

Gianna (Gigi) McMillan, D. Bioethics

Loyola Marymount University

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PROFESSIONAL EXPERIENCE

BIOETHICS INSTITUTE, LOYOLA MARYMOUNT UNIVERSITY, Los Angeles, CA

Associate Director 7/2022- present

Acting Graduate Director, 6/2021-7/2022

Graduate Division Lecturer (Research Ethics) 5/2019-present

Program Administrator, 8/2016 - 6/2022

Develops curriculum for undergraduate and graduate programs. Recruits and advises matriculating students. Manages Institute presence in regional and national bioethics community. Administers community outreach programs, lectures, continuing education, student engagement and graduate certificates.

NARRATIVE INQUIRY IN BIOETHICS, John Hopkins University Press, Baltimore, MD **7/2013 - present**

Director of Community Engagement

Narrative Inquiry in Bioethics explores issues in bioethics through the collection and analysis of personal stories, qualitative and mixed-methods research articles, and case studies. Responsible for symposium development including solicitation and selection of authors, editing, and facilitating access and use of content within relevant populations.

PRIM&R (PUBLIC RESPONSIBILITY IN MEDICINE & RESEARCH), Boston, MA **9/2004 - present**

Board of Directors: 1/2020 - present

Faculty member: Specializing in the topics of consent issues, the rights of children in clinical trials, and community involvement in research.

Curator/Content Manager: Compiled a multimedia collection of oral histories documenting the evolution of research ethics, including authors of the Belmont Report, creators of the original federal regulations, and current scholars and ethicists. Researched, interviewed, and filmed narrators; edited all content; created education modules based on the story archive.

U. S. FOOD AND DRUG ADMINISTRATION, Rockville, MD

Pediatric Advisory Committee, Patient and Family Representative

11/2020 - present

Pediatric Oncology Drug Advisory Committee, Patient Representative

8/2010 – 10/2020

This committee reviews development of treatment therapies for children and advises the FDA regarding the unique medical concerns of the pediatric population.

CEDARS-SINAI HOSPITAL, Los Angeles, CA

6/2009 - 12/2012

Stem Cell Research Oversight/IRB Committee Member

Developed policies and reviewed research involving stem cell therapies for use in human subjects.

WE CAN, PEDIATRIC BRAIN TUMOR NETWORK, Los Angeles, CA

2/1996 - 12/2011

Co-Founder/Executive Director, 1996 - 2008

Outreach Coordinator/Camp Director, 2008 - 2011

Developed parent-initiated support programs for pediatric brain tumor patients to serve California families by coordinating healthcare professionals and community resources. Chartered We Can as a non-profit and managed paid staff, consulting social workers, and large roster of volunteers. Responsible for every aspect of the organization, including development of face-to-face services for all members of families whose children have been diagnosed with a brain tumor, grant writing, weekend camps, and fundraising events. Developed Los Angeles-based Spanish-language programs to serve under-represented communities.

SECRETARY'S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTION (SACHRP)
Washington D.C. **10/2005 - 9/2011**

Sub-Part-A Subcommittee Member

Evaluated federal regulations that govern human subject protection in clinical research and proposed revision and guidance where applicable.

NATIONAL CANCER INSTITUTE, PEDIATRIC CENTRAL IRB, Washington D.C. **10/2004 – 11/2008**

Patient Advocate and Founding Member

Served as nonscientific/unaffiliated IRB member evaluating Children Oncology Group (COG) studies for nation-wide pediatric clinical trials.

UCLA MEDICAL CENTER, Los Angeles, CA **8/2002 – 8/2008**

Patient Advocate/IRB Committee Member

Served as nonscientific/unaffiliated member on the Oncology/HIV/Infectious Disease Committee reviewing clinical research protocols.

EDUCATION

Mount Saint Mary's University, Los Angeles, CA

Master of Fine Arts, Creative Non-Fiction (December 2022)

Loyola University Chicago, Chicago, IL

Doctorate in Bioethics, May 2019.

Loyola Marymount University, Los Angeles, CA

Master of Arts in Bioethics, June 2016.

California State University Los Angeles, Los Angeles, CA

Single Subject Secondary Teacher's Credential, Social Sciences, June 1986.

Loyola Marymount University, Los Angeles, CA

Bachelor of Arts: European Studies; Minors: German, Business, May 1982.

AWARDS

ARENA Legacy Award for promoting ethical conduct in research through mentoring, teaching, and leadership. Public Responsibility in Medicine & Research, National Harbor, MD (December 2011).

Founder's Award, We Can, Pediatric Brain Tumor Network, Los Angeles, CA (September 2011).

Community Leader Award for Innovation, National Brain Tumor Society, San Francisco, CA (September 2010).

Program Excellence Award for "We Can Family Camp Weekend," American Camp Association, (January 2007).

Citizen of the Year, Lion's Club of Manhattan Beach, CA (March 2003).

PROFESSIONAL SOCIETIES

American Society for Bioethics and Humanity (ASBH)
Board of Directors, 2016-2017

Association for Practical and Professional Ethics (APPE)

PRIM&R (Public Responsibility in Medicine & Research)
Board of Directors, 2020 - present

PUBLICATIONS

Antonijevic, Zoran, R. Beckman, J. Huml, Y. Lui, C. Mayer, **G. McMillan**, R. Tang. "Patient Benefits from Innovative Designs in Rare Disease." *Rare Disease Drug Development: Clinical, Scientific, Patient, and Caregiver Perspectives*, edited by Raymond A. Huml, Springer International Publishing, 2021, pp. 147-160.

McMillan, Gianna and Anna Iltis, editors. "Research on COVID-19: Stories from IRB Members, Research Administrators & Investigators." Commentary: IRBs during COVID-19: tried and true. *Narrative Inquiry in Bioethics*, Vol 11.1, 2021.

McMillan, Gianna, et al. Planning for the Next Pandemic: Ethics and Innovation Today for Improved Clinical Trials Tomorrow, *Statistics in Biopharmaceutical Research*, June 2021.

McMillan, Gianna. IRB Policies for Obtaining Informed Consent from Non-English-Speaking People. *Ethics & Human Research*, Vol. 42, No. 3, May/June 2020.

DuBois, James, E. Anderson, J. Chibnall, L. Diakov, D. Doukas, E. Holmboe, H. Koenig, J. Krause, **G. McMillan**, M. Mendelsohn, J. Mozersky, W. Norcross, A. Whelan. Preventing Egregious Ethical Violations in Medical Practice: Evidence-Informed Recommendations from a Multidisciplinary Working Group. *Journal of Medical Regulation*, Vol. 104, No. 4, 2018.

McMillan, Gianna. Community-Academic Partnerships in Research and Public Health: The Common Denominator. *Narrative Inquiry in Bioethics*, Vol 7.1, 2017.

Christy Rentmeester and **Gianna McMillan**, editors. "Confronting Pediatric Brain Tumors: Parent Stories," editor with Christy Rentmeester. *Narrative Inquiry in Bioethics*, Vol. 4.1, 2014.

McMillan, Gigi. Recruiting, Educating, and Retaining IRB Community Members. *Journal of Clinical Research Best Practices*, Vol. 6, No. 6, June 2010.

McMillan, Gigi. Informed Consent: The Parent's Point of View. *SoCRA Source* (Society of Clinical Research Associates), November 2009.

McMillan, Gigi. What Do Researchers Say? What do Subjects Hear?" *Protecting Human Subjects*, Spring 2005.

McMillan, Gigi and Marilyn Lash, *Brain Tumors in Children and Youths*. Lash & Associates Publishing/Training Inc., Wake Forest, NC, 2002.

Childhood Brain & Spinal Cord Tumors: A Guide for Families, Friends & Caregivers, T. Shiminski-Maher, P. Cullen. & M. Sansalone, Patient-Centered Guides/O'Reilly & Associates, 1st and 2nd edition. (Contributor and Technical Advisor).

PRESENTATIONS

"A Parent's Experience of Assent" (August 2021) and "Reflections on Pediatric Assent: Have we Outgrown this Concept?" (November 2021), ICON Global.

"Real-life Application of Ethical Principles to a Research Subject's Experience." Society of Clinical Research Associates (September 2021).

"Ethical Principles and Drug Development," Joint Statistical Meeting (August 2021).

"Pediatric Engagement in Research: Young People Have a Voice." DIA Global Annual Meeting (June 2021).

"Research Ethics in the Time of Pandemic." Panelist for Loyola Marymount University (October 2020).

"Community Engagement in Research: The Patient/Subject Perspective." BIO Digital International (June 2020).

"Innovative Clinical Trial Design and the Patient Voice," Keynote presentation for the FDA/DIA Conference, Washington D. C. (March 2020).

"Patient-reported Endpoints in Pediatric Clinical Trials" Duke-Margolis Center for Health Policy, Washington D.C. (December 2019).

"Returning Research Results to Participants: Whose Job Is It?" PRIM&R National Conference, Boston, MA (November 2019).

"Narrative as an Educational Tool in Bioethics," APPE (Association for Practical and Professional Ethics) Conference, Baltimore, MD (February 2019).

"Consenting Vulnerable Populations," University of North Carolina Chapel Hill, IRB Continuing Education Seminar, Raleigh, NC (February 2019).

"Tell Me What I Need to Know," Critical Role of Nursing in Cellular Therapies, City of Hope, Duarte, CA (August 2018). California Institute of Regenerative Medicine (CIRM) Board of Directors, Oakland, CA (June 2018). Alpha Stem Cell Clinic Symposium, UCLA, Los Angeles, CA (April 2018).

"Recruiting Educating and Retaining Non-Scientist IRB Members"; "Stories Matter: The Use of Narrative in IRB Member Education." PRIM&R National Conference, San Antonio, TX (November 2017).

"Children, Parents and Consent" and "IRB Impostor," PALISI (Pediatric Intensive Care/Critical Illness) Conference, San Diego, CA (March 2016).

"FDA Patient Representatives: Why We Were Invited to the Table," FDA Workshop, Rockville, MD (July 2015).

"When All Else Fails: The Promise and Peril of Expanded Access to Investigational Treatment," Panelist for PRIM&R National Conference, Baltimore, MD (December 2014).

"Ethical Considerations with the Use of Personal Narrative," American Society for Bioethics & Humanities, San Diego, CA (October 2014).

"Key Conversations," Omaha Children's Hospital and Medical Center, Grand Rounds (September 2012).

"IRB Community Members," University of Nebraska Medical Center, Regional IRB Continuing Education Conference (September 2012).

“Breaking Informed Consent Out of the Box: New and Emerging Issues in Informed Consent,” PRIM&R National Conference, National Harbor, MD (December 2011).

“The Role of the Unaffiliated/Non-Scientific Member”; “Honoring the Spirit of Informed Consent.” PRIM&R National Conference, San Diego, CA (December 2010).

"Subject Advocacy vs. Therapeutic Misconception," IRB Educational Conference, Columbia University, New York (April 2010).

"Improving the Consent Process and Reformatting the Form," PRIM&R National Conference, Nashville, TN (November 2009).

"Investigator Interactions with Vulnerable Populations: Special Considerations," Annual IRB Education Seminar, Duke University Health System, Durham, North Carolina (April 2009).

"How Brain Tumors Affect the Family," "Pediatric Brain Tumors and Daily Life," National Brain Tumor Foundation conference at UCSF, San Francisco, CA (January 2009).

"What's Different About Children in Research? They are not Small Adults!", "Tools for Talking to the Parents of Research Subjects," PRIM&R National Conference, Orlando, FL (November 2008).

"Is Conflict of Interest of *Any* Interest?" Research Ethics Symposium, NYU Langone Medical Center, New York, NY (October 2008).

"Informed Consent from the Subject's Perspective," IRB Supplemental Education Day, University of Virginia, Charlottesville, VA (October 2008).

"Informed Consent from the Subject's Perspective," IRB Educational Day, St. Jude's Children's Research Hospital, Memphis, TN (September 2008).

“Talking and Listening to the Parents of Research Subjects,” Plenary Panelist, PRIM&R National Conference, Boston, MA (December 2007).

“Non-Affiliated (Community) Members,” Webinar, Community-Campus Partnerships for Health and the Tuskegee University National Center for Bioethics in Research and Health Care (March 2007).

“The Psychology of an IRB Meeting”; “Community Members in the IRB: Ask the Chair”; PRIM&R National Conference, Washington D.C. (November 2006).

“A Parent’s Perspective on Informed Consent,” IRB Consortium Annual Meeting, University of Kentucky (September 2006).

“Children as Research Subjects,” Show Case Conference on Children in Research, Case Western University, Cleveland, OH (April 2006).

“Comprehension and Informed Consent: How Do Investigators Know if Subjects Understand?”, “Involving Communities in the Research Enterprise”; PRIM&R National Conference, Boston, MA (December 2005).

“In Their Voices: The Subjects Speak”; “How to Recruit, Train and Retain Community Members,” PRIM&R National Conference, San Diego, CA (October 2004).