

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

116th Meeting

Neuroscience Building  
6001 Executive Boulevard  
Rockville, Maryland

March 3-4, 2009  
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  
[Slide Presentation](#)

Sponsor: Diamyd, Inc.

RAC Reviewers: 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. 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 - [Slide Presentation](#)  
Heinz Feldmann, M.D., Ph.D., National Institute of Allergy  
and Infectious Diseases (NIAID), NIH, Hamilton, MT  
[Slide Presentation](#)  
Nancy P. Hoe, PH.D., Office of the Director, NIH, Hamilton,  
MT - [Slide Presentation](#)  
Michael Buchmeier, Ph.D., M.S., University of California,  
Irvine, Irvine, CA - [Slide Presentation](#)

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**

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

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*

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

Sponsor: Stratatech Corporation - [Slide Presentation](#)

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*

PIs: Brian P. Sorrentino, M.D., St. Jude Children's Research Hospital, Memphis, TN - [Slide Presentation](#)  
Mary Ellen Conley, M.D., St. Jude Children's Research Hospital, Memphis, TN - [Slide Presentation](#)  
John T. Gray, Ph.D., St. Jude Children's Research Hospital, Memphis, TN - [Slide Presentation](#)

**AND**

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

**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., NIAID, NIH, Bethesda, MD

[Slide Presentation](#)

Elizabeth M. Kang, M.D., NIAID, NIH, Bethesda, MD

Harry L. Malech, M.D., Ph.D., NIAID, NIH, Bethesda, MD

[Slide Presentation](#)

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

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. - [Slide Presentation](#)

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

9:15 AM            **Public Comment**

9:20 AM            **Review of RAC Recommendations for X-SCID Gene Transfer Trials**  
Jacqueline Corrigan-Curay, J.D., M.D., Office of the Director, NIH  
[Slide Presentation](#)

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 - [Slide Presentation](#)

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**