

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

**113th Meeting**

**NIH Campus  
Building 31, Sixth Floor, C Wing, Room 6**

**June 17-18, 2008  
Agenda**

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**Tuesday, June 17, 2008**

**8:15 AM Call to Order and Opening Remarks**

Howard Federoff, M.D., Ph.D., Chair, NIH RAC

Tab 2501 For Your Information  
Notice of Meeting  
Conflict of Interest Guidance

**8:20 AM Minutes of the March 11-12, 2008, RAC Meeting**

RAC Reviewers: Jeffrey Bartlett, Ph.D.  
Joseph Kanabrocki, Ph.D.

Tab 2502 Minutes of the March 11-12, 2008, RAC Meeting

**8:30 AM Gene Transfer Safety Assessment Board Report**

Tab 2503 Responses to M-I-C-1  
Protocol List  
Protocols Not Selected for In-Depth Review and  
Public Discussion

RAC Reviewers: Steven Albelda, M.D.  
Howard Federoff, M.D., Ph.D.  
Scott Strome, M.D.

**8:40 AM Discussion of Human Gene Transfer Protocol #0802-905: *Phase I Trial of Intravenous Recombinant Human 4-1BB Ligand Fusion Protein (hIg-h4-1BB-Ls) in Combination with Intratumoral Adenoviral Vector Expressing Human Interleukin-12 cDNA (Adv.hIL12) and Oral Sunitinib Malate in Patients with Metastatic Nonhematologic Neoplasms***

**Tuesday, June 17, 2008 (continued)**

PIs: Savio L.C. Woo, Ph.D., and Max W. Sung, M.D., Mount Sinai School of Medicine, New York, NY

RAC Reviewers: Steven Albelda, M.D.  
Hildegund Ertl, M.D.  
Robyn Shapiro, J.D.

*Ad hoc* Reviewer: Crystal L. Mackall, M.D., National Cancer Institute, NIH, Bethesda, MD

Tab 2504 Protocol

Tab 2505 Office of Biotechnology Activities (OBA) Summary  
OBA Letter to PIs on In-Depth RAC Review and Public Discussion  
Reviews from Drs. Albelda, Ertl, and Mackall and Ms. Shapiro  
PIs' Response

10:30 AM **Public Comment**

10:40 AM **BREAK**

10:50 AM **Discussion of Human Gene Transfer Protocol #0804-917: *A Phase IIa Randomized, Placebo-Controlled, Double-Blind, Multicenter, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Efficacy of AG011 in Subjects with Moderately Active Ulcerative Colitis***

PI: Kim L. Isaacs, M.D., Ph.D., The University of North Carolina at Chapel Hill, Chapel Hill, NC

RAC Reviewers: Howard Federoff, M.D., Ph.D.  
Jeffrey Kahn, Ph.D., M.P.H.  
John Zaia, M.D.

*Ad hoc* Reviewer: Carmelo Cuffari, M.D., Johns Hopkins University, Baltimore, MD (*via teleconference*)

Tab 2506 Protocol

Tab 2507 OBA Summary  
OBA Letter to PI on In-Depth RAC Review and Public Discussion  
Reviews from Drs. Federoff, Kahn, Zaia, and Cuffari  
PI's Response

12:45 PM **Public Comment**

**Tuesday, June 17, 2008 (continued)**

12:55 PM            **LUNCH**

1:30 PM            **Certificates of Appreciation for RAC Member Service to NIH**

Presenter:        Raynard S. Kington, M.D., Ph.D., Office of the Director,  
NIH, Bethesda, MD

2:00 PM            **Discussion of Human Gene Transfer Protocol #0804-913: *A Phase I Study of BikDD Therapy in Advanced Breast Cancer***

**AND**

**Discussion of Human Gene Transfer Protocol #0804-914: *A Phase I, Open-Label, Dose-Escalation Study to Assess the Safety and Tolerability of the BikDD Nanoparticle in Patients with Advanced Pancreatic Cancer***

**Human Gene Transfer Protocol #0804-913: *A Phase I Study of BikDD Therapy in Advanced Breast Cancer***

PI:                Gabriel N. Hortobagyi, M.D., The University of Texas M.D.  
Anderson Cancer Center, Houston, TX

RAC Reviewers:    Stephen Dewhurst, Ph.D.  
Robyn Shapiro, J.D.  
Scott Strome, M.D.  
Lee-Jen Wei, Ph.D.

Tab 2508            Protocol

Tab 2509            OBA Summary  
OBA Letter to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Dewhurst, Strome, and Wei and  
Ms. Shapiro  
PI's Response

**Human Gene Transfer Protocol #0804-914: *A Phase I, Open-Label, Dose-Escalation Study to Assess the Safety and Tolerability of the BikDD Nanoparticle in Patients with Advanced Pancreatic Cancer***

PI:                Milind Javle, M.D., The University of Texas M.D. Anderson Cancer  
Center, Houston, TX

RAC Reviewers:    Stephen Dewhurst, Ph.D.  
Ellen Grant, Ph.D., LCSW-R  
Scott Strome, M.D.  
Lee-Jen Wei, Ph.D.

**Tuesday, June 17, 2008 (continued)**

Tab 2510 Protocol

Tab 2511 OBA Summary  
OBA Letter to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Dewhurst, Grant, Strome, and Wei  
PI's Response

4:30 PM **Public Comment**

4:45 PM **ADJOURNMENT**

**Wednesday, June 18, 2008**

8:10 AM **Call to Order and Opening Remarks**

Howard Federoff, M.D., Ph.D., Chair, NIH RAC

8:15 AM **Discussion of Human Gene Transfer Protocol #0804-922: *Adoptive Immunotherapy for CD19+ B-Lymphoid Malignancies Using Sleeping Beauty Transposition to Express a CD19-Specific Chimeric Antigen Receptor in Autologous Ex Vivo Expanded T Cells***

PIs: Partow Kebriaei, M.D., and Laurence J.N. Cooper, M.D., Ph.D., The University of Texas M.D. Anderson Cancer Center, Houston, TX

RAC Reviewers: Hung Fan, Ph.D.  
Richard Vile, Ph.D.  
David Weber, M.D., M.P.H.  
David Williams, M.D.

Tab 2512 Protocol

Tab 2513 OBA Summary  
OBA Letter to PIs on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Fan, Vile, Weber, and Williams  
PIs' Response

10:00 AM **Public Comment**

10:15 AM ***NIH Guidelines for Research Involving Recombinant DNA Molecules: Noncontemporary Influenza and Highly Pathogenic Avian Influenza***

Jacqueline Corrigan-Curay, M.D., J.D., OBA, NIH

10:30 AM **ADJOURNMENT**