

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).

SUMMARY: This notice sets forth proposed actions to be taken under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496). 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 March 6-7, 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 February 27, 1995, will be reproduced and distributed to the Recombinant DNA Advisory Committee for consideration at its March 6-7, 1995, meeting.

ADDRESSES: Written comments and recommendations should be submitted to Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892-7052, 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, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892-7052, 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. Curiel and Alvarez

In a letter dated January 5, 1995, Drs. David T. Curiel and Ronald D. 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.

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

In a letter dated January 6, 1995, Dr. Harry L. Malech of the National Institutes of Health, Bethesda, Maryland, submitted a human gene transfer protocol entitled: Gene Therapy Approach for Chronic Granulomatous Disease 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. Black and Fakhrai

In a letter dated January 6, 1995, Drs. Keith L. Black and Habib Fakhrai of the University of California, Los Angeles, California, submitted a human gene transfer protocol entitled: Immunization of Glioblastoma Patients with TGF- β 2 Antisense and Interleukin-2 (IL-2) Gene Modified Autologous Tumor Cells: A Phase I Study 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/Dr. Gansbacher

In a letter dated January 6, 1995, Dr. Bernd Gansbacher of the Memorial Sloan-Kettering Cancer Center, New York, New York, submitted a human gene transfer protocol entitled: Phase I/II Study of Immunization with MHC Class I Matched Allogeneic Human Prostatic Carcinoma Cells Engineered to Secrete Interleukin-2 and Interferon- γ to the Recombinant DNA Advisory Committee for formal review and approval.

V. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Link and Moorman

In a letter dated January 6, 1995, Drs. Charles J. Link and Donald Moorman of the Human Gene Therapy Research Institute, Des Moines, Iowa, submitted a human gene transfer protocol entitled: A Phase I Trial of In Vivo Gene Therapy with the Herpes Simplex Thymidine Kinase/Ganciclovir System for the Treatment of Refractory or Recurrent

Ovarian Cancer 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. Morgan and Walker

In a letter dated January 9, 1995, Drs. Richard Morgan and Robert Walker of the National Institutes of Health, Bethesda, Maryland, submitted a human gene transfer protocol entitled: Gene Therapy for AIDS Using Retroviral Mediated Gene Transfer to Deliver HIV-1 Antisense TAR and Transdominant Rev Protein Genes to Syngeneic Lymphocytes in HIV Infected Identical Twins 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/Drs. Economou, Glaspy, and McBride

In a letter dated April 11, 1994, Drs. James Economou, John Glaspy, and William McBride of the University of California, Los Angeles, California, submitted a human gene transfer protocol entitled: A Phase I Testing of Genetically Engineered Interleukin-7 Melanoma Vaccines to the Recombinant DNA Advisory Committee for formal review and approval. At its June 9-10, 1994, meeting, the Recombinant DNA Advisory Committee deferred the protocol based on insufficient toxicology studies and failure to demonstrate biological efficacy. The Recombinant DNA Committee required a new submission for future review of the full Recombinant DNA Advisory Committee, not just the toxicology data.

In a letter dated January 17, 1995, Drs. James S. Economou, John A. Glaspy, and William H. McBride submitted a revised protocol to the Recombinant DNA Advisory Committee for formal review and approval at its March 6-7, 1995, meeting.

VIII. Proposed Amendments to Appendix B of the NIH Guidelines Regarding Updating the Classification of Microorganisms/Fleming

In a letter dated June 24, 1993, Dr. Diane Fleming, President of the Mid-Atlantic Biological Safety Association requested updating Appendix B, Classification of Microorganisms on the Basis of Hazard. The Mid-Atlantic Biological Safety Association submitted an updated list of the classification of microorganisms for the Committee to review which included the latest taxonomy and agent risk group classifications as defined by the Centers