

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

109th Meeting

**NIH Campus
Natcher Building Auditorium**

September 17, 2007

Monday, September 17, 2007

8:00 AM

Introduction

Opening Remarks
Conflict of Interest Statement

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

8:05 AM

Overview of AAV Vector-Based Clinical Protocols

Presenter: Jacqueline Corrigan-Curay, M.D., J.D., Acting
Executive Secretary, NIH RAC

8:10 AM

**Overview of Rheumatoid Arthritis and the Role of TNF
Inhibitors**

Presenter: Mary K. Crow, M.D., Associate Chief Division of
Rheumatology and Director of Rheumatology
Research at Hospital for Special Surgery, New
York, NY

8:25 AM

**TNF antagonists in Rheumatoid Arthritis: the Clinicians
Perspective**

Presenter: Eric L. Matteson, M.D., M.P.H., Professor of
Medicine, Division of Rheumatology, Mayo Clinic,
Rochester, MN

8:40 AM

Overview of OBA Protocol #0504-705: *A Phase I Dose
Escalation Study of Repeat Intra-Articular Administration of
tgAAC94, a Recombinant Adeno-Associated Vector Containing the
TNFR:Fc Fusion Gene, in Inflammatory Arthritis Subjects with
and without Concurrent TNF- α Antagonists*

PIs': Philip J. Mease, M.D., University of Washington,
Seattle, WA

Monday, September 17, 2007 (continued)

Edward J. Fudman, M.D., Austin Rheumatology
Research, Austin, TX

9:00 AM **Presentation of Case**

Presenter: D. Kyle Hogarth, M.D., Assistant Professor,
Pulmonary and Critical Care Medicine, University
of Chicago Hospitals, Chicago, IL

9:30 AM **Presentation of Autopsy Data**

Presenters: John Hart, M.D., Professor, Department of
Pathology, University of Chicago Hospitals,
Chicago, IL

Karen Frank, M.D., Ph.D., Assistant Professor,
Department of Pathology, University of Chicago
Hospitals,
Chicago, IL

9:55 AM **Discussion of Case by Expert Panel**

Panelists: Carol A. Kauffman, M.D., Chief, Department of
Infectious Disease, U.S. Department of Veterans
Affairs, Ann Arbor, MI and Professor of Medicine,
University of Michigan (*teleconference*)

Richard J. Whitley, M.D., Professor of Pediatrics,
Microbiology and Medicine,
The University of Alabama at Birmingham,
Birmingham, AL (*via videocast*)

Bernard Roizman, Sc.D., Professor Molecular
Genetics and Cell Biology, The University of
Chicago, Chicago, IL (*via videocast*)

Leonard B. Seeff, M.D., National Institute of
Diabetes and Digestive and Kidney Diseases
NIDDK, NIH, Bethesda, MD

Jay Lozier, M.D., Ph.D., Warren Grant Magnuson
Clinical Center,
NIH, Bethesda, MD

Monday, September 17, 2007 (continued)

10:20 AM

BREAK

RAC Discussion

Moderator: Howard Federoff, M.D., Ph.D.

10:30 AM

Assessment of the Possible Role of Gene Transfer

11:30 AM

Informed Consent and Subject Selection

11:50 AM

Summary of Meeting

12:10 PM

PUBLIC COMMENT

12:45 PM

ADJOURNMENT

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

109th Meeting

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

**September 17-18, 2007
Agenda**

Monday, September 17, 2007 (continued in Building 31, Sixth Floor, C Wing, Room 6)

1:15 PM **Discussion of Human Gene Transfer Protocol #0707-868:** *A Phase I Safety Study of Heat/Phenol-Killed, E. coli-Encapsulated, Recombinant Modified Peanut Proteins Ara h 1, Ara h 2, and Ara h 3 (EMP-123) in Normal Volunteers Followed by Subjects Allergic to Peanuts*

PIs: Robert A. Wood, M.D., Johns Hopkins University, Baltimore, MD

 Scott A. Sicherer, M.D., Mount Sinai School of Medicine,
 New York, NY (*via teleconference*)

RAC Reviewers: Steven Albelda, M.D.
 Eric Kodish, M.D.
 Richard Vile, Ph.D.

Ad hoc Reviewer: Gideon Lack, M.D., King's College London, London,
 United Kingdom (*via teleconference*)

Tab 2468 Protocol

Tab 2469 OBA Summary
 OBA Letter to PIs on In-Depth RAC Review and
 Public Discussion
 Reviews from Drs. Albelda, Kodish, Vile, and Lack
 PIs' Response

3:00 PM **Public Comment**

3:15 PM **BREAK**

3:30 PM **Consideration of a Proposed Major Action:** Under Section III-A-1 of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*: Deliberate Transfer of Chloramphenicol Resistance to *Rickettsia conorii* and *Rickettsia typhi*

Monday, September 17, 2007 (continued)

Presenters: David H. Walker, M.D., The University of Texas Medical
Branch at Galveston, Galveston, TX (*via videoconference*)

Abdu Azad, Ph.D., University of Maryland, Baltimore, MD

Tab 2470 Background Materials

5:15 PM **Public Comment**

5:30 PM **ADJOURNMENT**

Tuesday, September 18, 2007

8:15 AM **Call to Order and Opening Remarks**

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

8:20 AM **Minutes of the June 19-21, 2007, RAC Meeting**

RAC Reviewers: Hildegund Ertl, M.D.
Jeffrey Kahn, Ph.D., M.P.H.
Nikunj Somia, Ph.D.
Lee-Jen Wei, Ph.D.

Tab 2471 Minutes of the June 19-21, 2007, RAC Meeting

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

Tab 2472 Responses to M-I-C-1
Protocol List
Protocols Not Selected for In-Depth Review and
Public RAC Discussion

RAC Reviewers: Steven Albelda, M.D.
Howard Federoff, M.D., Ph.D.
Scott Strome, M.D.

8:45 AM **National Heart, Lung, and Blood Institute (NHLBI) Gene Therapy
Resource Program**

Presenter: Sonia Skarlatos, Ph.D., NHLBI, NIH, Bethesda, MD

