

**Jerry Alan Menikoff**  
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## **CURRENT POSITION**

### **Director**

Office for Human Research Protections  
Office of the Secretary  
Department of Health and Human Services

### **Bioethicist**

Adjunct Faculty  
Department of Bioethics  
National Institutes of Health

## **EDUCATION**

**M.D.** – 1982-1986

Washington University (St. Louis)

**M.P.P.** – 1973-1977

Kennedy School of Government  
Harvard University

**J.D.** – 1973-1977

Harvard Law School

**A.B.** – 1970-1973 (Mathematics)

Harvard College

## **POSTDOCTORAL TRAINING**

**Faculty Fellow, Program in Ethics and the Professions, 1995-1996**

Harvard University  
Cambridge, Massachusetts

**Resident in Ophthalmology, 1992-1995**

The New York Eye & Ear Infirmary  
New York, New York

**Roy and Sarita Warshawsky Fellow in Ethics, 1991-1992**

MacLean Center for Clinical Ethics

University of Chicago  
Chicago, Illinois

**Research Fellow in Ophthalmology, 1990-1991**

The New York Eye & Ear Infirmary  
New York, New York

**Transitional Internship, 1986-1987**

Deaconess Hospital  
St. Louis, Missouri

**PREVIOUS POSITIONS**

**Director, Office of Human Subjects Research, 2007-2008**

Office of the Director  
National Institutes of Health

**Associate Professor of Law, Ethics & Medicine, 2002-2009**

University of Kansas School of Medicine  
Kansas City, Kansas

**Associate Professor of Law, 2005-2009**

University of Kansas School of Law  
Lawrence, Kansas

**Assistant Professor of Law, Ethics & Medicine, 1997-2002**

University of Kansas School of Medicine  
Kansas City, Kansas

**Courtesy Assistant Professor of Law, 1997-2005**

University of Kansas School of Law  
Lawrence, Kansas

**Associate Professor, 1996-1997**

University of Akron, School of Law  
Akron, Ohio

**Lecturer in Law, 1991-1992**

University of Chicago School of Law  
Chicago, Illinois

**CURRENT BOARDS AND OTHER POSITIONS**

Member, Ethics Committee, International Council of Ophthalmology, 2010-present

Member, Board of Directors, American Society for Law, Medicine & Ethics, 2009-present

Member, Ethics Committee, American Board of Pediatrics, 2009-present

Executive Secretary, Secretary's Advisory Committee on Human Research Protections,  
Department of Health and Human Services, 2008-present

Member, Human Studies Review Board, 2006-present  
Environmental Protection Agency

Member, Board of Advisers, BNA Medical Research Law & Policy Report, 2006-present

### **PROFESSIONAL LICENSURE**

Medical licensure in New York and Kansas

Licensed as attorney in New York

### **PAST BOARDS AND OTHER POSITIONS**

Acting Co-Chair, Human Subjects Research Subcommittee, Committee on Science,  
Office of Science and Technology Policy, Executive Office of the President of the United  
States, 2008-2011

Member, Scholarly Activities Core Curriculum Examination Committee, 2007-2009  
American Board of Pediatrics

Executive Secretary, 2007-2008  
Human Subjects Research Advisory Committee  
National Institutes of Health

Member, Genome-Wide Association Studies Ad Hoc Working Group, 2007  
National Institutes of Health

Member, Trans NIH Bioethics Committee, 2007-2008  
National Institutes of Health

Member, GWAS Policy Implementation Committee, 2007  
National Institutes of Health

Chair, Human Subjects Committee, 1998-2007  
University of Kansas Medical Center

Chair, Hospital Ethics Committee, 1998-2007  
University of Kansas Hospital

Medical Director for Ethics, 2000-2006  
University of Kansas Hospital

Member, Human Subjects Committee, 1997-1998  
University of Kansas Medical Center

Director and Founder, Ethics Program, 1991-1992  
Oak Forest Hospital  
Oak Forest, Illinois

### **AWARDS AND HONORS**

*Law and Bioethics*, now in second printing, selected in 2002 by Association of American University Presses as one of "The Best of the Best from the University Presses: Books You Should Know About"

"The Myth and Reality of Informed Consent to Research" chosen as finalist for the University of Southern California's 2002 Mark S. Ehrenreich Prize in Healthcare Ethics Research

Invited Presenter at final (July, 2002) meeting of the federal National Human Research Protections Advisory Committee (NHRPAC)

Special Expert (one of four participating ethics experts) for federal Office for Human Research Protections (OHRP), June 2003, as part of panel assembled for evaluation of dispute regarding NIH-funded ARDS Network studies (see Jeffrey M. Drazen, Controlling Research Trials, *N. Engl. J. Med.* 2003;348:1377-80; Robert Steinbrook, How Best to Ventilate? Trial Design and Patient Safety in Studies of the Acute Respiratory Distress Syndrome, *N. Engl. J. Med.* 2003;348:1393-1401)

Member of OHRP team during site visits to universities in February 2004, February 2005, and March 2007

Testified as expert witness on medical ethics issue in appeal of federal death penalty conviction for multiple homicide by member of U.S. military. March 2005

Invited Participant in Definition of Death Working Group for United Network for Organ Sharing (UNOS), A National Donation after Cardiac Death Consensus Conference, April 7-8, 2005, Philadelphia

Invited Expert, Expert Panel Workshop on State-of-the-Science Approaches for Observational Exposure Measurement Studies, Environmental Protection Agency, November 28-29, 2006, Durham, North Carolina

“Where’s the Law? Uncovering the Truth about IRBs and Censorship,” made Top Ten download lists on Social Science Research Network (SSRN) lists for Health Law Journals, Public Health Law & Policy, Telecommunications & Regulated Industries, and Labor: Human Capital, March 2007

NIH Director’s Award, July, 2008

NIH Clinical Center Director’s Award, December 2008

## **PUBLICATIONS**

### **BOOKS**

Menikoff J. Law and Bioethics: An Introduction (Washington, D.C.: Georgetown University Press 2001, with Teacher’s Manual)

Coleman C, Menikoff J, Goldner J, Dubler N. The Ethics and Regulation of Research with Human Subjects. (LexisNexis 2005)

Coleman C, Menikoff J, Goldner J, Dubler N. Teacher’s Manual for The Ethics and Regulation of Research with Human Subjects (LexisNexis 2005)

Menikoff J, with Richards E. What the Doctor Didn’t Say: The Hidden Truth about Medical Research (New York: Oxford University Press 2006)

### **JOURNAL ARTICLES**

Emanuel EJ, Menikoff J. Reforming the Regulations Governing Research with Human Subjects. *N Engl J Med* 2011;365:1145

Millum J, Menikoff J. Streamlining Ethical Review. *Ann Intern Med* 2010;153:655

Menikoff J. Making Research Consent Transparent. *JAMA* 2010;304:1713

Menikoff J. The Paradoxical Problem with Multiple-IRB Review. *N Engl J Med* 2010;363:1591

Menikoff J. Void for Vagueness: A Problem in Research Consent? *Circ Cardiovasc Qual Outcomes* 2010;3:116

Menikoff J. The Vulnerability of the Very Sick. *Journal of Law, Medicine and Ethics* 2009;37:51

Menikoff J. Could Tuskegee Happen Today? *Saint Louis University Journal of Health Law and Policy* 2008;1:311

Menikoff, J. Beyond *Abigail Alliance*: The Reality behind the Right to Get Experimental Drugs. *Kansas Law Review* 2008;56:1045

Emanuel E, Grady C, Menikoff J. Case Study: Is Longer Always Better? *Hastings Center Report* 2008;38(3):10

Menikoff J. Toward a General Theory of Research Ethics. *Hastings Center Report* 2007;37(3):3

Menikoff J. Cutting into the Spongy Belly of Surgical Innovation. *IRB* 2007;29(1):19

Menikoff J. Where's the Law? Uncovering the Truth about IRBs and Censorship. *Northwestern University Law Review* 2007;101:791

Menikoff, J. (Too) Much Ado About the Ethics of Less-than-Universal Access to Health Care? *Kansas Law Review* 2007;55:1273

Menikoff J. How Being a Research Subject Differs from Being a Patient—And Why We Should Care. *American Bar Association Focus on Law Studies* 2006;XXII(1):2

Menikoff J. Obtaining Research Consent: What Tort Law Can Teach Us. *Research Practitioner* 2006;7:159

Menikoff J. Less Bull, Better Bioethics. *DePaul Journal of Health Care Law* 2005;9:1133

Menikoff J. Of Babies, Bugs and Bombast: A Look Behind the Crash-and-Burn of the CHEERS Pesticide Study. *Medical Research Law & Policy Review (BNA)* 2005;4:586

Menikoff J. Full Disclosure: Telling Patients When *Not* Being a Research Subject is a Good Choice. *Perspectives in Biology and Medicine* 2005;48:S139

Menikoff J. An Organ Sale by Any Other Name (Commentary). *American Journal of Bioethics* 2004;4:42

Menikoff J. The Involuntary Research Subject. *Cambridge Quarterly of Healthcare Ethics* 2004;13:338

Walling A, Montello M, Moser SE, Menikoff JA, Brink M. Which Patients Are Most Challenging for Second-year Medical Students? *Family Medicine* 2004;36:710

Menikoff J. Equipoise: Beyond Rehabilitation? *Kennedy Institute of Ethics Journal* 2003;13(4):347

Menikoff J. The Hidden Alternative: Getting Investigational Treatments Off-Study. *Lancet* 2003;361:63

Menikoff J. Why Being Alive Matters (Commentary). *American Journal of Bioethics* 2003;3:21

Marshall MF, Menikoff J. Emerging Data on IRB Members and Potential Financial Conflicts of Interest: More Questions Than Answers. *Medical Research Law & Policy Review (BNA)* 2003;2(17):646

Marshall MF, Menikoff J, Paltrow LM. Perinatal Substance Abuse and Human Subjects Research: Are Privacy Protections Adequate? *Mental Retardation and Developmental Disabilities Research Reviews* 2003;9:54

Menikoff J. The Importance of Being Dead: Non-Heart-Beating Organ Donation. *Issues in Law and Medicine* 2002;18:3

Menikoff J. Physicians Have Mandate to Follow Organ Donation Wishes. *Ethics Forum, American Medical News*, April 2, 2001.

Menikoff J. To Tell or Not to Tell: Mandating Disclosure of Genetic Testing Results (Commentary). *American Journal of Bioethics* 2001;1:19

Menikoff J. Just Compensation: Paying Research Subjects Relative to the Risk They Bear (Commentary). *American Journal of Bioethics* 2001;1:56

Dalglis et al., A Discussion of Ownership of Tissue Samples and Exculpatory Language in Informed Consent Documents. A lead discussant in publication of excerpts from discussion on internet IRB Discussion Forum. *Research Practitioner* 2000;1:119

Fost N, Menikoff J. Ethics Module for the *National Health Service Corps Educational Program for Clinical and Community Issues in Primary Care* (revision by Menikoff of work initially written by Norman Fost) (1999).

Menikoff J. Demanded Medical Care. *Arizona State Law Journal* 1998;30:1091

Menikoff J. Organ Swapping. *Hastings Center Report* 1999;29(6):28

Menikoff J. Doubts About Death: The Silence of the Institute of Medicine. *Journal of Law Medicine & Ethics* 1998;26:157 (with reply by Potts, Herdman, Beauchamp & Robertson).

Menikoff J. Ethics, Law and Managed Care: The Role of the Physician in Cost Control. *Ophth Clin of North America*. 1997;10(2):191-5

Menikoff J. Persistent Brain Death. (letter) *J. Law Medicine & Ethics* 1996;24:76

Speaker MG, Menikoff JA. Postoperative Endophthalmitis: Pathogenesis, Prophylaxis and Management. *Int Ophth Clin.* 1993;33:51-70

Menikoff J. Is Informed Consent Needed for Fluorescein Angiography? (letter) *Arch Ophthalmol.* 1993;111:1604

Raskin EM, Speaker MG, McCormick SA, Wong D, Menikoff JA, Pelton-Henrion K. Influence of Haptic Materials on the Adherence of Staphylococci to Intraocular Lenses. *Arch Ophthalmol.* 1993;111:250-253

Menikoff JA, Sachs GA, Siegler M. Beyond Advance Directives: Health Care Surrogate Laws. *N Engl J Med.* 1992;327:1165-1169

Speaker MG, Menikoff JA. Prophylaxis of Postoperative Endophthalmitis with Topical Povidone-iodine. *Ophthalmology.* 1991;98:1769-1775

Menikoff JA, Speaker MG, Marmor M, Raskin EM. A Case-Control Study of Risk Factors for Post-operative Endophthalmitis. *Ophthalmology.* 1991;98:1761-1768

Bittker, BI, Menikoff J. Restructuring Business Transactions for Federal Income Tax Purposes, in Bittker, BI, Collected Legal Essays (1990). Originally appeared in *Wis. L. Rev.* 1978;1978:715

Menikoff J. Initial Drafter of Par. 4.4 of Bittker BI, Lokken L, 1 Federal Taxation of Income, Estates & Gifts (2d Ed. 1989); edited/reviewed various other sections of Volumes 1 and 2.

## **NAMED LECTURES**

Seventeenth Annual Reverend Edward J. Drummond S.J. Lecture in Health Care Ethics at Saint Louis University, April 2002