# Journal of Investigative Medicine November 2004 • volume 52 number 7

## CONTENTS

#### **JIM Interview**

Milton Packer, MD, Director, Center for Biostatistics and Clinical Science at UT Southwestern 421

#### **COMINGS AND GOINGS**

- University of South Florida Names Stephen Klasko Vice President for Health Sciences and Dean of the College 425 of Medicine
- 425 Dr. Markus Heilig Named NIAAA Clinical Director
- 426 Parisi Named Dean of UTMB School of Medicine
- James Willson, MD, Departs Ireland Cancer Center and Joins UT Southwestern 426
- Dr. Roland T. Skeel Named Interim Dean of Medical College of Ohio School of Medicine 427
- University of Alabama Health System Names David Hoidal, MD, CEO 427
- 428 James Scott Named Dean of George Washington University School of Medicine and Health Sciences
- Dr. Ora Pescovitz Named President and CEO of Riley Hospital for Children 428
- Gerald J. Pepe, PhD, Appointed Interim Dean and Provost of Eastern Virginia Medical School 429
- Ireland Cancer Center of University Hospitals Appoints Stanton Gerson, MD, as Director 429
- 430 William Martin, MD, Steps Down as Dean of the University of Cincinnati College of Medicine
- 430 Daniel D. Sedmak, MD, Georgetown Executive Vice President for Health Sciences, Resigns
- Gerald Moss, MD, Dean of University of Illinois at Chicago School of Medicine, Resigns 430

#### NEWS

- 431 National Institutes of Health Unveils Open Access Draft
- 431 Researchers Identify Better Hepatitis C Treatment for People with HIV
- 432 National Institutes of Health's ClinicalTrials.gov Web Site Wins Prestigious Award
- 432 NIH Awards \$19 Million to University of Alaska
- 433 Scientists Discover New Approaches to Manipulating AIDS Virus
- 433 Hiroshni Nikaido, MD, of University of California, Berkeley, Wins Bristol-Meyers Squibb Infectious Diseases **Research Award**
- 434 Fewer Drugs and Biologics Advancing from Phase I Trials to Marketplace
- 435 Dr. Michael Drake Fifth Recipient of the Herbert W. Nickens, MD Award
- 436 Location of Potential Familial Lung Cancer Gene Discovered
- 436 FDA to Establish New Cancer Office and Program to Improve Cancer Product News
- 437 New Database Focuses on Genetic Policy and Laws
- 437 Mouse Brain Cells Capable of Converting into Blood Vessel Cells
- 437 NIAID Expands West Nile Virus Treatment Trial
- 438 New Method Enables Researchers to Make Human Antibodies Quickly
- Fogarty International Center Announced Recipients of the Fogarty-Ellison Fellowship in Global Health and 439 **Clinical Research**
- Nucleic Acid Amplification Testing Further Safeguards Nation's Blood Supply 439
- Scientists Establish Database of Genes Associated with Cancer Drug Resistance 440
- Rare Mutations Can Significantly Increase Risk Factor for Heart Disease 441
- Thomas C. Südhof, MD, The University of Texas Southwestern Medical Center at Dallas, Wins Bristol-Myers 442 Squibb Neuroscience Research Award

### **SPECIAL SERIES:** Data and Safety Monitoring

- 443 Considerations in Developing Data and Safety Monitoring Plans: A Framework Deborah R. Zucker
- **446 Monitoring Participant Safety in Phase I and II Interventional Trials: Options and Controversies** *Patricia L. Hibberd, Debra L. Weiner*
- **453** Forming Your Phase III Trial's Data and Safety Monitoring Board: A Perspective on Safety Janet Wittes
- **459** Evaluating and Implementing Data and Safety Monitoring Plans Michael L. Terrin
- **464 Role of Research Subject Advocates in the Development of Data Safety and Monitoring Plans** *Ricardo A. Martinez*
- 466 A Worksheet to Aid in Developing a DSMP

#### **Original Investigations**

- **470** Clinical Experience with Drotrecogin Alfa in Treating Gram-Positive and -Negative Pathogens in Patients with Severe Sepsis Lawrence A. Cone, Richard A. Stone, Kenneth Jesser, Richard Nelson
- **475 Ectonucleotidase NTPDase2 Is Selectively Down-Regulated in Biliary Cirrhosis** Jonathan A. Dranoff, Emma A. Kruglov, Joahd Toure, Norbert Braun, Herbert Zimmermann, Dhanpat Jain, Aileen F. Knowles, Jean Sévigny

#### **Grants and Contracts**

- **483** Alzheimer's Disease Clinical Scientist Development Award: RFA-AG-05-003
- **484** Developing Interventions For Multiple Morbidities: RFA-AG-05-007
- **485** Health Disparities among Minority and Underserved Women: PA-04-153
- **486** Exploratory Grant Program In Diabetes, Endocrinology, And Metabolism: PA-04-137
- **487** Biodefense And Emerging Infectious Diseases Research Opportunities: PA-04-119
- **488** Prescription Drug Abuse: PA-04-110

