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 4–5, 1995. 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 4, 1995, at approximately 9 a.m., and will recess at approximately 5 p.m. The meeting will reconvene on December 5, 1995, at approximately 8:30 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. Members of the public wishing to speak at this meeting may be given such opportunity at the discretion of the Chair.

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, Phone (301) 496–9838, FAX (301) 496–9839, will provide materials to be discussed at this meeting, roster of committee members, and substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable recommendations, should contact Dr. Wivel in advance of the meeting. A summary of the meeting will be available at a later date.

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: November 9, 1995.

Susan K. Feldman,

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 (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. The proposals will be considered by the Recombinant DNA Advisory Committee at its meeting on December 4–5, 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 November 27, 1995, will be reproduced and distributed to the Recombinant DNA Advisory Committee for consideration at its December 4–5, 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. 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: A Study of the Safety of Injecting Cancer Patients with Genetically Modified Tumor Cells; Injection of Glioblastoma Patients with Irradiated Autologous Glioma Tumor Cells Genetically Modified to Express a TGF–β2 Antisense mRNA Alone or in Combination with Increasing Doses of Tumor Cells Which Have Been Genetically Modified to Secrete Interleukin-2 (IL–2): A Phase I Study to the Recombinant DNA Advisory Committee for formal review and approval during the March 6–7, 1995, meeting.

During the March 6–7, 1995, Recombinant DNA Advisory Committee meeting, a motion was made and seconded to defer the protocol submitted by Drs. Black and Fakhrai based on the lack of sufficient preclinical data. The investigators and the primary reviewers were to agree on a mutually acceptable experimental design to address the scientific questions posed by the Recombinant DNA Advisory Committee members. Once these studies have been conducted, the investigators are required to submit this data to the full Recombinant DNA Advisory Committee for review and approval. The protocol was deferred by a vote of 16 in favor, 0 opposed, and no abstentions.

On August 9, 1995, Dr. Fakhrai submitted an experimental design that was reviewed by a Recombinant DNA Advisory Committee primary reviewer.