

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

116th Meeting

Neuroscience Building  
6001 Executive Boulevard  
Rockville, Maryland

March 3-4, 2009  
\*Draft Agenda

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*Tuesday, March 3, 2009*

- 8:30 AM            **Call to Order and Opening Remarks**
- Howard Federoff, M.D., Ph.D., RAC Chair
- Tab 2539        For Your Information  
                  Notice of Meeting  
                  Conflict of Interest Guidance
- 8:35 AM            **Minutes of the December 3-4, 2008, RAC Meeting**
- RAC Reviewers:    Jeffrey Bartlett, Ph.D.  
                          Louis Kirchhoff, M.D., M.P.H.
- Tab 2540        Minutes of the December 3-4, 2008, RAC Meeting
- 8:40 AM            **Discussion of Human Gene Transfer Protocol #0811-955: *Herpes Simplex Virus Gene Transfer of Glutamate Acid Decarboxylase for Painful Diabetic Neuropathy***
- PI:                David J. Fink, M.D., University of Michigan, Ann Arbor, MI
- Sponsor:         Diamyd, Inc.
- RAC Reviewers:    Michael Buchmeier, Ph.D., M.S.  
                          Howard Federoff, M.D., Ph.D.  
                          Robyn Shapiro, J.D.
- Ad hoc* Reviewer:    William J. Bowers, Ph.D., University of Rochester  
                          Medical Center, Rochester, NY (*via teleconference*)

**Tuesday, March 3, 2009 (continued)**

Tab 2541 Protocol

Tab 2542 OBA Summary  
OBA Letter to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Buchmeier, Federoff, and Bowers and  
Ms. Shapiro  
PI's Response

10:20 AM **Public Comment**

10:40 AM **Ebola Virus cDNA and the NIH Guidelines for Research Involving  
Recombinant DNA Molecules**

Tab 2543 Background Materials

Presenters: Robert Jambou, Ph.D., Office of the Director, NIH,  
Bethesda, MD  
Heinz Feldmann, M.D., Ph.D., Rocky Mountain Laboratories  
and NIH, Hamilton, MT  
Michael Buchmeier, Ph.D., M.S., University of California,  
Irvine, Irvine, CA

11:40 AM **Public Comment**

11:50 AM **Gene Transfer Safety Assessment Board Report**

Tab 2544 Responses to M-I-C-1  
Protocol List  
Protocols Not Selected for In-Depth Review and  
Public Discussion

RAC Reviewers: Howard Federoff, M.D., Ph.D.  
Scott Strome, M.D.  
David Williams, M.D.  
James Yankaskas, M.D., M.S.  
John Zaia, M.D.

12:00 NOON **Lunch**

12:50 PM **Discussion of Human Gene Transfer Protocol #0901-966: A Prospective,  
Randomized, Controlled, Multicenter, Unblinded, Safety, and Early Efficacy  
Trial of ExpressGraft™ Enhance Skin Tissue Versus Wet to Dry Dressings in  
the Treatment of Recently Occurring, Noninfected Foot Ulcers in Diabetic  
Patients**

*Tuesday, March 3, 2009 (continued)*

PI: Michael J. Schurr, M.D., University of Wisconsin, Madison, WI

Sponsor: Stratatech Corporation

RAC Reviewers: Prediman Shah, M.D.  
Scott Strome, M.D.  
John Zaia, M.D.

*Ad hoc* Reviewer: John Shively, Ph.D., M.S., City of Hope, Duarte, CA  
(via teleconference)

Tab 2545 Protocol

Tab 2546 OBA Summary  
OBA Letter to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Shah, Shively, Strome, and Zaia  
PI's Response

2:40 PM **Public Comment**

2:45 PM **Break**

3:00 PM **Discussion of Human Gene Transfer Protocol #0901-963:** *A Pilot Feasibility Study of Gene Transfer for X-Linked Severe Combined Immunodeficiency (X-SCID) in Newly Diagnosed Infants Using a Self-Inactivating Lentiviral Vector to Transduce Autologous CD34+ Hematopoietic Cells*

PI: Brian P. Sorrentino, M.D., St. Jude Children's Research Hospital, Memphis, TN

**AND**

**Discussion of Human Gene Transfer Protocol #0901-964:** *Lentiviral Gene Transfer for Treatment of Children Older Than 1 Year of Age with X-SCID*

PIs: Suk See De Ravin, M.D., Ph.D., National Institute of Allergy and Infectious Diseases (NIAID), NIH, Bethesda, MD  
Elizabeth M. Kang, M.D., NIAID, NIH, Bethesda, MD  
Harry L. Malech, M.D., Ph.D., NIAID, NIH, Bethesda, MD

Sponsor: Brian P. Sorrentino, M.D., St. Jude Children's Research Hospital, Memphis, TN

***Tuesday, March 3, 2009 (continued)***

RAC Reviewers: Hildegund Ertl, M.D.  
Hung Fan, Ph.D.  
Eric Kodish, M.D.  
Nikunj Somia, Ph.D.

Tab 2547 Protocol #0901-963

Tab 2548 Protocol #0901-964

Tab 2549 OBA Summary  
OBA Letter to PIs on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Ertl, Fan, Kodish, and Somia  
PIs' Response

5:30 PM **Public Comment**

5:35 PM **ADJOURNMENT**

***Wednesday, March 4, 2009***

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

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

8:20 AM **Biosafety Working Group Recommendations for the *NIH Guidelines for Research Involving Recombinant DNA Molecules: Human H2N2, Reconstructed 1918 H1N1, and Highly Pathogenic Influenza H5N1 Viruses***

Tab 2550 Background Materials

Presenter: Joseph Kanabrocki, Ph.D.

10:00 AM **Public Comment**

10:10 AM **Break**

10:20 AM **Discussion of Human Gene Transfer Protocol #0901-967: *A Phase 1/2a, Dose-Escalation, Safety, Pharmacokinetic, and Preliminary Efficacy Study of Intraperitoneal Administration of DTA-H19 in Subjects with Advanced-Stage Ovarian Cancer***

PI: George Coukos, M.D., Ph.D., University of Pennsylvania,  
Philadelphia, PA

***Wednesday, March 4, 2009 (continued)***

Sponsor: BioCancell Therapeutics, Inc.

RAC Reviewers: Robyn Shapiro, J.D.  
David Williams, M.D.  
James Yankaskas, M.D., M.S.

Tab 2551 Protocol

Tab 2552 OBA Summary  
OBA Letter to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Ms. Shapiro and Drs. Williams and Yankaskas  
PI's Response

12:20 PM **Public Comment**

12:30 PM **ADJOURNMENT**

*\*Draft agenda as of 02/12/2009*