

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

**105th Meeting**

**NIH Campus  
Natcher Building 45, Conference Room D**

**September 20, 2006  
Agenda**

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**Wednesday, September 20, 2006**

**12:00 NOON Call to Order and Opening Remarks**

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

Tab 2424 For Your Information  
Notice of Meeting  
Conflict of Interest Guidance

**12:05 PM Roundtable Introduction of RAC Members**

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

**12:25 PM Discussion of Human Gene Transfer Protocol #0607-788: *Multicenter, Randomized, Double-Blind, Sham Surgery-Controlled Study of CERE-120 (Adeno-Associated Virus Serotype 2 [AAV2]-Neurturin [NTN]) to Assess the Efficacy and Safety of Bilateral Intraputamenal (IPu) Delivery in Subjects with Idiopathic Parkinson's Disease***

PI: William J. Marks, Jr., M.D., University of California, San Francisco, San Francisco, CA

Submitter: Raymond T. Bartus, Ph.D., Ceregene, Inc., San Diego, CA

RAC Reviewers: Stephen Dewhurst, Ph.D.  
Howard Federoff, M.D., Ph.D.  
Robyn Shapiro, J.D.  
Nikunj Somia, Ph.D.

*Ad hoc* Reviewers: Don M. Gash, Ph.D., University of Kentucky, Lexington, KY  
Lee-Jen Wei, Ph.D., Harvard University, Boston, MA

Tab 2425 Protocol

**Wednesday, September 20, 2006 (continued)**

- Tab 2426      OBA Summary  
OBA Letter to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Dewhurst and Federoff; Ms. Shapiro; and Drs.  
Gash, Somia, and Wei  
PI's/Sponsor's Response
- 2:35 PM      Public Comment
- 2:50 PM      **Minutes of the June 21, 2006, RAC Meeting**
- RAC Reviewers:      Naomi Rosenberg, Ph.D.  
Richard Vile, Ph.D.
- Tab 2427      Minutes of the June 21, 2006, RAC Meeting
- 3:00 PM      **Gene Transfer Safety Assessment Board Report**
- Tab 2428      Response to M-I-C-1  
Protocol List  
Protocols Not Selected for RAC Public Review
- RAC Reviewers:      Steven Albelda, M.D.  
Howard Federoff, M.D., Ph.D.  
Helen Heslop, M.D.
- 3:20 PM      **Biosafety Considerations for Research Involving Lentiviral Vectors**
- Presenters:      Stephen Dewhurst, Ph.D., RAC Member  
Marina O'Reilly, Ph.D., Office of Biotechnology Activities Staff  
Member
- 4:00 PM      **ADJOURNMENT**