

Curriculum Vitae

David S. Wendler

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CURRENT POSITION

Senior Investigator
Head, Section on Research Ethics
Department of Bioethics, NIH Clinical Center

EDUCATION

2006-2007 University Fellow
 Center for Ethics, Harvard University

1994-1996 Bioethics Fellow
 Bioethics Program, National Institutes of Health

1993 Ph.D. Philosophy
 University of Wisconsin-Madison

1984 B.A. Biology and Philosophy
 University of Pennsylvania

SELECTED ACTIVE BOARDS AND POSITIONS

2015- Member, NIMH intramural DSMB

2014- Chair, DSMB, Default Options in Advance Directives

2013- Advisory Panel, Non-welfare interests and biobank research

2013- Member, Regulatory and Ethics Committee, NIH Collaboratory

2010- Associate Editor, Journal of Empirical Research on Human Research Ethics

2008- Associate Editor, Clinical Trials

2008- Contributor, Stanford Encyclopedia of Philosophy

2007- Member, CTSA Pediatric Research Ethics Consultation Group

2003- Member, Protocol review committee, NHLBI

2002- Organizer, NIH Ethics Grand Rounds

- 1996- Member, Institutional review board, NIDA
- 1994- Attending, NIH Clinical Center bioethics consultation service

SELECTED PAST BOARDS AND POSITIONS

- 2012 Member, NIDDK, External Expert Panel
- 2012 Panelist, President’s Commission medical countermeasures roundtable
- 2012 Visiting Scholar, University of Michigan
- 2011- 2014 Advisory Panel, Ethical issues in dementia research involving surrogates and partners
- 2011 Consultant, CIOMS executive committee
- 2011 Participant, WMA expert conference on placebo controls
- 2011 Faculty, Intensive Bioethics Course, Georgetown University
- 2011 Visiting Professor, University of Pennsylvania
- 2010 Masters of Surgery Lecturer, Montefiore/Albert Einstein College of Medicine
- 2009-2012 Member, PCRM, Roundtable on Research Protections for Animals
- 2008 Member, Ethics and Compliance in Oncology Research Executive Committee
- 2008 Consultant, Connecticut Department of Children and Families
- 2008 Discussant, Japanese research regulations advisory group
- 2008 Faculty, NCI principles and practice of cancer prevention and control course
- 2008 Panelist, risks in oncology research, MD Anderson Cancer Center
- 2007 Panelist, NICHD, minimal risk in adolescents
- 2007 Consultant, FDA, phase 1 research
- 2007 Lecturer, Johns Hopkins University
- 2007 Panelist, CTSA conference on IRB review of pediatric research
- 2007 Panelist, NCI Conference on phase 0 clinical trials
- 2007 Facilitator, Workshop on research capacity building, Tribhuvan University, Nepal
- 2007 Contributor, Principles of Health Care Ethics, 2nd edition, Wiley & Sons

2007 Panelist, symposium on assent, American Society for Clinical Oncology

2007 Visiting scholar, University of Illinois School of Medicine

2006 Panelist, Boston University, symposium on research in developing countries

2006 Panelist, Symposium on responsible clinical trials, University of Pennsylvania

2006 Visiting scholar, University of Virginia

2005-2014 Member, NIDDK data safety monitoring board, HALT-PKD

2005-2012 Member, NINR, data safety monitoring board

2005 Planning Committee, PRIMR/ARENA conference on assent

2005 Consultant, Secretary's Advisory Committee

2005 Lecturer, NIAID symposium on research with wards of the state

2005 Consulting expert, APA conference on minimal risk

2004 Member, scientific review committee, NHGRI

2004 Panelist, NIH clinical investigator student training

2004 Referee, JAMA/John Conley Essay Contest

2004 Consultant, NIAID/VaxGen consultation on research with stored samples

2004 Consultant, Institute of Medicine committee on pediatric research

2004 Pre-conference chairperson, American Society of Bioethics and Humanities

2003 Lecturer, Nagasaki University school of medicine

2003 Consultant, Research Council of Norway

2002-2012 Member, Ethics working group, National Children's Study

2002-2003 Member, executive advisory committee, NIDDK

2002 Moderator, NIH CRTP fellowship conference

2002 Discussant, study design of osteoporosis trials, American Society for Bone and Mineral Research

2002 Consultant, Merck Laboratories

2001 Participant, NIH consultation on proxy consent in geriatric research,

2001 Discussant, George Washington University hospital ethics committee retreat

2001 Panelist, Fordham University conference on research in minority children

2000 Member, NIMH work group on ethical issues in human subject research

2000 Participant, CIOMS consultation on research in developing countries

1999-2001 Member, NIH committee on ethics and research integrity

1999 Lecturer, College of Cardiology, emergency research panel

1996-1997 Member, institutional review board, NIDDK

1995-2006 Executive Secretary, NIH Clinical Center ethics committee

1995-2004 Consultant, NIMH geriatric psychiatry branch clinical rounds

1995-2000 Lecturer, NIH medical ICU fellows' training

1995-1998 Member, FDA, institutional animal care and use committee

1995-1998 Member, institutional review board, NIAID

1995-1997 Member, institutional review board, NIDR

1994-2004 Coordinator, NIH Clinical Center advance directives program

TEACHING

2012 Discussion leader, Georgetown University bioethics course

2011 Discussion leader and lecturer, Georgetown University bioethics course

2009 Discussion leader, Georgetown University bioethics course

2008 Discussion leader and lecturer, Georgetown University bioethics course

2006 Discussion leader and lecturer, Georgetown University bioethics course

2004 Lecturer, University of Bergen, Norway, school of medicine

2001 Discussion leader, Georgetown University bioethics course

1995 Lecturer, FAES, National Institutes of Health

1992 Lecturer, University of Wisconsin-Madison

1991 Lecturer, University of Wisconsin-Madison

1987-1991 Teaching assistant, University of Wisconsin-Madison

BOOKS

Danis M, Largent E, Wendler D, Hull SC, Shah S, Millum J, Berkman B, Grady C. *Research Ethics Consultation: A Casebook*. Oxford University Press 2012.

Wendler D. *The Ethics of Pediatric Research*. Oxford University Press 2010.

Emanuel E, Crouch R, Grady C, Lie R, Miller F, Wendler D. *The Oxford Textbook of Clinical Research Ethics*. Oxford University Press 2008.

JOURNAL ARTICLES

Dickert N, et al. Confronting Ethical and Regulatory Challenges of Emergency Care Research with Conscious Patients. *Annals of Emergency Medicine*. In press.

Wendler D, Wertheimer A. Why is coercion worse than no consent and deceived consent? *Journal of Medicine and Philosophy*. In press.

Johnson RA, Rid A, Emanuel E, Wendler D. Risks of phase 1 research with healthy participants: a systematic review. *Clinical trials*. In press.

Danis M, Wendler D, Kim S. Acceptable approaches to enrolling adults who cannot consent to more than minimal risk research *AJBOB*. In press.

Rulli T, Wendler D. The duty to take rescue precautions. *Journal of Applied Philosophy*. In press.

Wherrett DK, Chiang JL, Delamater AM, DiMeglio LA, Gitelman SE, Gottlieb PA, MD, Herold KC, Lovell DJ, Orchard TJ, Ryan CM, Schatz DA, Wendler D, Greenbaum CJ. Defining pathways for development of disease modifying therapies in children with type 1 diabetes consensus report. *Diabetes Care* 2015; 38:1975-1985.

Nayak R, Wendler D, Miller F, Kim S. Pragmatic randomized controlled trials without written consent: a national survey. *Annals of Internal Medicine* 2015; 163:356-364.

Lantos JD, Wendler D, Septimus E, Wahba S, Madigan R, Bliss G. Considerations in the evaluation and determination of minimal risk in pragmatic clinical trials. *Clinical Trials* 2015; 12:485-493.

Grady C, Eckstein L, Berkman B, Brock D, Cook-Deegan R, Fullerton SM, Greely H, Hansson MG, Hull S, Kim S, Lo B, Pentz R, Rodriguez L, Weil C, Wilfond BS, Wendler D. Broad consent for research with biological samples. *American Journal of Bioethics* 2015; 15:34-42.

Wiener L, Viola A, Wilfond BS, Wendler D, Grady C. Contrasting views of risk perception and influence of financial compensation between adolescent research participants and their parents. *Journal of Empirical Research on Human Research Ethics* 2015; 10:49-58.

Phillips J, Wendler D. Clarifying substituted judgment: the endorsed life approach. *Journal of Medical Ethics*. 2015; 41:723-730.

Rid A, Wesley R, Pavlick M, Maynard S, Roth K, Wendler D. Patients' priorities for treatment decision-making during periods of incapacity: quantitative survey. *Palliative & Supportive Care* 2015; 13:1165-1183.

Johnson R, Wendler D. Challenging the sanctity of donorism: patient tissue providers as payment-worthy contributors. *Kennedy Institute of Ethics Journal* 2015; 25:291-333.

Kantin H, Wendler D. Is there a role for assent or dissent in animal research? *Cambridge Quarterly of Healthcare Ethics* 2015; 24:459-472

Grady C, Nogues I, Wiener L, Wilfond BS, Wendler D. Adolescent research participants' descriptions of medical research. *AJOB Empirical Research* 2015 DOI: 10.1080/23294515.2015.1017059

Wendler D, Shah S. Involving communities in deciding what benefits they receive in multinational research. *The Journal of Medicine and Philosophy*. 2015; doi: 10.1093/jmp/jhv017

Emanuel E, Bedarida G, Macci K, Gabler N, Rid A, Wendler D. Quantifying the risks of non-oncology phase 1 research in healthy volunteers. *British Medical Journal* 2015; 350:h3271.

Shah N, Fry T, Wayne A, Grady C, Wendler D. Children as hematopoietic cell donors in research: when is it approvable? *Bone Marrow Transplantation* 2015; 50:15-19.

Emanuel E, Joffe S, Grady C, Wendler D, Persad G. Clinical research: Should patients pay to play? *Science Translational Medicine* 2015; 7:298ps16

Wendler D. Targeted consent for pragmatic clinical trials. *Journal of General Internal Medicine* 2015; 30:679-682.

Shah S, Wendler D, Danis M. Examining the ethics of clinical use of unproven interventions outside of clinical trials during the ebola epidemic. *American Journal of Bioethics* 2015; 15:11-16.

Brody B, Migueles SM, Wendler D. Should all research subjects be treated the same? *Hastings Center Report* 2015; 45:17-20.

Wendler D, Rid A. Genetic research on biospecimens poses minimal risk. *Trends in Genetics* 2015; 31:11-15.

Rid A, Abdoler E, Roberson-Nay R, Pine DS, Wendler D. Evaluating the risks of clinical research: direct comparative analysis. *Journal of Child and Adolescent Psychopharmacology* 2014; 24:390-398.

Wendler D. Justice and non-therapeutic pediatric research. *American Journal of Bioethics* 2014; 14:13-15.

Dal-Ré R, Ndebele P, Higgs E, Sewankambo N, Wendler D. Protections for clinical trials in low and middle income countries need strengthening not weakening. *British Medical Journal* 2014; 349:g4254.

Shah S, Gay HB, Kruger M, Wendler D, Taylor H, Persaud D, Grady C. Research on a functional cure for HIV in neonates: the need for ethical foresight. *Lancet Infectious Diseases* 2014; 14:893-898.

Phillips J, Wendler D. Which alternatives should investigators disclose to research participants? *American Journal of Bioethics* 2014; 14:54-55.

Wendler D. Should protections for research with humans who cannot consent apply to research with nonhuman primates? *Theoretical Medicine and Bioethics* 2014; 35:157-173.

Brock DW, Park JK, Wendler D. Making treatment decisions for oneself: weighing the value. *Hastings Center Report* 2014; 44:22-25.

Grady C, Wiener L, Abdoler E, Trauernicht E, Zadeh S, Diekema DS, Wilfond BS, Wendler D. Assent in research: the voices of adolescents. *Journal of Adolescent Health* 2014; 54:515-520.

Rid A, Wendler D. Treatment decision making for incapacitated patients: is development and use of a patient preference predictor feasible? *Journal of Medicine and Philosophy* 2014; 39:130-152.

Rid A, Wendler D. Use of a patient preference predictor to help make medical decisions for incapacitated patients. *Journal of Medicine and Philosophy* 2014; 39:104-129.

Wendler D. Problems with the consensus definition of therapeutic misconception. *Journal of Clinical Ethics* 2013; 24:387-394.

Wendler D. Do U.S. regulations allow more than minor increase over minimal risk pediatric research? Should they? *IRB: Ethics & Human Research* 2013; 35:1-8.

Wendler D. What should be disclosed to research participants? *American Journal of Bioethics* 2013; 13:3-8.

Millum J, Wendler D, Emanuel E. The 50th anniversary of the Declaration of Helsinki: progress but many remaining challenges. *JAMA* 2013; 310:2143-2144.

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

Wendler D. Broad versus blanket consent for research with human biological samples. *Hastings Center Report* 2013; 43:3-4.

Abdul-Karim R, Berkman B, Rid A, Wendler D, Khan J, Badgett T, Hull S. Disclosure of incidental findings from next generation sequencing in pediatric genomic research. *Pediatrics* 2013; 131:564-571.

Grady C, Wendler D. Making the transition to a learning health care system. *Hastings Center Report* 2013; 43:S32-S33.

Wendler D. Time to stop worrying about the therapeutic misconception. *The Journal of Clinical Ethics* 2012; 23:272-287.

- Wendler D, Abdoler E, Wiener L, Grady C. Views of adolescents and parents on pediatric research without the potential for clinical benefit. *Pediatrics* 2012; 130:692-699.
- Levine D, Cohen KJ, Wendler D. Shared medical decision-making: considering what options to present based on an ethical analysis of the treatment of brain tumors in very young children. *Pediatric Blood & Cancer* 2012; 59:216-220.
- Wendler D. Taking the measure of the therapeutic misconception. *Clinical Trials* 2012; 9:762-764.
- Rulli T, Emanuel EJ, Wendler D. The moral duty to buy health insurance. *JAMA* 2012; 308:137-138.
- Wendler D. The ethics of studying subjects in non-ideal circumstances. *Tobacco Control* 2012; 21:385-386.
- Kelly B, Rid A, Wendler D. Systematic review: individuals' goals for surrogate decision making. *Journal of the American Geriatrics Society* 2012; 60:884-895.
- Abdoler E, Wendler D. Using data to improve surrogate consent for clinical research with incapacitated adults. *Journal of Empirical Research on Human Research Ethics* 2012; 2:37-50.
- Wendler D. Consent for research with biological samples: one-time general consent versus a gift model. *Annals of Internal Medicine* 2012; 156:596-598.
- Friedman A, Robbins E, Wendler D. Which benefits of research participation count as 'direct'? *Bioethics* 2012; 26:60-67.
- Wendler D. A new justification for pediatric research without the potential for clinical benefit. *American Journal of Bioethics* 2012; 12:23-31.
- Rid A, Wendler D. A proposal and prototype for a research risk repository to improve the protection of research participants. *Clinical Trials* 2011; 8:710-721.
- Gronowski AM, Moye J, Wendler D, Caplan A, Christman M. The use of human tissues in research: what do we owe the research subjects? *Clinical Chemistry* 2011; 57:540-544.
- Wendler D. How to enroll participants in research ethically. *JAMA* 2011; 305:1587-1588.
- Wendler D, Rid A. The effect on surrogates of making treatment decisions for others. *Annals of Internal Medicine* 2011; 154:336-346.
- Wendler D. What we worry about when we worry about the ethics of clinical research. *Theoretical Medicine and Bioethics* 2011; 32:161-180.
- Lantos J, Matlock AM, Wendler D. Clinician integrity and limits to patient autonomy. *JAMA* 2011; 305:495-499.
- Rid A, Wendler D. A Framework for risk-benefit evaluations in biomedical research. *Kennedy Institute of Ethics Journal* 2011; 21:141-179.
- Smith W, Grady C, Krohmal B, Lazovski J, Wendler D. Empirical evaluation of the need for 'on-going consent' in clinical research. *AIDS* 2011; 25:107-114.

Chan B, Wendler D. International guidelines and ethical context. *AJOB Primary Research* 2010; 1:28-30.

Wendler D, Abdoler E. Does it matter whether investigators intend to benefit research subjects? *Kennedy Institute of Ethics Journal* 2010; 20:353-370.

Rid A, Emanuel E, Wendler D. Evaluating the risks of clinical research. *JAMA* 2010; 304:1472-1479.

Shah S, Wendler D. Interpretation of the subjects' condition requirement: A legal perspective. *Journal of Law, Medicine, & Ethics* 2010; 38:365-373.

Rid A, Wendler D. Can we improve decision-making for incapacitated patients? *Hastings Center Report* 2010; 40:36-45.

Largent E, Wendler D, Emanuel E, Miller FG. Is emergency research without initial consent justified? The consent substitute model. *Archives of Internal Medicine* 2010; 170:668-674

Wendler D. Are physicians obligated always to act in the patient's best interests? *Journal of Medical Ethics* 2010; 36:66-70.

Rid A, Wendler D., Risk-benefit assessment in medical research – critical review and open questions. *Law, Probability and Risk* 2010; 9:151-177.

Matsui K, Zeid AA, Zhang X, Krohmal B, Muthuswamy V, Koo YM, Wendler D, Chao J, Kita Y, Lie R. Informed consent to future research on stored tissue samples: the views of researchers, ethics review committee members and policy makers in five non-Western countries. *Asian Bioethics Review* 2009; 1:401-416.

Miller F, Wendler D. The ethics of sham invasive intervention trials. *Clinical Trials* 2009; 6:401-402.

Lazovski J, Losso M, Krohmal B, Emanuel EJ, Grady C, Wendler D. Benefits and burdens of participation in a longitudinal clinical trial. *Journal of Empirical Research on Human Research Ethics* 2009; 4:89-97.

Dickert N, Wendler D. Ancillary care obligations of medical researchers. *JAMA* 2009; 302:424-428.

Wendler D. Minimal risk in pediatric research as a function of age. *Archives of Pediatric and Adolescent Medicine* 2009; 163:115-118.

Wendler D. Must research participants understand randomization? *American Journal of Bioethics* 2009; 9:1-6.

Varma S, Jenkins T, Wendler D. How do children and parents make decisions about pediatric clinical research? *Journal of Pediatric Hematology and Oncology* 2008; 30:823-828.

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; 26:3987-3994.

Miller FG, Gluck JP, Wendler D. Debriefing and accountability in deceptive research. *Kennedy Institute of Ethics Journal* 2008; 18:235-251.

Abdoler E, Taylor H, Wendler D. The ethics of phase 0 oncology trials. *Clinical Cancer Research* 2008; 14:3692-3697.

Wendler D, Krohmal B, Emanuel EJ, Grady C. Why patients continue to participate in clinical research. *Archives of Internal Medicine* 2008; 168:1294-1299.

Grady C, Wagman J, Ssekubugu R, Wawer MJ, Serwadda D, Kiddugavu M, Nalugoda F, Gray RH, Wendler D, Dong O, Dixon DO, Townsend B, Wahl E, Emanuel E. Research benefits for hypothetical HIV vaccine trials: the views of Ugandans in the Rakai District. *IRB: Ethics & Human Research* 2008; 30:1-7.

Applbaum AI, Tilburt JC, Collins MT, Wendler D. A family's request for complementary medicine after patient brain death. *JAMA* 2008; 299:2188-2193.

Wendler D, Grady C. What should research participants understand to understand they are participants in research? *Bioethics* 2008; 22:203-208.

Wendler D. Is it possible to protect pediatric research subjects without blocking appropriate research? *Journal of Pediatrics* 2008; 152:467-470.

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

Varma S, Wendler D. Research involving wards of the state: protecting particularly vulnerable children. *Journal of Pediatrics* 2008; 152:9-14.

Wendler D, Jenkins T. Children's and their parents' views on facing research risks for the benefit of others. *Archives of Pediatrics & Adolescent Medicine* 2008; 162:9-14.

Varma S, Wendler D. Medical decision making for patients without surrogates. *Archives of Internal Medicine* 2007; 167:1711-1715.

Wendler D, Pentz B. How does the collection of genetic test results affect research participants? *American Journal of Medical Genetics* 2007; 143A:1733-1738.

Wendler D, Miller FG. Assessing research risks systematically: the net risks test. *Journal of Medical Ethics*. 2007; 33:481-486.

Wendler D, Glantz L. A new standard for assessing the risks of pediatric research: pro and con. *Journal of Pediatrics* 2007; 150:579-582.

Shalowitz D, Garrett-Mayer E, Wendler D. How should treatment decisions be made for incapacitated patients, and why? *PLoS Medicine* 2007; 4:e35.

Wendler D, Varma S. Minimal risk in pediatric research. *Journal of Pediatrics* 2006; 149:855-861.

Wendler D, Cornelio M. Overcoming language barriers in medical care. *Pediatric Blood and Cancer* 2006; 47:747.

- Wendler D. A Three step approach to assessing the risks of pediatric research. *PLoS Clinical Trials* 2006; September: e25.
- Pace C, Grady C, Wendler D, Bebhuk JD, Tavel JA, McNay LA, Forster HP, Killen J, Emanuel EJ. Post trial access to tested interventions: the views of IRB/REC chairs, investigators and research participants in a multinational HIV/AIDS study. *AIDS Research and Human Retroviruses* 2006; 22:837-841.
- Wendler D. Clinical research, clinical tragedies, and the assumption of responsibility. *Journal of Organizational Ethics* 2006; Spring/Summer: 46-49.
- Gbadegessin S, Wendler D. Protecting communities in health research from exploitation. *Bioethics* 2006; 20:248-253.
- Wendler D, Shah S. How can medical training and informed consent be reconciled with volume-outcome data? *Journal of Clinical Ethics* 2006; 17:149-157.
- Peerzada JM, Wendler D. Hematopoietic stem cell transplant research with pediatric donors: when can institutional review boards approve it? *Transplantation* 2006; 81:1616-1620.
- Gross CP, Krumholz HM, Van Wye G, Emanuel EJ, Wendler D. Does random treatment assignment cause harm to research participants? *PLoS Medicine* 2006; 3:e188.
- Wendler D. One-time general consent for research on biological samples: is it compatible with the Health Insurance Portability and Accountability Act? *Archives of Internal Medicine* 2006; 166:1449-1452.
- Shalowitz D, Wendler D. Informed consent for research and authorization under the health insurance portability and accountability act privacy rule: an integrated approach. *Annals of Internal Medicine* 2006; 144:685-688.
- Miller FG, Wendler D. The relevance of empirical research in bioethics. *Schizophrenia Bulletin* 2006; 32:37-41.
- Wendler D. Assent in paediatric research: theoretical and practical considerations. *Journal of Medical Ethics* 2006; 32:229-234.
- Pentz RD, Billot L, Wendler D. Research on stored biological samples: views of African American and White American cancer patients. *American Journal of Medical Genetics* 2006; 140:733-739.
- Wendler D. One-Time general consent for research on biological samples. *British Medical Journal* 2006; 332:544-547.
- Shalowitz D, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision-makers: a systematic review. *Archives of Internal Medicine* 2006; 166:493-497.
- Wendler D, Kington R, Madans J, Van Wye Heidi G, Christ-Schmidt H, Pratt LA, Brawley OW, Gross CP, Emanuel EJ. Are racial and ethnic minorities less willing to participate in health research? *PLoS Medicine* 2006; 3:e19.
- Muthappanian G, Forster H, Wendler D. Research advance directives: protection or obstacle? *American Journal of Psychiatry* 2005; 162:2389-2391.

- Wendler D, Emanuel EJ. What is a 'minor' increase over minimal risk? *Journal of Pediatrics* 2005; 147:575-578.
- Sabik L, Pace CA, Forster-Gertner H, Wendler D, Bebhuk J, Tavel JA, McNay L, Killen J, Emanuel EJ, Grady C. Informed consent: practices and views of investigators in a multinational clinical trial. *IRB: Ethics & Human Research* 2005; 27:13-18.
- Miller FG, Wendler D, Swartzman LC. Deception in research on the placebo effect. *PLoS Medicine* 2005; 2:853-859.
- Wendler D. Protecting subjects who cannot give consent: toward a better standard for 'minimal' risks. *Hastings Center Report* 2005; 35:37-43.
- Wendler D, Belsky L, Thompson KM, Emanuel EJ. Quantifying the federal minimal risk standard: implications for pediatric research without a prospect of direct benefit. *JAMA* 2005; 294:826-832.
- Pace C, Talisuna A, Wendler D, Maiso F, Wabwire-Mangen F, Bakyaite N, Okiria E, Garrett-Mayer ES, Emanuel EJ, Grady C. The quality of parental consent for a Ugandan malaria study. *American Journal of Public Health* 2005; 95:1184-1189.
- Ravitsky V, Wendler D. Dissolving the dilemma over forced treatment. *Lancet* 2005; 365:1525-1526.
- Wendler D, Pace C, Talisuna A, Maiso F, Grady C, Emanuel EJ. Research on stored biological samples: the views of Ugandans. *IRB: Ethics and Human Research* 2005; 27:1-5.
- Chen DT, Rosenstein DL, Muthappan PG, Hilsenbeck SG, Miller FG, Emanuel EJ, Wendler D. Research with stored biological samples: what do research participants want? *Archives of Internal Medicine* 2005; 165:652-655.
- Pace C, Emanuel EJ, Chuenyam T, Duncombe C, Bebhuk JD, Wendler D, Tavel JA, McNay LA, Phanuphak P, Forster HP, Grady C. The quality of informed consent in a clinical research study in Thailand. *IRB: Ethics and Human Research* 2005; 27:9-17.
- Wendler D. Can we ensure all research subjects give valid consent? *Archives of Internal Medicine* 2004; 164:2201-2204.
- Ulrich CM, Grady C, Wendler D. Palliative care: a supportive adjunct to pediatric phase I clinical trials for anti-cancer agents? *Pediatrics* 2004; 114:852-855.
- Whittle A, Shah S, Wilfond B, Gensler G, Wendler D. IRB practices regarding assent in pediatric research. *Pediatrics* 2004; 113:1747-1752.
- Wendler D, Emanuel EJ, Lie R. The standard of care debate: can researchers be ethical and helpful in developing countries? *American Journal of Public Health* 2004; 94:923-928.
- Wendler D. Risk standards for pediatric research: rethinking the *Grimes* ruling. *Kennedy Institute of Ethics Journal* 2004; 14:189-200.
- Lie R, Emanuel EJ, Grady C, Wendler D. The standard of care debate: the Declaration of Helsinki versus the international consensus opinion. *Journal of Medical Ethics* 2004; 30:190-193.

- Wendler D, Miller F. Deception in the pursuit of science. *Archives of Internal Medicine* 2004; 164:597-600.
- Miller F, Wendler D. Assessing the ethics of ethics research. *IRB: Ethics and Human Research* 2004; 26:9-12.
- Emanuel EJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Diseases* 2004; 189:930-937.
- Wendler D, Emanuel EJ. Assessing the ethical and practical wisdom of surrogate living organ donation. *JAMA* 2004; 291:732-735.
- Wendler D, Forster H. Why we need legal standards for pediatric research. *Journal of Pediatrics* 2004; 144:150-153.
- Shah S, Whittle A, Wilfond B, Gensler G, Wendler D. How do IRBs apply the federal risk and benefit standards for pediatric research? *JAMA* 2004; 291:476-482.
- Wendler D, Shah S. Should children decide whether they are enrolled in non-beneficial research? *American Journal of Bioethics* 2003; 3:1-7.
- Wendler D, Shah S, Whittle A, Wilfond B. Non-beneficial research with individuals who cannot consent: is it ethically better to enroll healthy or affected individuals? *IRB: Ethics and Human Research* 2003; 25:1-4.
- Miller F, Wendler D, Wilfond B. When do the federal regulations allow placebo-controlled trials in children? *Journal of Pediatrics* 2003; 142:102-107.
- Wendler D, Prasad K, Wilfond B. Does the current consent process minimize the risks of genetics research? *American Journal of Medical Genetics* 2002; 113:258-262.
- Wendler D, Rackoff J, Emanuel EJ, Grady C. The ethics of paying for children's research participation. *Journal of Pediatrics* 2002; 141:166-171.
- Wendler D, Emanuel EJ. The debate over research on stored biological samples: What do sources think? *Archives of Internal Medicine* 2002; 162:1457-1462.
- Wendler D, Rackoff J. Consent for continuing research participation: what is it and when should it be obtained? *IRB: Ethics and Human Research* 2002; 24:1-6.
- Participants in the 2001 Conference. Fair benefits for research in developing countries. *Science* 2002; 298:2133-2134.
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- Wendler D. What research with stored samples teaches us about research with human subjects. *Bioethics* 2002; 16:33-54.

Wendler D, Prasad K. Core safeguards for clinical research with adults who are unable to consent. *Annals of Internal Medicine* 2001; 135:514-523.

Wendler D, Rackoff J. Respecting individual autonomy: what's a signature got to do with it? *IRB: Ethics and Human Research* 2001; 23:1-4.

Wendler D, Dickert N. The consent process for cadaveric organ procurement: how does it work? how can it be improved? *JAMA* 2001; 285:329-333.

Wendler D. Informed consent, exploitation, and whether it is possible to conduct human subjects research without either one. *Bioethics* 2000; 14:310-339.

Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA* 2000; 283:2701-2711.

Wendler D. The importance of autonomy not being all-important. *BioLaw* 1999; S:445-451.

Wendler D. Understanding the conservative view on abortion. *Bioethics* 1999; 13:32-56.

Wendler D. When should 'riskier' subjects be excluded from research? *Kennedy Institute of Ethics Journal* 1998; 8:307-327.

Wendler D. Locke's acceptance of innate concepts. *Australasian Journal of Philosophy* 1996; 74:467-483.

Wendler D. Innateness as an explanatory concept. *Biology and Philosophy* 1996; 11:89-116.

Wendler D. Deception in medical and behavioral research: is it ever acceptable? *Milbank Quarterly* 1996; 74:87-114.

HONORS AND AWARDS

2012	Clinical Center Director's Award for scientific achievement
2012	NIDA Special Service award
2009	Clinical Center Director's award for teaching/training
2007	Award for Excellence in Human Research Protection
2006	NIDA Special Service award
2005	Clinical Center Director's award
2005	NIH mentoring award
2001	NIH clinical center special service award
1998	NIH clinical center special recognition award
1997	NIAID clinical service award
1996	NIH excellence in research ethics
1995	NIH citation for education in ethics
1994	NIH citation for clinical ethics
1991	WARF dissertation fellowship
1990	Outstanding teaching award
1989	Vilas academic achievement fellowship
1982	Honors in ethics

SELECTED PRESENTATIONS

“Risk-Benefit judgments in clinical research: components analysis and the net risks test,” Norway conference on research ethics, Bergen, Norway, June 17, 2015.

“Ebola, study design and the duty to rescue,” Georgetown Intensive Bioethics Course, Washington, DC, June 5, 2015.

“Risk-benefit analysis in HIV prevention trials,” Advanced course in research ethics, Harare, Zimbabwe, April 28, 2015.

“Procedural sedation and components analysis,” FDA conference on pediatric research, Silver Spring, MD, March 23, 2015.

“Ethical issues in pediatric drug development trials,” American Diabetes Association, Consensus Conference, Arlington, VA, January 14, 2015.

“Practice and policy of pediatric euthanasia,” American Philosophical Association, Eastern meeting, Philadelphia, PA, December 29, 2014.

“Targeted consent for comparative effectiveness trials,” OHRP Research Community Forum: Moving Beyond the Basics of Informed Consent, Philadelphia, PA, October 23, 2014.

“Ethical issues raised by the Ebola crisis,” Special Ethics Grand Rounds, NIH Clinical Center, October 22, 2014.

“Double standards: what are they; what can be done about them?” World Congress of Bioethics, Mexico City, Mexico, June 26, 2014.

“Scandals, models, and regulations,” Georgetown University, Intensive Bioethics Course, Washington, DC, June 4, 2014.

“Are there degrees of moral status?” New York University, Bioethics Colloquium, New York, NY, February 14th, 2014

“Ethical research and learning health care.” Ethics Grand Rounds, UT Southwestern, Dallas, TX, February 11, 2014.

“Implementing the minimal risk standard.” FDA meeting on pediatric research. Bethesda MD, September 9, 2013.

“Consent for high risk activities,” IOM/NASA Meeting, Ethics Principles for Long Duration and Exploration Spaceflights, Washington, DC, July 25, 2013.

“Minimal Risk: is it the limit for ethical pediatric research,” 1st Annual Pediatric Surgical Innovation Symposium, Washington, DC, June 13, 2013.

“Can we ethically combine clinical care and clinical research?” Georgetown University Medical School, Washington, DC, April 24, 2013.

“The ethics in observational trials,” NHLBI conference on embedding intervention trials in observational trials, Rockville, MD, April 8, 2013.

“The ethics of research with non-human primates,” PRIMR Conference on Animal Care and Use, Baltimore, MD, March 19, 2013.

“Conflicts of interest and ethics in rare diseases research,” 3rd Conference on Clinical Research for Rare Diseases, Rockville, MD, October 2, 2012.

“Ethical challenges in surrogate decision-making,” Grand Rounds, Saint Elizabeth’s Hospital, Washington, DC, September 5, 2012.

“Research in emergency settings,” NIH Grand Rounds for Clinical Fellows, Bethesda, MD, August 8, 2012.

“Principles for greater than minimal risk non-beneficial pediatric research,” President’s Commission for the Study of Bioethical Issues, Washington, DC, August 2, 2012.

“Engaging communities in clinical and biospecimen research,” NCI Community Network Program Centers, Bethesda, MD, July 31, 2012.

“Normative implications of the duty to rescue,” University of Michigan, Department of Bioethics and Social Sciences in Medicine, Ann Arbor Michigan, May 17, 2012.

“The ethics of assessing risks,” AAHRPP annual conference, Denver, Colorado, April 19, 2012.

“The risks of research without subjects,” Korean National Biobank, Osong, Korea, March 21, 2012.

“Should children have a say?” Ewha-NIH conference on research ethics, Seoul, Korea, March 19, 2012.

“Minimizing the risks of deceptive research,” PRIMR Advancing Research Ethics conference, National Harbor, MD, December 4, 2011.

“Getting risk evaluation right,” AAAS Meeting on Human Subjects Research, Washington, DC, September 26, 2011.

“The Fair Benefits approach,” World Medical Association Conference, Sao Paulo, Brazil, July 15, 2011.

“What counts as a risk of research participation?” Conference on Research Ethics, Beijing China, June 29, 2011.

“Clinicians involvement with incapacitated patients,” Spring Conference, Association of Healthcare Social Workers, Washington, DC, May 25, 2011.

“Non-beneficial research with individuals who lack the concept of other,” Grand Rounds, Seattle Children’s Hospital/University of Washington, Seattle, Washington, May 12, 2011.

“Making decisions at the end of life,” Pulmonary Grand Rounds, University of Pennsylvania, Philadelphia, PA, April 20, 2011,

“Ethical issues in research on rare diseases,” FDA workshop on drug development in rare diseases, Washington, DC, March 3, 2011.

“Evaluating the validity of subjects’ consent,” NIDA clinical rounds, Baltimore, MD, November 18, 2010.

“Research on adults with psychiatric conditions,” Rush University, Chicago, Illinois, November 17, 2010.

“A justification for research without consent,” American Heart Association, Annual conference, Chicago, Illinois, November 15, 2010.

“What is research?” PAHO Research Workshop, Washington, DC, November 1, 2010.

“Ethical issues in pediatric sham neurosurgical trials,” NIH Conference on Sham Neurosurgical Trials, Bethesda, MD, June 30, 2010.

“Non-therapeutic research with children: science and ethics,” Pediatric Academic Societies, Annual Meeting, Vancouver, Canada, May 1, 2010.

“Pediatric research and pediatric charities,” International Experts Workshop, Istanbul, Turkey, December 8, 2009.

“When are exclusions unfair?” NIH Course on Ethical and Regulatory Aspects of Clinical Research, Bethesda, MD, September 30, 2009.

“The ethics of risk-benefit evaluations,” Workshop on Advanced Research Ethics, Lima, Peru, September 3, 2009.

“Improving end of life treatment decisions for incapacitated patients,” NIH Grand Rounds, August 12, 2009.

“Ethics research and ethics regulations,” OHRP meeting on research ethics, Rockville, MD, July 17, 2009.

“A framework for evaluating risks and benefits,” Southeast Asian Infectious Disease Clinical Research Network, Ho Chi Minh City, Vietnam, April 20, 2009.

“Ethical research without informed consent,” University of the Philippines, Diliman, Philippines April 17, 2009.

“Why we should stop worrying about the therapeutic misconception,” NY Regional Bioethics Conference, NY, NY, March 6, 2009.

“Ethical recruitment of research subjects,” NIH STEP training forum, Bethesda, MD, February 19, 2009.

“How not to define a condition in pediatric research,” The Endocrine Society meeting on regulation of clinical research, Bethesda, MD, November 6, 2008.

“The ethics of research with children,” Nagasaki University, Nagasaki, Japan, June 30, 2008.

“Conducting ethical clinical research,” Clinical Research in Vietnam, Hanoi, Vietnam, June 25, 2008.

“Evaluating risks in pediatric research,” Pediatric Diabetes Network, Arlington, VA, April 16, 2008.

“How is clinical research different from clinical care and sneaker factories,” Washington University School of Medicine, Pulmonary and Critical Care Grand Rounds, February 14, 2008.

“Biotechnology and developing countries,” Biotechnology Industry Organization, October 24, 2007.

“Protecting communities in dementia research?” National Institute on Aging, summer retreat, Queenstown, MD, July 17, 2007.

“Research with children: what is the ethical worry?” Harvard University Program in Medical Ethics, Boston, MA, June 5, 2007.

“Assent and the implications of respect,” American Society for Clinical Oncology, Annual Meeting, Chicago, Illinois, June 2, 2007.

“Research with cognitively impaired adults: current guidelines and practice,” University of Illinois School of Medicine, Chicago, Illinois, June 1, 2007.

“Declaration of Helsinki and fair benefits: is there an ethical way forward for malaria chemoprophylaxis?” International Society of Travel Medicine, 10th Annual Conference, Vancouver, BC, Canada, May 22, 2007.

“Treatment decisions for incapacitated patients: how should they be made and why?” Harvard Medical School, Brigham and Women’s Hospital, Boston, MA, May 8, 2007.

“Implications of empirical data for the assent process in pediatric research,” Israel Ministry of Health Conference on Clinical Research, Jerusalem, Israel, December 21, 2006.

“Ethical issues in clinical trials,” NIAID Workshop on Clinical Research, Opatija, Croatia, June 25, 2006.

“How can we increase minority participation in clinical trials?” Office of Minority Health roundtable, Bethesda, MD, May 26, 2006.

“What does the standard of care debate have to do with caring?” Peru Conference on Collaborative Research, Iquitos, Peru, March 30, 2006.

“Is it ethical to keep interim data confidential?” University of Virginia, Colloquia, Bioethics Program, February 22, 2005.

“Risk-Benefit evaluation in clinical research,” Japan Research Ethics conference, Tokyo, Japan, December 10, 2005.

“Stored samples and consent,” WHO meeting on research ethics, Jakarta, Indonesia, December 2, 2005.

“Subject selection and assent in pediatric obesity research,” FDA Pediatric Advisory Committee, Gaithersburg, MD, November 16, 2005.

“Orphans in HIV research,” Pediatric AIDS Clinical Trials Groups, Annual Meeting, Washington, DC, October 22, 2005.

“Assessing risk in pediatric critical care research,” Collaborative Pediatric Critical Care Research Network (CPCCRN), Rockville, MD, September 7, 2005

“The ethical acceptability of research risks in children,” Latin America Conference on International Collaborative Research, Lima, Peru, June 23, 2005.

“Is research different?” Georgetown Intensive Bioethics Course, Washington, DC, June 10, 2005.

“Is it ethical to pay for children’s research participation?” Johns Hopkins, May 17, 2005.

“Assent and dissent in pediatric research,” SARETI conference on research ethics in developing countries, Durban, South Africa, March 1, 2005.

“What is minimal risk in children?” Africa Malaria Network Trust Advanced Course in Bioethics, Zanzibar, Tanzania, December 2, 2004.

“The ethics of international clinical trials,” NIH Clinical Center Grand Rounds, Bethesda MD, August 11, 2004.

“Why does unethical research occur?” NIDDK Conference on Clinical Research in Kidney and Urologic Diseases, Washington, DC, July 10, 2004.

“Consent for research with stored samples: the state of the data,” University of Sao Paulo School of Medicine, Sao Paulo, Brazil, June 9, 2004.

“How can we protect research subjects with dementia?” University of Maryland School of Medicine, Baltimore, MD, April 15, 2004.

“What is potential benefit research in children?” American Society of Clinical Oncology Symposium, Washington, DC, March 30, 2004.

“Pediatric research ethics,” NIH Conference on Research Ethics, Cairo, Egypt, March 17, 2004.

“Ethics of research in Southeast Asia on biological samples,” ICMR Research Ethics Conference, Chennai, India, January 16, 2004

“Is broad pathogen reduction just?” NHLBI Workshop on Pathogen Reduction and Blood Component Safety, August 1, 2000.

“The ethics of genetic research on stored biological samples,” Argentina conference on research ethics, Igauzu, Argentina, June 18, 2003.

“The current data on research with cognitively impaired adults,” University of Maryland School of Medicine, Baltimore, MD, April 10, 2003.

“Ethical issues in small trials,” NIH Antiviral Study Group, Annual Meeting, Bethesda, MD February 20, 2003.

“Subject selection in the developing world,” NIAID vaccine development conference, Bamako, Mali, January 20, 2003.

“The current data on the children’s research regulations,” Institute on Medicine, January 9, 2000.

“Clinical research without consent,” Harvard University Fellows’ Seminar, October 1, 2002.

“Ethical issues in orphan populations,” FDA conference on orphan drug development, Bethesda, MD, September 23, 2002.

“Assessing cognitive impairment at the end of life,” Conference on research at the end of life, Bethesda, MD, September 12, 2002.

“The data on subjects who cannot consent,” NIH Clinical Fellows Grand Rounds, August 28, 2002.

“Subject selection: getting it right,” Korea-NIH Conference on Human Subjects Research, Seoul, Korea, June 25, 2002.

“Placebo trials in osteoporosis: ethical considerations,” ASBMR 24th Annual Meeting, Bethesda, MD, June 14, 2002.

“Ethical Issues in conducting pharmacy research with children,” NIH conference on pharmacy research, May 18, 2002.

“Assessing investigators’ obligations to research subjects,” NIAID/Uganda Ministry of Health conference on research ethics, Kampala, Uganda, March 27, 2002.

“What are investigators’ obligations to treat subjects’ non-research related health needs?” NIH/European Union conference on research ethics, Accra, Ghana, March 27, 2002.

“How to conduct clinical research with adult who are unable to consent,” Harvard University Clinical Fellows’ Seminar, October 2, 2001.

“How to conduct randomized clinical trials and sleep at night,” NIDDK National Conference on preparing for a career in clinical nephrology, September 7, 2001.

“The present state of guidelines for multinational clinical research,” Indian Council of Medical Research conference, New Delhi, India, October 20, 2000.

“How to conduct randomized clinical trials and sleep at night,” NIDDK National Conference on preparing for a career in clinical nephrology, September 10, 2000.

“Drug research with parolees,” NIDA Clinical Trials Group, Bethesda, MD, July 31, 2000.

“International perspectives on research with adults unable to consent,” World Psychiatric Association Congress, Paris France, June 27, 2000.

“Clinical assessments of capacity: what are the conditions and who should assess them,” 15th Bioethics Summer Retreat, Monterey, CA, June 23, 2000.

“Research with individuals unable to consent: the problem, the proposals, and the data,” NIH Clinical Center Grand Rounds, June 7, 2000.

“Abortion: The state of the philosophical debate,” NIH Bioethics Seminar, December 8, 1999.

“Coma and death: in search of the limits of autonomy,” Session Chair, American Society of Bioethics and Humanities Second Annual Meeting, Philadelphia, PA, October 31, 1999.

Research with individuals unable to consent: are advance directives the answer?” National Institutes of Health Research Festival, October 7, 1999.

“The ethics of organ procurement and allocation,” Health Resources and Services Administration Grand Rounds, September 20, 1999.

“Ethical research in the international setting,” National Institute of Child Health and Human Development Global research working group, Bethesda MD, September 14, 1999.

“What makes clinical research ethical?” Multinational Initiative on Malaria Pan-African conference, Durban South Africa, March 17, 1999.

“What is the connection between moral theory and moral action?” Bioethics Fellows’ Seminar, December 16, 1998.

“Safeguarding research subjects with compromised consent capacity,” Bioethics Research Group, December 9, 1998.

“Ethics in the ICU,” Critical Care Department fellows seminar, July 28, 1998.

“Informed consent and genetic research,” National Institute on Dental Research working group on clinical research, July 8 1998.

“A patient with multi-organ failure in the intensive care unit,” Clinical Center Clinical Pathology Conference, May 20, 1998.

“HIV/AIDS and ethics,” Social Work Fellows’ Seminar, March 19, 1998.

“Developing an ethics research protocol,” Genetic Counseling Master’s Seminar, February 13, 1998.

“Writing a DNR policy that works,” Critical Care Medicine Department Senior Staff Conference, May 11, 1997.

"The variables involved in patient decision making," Critical Care Medicine Department Senior Staff Conference, June 12, 1996

“Sexual identity and discrimination,” Session Chair, World Congress of Bioethics, October 21, 1996.

"Deception in informed consent: is it acceptable?" Clinical Center bioethics colloquium, October 13, 1994.

"The geneticist's dilemma: notifying subjects of unanticipated results," Clinical Center bioethics colloquium, April 21, 1994.