

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.

[FR Doc. 98-3490 Filed 2-10-98; 8:45 am]

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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.

[FR Doc. 98-3491 Filed 2-10-98; 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 that NIH plans to consider 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, 62 FR 53335, 62 FR 56196, 62 FR 59032). NIH invites all interested parties to submit comments concerning these proposals. The Recombinant DNA Advisory Committee (RAC) will consider these proposals at its meeting on March 10, 1998. After consideration of these proposals and comments by the RAC, the NIH Director will issue decisions according to the NIH Guidelines.

DATES: Comments received by March 2, 1998 will be reproduced and distributed to the RAC for consideration at its March 10, 1998, meeting.

ADDRESSES: Interested parties should submit written comments and recommendations 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 ORDA offices on weekdays between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Interested parties can obtain background documentation and additional information 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/orда> for further information about the office.

I. Proposed Actions Regarding Amendments to the NIH Guidelines

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

I-A. Amendment to Appendix M-I, Submission Requirements—Human Gene Transfer Experiments, Under the NIH Guidelines Regarding Electronic Submission of Protocols

In January 1998, Dr. C. Estuardo Aguilar-Cordova, a member of the RAC, participated in a pilot test with ORDA staff regarding electronic submission to ORDA. In this test, the documents submitted electronically included a human gene transfer protocol; responses to Appendices M-II through M-V,

Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Subjects (Points to Consider); and the ORDA registration document. The 82-page electronic submission, including tables, satisfactorily proved the efficiency and effectiveness of using this method for submission of protocols.

ORDA recognizes that electronic submission of documents is an accepted standard of practice within the scientific community; therefore, this practice is not novel. The practice of using this medium to submit formal protocols to ORDA, however, is novel and therefore requires amendments to the NIH Guidelines. As a result, ORDA proposes to amend Appendix M-I of the NIH Guidelines to provide guidance to investigators regarding optional electronic submission procedures.

Electronic submission of human gene transfer protocols to ORDA offers several distinct advantages over the current practice of submitting protocols by printed matter, including: (1) ORDA can review protocols more expeditiously because they are received immediately; (2) electronic submission allows ORDA to search protocols electronically for keywords or phrases; (3) registration tasks performed at ORDA will be reduced substantially because the investigator has already completed most of the registration document as part of the electronic submission; and (4) ORDA can facilitate RAC review of the protocol by forwarding the complete protocol to RAC members electronically.

Appendix M-I is proposed to read:

“Appendix M-I. Submission Requirements—Human Gene Transfer Experiments

“Investigators must submit the following material (see exemption in Appendix M-VIII-A, Footnotes of Appendix M) to the Office of Recombinant DNA Activities, National Institutes of Health/MS 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, Phone 301-496-9838, FAX 301-496-9839. Investigators may submit this material electronically and can obtain specific instructions from the ORDA home page (<http://www.nih.gov/od/orда>) regarding electronic submission requirements. For all submissions, whether printed or electronic, ORDA will confirm receipt within three working days after receiving the submission. Investigators should contact ORDA if they do not receive this confirmation.

“Proposals in printed form and/or in an electronic version shall be submitted to NIH/ORDA in the following order: (1)

scientific abstract; (2) non-technical abstract; (3) Responses to Appendix M-II through M-V, Description of the Proposal, Informed Consent, Privacy and Confidentiality, and Special Issues (the pertinent responses can be provided in the protocol or as an appendix to the protocol); (4) clinical protocol as approved by the local Institutional Biosafety Committee and Institutional Review Board; (5) Informed Consent document as approved by the Institutional Review Board (see Appendix M-III, Informed Consent); (6) appendices (including tables, figures, and manuscripts); and (7) curricula vitae—no more than 2 pages for each key professional person in biographical sketch format.

“All submissions must include Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) approvals and their deliberations pertaining to your protocol. IBC approval must be obtained from each institution at which recombinant DNA material will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant DNA material into target cells for human application). Because these written IBC and IRB approvals require appropriate signatures, investigators cannot submit them electronically. Investigators should submit these signed approvals either by mail or by facsimile transmission.

“Investigational New Drug (IND) applications shall be submitted to the FDA in the format described in 21 CFR, Chapter I, Subchapter D, Part 312, Subpart B, Section 23, IND Content and Format. Submissions to the FDA should be sent to the Division of Congressional and Public Affairs, Document Control Center, HFM-99, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, Maryland 20852-1448.

Note: NIH/ORDA will accept submission material at any time. However, if a protocol is submitted less than eight weeks before a scheduled RAC meeting and subsequently is recommended for public discussion by the full RAC, the public discussion of that protocol will be deferred until the next scheduled RAC meeting. This eight-week period is needed to ensure adequate time for review by the committee members.

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 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.

Date: January 28, 1998.

Lana R. Skirboll,

*Associate Director for Science Policy,
National Institutes of Health.*

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