



Thursday
May 22, 1997

Part III

**Department of
Health and Human
Services**

National Institutes of Health

Recombinant DNA Advisory Committee
Meeting; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Recombinant DNA Advisory Committee Meeting**

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on June 12-13, 1997. The meeting will be held at the National Institutes of Health (NIH), Building 31C, 6th Floor, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on June 12, 1997, at approximately 9 a.m., and will recess at approximately 5 p.m. The meeting will reconvene on June 13, 1997, at approximately 9:00 a.m. and will adjourn at approximately 5 p.m. The meeting will be open to the public. Agenda items will include: (1) General discussion regarding a Human Gene Transfer Protocol #9703-179 entitled: A Phase I Study of Active Immunotherapy with Carcinoembryonic Antigen RNA-Pulsed Autologous a Human Cultured Dendritic Cells in Patients with Metastatic Malignancies Expressing Carcinoembryonic Antigen, Principal Investigator H. Kim Lyerly, M.D., Duke University, Durham, North Carolina (Note: NIH Office of Recombinant DNA Activities has determined that Recombinant DNA Advisory Committee review of the protocol is not necessary, the protocol will be reviewed for approval only by the Food and Drug Administration); (2) Discussion

regarding Genetic Vaccines Against Cancer-Related Antigens and Oncogene Proteins; (3) Discussion regarding Criteria for RAC Review of Novel Human Gene Transfer Protocols; (4) Discussion regarding Streamlined National Institutes of Health and Food and Drug Administration Submission Format and Revisions 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)*; (5) Discussion regarding Human Gene Transfer Protocols that are Exempt from NIH Registration (Footnote M-VI, *Points to Consider*); (6) Presentation Regarding Definition of Standards for Viral Vector Quantification by Estuardo Aguilar-Cordova, Ph.D., Texas Childrens Hospital, Houston, Texas; and (7) other matters to be considered by the Committee. 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: May 14, 1997.

LaVeen Ponds,

Acting Committee Management Officer, NIH.
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