

**CARL H. COLEMAN**  
**Professor of Law**  
**Seton Hall Law School**  
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## **EDUCATION**

**HARVARD LAW SCHOOL**, J.D., *magna cum laude*, June 1990; Supervising Editor, *Harvard Law Review*

**HARVARD UNIVERSITY**, A.M., East Asian Studies, June 1990

**GEORGETOWN UNIVERSITY**, B.S.F.S., *cum laude*, International Affairs, Certificate in Asian Studies, May 1986

**NATIONAL TAIWAN NORMAL UNIVERSITY**, Taipei, Taiwan, intensive Chinese language program, August 1984-May 1985

## **EMPLOYMENT**

**SETON HALL UNIVERSITY SCHOOL OF LAW**, Newark, NJ

*Professor of Law* (Fall 2005-present); *Associate Professor of Law* (Fall 2000-Spring 2005)

Courses Taught: Health Law; Public Health Law; Clinical Research and the Law; International Human Rights Law; European Union Law; Torts

Academic Director, [Division of Online Learning](#)

Core Faculty Member, [European Healthcare Compliance Program](#), (4-day, semiannual training program co-sponsored with Sciences Po, Paris, France)

Co-Director, [Executive Course in Intellectual Property, Diplomacy, and Global Public Health](#) (3-day executive course co-sponsored with the Graduate Institute of International and Development Studies, Geneva, Switzerland) (2011-2013)

Faculty Director, [European and Global Law Program](#) (summer program in Leuven, Belgium and Geneva, Switzerland) and [Chamonix-Geneva Program in International Human Rights Law](#) (winter intersession program in Chamonix, France and Geneva, Switzerland) (2010-2013)

Awarded the Andrea J. Catania Fellowship for Excellence in Teaching (2007-2009)

**SCIENCES PO**, Reims, France

*Professeur vacataire* (Fall 2014 and Fall 2015)

Course Taught: Global Public Health Law

**UNIVERSITÉ DE CERGY-PONTOISE**, Cergy-Pontoise, France

*Visiting Professor* (Fall 2013)

Course Taught: Pharmaceutical and Medical Device Law and Compliance

**WORLD HEALTH ORGANIZATION**, Geneva, Switzerland

*Bioethics and Law Adviser* (2006-07); *Consultant* (2007-present)

Lead author of the following publications: [Guidance on Managing Ethical Issues in Epidemic Outbreaks](#); [Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants](#), [Ethics of Tuberculosis Prevention, Care, and Control](#), [Research Ethics Committees: Basic Concepts for Capacity-Building](#), [Research Ethics in International Epidemic Response](#), and [Ethical Considerations in Developing a Public Health Response to Pandemic Influenza](#). Course director, *Legislation for Clinical Trials* (3-day course offered to regulators and research ethics committee members in developing countries)

**NEW YORK STATE TASK FORCE ON LIFE AND THE LAW**, New York, NY

**Executive Director** (Fall 1995-Spring 2000) — Directed nationally recognized interdisciplinary commission with mandate to develop legislative and regulatory responses to issues raised by medical advances. Responsibilities included designing projects, soliciting public and professional input, planning and running commission meetings, overseeing staff research, writing and editing reports, drafting proposed legislation and regulations, interacting with government officials, representing the Task Force in the media and before diverse public and professional audiences, and raising funds to support the Task Force's work. Secured grants totaling nearly \$2 million from the National Institutes of Health, the Robert Wood Johnson Foundation, the Ford Foundation, the Greenwall Foundation, and the Fan Fox and Leslie R. Samuels Foundation.

**Counsel** (Summer 1993-Fall 1995) — Advised Task Force on legal aspects of policy issues, wrote sections of Task Force reports, and contributed to development of legislative proposals.

**LEVENTHAL SLADE & KRANTZ**, New York, NY (formerly known as Meister Leventhal & Slade)

**Associate** (September 1991-June 1993) — Involved in all stages of trial and appellate litigation, including investigating facts, drafting pleadings, briefs and other documents, appearing in court, and counseling clients. Practice focused on employment discrimination and commercial litigation.

**HON. JAMES L. OAKES**, Chief Judge, U.S. Court of Appeals, Second Circuit, Brattleboro VT

**Law Clerk** (Summer 1990-Summer 1991) — Prepared bench memos and drafted opinions for chief judge of federal appellate court.

**PAUL, WEISS, RIFKIND, WHARTON & GARRISON**, New York, NY and Shanghai, China

**Summer Associate** (Shanghai, Summer 1988; New York, Summer 1989)

## **OTHER PROFESSIONAL ACTIVITIES**

Health Law Section co-editor, [Jotwell](#)

Occasional blogger, [Health Reform Watch](#); [HealthLawProf](#)

Member, [Secretary's Advisory Committee on Human Research Protections](#) (SACHRP), U.S. Department of Health & Human Services (March 2010-March 2013)

Visiting Scholar, Brocher Foundation, Hermance, Switzerland (Winter 2010)

Peer reviewer for Yale University Press; Cambridge University Press; New England Journal of Medicine; Journal of Law, Medicine & Ethics; American Journal of Bioethics; Milbank Quarterly; IRB: Ethics and Human Research; Public Health Ethics; International Review of Law and Economics; Journal of Empirical Issues in Human Research Ethics; Kennedy Institute of Ethics Journal; Journal of Law and the Biosciences; Empirical Bioethics; BMC Health Services Research; Hastings Center Report; Journal of Medical Ethics; American Journal of Law & Medicine; Health & Human Rights Journal

Member, Institutional Review Board, Seton Hall University (Fall 2003-Spring 2006); University of Medicine and Dentistry of New Jersey (Fall 2001-Spring 2003)

Member, Steering Committee, Family Health Decisions Coalition (Fall 2001-Winter 2010)

Member, New York State Bar Association (Spring 2001-Spring 2004)

Member, Health Law Section Executive Committee (Fall 2002-Spring 2004)

Co-Chair, Committee on Ethical Issues in the Provision of Health Care (Fall 2002-Spring 2004)

Chair, Special Committee on Treatment Decisions (Spring 2001-Spring 2002)

Member, Association of the Bar of the City of New York (Fall 1993-Spring 2000)

Member, Committee on Health Law (Fall 1999-Spring 2000)

Member, Committee on Bioethical Issues (Fall 1996-Spring 1999); Legislative Liaison (Fall 1996-Spring 1998)

Member, Committee on Legal Problems of the Aging (Fall 1993-Spring 1996); Chair, Subcommittee on Patient Self-Determination (Fall 1993-Spring 1995)

Member, Lesbian & Gay Law Association of New York (Fall 2005-Spring 2009)

Core Faculty, Certificate Program in the Ethics and Regulation of Research with Human Subjects, Montefiore Medical Center/Albert Einstein College of Medicine and New York University Division of Nursing (Spring 2003)

Member, Advisory Committee, Initiative to Improve the Effectiveness of Health Care Agents (Fall 1998-Spring 2001)

Member, Attorney General's Commission on Quality Care at the End of Life (April 1997-August 1998)

Admitted to practice in New York State; U.S. Supreme Court; U.S. Court of Appeals, Second Circuit; U.S. District Court (SDNY, EDNY)

## **PUBLICATIONS**

### **BOOK**

[THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS, 2D EDITION](#) (Carolina Academic Press, 2015) (with Jerry A. Menikoff, Jesse A. Goldner & Efthimios Paradisis)

### **ARTICLES**

[What Makes IRBs Tick? An Empirical Analysis of IRBs and Their Relationship to Researchers](#) (review of Robert Klitzman, THE ETHICS POLICE?), IRB: ETHICS & HUMAN RESEARCH, Sept.-Oct. 2016, at 19.

[Control Groups on Trial: The Ethics of Testing Experimental Ebola Treatments](#), 7 J. BIOSECURITY, BIOSAFETY & BIODEFENSE L. 3 (2016)

*Avoiding Unintentional Whistleblower Retaliation: Lessons from Haliburton v. Administrative Review Board*, REVUE INTERNATIONALE DE LA COMPLIANCE ET DE L'ETHIQUE DES AFFAIRES, at 35 (April 2015)

[Improving the Quality of Host Country Ethical Oversight of International Research: The Use of a Collaborative 'Pre-Review' Mechanisms for a Study of Fexinidazole for Human African Trypanosomiasis](#), DEVELOPING WORLD BIOETHICS (July 2014) (on behalf of the International Ethics Review Working Group)

*Attorneys as False Claims Act Whistleblowers: The Second Circuit Weighs In*, REVUE INTERNATIONALE DE LA COMPLIANCE ET DE L'ETHIQUE DES AFFAIRES, at 26 (December 2013)

[Toward Evidence-Based Conflicts of Interest Training for Physician-Investigators](#), 40 J.L. MED. & ETHICS 500 (2012) (with Kate Greenwood and Kathleen M. Boozang)

[The Role of Informed Consent in Tuberculosis Testing and Screening](#), 39 EUROPEAN RESPIRATORY J. 1057-59 (2012) (with Michael J. Selgelid, Andreas Reis, Lee B. Reichman, & Ernesto Jaramillo)

[An Argument against Embedding Conflicts of Interest Disclosures in Informed Consent](#), J. HEALTH & LIFE SCIENCES L., 230-267 (June 2011) (with Kathleen M. Boozang and Kate Greenwood)

[Allocating Vaccines and Antiviral Medications during an Influenza Pandemic](#), 39 SETON HALL L. REV. 1111 (2009)

[Do Physicians' Legal Duties Conflict with Public Health Values? The Case of Antibiotic Overprescription](#), 6 J. BIOETHICAL INQUIRY 181 (2009)

[Vulnerability as a Regulatory Category in Human Subject Research](#), 37 J.L. MED. & ETHICS 12 (2009)

[Beyond the Call of Duty: Compelling Health Care Professionals to Work During an Influenza Pandemic](#), 94 IOWA L. REV. 1 (2008)

[Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment](#), 83 IND. L.J. 743 (2008)

[The Contribution of Ethics to Public Health](#), 86 BULLETIN OF THE WORLD HEALTH ORG. 578 (2008) (with Marie-Charlotte Bouésseau & Andreas Reis)

[How Do We Know That Research Ethics Committees Are Really Working? The Neglected Role of Outcomes Assessment in Research Ethics Review](#), 9 BMC MED. ETHICS 6 (2008) (with Marie-Charlotte Bouésseau)

[Potential Penalties for Health Care Professionals Who Refuse to Work During a Pandemic](#), 299 JAMA 1471 (2008) (with Andreas Reis)

[Duties to Subjects in Clinical Research](#), 58 VAND. L. REV. 387 (2005)

[Rationalizing Risk Assessment in Human Subject Research](#), 46 ARIZ. L. REV. 1 (2004)

[Why Have IRBs at All? A Reply to Noah](#), 25 J. LEGAL MED. (2004) (response to article by Lars Noah)

[HIV, ARTs, and the ADA](#), AM. J. BIOETHICS, Winter 2003, at 43 (short commentary on article by Mark Sauer)

[Conceiving Harm: Disability Discrimination in Assisted Reproductive Technologies](#), 50 UCLA L. REV. 17 (2002)

[Assisted Reproductive Technologies and the Constitution](#), 30 FORDHAM URB. L.J. 57 (2002)

[The “Disparate Impact” Argument Reconsidered: Making Room for Justice in the Assisted Suicide Debate](#), 30 J. L. MED. & ETHICS 17 (2002) (commentary on article by Ronald Lindsay)

*Closing the Gaps in Genetics Legislation and Policy: A Report by the New York State Task Force on Life and the Law*, 5 GENETIC TESTING 275 (2001) (with Ann M. Carroll)

[Is There a Constitutional Right to Preconception Sex Selection?](#) AM. J. BIOETHICS, Winter 2001, at 27 (commentary on article by John Robertson), excerpted in JUDITH DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW (Lexis 2006)

*Developing Public Policy on Assisted Reproductive Technologies: Reflections on the Work of the New York State Task Force on Life and the Law*, 73 FERTILITY & STERILITY 21 (2000) (with Barbara A. DeBuono)

[Procreative Liberty and Contemporaneous Choice: An Inalienable Rights Approach to Frozen Embryo Disputes](#), 84 MINN. L. REV. 55 (1999)

*Treatment Decisions for Patients without Surrogates: Rethinking Policies for a Vulnerable Population*, 45 J. AM. GERIATRICS SOC’Y 369 (1997) (with Tracy E. Miller & Anna Maria Cugliari)

[Guidelines for Physician-Assisted Suicide: Can the Challenge Be Met?](#) 24 J. L. MED. & ETHICS 217 (1996) (with Alan R. Fleischman)

[Stemming the Tide: Assisted Suicide and the Constitution](#), 23 J. L. MED. & ETHICS 389 (1995) (with Tracy E. Miller); reprinted in PHYSICIAN-ASSISTED SUICIDE (Greenhaven Press, 1997)

*Developments in the Law — Sexual Orientation and the Law*, 102 HARV. L. REV. 1508, 1554-84 (1989) (primary author of section on employment law); reprinted as a book, [SEXUAL ORIENTATION AND THE LAW](#) (Harvard University Press 1990)

## **BOOK CHAPTERS**

*Informed Consent: Collection of Data and Biological Specimens*, in [ETHICS IN RESEARCH, SURVEILLANCE, AND PATIENT CARE IN EPIDEMICS, EMERGENCIES, AND DISASTERS](#) (World Health Organization 2015)

[\*The Common Rule: US Regulatory Protections for Human Research Participants\*](#), in INTERNATIONAL ENCYCLOPEDIA OF SOCIAL & BEHAVIORAL SCIENCES, 2D ED. (2015)

*International Issues*, in [FUNDAMENTALS OF LIFE SCIENCES LAW: DRUGS, DEVICES, AND BIOTECH, 2D ED.](#) (American Health Lawyers Association 2014) (with Simone Handler-Hutchinson)

*End-of-Life Treatment Decisions in United States Law*, in Stefania Negri ed., [SELF-DETERMINATION, DIGNITY AND END-OF-LIFE CARE: REGULATING ADVANCE DIRECTIVES IN INTERNATIONAL AND COMPARATIVE PERSPECTIVE](#) (2012)

*Assisted Reproductive Technologies*, in JAMES J. PONZETTI ET AL. ED., [INTERNATIONAL ENCYCLOPEDIA OF MARRIAGE AND FAMILY](#) 2D ED. (2002)

*Decision Making for Residents Without Surrogates*, in MATHY D. MEZEY & NANCY NEVELOFF DUBLER EDS., [VOICES OF DECISION IN NURSING HOMES: RESPECTING RESIDENTS' PREFERENCES FOR END-OF-LIFE CARE](#) 65 (2001) (with Michele Petruzzelli)

**REPORTS OF THE SETON HALL CENTER FOR HEALTH & PHARMACEUTICAL LAW & POLICY**  
[ETHICAL CONSIDERATIONS IN SELLING PHARMACEUTICALS IN EMERGING ECONOMIES](#) (2017) (primary author)

[THE LIMITS OF DISCLOSURE AS A RESPONSE TO FINANCIAL CONFLICTS OF INTEREST IN CLINICAL RESEARCH](#) (2010) (collaborator)

[CONFLICTS OF INTEREST IN CLINICAL TRIAL RECRUITMENT & ENROLLMENT: A CALL FOR INCREASED OVERSIGHT](#) (2009) (collaborator)

**REPORTS OF THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW**  
[GENETIC TESTING AND SCREENING IN THE AGE OF GENOMIC MEDICINE](#) (2000) (editor-in-chief)

[ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATIONS FOR PUBLIC POLICY](#) (1998) (editor-in-chief; primary author of selected chapters)

[WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT, SUPPLEMENT TO REPORT](#) (1997) (primary author); excerpts reprinted in JOHN D. ARRAS AND BONNIE STEINBOCK EDS., ETHICAL ISSUES IN MODERN MEDICINE, 5TH ED. (Mayfield Press, 1998)

[WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT](#) (1994) (primary author of chapter on legal issues)

#### **ONLINE COMMENTARIES**

[\*Strengthening Local Review of Research in Africa: Is The IRB Model Relevant?\*](#) [BIOETHICS FORUM](#), December 22, 2006 (with Marie-Charlotte Bouésseau)

[\*End-of-Life Decision-Making and the Politics of the Fetus\*](#), [BIOETHICS FORUM](#), July 26, 2006

#### **SELECTED PRESENTATIONS**

American Society of Law, Medicine & Ethics Health Law Professors Conference, Atlanta, Georgia (June 2017), “Ethical Considerations in Selling Pharmaceuticals in Emerging Economies”

13<sup>th</sup> World Congress of Bioethics, Edinburgh, Scotland (June 2016), “Managing Ethical Issues in Epidemic Outbreaks”

American Society of Law, Medicine & Ethics Health Law Professors Conference, Boston, Massachusetts (June 2016), “Regulating Physician Speech”

Drugs for Neglected Diseases Initiative, Geneva, Switzerland (May 2016), “The International Regulatory Environment Governing Biospecimen Research: Considerations for Developing Drugs for Neglected Diseases”

University of Toronto School of Law, Toronto, Canada (March 2016), “Regulating Physician Speech”

University of Toronto Joint Centre for Bioethics, Toronto, Canada (March 2016), “Ethical Issues in Clinical Trial Designs for Ebola Treatment and Prevention: Reflections on Studies Conducted in 2015”

Association of American Law Schools, Washington, D.C. (January 2015), “Control Groups on Trial”

African Vaccine Regulatory Forum, Entebbe, Uganda (August 2014), “Developing Research Ethics Committee Indicators”

Sciences Po, Paris, France (November 2013), “Follow the Money: A Sampling of European Healthcare Reimbursement and Delivery Programs”

University of Toronto Joint Centre for Bioethics, Toronto, Canada (July 2013), “Quality Indicators for Research Ethics Systems”

American Society of Law, Medicine & Ethics Health Law Professors Conference, Newark, New Jersey (June 2013), “Measuring IRB Effectiveness”

International Pharmaceutical Compliance Conference and Best Practices Forum, Madrid, Spain (May 2013), “Compliance as a Profession”

The Graduate Institute, Geneva, Switzerland (February 2013), “Intellectual Property and Global Public Health”

International Society of Healthcare Ethics and Compliance, Paris, France (September 2012), “Models of Ethical Compliance”

Bocconi University School of Management, Milan, Italy (May 2012), “Ethics as a Global Health Challenge”

World Health Organization Workshops on the Ethics of Tuberculosis Prevention, Care, and Control, Baku, Azerbaijan, (December 2011) and Beijing, China (June 2011), “Ethical and Legal Aspects of Public Health Measures in TB Care and Control”

World Health Organization Task Force on Cholera Control, Geneva, Switzerland (May 2011), “Ethical Considerations Related to Oral Cholera Use in Large-Scale Humanitarian Crises”

Seton Hall Law School, Newark, New Jersey (March 2011), “Financial Conflicts of Interest in Medical Research” (March 2011)

European Healthcare Compliance Ethics and Regulation Program, Paris, France (February 2011), “Lessons from U.S. Healthcare Fraud and Abuse Enforcement and Compliance Programs”

Forum for Ethical Review Committees in Asia and the Western Pacific, Shanghai, China (November 2010), “Assessing the Outcomes of Research Ethics Review”

University of Heidelberg Institute of Public Health, Heidelberg, Germany (September 2010), “Ethics and Global Public Health”

World Health Organization Consultation on Norms and Standards for Research Ethics Committees, Geneva, Switzerland (November 2009), “Assessing the Outcomes of Research Ethics Review”

International Consultative Workshop on DR-TB and the HIV/AIDS Crisis in the Southern Africa Region, Manzini Swaziland (October 2009), “Ethical Issues in the Management of Drug-Resistant TB”

World Health Organization Guidelines Committee on Infant and Young Child Feeding the Context of HIV, Geneva, Switzerland (October 2009), “The Role of Directive Counseling in HIV Infant Feeding Programs”

American Society for Reproductive Medicine, San Francisco, CA (November 2008), “ART and the HIV-Discordant Couple”

American Public Health Association, San Diego, CA (October 2008), “Ethical Issues in Pandemic Influenza Planning and Response: The Activities of WHO” (with Andreas Reis)

International Association of Bioethics, Rijeka, Croatia (September 2008), “Addressing Ethical Issues in Pandemic Preparedness: National Efforts, WHO Guidance, and Future Directions” (with Andreas Reis)

International Pharmaceutical Regulatory and Compliance Congress, Paris, France (May 2008), “Ethical Issues in Clinical Trials in Developing Countries”

Columbia University Center for Women’s Reproductive Care, Distinguished Guest Lecturer (April 2008), “Assisted Reproductive Technologies and Family Law”

Food and Drug Law Institute, Washington, D.C. (March 2008), “Ethical Issues in Representing Sponsors of Clinical Trials”

Ethics and Infectious Disease, Oxford University (July 2007), “The Role of Law in Limiting the Over-prescription of Antibiotics”

11<sup>th</sup> Futures Forum, Copenhagen, Denmark (June 2007), “Ethical Issues in Pandemic Preparedness”

9<sup>th</sup> Global Forum on Bioethics in Research, Vilnius, Lithuania (June 2007), “Quality Assurance for Research Ethics Committees”

University of Geneva, Institute of Graduate Studies (June 2007), “Ethics and Global Health Diplomacy”

European Network of Excellence Clinigene/Consert Think Tank (April 2007), “Overseeing Human Gene Therapy: Is The IRB Model Appropriate?”

University of Zurich Institute of Biomedical Ethics (March 2007), “Rethinking the Process of Research Ethics Review”

University of Ibadan, Nigeria (February 2007), “Strengthening Research Ethics Committees in Africa”

Brooklyn Law School, David G. Trager Public Policy Symposium (February 2007), “End-of-Life Decision-Making: U.S. Perspectives”

Italian Senate Health Law Committee (November 2006), Testimony on Proposed Legislation on End-of-Life Decision-Making

American Society of Law, Medicine & Ethics Health Law Teachers’ Conference (June 2006), “Surrogate Decision-Making in Medical Research”

New York State Assembly Health Committee (December 2005), Testimony in Support of the Family Health Care Decisions Act

National Association of Women Judges (October 2004), “Frozen Embryos in the Courts”

New York State Judicial Institute (June 2004), “Human Subject Research and the Law”

Human Biotechnology Governance Forum, Johns Hopkins University School of Advanced International Studies (May 2004), “Regulatory Models for Reproductive Technologies”

Serono Symposia International (April 2004), “Legal and Ethical Issues Surrounding HIV and Women”

New York Academy of Medicine Conference on Dementia Research (March 2004), “Legal and Ethical Challenges in Dementia Research”

Albany Law School (November 2003), “Informed Consent to Clinical Trials”

American Society of Bioethics and the Humanities (October 2003), “Human Subject Research and the Courts”

Fordham Law School, Symposium on Religious Values and Legal Dilemmas in Bioethics (January 2002), “Assisted Reproductive Technologies and the Constitution”

National Academy of Sciences, Institute of Medicine, Board on Health Sciences Policy (June 2000), “Assisted Reproductive Technologies and Public Policy”

Fordham Law School (April 2000), “The Culture of Death in America”

Long Island University (November 1998), Keynote speaker at conference, “Good Dying: Is it Possible?”

American Society of Law, Medicine, & Ethics/Gerontological Society of America (November 1998), “The Person Who Lacks a Surrogate”

St. John’s University School of Law (April 1997), “Assisted Suicide: Private Acts and Public Policy”

American Medical Association, Conference on State Legislation (January 1997), “Legislation on Assisted Suicide”

Association of the Bar of the City of New York (February 1996), “Confidentiality and Genetic Testing”

End-Stage Renal Disease Network (October 1995), “Starting and Stopping Dialysis: Ethical and Legal Considerations”

White House Conference on Aging and Developmental Disabilities (January 1995), “Treatment Decisions for Developmentally Disabled Patients”

## **LANGUAGES**

English (native speaker); French (professional working proficiency)