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Senior Research Scholar
Editor, *Ethics & Human Research*
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EDUCATION

Case Western Reserve University, M.A. Bioethics, 1999

Johns Hopkins University, PhD, Political Science, 1987
Major Field: Public Law
Minor Fields: American Government, Public Administration,

Georgia State University, M.A., 1981
Major Field: Public Law
Minor Field: Public Administration

Georgia State University, B.S., 1977
Major: Urban Politics

EMPLOYMENT

Senior Research Scholar, The Hastings Center: March 2003 – present

Research Scholar, The Hastings Center: May 2000 – February 2023

Editor, *Ethics & Human Research* (formerly *IRB: Ethics & Human Research*): May 2003 – present

Clinical Bioethics Fellow, The Cleveland Clinic: May 1999 – May 2000

Assistant Professor, Department of Political Science, University of Georgia: August 1989 – June 1996

Internship Supervisor, Criminal Justice Studies Program, University of Georgia: August 1989 – June 1996

Assistant Professor, Department of Political Science, Oakland University (Rochester, Michigan):
September 1985 – May 1989

Internship Coordinator/Pre-law Advisor, Department of Political Science, Oakland University
(Rochester, Michigan): September 1985 – May 1989

GRANTS AND CONTRACTS

Grants/Contracts Awarded

Lead Investigator and Co-Multiple Principal Investigator with Michael Gusmano and Elisa Gordon. Informing Ethical Translation of Xenotransplantation Clinical Trials. National Center for Advancing Translational Sciences, National Institutes of Health. 1R01TR003844-0. 8/1/21-7/30/25.

Co-Principal Investigator (with Josephine Johnston and Insoo Hyun). Actionable Ethics Oversight for Human-Animal Chimera Research. National Human Genome Research Institute, National Institutes of Health. 1R01HG010168-01. 7/1/18-6/30/21. No-cost extension through 6/30/22.

Co-Investigator (PIs Neuhaus and Crane). Understanding All of Us Enrollees and Decliners: Motivations to Enhance Recruitment and Retention: FQHC's Barriers to Caring for Patients with Clinically Actionable Genetic Research Results. National Human Genome Research Institute, National Institutes of Health. R21 HG010531-02S1. No-cost extension through spring 2022.

Consultant (PI Brendon Parent). Ethics of Big Data for AI in Healthcare: Identifying Key Issues for Practical Guidance. Funded by the Robert Wood Johnson Foundation (under subcontract from NYU Grossman School of Medicine). 3/1/22-3/30/22.

Co-Investigator (PIs: Greg Kaebnick and Michael Gusmano). Public Deliberation on Gene Editing in the Wild. National Science Foundation. 7/1/19-2/28/22.

Co-Investigator (PI: Greg Kaebnick). Values in Impact Assessment, National Science Foundation. 7/1/14-7/30/17.

Consultant. Le Bonheur Children's Hospital Foundation Biorepository and Integrative Genomics (BIG) Initiative (with the University of Tennessee Health Sciences Center). 9/1/15-8/31/16.

Co-Investigator (PI: Suzanne Rivera). Advancing Collaborative Genetic Research. National Human Genome Research Institute, National Institutes of Health. R01 HG005691. 5/26/11-2/28/16.

Hastings Center Co-PI. Subcontract from NFPLA/Harvard Accelerated Research Collaboration to Protect and Improve the Health of Football Players. 1/27/14/-2/29/16.

Consultant. Mayo Clinic Biomedical Ethics Program. 2010-2014.

Consultant. Mayo Clinic Biobank, Member, Biospecimen Trust Oversight Group; Member, Biobank Access Committee Member; Co-chair, Community Advisory Board. 2012-2013.

Consultant. National Cancer Institute. Cancer Biomedical Informatics Grid (caBIG), Data Sharing and Intellectual Capital Workspace (DSIC) Knowledge Center (subcontract from University of Michigan). 2011-2012.

Consultant/Author. Access to Medical Care for Pregnant Drug Users: Case Study of Ethics Issues. Prepared for the Law and Health Initiative of the Public Health Program of the Open Society Institute. 2010.

Consultant/Co-Author. Toward an Organizational Ethics Framework for Donors to Health-Related Programs in Compulsory Drug Detention Centers. White paper prepared for the International Harm Reduction Development Program of the Public Health Program of the Open Society Institute. 2010.

Collaborator and Editor. HIDE (Homeland Security, Biometric Identification and Personal Detection Ethics). European Commission. PI: Emilio Mordini, Centre for Science, Society and Citizenship, Rome, Italy. 2008-2011.

Faculty Collaborator (PI: Howard Stone). Law & Ethics of Drug Addiction Genetics Research (LEDGER). National Human Genome Research Institute, National Institutes of Health. R01 DA020119. 2007-2009.

Consultant. National Cancer Institute's Cancer Biomedical Informatics Grid (caBIG) Data Sharing and Intellectual Capital Workspace. 2007-2011.

Faculty Collaborator (PI: William Johnson). Building Research Ethics Capacity in Haiti. National Fogarty International Center, Institutes of Health. 2006-2008.

Faculty Collaborator (PI: Mark Rothstein). Education in Genetics Ethics (EDGE). National Human Genome Research Institute, National Institutes of Health. R25 HG002503 2003-2005.

Project Member (PIs: Josephine Johnston and Angela Wassuna). Intellectual Property Rights in Pharmaceutical and Biological Materials: Ensuring Innovation or Barring Access? Sasakawa Peace Foundation. 2005-2006.

Project Member (PI: Thomas Murray). Ethical Decision-making for Newborn Genetic Screening. National Human Genome Research Institute, National Institutes of Health. R01 HG002579. 2003-2006.

Project Member (PI: Mary Ann Baily). The Ethics of Improving Health Care Quality and Safety. Agency for Healthcare Research & Quality. 2003-2006.

Project Member (PI: Thomas Murray). Ethical, Conceptual and Scientific Issues in the Use of Performance Enhancing Technologies in Sports. United States Anti-Doping Agency (USADA). 2003-2004.

PUBLICATIONS

Books/Edited Volumes

Maschke, Karen J. and Gusmano, Michael K., *Debating Modern Medical Technologies: The Politics of Safety, Effectiveness, and Patient Access*. New York: Prager, 2018.

Murray, Thomas H., Wasunna, Angela, and **Maschke, Karen J.**, eds. *The Use of Performance-Enhancing Technologies in Sports: Ethical, Conceptual, and Scientific Issues*. Baltimore: Johns Hopkins University Press, 2009.

Maschke, Karen J., ed. *Gender and American Law*. Volumes 1-7. New York: Taylor & Francis, 1997.

Maschke, Karen J. *Litigation, Courts, and Women Workers*. New York: Praeger, 1989.

Book Chapters

Maschke, Karen J., “Governance Issues for Biobanks and Biospecimen Research,” In: *Specimen Science: Ethics and Policy Implications*, Rivera, Suzanne M., Bierer, Barbara E., and Cohen, I. Glenn, eds. Cambridge: MIT Press, October 2017.

Maschke, Karen J. “Ethical and Policy Issues Involving Research with Newborn Screening Blood Samples,” In: *Ethics and Newborn Genetic Screening: New Technologies, New Forces, New Challenges*, Baily, Mary Ann and Murray, Thomas H. eds. Baltimore: Johns Hopkins University Press, 2009.

Maschke, Karen J. “Ethical Issues in Sports Enhancement Research with Humans,” In: *The Use of Performance-Enhancing Technologies in Sports: Ethical, Conceptual, and Scientific Issues*, Murray, Thomas H., Wassuna, Angela, and Maschke, Karen J., eds. Baltimore: Johns Hopkins University Press, 2009).

Articles/Commentaries/Reviews

Neuhaus CP, Pacia, DM, Crane, JT, **Maschke KJ**, Berlinger N. “All of Us and the Promise of Precision Medicine: Achieving Equitable Access for Federally Qualified Health Center Patients,” *Journal of Personalized Medicine* 2023 Mar 31;13(4):615.

Maschke, Karen J., Matthews, Margaret M., Craig, Kaitlynn P., Neuhaus, Carolyn P., Hyun, Insoo, Johnston, Josephine, eds. *Creating Chimeric Animals: Seeking Clarity on Ethics and Oversight*. *Hastings Center Report*. Special Supplement. November-December 2022;S1-S56.

Johnston J, Hyun I, Neuhaus CP, **Maschke KJ**, Marshall P, Craig KP, Matthews MM, Drolet K, Greely HT, Hill LR, Hinterberger A. “Clarifying the Ethics and Oversight of Chimeric Research.” *Hastings Center Report*. November-December 2022;52:S2-3.

Neuhaus, Carolyn, Berlinger, Nancy, **Maschke, Karen**, Crane, Johanna. Issue Brief. “Strategies to Support Equitable Access to Precision Medicine for All of Us Participants from Federally Qualified Health Centers,” April 2022. <https://community.thehastingscenter.org/wp-content/uploads/2022/03/All-of-Us-Issue-Brief-FINAL.pdf>

Maschke, Karen J., Gordon Elisa J., Gusmano, Michael K. “Opinion: After the Pig-to-Human Heart Transplant, the FDA, Clinicians and Insurers Have Some Catching Up to Do,” Op Ed. *Washington Post* January 13, 2022. <https://www.washingtonpost.com/opinions/2022/01/13/what-comes-after-pig-to-human-transplant-breakthrough/>

Gusmano, Michael K., Kaebnick, Gregory E., **Maschke, Karen J.**, Neuhaus, Carolyn P., Will, Ben Curran. *Gene Editing in the Wild: Shaping Decisions through Broad Public Deliberation*. *Hastings Center Report*. Special Supplement. November-December 2021:S41-S100.

Maschke, Karen J., Gusmano, Michael K. “Regulating Gene Editing in the Wild: Building Regulatory Capacity to Incorporate Deliberative Democracy,” In, *Gene Editing in the Wild: Shaping Decisions through Broad Public Deliberation*. *Hastings Center Report*. Special Supplement. November-December 2021:S42-S47.

Gusmano, Michael K., Kaebnick, Gregory E., **Maschke, Karen J.**, Neuhaus, Carolyn P., Wills, Ben Curran. *Gene Editing in the Wild: Shaping Decisions through Broad Public Deliberation. Hastings Center Report*. Special Supplement. November-December 2021:S2.

Bolo, I, Wills, B.C., **Maschke, K.J.**, “Public Attitudes toward Human-Animal Chimera Research May Be More Complicated than They Appear,” *Stem Cell Reports* 2021 Feb 9;16(2):225-6.

Maschke, Karen J. and Gusmano, Michael K. “Ethics and Evidence in the Search for a Vaccine and Treatments for Covid-19,” *Bioethics Forum*, April 15, 2020.

Gusmano, Michael, K., **Maschke, Karen J.**, and Solomon, Mildred Z. “Patient-Centered Care, Yes; Patients As Consumers, No,” *Health Affairs* 2019;38(3):368-373.

Maschke Karen J. “Animals with Human Cells in Their Brains: Implications for Research,” *Hastings Center Report* 2019 Sep;49(5):36-7.

Maschke, Karen J., [Letter] “Off-label Use of Medications,” *JAMA* 2018;320(3):306-307.

Maschke, Karen J., Field Notes. “Evidence and Human Genome Editing,” *Hastings Center Report* 2018;48(5): npg.

Maschke, Karen J., “The Need for Open and High-Quality Preclinical Science,” *Bioethics Forum*, April 6, 2018.

Maschke, Karen J., Gusmano, Michael K., and Solomon, Mildred Z. “Breakthrough Cancer Treatments Raise Difficult Questions,” *Health Affairs* 2017;Oct 1;36(10):1698-1700.

Maschke Karen J. and Gusmano, Michael K. “Medicare and Amyloid PET Imaging: The Battle Over Evidence,” *Journal of Aging & Social Policy* 2017;15;29(2):105-22.

Maschke, Karen J. and Gusmano, Michael K. “Evidence and Access to Biomedical Interventions: The Case of Stem Cell Treatments,” *Journal of Health Politics, Policy and Law* 2016;41(5):917-936.

Solomon, Mildred Z., Gusmano, Michael K., and **Maschke, Karen J.** “The Ethical Imperative and Moral Challenges of Engaging Patients and the Public with Evidence,” *Health Affairs* 2016;35:4583-589.

Rivera, S.R., Goldenberg A., Rosenthal, B., Aungst, H., **Maschke, Karen J.**, Rothwell, E., Anderson, R. A., Botkin, J., and Joffe, S. “Investigator Experiences and Attitudes about Research with Biospecimens,” *Journal of Empirical Research on Human Research Ethics* 2015;10(5):449-456.

Goldenberg, A., **Maschke, K.J.**, Joffe, S., Botkin, J.R., Rothwell, E., Murray, T.H., Anderson, R., Deming, N., Rosenthal, B.F., and Rivera, S.M., “IRB Practices and Policies Regarding the Secondary Research Use of Biospecimens,” *BMC Medical Ethics* 2015 May 8;16:32. doi: 10.1186/s12910-015-0020-1.

Rothwell, E., **Maschke, K.J.**, Botkin, J.R., Goldenberg, A., Murray, T.H., and Rivera, S.M., “Biobanking Research and Human Subjects Protections: Perspectives of IRB Leaders,” *IRB: Ethics & Human Research* 2015;37(2):8-13.

Kimball, B.C., Nowakowski, K.E., **Maschke, K.J.**, and McCormick, J., "Genomic Data in the Electronic Medical Record: Perspectives from a Biobank Community Advisory Board," *Journal of Empirical Research on Human Research Ethics* 2014;9(5):16-24.

Bielinski, S.J., et al. (**Maschke, K.J.** a co-author), "Preemptive Genotyping for Personalized Medicine: Design of the Right Drug, Right Dose, Right Time, Using Genomic Data to Individualize Treatment Protocol," *Mayo Clinic Proceedings* 2014;89(1):25-33.

Botkin, J.R., Anderson, R., Murray, T., Beskow, L.M., **Maschke, K.J.**, and Cuttler, L., "Proposed Regulations for Research with Biospecimens: Responses from Stakeholders at CTSA Consortium Institutions," *American Journal of Medical Genetics* 2014;164A(4):892-897.

Reisfield, G.M. and **Maschke, K.J.**, "Urine Drug Testing in Long-term Opioid Therapy: Ethical Considerations," *Clinical Journal of Pain* 2014;30(8):679-684.

Maschke, Karen J., "When Evidence is Contested," *Hastings Center Report* 2014;44(3). DOI: 10.1002/hast.314

Trump, E., and **Maschke, K.J.**, "Do Allografts Equal Organs?" *MedPageToday*, July 10, 2014. <http://www.medpagetoday.com/Surgery/Transplantation/46711>

Horwitz, R.H., et al. (**Maschke, K.J.** a co-author) "Assessment of the Voluntariness of Consent for an HIV Vaccine Trial in Haiti," *Annals of Internal Medicine* 2013;158(3):222-224.

Olson, J.E., et al. (**Maschke, K.J.** a co-author), "The Mayo Clinic Biobank: A Building Block for Individualized Medicine," *Mayo Clinic Proceedings* 2013;88(9):952-962.

Maschke, Karen J., "Returning Genetic Research Results: Considerations for Existing No-return and Future Biobanks," *Minnesota Journal of Law, Science & Technology* 2012;13:559-574.

Wolf, S.M., et al. (**Maschke, K.J.** a co-author), "Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data," *Genetics in Medicine* 2012;14(4):361-384.

Hansson, M.G., and **Maschke, K.J.**, "Biobanks: Questioning Distinctions," *Science* 2009;326(5954):797; author reply. 799. doi: 10.1126/science.326_797b.

Maschke, K.J., "DNA and Law Enforcement," *Bioethics Briefing Book* (Garrison, New York: The Hastings Center, 2008).

Maschke, Karen J., "Biobanks: DNA and Research," *Bioethics Briefing Book* (Garrison, New York: The Hastings Center, 2008).

Maschke, Karen J., "Human Research Protections: Time for Regulatory Reform?" *Hastings Center Report* 2008;38(2):19-22.

Maschke, Karen J., "The Implication of the HIPAA Privacy Rule for Quality-Improvement Activities," In: *Health Care Quality Improvement: Ethical and Regulatory Issues*, Jennings, Bruce, Baily, Mary Ann, Botrell, Melissa, and Lynne, Joanne, eds., (Garrison, New York: The Hastings Center, 2007).

Maschke, Karen J., "Navigating an Ethical Patchwork – Human Gene Banks," *Nature Biotechnology* 2005;23(5):539-545.

Trump, E., and **Maschke, K.J.** "A Stranger in the Mirror: Should Doctors Transplant Faces?" *New York Times*, October 12, 2004.

Maschke, Karen J., "Review of *The Stored Tissue Issue: Biomedical Research, Ethics, and Law in the Era of Genomic Medicine*. Robert F. Weir and Robert S. Olick. New York: Oxford University Press, 2004. *NEJM* 2004;351(19):2023-2024.

Maschke, Karen J., Review of *Lesser Harms: The Morality of Risk in Medical Research*. Sydney A. Halpern. Chicago and London: University of Chicago Press, 2004. *Medical Humanities Review* 2005;1(2):39-44.

Maschke, Karen J., and Thomas H. Murray, "Ethical Issues in Tissue Banking for Research: The Prospects and Pitfalls of Setting International Standards," *Theoretical Medicine and Bioethics* 2004;25:143-155.

Maschke, Karen J., and Trump, Eric, "Facial Transplantation Research: A Need for Additional Deliberation," *American Journal of Bioethics* 2004;4(3):21-23.

Maschke, Karen J., "US and UK Policies Governing Research with Humans," *Psychopharmacology* 2003;171(1):47-55.

Weise, K.L., Smith, M.L., **Maschke, K.J.**, and Copeland, H.L., "National Practices Regarding Payment to Research Subjects for Participating in Pediatric Research," *Pediatrics* 2002;110(3):577-582.

Maschke, Karen J., Review of *Into Our Own Hands: The Women's Health Movement in the United States, 1969-1990*. Sandra Morgen. New Brunswick: Rutgers University Press, 2002. *Medical Humanities Review* 2002;16(2):51-55.

Maschke, Karen J., Review of *From Chance to Choice: Genetics and Justice*. Allen Buchanan, Dan W. Brock, Norman Daniels, and Daniel Wikler. Cambridge: Cambridge University Press, 2000. *Politics and the Life Sciences* 2000;19(2):18-19.

Maschke, Karen J., "Criminalization of Pregnancy, USA," In: *The Encyclopedia of Women and Crime*. Phoenix, AZ: Oryx Press, 2000.

Maschke, Karen J., "Prosecutors as Crime Creators: The Case of Prenatal Drug Use," *Criminal Justice Review* 1995;20:21-33.

Maschke, Karen J., Review of *Human Reproduction, Emerging Technologies, and Conflicting Rights*. Robert Blank and Janna C. Merrick. Washington, D.C.: CQ Press, 1995. *Politics and the Life Sciences* 1996;15:341-342.

Maschke, Karen J., "From the Workplace to the Delivery Room: Protecting the Fetus in the Post-Roe Era," *Politics and the Life Sciences* 1993;12:53-60.

SELECTED MEDIA INTERVIEWS & MEDIA COVERAGE

Surgeons perform second pig heart transplant, trying to save a dying man. Associated Press (AP). September 22, 2023. <https://apnews.com/article/pig-heart-transplant-d894f6ce27b7db71ecb0ec393cac3e86>

US man who got 1st pig heart transplant dies after 2 months. Associated Press (AP). March 9, 2022. <https://apnews.com/article/pig-heart-transplant-patient-dies-bc3b304de3c8d3bf3acbb3c221960ecf>
Picked up by ABC News.

Pig-heart transplantation surgeons look to the next steps. *The Lancet*. January 20, 2022.

Pig heart transplant gives ex-con a second chance. But is it ethical? *USA Today*. January 19, 2022.
US researchers test pig-to-human transplant in donated body. Associated Press (AP). January 20, 2022. <https://www.usatoday.com/story/news/health/2022/01/19/pig-heart-transplant-ex-con-second-chance-but-ethical/6559541001/?gnt-cfr=1>

The article ran in dozens of print, TV, and radio media outlets around the world, including *Washington Post*, *Time*, *US News and World Report*, MSN, CBS local news, Audacy.com.

Patient in Groundbreaking Heart Transplant Has a Violent Criminal Record. *New York Times*. January 13, 2022. <https://www.nytimes.com/2022/01/13/health/pig-heart-transplant-bennett.html#:~:text=An%20ailing%20Maryland%20man%20who,young%20man%2C%20leaving%20him%20paralyzed>

Pig-Heart Transplant Jolts Doctors Confronting Lack of Organ Donors. *Wall Street Journal*. January 12, 2022. <https://www.wsj.com/articles/pig-heart-transplant-donor-organs-11641948330>

In 1st, US surgeons transplant pig heart into human patient. Associated Press (AP). January 10, 2022. <https://apnews.com/article/pig-heart-transplant-6651614cb9d73bada8eea2ecb6449aef>
The article ran in dozens of media outlets around the world, including *Time*, *Newsweek*, *NY Daily News*, *LA Times*, *San Francisco Chronicle*, CNBC, and India.com.

Pig-to-human transplants come a step closer with new test. Associated Press (AP). October 20, 2021. <https://apnews.com/article/animal-human-organ-transplants-d85675ea17379e93201fc16b18577c35>
Bloomberg Law. Quoted me and cited and provided a link to the Maschke-Gusmano book, *Debating Modern Medical Technologies*, in an article about sham stem cell studies listed on ClinicalTrials.gov. June 26, 2019. <https://news.bloomberglaw.com/pharma-and-life-sciences/sham-stem-cell-studies-force-nih-to-weed-its-research-database>.

Medscape. Features a video of Arthur Caplan endorsing the Gusmano, Maschke, and Solomon *Health Affairs* article (March 2019) on patients as consumers. April 23, 2019. <https://www.medscape.com/viewarticle/911562?fbclid=IwAR2p0ZDtBhJzrZd-3qhllaJYngFsmDNgDp6fxqx9dKoSrEewTGdiE9VjZyE>

Politico's Morning e-Health newsletter. Features Gusmano, Maschke, and Solomon *Health Affairs* article (March 2019) on patients as consumers. March 6, 2019. <https://www.politico.com/newsletters/morning-ehealth/2019/03/05/are-patients-consumers-or-not-403980>

Politico. Interview with eHealth reporter Mohana Ravindranath about predictive algorithms for opioid use marketed by tech companies. January 17, 2019.

STAT News. Quoted me in an article about a controversial clinical trial for sepsis treatment. August 18, 2018. <https://www.statnews.com/2018/08/28/nih-sepsis-study-public-citizen/>

Vice News Tonight. Featured me in a video story about biohacking. April 10, 2018.

https://www.youtube.com/watch?time_continue=227&v=5JiNedvN4U8

The Atlantic. Interview with reporter about ethical questions regarding medical research with prisoners. May 16, 2018.

SELECTED PRESENTATIONS

CITI Program. Podcast. On Tech Ethics Podcast. Season 1 - Episode 12. "Ethical and Policy Issues for Xenotransplantation Clinical Trials." The podcast's primary audience is researchers, healthcare professionals, ethical review board committee members, students, and engineers. October 10, 2023.

"Ethical and Policy Challenges for Xenotransplantation," Hastings Center Advisory Council, November 1, 2022.

"Ethical and Policy Challenges for Xenotransplantation," Hastings Center Board of Trustees, June 20, 2022.

"Chimeric Animals with Human Stem Cells: Ethical and Oversight Issues, Genetic Engineering and Society Center, North Carolina State University, January 31, 2023.

"The Legacy of Eugenics," Gene Editing & Human Flourishing, A Summer Bioethics Workshop for Secondary School Teachers, August 3, 2018, The Hastings Center.

"Ethics in Biospecimen Research: Beyond Informed Consent." Annual Meeting of the American Society for Bioethics and Humanities, Washington, DC. October 6, 2016.

"Ethical and Policy Issues Related to Biospecimen Research: Implications for Collecting, Storing and Using Diagnostic Biospecimen Samples." NCI Tissue Block Workshop. Bethesda, MD, June 16, 2016.

"Governance Issues for Biobanks and Biospecimen Research." Symposium, Specimen Science: Ethics and Policy Implications. Petrie-Flom Center, Harvard Law School. November 16, 2015.

"Medicare and Amyloid PET Imaging: The Battle Over Evidence." Annual Meeting of the American Political Science Association, San Francisco, CA. September 4, 2015 (co-presenter Michael Gusmano).

"Evidence-based Insurance Coverage: Law, Politics, and Public Policy." Annual Meeting of the Midwest Political Science Association, Chicago, IL. April 18, 2015 (co-presenter Michael Gusmano).

"Ethical Dimensions of Policy for Ageing and Genetics." Chinese University of Hong Kong Launch Conference, Building Bioethics Capacity in Hong Kong. January 10, 2015.

"Ethics of Biobanking and Bio Applications of Big Data." Chinese University of Hong Kong Launch Conference, Building Bioethics Capacity in Hong Kong. January 10, 2015.

"Politics, Values, and Access to Untested Medical Interventions: The Case of Stem Cell Treatments." Annual Meeting of the American Political Science Association, Washington, DC. August 30, 2014 (co-presenter Michael Gusmano).

"Translating Whole Genome Sequencing into the Clinic: Ethical, Legal, Policy, and Social Considerations for Institutional Leaders." Annual Meeting of the American Society for Bioethics and Humanities, Atlanta, GA. October 2013 (co-presenter Jennifer McCormick).

"Ethical and Community Perspectives: The Need for Community Engagement in Biospecimen Collection. Biospecimen Science and Cancer Health Disparities Conference." Johns Hopkins Center to Reduce Cancer Disparities. Washington, DC. June 12, 2013.

"From Research to the Clinic: Ethical Challenges and Policy Implications of Translational Genomics." Individualizing Medicine 2012 Conference. Mayo Clinic. October 2, 2012.

"IRBs and Multisite Studies: Maintaining Local Context." NHLBI Working Group. Facilitating Clinical Trials through Optimization of the IRB Process: Are Central IRBs the Solution? Washington, DC. June 29, 2011.

"Retrofitting No-Results Biobanks and Biobanks in Development to Manage Individual Results and Incidental Findings. Symposium: Should We Return Individual Research Results and Incidental Findings from Genomic Biobanks & Archives?" (PI: Susan Wolf) Bethesda, MD. May 19, 2011.

"Biobanks as Research Resources: Key Challenges." The National Academies Committee on Science, Technology, and Law, Washington, DC. April 11, 2011.

"Genomic Biobanks: Structure and Capacity to Return Results." Working Group Meeting III: Managing Incidental Findings and Research Results in Genomic Biobanks & Archives. (PI: Susan Wolf), University of Minnesota. December 14, 2010.

"Genetic Testing, Genocentrism, and "the promise" of Personalized Medicine." Ethics Grand Rounds, University of Texas Southwestern Medical Center. April 2010.

"Cancer Genetics Research Using Biobanks: The Privacy/Confidentiality Conundrum." Mayo Clinic, Rochester Minnesota. January 2009.

"Research with Biological Data Collected in Social Surveys: The Role of IRBs in Informed Consent." Workshop on Collecting, Storing, Accessing, and Protecting Data Containing Biological Measures. National Academy of Sciences, Washington, DC. November 2008.

"Genetic Research and DNA Banking: Ethical, Legal, and Social Implications." The Human Genome Project: Training for Librarians. Baruch College, New York, NY. May 2007.

"Ethical Challenges in Surgical Innovation." Westchester Medical Center, NY. May 2007.

"Public Health in the Global Context: The Case of Haiti." New York Medical School. April 2007.

"Ethical and Policy Challenges for Clinical Translational Research: Research Results and Incidental Findings." University of California, Irvine Medical School. March 2007.

"Euthanasia and Physician-Assisted Suicide." U.S. Military Academy at West Point. February 2007.

“Institutionalizing Ethics: Power, Politics, and Unresolved Tensions.” Conference sponsored by the Project on Institutionalisation of Ethics and Science Policy, Practices and Impact (INES), a European Union funded project coordinated by the Center for Genomics, Ethics and Governance, Lancaster University, Lancaster UK. Brussels, Belgium. October 2006.

“Bioethics for Technology Transfer Managers.” Annual Conference of the Association for Technology Transfer Managers, Orlando, Florida. March 2006.

“Overview of Ethical, Legal and Social Issues Raised by Research with Children.” Canadian Institutes of Health Research, Montreal, Canada. June 2004.

“Research with Newborn Screening Blood Samples: Ethical and Policy Issues.” Washington University St. Louis. March 2004.

“The Gene Trials: Ethical Dilemmas, Policy Issues, and Regulatory Oversight.” University of Missouri. January 2001.

TEACHING EXPERIENCE

University Teaching

University Quisqueya, Port au Prince, Haiti

- Graduate course in the MPH program, Ethical Issues in Research with Humans. November 6-17, 2006.

University of Georgia, Department of Political Science (full-time faculty member)

- Criminal Justice Administration (undergraduate)
- Criminal Procedure (undergraduate)
- Law Enforcement Administration (undergraduate)

Oakland University, Department of Political Science (full-time faculty member)

- Administrative Law (graduate)
- American Government (undergraduate)
- Constitutional Law (undergraduate)
- Environmental Law and Policy (graduate/undergraduate)
- Judicial Politics (undergraduate)
- Law and Politics (undergraduate)

Sessions for Medical and Allied-Health Professionals

Cleveland Clinic

- Artificial Nutrition and Hydration: Policy, Practice, and Empirical Evidence
- Basic Bioethics
- End-of-Life Decision-making in the Hospital: Current Practice and Future Prospects
- Financial Reimbursement, Length-of-Stay, and Ethical Considerations
- Liver Transplantation Policies in the United States
- Payment to Pediatric Research Subjects: Current National Practice and Proposed Ethical Standards
- Physician-Assisted Suicide

- Recent Studies on Informed Consent
- Surrogate Decision-making

Guest Faculty Lectures

New York Medical College. Department of Health Policy and Management. Graduate Course: Regulatory and Market Approaches to U.S. Health Care. “Federal Regulation of Medical Products: Normative and Policy Issues.” March 16, 2017.

Hastings Center’s High School Bioethics Project. Kent Place School. Summit, New Jersey. “Ethics and Genomics.” October 18, 20, 21, 25, 2016.

Columbia University. Bioethics and the Law Graduate Course. “At the Intersection of Research, the Clinic, and Public Health: Access to Unapproved Medicines.” January 2014.

Columbia University. Bioethics and the Law Graduate Course. “Research with Human Biospecimens: The Consent Issue.” February 2012.

Sarah Lawrence College. Public Health Genomics Graduate Certificate Program. “The ELSI of Genetic Research: From the Biobank to the Clinic.” March 2011.

Sarah Lawrence College. Public Health Genomics Graduate Certificate Program. “Genetic Research and Medicine: Hype, Hope, and Conflicts in Ethics, Law and Public Policy.” March 2010.

Sarah Lawrence College. Public Health Genomics Graduate Certificate Program. “Genetic Research: Consent, Privacy and Governance.” April 2009.

Sarah Lawrence College. Public Health Genomics Graduate Certificate Program. “What’s So Different about Genetic Research?” March 2008.

New York University. Program in Environmental Health Sciences, Environmental Toxicology Graduate Course. “The Ethical, Legal and Social Implications of Genetic Research.” 2012, 2010, 2008.

OTHER PROFESSIONAL ACTIVITIES

Member, Ethics Committee, International Human Epigenome Consortium. 2013 – 2022.

Member, Ethics Committee, LeBonheur Children’s Hospital Foundation Biorepository and Integrative Genomics (BIG) Initiative (with the University of Tennessee Health Sciences Center), 2015 – 2020.

Member, Tribal Collaboration Working Group, NIH All of US Research Program, 2017- present.

Member, National Institutes of Health Chimpanzee Research Use Panel. 2013-2015.

Co-Chair, Ethics Subgroup. Cancer Human Biobank (caHUB), NCI/OBBR. 2009-2010.

Member, Ethics Subcommittee. Committee on Advocacy, Research, Communication, Ethics & Underserved Populations (CARE) for NCI’s CALGB. 2006-2008.

Member, Institutional Review Board, Vassar Brothers Medical Center. Poughkeepsie, NY. 2005-2011.

Invited Participant (Projects, Workshops)

Heart & Lung Transplantation: Science & Ethics of DCDD and Xenotransplants, March 20-21, 2023. Washington, D.C.

Xenotransplantation, National Kidney Foundation, April 10-23, 2022, Washington, D.C.

Managing Incidental Findings and Research Results in Genomic Biobanks and Archives. NIH/NHGRI #2-R01-HG003178 (PI: Susan Wolf) December 2010-May 2011.

Workshop on Release of Research Results to Participants in Biospecimen Studies. National Cancer Institute, Office of Biorepositories and Biospecimen Research (OBBR), Washington, DC. July 8-9, 2010.

Workshop on Collecting, Storing, Accessing, and Protecting Data Containing Biological Measures. National Academy of Sciences. Washington, DC. November 2008.

Workshop on Protecting Subject Privacy for Large-Scale Experimentation and Research. The Law Lab - Berkman Center for Internet & Society, Harvard University. November 2008.

Workshop on Protection for Human Research Subjects with Diminished Cognitive Capacity. Center for Practical Bioethics, Kansas City, MO. May 2006.

Workshop on Custodianship and Ownership Issue in Biospecimen Research. National Cancer Institute, Office of Biorepositories and Biospecimen Research (OBBR). May 2007.

The Data Release Workshop. National Cancer Institute/National Human Genome Institute. May 2006.

Workshop on Biospecimen Access and Ethical, Legal, and Policy Issues. National Cancer Institute, Office of Biorepositories and Biospecimen Research (OBBR). June 2005.

Insiders, Outsiders and the Law. American Bar Association. Atlanta, Georgia. March 1994

Faculty Workshop on Justice and Power in Legal Institutions and Legal Culture. American Bar Association. Amherst College. July 1992

Faculty Workshop on Litigation, Justice, and the Public Good. San Diego, California. American Political Science Association. April 1991.

Faculty Seminar on Civil Rights. American Political Science Association. Atlanta, Georgia, August 1989.

Grant Review Panels

Ethics Reviewer. NHGRI Grant Review Panel, Human Hereditary and Health in Africa (H3Africa): Ethical, Legal, and Societal Issues (ELSI) Research Program (U01). March 22, 2016.

Ethics reviewer. NIH Grant Review Panel, Precision Medicine Initiative® Cohort Program Biobank (U24). Alexandria, Virginia. 2016.

Chair of grant review panel for proposals submitted to the NHGRI in response to RFA-RM-13-005, Human Heredity and Health in Africa (H3Africa): Ethical, Legal, and Societal Issues (ELSI) Research Program (U01). 2013.

Ethics reviewer. Grant proposals submitted to the NIH in response to RFA-HD-13-010, Genomic Sequencing and Newborn Screening Disorders (U19). 2013.

Ethics reviewer. Grant proposals submitted to the NHGRI/ELSI in response to RFA-HG-11-022, The Electronic Medical Records and Genomics (eMERGE) Network, Phase II – Pediatric Study Investigators. 2011.

Ethics reviewer. Grant proposals submitted to the NHGRI/ELSI in response to RFA-HG-11-003, Development of a Preliminary Evidence Base to Inform Decision-making about Returning Research Results to Participants in Genomic Studies. 2011.

Ethics reviewer. Grant proposals submitted to the Congressionally Directed Medical Research Programs (CDMRP) for the Fiscal Year 2010 Prostate Cancer Research Program (Impact Award). 2010.

Ethics reviewer. Grant proposals submitted to the Congressionally Directed Medical Research Programs (CDMRP) for the Behavioral and Psychological Health and Operational Health and Performance program. 2009.

Ethics reviewer. Grant proposals submitted to the Congressionally Directed Medical Research Programs (CDMRP) for the Fiscal Year 2009 Prostate Cancer Research Program. 2009.

Ethics reviewer. Grant proposals submitted to the Congressionally Directed Medical Research Programs (CDMRP) for the Fiscal Year 2008 Breast Cancer Research Program. 2008.

FELLOWSHIPS, AWARDS, OTHER

National Institutes of Health. Office of Data Science Strategy. Innovation Lab: A Data Ecosystems Approach to Ethical AI for Biomedical and Behavioral Research. March 2022. I was selected from over 300 applicants to be one of 35 participants in the 5-day innovation lab. The purpose of the innovation lab was to “build a multi-disciplinary community of stakeholders interested in the social implications of technology that can help bridge the gap between artificial intelligence (AI) and ethics in biomedicine to advance the NIH mission.”

The Hastings Center Daniel Callahan and William Gaylin Fund. 2016. To support research and scholarship on topics related to the ethical, regulatory, and policy dimensions of evidentiary standards for patient access to new biomedical technologies. This funding supported the completion of Maschke, Karen J. and Gusmano, Michael K., *Debating Modern Medical Technologies: The Politics of Safety, Effectiveness, and Patient Access.* New York: Prager, 2018.

Center for Neuroscience & Society, University of Pennsylvania. Neuroscience Bootcamp. 2014. Selected through competitive process to be one of 40 scholars and professionals from the humanities, law, business, technology, and media to attend the 10-day seminar.

The Cleveland Clinic. Clinical Bioethics Fellowship. 1999-2000. Member of the interdisciplinary teams in the medical, surgical, neurological, and pediatric intensive care units. Attended weekly meetings of the liver and heart transplantation screening committees, as well as staff meetings and patient rounds with physicians in the Center for Palliative Medicine. Additional activities included conducting bioethics education sessions for clinicians and allied health professionals, assisting the staff of the Department of Bioethics with ethics consultations, and attending Ethics Committee meetings.

The Cleveland Clinic. The Bernard A. Loeschen Pastoral Care Award. 2000. For excellence as a teacher, advocate, and ethics consultant.

National Endowment for the Humanities. Summer Fellowship for Teachers. 1988.

UNIVERSITY SERVICE

Faculty Executive Committee (elected position). Department of Political Science, University of Georgia, 1990-1993.

Executive Committee, Criminal Justice Studies Program, University of Georgia, 1990-1996.

Admissions Committee, Criminal Justice Studies Program, University of Georgia, 1990-1996.

Internship Supervisor, Criminal Justice Studies Program, University of Georgia, 1989-1996.

Undergraduate Committee, Department of Political Science, University of Georgia, 1990-1991.

Doctoral Dissertation Committee, Department of Political Science, University of Georgia, 1991.

Curriculum Committee, Department of Political Science, Oakland University, 1988-1989.

Pre-Law Advisor, Department of Political Science, Oakland University, 1985-1989.