registration information will be required for 3,000 trials of drugs and biologics and 445 trials of medical devices each year.

Each initial registration is estimated to take 7 hours and each of the subsequent 8 updates to the record are estimated to take 2 hours, resulting in an annual burden of 79,235 hours. It is estimated that there will be voluntary submissions of registration information for 6,000 trials of drugs and biologics, 545 trials of devices, and 5,280 trials of other types of medical interventions. Using the same hour estimates as for mandatory registration, the burden associated with voluntary registrations is estimated at 271,975 hours, bringing the total registration burden to 351,210 hours. In the first year of operation, it is estimated that there will be an additional burden of 84,150 hours associated with the updating of information for 7,000 trials of drugs and biologics and 650 trials of medical devices that were previously registered in the databank and ongoing as of December 26, 2007 (90 days after enactment). It is estimated that such trials will require one update of 3 hours to bring them into compliance with the new law (FDAAA) and 4 subsequent updates of 2 hours each. Submisson of results information is required only for those applicable clinical trials of drugs, biologics, and devices that are subject to the mandatory registration requirements of FDAAA and for which the product(s) under study have been approved or cleared by the FDA. It is estimated that results reporting will be required for 1,645 trials of drugs and biologics and 375 trials of medical devices each year. Initial submission of results information is estimated to require 10 hours, and each result submission is expected to require two updates that take 5 hours each. It is estimated that 2,345 trials per year will submit certifications for delayed reporting of results information or a request for an extension of the reporting deadline. Preparation and submission of such information is estimated to take 1 hour. The total burden for results reporting is therefore estimated at 42,745 hours per year. There are no capital costs to report. The operating and maintenance budget for the Clinical Trials Registry Databank in FY2009 is projected to be approximately $3 million.

Request For Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301–402–9680 or e-mail your request to *sharlipd@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: December 17, 2008.

Betsy L. Humphreys,

Deputy Director, National Library of Medicine, National Institutes of Health.

[FR Doc. E8–31448 Filed 1–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine, Special Emphasis Panel, G08/K99/R01/R13 SEP.

Date: February 11, 2009.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Zoe E. Huang, MD, Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, National Institutes of Health, 6705 Rockledge Drive, Suite 301, MSC 7968, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov.*

Name of Committee: National Library of Medicine Special Emphasis Panel; G13 SEP.

Date: February 20, 2009.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Zoe E. Huang, MD, Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, National Institutes of Health, 6705 Rockledge Drive, Suite 301, MSC 7968, Bethesda, MD 20892–7968, (301) 594–4937, *huangz@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 22, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–31379 Filed 1–5–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–0961]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number: 1625–0073

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of