



RECOMBINANT DNA ADVISORY COMMITTEE

Minutes of Meeting

March 16, 2005

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

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[Note: The latest Human Gene Transfer Protocol List can be found at the Office of Biotechnology Activities' Web site at <www4.od.nih.gov/oba/rac/protocol.pdf>.]

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
RECOMBINANT DNA ADVISORY COMMITTEE
MINUTES OF MEETING¹**

March 16, 2005

The Recombinant DNA Advisory Committee (RAC) was convened for its 99th meeting at 8:00 a.m. on March 16, 2005, at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD. Dr. Diane Wara (Chair) presided. In accordance with Public Law 92-463, the meeting was open to the public from 8:00 a.m. until 5:30 p.m. on March 16. The following individuals were present for all or part of the meeting.

Committee Members

Steven M. Albelda, University of Pennsylvania Medical Center
W. Emmett Barkley, Howard Hughes Medical Institute
Martha C. Bohn, Northwestern University
Neal A. DeLuca, University of Pittsburgh
Stephen Dewhurst, University of Rochester Medical Center
Thomas D. Gelehrter, University of Michigan Medical School
Philip R. Johnson, Jr., The Children's Hospital of Philadelphia
Terry Kwan, TK Associates
Bernard Lo, University of California, San Francisco
Nicholas Muzyczka, University of Florida
Glen R. Nemerow, The Scripps Research Institute
Madison Powers, Georgetown University
Naomi Rosenberg, Tufts University
Robert D. Simari, Mayo Clinic and Foundation
Richard G. Vile, Mayo Clinic College of Medicine
Diane W. Wara, University of California, San Francisco

Office of Biotechnology Activities (OBA) Director/RAC Executive Secretary

Amy P. Patterson, Office of the Director, National Institutes of Health (NIH)

Ad Hoc Reviewers/Speakers

Raymond T. Bartus, Ceregene, Inc.
Elaine S. Collier, National Center for Research Resources (NCRR), NIH
Ronald G. Crystal, New York Presbyterian Hospital/Cornell University
Howard J. Federoff, University of Rochester (*via teleconference*)
Theodore Friedmann, University of California, San Diego
Diane E. Griffin, Johns Hopkins University (*via teleconference*)
Richard A. Knazek, NCRR
Stephen J. Russell, Mayo Clinic
Mark H. Tuszyński, University of California, San Diego
Elias A. Zerhouni, NIH

¹ The Recombinant DNA Advisory Committee is advisory to the National Institutes of Health (NIH), and its recommendations should not be considered as final or accepted. The Office of Biotechnology Activities should be consulted for NIH policy on specific issues.

Nonvoting Agency Representatives

Kristina C. Borrer, Office for Human Research Protections, U.S. Department of Health and Human Services (DHHS)
Stephanie L. Simek, U.S. Food and Drug Administration (FDA), DHHS

NIH Staff Members

Rosemarie Aurigemma, National Cancer Institute (NCI)
Robert Baughman, National Institute of Neurological Diseases and Stroke (NINDS)
Sandra H. Bridges, National Institute of Allergy and Infectious Diseases
Liza Dawson, John E. Fogarty International Center
Kelly Fennington, OD
Linda Gargiulo, OD
Dennis Hickstein, NCI
Tom Holohan, OD
Robert Jambou, OD
Laurie Lewallen, OD
Catherine McKeon, National Institute of Diabetes and Digestive and Kidney Diseases
R. Rita Misra, NCI
Karen Musynski, NCI
Marina O'Reilly, OD
Eugene Rosenthal, OD
Sonia Skarlatos, NHLBI
Karen Schweikart, NCI
Thomas Shih, OD
Danilo Tagle, NINDS
Anthony Welch, NCI
Gisele White, OD
Bradley C. Wise, National Institute on Aging

Others

There were 92 attendees at this 1-day RAC meeting. Attachment I contains a list of RAC members, *ad hoc* reviewers and speakers, and nonvoting agency and liaison representatives. Attachment II contains a list of public attendees.

I. Call to Order and Opening Remarks/Dr. Wara

Dr. Wara, RAC Chair, called the meeting to order at 8:00 a.m. on March 16, 2005. Notice of this meeting under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* was published in the *Federal Register* on February 8, 2005 (70 FR 6720). Issues discussed by the RAC at this meeting included public discussions of three protocols, a data management report, updates of three protocols reviewed by the RAC in prior years, and a presentation on General Clinical Research Center (GCRC) resources for long-term follow-up. In addition, Dr. Elias Zerhouni, M.D., Director of NIH, presented the RAC with the Scientific Freedom and Responsibility Award from the American Association for the Advancement of Science.

Dr. Patterson reminded RAC members of the rules of conduct that apply to them as Special Government Employees.

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