*** The Disclosure Statement Form and the Change of Listing Information form may be submitted by individual PSOs in different years. Due to changes in their operations, a PSO can submit more than one Change of Listing Information in a year. OCR is anticipating considerable variation in the number of complaints per year. Hence, the total for each year is expressed as an average of the expected total over the three year collection period.

**** The Profile Form collects data from listed PSOs each calendar year. The prior version of this form, the PSO Information Form, began collecting data from listed PSOs each calendar year in 2011.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Number of respondents	Total burden hours	Average hourly wage rate	Total cost
Certification for Initial Listing Form	17	306	$35.93	$10,994.58
Certification for Continued Listing Form	16	128	35.93	4,599.04
Two Bona Fide Contracts Requirement Form	30	30	35.93	1,077.90
Disclosure Statement Form	2	6	35.93	215.58
Profile Form	77	231	35.93	8,299.83
Patient Safety Confidentiality Complaint Form	3	1	35.93	35.93
Change of Listing Information	24	2	35.93	71.86
Common Formats	1,000	100,000	35.93	3,593,000.00
Total	1,169	100,704	NA	3,618,294.72

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupations, 29–0000, National Compensation Survey, May 2013, ''U.S. Department of Labor, Bureau of Labor Statistics.'' (*http://www.bls.gov/oes/current/oes_nat.htm#29-0000*).

Request for Comments

In accordance with the Paperwork Reduction Act, 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 health care research and health care 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: September 18, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–22700 Filed 9–26–14; 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: ''Improving Hospital Informed Consent with Training on Effective Tools and Strategies.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously titled and published as ''Improving Hospital Informed Consent with an Informed Consent Toolkit'' in the **Federal Register** on July 9th, 2014 and allowed 60 days for public comment. AHRQ received one substantive comment. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 29, 2014.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Improving Hospital Informed Consent With Training on Effective Tools and Strategies

The ultimate aim of this project is to pilot test training modules to improve the informed consent process in U.S. hospitals.

Clinical informed consent is the process by which a patient is told about the risks and benefits of proposed treatments or procedures, as well as alternatives, and makes a decision based on that information. Informed consent may be jeopardized by incorrect clinician assumptions about patient comprehension, the manner in which consent is sought, and poor readability of consent forms (Paasche-Orlow et al., 2013). All too frequently, patients do not understand the risks, benefits, and alternatives of their treatments even after signing a consent form (Braddock et al., 1999; Sudore et al., 2006). De-identified accreditation data analyzed as part of AHRQ's preliminary research for this data collection effort suggest that some hospitals are not following the basic ethical principles underlying informed consent. These data, as well as the guidance from the study's Expert and Stakeholder Panel, indicate that hospital administrators and clinicians could benefit from training on evidence-based practices to improve the informed

consent process. These include, improving communication, using interpreters to meet the communication needs of patients with limited English proficiency, using high-quality decision aids to support the informed consent discussion, and using teach-back to verify patient understanding (Temple University Health System, 2009). Hospital system changes that can facilitate these practices include improving hospitals' informed consent policies and the infrastructure that supports the informed consent process (e.g., interpreter services, high-quality decision aids, easy-to-understand forms).

Building upon a previously published guide, a review of the literature, and the aforementioned analysis of de-identified accreditation data, AHRQ has developed two new Informed Consent training modules of approximately 1 hour each (one for hospital leaders, the other for health care professionals), to be offered through a Learning Management System. Health care professionals taking the training will be eligible for continuing education (CE) credit.

In the project's next phase, AHRQ will pilot test the training modules to assess:

- Facilitators and barriers of implementing the tools and recommended improvements in the training modules
- Effectiveness of the training modules in improving informed consent processes and relevant outputs and outcomes

Pilot test results will be used to improve the training modules and provide information to hospitals considering using the training modules to improve their informed consent processes. The pilot test will take place in four hospitals. Each participating hospital will be asked to:

- Deliver the leader training module to hospital leaders of their choosing
- Champion improvements in their informed consent policies and processes based on the information and tools in the leader training
- Deliver the health care professional training module to health care professionals in four units, including at least one surgical unit
- Implement improvement initiatives over a period of two to six months in participating units based on materials presented in the health care professional training

○ In at least one unit: Implementation will last at least three months and use at least one of the techniques presented in the training (e.g., use teach-back to confirm patient understanding, use high quality decision aids, overcome communication barriers)

- Conduct and cooperate with assessment activities.

○ In at least one unit, use the Rapid Feedback Patient Survey.

○ In at least one surgical unit, collect surgical cancellation and delay rates.

○ Collect other metrics to assess the effectiveness of the informed consent training modules.

○ Cooperate with project team in the data collection efforts described below.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The following data collections efforts will be pursued in participating hospitals to achieve project goals:

1. The Hospital Informed Consent Baseline and Final Assessment will be completed by the four hospitals participating in the pilot testing at baseline and upon completion of the implementation period. The assessment, completed by the hospital's designated liaison to the project and the leaders of the participating units (unit leaders), will describe each hospital's informed consent policies and processes (e.g., procedures that require signed informed consent forms, clinical staff roles and responsibilities in informed consent, when interpreter services should be used), and document any changes that occurred as a result of implementing the training modules. Questions will include both open-ended questions (e.g., descriptions of process) and Likert scale questions (1 to 5) regarding the extent to which essential components are covered in informed consent discussions (e.g., benefits and risks of alternatives) and evidence-based practices to improve the informed consent process are used.

2. Pre-/Post-Training Quiz. The purpose of the Pre/post-Training Quiz is to measure whether knowledge (related to the content in the training modules) increases after completing the training module(s) and to identify potential training module improvements. The pre-test is given after the participant registers for the training but before they begin the course content. Immediately after the participant completes the course content, they will be given the post test. The post quiz will also include a separate section with questions regarding learner's reactions to and evaluation of the training modules. A post quiz score of 80% will be used as the threshold to obtain CE credits. There will be a pre/post quiz for each training module.

3. The Monthly Check-In Call. A project team member will hold a monthly check-in call with hospital liaisons and unit leaders to assess the progress of implementation of training and improvement initiatives at each hospital and within each unit. Check-in calls will occur monthly for up to six months. Each call will be up to 30 minutes in duration.

4. Health Care Professional Survey. A brief survey will be administered electronically to all clinicians who take the health care professionals training, both prior to training and approximately 2–3 months after completing it. Hospital liaisons will provide email addresses for the staff who will be invited to complete the training from each participating unit. These email addresses will be used to send health care professionals the pre and post-training surveys. The survey will collect information about clinicians' self-reported use of evidence-based practices described in the training module, a self-assessment rating of their informed consent effectiveness, attitudes regarding patients' rights in informed consent, and reported learning and implementation experiences. The survey will also collect information about the clinician and their background (e.g., years in practice, practitioner type) and department. The survey will consist largely of closed-ended questions (e.g., scale or Liken response options) with several open-ended questions.

5. Interview and Site Visit Guide. Site visits and interviews will be conducted at each of the four participating hospitals. Each site visit will occur over a two-day period at least 3 months after sites have trained the majority of their staff on the participating units. The project team will conduct up to 18 in-depth interviews at each pilot site with hospital leaders and frontline clinicians. Leaders will include hospital champions spearheading the pilot test in their hospital (such as chiefs of surgery, department chairs, chief anesthesiologist/head of anesthesiology, nurse managers, charge nurses, nurse educators, patient safety/quality officers, legal/risk management officers) and leaders of units where the training modules were piloted. Health care professional interviewees will be selected by unit leaders or hospital liaisons from the units where the training modules were piloted. Liaisons

and unit leaders will be asked to nominate a range of clinicians from those who embraced changes to those who were less willing to implement changes. Site visits will also involve limited observation (e.g., to observe documentation of informed consent completion, view new signage to remind clinicians to verify patient understanding in an informed consent discussion). The project team will also obtain relevant organizational documents (e.g., informed consent policies, training completion rates, implementation tracking data) and data (e.g., surgical cancellation rates). Interviews will capture qualitative data regarding clinician learning, training modules implementation, behavior, and results pertaining to patient engagement.

6. Rapid Feedback Patient Survey. Hospitals participating in the pilot test will be required to implement the Rapid Feedback Patient Survey provided in the training modules in a subset of patients in at least one participating unit to capture patient's understanding of the information conveyed during the informed consent process, and their satisfaction with the informed consent discussion and process. Time to complete the rapid feedback patient survey is estimated at 5 minutes. We expect hospitals to administer this survey to at least 50 patients before implementation and 50 patients after implementation in at least 1 unit.

Other outcome and output data from administrative records or electronic medical records (Secondary Data). Hospitals will also be asked to report on their rates of surgical cancellations and delays in at least one participating surgical unit, since prior research suggests that these rates can be improved (i.e., reduction in cancellations and some delays) when strategies such as teach-back were used in the informed consent process (NQF, 2005). Hospitals may also select other outcome measures of interest based on administrative records or electronic medical records. They may also report on output data such as number of informed consent forms improved or number of staff present during a teach-back or quality improvement exercise. Since these data collections involve extractions from existing clinic records or use of administrative records, they pose only minimal data collection burden to the hospital, specifically the person who needs to collect the data (i.e., hospital liaison or unit leader).

The purpose of the proposed data collection effort is to obtain information needed to modify and enhance the Informed Consent training modules and to provide information to hospitals considering using the training modules to improve their informed consent processes. Since this is only a pilot study in 4 sites, outcomes or impacts will not be generalizable.

The data collected will help the project team: (1) Understand the facilitators and barriers of implementing the tools and recommended improvements to informed consent policies and processes, and (2) assess the effectiveness of the training modules in improving informed consent processes and other outcomes in four pilot implementation sites. The data collection effort may also provide insights that could guide dissemination of the training modules. For example, if it was found that specific units (e.g., surgical units) across the pilot test hospitals strongly benefited from implementing a specific strategy suggested in the training modules, then AHRQ could tailor and target its dissemination of the training modules to those individuals and organizations that represent them. Once revisions are made based on results of the pilot study, the training modules will be published on AHRQ's Web site. A manuscript describing the pilot study and its results will also be produced for publication in a peer-reviewed journal.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on prior experiences with pilot testing materials in hospitals and what can reasonably be requested of participating hospitals. The number of respondents listed in column A, Exhibit 1 reflects a projected 80% response rate for data collection efforts 2a, 2b, 4, and 6 below.

1. The Hospital Informed Consent Baseline and Final Assessment will establish a baseline and final assessment of each hospital's informed consent policies and processes that is completed by the site liaisons (1 per hospital) and unit leaders (4 per hospital) and will take each person 30 minutes to complete each time.

2. Pre-/Post-Training Quiz will be administered after participants register for the training but before they begin the course (pre-test), and immediately after participants complete the course content (post-test). There will be a pre-post quiz for each module. Each quiz will take 20 minutes to complete:

a. Health care professionals Pre-/Post-Training Quiz: We assumed 40 health care professionals per unit for a total of 160 staff per hospital and a total of 640 across all four hospitals. We assumed 512 health care professionals will complete the pre-/post-training quiz based on an estimated 80% response rate.

b. Hospital Leader Pre-/Post-Training Quiz: We assumed 8 leaders per hospital for a total of 32 across all four hospitals. We assumed 26 will complete the pre-/post-training quiz based on an estimated 80% response rate.

3. The Monthly Check-In Calls will occur with hospital liaisons and four unit leaders for a total of 5 individuals per hospital to assess the progress of implementation of training programs at each site and within each unit. Check-in calls will occur monthly for six months and will each take 30 minutes.

4. Health Care Professional Survey. A brief survey will be emailed to all clinicians both prior to training and approximately 2–3 months after completing the training. We assumed 40 health care professionals per unit for a total of 160 staff per hospital and a total of 640 across all four hospitals. We assumed 512 health care professionals will complete the survey based on an 80% response rate. It is expected to take 15 minutes to complete.

5. Interview and Site Visit Guide. Each site visit will occur over a two-day period and include up to 18 1-hour interviews in each pilot site, with:

a. Two hospital leaders (e.g., legal, risk management) and four unit leaders (six per hospital);

b. Three front-line clinicians in each of four units (12 per hospital).

6. Rapid Feedback Patient Survey. The Rapid Feedback Patient Survey will be given to 100 patients (50 patients before implementation and 50 patients after) immediately following an informed consent discussion. It should take 5 minutes to complete. We assumed 100 patients per hospital for a total of 400 across all four hospitals. We assumed 320 patients will complete the survey based on an 80% response rate.

7. Other outcome and output data from administrative records or electronic medical records (Secondary Data). These secondary data will be provided by the hospital liaison or unit leaders. We have assumed 5 hours for each hospital liaison and unit lead to collect and provide these data.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method or project activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours
1. Hospital Informed Consent Baseline and Final Assessment (Attachment C)	20	2	1	40
2a. Health care professionals Pre-/Post-Training Quiz* (Attachment D)	512	2	20/60	341
2b. Hospital Leader Pre-/Post-Training Quiz* (Attachment E)	26	2	20/60	17
3. Monthly Check-in (Attachment F)	20	6	30/60	60
4. Health Care Professional Survey* (Attachment G)	512	1	15/60	128
5a. Interview—Clinical Staff (Attachment H)	48	1	1	48
5b. Interview—Hospital Leaders (Attachment H)	24	1	1	24
6. Rapid Feedback Patient Survey* (Attachment I)	320	1	5/60	27
7. Secondary data	4	1	5	20
Total	.....	na	na	705

*Number of respondents (Column A) reflects a sample size assuming an 80% response rate for these data collection efforts.

Exhibit 2, below, presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be about $25,270.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method or project activity	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
1. Hospital Informed Consent Baseline and Final Assessment (Attachment C)	20	40	$42.78	$1,711
2a. Health care professionals pre-/post-training quiz (Attachment D)	512	341.33	33.62	11,476
2b. Hospital leader pre-/post-training quiz (Attachment E)	26	17.33	51.95	900
3. Monthly Check-in Attachment F)	20	60	42.78	2,567
4. Health Care Professional Survey (Attachment G)	512	128	33.62	4,303
5a. Interview—Clinical Staff (Attachment H)	48	48	33.62	1,614
5b. Interview—Hospital Leaders (Attachment H)	24	24	51.95	1,247
6. Rapid Feedback Patient Survey (Attachment I)	320	26.67	22.33	596
7. Secondary data	4	20	42.78	856
Total	.....	.....	.....	25,270

The average hourly wage rate of $42.78 for the informed consent baseline, readiness assessment, and monthly check-in was calculated based on the 2013 average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions) of $33.62 and mean hourly wage rate for medical and health services managers, $51.95.

The average hourly rate of $33.62 of hospital staff pre- and post-training quiz and in-depth interviews was calculated based on the 2013 average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions), $33.62.

The average hourly rate of $51.95 for hospital leaders pre- and post-training quiz and in-depth interview was calculated based on the 2013 mean hourly wage rate for medical and health services managers, $51.95.

The average hourly wage rate for patients of $22.33 was calculated on the 2013 mean hourly wage rate for all occupations. Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on ''Occupational Employment and Wages, May 2013'' found at the following URL: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, 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 Me proposed information collection. All comments will become a matter of public record.

Dated: September 18, 2014.

Richard Kronick,

Director.

[FR Doc. 2014–22698 Filed 9–26–14; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2013–0022, NIOSH 153–B]

Issuance of Final Publications

AGENCY: National Institute for Occupational Safety and Health