

Friday, February 18, 2000

Part IV

Department of Health and Human Services

National Institutes of Health

Office of the Director, National Institutes of Health, Notices of Meeting

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, 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.

Name of Committee: Recombinant DNA Advisory Committee.

Date: March 8–10, 2000.

Time: March 8—9:00 am to 5:00 pm; March 9—8:00 am to 5:30 pm; March 10—8:00 am to 5:00 pm.

Agenda: The meeting will be open to the public. The agenda will include a discussion with the Advisory Committee to the Director Working Group on NIH Oversight of Clinical Gene Transfer Research, review of novel human gene transfer protocols, continued deliberation about on issues involving serious adverse event reporting, and a topic raised by a member of the public (separate notice to follow). Additional information is also available at ORDA's web site: http://www.nih.gov/od/oba/.

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

Contact Person: Amy P. Patterson, MD, Acting Executive Secretary, Office of Biotechnology Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, MD 20892– 7010, 301–496–9838.

OMB's "Mandatory Information
Requirements for Federal Assistance Program
Announcements" (45 FR 39592, June 11,
1980) requires a statement concerning the
official government programs contained in
the Catalog of Federal Domestic Assistance.
Normally NIH lists in its announcements the
number and title of affected individual
programs for the guidance of the public.
Because the guidance in this notice covers
virtually every NIH and Federal research
program in which DNA recombinant
molecule techniques could be used, it has

been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: February 11, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–4007 Filed 2–17–00; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Notice

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

ACTION: Notice.

SUMMARY: The purpose of this document is to inform the public of an additional agenda item that will be considered during the upcoming meeting of the Recombinant DNA Advisory Committee (RAC) meeting. The RAC has been asked to consider a proposal from a member of the public that a moratorium be placed on some human somatic gene therapy protocols using viral vectors.

DATES: The RAC will consider this proposal on the afternoon of the first day of the meeting, March 8–10, 2000.

FOR FURTHER INFORMATION CONTACT: If

you have questions, or require additional information about this agenda item, please contact the Office of Biotechnology Activities (OBA) by email at: ci4e@nih.gov, or telephone at: 301–496–9838. For additional information about the March 8–10, 2000, RAC meeting, please visit the NIH/OBA web site at: http://www.nin.gov/od/oba/.

SUPPLEMENTARY INFORMATION: In a letter dated November 22, 1999, Mr. Jeremy Rifkin, Foundation on Economic Trends, requested that the RAC consider the following:

Given the recent death of a patient undergoing somatic gene therapy at the University of Pennsylvania and the disclosure of six other deaths involving patients undergoing gene therapy, the Foundation on Economic Trends is formally requesting that the National Institutes of Health Recombinant DNA Advisory Committee (RCA) vote to impose an immediate moratorium on the consideration of any future human somatic gene therapy protocol that employs retro-, adeno-, or other viral vectors, except where the protocol can legitimately be considered a treatment of last resort for a life threatening illness.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: February 10, 2000.

Amy Patterson,

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

[FR Doc. 00-4008 Filed 2-17-00; 8:45 am]

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