performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nina Goodman, Senior Public Health Advisor, Office of Communications and Education (OCE), NCI, NIH, 6116 Executive Blvd., Suite 400, Rockville, MD 20892, call non-toll-free number 301–435–7789 or e-mail your request, including your address to: *goodmann@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: December 21, 2009.

Kristine Miller,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E9–31071 Filed 12–30–09; 8:45 am]

BILLING CODE 4140–01–P

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: ''Development and Evaluation of AHRQ's Quality Indicators Improvement Toolkit.'' 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 March 1, 2010.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *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.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Development and Evaluation of AHRQ's Quality Indicators Improvement Toolkit.

An important part of AHRQ's mission is to disseminate information and tools that can support improvement in quality and safety in the U.S. health care community. See 42 U.S.C. 299(b)(1)(F); 299a(a)(1) and (2). This proposed information collection supports that part of AHRQ's mission by developing and evaluating a toolkit that will enable hospitals to effectively use AHRQs Quality Indicators (QIs).

AHRQ has developed sets of QIs that can be used by the Agency and others to document quality and safety conditions at U.S. hospitals. Two sets of QIs will be used in this proposed toolkit: the Inpatient Quality Indicators (IQIs) and the Patient Safety Indicators (PSIs). The IQIs contain measures of volume, mortality, and utilization for common medical conditions and major surgical procedures. The PSIs are a set of measures to screen for potentially preventable adverse events that patients may experience during hospitalization. These QIs have been previously developed and evaluated by AHRQ, and are in use at a number of hospitals throughout the country. The QIs and supportive documentation on how to work with them are posted on AHRQ's Web site at *www.qualityindicators.ahrq.gov.* Many of the QIs have been endorsed by the National Quality Forum through its consensus review process.

Values for each QI can be estimated for a given hospital by applying computations in SAS programs developed by AHRQ to the hospital's pre-existing inpatient encounter data. To identify potential areas for improving the quality and safety of the care that a hospital provides, the hospital can use these data to examine its current performance on each QI measure, changes in its performance over time, and how its performance compares to that of other hospitals. However, despite the availability of the QIs as tools to help hospitals assess their performance, many U.S. hospitals have limited experience with the use of such measurement tools, or in using quality improvement methods to improve their performance as assessed by these measures.

An alpha version of the Quality Indicators Improvement Toolkit will be developed, which then will be field tested by six hospitals. During the field test, the proposed evaluation will assess the usability of the Toolkit for hospitals, and it will examine their experiences in implementing interventions to improve their performance on the AHRQ QIs, as well as effects on trends in the hospitals' AHRQ QI values. Using results from the evaluation, the alpha Toolkit will be revised to yield a final Toolkit that will be effective in supporting hospitals' quality improvement efforts.

The development and evaluation of the Quality Indicators Improvement Toolkit will be conducted by AHRQ's contractor, the RAND Corporation, under contract number HHSA2902006000 171. RAND has subcontracted with the University HealthSystem Consortium (UHC) to partner in the development of the Toolkit and field testing of it with hospitals as they use the Toolkit in carrying out initiatives designed to improve performance on the QIs.

Method of Collection

Case study research methods will be used for this qualitative study. The following four data collection instruments will be used in the evaluation: (1) *Pre/post-test interview protocol*—consisting of both open and closed ended questions will be administered prior to implementation of the Toolkit and again post implementation. The purpose of this data collection is to obtain data on the steps the hospitals took to implement actions to improve performance on the QIs; their plans for making process changes; and their experiences in achieving changes and perceptions

regarding lessons learned that could be shared with other hospitals.

(2) *Update protocol*—consisting of both open and closed ended questions will be administered three times during the study (quarterly during the implementation year). The purpose of this data collection is to capture longitudinal data regarding hospitals' progress in implementing changes, successes and challenges, and plans for subsequent actions. These data will include descriptive information on changes over time in the hospitals' implementation actions and how they are using the Toolkit, as well as experiential information on the perceptions of participants regarding the improvement implementation process and its effects. It also ensures the collection of information close to pertinent events, which avoids the recall bias associated with retrospective reporting of experiences.

(3) *Usability testing protocol*—also consisting of both open and closed ended questions will be administered once at the end of the evaluation period. The purpose of this data collection is to gather information from the hospitals on how they used each tool in the Toolkit, the ease of use of each tool, which tools were most helpful, suggested changes to improve each tool, and suggestions for other tools to add to the Toolkit. This information will be used in the revisions of the Toolkit following the end of the field test.

(4) *AHRQ QI data collection tool*—used to collect the IQI and PSI measures calculated by the hospitals both prior to implementation of the Toolkit and again post implementation. The purpose of this data collection is to determine if the hospitals' implementation actions, including use of the toolkit, had a measurable impact on the QI measures.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this information collection. Three protocols will be used to collect data from respondents in interviews that will take one hour each. The pre/post-test interview protocol will be administered twice—at the beginning and end of the field-test year. The pre-test interviews will be performed as one-hour group interviews conducted with the six hospitals' implementation teams at the start of the year. At the end of the year, post-test interviews will be performed as one-hour group interviews with three of the hospitals and during site visits with the other three hospitals. At each site visit, data will be collected through one-hour interviews with the hospital's implementation team as well as through other group interviews performed separately with each of the key stakeholder groups—physicians, nurses, clerks, and others. The additional data from the stakeholder groups will allow triangulation of variations in perceptions and experiences among different groups, of which the implementation teams might not be aware. The quarterly update protocol will be administered quarterly to 2 hospital staff members from each hospital during the year (in months 3, 6, and 9). The usability testing protocol will be administered to 4 staff members once at the end of the evaluation period. The AHRQ QI data collection tool will be used both pre- and post-implementation to collect the QI measures. The total burden is estimated to be 360 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in the evaluation. The total cost burden is estimated to be $9,886.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of hospitals	Number of responses per hours hospital	Hours per response	Total burden hours
Pre/Post-Test Interview Protocol	6	26	1	156
Quarterly Update Protocol	6	6	1	36
Usability Testing Protocol	6	4	1	24
AHRQ QI Data Collection Tool	6	2	*12	144
Total	24	NA	NA	360

* Includes time to program and run the computer programs necessary to produce the measures.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR HOSPITALS

Form name	Number of hospitals	Total burden hours	Average hourly wage rate *	Total cost burden
Pre/Post-Interview Protocol	6	156	$27.46	$4,284
Quarterly Update Protocol	6	36	27.46	989
Usability Testing Protocol	6	24	27.46	659
AHRQ QI Data Collection Tool	6	144	27.46	3,954
Total	24	360	NA	9,886

* Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States, March 2009, U.S. Department of Labor, Bureau of Labor Statistics. Used as an overall average wage rate across the various types of staff involved in the quality improvements.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost of this project to the government. The estimated total cost for the evaluation work is $209,827 over the two-year year project, with an annualized total cost of $104,914. These costs were developed based on estimates of staff days required, to which administrative expenses are applied, and based on airfare, hotel, and per diem costs for staff travel for the site visits at the end of the evaluation.

EXHIBIT 3—ESTIMATED COST OF THE EVALUATION

Cost component	Total cost	Annualized cost
Protocol Development	$40,278	$20,139
Data Collection Activities	91,104	45,552
Data Analysis	45,252	22,626
Publication of Results	24,370	12,185
Travel for Site Visits	8,823	4,412
Total	209,827	104,914

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: December 10, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–30957 Filed 12–30–09; 8:45 am]

BILLING CODE 4160–90–M

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.

Synergy of ABT–737 With an Immunotoxin To Kill Cancer Cells

Description of Technology: Programmed cell death (*i.e.,* apoptosis) represents an attractive approach for treating cancer. However, anti-apoptotic proteins that are frequently active in cancer cells can allow the cells to survive induction of apoptosis. While inhibiting anti-apoptotic proteins has shown promise in combination with apoptosis-inducing treatments, current inhibitors only show incomplete effectiveness in promoting the induction of apoptosis.

ABT–737 is one such inhibitor; it can only inhibit the function of three of the four major anti-apoptosis proteins. The fourth member, known as a MCL1, is a short-lived protein that can still prevent apoptosis in the presence of ABT–737. Importantly, because MCL1 is a short-lived protein, it requires protein synthesis to maintain levels that are sufficient to continue blocking apoptosis.

This technology uses a combination approach in the treatment of cancer. The inventors considered that combining ABT–737 with a protein synthesis inhibitor might completely inhibit anti-apoptotic proteins, leading to efficient induction of apoptosis. Specifically, NIH inventors found that combining ABT–737 and immunotoxins did result in enhanced killing of cancer cells. Because immunotoxins function by inhibiting protein synthesis, the two agents in combination are able to inhibit all of the anti-apoptotic proteins simultaneously. Furthermore, immunotoxins can be specifically targeted to cancer cells, thereby increasing their effectiveness over a non-specific protein synthesis inhibitor. The results suggest that the combination could represent an effective approach to enhancing the induction of apoptosis as an anti-cancer therapy.

Application: Combination anti-cancer therapy.

Advantages:

- Overcomes the anti-apoptotic proteins frequently associated with inducing apoptosis, thereby leading to an effective therapeutic approach.
- Synergistic effect improves toxicity of both the apoptosis-inducing agents and immunotoxins.
- Selective inhibition of protein synthesis by immunotoxins increases effectiveness versus using non-specific inhibitors.

Development Status: Preclinical stage of development.

Inventors: David J. FitzGerald (NCI) *et al.*

Patent Status: U.S. Provisional Application No. 61/238,032 (HHS Reference No. E–279–2009/0–US–01).

For more information, see:

- Pastan *et al.,* US Patent 4,892,827.
- Pastan *et al.,* US Patent 5,705,163.
- Pastan *et al.,* PCT Application PCT/US2008/075296 (WO 2009/032954).
- JE Weldon *et al.* A protease-resistant immunotoxin against CD22 with greatly increased activity against CLL and diminished animal toxicity. Blood 2009 Apr 16;113(16):3792–3800.
- DJ FitzGerald *et al.* Recombinant immunotoxins for treating cancer. Int J Med Microbiol. 2004 Apr;293(7–8):577–582.

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in