Curriculum Vitae

September 3, 2022

Robert Meland Nelson, M.D., Ph.D.

Office Address: 1400 McKean Road
Spring House, PA 19477
E-mail: rnelso30@its.jnj.com

Education:

1967 - 1970	Diploma	Deerfield Academy, Deerfield MA
1970 - 1974	B.A.	Wesleyan University, Middletown CT (Chemistry)
1974 - 1980	M.D.	Yale University School of Medicine, New Haven CT
1976 - 1980	M.Div.	Yale Divinity School, New Haven CT
1982 - 1985	A.M.	Harvard University, Cambridge MA (The Study of Religion)
1982 - 1993	Ph.D.	Harvard University, Cambridge MA (The Study of Religion)

Postgraduate Training and Fellowship Appointments:

1980 - 1983	Intern and Resident in Pediatrics, Massachusetts General Hospital, Boston MA
1980 - 1983	Clinical Fellow in Pediatrics, Harvard Medical School, Boston MA
1984 - 1985	Teaching Fellow, History of Science and Core Program, Harvard University, Cambridge MA
1985 - 1987	Fellow in Neonatology, Cardiovascular Research Institute and the Department of Pediatrics, University of California San Francisco, San Francisco CA
1985 - 1988	Fellow in Medical Ethics, Division of Medical Ethics, Department of Medicine, University of California San Francisco, San Francisco CA
1987 - 1988	Fellow in Pediatric Critical Care, Department of Pediatrics, University of California San Francisco, San Francisco CA

Additional Training:

2014	Federal Executive Institute Leadership Development Course (April/July 2014). Charlottesville VA

Military Service: None

Faculty and Professional Appointments:

1988 - 1990	Assistant Professor of Pediatrics & Medicine, Division of Pediatric Critical Care, Department of Pediatrics, and Program in Medical Ethics, Department of Medicine, University of California San Francisco, San Francisco CA
1990 - 1994	Assistant Professor of Pediatrics, Sections of Critical Care and Neonatology, Department of Pediatrics, Medical College of Wisconsin, Milwaukee WI
1990 - 1994	Assistant Professor of Bioethics, Center for the Study of Bioethics, Medical College of Wisconsin, Milwaukee WI
1994 - 2000	Associate Professor of Pediatrics, Sections of Critical Care and Neonatology, Department of Pediatrics, Medical College of Wisconsin, Milwaukee WI
1994 - 2000	Associate Professor of Bioethics, Health Policy Institute and the Center for the Study of Bioethics, Medical College of Wisconsin, Milwaukee WI
1998 - 2000	Adjunct Associate Professor, Department of Anthropology, University of Wisconsin - Milwaukee, Milwaukee WI

Faculty and Professional Appointments: (continued)

2000 - 2007	Associate Professor of Anesthesiology and Critical Care, Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine, Philadelphia PA
2000 - 2007	Associate Professor of Pediatrics, Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine, Philadelphia PA
2007 - 2009	Professor of Anesthesiology and Critical Care, Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine, Philadelphia PA
2007 - 2009	Professor of Pediatrics, Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine, Philadelphia PA
2006 - 2017	Deputy Director and Senior Pediatric Ethicist, Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, Silver Spring, MD (part-time contract with Children's Hospital of Philadelphia, Oct. 2006; full-time, Aug. 2009)
2018 - present	Senior Director, Pediatric Drug Development, Child Health Innovation Leadership Department (CHILD), Johnson & Johnson, Raritan NJ
2019 - present	Pediatric Strategy Lead, Pediatric Development Team, Immunology Janssen Research & Development, Spring House PA

Hospital, Administrative and Academic Appointments: (selected)

1988 - 1990	Attending Staff, University of California Medical Center, San Francisco CA
1990 - 1995	Associate Attending Staff, Section of Neonatology, Department of Pediatrics, Milwaukee County Medical Complex, Milwaukee WI
1990 - 2000	Courtesy (1990-92), Associate (1992-94) and Active (1994-2000) Medical Staff, Critical Care & Pediatrics, Children's Hospital of Wisconsin (CHW), Milwaukee WI
1990 - 1995	Medical Director, Neonatal Intensive Care Unit, CHW, Milwaukee WI
1990 - 2000	Associate Medical Director, Pediatric Intensive Care Unit, CHW, Milwaukee WI
1994 - 2000	Chair, Research & Publications Committee/Human Rights Review Board (IRB), Children's Hospital of Wisconsin, Milwaukee WI
1996 – 1997	Acting Director of Graduate Studies, Masters Program in Bioethics, Center for the Study of Bioethics, Health Policy Institute, Medical College of Wisconsin, Milwaukee WI
2000 - 2009	Assistant (2000-04) and Associate (2004-09) Physician, Division of Critical Care Medicine, Department of Anesthesiology and Critical Care, Children's Hospital of Philadelphia, Philadelphia PA
2000 - 2009	Senior Fellow, Center for Bioethics, University of Pennsylvania, Philadelphia PA
2000 - 2003	Chair, Committees for the Protection of Human Subjects. The Joseph Stokes Jr. Research Institute, Children's Hospital of Philadelphia, Philadelphia PA
2001 - 2004	Member, Conflict of Interest Standing Committee, University of Pennsylvania, Philadelphia PA
2003 - 2008	Attending, Critical Care Medicine, Department of Anesthesiology and Critical Care, Hospital of the University of Pennsylvania, Philadelphia PA
2006 - 2009	Associate Scholar, Epidemiology, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Philadelphia PA
2006 - 2009	Member, Institute for Translational Medicine and Therapeutics, University of Pennsylvania School of Medicine, Philadelphia PA

Medical Board Certification:

1981	National Board of Medical Examiners (#201601)
1986	The American Board of Pediatrics (ABP) (#33109)
1989	ABP, Perinatal-Neonatal Medicine (Recertification, 2013-2020) (#2107)
1990	ABP, Pediatric Critical Care Medicine (Recertification, 2014-2020) (#279)

Medical Licensure:

1982 - 1986	Massachusetts	(#49178; inactive)
1983 - 1985	New Jersey	(#42357; inactive)
1985 - 1990	California	(#G55274; inactive)
1990 - 2001	Wisconsin	(#31227-020; inactive)
2000 - present	Pennsylvania	(#MD-071035-L; retired status)

Awards, Honors and Memberships in Honorary Societies:

1973	Silverman Prize for Chemistry, Wesleyan University
1973	Phi Beta Kappa
1974	Hawk Prize for Biochemistry, Wesleyan University
1974	American Chemical Society Student Award
1974	Sigma Xi
1974	University Honors in Chemistry, Wesleyan University
1974	Magna Cum Laude, Wesleyan University
1977	Yale International Student Fellowship, Kijabe Medical Centre, Kenya
1977	MAP-Reader's Digest International Fellowship, Kijabe, Kenya
1982-1984	Joseph P. Kennedy, Jr. Fellowship in Medical Ethics, Harvard University
1985	Pass with Distinction, Ph.D. General Exam, Study of Religion, Harvard Univ.
2000	Distinguished Service Award, Applied Research Ethics National Association

Awards (Food and Drug Administration)

2008	Commissioner Special Citation, Center for Drug Evaluation and Research, FDA Pediatric Cough/Cold Drug Advisory Committee Team
2008	Group Recognition Award, Office of the Commissioner, FDA FDA/EMEA International Core Pediatric Collaboration Group
2008	Commissioner's Award of Excellence, Office of the Commissioner, FDA
2008	Special Recognition Award, Center for Drug Evaluation and Research, FDA Rare Disease Working Group
2010	Group Recognition Award, Office of the Commissioner, FDA September 2009 FDA-NICHD Planning Committee
2010	Group Recognition Award, Center for Drug Evaluation and Research, FDA Pediatric Research Equity Act Retrospective Review Working Group
2010	Group Recognition Award, Office of the Commissioner, FDA Strategic Plan for Risk Communication Workgroup
2011	Outstanding Intercenter Science Collaboration Extrapolation Working Group
2011	Outstanding Intercenter Science Collaboration Pediatric Anesthesia Safety (PASI) Team
2012	Commissioner's Award of Excellence, Office of the Commissioner, FDA
2013	Group Recognition Award, Office of the Commissioner, FDA Additional Safeguards for Children in Research Group
2013	Group Recognition Award, Center for Biologics Evaluation and Research, FDA Office of Cellular, Tissue and Gene Therapies (OCTGT) Learn Clinical Webinar Group
2015	Group Recognition Award, Office of the Commissioner, FDA 2014 Patient Network Meeting: Pediatric Drug Development
2015	FDA Group Recognition Award, The Rhizopus oryzae Incident Response Team
2016	Commissioner's Award of Excellence, Office of the Commissioner, FDA Clinical Trial Designs for Emerging Infectious Diseases

Awards (Food and Drug Administration) (continued)

2017 Commissioner's Special Citation, FDA Zika Virus Response Team
2017 Outstanding Service Award, Office of Pediatric Therapeutics

Awards (Johnson & Johnson)

2020 Healthcare Solutions Award

Membership in Professional and Scientific Societies:

National Societies (past):

American Academy of Pediatrics (Fellow)
(Junior Fellow, 1983-86; Section on Perinatal Pediatrics, 1985-2009; Fellow, 1986-2022; Member, Committee on Bioethics, CA Chapter 1, 1988-90; Section on Bioethics, 1990-2022; Section on Critical Care, 1990-2009; Liaison, Section on Critical Care to AAP Committee on Bioethics, 1993; Chair, Bioethics Committee, WI Chapter, 1994-98; Member, Executive Committee, WI Chapter, 1994-2000; Member, 1994-98, and Chair, 1998-01, AAP National Committee on Bioethics; Liaison, AMA Coalition for Quality End-of-Life Care, 1996-97; Liaison, Committee on Ethics, American College of Obstetricians and Gynecologists, 1998-01; Member, Council on Committees, 1998-01; Chair, Nominating Committee, Section on Bioethics, 2003-05); Section on Advances in Therapeutics and Technology, 2010-2022)

National/International Scientific Committees (selected - past):

Pediatric Subcommittee, Anti-Infective Drugs Advisory Committee, Food and Drug Administration (FDA), Washington DC (Member, 1999 - 2004)

Consultant (SGE), Food and Drug Administration, Washington DC (1999 - 2006)
Anti-Infective Drugs Advisory Committee (02/19/02; 06/11/02); Oncologic Drugs Advisory Committee (ODAC) (02/27/02); Pediatric Subcommittee of ODAC (10/17/02); Ethics Working Group, Office of Counterterrorism & Pediatric Drug Development (10/09/02); Joint Meeting of the Dermatologic and Opthalmic Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee (03/24/2005); Neurological Devices Panel (06/17/2005); Circulatory Systems Devices Panel (06/23/2005)

Special Emphasis Panel (Research Ethics), National Institutes of Health, Center for Scientific Review, Bethesda MD (August 2000; December 2000; September 2001; March 2002; September 2005)

Committee on Research Involving Children, Institute of Medicine, The National Academies, Washington DC (Member, 2002 - 2004)

National Institute of Child Health and Human Development and Food and Drug Administration (NICHD-FDA) Neonatal Drug Development Workshop. Newborn Initiative. Chair, Ethics Working Group. (2003 - 2004)

Pediatric Advisory Committee, Food and Drug Administration (Member, 2004 - 2006; Chair 2005 - 2006; Chair, Pediatric Ethics Subcommittee, 2004-2005)

Canadian Institutes of Health Research, Ottawa, Ontario. Ad Hoc Peer Review Committee. RFA: Empirical and Conceptual Research on Ethical, Legal and Social Issues in Studies Involving Pregnant Women and Children. (Member, September 2005)

Human Studies Review Board (HSRB). United States Environmental Protection Agency, Washington DC (Member, 2006)

Clinical and Translational Research Awards, National Center for Research Resources, National Institutes of Health, Washington, DC. CTSA Research Ethics Working Group (CREW) (Member, 2007 - 2009); CREW Regulatory and Ethics IRB Task Force (Member, 2007 - 2009); Pediatric Research Ethics Consultation Group (Member, 2007 - 2009)

National Scientific Committees (selected - past): (continued)

Poster Abstract Sub-Committee, 2008 Annual HRPP Conference, Public Responsibility in Medicine and Research (PRIM&R) (Member, 2008)

Data and Safety Monitoring Board (EPIC). National Heart, Lung, and Blood Institute. National Institutes of Health, Washington, DC (Member, 2004 - 2009)

Data Safety Monitoring Board – Division of Lung Diseases SCCOR, National Heart, Lung, and Blood Institute. National Institutes of Health, Washington, DC (Member, 2007 - 2014)

Council of Canadian Academies Expert Panel, State of Therapeutic Products for Infants, Children, and Youth. Ottawa, ON (Member, 2012 - 2014)

Scientific Advisory Board (Co-Chair). SMARTTOTS Anesthesia Initiative (Public-Private Partnership: FDA and International Anesthesia Research Society - http://smarttots.org/). (2010 - 2017)

National/International Scientific Committees (current):

International Council for Harmonization (ICH), Expert working Group on Pediatric Extrapolation (ICH E11A). (Topic Leader, PhRMA delegation, 2018 – present)

Secretary's Advisory Committee on Human Research Protections (SACHRP), Office of Human Research Protections, Department of Health & Human Services (Member, 2019 - present)

Editorial Positions/Reviewer for Journals: (selected)

1999 - present	Ad Hoc Reviewer, Accountability in Research, AJOB Empirical Bioethics, American Journal of Bioethics, Archives of Pediatrics & Adolescent Medicine, Bioethics, Clinical Trials, Hastings Center Report, Journal of the American Medical Society, Journal of Empirical Research on Human Research Ethics, Journal of Medical Ethics, Journal of Pediatrics, Kennedy Institute of Ethics Journal, Paediatrics & Child Health, Pediatrics, PLOS Medicine, Science and Engineering Ethics, Therapeutic Innovation & Regulatory Science
2000 - 2006	Editorial Board, Critical Care Medicine
2001 - 2017	Editorial Board & Contributing Editor, IRB: Ethics and Human Research
2001 - 2017	Editorial Advisory Board, IRB Advisor
2004 - 2009	Editorial Advisory Board, BNA Medical Research Law & Policy Report
2005 - 2009	Editorial Board, Accountability in Research
2009 - 2015	Editorial Board, American Journal of Bioethics
2010 - 2015	Editor-in-Chief, AJOB Empirical Bioethics
2015 - 2018	Editorial Board, AJOB Empirical Bioethics

External Presentations and Panel Participation by Invitation: (2014 - present)

Feb. 10, 2014	Presentation: Selected Ethical and Legal Issues in Pediatric Clinical Research. Sponsored by The American Health Lawyers Association Children's Hospital Affinity Group. Co-Presenter: Robyn S. Shapiro JD, Partner, Drinker Biddle & Reath, Milwaukee WI (on-line webinar)
March 12, 2014	Presentation: Assessing the Prospect of Direct Benefit in Pediatric Studies and Component Analysis. National Comprehensive Cancer Network Institutional Review Board (IRB) Directors Forum. Hollywood FL (remote participation)
May 5, 2014	Presentation: Enhancing Regulatory Oversight for Challenging Clinical Trials: Observations from FDA. Panel: Ethical Challenges Conducting Research in Newborns to Better Define Standard of Care: Lessons from SUPPORT. Joint Meeting of the Pediatric Academic Societies and Asian Society for Pediatric Research. Vancouver, BC
May 20, 2014	Presentation: From Bench to Bedside - Meeting the Ethical Challenge of Pediatric Clinical Trials. American Society of Gene & Cell Therapy Clinical Trials Training Course. Washington DC

External Presentations and Panel Participation by Invitation: (2014 - present) (continued)

June 5, 2014	Presentation: Enrolling Children in Pre-Pandemic Vaccine Studies: Framing the Ethical Issues. Panel: Clinical Studies in Pediatric populations to Evaluate Pre-Pandemic Influenza Vaccines. Flu Risk Management Meeting. Washington DC
Sept. 30, 2014	Presentation: Pediatric Drug Development: A View from FDA. RAPS 2014: The Regulatory Convergence. Regulatory Affairs Professional Society Annual Meeting. Austin TX (remote participation)
Oct. 28, 2014	Panel Member: Issues of informed consent in neonatal trial networks. First Annual Neonatal Scientific Workshop - Roadmap for Applying Regulatory Science to Neonates. Silver Spring MD
Oct. 30, 2014	Panel Member: Rare Diseases: Lessons from the path less chosen. Boston Children's Hospital: Taking on Tomorrow Global Pediatric Summit. Boston MA
Nov. 7, 2014	Presentation: Risky Business: When Children are First-in-Line for Experimental Treatments. DIA Pediatric Meeting. Bethesda MD
Nov. 20, 2014	Panel Member: TEDMED Great Challenges Hangout: Public Private Partnerships and Medical Innovation. Silver Spring MD (webcast)
Dec. 1, 2014	Podcast: More than meets the IRB – Rethinking the vulnerability of children in comparative effectiveness research. Washington University School of Medicine. St. Louis MO (Available at: http://digitalcommons.wustl.edu/hrpopods/10/)
Dec. 5, 2014	Presentation: Assessing the Prospect of Direct Benefit in Pediatric Studies and Component Analysis. 2014 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Baltimore MD
Dec. 7, 2014	Presentation: A pediatric perspective on biobanking research. Case Study: Embedding correlative biology research, including biobanks, in pediatric clinical trials. 2014 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Baltimore MD
Dec. 10, 2014	Presentation: Benefit/Risk Considerations for Initiation of Pediatric Clinical Trials: The Relationship between Expanded Access and the Special Protections for Children. Panel 3: Special Considerations for Pediatric Patients. Stakeholder Workshop on Expanded Access: The Role of Investigational New Drugs in Patient Care. Washington DC
March 13, 2015	Presentation: Additional Safeguards for Children Enrolled in Research 21 CFR 50 and 45 CFR 46, Subpart D. NIH Workshop: Children as Stem Cell Donors in Research - When is it Ethical. When is it Approvable. Bethesda MD
March 18, 2015	Presentation: FDA Meeting Process (including meetings with sponsors/applicants, dispute resolution, advisory committee meetings). Annual FDA Seminar: Ministry of Foreign Affairs, Copenhagen, Denmark
March 18, 2015	Presentation: Drug Development in Rare and Orphan Diseases, including Expanded Access. Annual FDA Seminar: Ministry of Foreign Affairs, Copenhagen, Denmark
March 18, 2015	Presentation: The Process and Substance of FDA Review of Pediatric Study Plans and Proposed Pediatric Study Requests. Annual FDA Seminar: Ministry of Foreign Affairs, Copenhagen, Denmark
March 18, 2015	Presentation: International collaboration from an FDA Perspective. Annual FDA Seminar: Ministry of Foreign Affairs, Copenhagen, Denmark
March 19, 2015	Presentation: Challenging Topics in Pediatric Product Development. Annual FDA Seminar: Ministry of Foreign Affairs, Copenhagen, Denmark
March 19, 2015	Presentation: Ethics and Conduct of Pediatric Clinical Trials in Low- and Middle-Income Countries. Annual FDA Seminar: Ministry of Foreign Affairs, Copenhagen, Denmark

External Presentations and Panel Participation by Invitation: (2014 - present) (continued)

March 27, 2015 Presentation and Discussion: FDA draft guidance on General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological. Western IRB. Silver Spring MD (webinar)

April 1, 2015 Presentation and Panel Discussion: Designing an ethically acceptable investigation of Mitochondrial Replacement Therapy in the United States. IOM Committee on Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases. Institute of Medicine of the National Academies. Board on Health Science Policy. Washington DC

April 25, 2015 Presentation: Data Quality and Usability: Investigator Responsibilities Beyond the Conduct of Pediatric Clinical Trials. PAS Topic Symposium: Pediatric Drug Studies and the Need for Investigator Accountability. 2015 Pediatric Academic Societies Annual Meeting. San Diego CA

April 27, 2015 Presentation: Rare Disease Clinical Research: Role of the FDA. PAS Session: Clinical and Translational Research on Rare Diseases: A Team Sport. 2015 Pediatric Academic Societies Annual Meeting. San Diego CA

May 22, 2015 Presentation: Ethical Issues in the Development and Deployment of Pediatric Medical Counter Measures. National Advisory Committee on Children and Disasters (NACCD) Healthcare Preparedness Working Group. Washington DC (webinar)

June 17, 2015 Presentation: Ethical and Regulatory Considerations in Adolescent HIV Treatment and Prevention Research. 2015 HPTN/IMPAACT Annual Meeting. Arlington VA

June 24, 2015 Presentation: Ethical and Regulatory Considerations in Adolescent HIV Treatment and Prevention Research. NIH Workshop: The Mature Minor and Consent for Research Participation. Bethesda MD

Aug. 18, 2015 Presentation and Discussion (Oct. 7, 2015): Regulatory Science and Bioethics. PHAR620 Intro. to Regulatory Science. Georgetown University. Georgetown MD

Sept. 25, 2015 Presentation: Protecting Children in Research: Applying the Regulations to Contemporary Case Studies. Achieving Excellence in Clinical Research: Scientific, Ethical and Operational Considerations. Advocate Children's Hospital. Oak Brook IL

Nov. 4, 2015 Presentation: Research Involving Children (Focusing on FDA Regulations). Ethical & Regulatory Aspects of Clinical Research. National Institutes of Health. Bethesda MD

Nov. 13, 2015 Presentation: How to Read the Empirical Ethics Literature. 2015 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Boston MA

Nov. 15, 2015 Presentation: Assessing the Prospect of Direct Benefit in Pediatric Studies and Component Analysis. 2015 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Boston MA

Feb. 11, 2016 Presentation: The SUPPORT Trial: Understanding the "Risks" of Clinical Research on "Standard" Practices. Berman Institute of Bioethics and Johns Hopkins Bloomberg School of Public Health. Baltimore MD

April 4, 2016 Presentation: Ethics and the Conduct of Pediatric Clinical Trials in Low- and Middle-Income Countries. NIH Bioethics Interest Group. Bethesda MD

April 11, 2016 Presentation: Ethical Considerations in Pediatric Clinical Research. Pediatric Clinical Studies for Pharmaceutical and Device Products. Arlington VA

May 23, 2016 Presentation: To biopsy or not to biopsy – that is the question. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Kidney Precision Medicine Workshop. Bethesda MD

June 22, 2016 Presentation: Informed Consent: Parental Permission and Child Assent. NICHD 2015-2016 Principles of Pediatric Clinical Pharmacology Course. Bethesda MD (webinar)

External Presentations and Panel Participation by Invitation: (2014 - present) (continued)

June 28, 2016	Presentation: Ethical Issues in Long Term Open Label Extension Studies. Panel Session: Open-label, long-term extension studies: Study Designs and Ethics. DIA 2016 Annual Meeting. Philadelphia PA
July 13, 2016	Presentation: Ethical Considerations in Conducting Pediatric Clinical Trials in Developing Countries. Health and Human Services International Working Group. Washington DC (webinar)
Sept. 8, 2016	Presentation: Pediatric legislation in the United States (Best Pharmaceuticals for Children's Act, Pediatric Research Equity Act [PREA]/Pediatric exclusivity). Duke Clinical Research Institute Workshop: Issues in Pediatric Cardiovascular Drug Development. McLean VA
Sept. 13, 2016	Presentation: Extrapolation in Pediatric Product Development: Practical Application of the Principle of Scientific Necessity. Fifth Annual Meeting of NIGMS-NICHD and NICHD T32 Programs in Pediatric Clinical Pharmacology. Bethesda MD
Sept. 28, 2016	Presentation and Panel Discussion: Regulatory Science and Bioethics. PHAR620 Intro. to Regulatory Science. Georgetown University. Georgetown MD
Oct. 19, 2016	Presentation: Research Involving Children (Focusing on FDA Regulations). Ethical & Regulatory Aspects of Clinical Research. National Institutes of Health. Bethesda MD
Nov. 14, 2016	Presentation: Research with Children - Regulations and Beyond. 2016 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Anaheim CA
Nov. 15, 2016	Presentation: Risky Business - Exposing Children to Potential Harm Without Compensating Clinical Benefit. 2016 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Anaheim CA
Nov. 16, 2016	Presentation and Panel Discussion: Ethical Considerations in the Design and Conduct of Clinical Lactation Studies. 2016 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). Anaheim CA
Nov. 29, 2016	Ethical Challenges in Clinical Trial Design: Lessons Learned from DMD (Duchenne Muscular Dystrophy). Muscular Dystrophy Coordinating Committee Meeting. National Institutes of Health. Bethesda MD
March 20, 2017	Presentation: Summary of Major Changes to HHS Common Rule (45 CFR 46) and Impact on Pediatric Research. Children's Hospital of Ottawa IRB Retreat. Ottawa ON
March 28, 2017	Panel Discussion: Multiple Enrollment in Clinical Trials. Third Annual FDA-INC Neonatal Scientific Workshop. Bethesda MD
April 4, 2017	Presentation: Selected Issues in Pediatric Clinical Trials: An "FDA" Perspective. Fourth Annual Harvard Catalyst Child Health Symposium: Putting Kids First: Facilitating Multisite Pediatric Studies. Boston MA
Sept. 20, 2017	Presentation and Panel Discussion: Regulatory Science and Bioethics. PHAR620 Intro. to Regulatory Science. Georgetown University. Georgetown MD
Oct. 11, 2017	Pediatric Grand Rounds: Risky Business: Exposing Children to Potential Harm Without Compensating Clinical Benefit. Montreal Children's Hospital and McGill University. Montreal, Quebec, Canada
Oct. 18, 2017	Presentation: Recent FDA Experience with Review under 21 CFR 50.54 – Lessons Learned. Secretary's Advisory Committee for Human Research Protections. Rockville MD
Oct. 25, 2017	Presentation: Research Involving Children (Focusing on FDA Regulations). Ethical & Regulatory Aspects of Clinical Research. National Institutes of Health. Bethesda MD
Nov. 6, 2017	Presentation: A Pediatric Case Study: Referral of a FDA-Regulated Clinical Investigation Under 21 CFR 50.54. 2017 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). San Antonio TX

External Presentations and Panel Participation by Invitation: (2014 - present) (continued)

Nov. 6, 2017	Presentation: Research with Children: Complexities in Practice (Populations Requiring Additional Protections Track). 2017 Advancing Ethical Research Conference. Professional Responsibility in Medicine & Research (PRIM&R). San Antonio TX
Jan. 25, 2018	Panel Discussion: Population-Specific Issues in HIV Cure Research: Implications for Children. Regulation of Clinical Research Related to HIV Cure. The Forum for Collaborative Research. Bethesda MD
Feb 28, 2018	Panel Discussion: Developing Drugs for Rare Pediatric Diseases: Balancing Ethical Considerations with Access. Jett Foundation 3rd Annual Rare Disease Day Luncheon. Cambridge MA
March 28, 2018	Panel Discussion: Understanding the Role of Extrapolation of Data from Varying Age Cohorts: Regulatory Requirements for Pediatric/Rare Disease Drug Development. Developing Rare Disease Regulatory Strategy Under Current Global Regulatory Statutes: A Stakeholder Discussion. Bio NJ and Amicus Therapeutics. Cranbury NJ
April 5, 2018	Presentation: The Ethics of Parental Decisions to Expose Children to Research Risks. Grand Rounds, St. Jude Children's Research Hospital. Memphis, TN
April 16, 2018	Presentation (and Panel Participation): What Leads to Underrepresentation: Addressing the Exclusion of Children from Clinical Research. Evaluating Inclusion and Exclusion Criteria in Clinical Trials. Robert J. Margolis, MD, Center for Health Policy at Duke University and the Food and Drug Administration. Washington DC
April 18, 2018	Presentation: Leveraging Data in Support of Pediatric Clinical Trials. Challenges and Opportunities in Pediatric Clinical Trials. CTSA Investigator Training. Clinical and Translational Science Institutes of Tufts and Children's National. Washington DC
May 4, 2018	Presentation: The Ethics of Pediatric Research: Including Children in Drug Development. 2018 Association of Pediatric Program Directors (APPD)/Pediatric Academic Societies (PAS) Fellows' Core Curriculum. PAS 2018 Meeting, Toronto ON
June 27, 2018	Moderator: Regulatory and Ethical Considerations with Placebo Administration Using a Central Venous Access Device in a Pediatric Trial. DIA 2018 Global Annual Meeting, Boston MA
July 30, 2018	Presentation: The Promise and Peril of Pediatric Extrapolation. 2018 Joint Statistical Meetings, Vancouver BC Canada
Oct. 22, 2018	Presentation: Reflections on Pediatric Extrapolation. Workshop: Use of Innovative Analytic Tools and Study Designs for Efficient and Feasible Pediatric Drug Development. Biotechnology Innovative Organization, Washington, DC
Nov. 15, 2018	Presentation: Ethical Concerns about the IMPACT-Afib Study. Session: The Generation and Utilization of Real-World Evidence (RWE): Ethical and Regulatory Considerations. 2018 Advancing Ethical Research Conference. PRIM&R, San Diego CA
Nov. 16, 2018	Presentation: Scientific and Ethical Considerations in Choosing a Study Control Group. 2018 Advancing Ethical Research Conference. PRIM&R, San Diego CA
Dec. 7, 2018	Presentation: Ethics of Conducting (Gene Transfer) Clinical Studies in Vulnerable Populations. Amicus Therapeutics, Cranbury, NJ
Jan. 10, 2019	Presentation: The Ethical Obligation of Extrapolation in Pediatrics: Leveraging Data to Reduce Research Risks. Clinical Development & Analytics Scientific Forum on Pediatric Innovation and Extrapolation. Novartis Pharmaceuticals Corporation, East Hanover, NJ
March 7, 2019	Presentation: Establishing the Evidence Supporting "First-in-Human" Trials in Children. Conference: BioNJ's Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments. Amicus Therapeutics, Cranbury NJ

External Presentations and Panel Participation by Invitation: (2014 - present) (continued)

March 29, 2019	Presentation: Prospect of Direct Benefit and Pediatric Extrapolation. Duke/FDA Workshop: Prospect of Direct Benefit in Pediatric Clinical Trials. Washington DC
April 26, 2019	Presentation: From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research. 2019 Association of Pediatric Program Directors (APPD)/Pediatric Academic Societies (PAS) Fellows' Core Curriculum. PAS 2019 Meeting, Baltimore MD
June 26, 2019	Presentation: The Use of Extrapolation in Pediatric Drug Development. DIA 2019 Global Annual Meeting, San Diego CA
Aug. 28, 2019	Presentation: A Clinician's View of the Importance of Extrapolation. Session: Innovative Methods to Support the Development of New Pediatric Medicine. The 6th International Symposium on Biopharmaceutical Statistics: Statistical Innovation and Contribution in the Era of Precision Healthcare. The International Society for Biopharmaceutical Statistics. Kyoto, Japan
Oct. 2, 2019	Presentation: Scientific Necessity and Pediatric Extrapolation using Adult Data. Workshop: Accelerating Drug Development for Polyarticular Juvenile Idiopathic Arthritis. Collaborative workshop hosted by the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Food and Drug Administration. Silver Spring, MD
Oct. 3, 2019	Presentation: Accelerating Pediatric Drug Development: Balancing Protection and Access. 2019 Ellen Hyman-Browne Memorial Lecture. The Children's Hospital of Philadelphia Research Institute. Philadelphia, PA
Oct. 26, 2019	Presentation and Panel Discussion: Establishing the Evidence Supporting "First-in-Human" Trials in Children. Session: Ethical Issues in Translating Gene Transfer Studies involving Children with Neurodegenerative Disorders. 21st Annual Conference. The American Society for Bioethics and Humanities. Pittsburgh, PA
Oct. 28, 2019	Presentation and Panel Discussion: The Use of Extrapolation in Pediatric Drug Development. Session 2: Innovation Through Extrapolation: Improving the Efficiency and Effectiveness of Pediatric Drug Development. Pediatric Drug Development Workshop. Drug Information Association. Bethesda MD
July 28, 2020	Presentation: The Role of Extrapolation in Pediatric Drug Development. Janssen Workshop for Center for Drug Evaluation, China.
Aug. 5, 2020	Presentation: Pediatric Drug Development Using Extrapolation. 2020 Joint Statistical Meetings (virtual conference)
Sept. 23, 2020	Presentation: The Role of Extrapolation in Pediatric Drug Development. 2020 Virtual ACCP Annual Meeting.
Nov. 4, 2020	Session Chair: Pediatric Data Extrapolation. Joint Health Canada-Canadian Society of Pharmaceutical Sciences Pediatric Workshop (Virtual).
March 30, 2021	Presentation and Discussion: A Case Study in the Scientific and Ethical Issues Associated with Pediatric Clinical Trials. Temple University School of Pharmacy Master's Program in Regulatory Affairs and Quality Assurance (Virtual).
April 30, 2021	Presentation and Discussion: The Ethics of Pediatric Research: Including Children in Drug Development. Association of Pediatric Program Directors/Pediatric Academic Societies Fellows' Core Curriculum: Track II (Virtual).
June 2021	On Demand (Virtual). Topic 3: Meeting the Practical Challenges and Concluding Remarks. Session: A Collaborative Cross-Company Pediatric Platform Trial in Pediatric Crohn's Disease Using an Innovative Bayesian Analysis. Presentation of IL-23 Pediatric Platform Trial with Lilly. DIA 2021 Global Annual Meeting.

External Presentations and Panel Participation by Invitation: (2014 - present) (continued)

Sept. 2, 2021	Panelist: Session 2: Bayesian techniques in Pediatric Studies. ADEPT 7: Advancing the Development of Pediatric Therapeutics. Complex Innovative Trial Design. FDA/UMD Public Workshop (Virtual).
Oct. 28, 2021	Presentation: Evidence to Support Pediatric Approval through Extrapolation: Reflections on Pediatric Plans. New Horizons in Pediatric Drug Development Symposium (Virtual).
March 2, 2022	Panelist: Clinical Trial Designs. Virtual Public Webinar Series: Advancing Pathways for the Development of Innovative Therapies for Children with Inflammatory Bowel Disease. Institute for Advanced Clinical Trials (I-ACT) for Children (Virtual).
April 1, 2022	Seminar and Discussion: ICH E11A Pediatric Extrapolation (with Dr. Sabine Fuerst-Recktenwald, M.D., F. Hoffmann-La Roche Ltd.). American Statistical Association Biopharmaceutical Section Pediatric Working Group (Virtual).
April 11, 2022	Presentation and Discussion: ICH Efficacy Training - ICH Guidance on Pediatrics (E11; E11(R1) and E11A). Sponsored by DIA for Anvisa (Brazilian Health Regulatory Agency). (Virtual).
May 5, 2022	Presentation: The Use of Extrapolation in Pediatric Drug Development. Invited Session 4: Pediatric Oncology Research and Drug Development. Fifth Stat4Onc Annual Symposium 2022. Chicago, IL
May 17, 2022	Presentation: ICH E11A: The Use of Extrapolation in Pediatric Drug Development. eSymposium on Phytotherapeutics in Children: Rationalizing optimal Dosing for use in Children. A joint symposium of Foundation Plants for Health, Society of Medicinal Plant and Natural Product Research, and Gesellschaft für Phytotherapie. (Virtual)
June 8, 2022	Presentation: ICH E11A: The Use of Extrapolation in Pediatric Drug Development. Janssen Pediatric Development Workshop for China CDE (Regulatory Agency) (Virtual).

Presentations at Johnson & Johnson Internal Meetings (2018 – present)

April 10, 2018	Presentation: The Ethics of Pediatric Research: Including Children in Drug Development. Office of the Chief Medical Officer Extended Leadership Team Quarterly Meeting. New Brunswick, NJ
Sept. 17, 2018	Presentation: An Overview of the Science and Ethics of Pediatric Drug Development. Immunology Lunch and Learn, Spring House PA
Nov. 12, 2019	Presentation: Immunology Pediatric Development Team. Actelion. Basel, Switzerland
Nov. 13, 2019	Presentation: Accelerating Pediatric Drug Development: Balancing Protection and Access. Actelion “Lunch Talk.” Basel, Switzerland
March 10, 2020	Presentation: The Role of Extrapolation in Pediatric Drug Development (with a Regulatory Case Study). Presented with Mian Saeed. RED Scientific Education Seminar Series (virtual)
Oct. 12, 2020	CHILD Symposium: A Collaborative Cross-Company Pediatric Platform Trial Using an Innovative Bayesian Analysis to Establish the Efficacy of IL-23 p19 Subunit Inhibitors in Pediatric Crohn’s Disease. Introduction – Challenge of Pediatric Crohn’s Disease Trials and Conclusions and Reflections on the Journey.
Feb. 9, 2021	Presentation (with Michael Li): An innovative pediatric IL-23 inhibitor Crohn’s disease platform trial: A Bayesian Approach. Food for Thought, Immunology TA (Virtual).
April 25, 2022	Presentation: ICH E11A Pediatric Extrapolation. Immunology Pediatric Alliance, Immunology TA (Virtual).
May 13, 2022	Presentation: ICH E11A Pediatric Extrapolation. Immunology Pediatric Development Team, Immunology TA (Virtual).
May 24, 2022	Presentation: ICH E11A Pediatric Extrapolation. CHILD Pediatric Expert Panel (Virtual).

Presentations at Johnson & Johnson Internal Meetings (2018 – present) (continued)

June 13, 2022 Presentation: ICH E11A Pediatric Extrapolation. Global Regulatory Affairs. Immunology TA (Virtual).

Presentations and Panel Participation at FDA Public Meetings: (2014 - 2017)

Jan. 8, 2014 Presentation: IRB Oversight of Humanitarian Use Devices: What's an IRB to do? Public FDA Workshop – Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases. Silver Spring MD

March 11, 2014 Presentation: Summary of Additional Safeguards for Children in FDA-Regulated Clinical Investigations. Japanese Visitors - National Center for Child Health and Development (at FDA). Silver Spring MD

Sept. 10, 2014 Presentation: Ethical Issues Impacting Pediatric Product Development. Patient Network Meeting (Under the Microscope: Pediatric Product Development). Washington DC

Sept. 22, 2014 Presentation: What do you need to know about the special protections for pediatric subjects. FDA Workshop: Pediatric Clinical Investigator Training. Bethesda MD

Jan. 22, 2015 Presentation: Pediatric Extrapolation: Using Exposure as a Surrogate for Efficacy. FDA Public Workshop: The Use of Exposure Matching and Exposure-Response in Pediatric Product Development. Silver Spring MD

March 23, 2015 Presentation: Ethical Analysis of Clinical Trial Protocols, Component Analysis, and Protocols Involving Sedation for Non-Beneficial Procedures. Meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee. Silver Spring MD

March 25, 2015 Presentation: Scientific Challenges and the Future: Neonatology. Pediatric Stakeholder Meeting. Silver Spring MD

April 27, 2016 Presentation: Ethical Considerations in the Design and Conduct of Clinical Lactation Studies. FDA Public Workshop: Evaluation of the Safety of Drugs and Biological Products used during Lactation. Silver Spring MD

June 1, 2016 Presentation: Extrapolation in Pediatric Product Development: Practical Application of the Principle of Scientific Necessity. Workshop: Quantitative Assessment of Assumptions to Support Extrapolation of Efficacy in Pediatrics. Silver Spring MD

June 29, 2016 Presentation: To biopsy or not to biopsy – that is the question. Meeting of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee. Silver Spring MD

Sept. 13, 2016 Presentation: What do you need to know about special protections for pediatric subjects? FDA Public Workshop: Pediatric Clinical Investigator Training. Bethesda MD

Sept. 15, 2016 Presentation: Additional Safeguards for Children in Clinical Investigations (21 CFR 50 subpart D). Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee, the Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee Meeting. Silver Spring MD

June 17, 2013 Presentation: Presidential Commission Report on Pediatric Medical Countermeasures. FDA Medical Countermeasures Initiative Lecture Series. Silver Spring MD

Nov. 19, 2013 Panel Member: Office of Clinical Pharmacology (OCP) Scientific Rounds. Discussion of 4 Pediatric Guidances and What They Mean for OCP. Silver Spring MD

May 13, 2014 Presentation: Risk and Benefit in Fatal Pediatric Diseases: Use of Biomarkers and Exploratory Procedures without Prospect of Benefit. Division of Gastroenterology and Inborn Errors Products. Center for Drug Evaluation and Research. Silver Spring MD

May 28, 2014 Panel Member: CDER Scientific Rounds: Analysis of Similarities and Differences Between FDA's Pediatric Study Plan (PSP) and EMA's Pediatric Investigational Plan (PIP): Case Studies. Silver Spring MD

Presentations and Panel Participation at FDA Internal Meetings: (2014 - 2017) (continued)

Feb. 18, 2015	Panel Member: CDER Scientific Rounds (Office of Clinical Pharmacology): Lessons Learned from Failed Pediatric Trials. Silver Spring, MD
March 11, 2015	Presentation: FDA Neonatal Subcommittee; Neonatal Ethical Issues pertaining to product development and enrollment in trials. Meeting with representatives from Japan's National Center for Child Health and Development/Osaka Medical Center and Research Institute for Maternal Child Health. Silver Spring MD
May 26, 2015	Presentation: Initiating Trials in Pediatric Rare Disease Populations: Key Issues to Consider. 2015 Rare Disease Training: Rare Disease Drug Development – Beyond the Boundaries. Silver Spring MD
June 22, 2015	Presentation: Pediatric Ethics Subcommittee Recommendations: Nontherapeutic Procedures in Children. Division of Gastroenterology and Inborn Errors Products. Silver Spring MD
Aug. 12, 2015	Case Discussion: Special Protections for Children in Biomedical Research (Subpart D Regulations). Office of Vaccines Research and Review (CBER). Silver Spring MD
Feb. 29, 2016	Case Discussion: Ethical Considerations in Conducting Pediatric Research: Evaluating Pediatric IND Applications. Division of Anesthesia, Analgesia, and Addiction Products (CDER). Silver Spring MD
Oct. 20, 2016	Presentation: Ethics of Pediatric Product Development. New Reviewer Foundation Series: Introduction to Clinical Review (CDER). Silver Spring MD
Dec. 1, 2016	Presentation: Additional Protections for Children Enrolled in Clinical Trials. Clinical Bioresearch Monitoring (BR225). Gaithersburg, MD
March 30, 2017	Presentation: Ethics of Pediatric Product Development. New Reviewer Foundation Series: Introduction to Clinical Review (CDER). Silver Spring MD
Aug. 14, 2017	Presentation: Applying the Additional Safeguards for Children in Research (21 CFR 50 Subpart D). Scientific Rounds, Division of Pediatric and Maternal Health, Office of New Drugs (CDER). Silver Spring MD
Sept. 13, 2017	Presentation: Pediatric Case Studies: Safeguards for children in FDA-Regulated Clinical Investigations. Cross-Center Discussion: Hot Topics in Bioethics at the FDA. Silver Spring MD

Other Professional Activities:

Organizing Roles in Scientific Meetings: (selected)

March 2004	National Institute of Child Health and Human Development and Food and Drug Administration (NICHD-FDA) Neonatal Drug Development Workshop. Newborn Initiative. Chair, Ethics Working Group. Baltimore MD (03/08-09/2004)
January 2005	EFGCP 2005 Annual Conference: Developing a European Framework for Research on Children's Medicines. Member, Conference Scientific Committee. Workshop Facilitator: A Good Clinical Practice Framework for Paediatric Clinical Research. Brussels, Belgium (01/25 - 01/26/2005)
January 2006	Chair, Planning Committee, and Workshop Moderator, NICHD Conference on the Emergency Exception from Informed Consent. Bethesda MD (January 12-13, 2006)
Sept. 2009	Chair, Planning Committee, Workshop on Ethical and Regulatory Issues in Global Pediatric Trials. Co-sponsored by the Office of Pediatric Therapeutics, Food and Drug Administration and the Eunice Kennedy Shriver National Institute of Child Health and Human Development. Bethesda MD (September 20-22, 2009)

Organizing Roles in Scientific Meetings: (selected) (continued)

Sept. 2013	Chair, Planning Committee: Ethical Issues in Pediatric Product Development, including Medical Counter Measures. Pediatric Ethics Subcommittee of the Pediatric Advisory Committee. Silver Spring MD (September 9-10, 2013)
Jan. 2014	Planning Committee and Session Chair: Public Workshop on Encouraging and Accelerating Development of New Therapies for Pediatric Rare Diseases. Silver Spring MD (January 7, 2014)
April 2014	Planning Committee: Electrical Stimulation Devices for Aversive Conditioning. Neurological Devices Panel of the Medical Devices Advisory Committee. Center for Devices and Radiological Health. Gaithersburg, MD (April 24, 2014)
March 2015	Planning Committee and Speaker: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee. The Use of Procedural Sedation for Non-Therapeutic Procedures in Pediatric Clinical Trials. Silver Spring MD (March 23, 2015)
April 2015	Panel Member: Part 15 Public Hearing. Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century. Silver Spring MD (April 20-21, 2015)
Nov. 2015	Planning Committee and Meeting Chair. Workshop – Clinical Trial Designs for Emerging Infectious Disease. Food and Drug Administration and the National Institutes of Health. Bethesda MD (Nov. 9-10, 2015)
May 2017	Planning Committee: Joint Meeting of the Pediatric Ethics Subcommittee and the Pediatric Advisory Committee. Federal Panel Review of Pediatric Protocol under 21 CFR 50.54. Silver Spring MD (May 18, 2017)

Advisory Committees/Boards/Consulting: (selected)

2001, 2003	Chair, Panels (5) for Review of Protocols under 45 CFR §46.407. Office for Human Research Protections (OHRP), DHHS, Washington, DC
2001 - 2002	Program Evaluation Site Visitor, Association for the Accreditation of Human Research Protection Programs, Inc., Washington, DC
2001 - 2002	Member, Children's Working Group, National Human Research Protections Advisory Committee (NHRPAC). DHHS, Washington DC
2003 - 2006	Member, Subcommittee on Research Involving Children, Secretary's Advisory Committee on Human Research Protections, DHHS, Washington DC
2002, 2005	Ad hoc Expert, National Institute of Mental Health Human Subjects Research Council Workgroup (06/04/2002; 07/11/2005)
2004 - 2005	Consultant, Ethical Issues in Housing-Related Health Hazard Research Involving Children, Youth and Families, Institute of Medicine, Washington DC
2005	Consultant, Understanding Premature Birth and Assuring Healthy Outcomes, Institute of Medicine, Washington DC
2006	Consultant, Governor's Special Panel for the Review of the Haleigh Poutre Case (Report issued March 20, 2006), Massachusetts
2006 - 2008	Consultant: Research Extenders & Research Integrity: A New Frontier. Principal Investigator: Leslie Alexander, Ph.D., Bryn Mawr College; National Institute for Nursing Research, NIH, Bethesda MD
2015	Meeting Participant (May 25-26, 2015): Development of "Guidance for Managing Ethical Issues in Infectious Disease Outbreaks." World Health Organization, 2016. (URI: http://www.who.int/iris/handle/10665/250580; ISBN: 9789241549837).

Advisory Committees/Boards/Consulting: (selected) (continued)

2015	Member, Expert Panel. GRiP – Global Research in Pediatrics. "A guidance-based tool for the ethics review of paediatric drug trials." Deliverable number D3.23. Author(s): A. Needham, P. Thurairajah, W. Chan, M. Offringa. Revision date: 31 August 2015. Available at: http://www.grip-network.org.
2018 - present	Johnson & Johnson Sustaining Member Representative, Board of Directors, Institute for Advanced Clinical Trials (I-ACT) for Children, Rockville MD
2018 - present	Pharmaceutical Research and Manufacturers of America (PhRMA) Topic Lead, International Council for Harmonisation (ICH) E11A Expert Working Group on Pediatric Extrapolation. ICH, Geneva, Switzerland
2019 – present	Member, Secretary's Advisory Committee on Human Research Protection (SACHRP), Department of Health and Human Services, Washington DC

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1. Duncombe DC, Gershkoff AM and Nelson RM: Medical Students in Clinical Pastoral Education. The Journal of Pastoral Care 32(3):179-83, 1978.
2. Haake P and Nelson RM: Thiamin. VII. Beyond Ylids and Carbonyl Addition. Ann NY Acad Sci 378:107-116, 1982.
3. Nelson RM: Decisions Concerning the Care of Very Low Birthweight Infants. Neonatal Network 5(1):16-21, 1986.
4. Nelson RM: A Policy Concerning the Therapeutic Use of Human Fetal Tissue in Transplantation. Western Journal of Medicine 152(4):447-48, 1990.
5. Duncan BW, Adzick NS, Longaker MT, Edwards JR, Nelson RM, and Koerper MA: In utero arterial embolism from renal vein thrombosis with successful postnatal thrombolytic therapy. Journal of Pediatric Surgery 26(6): 741-43, 1991.
6. Nelson RM and Drought T: Justice and the Moral Acceptability of Rationing Medical Care: The Oregon Experiment. The Journal of Medicine and Philosophy 17(1): 97-117, 1992. Reprinted in: Readings in Biomedical Ethics. Ed. EW Kluge. Prentice Hall Allyn & Bacon, 1998: 78-90.
7. Nelson LJ and Nelson RM: Ethics and the Provision of Burdensome, Harmful or Futile Therapy to Children. Critical Care Medicine 20(3): 427-33, 1992.
8. Nelson RM: What is the Purpose of Neonatal Drug Testing: Towards a Rational Social Policy. Women and Politics 13(3/4): 83-97, 1993.
9. Emond JC, Nelson RM, Blank EL, Shapiro RS, and MacKay C: Living Related Liver Transplantation: Request for an International Ethics Consultation from the Research Center for Surgery in Moscow. Cambridge Q of Healthcare Ethics 3(4): 602-03; disc. 603-21, 1994.
10. Nelson RM and Shapiro RS: The Role of an Ethics Committee in Resolving Conflict in the NICU. J Law, Med & Ethics 23(1):27-32, 1995.
11. Nelson LJ, Rushton CH, Cranford RE, Nelson RM, Glover JJ and Truog RD: Forgoing Medically Provided Nutrition and Hydration in Pediatric Patients. J Law, Med & Ethics 23(1):33-46, 1995.
12. Nelson RM: VI. Emily's Story. In Charon R, Brody H, Clark MW, Davis D, Martinez R, and Nelson RM: Literature and Ethical Medicine: Five Cases from Common Practice. Journal of Medicine & Philosophy 21(3): 243-265, 1996.

Research Publications, peer-reviewed: (continued)

13. Committee on Bioethics, Amer Acad of Pediatrics (AAP) (Frader JE, Crain LS, Moseley KL, Nelson RM, Porter IH, Vizcarrondo FE, Bowes WA, Kazura A, Krug EF, Caniano DA, King NMP): Ethics and the Care of Critically Ill Infants and Children. Pediatrics 98(1):149-152, 1996.

14. Committee on Drugs and Committee on Bioethics, AAP (Frader JE, Crain LS, Moseley KL, Nelson RM, Porter IH, Vizcarrondo FE, Bowes WA, Kazura A, Krug EF, Caniano DA, Dresser R, King NMP) Considerations Related to the Use of Recombinant Human Growth Hormone in Children. Pediatrics 99(1):122-129, 1997.

15. Committee on Bioethics, AAP (Frader JE, Crain LS, Moseley KL, Nelson RM, Porter IH, Vizcarrondo FE, Bowes WA, Kazura A, Krug EF, Caniano DA, King NMP): Religious Objections to Medical Care. Pediatrics 99(2):279-281, 1997.

16. Committee on Bioethics, AAP (Frader JE, Botkin JR, Moseley KL, Nelson RM, Wilfond BS, Kazura A, Bowes WA, Krug E, Caniano DA, King NMP): Female Genital Mutilation. Pediatrics 102(1): 153-156, 1998.

17. Randolph AG, Zollo MB, Guyatt GH, Egger M, Nelson, RM, and Stidham GL: Variability in Physician Opinion on Limiting Pediatric Life Support. Pediatrics 103(4):807, 1999. URL: http://www.pediatrics.org/cgi/content/full/103/4/e46

18. Committee on Bioethics, AAP (Nelson RM, Botkin JR, Levetown M, Moseley KL, Truman JT, Wilfond BS, Bowes WA, Kazura A, Krug EF, Caniano DA, Frader JE, King NMP): Fetal Therapy -- Ethical Considerations. Pediatrics 103(5): 1061-1063, 1999.

19. Committee on Bioethics, AAP (Nelson RM, Botkin JR, Levetown M, Moseley KL, Truman JT, Wilfond BS, Kazura A, Bowes WA, Krug EF, Caniano DA, Donovan GK, Frader JE, Davis DS): Appropriate Boundaries in the Pediatrician-Family-Patient Relationship. Pediatrics 104(2): 334-336, 1999.

20. Committee on Bioethics, AAP (Nelson RM, Botkin JR, Levetown M, Moseley KL, Truman JT, Wilfond BS, Kazura A, Bowes WA, Krug E, Caniano DA, Donovan GK, Frader JE, Davis DS): Sterilization of Minors with Developmental Disabilities. Pediatrics 104(2): 337-340, 1999.

21. Committee on School Health and Committee on Bioethics, AAP (Nelson RM, Botkin JR, Kodish ED, Levetown M, Truman JT, Wilfond BS, Kazura A, Schwartz PA, Krug EF, Caniano DA, Donovan GK, Davis DS): Do Not Resuscitate Orders in Schools. Pediatrics 105(4): 878-879, 2000.

22. Committee on Bioethics and Committee on Hospital Care, AAP (Nelson RM, Botkin JR, Kodish ED, Levetown M, Truman JT, Wilfond BS, Kazura A, Krug EF, Schwartz PA, Caniano DA, Donovan GK, Davis DS): Palliative Care for Children. Pediatrics 106(2): 351-357, 2000.

23. Nelson RM and Brodwin P: Professional Power and the Cultural Meanings of Biotechnology. In: Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology. T.H. Murray and M.J. Mehlman, eds. John Wiley & Sons, Inc., 2000: 888-896.

24. Committee on Child Abuse and Neglect and Committee on Bioethics, AAP (Nelson RM, Botkin JR, Kodish ED, Levetown M, Truman JT, Wilfond BS, Kazura A, Krug EF, Schwartz PA, Donovan GK, Fallat M, Frader JE, Davis DS): Forgoing Life-Sustaining Medical Treatment in Abused Children. Pediatrics 106(5): 1151-1153, 2000.

25. Committee on Bioethics, AAP (Nelson RM, Botkin JR, Kodish ED, Levetown M, Truman JT, Wilfond BS, Harrison CE, Kazura A, Krug EF, Schwartz PA, Donovan GK, Fallat M, Davis DS): Institutional Ethics Committees. Pediatrics 107(1): 205-209, 2001.

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26. Committee on Bioethics, AAP (Nelson RM, Botkin JR, Kodish ED, Levetown M, Truman JT, Wilfond BS, Kazura A, Krug EF, Schwartz PA, Donovan GK, Fallat M, Davis DS): Ethical Issues with Genetic Testing in Pediatrics. Pediatrics 107(6): 1451-55, 2001.
27. Committee on Pediatric Research and Committee on Bioethics, AAP (Nelson RM, Botkin JR, Kodish ED, Levetown M, Truman JT, Wilfond BS, Kazura A, Krug EF, Schwartz PA, Fallat M, Davis DS): Human Embryo Research. Pediatrics 108(3): 813-816, 2001.
28. Hedrick HL and Nelson RM: Handling Ethical Conflicts in the Clinical Setting. Seminars in Pediatric Surgery 10(4): 192-197, 2001.
29. Nelson RM: Protocol 126 and "The Hutch". IRB: Ethics & Human Research 23(3):14-16, 2001.
30. Nelson RM: Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study. IRB: Ethics & Human Research 23(6):7-11, 2001.
31. Jew RK and Nelson RM: Research in Pediatric Medicine and the Impact on Formulary Decisions. Drug Benefit Trends 14(6): 29-42, 2002.
32. Nelson RM: Appropriate risk exposure in environmental health research. The Kennedy-Krieger lead abatement study. Neurotoxicology and Teratology 24(4):445-49, Jul-Aug 2002.
33. Weil E, Nelson RM and Ross LF: Are research ethics standards satisfied in pediatric journal publications? Pediatrics 110(2 Pt 1):364-70, 2002.
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35. Leuthner SR, Bolger M, Frommelt M and Nelson RM: The Impact of Abnormal Fetal Echocardiography on Expectant Parents' Experience of Pregnancy: A Pilot Study. Journal of Psychosomatic Obstetrics and Gynecology 24(2):121-129, 2003.
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39. Silverman HJ, Druml C, Lemaire F, and Nelson RM. The European Union Directive and the protection of incapacitated subjects in research: an ethical analysis. Intensive Care Medicine 30: 1723-29, 2004.
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1988 - 1990 "Team Decision-Making in the Intensive Care Nursery." Total funds (1988-90) $100,500; National Research Service Award, Bioethics. National Center for Nursing Research, National Institutes of Health (NIH), Bethesda MD

1998 - 2001 "Ill Children and Their Parents: Experience with Research." Total subcontract funds: $28,942; Principal Investigator: Marion F. Broome, RN, PhD, University of Alabama at Birmingham; Total funds: $624,150; Research on Informed Consent Initiative, NIH, Bethesda MD

1999 - 2004 "Evaluating Research: Views of Children and Parents." Total funds (1999-2004): $410,650; Research Scientist Development Award (K01). Mentors: Arthur L. Caplan (Bioethics Ctr, Univ of Penn) and Janet A. Deatrick (Univ of Penn School of Nursing). National Institute of Neurological Disorders and Stroke, NIH, Bethesda MD

2002 - 2004 "The Networked IRB Database." Total subcontract funds: $82,290 (co-investigator); Principal Investigator: Mary L. Guerinot, PhD, Dartmouth College; Total funds: $600,000; Human Subjects Research Enhancements Program, National Center for Research Resources, NIH, Bethesda MD

2003 - 2004 "Decision Making by Adolescents and Parents about Research Participation: A Qualitative Study of the Influence of Risk Perception." Total funds (2003-2004): $77,145 (principal investigator); The Greenwall Foundation, New York, NY

2005 – 2006 "Research Extenders & Research Integrity: A New Frontier." Total subcontract funds: $4610. (consultant); Principal Investigator: Leslie Alexander, Ph.D., Bryn Mawr College; National Institute for Nursing Research, NIH, Bethesda MD

2006 "Planning Hypothermia Trial for Pediatric Cardiac Arrest." Total subcontract funds: $4,726. (consultant); Principal Investigator: Frank Moler, M.D., University of Michigan; National Institute of Child Health and Human Development, NIH, Bethesda MD

2006 - 2009 "DRU: (Collaborative Proposal) Developing a Measure of Voluntary Consent for Protocol-Based Treatment Decisions." Total funds (2006-2009): $274,000 (principal investigator); National Science Foundation, Washington DC

Research Grants, Contracts, Awards: (continued)

2006 - 2008 "Developing a Measure of Voluntary Consent for Protocol-Based Treatment Decisions." Total funds (2006-2008): $209,000 (principal investigator); (R21) National Cancer Institute, NIH, Bethesda MD

2006 - 2009 "Pediatric Ethics Program." IPA Mobility Program (contract). Total annual funds: $165,000. Pediatric Ethicist (Medical Officer), Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, Rockville MD

2006 – 2009 "Institutional Clinical and Translational Science Award (CTSA)." Research Ethics Program. (Peter Adamson, M.D. – CHOP PI). National Center for Research Resources, NIH, Bethesda MD

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