

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

**Bethesda Marriott Hotel
Bethesda, Maryland**

March 6-7, 2003

MEETING AGENDA

Thursday, March 6, 2003

1:00 PM **Call to Order and Opening Remarks**
Theodore Friedmann, M.D., RAC Chair

Tab 2286 For Your Information
 - Notice of Meeting
 - Conflict of Interest Guidance

1:15 PM **Minutes of the December 4-6, 2002 RAC Meeting**

RAC Reviewers: Thomas Gelehrter, M.D.
 James Childress, Ph.D.

Tab 2287 Minutes of the December 4-6, 2002 Meeting

1:25 PM **Data Management Report**

Tab 2288 Protocol List
 Protocols Not Selected for RAC Public Review

RAC Reviewers: Robert Simari, M.D.
 Diane Wara, M.D.
 Linda Gooding, Ph.D.
 Larry Johnson, M.D.
 Baruch Brody, Ph.D.

1:40 PM **Discussion of Human Gene Transfer Protocol #0301-570 entitled:**
*Use of in vivo Expression Technology To Identify Virulence Factors and
Protective Antigens of Vibrio cholerae 01*

PI: Carol O. Tacket, M.D., University of Maryland

RAC Reviewers: Martha Bohn, Ph.D.
 Diane Wara, M.D.
 Philip Johnson, M.D.
 Terry Kwan, M.S.Ed.

Thursday, March 6, 2003 (continued)

Ad Hoc Reviewer: Mitchell Cohen, M.D., Cincinnati Children's Hospital
Medical Center

Tab 2289 Protocol

Tab 2290 OBA Summary
OBA Letter to PI on in-depth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews From Drs. Bohn, Wara, P. Johnson, Ms. Kwan, and
Dr. Cohen
PI's/Sponsor's Response

4:00 PM **Public Comment**

4:15 PM **ADJOURNMENT**

Friday, March 7, 2003

8:30 AM **Call to Order and Opening Remarks**
Theodore Friedmann, M.D., RAC Chair

8:35 AM **Discussion of Human Gene Transfer Protocol #0301-564 entitled:**
Phase Ia/Ib Trial of Second-Generation Designer T Cells in Adenocarcinoma

PI: Richard Junghans, Ph.D., M.D., Harvard Medical School

RAC Reviewers: Larry Johnson, M.D.
Theodore Friedmann, M.D.
Madison Powers, J.D., D.Phil.

Tab 2291 Protocol

Tab 2292 OBA Summary
OBA Letter to PI on in-depth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews From Drs. L. Johnson, Friedmann, and Powers
PI's/Sponsor's Response

10:35 AM **Public Comment**

10:50 AM **BREAK**

Friday, March 7, 2003 (continued)

11:05 AM **Discussion of Human Gene Transfer Protocol #0212-563 entitled:**
*Administration of Peripheral Blood T Cells and Epstein-Barr-Virus-Specific
Cytotoxic T Lymphocytes Transduced To Express GD-2-Specific Chimeric T-Cell
Receptors to Patients With Neuroblastoma*

PI: Heidi Russell, M.D., Texas Children's Cancer Center, Baylor
College of Medicine

RAC Reviewers: Bernard Lo, M.D.
 Neal DeLuca, Ph.D.
 Maxine Linial, Ph.D.

Tab 2293 Protocol

Tab 2294 OBA Summary
 OBA Letter to PI on in-depth RAC Review and Public Discussion
 Outcome of Initial Review by RAC Members
 Reviews From Drs. Lo, DeLuca, and Linial
 PI's/Sponsor's Response

12:50 PM **Public Comment**

1:00 PM **ADJOURNMENT**

