

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.

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.

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.

(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.

(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.

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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. 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