DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Notice is hereby given of a Gene Therapy Policy Conference entitled: Human Gene Transfer—Beyond Life-threatening Disease, on September 11, 1997. The conference will be held at the Bethesda Holiday Inn Hotel, 8120 Wisconsin Avenue, Bethesda, Maryland, 20814, starting on September 11, 1997, at approximately 8:00 a.m., and will recess at approximately 5:30 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/orda or you can contact Dr. Elham-Eid Alldredge, REDA International, 11141 Georgia Avenue, Suite 517, Wheaton, Maryland 20902, Phone 301–946–9790, Fax 301–946–1911. Dr. Alldredge 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 Dr. Alldredge 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 of 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.

At its March 6–7, 1997 meeting, the RAC recommended that the first Gene Therapy Policy Conference (GTPC) should be held to discuss the scope of ethical and scientific issues regarding genetic enhancement and the inclusion of normal subjects in human gene transfer protocols.

The first CTPC is scheduled for September 11, 1997. The title of this first GTPC is: Human Gene Transfer—Beyond Life-threatening Disease. The tentative topics for discussion during this conference are: (1) Scientific prospects for enhancement through gene therapy. This topic will cover the following issues: (a) Historical perspective, current state, and theoretical feasibility; (b) prospects for ''preventive'' gene therapies that enhance organ or system function; and (c) assessing the long-term safety and efficacy of enhancement gene therapies. (2) The treatment/enhancement distinction: conceptual, ethical and social issues. This topic will cover the following issues: (a) Ethical and social concerns; and (b) conceptual clarification of treatment/enhancement distinction, and (3) Development of a ''treatment/enhancement'' distinction as part of a guidance document. This topic will cover the following issues: (a) Operational criteria for treatment/enhancement distinction; (b) current regulatory significance of the distinction; and (c) development of a guidance framework/document.

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

Dated: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–22028 Filed 8–19–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on September 12, 1997. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on September 12, 1997, 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 not only virtually every NIH program but also essentially every 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: August 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–22029 Filed 8–19–97; 8:45 am]

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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).

SUMMARY: This notice sets forth proposed actions to be taken under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496, amended 59 FR 40170, 60 FR 20726, 61 FR 1482, 61 FR 10004, 62 FR 4782). Interested parties are invited to submit comments concerning these proposals. These proposals will be considered by the Recombinant DNA Advisory Committee (RAC) at its meeting on September 12, 1997. After consideration of these proposals and comments by the RAC, the NIH Director will issue decisions in accordance with the NIH Guidelines.

DATES: Interested parties are invited to submit comments concerning this proposal. Comments received by September 5, 1997, will be reproduced and distributed to the RAC for consideration at its September 12, 1997, meeting. After consideration of this proposal and comments by the RAC, the NIH Director will issue decisions in accordance with the NIH Guidelines.

ADDRESSES: Written comments and recommendations should be submitted to Debra Knorr, 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.

All comments received in response to this notice will be considered and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the 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. The Office of Recombinant DNA Activities web site is located at Http://www.nih.gov/od/orda for further information about the office.

SUPPLEMENTARY INFORMATION: The NIH will consider the following actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines):

A. Amendment to the Submission Requirements—Human Gene Transfer Experiments Under Appendix M of the NIH Guidelines

During the June 12–13, 1997, RAC meeting, the following motions were approved by the Committee:

(1) A motion was made to eliminate the point-by-point responses to Appendix M–II, Description of the Proposal; however, the questions raised in Appendix M–II must be addressed in the clinical protocol. The motion passed by a vote of 8 in favor, 0 opposed, and 1 abstention.

(2) A motion was made that the RAC should not review any gene transfer protocol until the investigator has provided ORDA with evidence of protocol submission to the Institutional Biosafety Committee (IBC). IBC notification is needed in order to avoid the circumstances in which the RAC might review a protocol that has not been submitted to the IBC. The motion passed by a vote of 8 in favor, 1 opposed, and no abstentions.

(3) A motion was made to delete prior IBC and Institutional Review Board (IRB) approvals, responses to Appendix M–II through M–V, and vector sequence diskettes from Appendix M–I, Submission Requirements—Human Gene Transfer Experiments. The RAC accepted the submission requirements as follows:

''Appendix M–I, Submission Requirements—Human Gene Transfer Experiments''

''Investigators must submit the following material to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, 301–496–9838 (see exemption in Appendix M–IX–A, Footnotes of Appendix M). Proposals will be submitted in the following order: (1) Scientific abstract; (2) non-technical abstract; (3) protocol (including discussion of issues in Appendix M–II through M–V); (4) Informed Consent document prepared for IRB submission (see Appendix M–III, Informed Consent); (5) letter stating that submission has been made to the IBC; (6) appendices (including tables, figures, and manuscripts); and (7) curricula vitae for each key professional person in biographical sketch format.''

The motion passed by a vote of 7 in favor, 0 opposed, and 1 abstention.

B. Amendment to Institutional Biosafety Committee (IBC) Approvals of Experiments Involving Transgenic Rodents Under Section III of the NIH Guidelines

Section III–C–4, Experiments Involving Whole Animals, of the NIH Guidelines stipulates that all transgenic animal experiments are subject to IBC approval before initiation. In correspondence dated April 22, 1997, Dr. George Gutman, an IBC representative of the University of California, Irvine, California, inquired whether experiments involving the production or use of transgenic mice under Biosafety Level 1 containment could be initiated simultaneously with IBC notification. Current requirements under the NIH Guidelines require that IBC approval be obtained prior to initiation of such experiments. The RAC discussed this issue during its June 1997 meeting, recommending that this requirement be changed to initiation simultaneous with IBC notification. The RAC agreed that the requirement of IBC approval prior to initiation is unnecessary and recommended that the NIH Guidelines should be amended such that: (1) The generation of transgenic rodents at the Biosafety Level 1 containment (not all animals) can be initiated simultaneous with IBC notification, and (2) the purchase and use of transgenic rodents should be exempt from the NIH Guidelines.

A motion was made that these proposed changes to the NIH Guidelines should be published in the **Federal Register** for consideration at the September 12, 1997, RAC meeting. The proposed action would allow: (1) The generation of transgenic rodents that require Biosafety Level 1 containment to be included under Section III–D, Experiments that Require IBC Notice Simultaneous with Initiation; and (2) the purchase and use of transgenic rodents should be exempt from the NIH Guidelines. The motion passed by a vote of 9 in favor, 0 opposed, and no abstentions.

C. The Dissociation of Simultaneous Submission of Responses to Appendix M of the NIH Guidelines to NIH/ORDA and the Food and Drug Administration (FDA)

In a letter dated November 20, 1996, Dr. Andra Miller, Food and Drug Administration, requested that the NIH Guidelines should be amended