

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 (59 FR 34496, amended 59 FR 40170, amended 60 FR 20726).

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, amended 60 FR 20726). Interested parties are invited to submit comments concerning these proposals. These proposals will be considered by the Recombinant DNA Advisory Committee at its meeting on September 11–12, 1995. After consideration of these proposals and comments by the Recombinant DNA Advisory Committee, the Director of the National Institutes of Health will issue decisions in accordance with the NIH Guidelines.

DATES: Comments received by September 4, 1995, will be reproduced and distributed to the Recombinant DNA Advisory Committee for consideration at its September 11–12, 1995, meeting.

ADDRESSES: Written comments and recommendations should be submitted to Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, or sent by FAX to 301–496–9839.

All comments received in timely 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 to 301–496–9839.

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

I. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Steiner and Holt

On April 13, 1995, Drs. Mitchell Steiner and Jeffrey Holt of Vanderbilt University School of Medicine, Nashville, Tennessee, submitted a human gene transfer protocol entitled: Gene Therapy for the Treatment of Advanced Prostate Cancer by In Vivo Transduction with Prostate-Targeted Retroviral Vectors Expressing Antisense c-myc RNA to the Recombinant DNA Advisory Committee for formal review and approval during the June 8–9, 1995, meeting. Due to reviewers' comments before the June 1995 meeting, the protocol was deferred and not forwarded to the committee.

On July 7, 1995, Drs. Steiner and Holt submitted a revised protocol to the Recombinant DNA Advisory Committee for formal review and approval during the September 11–12, 1995, meeting.

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

In a letter dated July 17, 1995, Dr. Ronald Crystal of the New York Hospital—Cornell Medical Center, New York, New York, submitted a human gene transfer protocol entitled: A Phase I Study of Direct Administration of a Replication Deficient Adenovirus Vector Containing the E. coli Cytosine Deaminase Gene to Metastatic Colon Carcinoma of the Liver in Association with the Oral Administration of the Pro-Drug 5-Fluorocytosine to the Recombinant DNA Advisory Committee for formal review and approval.

III. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Hortobagyi, Lopez-Berestein, Hung

In a letter dated July 11, 1995, Drs. Gabriel Hortobagyi, Gabriel Lopez-Berestein, and Mien-Chie Hung of the University of Texas, MD Anderson Cancer Center, Houston, Texas, submitted a human gene transfer protocol entitled: Phase I Study of E1A Gene Therapy for Patients with Metastatic Breast or Ovarian Cancer that Overexpress HER-2/neu to the Recombinant DNA Advisory Committee for formal review and approval.

IV. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Curiel and Alvarez

In a letter dated January 5, 1995, Drs. David Curiel and Ronald Alvarez of the University of Alabama, Birmingham, Alabama, submitted a human gene transfer protocol entitled: A Phase I

Study of Recombinant Adenovirus Vector-Mediated Delivery of an Anti-erbB-2 Single-Chain (sFv) Antibody Gene for Previously Treated Ovarian and Extraovarian Cancer Patients to the Recombinant DNA Advisory Committee for formal review and approval at its March 6–7, 1995, meeting. Due to reviewers' comments before the March 1995 meeting, the protocol was not forwarded to the committee.

In a letter dated April 12, 1995, Drs. Curiel and Alvarez submitted a revised protocol to the Recombinant DNA Advisory Committee for formal review and approval at its June 8–9, 1995, meeting. Due to reviewers' comments before the June 1995 meeting, the protocol was deferred and not forwarded to the committee.

On July 14, 1995, Drs. Curiel and Alvarez submitted a revised protocol to the Recombinant DNA Advisory Committee for formal review and approval during the September 11–12, 1995, meeting.

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

In a letter dated July 14, 1995, Dr. Jeffrey Isner of St. Elizabeth's Medical Center, Tufts University School of Medicine, Boston, Massachusetts, submitted a human gene transfer protocol entitled: Arterial Gene Transfer for Restenosis to the Recombinant DNA Advisory Committee for formal review and approval.

VI. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Bozik, Gilbert, Lotze

In a letter dated July 13, 1995, Drs. Michael Bozik, Mark Gilbert, and Michael Lotze of the University of Pittsburgh Cancer Institute, Pittsburgh, Pennsylvania, submitted a human gene transfer protocol entitled: Gene Therapy of Malignant Gliomas: A Phase I Study of IL-4 Gene-Modified Autologous Tumor to Elicit an Immune Response to the Recombinant DNA Advisory Committee for formal review and approval.

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

In a letter dated July 11, 1995, Dr. Stanley Riddell of the Fred Hutchinson Cancer Research Center, Seattle, Washington, submitted a human gene transfer protocol entitled: Phase I Study to Evaluate the Safety of Cellular Adoptive Immunotherapy using Autologous Unmodified and Genetically Modified CD8+ HIV-Specific T Cells in

HIV Seropositive Individuals to the Recombinant DNA Advisory Committee for formal review and approval.

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

In a letter dated July 13, 1995, Dr. Joseph Rosenblatt of the University of California, Los Angeles, California, submitted a human gene transfer protocol entitled: A Phase I Trial of Autologous CD34+ Hematopoietic Progenitor Cells Transduced with an Anti-HIV-1 Ribozyme to the Recombinant DNA Advisory Committee for formal review and approval.

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.

Effective Date: July 31, 1995.

Suzanne Medgyesi-Mitschang,

Acting Deputy Director for Science Policy and Technology Transfer.

[FR Doc. 95-19872 Filed 8-9-95; 8:45 am]

BILLING CODE 4140-01-P