

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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel ZDK1 GRB B J2 S

Date: January 10, 2000

Time: 3:00 PM to 4:00 PM

Agenda: To review and evaluate grant applications

Place: Natcher Building, 45 Center Drive, Room 6AS.25S, Bethesda, Maryland, MD 20892, (Telephone Conference Call).

Contact Person: Ned Feder, MD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS25s, National Institutes of Health, Bethesda, MD 20892, (301) 594-8890.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 17, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99-33296 Filed 12-22-99; 8:45 am]

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such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National deafness and Other Communication Disorders Advisory Council.

Date: January 21, 2000.

Open: 9:30 a.m. to 11:30 a.m.

Agenda: Staff reports on divisional, programmatic and special activities.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Closed: 11:30 AM to adjournment.

Agenda: To review and evaluate grant applications.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, PhD, Chief, Scientific Review Branch, NIH/NIDCD/DER, Executive Plaza South, Room 400C, Bethesda, MD 20892-7180, 301-496-8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 17, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: January 24-25, 2000.

Open: January 24, 2000, 10:00 AM to 5:00 PM.

Agenda: The agenda includes: Report of the Director, NICHD, A presentation by the Pregnancy and Perinatology Branch, CRMC, and other business of the Council.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

Closed: January 25, 2000, 8:00 AM to 1:00 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

Open: January 25, 2000, 1:00 PM to Adjournment.

Agenda: The meeting will reopen to discuss any policy issues that were raised.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

Contact Person: Mary Plummer, Committee Management Officer, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., room 5E03, Bethesda, MD 20892, (301) 496-1485.

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

Dated: December 17, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communications Disorders; Notice of 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 National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to 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 below in advance of the 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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of 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 National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to 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 below in advance of the 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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, December 1, 1999, 3:00 PM to December 1, 1999, 4:00 PM, NIH, Rockledge 2, Bethesda, MD 20892 which was published in the **Federal Register** on November 22, 1999, 64FR63824.

The meeting will be held January 6, 2000. The time will be 11:00 AM to 12:00 PM. The place remains the same.

The meeting is closed to the public.

Dated: December 16, 1999.

LaVerne Y. Stringfield,
Director, Office of Federal Advisory
Committee Policy.

[FR Doc. 99-33295 Filed 12-22-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice

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

SUMMARY: On May 25, 1999 the National Institutes of Health (NIH) published for public comment in the **Federal Register** a proposed policy entitled SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guideline for Recipients of NIH Research Grants and Contracts [64 FR 28205]. This policy is designed to provide recipients of NIH funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds and is intended to assist recipients in complying with their obligations under the Bayh-Dole Act and NIH funding policy. Comments on the Principles and Guidelines were requested by August 23, 1999. This Notice presents the final Principles and Guidelines together with NIH's response to the public comments received.

Background

The Present policy represents part of the overall implementation of recommendations made by the Advisory Committee to the Director (ACD) to Dr. Harlod Varmus, Director, NIH. Dr. Varmus requested that a Working Group of the ACD look into problems encountered in the dissemination and use of proprietary research tools, the competing interests of intellectual property owners and research users underlying these problems, and possible NIH responses. One of the recommendations in the Report was that NIH issue guidance to the recipients of NIH funding.

Purpose

The present policy is a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines providing specific information to patent and license professionals and sponsored research administrators for implementation. The

purpose of these Principles and Guidelines is to assist NIH funding recipients in determining. (1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and (2) restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help Recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding agreements. It is also hoped that these Principles and Guidelines will be adopted by the wider research community so that all biomedical research and development can be synergistic and accelerated.

Comments and Agency Response

The National Institutes of Health (NIH) recognizes the importance of public involvement in the development of policy and sought widespread comment and participation by the various stakeholders in the biomedical research and development communities regarding the proposed policy. To this end, NIH sought comment not only from NIH grantees, but also from academic, not-for-profit, government, and private sector participants in biomedical research and development. In order to involve as many stakeholders as possible in the comment process, the proposed policy was advertised and comments solicited in a wide variety of venues. In addition to its publication on May 25, 1999, in the **Federal Register**, the proposed policy was made available on several different websites including the Federal Register Online, numerous NIH websites (Edison, NIH Office of Technology Transfer, NIH Office of Extramural Research and the NIH Director's Policy Forum), the Association of University Technology Managers (AUTM) website and Recombinant Capital's Signals Magazine. The proposed policy was also advertised on a variety of e-mail lists (including Techno-L) as well as in direct letters and e-mail to various stakeholders. In addition, the proposed policy was profiled in articles appearing in a variety of journals and magazines, including Science, Nature and Nature Biotechnology.

In response to the May 25 proposal, NIH received 45 letters, each of which contained one or more comments. Comments were received from academic institutions, scientific foundations,

pharmaceutical companies, biotechnology companies (including providers of research instruments, biological reagents and genomic data), an industry trade association, professional societies, individual researchers and other individual commenters. Below is NIH's response to comments offered, organized by the section of the proposed policy to which they pertain.

Introduction

Several commenters suggested that sponsored research administrators be included within the target audience to which this policy is addressed. This suggestion has been adopted in the final policy.

Several commenters suggested that the policy is a de facto regulation and should either be promulgated in accordance with regulatory process or withdrawn. Several other commenters suggested that as a policy the Principles/Guidelines are not enforceable as law and that NIH should issue them as a regulation to ensure compliance. The NIH does not believe that a regulation, enforceable as law, is required at this time to facilitate sharing and access to research tools for its Recipients. Although the final policy is issued as a grants policy, to be incorporated into the NIH Grants Policy Statement, the NIH has not precluded the possibility of engaging in the regulatory process if widespread problems continue in access to NIH-funded research tools by NIH Recipients. In addition, on a case-by-case basis, the expectations set forth in the Principles and Guidelines may be imposed as specific requirements of NIH funding awards where the Recipient has failed to demonstrate sufficient progress in implementing the Principles and Guidelines.

Some commenters suggested that the policy should not be applicable to all projects that include NIH grant funds, but that NIH should set a minimum level of NIH funding that would trigger application of the policy. NIH has determined that the establishment of such a threshold would not be consistent with NIH's objective of ensuring that broad availability of research tools.

One commenter expressed concern that the proposed policy, if applied to recipients of Small Business Innovation Research (SBIR) grants, would place SBIR recipients under conflicting directives. The commenter suggests that because SBIR recipients are required, as a condition of their grant, to focus on the commercialization of technology, they would be unable to disseminate