

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

103rd Meeting

**NIH Campus
Building 31, Sixth Floor, C Wing, Room 10**

**March 15, 2006
Agenda**

Wednesday, March 15, 2006

9:00 AM Call to Order and Opening Remarks

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

Tab 2407 For Your Information
Notice of Meeting
Conflict of Interest Guidance

9:10 AM Minutes of the December 13-14, 2005, RAC Meeting

RAC Reviewers: Howard Federoff, M.D., Ph.D.
Richard Vile, Ph.D.

Tab 2408 Minutes of the December 13-14, 2005, RAC Meeting

9:20 AM Risk Assessment for Research with Lentiviral Vectors

Tab 2409 Background Material

RAC Presenter: Nikunj Somia, Ph.D.

RAC Reviewers: Stephen Dewhurst, Ph.D.
Naomi Rosenberg, Ph.D.

Ad Hoc Reviewer: LouAnn Burnett, M.S., CBSP, Vanderbilt University,
Nashville, TN

11:20 AM Gene Transfer Safety Assessment Board Report

Tab 2410 Response to M-I-C-1
Protocol List
Protocols Not Selected for RAC Public Review

Wednesday, March 15, 2006 (continued)

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

11:45 AM **LUNCH**

1:00 PM **Discussion of Human Gene Transfer Protocol #0512-752: *Phase I Trial to Assess Safety and Immunogenicity of Xenogeneic CD20 DNA Vaccination in Patients with B-Cell Lymphoma***

PI: M. Lia Palomba, M.D., Memorial Sloan-Kettering Cancer Center, New York, NY

RAC Reviewers: Helen Heslop, M.D.
Terry Kwan, M.S.Ed.
Diane Wara, M.D.

Tab 2411 Protocol

Tab 2412 OBA Summary
OBA Letter to PI on In-Depth RAC Review and Public Discussion
Outcome of Initial Review by RAC Members
Reviews from Drs. Heslop and Wara and Ms. Kwan
PI's/Sponsor's Response

2:15 PM **Public Comment**

2:30 PM **ADJOURNMENT**