DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the General Atomics Facility in La Jolla, California, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the General Atomics facility in La Jolla, California, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: General Atomics.

Location: La Jolla, California.

Job Titles and/or Job Duties: All Atomic Weapons Employees who worked for General Atomics at its facility in La Jolla, California, during the period from January 1, 1960 through December 31, 1969, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

Period of Employment: January 1, 1960 through December 31, 1969.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

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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 an Informed Consent Toolkit.'' In accordance with the Paperwork Reduction Act, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by September 8, 2014.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email 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 email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Improving Hospital Informed Consent With an Informed Consent Toolkit

The ultimate aim of this project is to pilot test a toolkit 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 enhancing 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 a new Informed Consent Toolkit. Toolkit content will be delivered via two training modules of approximately one hour each (one for hospital leaders, the other for frontline clinical staff), to be offered through a Learning Management System. Clinical staff taking the training will be eligible for continuing education (CE) credit.

AHRQ will pilot test the toolkit to assess:

- Facilitators of and barriers to implementing the toolkit
- Effectiveness of the toolkit in improving informed consent processes and relevant outputs and outcomes

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

- Train the leaders of their choosing using the training module Champion improvements in their informed consent policies and processes based on the information and tools in the leader training.
- Train frontline staff members in four units, including at least one surgical unit. Using the frontline training module.
- Implement improvement initiatives over a period of two to six months in participating units based on materials presented in the frontline training.
  - In at least one unit implementation will last at least three months and use