

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

102nd Meeting

**Bethesda Marriott Hotel
Bethesda, Maryland**

**December 13-14, 2005
Meeting Agenda**

Tuesday, December 13, 2005

9:00 AM Call to Order and Opening Remarks

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

Tab 2392 For Your Information
Notice of Meeting
Conflict of Interest Guidance

9:10 AM Minutes of the September 21, 2005, RAC Meeting

RAC Reviewers: Naomi Rosenberg, Ph.D.
Nikunj Somia, Ph.D.

Tab 2393 Minutes of the September 21, 2005, RAC Meeting

9:15 AM Gene Transfer Safety Assessment Board Report

Tab 2396 Response to M-I-C-1
Protocol List
Protocols Not Selected for RAC Public Review

RAC Reviewers: Steven Albelda, M.D.
Helen Heslop, M.D.
Howard Federoff, M.D., Ph.D.
Diane Wara, M.D.

9:30 AM Risk-Benefit Assessment in Early-Phase Pediatric Research

Presenter: Gilman Grave, M.D., National Institute of Child Health and
Human Development, National Institutes of Health, Bethesda, MD

10:00 AM BREAK

Tuesday, December 13, 2005 (continued)

10:15 AM **Discussion of Human Gene Transfer Protocol #0510-740: *A Phase I Safety Study in Subjects with Leber Congenital Amaurosis (LCA) Using Adeno-Associated Viral Vector to Deliver the Gene for Human RPE65 into the Retinal Pigment Epithelium (RPE)***

PI: Albert M. Maguire, M.D., Scheie Eye Institute, University of Pennsylvania Health System, Philadelphia, PA

Sponsor: Katherine A. High, M.D., University of Pennsylvania Health System, Philadelphia, PA

RAC Reviewers: Madison Powers, J.D., D.Phil.
 Robyn Shapiro, J.D.
 Richard Vile, Ph.D.
 Diane Wara, M.D.

Tab 2394 Protocol

Tab 2395 OBA Summary
 OBA Letter to PI on In-Depth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews from Drs. Powers, Vile, and Wara and Ms. Shapiro
 PI's/Sponsor's Response

12:05 PM **Public Comment**

12:15 PM **LUNCH**

1:15 PM **Discussion of Human Gene Transfer Protocol #0510-732: *A Phase I/IIA Dose-Escalation Trial of Intratumoral Injection with Oncolytic Adenovirus Vector INGN 007 (VRX-007) in Patients with Advanced Solid Tumors***

PI: John Nemunaitis, M.D., Mary Crowley Medical Research Center, Dallas, TX

Sponsor: Introgen Therapeutics, Inc., Houston, TX

RAC Reviewers: Steven Albelda, M.D.
 Stephen Dewhurst, Ph.D.
 Madison Powers, J.D., D.Phil.

Tab 2397 Protocol

Tuesday, December 13, 2005 (continued)

Tab 2398 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Albelda, Dewhurst, and Powers
PI's/Sponsor's Response

2:45 PM **Public Comment**

3:00 PM **BREAK**

3:15 PM **Discussion of Human Gene Transfer Protocol #0510-734: *An Open-Label, Phase I, Dose-Escalation Study of AD-EGFR-CD533 and Surgery for Patients with Resectable Recurrent High-Grade Glioma***

PIs: William C. Broaddus, M.D., Ph.D., Virginia Commonwealth University
Medical Center, Richmond, VA

Theodore D. Chung, M.D., Ph.D., Virginia Commonwealth University
Medical Center, Richmond, VA

RAC Reviewers: Howard Federoff, M.D., Ph.D.
Terry Kwan, M.S.Ed.
Glen Nemerow, Ph.D.

Tab 2399 Protocol

Tab 2400 OBA Summary
OBA Letter to PIs on In-Depth RAC Review and
Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Federoff and Nemerow and Ms. Kwan
PIs'/Sponsor's Response

4:45 PM **Public Comment**

5:00 PM **ADJOURNMENT**

Wednesday, December 14, 2005

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

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

8:40 AM **Discussion of Human Gene Transfer Protocol #0510-739:** *Transduction of the Upper Airway Epithelium in Humans with Cystic Fibrosis by an AAV6 Vector That Encodes Human Placental Alkaline Phosphatase*

PI: Moira L. Aitken, M.D., University of Washington, Seattle, WA

Sponsor: Dusty Miller, Ph.D., Fred Hutchinson Cancer Research Center, Seattle, WA

RAC Reviewers: Stephen Dewhurst, Ph.D.
Terry Kwan, M.S.Ed.
Helen Heslop, M.D.

Tab 2401 Protocol

Tab 2402 OBA Summary
OBA Letter to PI on In-Depth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Dewhurst and Heslop and Ms. Kwan
PI's/Sponsor's Response

10:10 AM **Public Comment**

10:25 AM **BREAK**

10:40 AM **Discussion of Human Gene Transfer Protocol #0509-727:** *Clinical Translation of a Mammaglobin-A DNA Vaccine for Breast Cancer Prevention and Therapy*

PI: William E. Gillanders, M.D., Washington University School of Medicine, St. Louis, MO

RAC Reviewers: Steven Piantadosi, M.D., Ph.D.
Madison Powers, J.D., D.Phil.
Richard Vile, Ph.D.

Tab 2403 Protocol

Wednesday, December 14, 2005 (continued)

Tab 2404 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Piantadosi, Powers, and Vile
PI's/Sponsor's Response

12:10 PM **Public Comment**

12:25 PM **LUNCH**

1:25 PM **Discussion of Human Gene Transfer Protocol #0510-731: *Open-Label, Dose-Escalation Study Evaluating the Safety of a Single Administration of an Adenoviral Vector Encoding Human Aquaporin-1 to One Parotid Salivary Gland in Individuals with Irradiation-Induced Parotid Salivary Hypofunction***

PI: Bruce J. Baum, D.M.D., Ph.D., National Institute of Dental and
Craniofacial Research, National Institutes of Health, Bethesda, MD

RAC Reviewers: Howard Federoff, M.D., Ph.D.
Terry Kwan, M.S.Ed.
Nicholas Muzyczka, Ph.D.

Ad Hoc Reviewers: Athena S. Papas, D.M.D., Ph.D., Tufts University,
Boston, MA

Scott E. Strome, M.D., University of Maryland,
Baltimore, MD

Tab 2405 Protocol

Tab 2406 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Federoff, Muzyczka, Papas, and Strome and
Ms. Kwan
PI's/Sponsor's Response

3:00 PM **Public Comment**

3:15 PM **ADJOURNMENT**