FRANKLIN G. MILLER, Ph.D.

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EDUCATION

1977 Columbia University, Ph.D. in philosophy.
Dissertation: *A Theory of Political Obligation*,
an inquiry into the grounds for a moral obligation to obey the law;
awarded Distinction.
Specialized in ethics and political philosophy.

1971 Columbia College, B.A., majored in philosophy.

PROFESSIONAL EXPERIENCE

Current Position

2014- Professor of Medical Ethics in Medicine (Courtesy) Weill Cornell Medical College

2015- Adjunct Faculty, Department of Bioethics, National Institutes of Health

Previous Position

1999-2015 Senior faculty, Department of Bioethics, National Institutes of Health; special expert Intramural Research Program, National Institute of Mental Health.

Teaching

2001-2003 Bioethics seminar for Faculty Associates, Division of Medical Ethics, Cornell University Medical School

June 2001, June 2007 Small group leader, Kennedy Institute of Ethics, Intensive Bioethics Course

1999-2009 Seminar for NIMH psychiatric research fellows on the ethics of psychiatric research. Awarded 2002 Alan Stoudemire Award for Innovation and Excellence in Consultation-Liaison Education.

1990-1999 Associate Professor of Medical Education (from 7/1/97)

University of Virginia, Center for Biomedical Ethics.
Courses taught included: Foundations of Bioethics, Bioethics Internship Seminar, Introduction to Clinical Ethics, Clinical Ethics Proseminar, Figures and Traditions in Philosophical and Religious Ethics, History of Bioethics via the Great Cases, and Issues in Bioethics.

1998 The New York Hospital-Cornell Medical Center, Advanced Seminar in Medical Ethics.

1975-76 Kean College of New Jersey, taught course on philosophy of law.

1973-74 Columbia University, School of General Studies, taught course on introduction to moral philosophy.

Consultation in Biomedical Ethics

2017- Member, Ethics Advisory Committee, Orphan Disease Center, Perelman School of Medicine, University of Pennsylvania

2016-17 Member of Planning Group and Writing Group for NIH Consultation on the Ethics of ZIKV Human Challenge Trials

2015- Ethics consultant, Jewish Social Service Agency Hospice Program

2012-2015 Member of Data Safety and Monitoring Board, NIMH Intramural Research Program

9/1/12-2013 Member of Data Safety and Monitoring Board, PITCH-HF, National Heart, Lung, and Blood Institute

3/5/08-2010 Member of Protocol Review Committee, Cardiothoracic Surgical Trials Network, National Heart, Lung, and Blood Institute

2/8/08 Member of NIH Study Section, Research on Ethical Issues in Human Studies

2007-2012 Member of Data Safety Monitoring Committee, Comparison of Age-related Macular Degeneration Treatment Trials, National Eye Institute

1991-2006 Member of Institutional Review Board, National Institute of Mental Health.

2007-2012 Member of CNS Institutional Review Board, Intramural Research Program, National Institutes of Health

2012-2014 Member of NHLBI Institutional Review Board,
Intramural Research Program, National Institutes of Health

1990-2010 Member of Ethics Committee, Clinical Center, National Institutes of Health.

2001-2004 Member of Data Safety and Monitoring Board, National Institute of Mental Health

1/9/04 Member, Protocol Review Committee for the Coronary Revascularization in Diabetic Patients with Multivessel Disease Trial, sponsored by the National Heart, Lung, and Blood Institute.

1995-2003 Member of Ethics Committee, Jewish Social Service Agency of Metropolitan Washington, Home Care Services and Hospice.

1997-2000 Member of Data Safety and Monitoring Board for Clinical Studies of Chronic Lyme Disease, sponsored by National Institute of Allergy and Infectious Diseases.

1996-1998 Consultant Ethicist to The New York Hospital: consultation in research and program planning concerning improving the care of hospitalized dying patients.

4/6/98 Member of NIAID Expert Panel on Effects of Donor Pool Size on Safety and Efficacy of Immunoglobulin Products.

1993-97 Member of Data Safety and Monitoring Board for clinical trial of HIV Hyperimmune globulin in HIV-infected pregnant woman to prevent vertical transmission of HIV, sponsored by National Heart, Lung, and Blood Institute.

6/26/95 Member of Ad Hoc Panel to Review Randomized Clinical Trial of T-cell Depletion in Unrelated Donor Marrow Transplantation, convened by National Heart, Lung, and Blood Institute.

1988-90 Counselor to Biomedical Ethics Program, University of Virginia: help in organizing a Center for Biomedical Ethics, program development, and financial planning.

1985-90 Member of Institutional Review Board, National Institute of Child Health and Human Development.

Planning and Program Development

1977-82 Vera Institute of Justice, New York City, Project Director from 1979-82, Senior Planner from 1977-79: responsible for planning, technical assistance, program development, and research in child welfare and juvenile justice.

PUBLICATIONS

Articles

Miller FG. Challenging the conventional wisdom: from philosophy to bioethics. *Perspectives in Biology and Medicine* 2017;60:3-18.

Miller FG. Should a legal option of physician-assisted death include those who are "tired of life"? *Perspectives in Biology and Medicine*. 2016;59:351-63.

Miller FG. Henry Beecher and consent to research: a critical re-examination. *Perspectives in Biology and Medicine* 2016;59:78-94.

Barnhill A, Joffe S, **Miller FG**. The ethics of infection challenges in primates. *Hastings Center Report* 2016;46(4):20-26.

Nugent AC, . . . **Miller FG**, et al. Safety of research into severe and treatment-resistant mood disorders: analysis of outcome data for 12 years of clinical trials at the US National Institute of Mental Health. *Lancet Psychiatry* 2016;3:436-42.

Cassel JB, … **Miller FG**. Phase 1 cancer trials and palliative care: antagonism, irrelevance, or synergy? *Journal of Pain and Symptom Management* 2016;52:437-45.

Rid A, **Miller FG**. Rationale for the Ebola "ring vaccination" trial design. *American Journal of Public Health* 2016;106:432-5.

Miller FG. On changing one's mind in bioethics, *Perspectives in Biology and Medicine* 2015;58:507-17.

Colloca L, . . . **Miller FG**, et al. Vasopressin boosts placebo effects in women: a randomized trial. *Biological Psychiatry* 2016;79:794-802.

Kim S, **Miller FG**. Ethical complexities in standard of care randomized trials: a case study of morning versus nighttime dosing of blood pressure drugs. *Clinical Trials* 2015;12:557-63.

Nayak R, Wendler D, **Miller FG**, Kim S. Pragmatic trials without standard informed consent: a national survey. *Annals of Internal Medicine* 2015;163:356-64.

Dickert N, **Miller FG**. Involving patients in enrollment decisions for acute myocardial infarction trials. *BMJ* 2015;July 29; 351:h3791.

Kaptchuk TJ, **Miller FG**. Placebo effects in medicine. *New England Journal* 2015;373:8-9.

Barnhill A, **Miller FG**. The ethics of placebo treatments in clinical practice: a reply to Glackin. *Journal of Medical Ethics* 2015;41:673-76.

du Toit J, **Miller FG**. The ethics of continued life-sustaining treatment for those diagnosed as brain dead. *Bioethics* 2016;30:151-8.

Miller LR, **Miller FG**. Understanding placebo effects: implications for nursing practice. *Nursing Outlook* 2015;63:601-6.

Miller FG, Kim SYH. Personal care in learning health care systems. *Kennedy Institute of Ethics Journal* 2015;25:419-35.

Kim S, **Miller FG**. Varieties of standard-of-care treatment randomized trials: ethical implications. *JAMA* 2015;313:895-6.

Annoni M, **Miller FG**. Placebos in clinical practice: an overview, *Douleur et Analgesie*, in press.

Annoni M, **Miller FG**. The ethics of therapeutic communication: a pragmatic perspective, *Kennedy Institute of Ethics* 2016;26: 79-103.

Miller FG, Joffe S, Kesselheim A. Evidence, errors, and ethics. *Perspectives in Biology and Medicine* 2014;57:299-307.

Colloca L, Jonas WB, Killen J, **Miller FG**, Shurtleff D. Reevaluating the placebo effect in medical practice. *Z Psychology* 2014;222(3):124-7.

Kim S, **Miller FG**. Waivers and alterations to consent in pragmatic trials. *IRB* 2016;38(1):1-5.

Gelinas L, Wertheimer A, **Miller FG**. When and why is research without consent permissible. *Hastings Center Report* 2016;46(2):35-43.

Barnhill A, **Miller FG**. Placebo and deception: a commentary. *Journal of Medicine and Philosophy* 2015;40:69-82.

Moustgaard H, . . . **Miller FG**, et al. Outcome classification in randomised clinical trials: definitions of subjects and objective outcomes differed in methods publications but were absent from trial reports. *Journal of Clinical Epidemiology* 2014;67:1327-34.

Geers A, **Miller FG**. Understanding and translating knowledge about placebo effects: the contribution of psychology. *Current Opinion in Psychiatry* 2014;27:326-31.

Joffe S, **Miller FG**. The ethics of cancer clinical trials in low-resource settings. *Journal of Clinical Oncology* 2014;32:3192-6.

Truog RD, **Miller FG**. The meaning of brain death: a different view. *JAMA Internal Medicine* 2014;174:1215-6.

Truog RD, **Miller FG.** Defining death: the importance of scientific candor and transparency. *Intensive Care Medicine* 2014;40:885-7.

Truog RD, **Miller FG**. Changing the conversation about brain death. *American Journal of Bioethics* 2014;14(8):9-14.

Shah SK, Kasper K, **Miller FG**. A narrative review of the empirical evidence on public attitudes on brain death and vital organ transplantation: the need for better data to inform policy. *Journal of Medical Ethics* 2015;41:291-6.

Dickert NW, **Miller FG**. Learning from FAME: The need for sham controls in trials of stable coronary disease. *JACC: Cardiovascular Interventions* 2014;7:342-4.

Nayak RK, Pearson SD, **Miller FG**. Cost-related motivations for conducting research: participants should be informed, *JAMA* 2014;311:1491-2.

Kim S, **Miller FG**. Informed consent for pragmatic randomized clinical trials: the integrated consent model, *New England Journal* 2014;370:769-772.

Miller FG. The Stateville Penitentiary malaria experiments: a case study in retrospective ethical assessment, *Perspectives in Biology and Medicine* 2013;56:548-67.

Wendler D, **Miller FG**. The ethics of peer review in bioethics, *Journal of Medical Ethics* 2014;40:697-701.

Truog RD, **Miller FG**, Halpern S. The dead donor rule and the future of organ donation, *New England Journal* 2013;369:1287-9.

Miller FG. Clinical research before informed consent. *Kennedy Institute of Ethics Journal* 2014;24:141-57.

Brody H, Miller FG. The research/clinical practice distinction, learning health systems, and relationships. Hastings Center Report 2013;43(4):41-7.

Hull S, . . . **Miller FG**. A survey of patients' attitudes about the use of placebo treatments, *BMJ* 2013;346:f3757 doi: 10.1136/bmj.f3757.

Miller FG. Two philosophical deaths: Hume and Hitchens, *Perspectives in Biology and Medicine* 2013;56:251-58.

Brim R, **Miller FG**. The potential benefit of the placebo effect in sham-controlled trials: implications for risk/benefit assessment and informed consent, *Journal of Medical Ethics* 2013;39:703-7.

Miller FG, Joffe S. Phase 1 oncology trials and informed consent, *Journal of Medical Ethics* 2013;39:761-4.

Miller FG. The enduring legacy of sham-controlled trials of internal mammary artery ligation, *Progress in Cardiovascular Diseases* 2012;55:246-50.

Sommers R, **Miller FG.** Forgoing debriefing in deceptive research: is it ever ethical? *Ethics and Behavior* 2013;23:98-116.

Rhodes K, **Miller FG.** Simulated patient studies: an ethical analysis, *Milbank Quarterly* 2012;90:706-24.

Miller FG. Clinical equipoise and risk-benefit assessment, *Clinical Trials* 2012;9:621-7.

Miller FG. Homage to Henry Beecher, *Perspectives in Biology and Medicine* 2012;55:218-29.

Largent E, Grady C, **Miller FG**, Wertheimer A. Misconceptions about coercion and undue influence. *Bioethics* 2013;27:500-7.

Brody H, Colloca L, **Miller FG**. The placebo phenomenon: implications for the ethics of shared decision-making. *Journal of General Internal Medicine* 2012;27:739-42.

Joffe S, **Miller FG**. Equipoise: asking the right questions for clinical trial design. *Nature Reviews Clinical Oncology* 2012;9(4):230-5.

Sinnot-Armstrong W, **Miller FG**. Why killing by itself is not morally wrong. *Journal of Medical Ethics* 2013;39:3-7.

Brody H, **Miller FG**. From art to science: what has recent research taught us about the placebo effect in clinical practice? *JAMA* 2011;306:2612-3.

Largent E, Grady C, **Miller FG**, Wertheimer A. Money, coercion, and undue inducement: attitudes about payment to research participants, *IRB* 2012;34(1):1-8.

Wulff K, **Miller FG**, Pearson SD. Can coverage be rescinded when negative results threaten a popular procedure? The ongoing saga of vertebroplasty. *Health Affairs* 2011;30:2269-76..

Miller FG, Pearson SD. Linking insurance coverage for innovative invasive procedures with participation in clinical research, *JAMA* 2011;306:2024-5.

Shah SK, Truog RD, **Miller FG**. Death and legal fictions. *Journal of Medical Ethics* 2011;37:719-22.

Colloca L, **Miller FG**. The nocebo effect and its relevance for clinical practice. *Psychosomatic Medicine* 2011;73:598-603.

Miller FG. Dispensing with equipoise. *American Journal of the Medical Sciences* 2011;342:276-81.

Miller FG. Research and complicity: the case of Julius Hallervorden. *Journal of Medical Ethics* 2012;38:53-56.

Miller FG, Joffe S. Balancing access and evaluation in the approval of new cancer drugs. *JAMA* 2011;305:2345-6.

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Lie RK, **Miller FG**. What counts as reliable evidence for public health policy: the case of circumcision for preventing HIV infection. *BMC Medical Research Methodology* 2011;11:34.

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Miller FG, Kallmes DF, Buchbinder R. Vertebroplasty and the placebo response. *Radiology* 2011;259:621-5.

Hrobjartsson A, Kaptchuk TJ, **Miller FG**. Placebo effect studies are susceptible to response biases and other types of biases. *Journal of Clinical Epidemiology* 2011;64:1223-9.

Colloca L, **Miller FG**. Role of expectation in health. *Current Opinion in Psychiatry* 2011;24:149-55.

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Litton P, **Miller FG**. What do physicians-investigators owe patients who participate in research? *JAMA* 2010;304:1491-2.

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Miller FG, Kallmes DF. The case of vertebroplasty trials: promoting a culture of evidence-based procedural medicine. *Spine* 2010;35:2023-26.

Lev O, **Miller FG**, Emanuel EJ. The ethics of research on enhancement interventions. *Kennedy Institute of Ethics Journal* 2010;20:101-13.

Resnik DB, **Miller FG**. The ethics of sham surgery on research subjects with cognitive impairments that affect decision-making capacity. *Contemporary Clinical Trials* 2010;31:407-10.

Miller FG, Truog RD. Decapitation and the definition of death, *Journal of Medical Ethics* 2010;36:632-4 .

Shah S, **Miller FG**. Can we handle the truth? Legal fictions in the determination of death, *American Journal of Law and Medicine* 2010;36:540-585.

Tilburt JC, **Miller FG**, et al. Factors that influence practitioners' interpretation of evidence from alternative medicine trials: a factorial vignette experiment embedded in a national survey. *Medical Care* 2010;48:341-8.

Miller FG, Brody H. Understanding and harnessing the placebo effect: clearing away the underbrush. *Journal of Medicine and Philosophy* 2011;36:69-78.

Largent EA, Wendler D, Emanuel EJ, **Miller FG**. Is Emergency research without initial consent justified? The consent substitute model. *Archives of Internal Medicine* 2010;170:668-74.

Heyd D, **Miller FG**. Life plans: do they give meaning to our lives. *Monist* 2010;93:17-37.

Finniss DG, Kaptchuk TJ, **Miller F**, Benedetti F. Placebo effects: biological, clinical, and ethical advances, *Lancet* 2010;375:686-95.

Curlin FA, Rasinski KA, Kaptchuk TJ, Emanuel EJ, **Miller FG**, Tilburt JC. Religion, clinicians, and the integration of complementary and alternative medicine. *Journal of Complementary and Alternative Medicine* 2009;15:987-94.

Miller FG, Truog RD, Brock DW. The dead donor rule: can it withstand critical scrutiny? *Journal of Medicine and Philosophy* 2010;35:299-312.

Miller FG, Colloca L, Kaptchuk TJ. The placebo effect: illness and interpersonal healing, *Perspectives in Biology and Medicine* 2009;52:518-39.

Largent, **Miller FG**, Pearson SD. Going off-label without venturing off-course: evidence and ethical off-label prescribing, *Archives of Internal Medicine* 2009;169:1745-47.

Miller FG, Colloca L. The legitimacy of placebo treatments in clinical practice: evidence and ethics, *American Journal of Bioethics* 2009;9(12): 39-47.

Miller FG. Death and organ donation: back to the future. *Journal of Medical Ethics* 2009;35:616-20.

Miller FG, Joffe S. Limits to research risks. *Journal of Medical Ethics* 2009;35:445-449.

Miller FG, Truog RD. The incoherence of determining death by neurological criteria: Commentary on *Controversies in the Determination of Death*, A White Paper by the President's Council on Bioethics. *Kennedy Institutes of Ethics Journal* 2009;19:185-93.

Miller FG, Truog RD, Brock DW. Moral fictions and medical ethics. *Bioethics* 2010;24;453-60; reprinted in *Bioethics: An Anthology*, 3d edition, ed. by H. Khuse, U. Schuklenk, and P. Singer, John Wiley & Sons, Inc., 2016.

Miller FG. A planned death in the family. *Hastings Center Report* 2009;39(2):28-30.

Tilburt J, Curlin FA, Kaptchuk TJ, Clarridge B, Bolcic-Jankovic D, Emanuel EE, **Miller FG**. Alternative medicine research in clinical practice: A U.S. national survey. *Archives of Internal Medicine* 2009;169:670-77.

O'Neil C, **Miller FG**. When scientists deceive: applying the federal regulations. *Journal of Law, Medicine & Ethics* 2009;37:344-50.

Tilburt JC, Emanuel EJ, Kaptchuk TJ, Curlin FA, **Miller FG**. Prescribing "placebo treatments" in clinical practice: results of a national survey of U.S. internists and rheumatologists. *BMJ* 2008;337:a1938.

Miller FG, Joffe S. Benefit in phase 1 oncology trials: therapeutic misconception or reasonable treatment option? *Clinical Trials* 2008;5:617-23.

Peppercorn J, . . . **Miller FG**, et al. Self-reported practices and attitudes of U.S. oncologists regarding off-protocol therapy. *Journal of Clinical Oncology* 2008;26:5994-6000.

Truog RD, **Miller FG**. The dead donor rule and organ donation. *New England Journal* 2008;359:674-5.

Miller FG, Gluck JP, Wendler D. Debriefing and accountability in deceptive research. *Kennedy Institute of Ethics Journal* 2008;18:235-51.

Tilburt JC, **Miller FG**, Emanuel EJ. Does the evidence make a difference in consumer behavior? Sales of supplements before and after publication of negative research results. *Journal of General Internal Medicine* 2008;23:1495-98.

Miller FG, Kaptchuk TJ. The power of context: reconceptualizing the placebo effect. *Journal of the Royal Society of Medicine* 2008;101:222-25.

Miller FG. Collaborative research in bioethics, American Philosophical Association, *Newsletter on Medicine and Philosophy* 2008;7(2):17-20.

Brown AP, Wendler D, Camphausen KA, **Miller FG**, Citrin D. Performing non-diagnostic research biopsies in irradiated tissue: a review of scientific, clinical, and ethical considerations, *Journal of Clinical Oncology* 2008;26:3987-94.

Miller FG, Kaptchuk. Deception of subjects in neuroscience: an ethical analysis, *Journal of Neuroscience* 2008;28:4841-43.

Miller FG, Truog RD. An apology for Socratic bioethics, *American Journal of Bioethics* 2008;8(7):3-7.

Miller FG, Truog RD. Rethinking the ethics of vital organ donations, *Hastings Center Report* 2008;38(6):38-46; reprinted in ASBH Reader Spring 2009.

Brendel D, **Miller FG**. A plea for pragmatism in clinical research ethics, *American Journal of Bioethics* 2008;8(4):24-31.

Miller FG. Research on medical records without informed consent, *Journal of Law, Medicine & Ethics* 2008;36:560-66.

Shalowitz D, **Miller FG**. Communicating the results of clinical research to participants: Attitudes, practices, and future directions. *PLoS Medicine* 2008;5(5):e91.

Miller FG, Emanuel EJ. Quality improvement research without informed consent, *New England Journal of Medicine* 2008;358:765-67.

Joffe S, **Miller FG**. Bench to bedside: mapping the moral terrain of clinical research, *Hastings Center Report* 2008;38(2):30-42.

Miller FG, Mello MM, Joffe S. Incidental findings in human subjects research: What do investigators owe research participants? *Journal of Law, Medicine & Ethics* 2008;36:271-79.

Miller FG, Pearson SD. Coverage with evidence development: ethical issues and policy implications. *Medical Care* 2008;46:746-57.

Henderson GE, . . . **Miller FG**, et al. Defining the therapeutic misconception: problems and prospects. *PLoS Medicine* 2007;4(11):e324.

Wertheimer A, **Miller FG**. Payment for research participation: A coercive offer? *Journal of Medical Ethics* 2008;34:389-92.

Horng S, **Miller FG.** Placebo controlled procedural trials for neurological conditions. *Neurotherapeutics* 2007;4:531-6.

Miller FG, Wendler D. Is it ethical to keep interim findings of randomized controlled trials confidential? *Journal of Medical Ethics* 2008;34:198-201.

Tilburt J, **Miller FG**. Responding to medical pluralism in practice: a principled ethical approach. *Journal of the American Board of Family Medicine* 2007;20:489-94..

Buchanan D, **Miller FG**, Wallerstein N. Ethical issues in community based participatory research: balancing rigorous research with community participation in intervention studies. *Progress in Community Health Partnerships* 2007;1.2:153-160.

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Emanuel EJ, **Miller FG**. Money and distorted ethical judgments about research: Ethical assessment of the TeGenero TGN1412 trial. *American Journal of Bioethics* 2007;7(2):76-81.

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Groopman L, **Miller FG**, Fins JJ. The patient's work. *Cambridge Quarterly of Healthcare Ethics* 2006;16:44-52. Reprinted in J. Pierce, G. Randels, eds., *Contemporary Bioethics: An Integrated Approach*, Oxford University Press, 2009.

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Shalowitz D, **Miller FG**. Disclosing individual results of clinical research: the implications of respect for participants. *JAMA* 2005;294:737-40.

Miller FG, Wendler D, Swartzman L. Deception in research on the placebo effect. *PLoS Medicine* 2005;2(9):e262.

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Buchanan D, **Miller FG**. Justice and fairness in the Kennedy Krieger Institute lead paint study: the ethical justification for public health research on less expensive yet less effective interventions. *American Journal of Public Health* 2006;96:781-87.

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Miller FG, Brody H. Professional integrity in industry-sponsored clinical trials. *Academic Medicine* 2005;80:899-904.

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Miller FG, Kaptchuk TJ. Sham procedures and the ethics of clinical trials. *Journal of the Royal Society of Medicine* 2004;97:576-78.

Raik BL, **Miller FG**, Fins JJ. Screening and cognitive impairment: ethics of forgoing mammography in older women. *Journal of the American Geriatrics Society* 2004;52:440-4.

Miller FG, Silverman HJ. The ethical relevance of the standard of care in the design of critical care trials. *American Journal of Respiratory and Critical Care Medicine*. 2004;169:562-64.

Miller FG, Emanuel EJ, Rosenstein DL, Straus SE. Ethical issues concerning research on complementary and alternative medicine. *JAMA* 2004;291:599-604.

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<u>Other Publications</u>

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PRESENTATIONS

Seminar on Research Ethics, Division of Medical Ethics, Weill Cornell Medical College, February 15, 2017.

Panel on consent and internet research, Ethics Grand Rounds, National Institutes of Health, December 7, 2016.

"Placebos in research and practice," University of Marburg, seminar for medical students, Kleinwalsertal, Austria, September 28, 2015.

"On Collaboration," The Frontiers of Bioethics: a conference honoring the career and collaborations of Franklin G. Miller, National Institutes of Health, May 29, 2015.

"Comparative Effectiveness Trials and Informed Consent," Workshop, "Risk-adapted approaches to regulating health research: ethical challenges," Kings College London, April 20, 2015.

"Determination of Death and Organ Transplantation," Department of Bioethics, NIH, Fellows seminar, April 15, 2015; November 16, 2015; April 12, 2017.

"Comparative Effectiveness Trials and Informed Consent," NIH Human Subjects Research Course, October 29, 2014.

"Phase I oncology trials and informed consent," Brocher Foundation symposium on "Recent developments in phase 1 oncology trials," Hermance, Switzerland, July 15, 2014.

"Infection challenge studies: an ethical perspective, NIAID/FDA Workshop on Dengue human infection model, Rockville, MD, April 3, 2014.

"Crisis in the ethics of vital organ donation," George Washington University Ethics Committee Retreat, March 26, 2014.

"Placebos and the ethics of therapeutic communication," Symposium on Placebo Effects in Guidelines, Practice, and Patient Choice, Boston, December 10, 2013.

"Research without consent: the case of 'mystery shopper' studies," panel on the Ethics of Research without Consent, Advancing Ethical Research Conference, Public Responsibility in Medicine and Research, Boston, November 8, 2013.

"Ethics of single-blind trials in biomedicine," symposium on "When Less Information is better: blinding as a solution to institutional corruption," The Edmond J. Safra Center for Ethics at Harvard, November 1, 2013.

"Crisis in the ethics of vital organ donation: Where do we go from here?" Workshop on The importance of being dead—The dead donor rule and ethics of transplantation medicine, Center for Interdisciplinary Research, University of Bielefeld, Bielefeld Germany, September 14, 2013.

"Deception and research: ethics and regulation," NHGRI IRB retreat, NIH Clinical Center, June 13, 2013.

"Placebo-controlled trials without informed consent: What were they thinking?" Panel on RCTs and Informed Consent, Princeton University, April 25, 2013.

"Limits to Research Risks," George Mason University, March 7, 2014; April 5, 2013.

"Abandoning the Dead Donor Rule," Society for Thoracic Surgeons annual meeting, Los Angeles, CA, January 29, 2013.

"Simulated Patient Studies," Division of Medical Ethics, Cornell Medical School, January 17, 2013.

"Limits to risks in research with healthy volunteers," Advanced Research Ethics workshop, PRIM&R annual meeting, San Diego, CA, 12/3/12.

"Placebo-controlled trials before informed consent: What were they thinking?" Program in Placebo Studies, Beth Israel Deaconess Medical Center, Harvard University, October 25, 2012.

"Doctors must not Kill," panel presentation at annual meeting of American Society for Bioethics and the Humanities, Washington, D.C., October 19, 2012.

"Sham-controlled trials: an ethical perspective," Gastroenterology and Urological Devices Panel of the FDA Medical Devices Advisory Committee, Gaithersburg, MD, May 10, 2012.

"Data Safety and Monitoring Boards: An Ethical Perspective," "Limits to Risks in Research with Healthy Volunteers," "Therapeutic Orientation to Clinical Trials," Ewha-NIH Intensive Course in Human Subject Research Ethics, Seoul, South Korea, March 19-22, 2012.

"Research without consent: the case of mystery shopping studies," conference on Rethinking the Ethics of Clinical Research, Duke University, Durham, North Carolina, February 24, 2012.

"Legitimacy of Placebo Treatments," Placebo Conference, sponsored by Samueli Institute, Bethesda, Maryland, January 20, 2012.

"Placebo treatments in clinical practice: ethical issues," Healing and Placebo panel discussion, Embassy of Italy, January 20, 2012.

"Dispensing with equipoise," Advanced Research Ethics, PRIM&R, National Harbor, MD, December 1, 2011.

"Sham-controlled trials—ethical and policy considerations," conference on Device development in obesity, sponsored by FDA and Massachusetts General Hospital, Bethesda, Maryland, October 17, 2011.

"Organ Donation Without the Dead Donor Rule," University of Marburg, seminar on death, organ donation, and ethics, Kleinwalsertal, Austria, October 3, 2011.

"The Therapeutic Misconception and Informed Consent," Grand Rounds, Clinical Center, NIH, August 31, 2011.

"Therapeutic Orientation to Clinical Trials," First Annual Biomedical Ethics Lecture, University of Rochester Medical Center, Rochester, New York, June 21, 2011.

"Limits to research risks," National Institute of Environmental Health Sciences, Research Triangle, North Carolina, May 25, 2011.

"Drug evaluation: public policy and research ethics," Office of Oncology Drug Products, FDA, April 29, 2011.

"Deception and research: ethics and regulation," Department of Veterans Affairs, Central IRB, Washington, DC, February 24, 2011.

"Vertebroplasty and the Placebo Response," Radiological Society of North America annual meeting, Chicago, December 1, 2010.

"Beyond Superiority to Placebo: The Legitimacy of Placebo Efficacy?" Integrative Medicine Research Lecture series, National Center for Complementary and Alternative Medicine, NIH, November 8, 2010.

"Dispensing with Equipoise," Pitts Memorial Lectureship, Medical University of South Carolina, Charleston, SC, October 30, 2010.

"Coverage with Evidence Development: Ethical Issues," panel on research and practice, American Society for Bioethics and the Humanities, annual meeting, San Diego, CA, October 23, 2010.

"Deception in Research: Ethics and Regulation," Secretary's Advisory Committee on Human Research Protections, Washington, D.C., October 20, 2010.

"Placebo Treatments in Clinical Practice: Ethical Issues," Grand Rounds, Comprehensive Cancer Support Program, University of North Carolina, September 13, 2010.

"The Ethics of Placebo-Controlled Trials," Rush University Medical Center, Chicago, June 16, 2010.

"Therapeutic orientation to clinical trials," Grand Rounds, Children's Hospital of Philadelphia, May 12, 2010.

"Organ Donation without the Dead Donor Rule," American Philosophical Association, central division meeting, Committee for Medicine and Philosophy, Chicago, February 20, 2010.

"Risks and Placebo Controls," World Medical Association expert conference on the ethics of placebo controls in clinical trials, Sao Paulo, Brazil, February 1, 2010.

"Therapeutic Orientation to Clinical Trials," Clinical Research Ethics Seminar, University of Texas Southwestern, December 8, 2009.

"Organ Donation without the Dead Donor Rule," Ethics Grand Rounds, University of Texas Southwestern, December 8, 2009.

"Placebo Treatments in Clinical Practice: Ethical Issues," at a conference on placebo interventions in medical practice sponsored by the Institute for Biomedical Ethics, University of Zurich, Zurich, Switzerland, November 18, 2009.

"Informed Consent and Therapeutic Misconception," International Association of Law and Mental Health, New York City, June 30, 2009.

"Placebo treatments in clinical practice: ethical issues," George Washington University Medical School, April 8, 2009.

"Research Ethics at the NIH," Global Alliance of Biomedical Ethics Centers Project, Tokyo, Japan, March 13, 2009.

"Standard of Care and the Ethics of Study Design," IMPAACT Leadership Retreat, Division of AIDS, NIAID, NIH, December 12, 2008.

"Facing up to deception in placebo research," The Placebo Effect: Satellite symposium of the X11 World Congress on Pain, Copenhagen, August 15, 2008.

"Placebo treatments in clinical practice: ethical issues," X11 World Congress on Pain, Glasgow, August 18, 2008.

"Ethical Issues in CAM Clinical Trials," National Center for Complementary and Alternative Medicine, Grantsmanship Workshop, Rockville, MD, June 5, 2008.

"Epidemiological and Health Services Research without Consent," Medical Ethics Seminar, Division of Medical Ethics, Department of Public Health, Weill Medical College of Cornell University, March 6, 2008.

"Therapeutic Orientation to Clinical Trials," Advanced Research Ethics, PRIM&R Annual HRPP Conference, Boston, MA 12/1/07.

"Therapeutic Orientation to Clinical Trials," NIH Human Subjects Research Ethics Course, October 3, 2007.

"Don't Look, Don't Tell, Why Not?" conference on Managing Incidental Findings in Human Subjects Research, University of Minnesota, May 1, 2007.

"Deception, Respect for Persons, and Informed Consent," retreat for Institutional Review Board of the Intramural Research Program, National Human Genome Research Institute, March 19, 2007.

"Coverage Conditional on Research: An Ethical Perspective," workshop on Ethical Considerations for Post-marketing Evaluations of Pharmaceuticals," sponsored by Health Canada, The Canadian Institutes of Health Research, and The Manitoba Centre for Health Policy, Toronto, Canada, March 5, 2007.

"Deception, Respect for Persons, and Informed Consent," RAND Corporation, conference on Ethical Principles in Social-Behavioral Research on Terrorism, Arlington, VA January 10, 2007.

"Against Clinical Equipoise," PRIM&R Annual HRPP Conference, Washington, DC, November 16, 2006.

"Therapeutic Orientation to Clinical Trials," Ethics Grand Rounds, Dana-Farber Cancer Institute, Harvard School of Medicine, October 16, 2006.

"Facing up to Paternalism in Research Ethics," Division of Medical Ethics, Harvard Medical School, October 16, 2006.

"Data Safety and Monitoring Boards: An Ethical Perspective," Indo-U.S. Workshop on Bioethics in Clinical Research," New Delhi, India, June 21, 2006.

"The Therapeutic Misconception and Informed Consent," Indo-U.S. Workshop on Bioethics in Clinical Research," New Delhi, India, June 22, 2006.

"Evaluating the Therapeutic Misconception," panel on Therapeutic Misconception in Clinical Research, American Psychiatric Association, May 22, 2006.

"Deception in Clinical Research: the Challenge to Informed Consent," Medical Ethics Seminar, Division of Medical Ethics, Department of Public Health, Weill Medical College of Cornell University, May 11, 2006.

"Therapeutic Orientation to Clinical Trials," University of Marburg Comprehensive Cancer Center, March 15, 2006.

"Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care," Panel on The Belmont Report, American Philosophical Association, December 29, 2005.

"Ethics of Placebo-Controlled Trials," Human Subjects Research Course, National Institutes of Health, October 19, 2011; October 5, 2010; October 28, 2009; October 15, 2008; October 10, 2007; October 11, 2006; November 2, 2005.

"Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care," Panel on The Belmont Report, American Society for Bioethics and the Humanities, October 22, 2005.

"The Therapeutic Orientation to Clinical Trials," University of Maryland School of Medicine, June 16, 2005.

"Deception in Clinical Research on the Placebo Effect," Osher Institute, Harvard Medical School, May 24, 2005.

"Deception in Clinical Research: The Case of Experiments to Investigate the Placebo Effect," University of New Mexico, April 14, 2005.

"Data Safety and Monitoring Boards: An Ethical Perspective," AMANET/NIH Advanced Ethics Workshop, Zanzibar, Tanzania, December 1, 2004.

"The Ethics of Medical Research with Human Subjects," Cedar Lane Unitarian Church, Chevy Chase , Maryland, October 17, 2004.

"The Ethics of Placebo-Controlled Trials," Quorum IRB retreat, Seattle, Washington (by telephone), October 2, 2004.

"Professional Integrity in Industry-Sponsored Trials," Aventis Editorial Forum, Bridgewater, New Jersey, October 1, 2004.

"Ethical Framework for Randomized Controlled Trials," National Institute of Aging conference, "From Bench to Bedside: Estrogen as a Case Study," September 29, 2004.

"Deception in Placebo Research," Human Subjects Research Ethics Board Retreat, University of Western Ontario, June 8, 2004.

The Ethics of Placebo Surgery," Society for Clinical Trials Annual Meeting, New Orleans, May 26, 2004.

"William James and Medical Ethics," Bioethics Seminar, Division of Medical Ethics, Cornell University Medical College, March 25, 2004.

"Is 'Faith Healing' Compatible with Scientific Medicine? The Ethics of Placebo Therapy," Placebo Working Group, Osher Institute, Harvard Medical School, December 18, 2003.

"Kant and Bioethics," Bioethics Seminar, Division of Medical Ethics, Cornell University Medical College, December 12/4/03.

"The Therapeutic Orientation to Clinical Trials," at The Ethical Conduct of Clinical Research Involving Critically Ill Subjects in North America Conference, American Thoracic Society, November 21, 2003.

"Commentary on a Complex Trial Design," Inter-Institute Bioethics Interest Group, National Institutes of Health, November 3, 2003.

"Professional Integrity in Clinical Research," Key Plenary Conference, XXI Biomedical Research National Congress, Monterrey, Mexico, October 23, 2003.

"Placebo-controlled Trials in Children: Ethical and Regulatory Considerations," North American Cystic Fibrosis Conference, Anaheim, CA, October 16, 2003.

"The Ethics of Placebo Surgery," Conference on "Placebo—Its Action and Place in Health Research Today," The Medical University of Warsaw, Warsaw, Poland, April 13, 2003.

"The Ethics of Sham Surgery," Alumni Reunion, Clinical Research Training Program, National Institutes of Health, October 5, 2002.

"The Ethics of Placebo-controlled trials," Collegium Internationale Neuro-Psychopharmacologicum, Montreal, Canada, June 25, 2002.

"Assessing Decisionmaking Capacity in Psychiatric Research," Society of Biological Psychiatry, Philadelphia, PA, May 16, 2002.

"Clinical Research with Healthy Volunteers," American Federation for Medical Research," Baltimore, MD, April 13, 2002.

"The Ethics of Placebo-Controlled Trials," Society of Behavioral Medicine, Washington, DC, April 6, 2002.

"The Ethics of Assessing Decisionmaking Capacity in CNS Research," CNS Clinical Trials and Drug Development, Philadelphia, PA, March 19, 2002.

"The Ethics of Placebo-Controlled Trials in Psychiatric Research," CNS Clinical Trials and Drug Development, Philadelphia, PA, March 18, 2002.

"The Ethics of Randomized Clinical Trials," National Institute of Dental and Craniofacial Research, Bethesda, MD, December 12, 2001.

"The Ethics of Placebo-Controlled Trials," National Institutes of Health, Ethical and Regulatory Aspects of Human Subjects Research, Bethesda, MD, November 14, 2001.

"The Rationale for Independent Capacity Assessment," American Society for Bioethics and Humanities, Nashville, TN, October 25, 2001.

"Addressing Ethical Issues in the Medical Research Literature," American Society for Bioethics and Humanities, Nashville, TN, October 28, 2001.

"The Ethics of Placebo-Controlled Trials," Dalhousie University, Halifax, Canada, Workshop on Placebo Controls in Clinical Trials, September 24, 2001.

"The Ethical Challenge of Psychiatric Challenge Studies," Max-Planck Institute for Psychiatry, Munich, Germany, June 27, 2001.

"Ethics of Placebo-Controlled Trials in Psychiatry," New Clinical Drug Evaluation Unit, Phoenix, Arizona, May 30, 2001

"Placebo-controlled Trials in Psychiatric Research: An Ethical Perspective," American Academy of Pharmaceutical Physicians, Baltimore, MD, October 30, 2000.

"Ethics of Randomized Clinical Trials," National Cancer Institute, Fundamentals of Clinical Trials, October 14, 2000.

"Defining the Ethical Issues in Randomized Clinical Trials," Society of Surgical Oncology Annual Cancer Symposium, New Orleans, Louisiana, March 17, 2000.

"Placebo-controlled Trials in Psychiatric Research: An Ethical Perspective," Grand Rounds in Psychiatry, Cornell University Medical School, January 12, 2000.

“The Ethical Challenge of Human Challenge Models,” National Institute of Allergy and Infectious Diseases, Development of a Standardized *Helicobacter pylori* Human Challenge Model Suitable for Studies of Pathogenesis and Vaccine Efficacy, November 30, 1999.

“Professional Integrity in Psychiatric Research,” NIMH Fellows Seminar, May 25, 1999.

“Advertising in Clinical Research,” NIH IRB bioethics consultants, April, 27, 1999.

“Ethical Issues in Psychiatric Research: Placebos and Drug Washouts,” NIMH Fellows Seminar, July 28, 1998.

"Professional Integrity in Clinical Research," paper (co-authored with D.L. Rosenstein and E.G. DeRenzo), NIH Department of Clinical Bioethics Journal Club, April 22, 1998.

"Safeguards for Physician-Assisted Suicide, Fair Oaks Hospital, Fairfax Virginia, March 25, 1998.

"Professional Integrity in Clinical Research," Kennedy Institute of Ethics Seminar for Scholars and Fellows, February 10, 1998.

"The Ethical Challenge of Challenge Studies," Center for Bioethics, University of Pennsylvania, December 5, 1997.

"Clinical Pragmatism and Reform of Clinical Pragmatism," with J.J. Fins, The Joint Meeting of the American Association of Bioethics, Society for Bioethics Consultation, and Society for Health and Human Values, Baltimore, MD, November 7, 1997.

Comments on draft legislation concerning research with decisionally incapacitated individuals developed by Maryland Attorney General's Research Working Group, at conference sponsored by University of Maryland School of Law, May 28, 1997.

"Voluntary Death by Terminal Dehydration Versus Physician-Assisted Suicide," AMA-MSS Sectional Conference, University of Maryland School of Medicine, February 22, 1997.

"Voluntary Death by Terminal Dehydration," paper (co-authored with Diane Meier) presented at Kennedy Institute of Ethics Seminar for Scholars and Fellows, February 11, 1997.

"Regulating Physician-Assisted Suicide: The Oregon Referendum, The Circuit Court Opinions, and the Future," Death with Dignity Leaders' Forum, San Francisco, April 28, 1996.

"A Communitarian Approach to Physician-Assisted Death," paper presented at Kennedy Institute of Ethics Seminar for Scholars and Fellows, February 20, 1996.

Member of panel on Physician-Assisted Death, Metropolitan Washington Bioethics Network, January 27, 1996.

"A Communitarian Approach to Physician-Assisted Death," Death with Dignity Leaders' Forum, Seattle, Washington, January 21, 1996.

"Reconstruction of Hospital Care for Dying Patients," The New York Hospital Medical Ethics Committee, December 13, 1995

Member of panel discussing cases concerning ethics of medical research at Tri-Institutional Ethics Course: Sloan-Kettering Institute, Cornell University Medical College, and Rockefeller University, January 7, 1997 and October 31, 1995.

"Regulating Physician-Assisted Death: Oregon and Beyond," University of Maryland Medical System, Medical Humanities Hour, June 8, 1995.

"Regulating Physician-Assisted Death," Martha Jefferson Hospital, Ethics Committee Educational Forum, Charlottesville, Virginia, April 12, 1995.

"The Regulation of Physician-Assisted Death," Georgetown University Bioethics Colloquium, December 13, 1994.

Keynote Speaker, Forum on Physician-Assisted Death, The Memorial Society of Maryland, November 19, 1994.

"The Limits of Justified Physician-Assisted Death, " American Society of Law, Medicine & Ethics 1994 annual meeting, October 7, 1994.

"Regulation of Physician-Assisted Death," Hemlock Society of the National Capital Area, November 14, 1993.

"The Case for Legalized Euthanasia," Fairfax Hospital, Annual Ethics Conference: Euthanasia Pros and Cons, April 27, 1993.

"Safeguards to Prevent Abuse in Legalized Euthanasia," The Emory University Program on Quality of Life, Symposium: Death with Dignity: Is Palliative Care Enough?, February 13, 1993.

"The Case for Legalized Euthanasia," The American Medical Student Association Annual Convention, March 21, 1992.

PEER REVIEWS

The New England Journal of Medicine

Journal of the American Medical Association
Annals of Internal Medicine
Science
The Journal of General Internal Medicine
The American Journal of Medicine
Archives of General Psychiatry
Biological Psychiatry
The American Journal of Psychiatry
The Hastings Center Report
Milbank Quarterly
The Journal of Medicine and Philosophy
The Journal of Clinical Ethics
Cancer Control
The Lancet
Pediatrics
IRB
Theoretical Medicine and Bioethics
American Journal of Bioethics
The Journal of Medical Ethics
The American Journal of Respiratory and Critical Care Medicine
Perspectives in Biology and Medicine
Kennedy Institute of Ethics Journal
Clinical Trials
Lancet Neurology
Canadian Medical Association Journal
Social Science & Medicine
CNS Drugs
Journal of Clinical Oncology
Journal of Clinical Epidemiology
Intensive Care Medicine
Accountability in Research
Drug Discovery Today
Biomed Central: Health Services Research
Clinical Pharmacology & Therapeutics
Journal of Psychosomatic Research
Journal of Empirical Research on Human Research Ethics
Developing World Bioethics
Gastroenterology
Nature Reviews Clinical Oncology
Trials
Journal of Theoretical and Philosophical Psychology
The Journal of Pain and Symptom Management
International Journal of Epidemiology
AJOB Empirical Bioethics
Nous

Synthese
The Journal of Pain
PLoS Medicine
Harvard University Press

FELLOWSHIPS

2002- Fellow, Hastings Center

2001- Faculty Affiliate, Kennedy Institute of Ethics

1994-2001 Senior Research Fellow, Kennedy Institute of Ethics

EDITORIAL

2015- Deputy Editor, *Perspectives in Biology and Medicine*

2014-2015 Associate Editor, *Perspectives in Biology and Medicine*

2003-2009 Editorial Board, *American Journal of Bioethics*

BOARD MEMBERSHIPS

1996-1997 Board of Directors, Choice in Dying, New York, NY

1995-1997 Board of Directors, Death with Dignity Education Center, San Mateo, CA

OTHER PROFESSIONAL ACTIVITIES

2015- Scientific Advisor, Foundation for the Science of the Therapeutic Encounter, Cambridge, MA.

1997-1998 University of Pennsylvania, Center for Bioethics, Assisted Suicide Panel

PROFESSIONAL RECOGNITION

Thomson Reuters Highly Cited Researchers, top one percent of most cited authors of papers indexed in Web of Science in the field of Social Sciences, general, October 2014

PROFESSIONAL ASSOCIATIONS

American Society for Bioethics and Humanities