

**National Institutes of Health  
Recombinant DNA Advisory Committee (RAC)  
Building 45/Natcher Conference Center, Conference Room D  
Bethesda, Maryland  
June 14-15, 2001**

**Meeting Agenda\***

Thursday, June 14, 2001

- 8:30 AM      **Call to Order and Opening Remarks**  
Claudia Mickelson, Ph.D., RAC Chair
- Tab 2200                      For Your Information:  
                    Notice of Meeting  
                    Conflict of Interest Statement
- 8:35 AM      **Minutes of the March 8, 2001, RAC Meeting**  
RAC Reviewers:      Jon Gordon, M.D., Ph.D.  
                    Sue Levi-Pearl
- Tab 2201                      Minutes From the March 8, 2001, Meeting
- 8:45 AM      **Discussion of Human Gene Transfer Protocol #0104-469 entitled:**  
*Subthalamic GAD Gene Transfer in Parkinson's Disease Patients Who Are  
Candidates for Deep Brain Stimulation*
- PIs:                                      Matthew J. During, M.D., Jefferson Medical College  
                    Michael Kaplitt, M.D., Ph.D., New York Hospital and  
                    Weill Medical College, Cornell University
- Sponsor:                                      N/A
- RAC Reviewers:                      Xandra Breakefield, Ph.D.  
                    Nancy King, J.D.  
                    Louise Markert, M.D., Ph.D.
- Ad hoc* Reviewers:                      Howard Federoff, M.D., Ph.D., University of Rochester  
                    Roy A.E. Bakay, M.D., Ph.D., Rush-Presbyterian-  
                    St. Luke's Medical Center
- Tab 2202                      Protocol
- Tab 2203                      OBA Summary  
                    OBA Letter to PI on RAC Public Review  
                    Outcome of Preliminary RAC Review  
                    Reviews From Breakefield, King, Markert, and Federoff  
                    Sponsor's Response
- 10:00 AM      **Final Serious Adverse Event Reporting Action Update**  
Amy Patterson, M.D., Director, OBA

- 10:30 AM **Break**
- 10:45 AM **A Strawman Proposed Action on *E. coli* Risk Group Assessment**  
 RAC Discussants: Claudia Mickelson, Ph.D.  
 Dale Ando, M.D.  
*Ad hoc Reviewer:* James Kaper, Ph.D., University of Maryland
- Tab 2204 Strawman Proposal: Risk Group Designation for *E. coli* Strain B  
 Letter From Philip S. Collis, Ph.D., Secretary, UF IBC  
 Manuscripts by Kuhnert et al. and Kazuyoshi et al.  
 U.S. Patent: Ethanol Production by *E. coli* Strains Co-Expressing *Zymomonas* PDC and ADH Genes
- 11:45 AM **GeMCRIS Database Update**  
 Amy Patterson, M.D., Director, OBA
- 12:00 NOON **Update on IBC Policy Conference**  
 Allan Shipp, Director of Outreach, OBA
- 12:15 PM **Conflict of Interest and Research Objectivity: Current NIH Policy**  
 Wendy Baldwin, Ph.D., Deputy Director for Extramural Research, NIH
- Tab 2205 *NIH Guide: Objectivity in Research*, Vol. 24, No. 25.  
 Financial Conflicts of Interest and Research Objectivity:  
 Issues for Investigators and Institutional Review Boards,  
 June 5, 2000
- 1:15 PM **Lunch**
- 2:15 PM **Communication of Issues Raised by Individual RAC Members Following the Preliminary RAC Review of Human Gene Transfer Protocols**  
 RAC Discussant: Nancy King, J.D.
- Tab 2206 Discussion Outline
- 3:30 PM **Break**
- 3:45 PM **Discussion of Human Gene Transfer Protocol #0104-470 entitled: *A Phase I/II Dose Escalation and Activity Study of Intravenous Injections of OCaPI in Subjects With Refractory Osteosarcoma Metastatic to Lung***  
 PI: Paul A. Meyers, M.D., Memorial Sloan-Kettering Cancer Center  
 Sponsor: DirectGene, Inc.  
 RAC Reviewers: Louise Chow, Ph.D.  
 Louise Markert, M.D., Ph.D.  
 Nancy King, J.D.  
*Ad hoc Reviewer:* None

Tab 2207 Protocol  
Tab 2208 OBA Summary  
OBA Letter to PI on RAC Public Review  
Outcome of Preliminary RAC Review  
Reviews From Chow, Markert, and King  
Sponsor's Response

5:00 PM **Adjournment**

Friday, June 15, 2001

8:30 AM **Opening Remarks**  
Claudia Mickelson, Ph.D., RAC Chair

8:35 AM **Discussion of Human Gene Transfer Protocol #0104-462 entitled: *A Phase I Trial of Genetically Modified Salmonella typhimurium Expressing Cytosine Deaminase (TAPET-CD, VNP20029) Administered by Intra-tumoral Injection in Combination With 5-Fluorocytosine for Patients With Advanced or Metastatic Cancer***

PIs: John J. Nemunaitis, M.D., and Charles Cunningham, M.D.,  
Mary Crowley Medical Research Center (US Oncology)

Sponsor: Vion Pharmaceuticals, Inc.

RAC Reviewers: Dale Ando, M.D.  
Claudia Mickelson, Ph.D.  
Ruth Macklin, Ph.D.

*Ad hoc* Reviewer: Carol O. Tacket, M.D., University of Maryland

Tab 2209 Protocol

Tab 2210 OBA Summary  
OBA Letter to PI on RAC Public Review  
Outcome of Preliminary RAC Review  
Reviews From Ando, Mickelson, Macklin, and Tacket  
Sponsor's Response

9:45 AM **Break**

10:00 AM **Discussion of Appendix M-VI-A on Vaccine Exemption from OBA Registration and RAC Submission: Interpreting the Clause "persistence of the vector-encoded immunogen"**

RAC Discussants: Xandra Breakefield, Ph.D.  
Estuardo Aguilar-Cordova, Ph.D.

*Ad hoc* Discussants: TBA

Tab 2211 Historical Background of Appendix M-VI-A

