

Dated: October 24, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-5393 Filed 10-30-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: November 27–28, 2007.

Time: November 27, 2007, 7 p.m. to 10 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hilton Washington DC/Rockville Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Time: November 28, 2007, 8:30 a.m. to 1 p.m.

Agenda: To review and evaluate the Section on Directed Gene Transfer, Section on Neurocircuitry, Section on Functional Imaging Methods, and Section on Cognitive Neuropsychology.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C, Rockville, MD 20852.

Time: November 28, 2007, 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate the Training Fellows and Staff Scientists.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C, Rockville, MD 20852.

Time: November 28, 2007, 2:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C, Rockville, MD 20852.

Contact Person: Richard K. Nakamura, PhD, Acting Scientific Director, Division of Intramural Research Programs, National Institutes of Mental Health, NIH, 10 Center Drive, Room 4N222, MSC 1381, Bethesda, MD 20892-1381, 301-496-4183, rnakamur@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Institute of Child Health and Human Development Special Emphasis Panel, The Central Medulla and the Sudden Infant Death Syndrome.

Date: November 16, 2007.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Bldg Rm 5B01, Rockville, MD 20852, (301) 435-6889, bhatnagg@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 24, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of final action under the *NIH Guidelines*.

SUMMARY: Specific proposals to conduct research involving the deliberate transfer of a drug resistance trait to a microorganism that causes disease in humans have been reviewed by the Recombinant DNA Advisory Committee (RAC) and approved by the NIH Director. Approval of these experiments constitutes a Major Action under section III-A-1 of the *NIH Guidelines*.

DATES: This final action is effective September 24, 2007.

FOR FURTHER INFORMATION: Background documentation and additional information can be obtained from the Office of Biotechnology Activities (OBA), National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7958, Bethesda, Maryland 20892-7958; e-mail at oba@od.nih.gov, or telephone at 301-496-9838. The NIH/OBA Web site is located at: <http://www4.od.nih.gov/oba/>.

SUPPLEMENTARY INFORMATION: This final action allows Dr. Dan Rockey and Dr. Walter Stamm (at Oregon State University and the University of Washington, respectively) to deliberately transfer a gene encoding tetracycline resistance from *Chlamydia suis* (a swine pathogen) into *C. trachomatis* (a human pathogen). This approval is specific to Drs. Rockey and Stamm and research with these resistant organisms may only occur under the conditions outlined below. It should be

noted that any work involving the introduction of tetracycline resistance into Chlamydia by other investigators would need to be reviewed by the RAC and specifically approved by the NIH Director.

Background Information and Response to Comments

On May 9, 2007, background on the proposed action, and information on how to submit public comment, was published in the **Federal Register** (72 FR 26415). On June 20, 2007, the RAC discussed the proposed action at its quarterly public meeting and reviewed the one public comment received. The RAC recommended to the NIH Director that this work be allowed to proceed under Biosafety level (BL) 2+ containment with additional provisions/stipulations. On September 24, 2007, the NIH Director approved the proposed experiments with the following conditions.

(1) Tetracycline resistance will only be introduced into non-ocular strains of *C. trachomatis*. In conducting this work on tetracycline resistance in *C. trachomatis*, the following containment standard must be followed:

(2) All research involving the introduction of tetracycline resistance into *C. trachomatis* must be performed at BL 2 using BL3 practices (referred to as BL2+). The *NIH Guidelines* articulates requirements for BL2 laboratory facilities and equipment in Appendices G-II-B-3 and G-II-B-4 while BL3 practices are described in Appendices G-II-C-1 and C-2 of the *NIH Guidelines*. Specifically, the following BL3 practices must be followed:

(a) Access must be restricted to well-trained personnel whose presence is required for the conduct of this work, and

(b) The investigators must use sealed centrifuge rotors and tubes.

(3) In addition, the following procedures and practices must be followed:

(a) Cup sonication must be used rather than probe sonication to separate the infectious form [elementary bodies (EB)] from the metabolically active [reticulate bodies (RB)] form of the bacterium.

(b) If possible, consider using other techniques that do not involve the potential for the generation of aerosols, such as freeze-thaw, to separate EBs from RBs.

(c) No work with the *Chlamydia* serovars A, B, or C, which cause the ocular disease trachoma, may be conducted in the same laboratory in which tetracycline resistance is being

introduced into *C. trachomatis* serovars that cause genital disease (L, E and G).

(d) An assay to detect the tetracycline resistant genetic element should be developed so that, in the event of a laboratory acquired infection, it will be possible to determine whether the genetically modified strain of *Chlamydia* is the source of the infection.

(e) The following preventive health surveillance steps should be implemented for any member of the laboratory working with tetracycline resistant *C. trachomatis*:

(i) In addition to being trained on proper biosafety practices, laboratory workers must be provided education on the possible clinical manifestations of laboratory acquired chlamydial infection.

(ii) Each laboratory must have a detailed, written action plan outlining the specific steps to be taken in the case of a laboratory exposure or infection. This plan should include at a minimum:

(1) Identification of key personnel who would provide diagnostic testing and treatment;

(2) Instructions on managing exposures or infections discovered during off hours (after close of business, holidays, weekends, etc.);

(3) Specific recommendations for managing azithromycin-allergic or sensitive lab workers; and a provision *excluding individuals with known macrolide antibiotic allergies from working on these experiments*;

(4) Specific recommendations for treatment of infected laboratory personnel who develop side effects while being treated with azithromycin, and

(5) Specific precautions to be taken by infected laboratory workers with respect to protecting close contacts (e.g. family members) from further infection.

(iii) In order to ensure that laboratory members will receive adequate healthcare in the event of infection, an outreach program should be developed to inform healthcare providers who may treat laboratory members about the diagnosis and treatment of tetracycline-resistant *Chlamydia*. In addition, members of the laboratory should be provided with a medical card that includes at least the following information:

(1) Identification of the personnel responsible for providing diagnosis and treatment;

(2) A CDC telephone number for reporting the infection and obtaining treatment recommendations, and

(3) A twenty-four hour contact number for the principal investigators.

(4) Finally, if tetracycline resistant *C. trachomatis* is transferred to other

laboratories, the investigators working with this tetracycline resistant *Chlamydia* must follow the identical practices and procedures set forth by the NIH Director. It is the responsibility of Dr. Rockey and Dr. Stamm to ensure and document that the investigators to whom they transfer these strains are apprised of and agree to abide by these requirements. As noted, however, since the NIH Director's approval for the de novo creation of tetracycline resistant strains of non-ocular serovars of *C. trachomatis* applies only to experiments conducted by Drs. Rockey and Stamm, any work involving the introduction of tetracycline resistance into Chlamydia by other investigators would need to be reviewed by the RAC and specifically approved by the NIH Director.

Dated: October 23, 2007.

Amy P. Patterson,

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

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2007-0072]

**Science and Technology Directorate;
Submission for Review; DHS S&T BAA
Web Site Registration Form; DHS S&T
BAA Registration Form; DHS S&T BAA
White Paper and Proposal Submission
Form; DHS S&T RFI Response Form**

AGENCY: Science and Technology Directorate, DHS.

ACTION: 30-day Notice and request for comment.

SUMMARY: The Department of Homeland Security (DHS) invites the general public to comment on new data collection forms for collecting Request for Information (RFI) responses and unclassified white papers and proposals through the Broad Agency Announcement (BAA) Web site. The forms will standardize the collection of information that is both necessary and sufficient for the DHS S&T Directorate to record and track the receipt of RFI responses, unclassified white papers, and proposals. As explained herein, these forms are intended to eliminate cost and delay associated with the submission and review of documents received via non-electronic means and to improve tracking and records keeping. The Department is committed to improving its BAA processes and invites interested persons to comment on the following forms and instructions (hereinafter "Forms Package") for the