

**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