

meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a matter that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The clinical hold committee review process is now a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending hold to have that hold considered "anonymously." The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and FDA's Chief Mediator and Ombudsman. The committee now meets semiannually. The committee last met in October 1994.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should consider requesting review when it disagrees with the agency's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to FDA's Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CDER staff, with the exception of the Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available from the Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its June meeting. Submissions should be made by April 27, 1995, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: March 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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National Institutes of Health

Division of Research Grants; 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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda

To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: April 12, 1995.

Time: 2 p.m.

Place: NIH, Westwood Building, Room 303, Telephone Conference.

Contact Person: Dr. Joe Marwah, Scientific Review Administrator, 5333 Westbard Ave., Room 303, Bethesda, MD 20892, (301) 594-7158.

Name of SEP: Biological and Physiological Sciences.

Date: April 18, 1995.

Time: 12:30 p.m.

Place: NIH, Westwood Building, Room 417B, Telephone Conference.

Contact Person: Dr. Gerald Greenhouse, Scientific Review Admin., 5333 Westbard Ave., Room 417B, Bethesda, MD 20892, (301) 594-7385.

Name of SEP: Multidisciplinary Sciences.

Date: April 26, 1995.

Time: 10 a.m.

Place: NIH, Westwood Building, Room 2A15, Telephone Conference.

Contact Person: Dr. Houston Baker, Scientific Review Administrator, 5333 Westbard Ave., Room 2A15, Bethesda, MD 20892, (301) 594-7374.

The meetings will be closed in accordance with the provisions set forth in secs.

552b(c)(4) and 552b(c)(6), Title 5, U.S.C.

Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 83.892, 93.893, National Institutes of Health, HHS)

Dated: March 21, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

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Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 59 FR 60997-8, November 29, 1994) is amended to reflect the reorganization of the Office of the Director, National Institute of Allergy and Infectious Diseases (OD/NIAID). The reorganization consists of the following: (1) Retitle the (a) Office of Administrative Management (HNMI17) to the Office of Administrative Services (HNMI17); (b) Financial Management and Information Systems Branch (HNMI173) to the Office of Financial Management (HNMI2); and (c) Personnel Management Branch (HNMI74) to the Office of Human Resources Management (HNMI14); (2) establish the Office of Technology Information Systems (HNMI15); and (3) transfer the functions of the Office of Tropical Medicine and International Research (OTMIR) (HNMI19) to the Division of Microbiology and Infectious Diseases (HNMI5) and abolish the OTMIR. This reorganization will enable the NIAID to better fulfill its mission by restructuring the OD/NIAID to better integrate related program areas and streamline operations.

Section HN-B, Organization and Functions is amended as follows: (1) Under the heading *Office of the Director (HNMI1)*, *National Institute of Allergy and Infectious Diseases (HNMI)*, insert the following:

Office of Financial Management (HNMI2). (1) Serves as principal advisor to the Institute Director, Deputy Director for Management and Operations, and Division Directors in the financial management aspects of the planning, formulation, execution, and evaluation of the Institute's research grant, training, and intramural research programs; (2) collaborates with program planning staff in the development and coordination of the Institute programs with the budget process; (3) formulates and monitors the Institute's financial management program and establishes a system of effective control of funds utilized