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[FR Doc No: 05-23670]

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by January 5, 2006.

Title and OMB Number: A Case Control Study to Identify Risk Factors Associated with Myocarditis or Pericarditis Among Smallpox Primary Vaccinees in the U.S. Military, OMB Number 0720-TBD.

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Type of Request: New.

Number of Respondents: 400.

Responses per Respondent: 1.

Annual Responses: 400.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 200.

Needs and Uses: Section 743 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 authorized the Secretary of Defense to establish a center devoted to ``***longitudinal study to evaluate data on the health condition of members of the Armed Forces upon their return from deployment ***'' Based upon this legislation, the Assistant Secretary of Defense for Health Affairs established the DoD Center for Deployment Health Research on September 30, 1999 (OSD/HA Policy 99-028). The Department of Defense shares with the President and Congress a firm commitment to improve the health of our veterans, their families, and all who service our nation, now and in the future. The National Science and Technology Council (NSTC) Presidential Review Directive 5 (PRD-5), Planning for Health Preparedness for and Readjustment of the Military, Veterans, and their Families after Future Deployments is an interagency plan which provides a comprehensive set of recommendations designed to help ensure this obligation is met in a manner that takes into consideration the successes and failures of past deployments. A key recommendation in this plan and necessity if we are to meet this commitment is treatment, research, and surveillance efforts aimed at minimizing adverse health effects that may be experienced during and after deployment.

In its ongoing response to this legislation, DoD plans to conduct a

postal survey of current and past U.S. service members who received the smallpox vaccine under the DoD Smallpox Vaccination Program, which began on December 13, 2002. Subsequent to initiation of this program, a small percentage of service members developed either myocarditis or pericarditis following a primary smallpox vaccination. (Refs: Halsell JS, et al., JAMA 2003; 289:3283-9; Arness MK, et al., AJE 2004; 160:642-51). In response to these cases, the DoD established additional policies and guidelines: (1) Policy for Smallpox Vaccination and Persons with Cardiac Conditions (OSD/HA, Policy 03-002), and (2) Establishment of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis (OSD/HA, June 9, 2003). The survey will obtain risk factor information from identified myocarditis or pericarditis cases and a number of smallpox vaccinated but healthy controls. The objective of the study is to understand why a small percentage of smallpox-vaccinated service members develop myocarditis or pericarditis.

Affected Public: Individuals or households.

Frequency: On Occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. John Kraemer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Kraemer at the Office of Management and Budget, Desk Office for DoD Health, Room 10102, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings, WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209-2133.

Dated: November 29, 2005.

Patricia L. Toppings,
Alternate OSD Federal Register Liaison Officer, Department of Defense.
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