

NATIONAL INSTITUTES OF HEALTH  
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)

98<sup>th</sup> Meeting

Bethesda Marriott Hotel  
Bethesda, Maryland

December 16, 2004  
Meeting Agenda

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*Thursday, December 16, 2004*

8:30 AM     **Call to Order and Opening Remarks**

Diane Wara, M.D., Chair, NIH RAC

Tab 2357     For Your Information  
                  Notice of Meeting  
                  Conflict of Interest Guidance  
                  National Gene Vector Laboratories Notice of New Services

8:40 AM     **Minutes of the September 23, 2004, RAC Meeting**

RAC Reviewers:     Martha Bohn, Ph.D.  
                          Stephen Dewhurst, Ph.D.

Tab 2358     Minutes of the September 23, 2004, Meeting

8:50 AM     **Discussion of Human Gene Transfer Protocol #0410-679:**  
*Phase I Clinical Trial of rAAV2.5-CMV-Minidystrophin Gene Vector in  
Duchenne Muscular Dystrophy*

PI:     Jerry Mendell, M.D.  
          Columbus Children's Research Institute, Columbus, OH

RAC Reviewers:     Thomas Gelehrter, M.D.  
                          Bernard Lo, M.D.  
                          Glen Nemerow, Ph.D.

*Ad Hoc* Reviewer:     Jeffrey Chamberlain, Ph.D.  
                          University of Washington, Seattle, WA

Tab 2359     Protocol

Tab 2360     OBA Summary  
                  OBA Letter to PI on In-Depth RAC Review and  
                  Public Discussion  
                  Outcome of Initial Review by RAC Members  
                  Reviews from Drs. Gelehrter, Lo, Nemerow, and Chamberlain  
                  PI's/Sponsor's Response

**Thursday, December 16, 2004 (continued)**

10:30 AM     **BREAK**

10:45 AM     **Data Management Report**

Tab 2361     Protocol List  
                  Protocols Not Selected for RAC Public Review

RAC Reviewers:     Steven Albelda, M.D.  
                          Helen Heslop, M.D.  
                          Robert Simari, M.D.  
                          Diane Wara, M.D.

11:45 AM     **LUNCH**

1:30 PM     **Followup on Safety Symposium: Safety Considerations in Recombinant DNA Research with Pathogenic Viruses—Development of a Web-Based Resource**

Marina O'Reilly, Ph.D., Office of Biotechnology Activities  
Neal DeLuca, Ph.D., RAC  
Kathryn Holmes, Ph.D., University of Colorado, Denver, CO (*via teleconference*)

2:00 PM     **The Immune Response to Lymphopenia**

Speaker:         Crystal MacKall, M.D., National Cancer Institute, Bethesda, MD

2:30 PM     **Discussion of Human Gene Transfer Protocol #0410-675:**

*Development of Effective Immunotherapy for Prostate Cancer Patients: Phase I/II Study of Human GM-CSF Gene-Transduced Irradiated Prostate Allogeneic Cancer Cell Vaccines (Allogeneic Prostate GVAX<sup>®</sup>) in Advanced Prostate Cancer Patients Made Lymphopenic by Chemotherapy and Infused with Autologous Peripheral Blood Mononuclear Cells*

PIs:     Walter Urba, M.D., Ph.D.  
          Earle A. Chiles Research Institute, Portland, OR

          Bernard Fox, Ph.D.  
          Earle A. Chiles Research Institute, Portland, OR

RAC Reviewers:     Helen Heslop, M.D.  
                          Nicholas Muzyczka, Ph.D.  
                          Madison Powers, J.D., D.Phil.

**Thursday, December 16, 2004 (continued)**

*Ad Hoc* Reviewer: Jonathan Simons, M.D.  
Emory University, Atlanta, GA (*written response*)

Tab 2362 Protocol

Tab 2363 OBA Summary  
OBA Letter to PIs on In-Depth RAC Review and  
Public Discussion  
Outcome of Initial Review by RAC Members  
Reviews from Drs. Heslop, Muzyczka, Powers, and Simons  
PIs'/Sponsor's Response

4:00 PM **Public Comment**

4:15 PM **ADJOURNMENT**