

Dated: April 7, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-8479 Filed 4-13-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute of Neurological Disorders and Stroke Special Emphasis Panel; Aneurysm Trial.

Date: April 23, 2009.

Time: 3:15 p.m. to 5:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-594-0635, rc218u@nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of NINDS PPG on CA²⁺ Signaling in Spines.

Date: April 24, 2009.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ernest W Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-4056, lyonse@ninds.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research

Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 7, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of a Public Consultation Meeting on Proposed Revisions to the NIH Guidelines for Research Involving Recombinant DNA Molecule (NIH Guidelines)

There will be a public consultation meeting to solicit stakeholder input regarding the proposed revisions to the NIH Guidelines. The meeting will be held on Tuesday, June 23, 2009 at the Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia, 22202, from approximately 8 a.m. to 5 p.m.

Discussions will focus on the proposed revisions to the NIH Guidelines which include: (1) Broadening the scope of the NIH Guidelines, which currently cover laboratory and clinical research involving DNA molecules created via recombinant techniques (i.e., joining of DNA molecules), to apply to nucleic acids that are synthesized chemically or by other means without the use of recombinant technology; (2) Revising the criteria for determining when the introduction of a drug resistance trait into a microorganism must be reviewed by the Recombinant DNA Advisory Committee and approved by the NIH Director; and (3) Changing the level of review required for recombinant or synthetic experiments involving more than one-half but less than two-thirds of the genome of certain viruses in tissue culture as described in Section III-E-1 of the NIH Guidelines.

The Notice of Consideration of a Proposed Action under the NIH Guidelines was published in the **Federal Register** on March 4, 2009 (74 FR 9411) and may be located at the following link: <http://oba.od.nih.gov/rdna/rdna.html>.

For further information concerning this meeting contact Ms. Laurie Lewallen, Advisory Committee Coordinator, Office of Biotechnology Activities, Office of the Director, National Institutes of Health, 6705

Rockledge Drive, Room 750, Bethesda, MD 20892-7985, 301-496-9838, lewallenl@od.nih.gov.

The meeting will be open to the public, with attendance limited to the space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed above in advance of the meeting.

A draft agenda and additional information for the meeting will be posted on the OBA Web site: <http://oba.od.nih.gov/rdna/rdna.html>. Background and supplemental information may also be obtained by contacting NIH OBA by e-mail oba@od.nih.gov.

Dated: April 8, 2009.

Jacqueline Corrigan-Curay,

Acting Director, Office of Biotechnology Activities, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Research Sites To Measure Composition of Sealed Area Atmosphere in Coal Mines

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), is seeking research sites to measure composition of sealed area atmosphere in coal mines.

NIOSH seeks to conduct scientific studies of the composition of sealed area atmospheres and the mechanisms of methane accumulation within sealed areas. Research questions to be addressed are: (1) Whether potentially explosive gas mixtures exist within sealed areas, (2) how extensive such mixtures might be, (3) how the gas composition changes over time, (4) whether methane layering exists, (5) the homogeneity of the atmosphere, and (6) how barometric pressure changes impact the sealed atmosphere. NIOSH will document measurements of the composition of the sealed area atmosphere over time, analyze the

findings, and report the findings generically to all interested parties.

DATES: Letter of interest must be received within 90 calendar days of publication in the **Federal Register**.

ADDRESSES: Mining companies able to provide NIOSH with mine sites for this research should submit a letter of interest to the NIOSH Pittsburgh Research Laboratory (PRL) Director. The letter should provide the name of the mine and a brief description of the anticipated sealing plans. Any questions should be addressed by phone or e-mail. Please send letter of interest to: R. Güner Gürtunca, PhD, NIOSH Pittsburgh Research Laboratory (PRL), 626 Cochran Mill Road, Post Office Box 18070, Pittsburgh, PA 15236, telephone (412) 386-6601, E-mail GGurtunca@cdc.gov.

Background: Recent research reports published by NIOSH and the U.S. Army Corps of Engineers describe the potential for explosive methane mixtures to develop within sealed areas of underground coal mines. The composition and behavior of the atmosphere within sealed areas are not scientifically well-understood. Areas of interest include the extent and nature of explosive mixtures of gases, how the composition of these mixtures change over time, whether methane layering exists, the homogeneity of the atmosphere, and how barometric pressure changes impact the atmosphere behind seals.

Description: To conduct these measurements, NIOSH will deploy a tube bundle system (TBS) at the mine site for a period of 2 to 5 months (usually not more than 3 months). A TBS is a mechanical system for collecting and analyzing atmospheric samples continuously from anywhere in a mine. The TBS that NIOSH plans to use is a system that is currently being successfully deployed in many Australian underground coal mines. NIOSH seeks three to four underground coal mines throughout the U.S. to cooperate in this study. Underground coal mines covering at least one square mile and producing a medium to high volume of methane are needed. Sampling will be conducted one mine at a time. Either longwall or room-and-pillar mines are acceptable. NIOSH wants to deploy the system in a variety of geological conditions. A soon-to-be-abandoned coal mine is another option for deployment of the TBS.

Prior to sealing, NIOSH will install plastic sample tubing throughout the mine and the future sealed area. This should require a few days to accomplish and will require minimal effort from the

cooperating mine. NIOSH will need to be present during the sealing process to insure that the tubing is properly installed through the seals. After sealing, NIOSH will monitor the composition of the atmosphere throughout the sealed area during the initial methane-accumulation phase and for several months thereafter until stability of the sealed atmosphere develops. Collected data will not be analyzed on a real time basis other than to insure that the system is properly working.

NIOSH will require the following assistance from mining company personnel:

- Site-specific guidance concerning the area to be sealed and how to most efficiently run the sampling tube out of the mine to the sampling analysis location.
- Transportation to and from the sealed area during the installation phase of the TBS and to occasionally check the status of the TBS underground.
- A surface location to locate the sampling trailer.
- For a mine site to be acceptable to NIOSH for this testing, the cooperating mine must be installing 120 psi seals that meet the current design standard.
- After installation, NIOSH will require little assistance from mining company personnel until NIOSH is ready to remove the system from the mine when some transportation assistance will be needed.

After the data is analyzed, the cooperating mine will be provided the data pertaining to its mine. NIOSH will present and/or publish data in a manner that does not identify the cooperating mines. Cooperating mines will have the opportunity to review publications and presentations by NIOSH prior to their release. While NIOSH will not identify the mines in its publications, the identity of cooperating mines may be subject to release in response to a request for documents made under the Freedom of Information Act. This announcement does not obligate NIOSH to enter into an agreement with any respondent.

FOR FURTHER INFORMATION CONTACT: R. Güner Gürtunca, PhD, NIOSH Pittsburgh Research Laboratory (PRL), 626 Cochran Mill Road, Post Office Box 18070, Pittsburgh PA, 15236, telephone (412) 386-6601, e-mail GGurtunca@cdc.gov.

Dated: April 6, 2009.

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. E9-8462 Filed 4-13-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

ACTION: Notice.

SUMMARY: For many decades, the pediatric medical community, the public health community, and government agencies have recognized a range of questions regarding the use of therapeutics in children, including the shortage of clinical studies of drugs in children resulting in inadequate labeling for pediatric use. The lack of appropriate labeling results in off-label use of prescription drugs in many children and for many conditions. Contributing factors to this frequent off-label use of drugs in pediatrics include the rarity of some conditions in children with limited patient availability, the ethical concerns regarding the conduct of clinical trials in children, the lack of accurate information about which drugs are used by children, and the lack of long-term data on the medications that are frequently used.

Several steps have been taken in response to the growing awareness of the knowledge gaps that exist in pediatric therapeutics. The BPCA was originally enacted in January 2002 and reauthorized in September 2007, with the overall purpose of improving the level of information about pharmaceuticals used to treat children (<http://www.fda.gov/opacom/laws/pharmkids/contents.html>). The BPCA outlines a number of goals, including the identification and prioritization of therapeutic needs in pediatrics, especially drugs, biologics, or indications that require study. The legislation also calls for the conduct of pediatric research to learn more about the efficacy and safety of drugs in children as well as the training of experts needed to address the knowledge gaps in pediatric pharmacology. To identify drugs in need of further study, the BPCA mandates that the National Institutes of Health (NIH), in consultation with the U.S. Food and Drug Administration (FDA) and experts in pediatrics, develop