

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

94th Meeting

**Bethesda Marriott Hotel
Bethesda, Maryland**

**December 3-4, 2003
Meeting Agenda***

Wednesday, December 3, 2003

9:00 AM **Call to Order and Opening Remarks**
Theodore Friedmann, M.D., Chair, NIH RAC

Tab 2316 For Your Information
Notice of Meeting
Conflict of Interest Guidance

9:10 AM **Minutes of the September 17, 2003**
Tab 2317

RAC Reviewers: Philip Johnson, M.D.
Thomas Gelehrter, M.D.

9:20 AM **Update on the RAC Gene Transfer Clinical Trial Design Working Group**

Presenters: David DeMets, Ph.D., NIH RAC
Cheryl McDonald, M.D., NIH Office of Biotechnology Activities
(OBA) Staff

9:40 AM **Data Management Report**
Tab 2318 Protocol List
Protocols Not Selected for RAC Public Review

RAC Reviewers: Larry Johnson, M.D.
Robert Simari, M.D.
Diane Wara, M.D.

10:10 AM **Update on the Development of a Mechanism to Apprise the RAC of Investigator and Institutional Responses to RAC Reviews**

Presenters: Cheryl McDonald, M.D., NIH OBA Staff
Thomas Shih, M.D., Ph.D., NIH OBA Staff

10:40 AM **BREAK**

11:00 AM **Amendments and Updates to Human Gene Transfer Protocol #0010-419:**
Intratumoral Injections of a Replication-Incompetent Adenoviral Vector Encoding a Factor VII Immunconjugate to Induce a Cytolytic Immune Response Against Melanoma Tumors: A Pilot Trial (Indepth review and public discussion at the December 2000 RAC meeting)

PI: Albert B. Deisseroth, M.D., Ph.D.
 Sidney Kimmel Cancer Center, San Diego, CA

Tab 2319 Protocol, amendments, December 2000 RAC recommendation letter,
 and Dr. Deisseroth's slides

12:00 NOON **LUNCH**

1:00 PM **Discussion of Human Gene Transfer Protocol #0310-610:**
A Phase I/II Study of the Treatment of Recurrent or Progressive Malignant Glioma Using Autologous Bone Marrow-Derived Stromal Cells (BMSC) Nonvirally Transduced to Express IL-12

PI Tom Mikklesen, M.D.
 Henry Ford Cancer Center, Detroit, MI

RAC Reviewers: Martha Bohn, Ph.D.
 David Sidransky, M.D.
 James Childress, Ph.D.
 Diane Wara, M.D.

Ad Hoc Reviewer: Evan Y. Snyder, M.D., Ph.D. (*via teleconference*)
 The Burnham Institute, La Jolla, CA

Tab 2320 Protocol

Tab 2321 OBA Summary
 OBA Letter to PI on Indepth RAC Review and
 Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews from Drs. Bohn, Sidransky, Childress, Wara, and
 Snyder
 PI's/Sponsor's Response

3:00 PM **Public Comment**

3:10 PM **Educational Seminar Series on Retroviruses: “Global Site Preferences for MLV and HIV-1 Proviral Integration in the Human Genome”**

Speaker: Shawn M. Burgess, Ph.D.
National Human Genome Research Institute, NIH

4:10 PM **ADJOURNMENT**

Thursday, December 4, 2003

8:30 AM **Call to Order and Opening Remarks**
Theodore Friedmann, M.D., Chair, NIH RAC

8:35 AM **Discussion of Human Gene Transfer Protocol #0307-589:**
A Phase I Study in Glaucoma Subjects Receiving SCH 412499 (rAd-p21) Administered as a Single Injection into the Subconjunctival Space Prior to Primary Trabeculectomy

PIs: Paul L. Kaufman, M.D.
University of Wisconsin Medical School, Madison
Robert N. Weinreb, M.D.
University of California, San Diego

RAC Reviewers: Neal DeLuca, Ph.D.
Robert Simari, M.D.
Terry Kwan, M.S.Ed.

Ad Hoc Reviewer: Donald L. Budenz, M.D.
Bascom Palmer Eye Institute, Miami, FL

Tab 2322 Protocol

Tab 2323 OBA Summary
OBA Letter to PI on Indepth RAC Review and
Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. DeLuca and Simari and Ms. Kwan
PIs’/Sponsor’s Response

10:35 AM **Public Comment**

10:45AM **BREAK**

11:00 AM **“NIH
Guidance on Informed Consent for Gene Transfer Research”—A Web-Based Resource**

Presenter: Nancy M.P. King, J.D., University of North Carolina, Chapel Hill
Sue L. Levi-Pearl, Tourette’s Syndrome Association, Inc.,
Bayside, NY

12:00 NOON **LUNCH**

1:00 PM **Discussion of Human Gene Transfer Protocol #0307-592:**
*A Phase I Study to Determine the Safety and Immunogenicity of Vaccination With Listeria
Monocytogenes Expressing Human Papillomavirus 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, Washington, DC

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

Tab 2324 Protocol

Tab 2325 OBA Summary
OBA Letter to PI on Indepth RAC Review and
Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Barkley, L. Johnson, and Lo
PI’s/Sponsor’s Response

3:00 PM **Public Comment**

3:10 PM **ADJOURNMENT**

*Draft agenda as of 11/21/03