

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Recombinant DNA Activities; Gene Therapy Policy Conference, Notice of Conference

Notice is hereby given of a Gene Therapy Policy Conference entitled: Lentiviral Vectors for Gene Delivery, on March 9, 1998. The conference will be held at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20892, starting on March 9, 1998, at approximately 8:30 a.m., and will recess at approximately 5:00 p.m. The conference will be open to the public and free of charge; however, registration is required. Registration is available online at <http://www.nih.gov/od/orca> or you can contact Ms. Anne Dunne, Strategic Results, 6004 Lakeview Road, Baltimore, Maryland 21210, Phone 410-377-0110, Fax 410-377-6429. Ms. Dunne will provide conference information upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Dunne in advance of the meeting.

On July 8, 1996, the NIH Director published a Notice of Intent to Propose Amendments to the NIH Guidelines for Research Involving Recombinant DNA Molecules Regarding Enhanced Oversight of Recombinant DNA Activities (61 FR 3577). One significant component of the NIH Director's proposal was to establish Gene Therapy Policy Conferences (GTPC). These conferences are intended to offer the unique advantage of assembling numerous participants who possess significant scientific, ethical, and legal expertise and/or interest that is directly applicable to specific recombinant DNA issues. In order to enhance the depth and value of scientific and ethical/social discussion, each GTPC will be devoted to a single issue relevant to scientific merit and/or safety as it relates to research on the use of novel gene delivery vehicles and applications to human gene therapy, novel applications of gene transfer, or relevant ethical/social implications of a particular application of gene transfer technology.

The findings and recommendations of each GTPC will be made available to multiple Department of Health and Human Services (DHHS) components, including the Food and Drug Administration (FDA) and the Office for Protection from Research Risks (OPRR).

The NIH Director anticipates that this expanded public policy forum will serve as a model of interagency communication and collaboration, concentrated expert discussion of novel scientific issues and their potential societal implications, and enhanced opportunity for public discussion of specific issues and the potential impact of such applications on human health and the environment.

On March 9, 1998, the NIH will hold its second GTPC entitled: Lentiviral Vectors for Gene Delivery. Tentative topics for discussion include: (1) Vector design and genetic requirements for lentivirus-based systems; (2) in vivo gene transfer and issues relating to vector distribution and gene expression; (3) packaging cell line strategies; (4) issues related to testing for replication-competent virus; (5) strategies for patient monitoring, e.g., possible seroconversion; (6) potential clinical applications (both in vivo and ex vivo); (7) potential for mobilization (by recombination) with wild-type HIV in infected hosts; and (8) relevant social and ethical issues.

The findings and recommendations of this conference will be submitted in the form of a report to the NIH Director.

Dated: February 2, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on March 10, 1998. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on March 10, 1998, at approximately 9 a.m., and will recess at approximately 5 p.m. The meeting will be open to the public to discuss Proposed Actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496) and other matters to be considered by the Committee. The Proposed Actions to be discussed will follow this notice of meeting. Attendance by the public will be limited to space available.

Debra W. Knorr, Acting Director, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, Phone (301) 496-9838, FAX (301) 496-9839, will provide summaries of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Knorr in advance of the meeting.

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 2, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research: Proposed Actions Under the Guidelines

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

ACTION: Notice of Proposed Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).