

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

*Contact Person:* Paek-Gyu Lee, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4201, MSC 7812, Bethesda, MD 20892, 301-435-1277, [leepg@csr.nih.gov](mailto:leepg@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel: Member Conflict: Influences on Behavior, Thought Processes, and Mental Health.

*Date:* June 26, 2008.

*Time:* 3 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Karen Lechter, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3128, MSC 7759, Bethesda, MD 20892, 301-496-0726, [lechtk@csr.nih.gov](mailto:lechtk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel: Small Business: Psychopathology and Adult Disorders.

*Date:* June 27, 2008.

*Time:* 8:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.

*Contact Person:* Estina E. Thompson, MPH, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301-496-5749, [thompson@mail.nih.gov](mailto:thompson@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

*Dated:* May 13, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-11187 Filed 5-20-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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 meeting.

The meeting 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Vascular Disease Program Project.

*Date:* June 9, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

*Contact Person:* Shelley S. Sehnert, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892-7924, 301-435-0303, [ssehnert@nhlbi.nih.gov](mailto:ssehnert@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

*Dated:* May 13, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-11186 Filed 5-20-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Public Process for the Expansion of the ClinicalTrials.gov Registry and Availability for Public Comment of Preliminary Information Related to the Establishment of a Basic Results Database

**SUMMARY:** Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA; Pub. L. 110-85) mandates the expansion of the existing ClinicalTrials.gov registry and the establishment of a clinical trial results database. This notice announces our intent to implement the expanded registry and the basic results database via rulemaking and to post for public comment on the website identified below preliminary materials related to the basic results database. Comments received on the preliminary basic results materials will be considered in the development of an operational version of the basic results database and in the drafting of the associated regulation and any necessary guidance

documents. The regulation will be subject to a separate public comment process.

**ADDRESSES:** Comments may be submitted using an electronic form available on the public Web site <http://prsinfo.clinicaltrials.gov/fdaaa.html>. They may also be submitted by e-mail to the address: [register@prs.clinicaltrials.gov](mailto:register@prs.clinicaltrials.gov). E-mail entries should include the words "Comment on FDAAA Basic Results" in the subject line.

**DATES:** Basic results materials will be made available for comment as they become available. New and revised materials will be posted on the NIH Web site <http://prsinfo.clinicaltrials.gov/fdaaa.html> several times between May 2008 and September 30, 2008. Specific comment periods will be identified for each item as they are posted. Comments must be received on or before the posted deadlines in order to ensure their consideration in the development of the operational version of the basic results database and in preparation of the planned regulation and any necessary guidance documents.

**FOR FURTHER INFORMATION CONTACT:**

Tony Tse, Ph.D., National Library of Medicine, National Institutes of Health, MSC 3828, 9000 Rockville Pike, Bethesda, MD 20894, 301-402-0650 (not toll-free).

**SUPPLEMENTARY INFORMATION:** Section

801 of the Food and Drug Administration Amendments Act of 2007 mandates expansion of the existing *ClinicalTrials.gov* registry to include additional information about Applicable Clinical Trials of drugs, biologics, and devices (as defined in the law). It also mandates establishment of a clinical trial results database and requires, beginning not later than 12 months after enactment (i.e., by September 27, 2008), the inclusion of the basic results information described in the law. Additional statutory provisions outline processes for adding information about serious and frequent adverse events observed in a trial and for further expanding the registry and results database.

We plan to provide clarification of the requirements for the expanded clinical trial registry and the basic results database via rulemaking. The Notice of Proposed Rulemaking (NPRM) for the expanded registry is expected to be published for public comment in Fall 2008. A separate NPRM for the basic results database will be issued for public comment at a later date. Prior to the issuance of the NPRM for the basic results database, NIH will post for comment on the public Web site

<http://prsinfo.clinicaltrials.gov/fdaaa.html> preliminary versions of the data entry and display formats for the results database, as well as related descriptive information. Comment periods will be specified each time an item is posted. Public comments received on these preliminary materials will be considered by the agency and will inform development of an operational basic results database and preparation of the NPRM for basic results information that will be published for public comment at a later date. NIH intends to begin posting new materials in May 2008; additional or revised materials will be posted several times before September 30, 2008. Interested members of the public may elect to receive electronic notification when new draft materials are posted and available for comment. Instructions for subscribing to these alerts will be posted on the public Web site.

Dated: May 8, 2008.

**Lana R. Skirboll,**

Director, Office of Science Policy, National Institutes of Health (NIH).

[FR Doc. E8-11042 Filed 5-20-08; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2007-0180]

#### Collection of Information Under Review by Office of Management and Budget: OMB Control Numbers: 1625-0001, 1625-0013, and 1625-0096

**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 three Information Collection Requests (ICRs), abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) requesting an extension of their approval for the following collections of information: (1) 1625-0001, Marine Casualty Information & Periodic Chemical Drug and Alcohol Testing of Commercial Vessel Personnel; (2) 1625-0013, Plan Approval and Records for Load Lines, and (3) 1625-0096, Report of Oil or Hazardous Substance Discharge; and Report of Suspicious Maritime Activity. Our ICRs describe the information we seek to collect from the public. Review

and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** Please submit comments on or before June 20, 2008.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2007-0180] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) or to OIRA. To avoid duplication, please submit your comments by only one of the following means:

(1) *Electronic submission.* (a) To Coast Guard docket at <http://www.regulation.gov>. (b) To OIRA by e-mail to: [nlesser@omb.eop.gov](mailto:nlesser@omb.eop.gov).

(2) *Mail or hand delivery.* (a) DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001. Hand deliver between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329. (b) To OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard.

(3) *Fax.* (a) To DMF, 202-493-2251. (b) To OIRA at 202-395-6566. To ensure your comments are received in time, mark the fax to the attention of Mr. Nathan Lesser, Desk Officer for the Coast Guard.

The DMF maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://www.regulations.gov>.

Copies of the complete ICRs are available through this docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from Commandant (CG-611), U.S. Coast Guard Headquarters, (Attn: Mr. Arthur Requina), 2100 2nd Street, SW., Washington, DC 20593-0001. The telephone number is 202-475-3523.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523 or fax 202-475-3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

**SUPPLEMENTARY INFORMATION:** The Coast Guard invites comments on whether

this information collection request should be granted based on it being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of information subject to the collections; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology.

Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR addressed. Comments to Coast Guard must contain the docket number of this request, [USCG 2007-0180]. For your comments to OIRA to be considered, it is best if they are received on or before June 20, 2008.

*Public participation and request for comments:* We encourage you to respond to this request by submitting comments and related materials. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the paragraph on DOT's "Privacy Act Policy" below.

*Submitting comments:* If you submit a comment, please include the docket number [USCG-2007-0180], indicate the specific section of the document to which each comment applies, providing a reason for each comment. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission. You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them. The Coast Guard and OIRA will consider all comments and material received during the comment period.

*Viewing comments and documents:* Go to <http://www.regulations.gov> to