

**NATIONAL INSTITUTES OF HEALTH
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)**

**DoubleTree Hotel & Executive Meeting Center
Rockville, Maryland**

June 20-21, 2002

MEETING AGENDA*

Thursday, June 20, 2002

8:00 AM Call to Order and Opening Remarks
Theodore Friedmann, M.D., RAC Chair

Tab 2251 For Your Information
- Notice of Meeting
- Conflict of Interest Statement

8:10 AM Minutes of the March 7-8, 2002, RAC Meeting

RAC Reviewers: Sue Levi-Pearl, RAC Member
Linda Gooding, Ph.D., RAC Member

Tab 2252 Minutes of the March 7-8, 2002, Meeting

**8:15 AM Discussion of Human Gene Transfer Protocol #0201-523 entitled:
Phase I Trial of Intraperitoneal Administration of an Attenuated Strain
(Edmonston strain) of Measles Virus, Genetically Engineered to Produce
Carcinoembryonic Antigen, in Patients With Recurrent Ovarian Cancer**

PIs: Evanthia Galanis, M.D., Mayo Clinic
Jeff Sloan, Ph.D., Mayo Clinic (via teleconference)

RAC Reviewers: Philip Johnson, M.D.
Linda Gooding, Ph.D.
Baruch Brody, Ph.D. (written review)
Neal DeLuca, Ph.D.

Ad Hoc Reviewer: Diane Griffin, Ph.D., M.D., Johns Hopkins University

Tab 2253 Protocol

Tab 2254 OBA Summary
OBA Letter to PIs on Indepth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews From P. Johnson, Gooding, Brody, DeLuca, and Griffin
Sponsor's Response

Thursday June 20, 2002 (continued)

10:15 AM **BREAK**

10:30 AM **Discussion of Human Gene Transfer Protocol #0201-521 entitled:**
Inducible Nitric Oxide Synthase Gene Therapy for the Prevention of Intimal
Hyperplasia in Arteriovenous Grafts Used for Hemodialysis Access

PI: Edith Tzeng, M.D., University of Pittsburgh Medical Center

RAC Reviewers: Robert Simari, M.D.
 Nancy King, J.D.
 Theodore Friedmann, M.D.

Ad Hoc Reviewer: Michael Mann, M.D., University of California,
 San Francisco

Tab 2255 Protocol

Tab 2256 OBA Summary
 OBA Letter to PI on Indepth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews From Simari, King, Friedmann, and Mann
 Sponsor's Response

12:00 NOON **LUNCH**

1:15 PM **Discussion of Human Gene Transfer Protocol #0201-528 entitled:**
Pilot Study of the Use of the Human hSlo/maxi-K Gene to Treat Erectile
Dysfunction

PI: Arnold Melman, M.D., Albert Einstein College of Medicine

RAC Reviewers: Kwaku Ohene-Frempong, M.D.
 James Childress, Ph.D.
 Thomas Gelehrter, M.D.

Ad Hoc Reviewers: Ira Fox, M.D., University of Nebraska Medical Center
 John Mulcahy, M.D., Indiana University School of
 Medicine (via teleconference)
 Mark Nelson, Ph.D., University of Vermont

Tab 2257 Protocol

Thursday, June 20, 2002 (continued)

Tab 2258

OBA Summary
OBA Letter to PI on Indepth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews From Ohene-Frempong, Childress, Gelehrter, Fox,
Mulcahy, and Nelson

Sponsor's Response

3:15 PM **BREAK**

3:30 PM **Discussion of Human Gene Transfer Protocol #0201-529 entitled: Gene Transfer for Intractable Pain: A Phase I Clinical Trial to Determine the Maximum Tolerable Dose of a Replication-Defective HSV Vector Expressing Human Proenkephalin**

PIs: David Fink, M.D., University of Pittsburgh School of Medicine
 Joseph Glorioso, Ph.D., University of Pittsburgh School of Medicine

RAC Reviewers: Xandra Breakefield, Ph.D.
 Sue Levi-Pearl
 Diane Wara, M.D.

Ad Hoc Reviewers: Bernard Lo, M.D., University of California, San Francisco
 (via teleconference)
 Howard Federoff, M.D., Ph.D., University of Rochester
 (written reponse)

Tab 2259 Protocol

Tab 2260 OBA Summary
OBA Letter to PIs on Indepth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews From Breakefield, Levi-Pearl, Wara, Lo, and Federoff
Sponsor's Response

5:00 PM **ADJOURNMENT**

Friday, June 21, 2002

8:15 AM **Presentation of RAC Member Certificates and Induction of New RAC Members**

Elias Zerhouni, M.D., Director, NIH
Amy Patterson, M.D., OBA Director

8:35 AM **Call to Order**
Theodore Friedmann, M.D., RAC Chair

8:40 AM **Informed Consent Working Group Report**
Nancy King, J.D.

9:25 AM **Discussion of Human Gene Transfer Protocol #0112-533 entitled:
Phase I Trial of *in situ* Gene Therapy for Locally Recurrent Prostate Cancer
Following Radiation Therapy Failure Using Sodium/Iodide Symporter and
Radioiodine**

PI: John Morris, M.D., Mayo Clinic

RAC Reviewers: Larry Johnson, M.D.
James Childress, Ph.D.
Theodore Friedmann, M.D.

Ad Hoc Reviewers: Terry Kwan
Paul Ladenson, M.D., Johns Hopkins Medical Institute
(via teleconference)
Nancy Carrasco, M.D., Albert Einstein College of
Medicine

Tab 2261 Protocol

Tab 2262 OBA Summary
OBA Letter to PI on Indepth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews From L. Johnson, Childress, Friedmann, Kwan,
Ladenson, and Carrasco
Sponsor's Response

11:10 AM **BREAK**

Friday, June 21, 2002 (continued)

11:30 PM **Data Management Report**

Tab 2263 Protocol List
 Protocols Not Selected for RAC Public Review
 Serious Adverse Event Summary Report
 Amendments and Update Summary Table

12:30 PM **LUNCH**

1:30 PM **Discussion of Human Gene Transfer Protocol #0201-534 entitled:**
Phase I Study of AD4- Δ E3-HIV_{env} and AD4- Δ E3-HIV_{gag/pro} Recombinant
Vaccines in HIV-Negative Volunteers

PI: Mark Connors, M.D., National Institute of Allergy and Infectious
 Diseases

RAC Reviewers: Xandra Breakefield, Ph.D.
 Maxine Linial, Ph.D.
 Diane Wara, M.D.
 Nancy King, J.D.

Ad Hoc Reviewers: Ira Fox, M.D., University of Nebraska
 Stephen Dewhurst, Ph.D., University of Rochester

Tab 2264 Protocol

Tab 2265 OBA Summary
 OBA Letter to PI on Indepth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews From Breakefield, Linial, Wara, King, Fox, and Dewhurst
 Sponsor's Response

3:30 PM **Closing Remarks**

4:10 PM **ADJOURNMENT**

* Final agenda as of 06/10/02.

Please Note: If you wish to make public comments at the meeting, please contact Laurie Harris at
(301) 496-9838 or e-mail at harrisla@od.nih.gov.