SUPPORTING STATEMENT

Part A

Improving Hospital Informed Consent with Training on Effective Tools and Strategies

Version: *October 6, 2014*

Agency for Healthcare Research and Quality (AHRQ)

A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care;

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

The project "Improving Hospital Informed Consent with Training on Effective Tools and Strategies" fully supports AHRQ's mission. The ultimate aim of this project is to pilot test two 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).[1,2]

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, engaging in shared decision-making, using high-quality decision aids to support the informed consent discussion, and using teach-back to verify patient understanding (Temple University Health System, 2009).[3] Hospital system changes that can facilitate these practices include improving hospitals' informed consent policies and enhancing the infrastructure that

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[1] Braddock, C. H., 3rd, K. A. Edwards, et al. (1999). "Informed decision making in outpatient practice: time .to get back to basics." *JAMA* 282(24): 2313-20

[2] Sudore, R. L., C. S. Landefeld, et al. (2006). "Use of a modified informed consent process among vulnerable patients: a descriptive study." *J Gen Intern Med* 21(8): 867-873

[3] Temple University Health System, Fox Chase Cancer Center, Hablamos Juntos at the University of California San Francisco and Fresno Center for Medical and Education Research. (2009). *A Practical Guide to Informed Consent: With Tools for Providing Simple and Effective Informed Consent in Everyday Clinical Practice*. Available at: www.templehealth.org/ICTRAINING MODULES. AHRQ obtained permission from the Robert Wood Johnson Foundation to use the guide as a basis for this Training modules.

supports the informed consent process (e.g., interpreter services, high-quality decision aids, easy-to-understand forms).

Building upon a previously published guide[3], a review of the literature, and the aforementioned analysis of de-identified accreditation data, AHRQ has developed two informed consent training modules. Training modules of approximately 1 hour each (one for hospital leaders, the other for health care professionals) will be offered through a Learning Management System. (**Attachment A- Informed Consent Leaders Training Module** and **Attachment B-Informed Consent Health Care Professionals Training Module).** Health care professionals taking the training will be eligible for continuing education (CE) credit.

AHRQ will pilot test the training modules to assess:

1. Facilitators and barriers to implementing the tools and recommended improvements in the informed consent training modules
2. To assess the 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 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 Informed Consent Leaders Training Module.
- Champion improvements in their informed consent policies and processes based on the information and tools in the leader training.
- Deliver the Informed Consent Health Care Professionals 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 (Attachment I).
    - 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.

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

1. The **Hospital Informed Consent Baseline and Final Assessment (Attachment C)** 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**. A quiz is given both before and after the training to measure whether knowledge (related to the content in the training modules) increases after completing the training module(s) and to identify potential training modules

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 training. 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: **Health Care Professionals Pre-/Post-Training Quiz (Attachment D)** and **Leader Pre-/Post-Training Quiz (Attachment E)**.

3. The **Monthly Check-In Call (Attachment F).** 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 (Attachment G)**. A brief survey will be administered electronically to all clinicians who take the Informed Consent Health Care Professionals Training Module, 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 Health Care Professionals 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 Likert response options) with several open-ended questions.

5. **Interview and Site Visit Guide (Attachment H).** 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 in 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 module implementation, behavior, and results pertaining to patient engagement.

6. **Rapid Feedback Patient Survey (Attachment I).** 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.

7. **Other outcome and output data from administrative records or electronic medical records (Attachment M - 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).

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 health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

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 website. A manuscript describing the pilot study and its results will also be produced for publication in a peer-reviewed journal.

3. Use of Improved Information Technology

A broad range of the data collected during the pilot test will use information technology. All training modules will be delivered to participants via an online Learning Management System (LMS), which will introduce each element of the training modules, orient trainees to the content, and allow each individual to use the pathway analysis tool and checklists to interactively navigate through the Training modules. The courses will be set up as enduring education events thus making them available to participants at any time; participants will have the ability to bookmark materials and resume training where they left off. This format is ideal for busy clinicians who can access the training modules multiple times in a progressive fashion and at their convenience.

Each trainee will be asked to complete an online pre/post knowledge quiz. Trainees who complete the course and pass the post-test knowledge test will be awarded continuing education (CE) units through Joint Commission Resources (JCR) by the Accreditation Council for Continuing Medical Education for physicians and physician assistants or by the American Nurses Credentialing Center for nurses.

The use of the LMS for training will allow the project team to actively monitor the test, including the number of participants who have begun training, completed training and completed the post quiz and survey. This information will be monitored on a weekly basis and communicated back to the hospital champions, to encourage timely completion of the training.

A clinician survey will also be conducted electronically via an online survey application. The participant list of who has completed the LMS training on informed consent will be the basis for trainees who will complete a follow up survey 2-3 months after training.

4. Efforts to Identify Duplication

The training modules build on a previous guide funded by the Robert Wood Johnson Foundation, augments it substantially, and makes the delivery format more user-friendly in a way that could not previously be achieved with a static document. Updating the research foundations of *A Practical Guide to Informed Consent* was an important first step in ensuring the training modules would address the clinical challenges of today. To update the information contained in the guide and identify new content areas of interest, an environmental scan of both the peer-reviewed and grey literature was conducted.

A systematic process was employed to identify new research and resources related to informed consent in health care, and to link findings to the training modules development process. An Expert and Stakeholder Panel (ESP) was gathered to provide input on resources for our literature review, key challenges to be addressed in the area of informed consent to care, barriers to addressing those challenges, and proposed learning objectives and audiences for informed consent training modules.

Further, to identify common challenges experienced by hospitals in the implementation of informed consent policies and processes, The Joint Commission, which accredits most U.S.-based hospitals, reviewed de-identified data on informed consent from hospital accreditation inspections, as well as data from external inquiries about informed consent directed to the Joint Commission's standards interpretation group (SIG) between January 2011 and June 2013. The findings highlighted a need for new content to advance the training of clinicians regarding the informed consent process.

5. Involvement of Small Entities

This project does not intend to intentionally involve nor exclude or impact any small entities. However, to the extent an identified and recruited hospital meets the requirements for participation and is a small entity, we will involve them and expect no greater impact than on other participating hospitals. The instruments and procedures used to collect data are designed to minimize the burden on all respondents.

6. Consequences if Information Collected Less Frequently

This project is a one-time data collection effort. The data collection period will last for approximately 9 months at each of four participating sites.

Not collecting the data, or shortening the data collection period (either by decreasing the study duration or number of sites) places us at risk of not collecting adequate information for the pilot testing of the training modules. Should we shorten the data collection period, we might not identify potential barriers, facilitators or outcomes of implementing the informed consent training modules. This would limit the extent to which the final training modules would meet hospitals' needs related to the improvement of informed consent processes.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register July 9, 2014 on Page 38898 for 60 days (see Attachment J). AHRQ received and responded to one comment from the public (Attachments K and L respectively).

8.b. Outside Consultations

The following experts and stakeholders were consulted to identify essential content for the informed consent training modules and to identify appropriate inclusion criteria for hospitals to be included in the pilot test.

- Mary Ann Abrams, MD, MPH, Department of Pediatrics at the Ohio State University College of Medicine
- David Andrews, Patient Advisor, Georgia Regents Medical Center
- Ellen Fox, MD, National Center for Ethics in Health Care, U.S. Department of Veterans Affairs
- Barbara Giardino, RN, BSN, MJ, CPHRM, CPPS, Rockford Memorial Hospital
- James Oberman, MD, Clinical Quality Officer of the National Capital Region Medical Directorate and a Staff Otolaryngologist at Walter Reed National Military Medical Center
- Yael Schenker, MD, Center for Bioethics and Health Law
- Faye Sheppard, RN, MSN, JD, CPHRM, CPPS, FASHRM, Principal for Patient Safety Resources, Inc.
- Jana Towne, RN, Nurse Executive, Whiteriver Indian Hospital
- Dale Collins Vidal, MD, MS, Dartmouth-Hitchcock Medical Center; Center for Informed Choice
- Matthew Wynia, MD, MPH, FACP, Director at the Institute for Ethics & Center for Patient Safety at the American Medical Association

9. Payments/Gifts to Respondents

A range of non-monetary incentives will be offered to study participants. These non-monetary benefits include:

- Free, high-quality training on good informed consent practices
- Free continuing education (CE) for individual staff clinicians and leaders
- Opportunity to participate in a patient safety / informed consent project
- Opportunity to participate in a project funded by AHRQ and with the Joint Commission
- Potential to improve hospital's informed consent processes

In addition, we request an honoraria of $30 for each interviewee's time (n=72 for a total of $2160). The team's belief is that hospitals and clinicians will be motivated to participate because of their interest in improving their informed consent processes or because of the opportunity to participate in a research project with the Joint Commission, not because of monetary incentives. However, providing a $30 incentive to those who, in addition to performing their jobs, take the time to be interviewed (1 hour) by the site visit team increases the likelihood of recruiting a diverse and cooperative set of respondents.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

11. Questions of a Sensitive Nature

The data collection protocols do not contain any questions concerning sexual behavior and attitudes, religious beliefs, income or proprietary business information. However, surveys may elicit sensitive information that reflects negatively on staff or hospital performance related to the informed consent process. Respondents to the survey will be explicitly informed that their participation is voluntary, information they provide is confidential to the extent provided by law, and they may choose to withdraw from the study or not respond to specific items without penalty. We will also remove individual staff and hospital names from written interview records and reports to maintain respondent confidentiality.

12. Estimates of Annualized Burden Hours and Costs

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 (Attachment C)** 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 Professional Pre-/Post-Training Quiz (Attachment D):** 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. **Leader Pre-/Post-Training Quiz (Attachment E):** 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 (Attachment F)** 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 (Attachment G).** 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 (Attachment H)**. 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 (Attachment I)** 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 Professional Pre-/Post-Training Quiz* (Attachment D)	512	2	20/60	341
2b. 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 – 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 $25,268.87.

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. 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 – 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 health care 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 health care 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

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

The total cost of this data collection to the government is $261,467, $256,754 in contract costs and $4,713 in government personnel costs. The contract costs include $8,800 in monetary incentives to 92 research participants. The project extends over 3 fiscal years, although data collection will take place over the course of 9 months. Exhibit 3 shows a breakdown of the total cost and annualized cost for the data collection and data processing and analysis led by the contractor. Exhibit 4 shows a breakdown of the government personnel costs related to this data collection effort.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Data Collection Activities	$128,377	$42,792
Data Processing and Analysis	$128,377	$42,792
Total	**$256,754**	**$85,584**

Exhibit 4. Government Personnel Cost

Tasks/Personnel	Annual Salary	% of Time	Cost
PRE OMB Approval Costs			
Government Personnel Costs			
Social Science Analyst – GS15*, Step 9	$157,100	1%	$1,571
POST OMB Approval Costs			
Government Personnel Costs			
Social Science Analyst – GS15*, Step 9	$157,100	2%	$3,142

Grand Total			**$4,713**

*Based on 2013 OPM Pay Schedule for Washington/DC area: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/

15. Changes in Hour Burden

This is a new information collection.

16. Time Schedule, Publication and Analysis Plans

Exhibit 5 Project Timeline

Description (in chronological order)	**Due Date**
Final Pilot Test training modules	May 30, 2014
Identify potential pilot test hospitals	October-November 2014
Final list of recommended hospitals	December 7, 2014
Launch pilot testing	January 2014
Health Care Professionals and Leaders pre-/post-training quiz	March 2015 - November 2015
Training via learning management system (LMS)	March 2015 - November 2015
Health Care Professionals and Leaders Pre-/Post-training Quiz	March 2015 - November 2015
Clinicians and Leaders In-depth Interviews	August 2015 - November 2015
Site visit	August 2015 - November 2015
Complete analysis	August 2015 - November 2015
Draft pilot test report	Mar. 7, 2016
Final pilot test report	Apr. 4, 2016
Revised Training modules	Jul. 31, 2016
Final Training modules	Aug. 31, 2016

Publication Plan:
Study results will be disseminated through a peer-reviewed publication. The final training modules will be posted on the appropriate section of the AHRQ web site and disseminated via AHRQ's Office of Communication and Knowledge Transfer (e.g., e-mails to relevant professional associations and postings on listservs).

Analysis Plan:
As described above, the purpose of this data collection is twofold: 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. AHRQ has proposed to use multiple data sources to triangulate findings to meet both of these goals.

The data analysis strategies therefore differ, each of which are described below:

Goal 1:	Understand the facilitators and barriers of implementing the tools and improvements to informed consent policies and processes and identify opportunities to improve the informed consent training modules
Data collection strategy:	informed consent baseline and follow-up assessment, monthly check-ins, interviews and site visits
Data analysis strategy:	Qualitative synthesis

Data will be qualitatively analyzed, identifying themes of facilitators and barriers to implementing the training modules and improvements to hospitals' informed consent processes and qualitative data from the readiness assessment. Qualitative analysis software (NVivo) will be used to synthesize and analyze the data as well as to allow for qualitative comparisons and synthesis by each unit, unit type (e.g., surgical unit), staff

type (e.g., leader, physician), hospital, and in aggregate. Qualitative comparisons of the data from the baseline and follow-up assessment of informed consent processes will be similarly analyzed. The insights regarding facilitators and barriers to implementation will be used in the final training modules to describe how other hospitals might more smoothly implement changes, and may also inform training modules content (e.g., how to obtain buy-in from hospital leadership).

Goal 2: Assess the effectiveness of the training modules in improving informed consent processes and other outcomes

Data collection strategy: Pre-/post-training quiz, health care professional survey, rapid feedback patient survey, other outcome and output (secondary) data

Data analysis strategy: Quantitative analyses

Quantitative data will be collected through the pre-/post-training quiz, health care professional survey, rapid feedback patient survey, and other outcome and output (secondary) data. AHRQ will analyze the data using descriptive statistics (i.e., frequencies, averages) by staff, staff type, unit, and unit type to allow comparisons, as well as in aggregate by hospital and across all 4 hospitals. Additional analysis will include comparisons of pre- and post-tests to measure changes. Analysis sub-goals for each set of instruments and analysis plans are summarized in Exhibit 6, below.

Exhibit 6. Informed Consent Data Collection and Analysis Plans

Instrument	When administered and to whom	Analysis sub-goal	Analysis Plan
Health care professionals Pre-/Post-Training Quiz (Attachment D)	▪ Immediately before and after LMS training ▪ Health care professional	Assess baseline knowledge and knowledge after LMS training; reactions to and evaluation of training (post only)	▪ Descriptive statistics (i.e., frequencies, average) ▪ Qualitatively analyze open-ended comments ▪ Pre- and post-test summary scores-percent correct (range: 0-100%) ▪ Paired t-test to compare pre- and post-test scores.
Leaders Pre-/Post-Training Quiz (Attachment E)	▪ Immediately before and after LMS training ▪ Hospital leaders	Assess baseline knowledge and knowledge after LMS training; reactions to and evaluation of training (post only)	▪ Descriptive statistics (i.e., frequencies, average) ▪ Qualitatively analyze open-ended comments ▪ Pre- and post-test summary scores-percent correct (range: 0-100%) ▪ Paired t-test to compare pre- and post-test scores.
Health Care Professional Survey (Attachment G)	▪ Before LMS training and 2-3 months after training ▪ Frontline clinicians	Assess reported informed consent processes and techniques used, and effectiveness	▪ Descriptive statistics (i.e., frequencies, average) ▪ Average scores (0-5) for each domain (e.g., clinician self-report on use of strategies to facilitate patient understanding) ▪ Paired t-test
Rapid Feedback Patient Survey (Attachment I)	▪ Immediately after engaged in an informed consent discussion and signed (or not) a consent form ▪ Patients	Assess patient-reported outcomes	▪ Descriptive statistics (counts, frequencies, averages) ▪ Binary variables (yes/no) and ordinal variables recoded to binary form (meets/does not meet minimum standard) ▪ Average scores (0-10) for several domains (e.g.,

			overall satisfaction with consent process) ▪ Binomial tests (for binary variables) ▪ Unpaired t-tests (for average scores)
Secondary data and other outcome data (e.g., surgical cancellation and delay rates)	• During implementation	• Assess implementation process • Assess outcomes	▪ Qualitatively analyze open-ended data ▪ Descriptive statistics (counts, frequencies, averages); unpaired t-tests for average surgical delay and cancellation rates (%) pre-/post-implementation (if feasible)

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

- Attachment A - Informed Consent - Leaders Training Module
- Attachment B - Informed Consent - Health Care Professionals Training Module
- Attachment C - Hospital Informed Consent Baseline and Final Assessment
- Attachment D - Health Care Professionals Pre-/Post-Training Quiz
- Attachment E - Leaders Pre-/Post-Training Quiz
- Attachment F - Monthly Check-In
- Attachment G - Health Care Professional Survey
- Attachment H - Interview and Site Visit Guide
- Attachment I - Rapid Feedback Patient Survey
- Attachment J - Federal Register Notice
- Attachment K - Public Comment
- Attachment L - Response to Public Comment
- Attachment M – Secondary Data