

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

92nd Meeting of the NIH RAC

**Bethesda Marriott Hotel
Bethesda, Maryland**

September 17-18, 2003

MEETING AGENDA

Wednesday, September 17, 2003

10:30 AM **Call to Order and Opening Remarks**
Theodore Friedmann, M.D., Chair, NIH RAC

Tab 2304 For Your Information
 - Notice of Meeting
 - Conflict of Interest Guidance

10:40 AM **Minutes of the June 18-19, 2003 RAC Meeting**
Tab 2305

RAC Reviewers: Theodore Friedmann, M.D.
 David DeMets, Ph.D.

10:50 AM **Discussion of Human Gene Transfer Protocol #0307-594 entitled:**
A Phase Study to Determine the Safety and Biological Activity of Cell-Mediated Gene Therapy Using Tissue Gene-C in Patients with Degenerative Joint Disease of the Knee Prior to Total Knee Arthroplasty
PI: Michael A. Mont, M.D., Sinai Hospital, Baltimore, MD

RAC Reviewers: Terry Kwan
 Diane Wara, M.D.
 Neal DeLuca, Ph.D.

Ad Hoc Reviewers: Robert H. Carter, M.D., University of Alabama

Tab 2306 Protocol
Tab 2307 OBA Summary
 OBA Letter to PI on in-depth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews from Ms. Kwan, and Drs. Wara, DeLuca, Carter
 PI's/Sponsor's Response

12:40 PM **Public Comment**

12:50 PM **LUNCH**

1:50 PM **Discussion of Human Gene Transfer Protocol #0307-588 entitled:**

A Phase I Dose Escalation Study of Intra-Articular Administration of tgAAC94, a Recombinant Adeno-Associated Vector containing the TNFR: Fc Fusion Gene in Rheumatoid Arthritis

PI: Philip J. Mease, M.D., Swedish Hospital, Seattle, WA

RAC Reviewers: Robert Simari, M.D.
Baruch Brody, Ph.D.
Thomas Gelehrter, M.D.

Ad Hoc Reviewers: Robert H. Carter, M.D., University of Alabama
Christopher H. Evans, D.Sc., Ph.D., Harvard Medical School

Tab 2308 Protocol
Tab 2309 OBA Summary
OBA Letter to PI on in-depth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Simari, Brody, Gelehrter, Carter, and Evans
PI's/Sponsor's Response

3:40 PM **Public Comment**

3:50 PM **BREAK**

4:05 PM **Data Management Report**

Tab 2310 Protocol List
Protocols Not Selected for RAC Public Review

RAC Reviewers: Baruch Brody, Ph.D.
Linda Gooding, Ph.D.
Larry Johnson, M.D.
Robert Simari, M.D.
Diane Wara, M.D.

4:20 PM **Informed Consent Working Group Update**

4:45 PM **ADJOURNMENT**

Thursday, September 18, 2003

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

8:10 AM **Amendments and Updates to Protocol 0010-419: Intratumoral Injections of a Replication-Incompetent Adenoviral Vector Encoding a Factor VII Immunoconjugate to Induce a Cytolytic Immune Reponse Against Melanoma Tumors: A Pilot Trial**
Speaker: Albert B. Deisseroth, M.D., Ph.D., Sidney Kimmel Cancer Center

9:10 AM **Discussion of Human Gene Transfer Protocol #0307-592 entitled:**
A Phase I Study to Determine the Safety and Immunogenicity of Vaccination with Listeria Monocytogenes Expressing Human Papilloma Virus type 16 E7 for the Treatment of Progressive, Recurrent and Advanced Squamous Cell Cancer of the Cervix

PI: John Marshall, M.D., Georgetown University Medical Center

RAC Reviewers: Emmett Barkley, Ph.D.
 Larry Johnson, M.D.
 Bernard Lo, M.D.

Tab 2311 Protocol
Tab 2312 OBA Summary
 OBA Letter to PI on In-depth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews from Drs. Barkley, L. Johnson, Lo and PI's/Sponsor's
 Response

11:00 AM **Public Comment**

11:10 AM **BREAK**

11:25 AM **Global Site Preferences for MLV and HIV-1 Proviral Integration in the Human Genome**
Speaker: Shawn M. Burgess, Ph.D., NIH

12:10 PM **LUNCH**

1:10 PM **Discussion of Human Gene Transfer Protocol #0307-593 entitled:**
A Phase I Open-label Safety Study of Intrastratial infusion of Adeno-associated virus encoding human aromatic L-amino acid decarboxylase (AAV-hAADC-2) in subjects with advanced Parkinson's Disease [AAV-hAADC-2-003]

PI: Michael Aminoff, M.D., D.Sc., University of California, San Francisco

RAC Reviewers: Philip Johnson, M.D.
 Martha Bohn, Ph.D.
 Madison Powers, Ph.D.

Ad Hoc Reviewer: Eugene Redmond, M.D., Yale University, (tel-conference)

Tab 2313 Protocol
Tab 2314 OBA Summary
 OBA Letter to PI on In-depth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews from Drs. P. Johnson, Bohn, Powers, and Redmond,
 PI's/Sponsor's Response

2:45 PM **Public Comment**

3:00 PM **ADJOURNMENT**

