NATIONAL INSTITUTES OF HEALTH
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)

101st Meeting

Bethesda Marriott Hotel
Bethesda, Maryland

September 21, 2005
***Draft Meeting Agenda**

Wednesday, September 21, 2005

8:00 AM **Call to Order and Opening Remarks**

Diane Wara, M.D., Chair, NIH RAC

Tab 2386 For Your Information
Notice of Meeting
Conflict of Interest Guidance

8:10 AM **Introductions of New RAC Members**

Amy Patterson, M.D., Director, Office of Biotechnology Activities

8:20 AM **Minutes of the June 15-16, 2005, RAC Meeting**

RAC Reviewers: Steven Albelda, M.D.
Glen Nemerow, Ph.D.

Tab 2387 Minutes of the June 15-16, 2005, RAC Meeting

8:25 AM **Gene Transfer Safety Assessment Board Report**

Tab 2388 Response to M-I-C-1
Protocol List
Protocols Not Selected for RAC Public Review

RAC Reviewers: Steven Albelda, M.D.
Helen Heslop, M.D.
Diane Wara, M.D.

8:35 AM **RNAi and Its Potential Application as a Therapeutic Strategy**

Speaker: Natasha Caplen Ph.D, National Cancer Institute, National Institutes of Health, Bethesda, M.D.

8:55 AM **Discussion**

Wednesday, September 21, 2005 (continued)

9:25 AM **BREAK**

9:40 AM **Discussion of Human Gene Transfer Protocol #0508-725 entitled:** *A phase I pilot study of safety and feasibility of stem cell therapy for AIDS lymphoma using stem cells treated with a lentivirus vector encoding multiple anti-HIV RNAs*

PI: Amrita Krishnan, M.D., City of Hope National Medical Center,
Duarte, CA

RAC Reviewers: Naomi Rosenberg, Ph.D.
Diane Wara, M.D.
Madison Powers, J.D., D.Phil.

Ad Hoc Reviewer: Natasha Caplen Ph.D, National Cancer Institute, National Institutes of Health, Bethesda, M.D.

Tab 2389 Protocol

Tab 2390 OBA Summary
OBA Letter to PI on In-Depth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Rosenberg, Wara, Powers, and Caplen
PI's/Sponsor's Response

11:00 AM **Public Comment**

11:10 AM **A User's Guide to FDA's Draft Guidance: Gene Therapy Clinical Trials - Observing Participants for Delayed Adverse Events**

Speaker: Carolyn A. Wilson, Ph.D., U.S. Food and Drug Administration

Tab 2391 Draft Guidance: Gene Therapy Clinical Trials - Observing Participants for Delayed Adverse Events

11:30 AM **Discussion**

12:00 PM **ADJOURNMENT**

* draft agenda as of 09/12/2005