

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.

[FR Doc. 95-7515 Filed 3-27-95; 8:45 am]

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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

through intramural research, grants, and contractual processes, including provision of the full range of program fiscal control for the Institute's extramural grant and contract programs; (4) is responsible for: (a) providing budget guidance to NIAID program areas; (b) compiling and preparing the Institute budget and assuring that the budget meets the needs of the Institute management in controlling the financial aspects of its diverse and complex research programs in allergic and infectious diseases; (5) is responsible for devising financial data systems for NIAID that are beneficial in obtaining data for management decisions, and at the same time are sufficiently compatible with the central NIH accounting system so that dual reporting does not exist; (6) develops budget backup material for OMB and Congressional appropriation hearings and assists in the briefing of witnesses in defense of the budget before NIH, PHS, DHHS, and Congress; (7) serves as a focal point for the monitoring and clearance of budgetary and fiscal data as the result of Congressional and public inquiries; (8) provides fiscal data required in program evaluation and development, including developing, charting, and analyzing historical information depicting Council and fiscal year activity; (9) prepares special reports for the OD/NIAID Advisory Council and Subcommittees, and the NIH, DHHS, and OMB; (10) provides fact-finding, evaluation, and advisory staff services to the Division Directors; (11) maintains dollar control over the international transactions for the Institute; (12) designs, develops, and maintains the computer-based scientific and fiscal data collection, storage, and retrieval system for the Institute's contracts, grants, intramural research projects, fellowships and training awards; and (13) serves as an advisor to senior staff in the development of appropriate criteria and formats for the production of reports based on the data.

(2) After the heading *Office of Communications (HNM13)*, insert the following:

Office of Human Resources Management (HNM14). (1) Advises the Director, Deputy Director for Management and Operations, and Division Directors and their staff on all aspects of personnel management; (2) evaluates Institute personnel programs; (3) provides central personnel management services for the NIAID; (4) provides leadership and planning for the NIAID on personnel policy development, training, personnel planning, recruitment, employee development, salary administration, equal employment opportunity, and

other personnel functions; (5) makes studies and recommendations to top Institute management for new or redirected personnel efforts and policies; and (6) works closely with the Director, OHRM/NIH and staff in all aspects of personnel management.

Office of Technology Information Systems (HNM15). (1) Plans and evaluates requirements for database management systems (DBMS); (2) supports the day-to-day operation of client/server database systems; (3) directs the integration of the NIAID database systems into a cohesive, unified environment; (4) coordinates the database information systems to provide a secure, streamlined, and integrated information repository; (5) directs the development of DBMS systems from the initial requirements analysis to the final deployment of production systems and project management of externally developed systems; (6) interacts with the NIH DBMS technical community to further the integration of NIAID systems with global NIH systems (ADB, MIS, IMPACT); (7) provides oversight for the migration of existing stand-alone applications (EDS, PAF, PATS, PAM) into an integrated, client/server platform; (8) provides basic personal computer hardware and software support services to the staff; (9) provides in-depth guidance and supports working with existing information technology personnel; (10) maintains or provides guidance for the maintenance of the LAN/WAN infrastructure, including the Local and Wide area network cabling plant, backbone connections, routers, protocol routing, and problem resolution; (11) maintains or consults on the support of file and print servers, e-mail, host access (Delpro), and backup services; (12) is responsible for the design and implementation of new LAN/WAN infrastructures (including renovations and upgrades to meet changes in technical industry standards; (13) provides solution enhancements and extensions to existing systems; (14) extends the reach of in-house E-mail systems to inter-operate with other E-mail systems; and maintains streamlined connectivity with other NIH systems; (15) is responsible for vision, trial, and implementation of new technologies (e.g.: video-conferencing; digital imaging; remote computing/telecommuting; document imaging and archiving; virtual reality technologies, cellular/wireless technologies (voice and data); and Internet access to multimedia information [Gopher, Mosaic] electronic scientific journals.); and (16) as negotiated with other

organizations, provides all or selected functions noted above under the NIH service center concept.

(3) Under the heading *Office of Administrative Management (HNM17)*, delete the title and functional statement in their entirety and substitute the following:

Office of Administrative Services (HNM17). (1) Exercises the responsibilities of the Executive Officer, NIAID; (2) directs, coordinates, and conducts administrative activities of the Institute by providing assistance in the areas of: (a) administrative management and services for the extramural, intramural, and OD organizations of the Institute; (b) management analysis services; (c) network services; and (d) acquisition management services; (3) advises the Director, Deputy Director for Management and Operations, and Division Directors on developments in management and their implications and effects on program management; (4) develops policies on administrative management and prepares and issues procedures and guidelines for implementation of administrative policies and requirements; and (5) coordinates the government ethics program of the Institute.

(4) Under the heading *Office of Tropical Medicine and International Research (HNM19)*, delete the title and functional statement in their entirety.

Dated: January 26, 1995.

Harold Varmus,

Director, NIH.

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BILLING CODE 4140-01-M

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse Prevention Conference Review Committee

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Substance Abuse Prevention Conference Review Committee, in April 1995.

The meeting of the Committee will include discussion of announcements and reports of administrative, legislative, and program developments. The Committee will also be performing review of applications for Federal assistance; therefore, a portion of this meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(6) and 5 U.S.C. app. 2 10(d).

A summary of the meeting and roster of committee members may be obtained from: Ms. D. Herman, Committee Management Liaison, Office of