena. The survey can also serve as a baseline for changes about hospital-based adverse event reporting to Patient Safety Organizations and how the Patient Safety Act might have affected reporting structures and processes.

### Estimated Annual Respondent Burden

Exhibit I shows the estimated annualized burden hours for the respondents time to participate in this project. Semi-structured interviews will be conducted with 9 persons representing 7 hospitals and 2 PSOs and will last for about an hour. Cognitive interviews will be conducted with one person in each of 30 participating hospitals and are expected to take one hour to complete. The total annual burden hours are estimated to be 39 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in the research. The total annual cost burden is estimated to be \$1,664.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of organizations	Number of responses per responding organization	Hours per response	Total burden hours
Semi-structured interviews .....	9	1	1	9
Cognitive interviews .....	30	1	1	30
Total .....	39	NA	NA	39

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Semi-structured interviews .....	9	9	\$42.67	\$384
Cognitive interviews .....	30	30	42.67	1,280
Total .....	39	39	NA	1,664

\* Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States 2008, "U.S. Department of Labor, Bureau of Labor Statistics."

**Estimated Annual Costs to the Federal Government**

Exhibit 3 shows the estimated total and annualized cost to the Federal

government to conduct this redesign of the Adverse Event Reporting Questionnaire and associated sample design. Since this project will last for

one year the total and annualized costs are the same. The total cost is estimated to be \$120,000.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development .....	\$24,000	\$24,000
Data Collection Activities .....	46,000	46,000
Data Processing and Analysis .....	26,000	26,000
Project Management .....	24,000	24,000
Total .....	120,000	120,000

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All

comments will become a matter of public record.

Dated: April 20, 2010.  
**Carolyn M. Clancy**,  
*Director*.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent

applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Retroviral Vectors for Selective Reversible Immortalization of Stimulus-responding Primary Cells**

*Description of Invention:* Researchers at the National Cancer Institute-Frederick, NIH, have developed a novel set of retroviral vectors and producer cell lines useful for selective reversible immortalization of primary cells (*i.e.* lymphocytes) that respond to a stimulus, such as a viral antigen (*e.g.*