

NATIONAL INSTITUTES OF HEALTH
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)

97th Meeting

Bethesda Marriott Hotel
Bethesda, Maryland

September 23, 2004
Meeting Agenda

Thursday, September 23, 2004

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

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

Tab 2352 For Your Information
Notice of Meeting
Conflict of Interest Guidance

8:35 AM **Introduction of New RAC Members**

8:50 AM **Minutes of the June 8-9, 2004, RAC Meeting**

RAC Reviewers: Helen Heslop, M.D.
Robert Simari, M.D.

Tab 2353 Minutes of the June 8-9, 2004, Meeting

9:00 AM **Update on the RAC Gene Transfer Clinical Trial Design Working Group**

Presenters: David DeMets, Ph.D.
NIH RAC

Terry Kwan, M.S.Ed.
NIH RAC

Tiffany Scharschmidt
University of California, San Francisco

10:00 AM **Data Management Report**

Tab 2354 Protocol List
Protocols Not Selected for RAC Public Review

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

Thursday, September 23, 2004 (continued)

10:15 AM **Discussion of Human Gene Transfer Protocol #0407-669:**
Hippocampal NPY Gene Transfer in Subjects with Intractable Mesial Temporal Lobe Epilepsy

PIs: Matthew During, M.D., D.Sc.
 Cornell University, New York, NY

 Itzhak Fried, M.D., Ph.D.
 University of California, Los Angeles (UCLA)

 John Stern, M.D.
 UCLA

RAC Reviewers: Martha Bohn, Ph.D.
 Stephen Dewhurst, Ph.D.
 Philip Johnson, M.D.
 Madison Powers, J.D., D.Phil.

Ad Hoc Reviewer: Marc A. Dichter, M.D., Ph.D.
 University of Pennsylvania, Philadelphia, PA
 (*via teleconference*)

Tab 2355 Protocol

Tab 2356 OBA Summary
 OBA Letter to PI on In-Depth RAC Review and
 Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews from Drs. Bohn, Dewhurst, Johnson, Powers, and Dichter
 PIs'/Sponsor's Response

12:00 NOON **Public Comment**

12:15 PM **Synopsis of RAC Discussion and RAC Recommendations**

12:45 PM **ADJOURNMENT**