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 December 15–16, 1997. 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 December 15, 1997, at approximately 9 a.m., and will recess at approximately 5 p.m. The meeting will reconvene on December 16, 1997, at approximately 9:00 a.m. and will adjourn 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: October 7, 1997.

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).

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 December 15–16, 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 the proposed actions. Comments received by December 8, 1997, will be reproduced and distributed to the RAC for consideration at its December 15–16, 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 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.

I. Supplementary Information

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

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

(1) A motion was made that Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, should be amended to require investigators to submit documentation verifying that a human gene transfer protocol has been submitted to an appropriate Institutional Biosafety Committee (IBC). Evidence of IBC notification shall be provided at the time the protocol is submitted to ORDA. The motion passed by a vote of 8 in favor, 1 opposed, and no abstentions.

(2) A motion was made to delete the requirement for submission of IBC and Institutional Review Board (IRB) approvals at the time of ORDA submission from Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, of the NIH Guidelines. The motion passed by a vote of 7 in favor, 0 opposed, and 1 abstention.

On September 10, 1997, a letter was received from the American Biological Safety Association requesting that the public comment period for the proposed actions under the NIH Guidelines published in the **Federal Register** on August 20, 1997 (62 FR 44387) be extended for an additional 60 days.

During the September 12, 1997, RAC meeting, the RAC was scheduled to vote on the proposed actions to delete prior IBC and IRB approvals from the submission requirements, and to require investigators or sponsors to provide evidence of protocol submission to IBC.

Considering the request by the American Biological Safety Association to extend the public comment period, the RAC decided to modify the language of the proposed actions and to publish the revised version in the **Federal Register** for an additional 60 days.

A motion was made by the RAC to amend the proposed actions published in the **Federal Register** on August 20, 1997, regarding the submission requirements as follows:

''The RAC recommends that final approvals from IBC and IRB should be withheld until after NIH/ORDA provides the IBC and IRB with RAC concerns (if any), and (1) NIH/ORDA notification that the protocol is exempt from full RAC review, or (2) NIH/ORDA notification that the protocol has triggered full RAC review. Human gene transfer protocols shall not be initiated prior to submission of final IBC and IRB approvals to NIH/ORDA.''

The motion passed by a vote of 10 in favor, 0 opposed, and 2 abstentions.

I–B. Amendments 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 a correspondence dated April 22, 1997, Dr. George Gutman, an IBC representative of the University of California, Irvine, California, inquired whether experiments involving production or use of transgenic mice under Biosafty Level 1 containment could be initiated simultaneous 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 for 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 it 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.

On September 10, 1997, a letter was received from the American Biological Safety Association requesting that the public comment period for the proposed actions under the NIH Guidelines published in the **Federal Register** on August 20, 1997 (62 FR 44387) be extended for an additional 60 days.

During the September 12, 1997, RAC meeting, the RAC was scheduled to vote on the issues surrounding the amendments to IBC approvals of experiments involving transgenic rodents. Considering the request by the American Biological Safety Association to extend the public comment period, the RAC decided to modify the language of the proposed actions and to publish the revised version in the **Federal Register** for additional public comment as requested by the American Biological Safety Association. The RAC accepted the proposed actions with the deletion of two words ''and use'' from the language, ''the purchase and use of transgenic rodent * * *'' A motion was made by the RAC to accept the amendments to the NIH Guidelines with regard to: (1) The generation of transgenic rodents at the Biosafety Level 1 containment (not all animals) can be initiated simultaneously with IBC notification, and (2) the purchase of transgenic rodents should be exempt from the NIH Guidelines. The motion passed by a vote of 11 in favor, 0 opposed, and no abstentions.

II. Proposed Actions Regarding Amendments to the NIH Guidelines

The NIH will consider the following proposed actions under the NIH Guidelines:

II–A. Proposed Amendments to Section III–C–4, Experiments Involving Whole Animals

[Section III–C are experiments that require Institutional Biosafety Committee approval before initiation.]

Section III–C–4–c is proposed to be amended to read:

''Section III–C–4–c. Exceptions under Section III–C–4.

''Section III–C–4–c–(1). Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III–D–3, Experiments Involving Transgenic Rodents.

''Section III–C–4–c–(2). The purchase of transgenic rodents is exempt from the NIH Guidelines under Section III–E, Exempt Experiments (see Appendix C–VI, The Purchase of Transgenic Rodents).''

II–B. Proposed Amendments to Section III–D, Experiments That Require Institutional Biosafety Committee Notice Simultaneous With Initiation

Section III–D–3 is proposed to be amended to read:

''Section III–D–3. Experiments Involving Transgenic Rodents

''This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (trangenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under Section III–C–4, Experiments Involving Whole Animals.''

II–C. Proposed Amendments to Appendix C, Exemptions Under Section III–E–6

A new section, Appendix C–VI, is proposed to read:

''Appendix C–VI. The Purchase of Transgenic Rodents

''The purchase of transgenic rodents for experiments that require BL1 containment are exempt from the NIH Guidelines.''

[The old Appendix C–VI, Footnotes and References of Appendix C, will be renumbered to Appendix C–VII through Appendix C–VII–E.]

II–D. Proposed Amendments to Appendix M, The Points To Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules Into the Genome of One or More Human Subjects (Points To Consider)

Appendix M–I is proposed to be amended to read:

''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) Responses to Appendix M–II through Appendix M–V, Description of the Proposal, Informed Consent, Privacy and Confidentiality, and Special Issues (the pertinent responses can be provided in the clinical protocol or as an appendix to the clinical protocol); (4) clinical protocol (as submitted to the local IBC and IRB); (5) Informed Consent document prepared for IRB submission (see Appendix M–III, Informed Consent); (6) a letter stating that submission has been made to the IBC; (7) appendices (including tables, figures, and manuscripts); and (8) curricula vitae for each key professional person in biographical sketch format.

Note: The final approvals from IBC and IRB should be withheld until after NIH/ORDA provides IBC and IRB with RAC concerns (if any), and (1) NIH/ORDA notification that the protocol is exempt from full RAC review, or (2) NIH/ORDA notification that the protocol has triggered full RAC review. Human gene transfer protocols shall not be initiated prior to submission of final IBC and IRB approvals to NIH/ORDA.

III. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Crystal

In a letter dated August 25, 1997, Dr. Ronald Crystal of New York Hospital-Cornell Medical Center, New York, New York, submitted a human gene transfer protocol entitled: Systemic and Respiratory Immune Response to Administration of an Adenovirus Type 5 Gene Transfer Vector ($Ad_{GV}CD.10$) (NIH Protocol 9708–209) to NIH/ORDA in accordance with Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, of the NIH Guidelines. Dr. Crystal requested permission to present a brief overview of relevant data during the September 12, 1997, RAC meeting, prior to the RAC's final recommendation on the necessity for full RAC review. The RAC agreed to allow Dr. Crystal to give a brief presentation on the relevant data. Following the September 12, 1997, RAC meeting, the RAC noted that there were a significant number of issues remaining; therefore, the protocol should be discussed by the full RAC at its next scheduled meeting.

IV. Discussion on Novel Gene Transfer Technologies

The RAC will have a discussion on novel gene transfer technologies. Presentations may include herpesvirus vectors and human artificial chromosomes.

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 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 to be not 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: October 8, 1997.

Lana R. Skirboll,

Associate Director for Science Policy, National Institutes of Health.

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