SUPPLEMENTARY INFORMATION: The PREP Act, which is a part of the ''Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006'' (Pub. L. 109–148), was enacted on December 30, 2005, and confers broad liability protections on covered persons, as defined in section 319F–3(i)(2) of the PHS Act, and compensation to individuals injured by the receipt of covered countermeasures, as defined in section 319F–3(i)(1) of the PHS Act, in the event of designated public health emergencies. A covered countermeasure means: (A) A qualified pandemic or epidemic product (as defined in section 319F–3(i)(7) of the PHS Act); (B) a security countermeasure (as defined in section 319F–2(c)(1)(B) of the PHS Act); or (C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564 of the Federal Food, Drug and Cosmetic Act.

Passed primarily to address the pandemic influenza threat, the PREP Act provides liability protections after a Secretarial declaration of covered countermeasures for any disease or health condition that the Secretary views as constituting a public health emergency, either presently or in the future. Liability protections cover the manufacture, testing, development, distribution, or use of the designated covered countermeasure absent willful misconduct as defined in section 319F–3(c)(1) of the PHS Act. A Secretarial declaration specifies the categories of health threats or conditions for which countermeasures are recommended, the period liability protections are in effect, the population of individuals protected, and the geographic areas for which the protections are in effect.

In addition to liability protections, the PREP Act provides the Secretary the authority, which was delegated by the Secretary on November 8, 2006 to the Administrator of the Health Resources and Services Administration, to compensate eligible individuals for covered injuries from a covered countermeasure.

The first Declaration under the PREP Act was published in the **Federal Register** on February 1, 2007 (72 FR 4710). It designated the pandemic influenza A (H5N1) vaccine as a covered countermeasure, with an effective time period of December 1, 2006–February 28, 2010. As a result of this Declaration, individuals injured by this vaccine can file a request for compensation. Individuals have one (1) year from the time they receive the vaccine to apply for compensation. Currently, no funds have been appropriated to provide compensation. However, all potential claims must still be filed within the one (1) year limit.

This Declaration specifies that the following individuals with covered injuries may be eligible to receive compensation under the PREP Act: (1) All persons who use a covered countermeasure or to whom such a covered countermeasure is administered as an Investigational New Drug in a human clinical trial conducted directly by the Federal Government, or pursuant to a contract, grant or cooperative agreement with the Federal Government; (2) all persons who use a covered countermeasure or to whom such a countermeasure is administered in a pre-pandemic phase; and/or (3) all persons who use a covered countermeasure, or to whom such a covered countermeasure is administered in a pandemic phase. The Pre-Pandemic Phase means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas. The Pandemic Phase means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Eligible individuals may be compensated for out-of-pocket medical expenses, lost employment income, and survivor death benefits. Reasonable and necessary medical items and services may be paid or reimbursed to treat a covered countermeasure-related injury of an eligible individual. The payments or reimbursements for services or benefits are secondary to other forms of coverage. The individual may receive compensation for loss of employment income incurred as a result of the covered countermeasure injury. The amount of compensation is based on income at the time of injury. Death benefits may be paid to certain survivors of covered countermeasures recipients who have died as a direct result of the covered countermeasure injury. Since HHS is payer of last resort, payments are reduced by those of other third party payers.

Interested parties may obtain request packages that contain copies of all necessary forms and instructions by writing to the Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857, calling at 1–888–496–0338, or downloading them from the HRSA Web site at *http://www.hrsa.gov/countermeasurescomp.*

Completed request packages must be postmarked by the U.S. Postal Service, a commercial carrier, or a private courier service. HRSA will not accept request packages electronically or by hand-delivery. The postmark date is used to determine whether the filing deadline of one year from receipt of the countermeasure has been met.

Paperwork Reduction Act of 1995

HRSA will submit to the Office of Management and Budget (OMB) an Information Collection Request (ICR) for approval of the required forms.

Dated: December 18, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. 07–6180 Filed 12–19–07; 1:36 pm]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Cancer Care for Uninsured Individuals: A Feasibility Study (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) of the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Cancer Care For Uninsured Individuals: A Feasibility Study. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of this information collection is to conduct a pilot study to assess the feasibility of obtaining health insurance information for participants of the Prostate, Lung, Colon and Ovarian (PLCO) Cancer Screening Trial participants from health

care providers and self reports. The ultimate objective is to compare the health care utilization of insured and uninsured PLCO participants. The PLCO data provides a unique opportunity to study health care seeking behavior after an abnormal cancer screening test and the effect of lack of health insurance. Individuals randomized to the intervention arm of the trial received screening for the PLCO cancers. Individuals with positive findings were referred to their doctors for follow-up care, but no additional care was provided by the trial. The PLCO study then collected detailed information on tests received for diagnosis, clinical presentation of disease, and cancer treatment. Since the PLCO original data collection had not recorded the health insurance of participants at the time of their screening, it is necessary to collect it retrospectively. This feasibility study will request information from 50 physicians and 150 participants. The aims are to determine:

(1) The total number of physicians to be contacted to obtain insurance information on all PLCO participants who had a positive cancer screening test;

(2) The percentage of physicians willing and able to provide insurance information;

(3) The percentage of respondents' patients with and without insurance, and possibly distribution of patients by insurance type;

(4) The number of participants for whom the insurance status can be only determined by self report;

(5) The percentage of PLCO participants who are willing to respond to the survey;

(6) The percentage of individuals who are willing to provide information on insurance status and type; and,

(7) The potential proportion of PLCO participants without health insurance at the time of screening.

The results of this feasibility study will be used to design of a larger study to examine the health care behavior of insured and uninsured PLPCO participants. This is relevant to understand the results of the PLCO Cancer Screening Trial and other screening trials currently being conducted in the U.S. The success of these trials is conditional on participants' access to care following a recommendation for follow-up. Uninsured individuals may be more likely to join these trials than insured ones in order to get free preventive care. They may also be more likely to not seek, or delay seeking, care after an abnormal screening test even though they are encouraged to get care and they may be highly motivated to receive the best care possible. It is relevant for other decision makers to understand whether uninsured persons are receiving appropriate care after abnormal screening results. The efforts to control cancer disease and the loss of life associated with it are concentrated on population wide screening. These endeavors may be compromised if a significant proportion of the population does not get appropriate follow-up after screening or does not get the care known to be effective for their disease.

Frequency of Response: One time. *Affected Public:* Individuals or households; Businesses or other for-profit. *Type of Respondents:* Men and women older than 55 who participated in the PLCO Screening trial and physicians who provided care for them. The annual reporting burden is shown in the following table.

Type of respondents	Number of respondents	Frequency of response	Average burden hours per response	Annual hour burden
PLCO participants	150	1	5 minutes (0.08)	12.5
Physicians office staff	50	1	20 minutes (0.33)	16.7
Totals	200			29.2

The annualized cost to respondents is estimated at: $488. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Maria Pisu, Division of Preventive Medicine, University of Alabama at Birmingham, MT 628, 1530 3rd Avenue South, Birmingham, AL 35294–4410, or call non-toll-free number (205) 975–7366 or e-mail your request, including your address to: *mpisu@uab.edu.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: December 11, 2007.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E7–24872 Filed 12–20–07; 8:45 am]

BILLING CODE 4140–01–P

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