

# DHHS, FDA, NIH Locator

## Department of Health and Human Services

### Office for Human Research Protection

**Director**  
Position vacant (301) 435-7005

**Associate Director and Director, Division of Compliance Oversight**  
Michael Carome (301) 402-5567

**Deputy Director and Director, Office of International Activities**  
Melody Lin (301) 435-5647

**Director for Education**  
Jeffrey Cohen (301) 402-5552

**Director of Assurances and Quality Improvement**  
George Gasparis (301) 402-5164

## Food and Drug Administration

### Office of the FDA Commissioner

**Commissioner**  
Mark McClellan (301) 827-3310

**Deputy Commissioner**  
Lester Crawford (301) 827-3310

**Principal Associate Commissioner for International Activities & Strategic Initiatives**  
Murray Lumpkin (301) 827-3310

**Associate Commissioner for External Relations**  
Linda Skladany (301) 827-3330

**Associate Commissioner for Policy, Planning, and Legislation**  
William Hubbard (301) 827-3370

**Associate Commissioner for Management and Systems**  
Jeffrey Weber (301) 827-3443

**Associate Commissioner for Science for the Office of Science and Health Coordination**  
Norris Alderson (301) 827-3340

**Senior Advisor for Science**  
Bernard Schwetz (301) 827-2410

**Associate Director for Bioresearch Monitoring**  
Stan Woollen (301) 827-7318

**Associate Director for Human Subject Protection Policy**  
Bonnie Lee (301) 827-0415

**Chief Counsel**  
Daniel Troy (301) 827-1137

**Director, Office of Orphan Products Development**  
Marlene Haffner (301) 827-3666

**Director, Office of Women's Health**  
Susan Wood (301) 827-0350

**Chief Information Officer, Acting**  
Glenn Rogers (301) 827-4280

### Office of Regulatory Affairs

**Associate Commissioner for Regulatory Affairs**  
John Taylor (301) 827-3101

**Coordinator, Office of Enforcement, Bioresearch Monitoring Program**  
James McCormack (301) 827-0425

## Center for Devices and Radiological Health

**Director, David Feigal, Jr.** (301) 443-4690

**Director, Office of Device Evaluation**  
Daniel Schultz (301) 594-2022

**Director, Division of Bioresearch Monitoring**  
Charma Konnor (301) 594-4720

## National Center for Toxicological Research

**Acting Director**  
Daniel Casciano (870) 543-7517

## Center for Drug Evaluation & Research (CDER)

**Director**  
Janet Woodcock (301) 594-5400

**Deputy Director**  
Steven Galson (301) 594-5400

**Associate Director for Policy**  
Jane Axelrad (301) 594-5400

**Associate Director for Information Management**  
Randy Levin (301) 594-5411

**Associate Director for International Programs**  
Justina Molzon (301) 594-5400

**Ombudsman**  
James Morrison (301) 594-5443

**Director, Office of Executive Programs**  
Deborah Henderson (301) 594-6779

**Director, Office of Management**  
Russell Abbott (301) 594-6741

**Director, Office of Training and Communications**  
Nancy Smith (301) 827-1651

**Acting Director, Office of Information Technology**  
Patrick David (301) 827-6240

**Director, Office of Compliance**  
David Horowitz (301) 594-0054

**Director, Office of Counter-Terrorism and Pediatric Drug Development**  
Diane Murphy (301) 827-7777

### Office of Medical Policy

**Director**  
Robert Temple (301) 594-6758

**Director, Division of Scientific Investigations**  
Joanne Rhoades (301) 594-0020

**Deputy Director**  
Joseph Salewski (301) 594-0020

**Acting Chief, Good Clinical Practices Branch I**  
Khin U (301) 594-1026

**Chief, Good Clinical Practices Branch II**  
Antoine El-Hage (301) 594-1032

**Chief, GLP/Bioequivalence Investigations Branch**  
C.T. Viswanathan (301) 827-5460

**Director, Division of Drug Marketing, Advertising, and Communications**  
Thomas Abrams (301) 827-2828

### Office of New Drugs

**Director**  
John Jenkins (301) 594-5400

**Director, Office of Drug Evaluation I**  
Robert Temple (301) 594-3937

**Director, Office of Drug Evaluation II**  
Robert Meyer (301) 827-5920

**Director, Office of Drug Evaluation III**  
Florence Houn (301) 827-3144

**Director, Office of Drug Evaluation IV**  
Mark Goldberger (301) 827-2350

**Director, Office of Drug Evaluation V**  
Jonca Bull (301) 827-2250

### Office of Pharmaceutical Science

**Acting Director**  
Helen Winkle (301) 594-2847

**Deputy Director**  
Ajaz Hussain (301) 594-2847

**Director, Office of New Drug Chemistry**  
Yuan-Yuan Chiu (301) 827-5918

**Director, Office of Generic Drugs**  
Gary Buehler (301) 827-5845

**Director, Office of Clinical Pharmacology & Biopharmaceutics**  
Lawrence Lesko (301) 594-5690

**Acting Director, Office of Testing & Research**  
Moneb Nasr (301) 827-5917

## Office of Pharmacoepidemiology & Statistical Science

**Director**  
Paul Seligman (301) 827-6276

**Director, Office of Drug Safety**  
Victor Raczkowski (301) 827-3219

**Director, Office of Biostatistics**  
Robert O'Neill (301) 827-3195

## Center for Biologics Evaluation Research (CBER)

**Director**  
Kathryn Zoon (301) 827-0372

**Deputy Director for Operations**  
Mark Elengold (301) 827-0376

**Deputy Director for Medicine**  
Jesse Goodman (301) 435-5680

**Associate Director for Policy**  
Diane Maloney (301) 827-0373

**Associate Director for Research**  
Neil Goldman (301) 827-0377

**Associate Director for Medical & International Affairs**  
(vacant) (301) 827-0641

**Associate Director for Quality Assurance**  
Sheryl Lard-Whiteford (301) 827-0379

**Associate Director for Review Management**  
Robert Yetter (301) 827-0373

**Senior Policy Advisor & Counselor for Biologics**  
Jill Warner (301) 827-0372

**Director, Office of Biostatistics & Epidemiology**  
Susan Ellenberg (301) 827-3034

**Director, Office of Communication, Training, and Manufacturers Assistance**  
Mary Meyer (301) 827-2000

**Director, Office of Management**  
Joseph Biviano (301) 827-1320

**Director, Office of Information Technology Management**  
Michael Currie (301) 827-1368

**Director Office of Blood Research & Review**  
Jay Epstein (301) 827-3518

**Director Office of Vaccines Research & Review**  
Karen Midthun (301) 827-0655

**Director, Office of Cellular, Tissue and Gene Therapies**  
Philip Noguchi (301) 827-0680

**Director, Office of Therapeutics Research & Review**  
Jay Siegel (301) 827-5098

**Director, Division of Therapeutic Proteins**  
Amy Rosenberg (301) 827-1790

**Director, Division of Monoclonal Antibodies**  
Keith Webber (301) 827-0850

**Director, Division of Clinical Trial Design and Analysis**  
Karen Weiss (301) 827-5093

**Director, Division of Application Review and Policy**  
Glen Jones (301) 827-5099

**Director, Office of Compliance & Biologics Quality**  
Steven Masiello (301) 827-6190

**Director, Division of Inspections & Surveillance**  
Elaine Cole (301) 827-6220

**Chief, Bioresearch Monitoring Branch**  
Robert Leedham (301) 827-6350

Information current as of November 2002.

## Researchers Examine Voluntary Standards, FDA Faces Change

Jill Wechsler is the Washington editor of *Applied Clinical Trials*, (301) 656-4634.

This has been a year for analysis and consolidation in the human subjects research community. Congress held off enacting legislation mandating compliance with new protections for clinical trial participants in order to test whether new voluntary accreditation programs can ensure adherence to standards and regulations. The Institute of Medicine (IOM) issued a report last spring that encourages accreditation of biomedical research organizations, and followed up this fall with a hefty tome on developing "A Systems Approach to Protecting Research Participants." Independent organizations have established private accreditation programs for academic research centers, government agencies, and clinical trial sponsors as a first step in demonstrating that the research community can meet standards without government mandates.

The voluntary approach fits the preferences of the Bush administration and most entities involved in biomedical research. However, it has generated criticism from some subject advocates

that stronger action is needed to really manage conflicts of interest and improve subject consent practices. At the same time, scientists and researchers are concerned about signs of increased politicization of human research protection policies. The White House recently revised the charter of the HHS advisory committee on human research protections to extend such protections to embryos, a move that observers fear could open the door to new research standards.

Around the same time, Greg Koski, director of the HHS Office of Human

inspections of IRBs, clinical laboratories, sponsors, and investigators. They also are visiting clinical sites earlier in the clinical trial process, a change that reflects increased FDA attention to protecting the rights of study participants, in addition to the agency's traditional role of ensuring the quality of data submitted in market applications for new medical products. Similarly, FDA inspectors are scrutinizing IRBs more broadly and not just when an institution is involved in an application under review.

How FDA deals with clinical research issues may be shaped by major changes

## FDA finally has a new commissioner, former White House health policy advisor Mark McClellan.

Research Protections, decided to return to academe after two years on the job. Despite Koski's insistence that his move reflects personal needs, his departure has raised questions about HHS research policy. Congressional leaders say they will revisit clinical research policy in the coming year to see how well a voluntary approach may work.

BIMO (bioresearch monitoring) remains active, though less high-profile, at the Food and Drug Administration. Compliance officers are conducting more

at the agency. FDA finally has a new commissioner, former White House health policy advisor Mark McClellan. The agency is involved with major policy initiatives as it adopts more risk-based regulation and shifts oversight of biotech therapies in its drug review center. It also is struggling to implement new requirements of a revised user fee program. These changes will affect clinical study requirements, application review processes, and FDA staff assignments all around. □

## NIH Institutes, Centers, and Divisions

### Director

Elias Zerhouni  
(301) 496-2433

**Office of Extramural Research, Deputy Director**  
Wendy Baldwin  
(301) 496-1096

**Office of Intramural Research, Deputy Director**  
Michael M. Gottesman  
(301) 496-1921

**Office of Human Subjects Research (OHSR)**  
(301) 402-3444

**Office of Technology Transfer (OTT)**  
(301) 496-7057

**Office for Research on Women's Health (ORWH)**  
(301) 402-1770

**Office of AIDS Research (OAR)**  
(301) 496-0357

**National Cancer Institute (NCI)**  
(301) 435-3848

**National Eye Institute (NEI)**  
(301) 496-5248

**National Heart, Lung, and Blood Institute (NHLBI)**  
(301) 496-4236

**National Human Genome Research Institute (NHGRI)**  
(301) 402-0911

**National Institute on Aging (NIA)**  
(301) 496-1752

**National Institute on Alcohol Abuse and Alcoholism (NIAAA)**  
(301) 443-3860

**National Institute of Allergy and Infectious Diseases (NIAID)**  
(301) 496-5717

**National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)**  
(301) 496-8190

**National Institute of Biomedical Imaging and Bioengineering (NIBIB)**  
(301) 451-4246

**National Institute of Child Health and Human Development (NICHD)**  
(301) 496-5133

**National Institute on Deafness and Other Communication Disorders (NIDCD)**  
(301) 496-7243

**National Institute of Dental & Craniofacial Research (NIDCR)**  
(301) 496-4261

**National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**  
(301) 496-3583

**National Institute on Drug Abuse (NIDA)**  
(301) 443-1124

**National Institute of Environmental Health Sciences (NIEHS)**  
(919) 541-3345

**National Institute of General Medical Sciences (NIGMS)**  
(301) 496-7301

**National Institute of Mental Health (NIMH)**  
(301) 443-4513

**National Institute of Neurological Disorders and Stroke (NINDS)**  
(301) 496-5751

**National Institute of Nursing Research (NINR)**  
(301) 496-0207

**National Library of Medicine (NLM)**  
(301) 496-6308

**Warren Grant Magnuson Clinical Center (CC)**  
(301) 496-2563

**Center for Information Technology (CIT)**  
(301) 496-6203

**National Center for Complementary and Alternative Medicine (NCCAM)**  
(888) 644-6226

**National Center for Research Resources (NCRR)**  
(301) 435-0888

**National Center on Minority Health and Health Disparities (NCMHD)**  
(301) 435-3481

**John E. Fogarty International Center (FIC)**  
(301) 496-2075

**Visitor Information Center**  
(301) 496-1776