

Informed Consent Document. On September 17, 1994, Dr. Nelson Wivel, Office of Recombinant DNA Activities, National Institutes of Health, informed Dr. Curiel that Dr. Harold Varmus, Director, National Institutes of Health, concluded that the protocol should be reviewed again by the committee when additional preclinical data are available.

In a letter dated April 12, 1995, Dr. David T. Curiel of the University of Alabama, Birmingham, Alabama, submitted a revised protocol to the Recombinant DNA Advisory Committee for formal review and approval at its June 8-9, 1995, meeting.

III. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Paulson and Lyerly

In a letter dated March 31, 1995, Drs. David F. Paulson and H. Kim Lyerly of Duke University Medical Center, Durham, North Carolina, submitted a human gene transfer protocol entitled: A Phase I Study of Autologous Human Interleukin-2 Gene Modified Tumor Cells in Patients with Locally Advanced or Metastatic Prostate Cancer 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. Berchuck and Lyerly

In a letter dated April 10, 1995, Drs. Andres Berchuck and H. Kim Lyerly of Duke University Medical Center, Durham, North Carolina, submitted a human gene transfer protocol entitled: A Phase I Study of Autologous Human Interleukin 2 (IL-2) Gene Modified Tumor Cells in Patients with Refractory Metastatic Ovarian Cancer 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. Steiner and Holt

On April 13, 1995, Drs. Mitchell S. Steiner and Jeffrey T. 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 Vectors Expressing Antisense c-myc RNA 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/Dr. McIvor

In a letter dated April 12, 1995, Dr. R. Scott McIvor of the Institute of Human Genetics, University of Minnesota, Minneapolis, Minnesota, submitted a human gene transfer protocol entitled: Gene Therapy for Purine Nucleoside Phosphorylase Deficiency 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. Scardino, Thompson, Woo

In a letter dated April 11, 1995, Drs. Peter T. Scardino, Timothy C. Thompson, and Savio L.C. Woo of Baylor College of Medicine, Houston, Texas, submitted a human gene transfer protocol entitled: Phase I Study of Adenoviral Vector Delivery of the HSV-tk Gene and the Intravenous Administration of Ganciclovir in Men with Local Recurrence of Prostate Cancer After Radiation Therapy 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. Whitley

In a letter dated April 12, 1995, Dr. Chester B. Whitley of the Institute of Human Genetics, University of Minnesota, Minneapolis, Minnesota, submitted a human gene transfer protocol entitled: Gene Therapy for Scheie Keratopathy to the Recombinant DNA Advisory Committee for formal review and approval.

IX. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Munshi and Barlogie

In a letter dated April 13, 1995, Drs. Nikhil C. Munshi and Bart Barlogie of the University of Arkansas, Little Rock, Arkansas, submitted a human gene transfer protocol entitled: Thymidine Kinase (TK) Transduced Donor Leukocyte Infusions as a Treatment for Patients with Relapsed or Persistent Multiple Myeloma after T-cell Depleted Allogeneic Bone Marrow Transplant to the Recombinant DNA Advisory Committee for formal review and approval.

X. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Fox and Urba

In a letter dated April 12, 1995, Drs. Bernard A. Fox and Walter J. Urba of Chiles Research Institute, Providence Portland Medical Center, Portland,

Oregon, submitted a human gene transfer protocol entitled: Adoptive Cellular Therapy of Cancer Combining Direct HLA-B7/β2-Microglobulin Gene Transfer with Autologous Tumor Vaccination for the Generation of Vaccine-Primed Anti-CD3 Activated Lymphocytes to the Recombinant DNA Advisory Committee for formal review and approval.

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

In a letter dated April 12, 1995, Dr. Patrick Hwu of the National Institutes of Health, Bethesda, Maryland, submitted a human gene transfer protocol entitled: Treatment of Patients with Advanced Epithelial Ovarian Cancer using Anti-CD3 stimulated Peripheral Blood Lymphocytes Transduced with a Gene Encoding a Chimeric T-cell Receptor Reactive with Folate Binding Protein to the Recombinant DNA Advisory Committee for formal review and approval.

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

In a letter dated April 12, 1995, Dr. Wayne A. Marasco of the Dana-Farber Cancer Institute, Boston, Massachusetts, submitted a human gene transfer protocol entitled: Intracellular Antibodies Against HIV-1 Envelope Protein for AIDS Gene Therapy to the Recombinant DNA Advisory Committee for formal review and approval.

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

In a letter dated April 12, 1995, Dr. Catherine Verfaillie of the University of Minnesota, Minneapolis, Minnesota, submitted a human gene transfer protocol entitled: Autologous Marrow Transplantation for Chronic Myelogenous Leukemia Using Stem Cells Obtained After In Vivo Chemotherapy Cytokine Priming to the Recombinant DNA Advisory Committee for formal review and approval.

XIV. 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