

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

107th Meeting

**NIH Campus
Building 31, Sixth Floor, C Wing, Room 6**

**March 14, 2007
Draft Agenda**

Wednesday, March 14, 2007

8:00 AM Call to Order and Opening Remarks

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

Tab 2441 For Your Information
Notice of Meeting
Conflict of Interest Guidance

8:10 AM Minutes of the December 5-6, 2006, RAC Meeting

RAC Reviewers: Louis Kirchhoff, M.D., M.P.H.
Richard Vile, Ph.D.

Tab 2442 Minutes of the December 5-6, 2006, RAC Meeting

**8:15 AM Discussion of Human Gene Transfer Protocol #0612-821: A
*Randomized, Double-Blind, Placebo-Controlled, Parallel-Group,
Multicenter Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in
Female Patients with Stable Angina Pectoris Who Are Not Candidates for
Revascularization***

PI: Matthew Watkins, M.D., Vermont College of Medicine,
Burlington, VT

Sponsor: Cardium Therapeutics, Inc.

RAC Reviewers: Glen Nemerow, Ph.D.
Robyn Shapiro, J.D.
Lee-Jen Wei, Ph.D.

Ad hoc Reviewer: Sanjay Rajagopalan, M.D., Ohio State University,
Columbus, OH (*via teleconference*)

Wednesday, March 14, 2007 (continued)

- Tab 2443 Protocol
- Tab 2444 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Dr. Nemerow, Ms. Shapiro, Dr. Wei,
and Dr. Rajagopalan
PI's/Sponsor's Response
- 9:35 AM Public Comment
- 9:45 AM **BREAK**
- 10:00 AM **Gene Therapy: Opportunities and Challenges—The Next Decade**
- Speaker: Theodore Friedmann, M.D., University of California,
San Diego, San Diego, CA
- 10:45 AM **Gene Transfer Safety Assessment Board Report**
- Tab 2445 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.
- 11:00 AM **Thrombosis and Malignancy: Implications for Therapy**
- Speaker: Jay Lozier, M.D., Ph.D., Warren Grant Magnuson Clinical
Center, National Institutes of Health (NIH), Bethesda, MD
- 11:50 AM **BREAK**
- 12:10 PM Lunchtime Presentation
- Human Cancer Immunotherapy Using Genetically Modified
Autologous Lymphocytes**
- Speaker: Steven Rosenberg, M.D., Ph.D., National Cancer Institute,
NIH

Wednesday, March 14, 2007 (continued)

1:15 PM **Discussion of Human Gene Transfer Protocol # 0701-827: Phase I or Phase I/II Single-Center Trial of Gene Transfer for Recessive Dystrophic Epidermolysis Bullosa (RDEB)**

PI: Alfred T. Lane, M.D., Stanford University School of Medicine,
Palo Alto, CA

RAC Reviewers: Helen Heslop, M.D.
Eric Kodish, M.D.
Naomi Rosenberg, Ph.D.

Ad hoc Reviewer: Elena Pope, M.D., FRCPC, The Hospital for Sick
Children and University of Toronto, Toronto,
Ontario, Canada (*via teleconference*)

Tab 2446 Protocol

Tab 2447 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Heslop, Kodish, Pope, and Rosenberg
PI's/Sponsor's Response

3:10 PM Public Comment

3:15 PM BREAK

3:30 PM **New Developments in X-SCID Gene Transfer**

Tab 2448 Background Material

Moderators: Drs. Federoff and Friedmann

Speakers: Marina O'Reilly, Ph.D., Office of Biotechnology Activities
(OBA), NIH

Jacqueline Corrigan-Curay, J.D., M.D., OBA, NIH

Harry Malech, M.D., National Institute of Allergy and
Infectious Diseases, NIH

Fabio Candotti, M.D., National Human Genome Research
Institute, NIH

Carolyn Wilson, Ph.D., Food and Drug Administration

5:00 PM **ADJOURNMENT**