

BIOGRAPHICAL SKETCH

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NAME: Karen J. Maschke

eRA COMMONS USER NAME (credential, e.g., agency login): MASCHKETHC

POSITION TITLE: Senior Research Scholar

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Georgia State University, Atlanta, GA	BS	06/1977	Urban Politics
Georgia State University, Atlanta, GA	MS	12/1981	Political Science
Johns Hopkins University, Baltimore MD	PhD	12/1987	Political Science
Case Western Reserve University, Cleveland OH	MA	06/1999	Bioethics
Cleveland Clinic, Cleveland OH	Fellowship	05/2000	Clinical Bioethics

A. Personal Statement

As a researcher with training in political science, legal studies, and bioethics, I focus on policy and ethical issues related to the introduction, use, regulation, and oversight of new biomedical technologies. My work has contributed to institutional and national policy and practice regarding the ethical conduct and oversight of research with human subjects (including genetics/genomic research). I use a variety of social science methods including document analysis, case studies, legal and policy analysis, and qualitative/quantitative studies. I have extensive experience as a member of collaborative teams engaged in research, writing, developing and holding professional/lay educational sessions and discussion groups, and developing policy and practice recommendations for various stakeholder groups (federal regulatory agencies; federal research funders; IRBs; and leaders in research, legal affairs, data management, and privacy protections at medical research institutions). I am committed to improving policies and practices for the ethical development and use of new biomedical technologies.

Ongoing and recently completed projects that I would like to highlight include:

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

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. NIH/National Human Genome Research Institute. R21 HG010531-02S1. No-cost extension through 2022.

Co-Multiple Investigator (with Josephine Johnston and Insoo Hyun). Actionable Ethics Oversight for Human-Animal Chimera Research. NIH/National Human Genome Research Institute. 1R01HG010168-01. No-cost extension through 6/30/22.

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). 3/1/21 - 3/30/22.

Co-Investigator (PIs Greg Kaebnick and Michael Gusmano). Public Deliberation on Gene Editing in the Wild. National Science Foundation. Award #1827935. 7/1/19 - 2/28/22.

The following articles are most relevant to the present study:

- a. **Maschke KJ**, Gusmano MK. *Debating Modern Medical Technologies: The Politics of Safety, Effectiveness, and Patient Access*. New York: Prager, 2018. DOI: 10.1002/hast.924
- b. **Maschke KJ**, Gusmano MK. Medicare and Amyloid PET Imaging: The Battle Over Evidence. *Journal of Aging & Social Policy* 2017;29(2):105-22. DOI: 10.1080/08959420.2016.1198970
- c. **Maschke KJ**, Gusmano MK, Solomon MZ. Breakthrough Cancer Treatments Raise Difficult Questions. *Health Affairs* 2017;36:1698-1700. DOI: 10.1377/hlthaff.2017.1032
- d. Solomon MZ, Gusmano MK, **Maschke KJ**. The Ethical Imperative and Moral Challenges of Engaging Patients and the Public with Evidence. *Health Affairs* 2016;35:4583-589. DOI: 10.1377/hlthaff.2015.1392

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2023 -	Senior Research Scholar, The Hastings Center
2003 - 2023	Research Scholar, The Hastings Center
2003 -	Editor, <i>Ethics & Human Research</i> (published by the Hastings Center/Wiley; formerly <i>IRB: Ethics & Human Research</i>)
1999-2000	Clinical Bioethics Fellow, Cleveland Clinic

Honors

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

C.1. Ethical and policy challenges for emerging technologies

My research has focused on how various stakeholders, institutions, and regulatory officials and other policy makers have characterized and addressed ethical and policy challenges related to the development and use of new biomedical technologies.

- a. **Maschke KJ**, Gordon EJ, Gusmano MK. 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/>
- b. Neuhaus C, Berlinger N, **Maschke K**, Crane J. 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>
- c. **Maschke KJ**, Gusmano MK. Evidence and Access to Biomedical Interventions: The Case of Stem Cell Treatments. *Journal of Health Politics, Policy and Law* 2016;41(5):917-936. PMID: 27256806 DOI: 10.1215/03616878-3632212
- d. **Maschke KJ**. Ethical and Policy Issues Involving Research with Newborn Screening Blood Samples, In: *Ethics and Newborn Genetic Screening: New Technologies, New Forces, New Challenges*. Baily M, Murray TH. eds. Baltimore: Johns Hopkins University Press, 2009.

C.2. Ethical and policy challenges for governance and oversight of biomedical research

The findings of the NHGRI/ELSI-funded project, “Advancing Collaborative Genetic Research” (Maschke Co-I; PI Rivera), identified the experience and concerns of researchers and IRB administrators/members regarding ethical challenges related to research with human biospecimens and associated data (Maschke; Goldenberg et al.; Rothwell et al.). I have also written about ethical and policy challenges regarding proposed and actual governance and oversight approaches for national and institutional biobanks (Wolf, et al.).

- a. **Maschke KJ**. Governance Issues for Biobanks and Biospecimen Research. In: *Specimen Science: Ethics and Policy Implications*. Rivera SM, Bierer BE, Cohen IG, eds. Cambridge: MIT Press, 2017.
- b. Goldenberg AJ, **Maschke KJ**, Joffe S, Botkin JR, Rothwell E, Murray TH, Anderson R, Deming N, Rosenthal BF, Rivera SM. IRB Practices and Policies Regarding the Secondary Research Use of Biospecimens. *BMC Medical Ethics* 2015;16:32. PMID: 25953109 PMCID: PMC4426182 DOI: 10.1186/s12910-015-0020-1
- c. Rothwell E, **Maschke KJ**, Botkin JR, Goldenberg A, Murray TH, Rivera SM. Biobanking Research and Human Subjects Protections: Perspectives of IRB Leaders. *IRB: Ethics & Human Research* 2015;37(2):8-13. PMID: 26331182 PMCID: PMC5854323
- d. Wolf SM, Crock BN, Van Ness B, Lawrenz F, Kahn JP, Beskow LM, Cho MK, Christman MF, Green RC, Hall R, Illes J, Keane M, Knoppers BM, Koenig BA, Kohane IS, Leroy B, **Maschke KJ**, McGeeveran W, Ossorio P, Parker LS, Petersen GM, Richardson HS, Scott JA, Terry SF, Wilfond BS, Wolf WA. Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data. *Genetics in Medicine* 2012;14(4):361-384. PMID: 22436882 PMCID: PMC3597341 DOI: 10.1038/gim.2012.23

C.3. Emerging technologies, stakeholder views, and public engagement

My work has also included examining the views of various stakeholders about emerging technologies, as well as issues related to public engagement in science and technology policymaking.

- a. Gusmano MK, Kaebnick GE, **Maschke KJ**, Neuhaus CP, Wills BC. Public Deliberation About Gene Editing in the Wild. *Hastings Center Report* 2021;51:S2-10. DOI: 10.1002/hast.1314
- b. **Maschke KJ**, Gusmano MK. Regulating Gene Editing in the Wild: Building Regulatory Capacity to Incorporate Deliberative Democracy. *Hastings Center Report*. 2021;51:S42-7. PMID: 34905250 DOI: 10.1002/hast.1319
- c. Bolo I, Wills, BC, **Maschke KJ**. Public Attitudes toward Human-Animal Chimera Research May Be More Complicated than They Appear. *Stem Cell Reports* 2021;16(2):225-6. PMCID: PMC7878820 DOI: 10.1016/j.stemcr.2021.01.002
- d. Rivera SR, Goldenberg A, Rosenthal B, Aungst H, **Maschke KJ**, Rothwell E, Anderson RA, Botkin J, Joffe S. Investigator Experiences and Attitudes about Research with Biospecimens. *Journal of Empirical Research on Human Research Ethics* 2015;10(5):449-456. PMID: 26564943 PMCID: PMC4646730 DOI: 10.1177/1556264615610199