## **KAREN J. MASCHKE, PhD**

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## **EDUCATIONAL BACKGROUND**

M.A.	Case Western Reserve University, 1999	Bioethics
Ph.D.	Johns Hopkins University, 1986	Political Science
M.A.	Georgia State University, 1981	Political Science
B.S.	Georgia State University, 1977	Urban Studies

## **PROFESSIONAL EXPERIENCE**

The Hastings Center	Associate for Ethics and Science Policy and Editor, <i>IRB: Ethics &amp; Human Research</i> , 2003-	
Floyd College	Adjunct Faculty, Political Science, 2003	
The Cleveland Clinic	Clinical Bioethics Fellow, Department of Bioethics, 1999-2000	
University of Georgia	Assistant Professor, Department of Political Science and Internship Instructor/Supervisor, Criminal Justice Studies Program, 1989-1996	
Oakland University	Assistant Professor, Department of Political Science, 1985-1989 Internship Coordinator, Department of Political Science, 1988-1989	

### UNIVERSITY TEACHING EXPERIENCE

Administrative Law and Politics Constitutional Law Criminal Procedure Environmental Law and Policy Introduction to American Government Introduction to Criminal Justice Administration Judicial Process Law and Politics Law Enforcement Administration Women, Law, and Politics

## PUBLICATIONS

### **Authored Books**

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

#### **Edited Books**

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

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

#### Articles, Essays, and Book Chapters

Maschke, Karen J. "Alternative Consent Approaches to Biobank Research," *Lancet Oncology* 2006;7:193-194.

Maschke, Karen, "Reconciling Protection with Scientific Progress," *Hastings Center Report* 2005:35(5):3.

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

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

Trump, Eric and Maschke, Karen. "A Stranger in the Mirror: Should Doctors Transplant Faces?" *New York Times* (Science Times Section), October 12, 2004.

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

Maschke, Karen J. "The Hastings Center." Clinical Researcher 2004;4:29-32.

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

Maschke, Karen J. "Proxy Research Consent and the Decisionally Impaired: Science, the Common Good, and Bodily Integrity." *Journal of Disability Policy Studies* 2003;13(4):254-259.

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

Maschke, Karen J. "Armed with Questions: Here's What to Ask Before Enrolling Your Child in a Clinical Study." http://www.*offspringmag.com*, September 2000.

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

Maschke, Karen J. and Siggelakis, Susan J. "To Whom it May Concern: Senators' Opening Statements at Supreme Court Confirmation Hearings." *Southeastern Political Review* 1996;24:1-21.

Maschke, Karen J. "Gender in the Prison Setting: The Privacy-Equal Employment Dilemma." *Women and Criminal Justice* 1996;7:23-42.

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

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.

Klemanski, John S. and Maschke, Karen J. "Managing Freedom of Information Laws: A Survey of State-Level Departments." In C. David Garson and Stuart S. Nagel, eds., Legal Implications of Computing, Part III, *Advances in Social Sciences and Computers*. Greenwich, CT: JAI Press, Inc. 1993;3:51-66.

### **Book Reviews**

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. Forthcoming, *Medical Humanities Review*.

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 *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. 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. Review of *For Whose Protection? Reproductive Hazards and Exclusionary Policies in the United States and Britain*. Sally J. Kenney. Ann Arbor: University of Michigan Press, 1992. *American Political Science Review* 1993;87:1043-1044.

## **COLLABORATIVE PROJECTS**

## **Current Project**

Hastings Center Principal Investigator. Ethics Capacity Building in Haiti. Funded by the NIH Fogarty International Center through a subcontract with Cornell-Weill Medical College. I am assisting medical college faculty at the University of Quisqueya in Port-au-Prince, Haiti to develop a research ethics curriculum for a public health master's program. I am also providing ethics consultation to the staff at GHESKIO, an HIV/AIDS clinic in Port-au-Prince on ethical issues surrounding HIV vaccine services and research with adolescents.

## **Proposed Projects**

Co-Investigator. Law & Ethics in Drug Addiction Genetics Research (LEDGER). RO1 grant submitted by Principal Investigator Howard Stone to the National Institute on Drug Abuse. Proposed project will examine and elucidate the ethical, legal, and social implications of the use of drug addiction genetic information in criminal justice settings.

Research Collaborator. Assessing Subjects' Protection in Research (ASPIRE). RO1 grant proposal to be submitted by Principal Investigator Howard Stone to the National Institutes of Health. Proposed project will investigate how incarceration may serve to affect evaluations of risks versus potential benefits for researchers, Institutional Review Board members, and prisoners who are research subjects.

Research Collaborator. Project to Assess Stigma, Offenders and Rural Addiction Linkages (PAsTORAL). RO1 grant proposal to be submitted by Principal Investigator Howard Stone to the National Institutes of Health. Proposed project will study the role of stigma and discrimination in rural drug abuse services and treatment for offenders.

## **Completed Projects**

Faculty Participant, EDGE: Education in Genetic Ethics. Collaborative project with the Institute for Bioethics, Health Policy, and Law at the University of Louisville and the Stanford University Center for Biomedical Ethics. Funded by the National Human Genome Research Institute, ELSI (Ethical, Legal and Social Implications of the Human Genome Project). Principal Investigator: Mark Rothstein, University of Louisville. I served as a faculty member on nine training sessions held throughout the country for investigators, Institutional Review Board members, and others who work or have interests related to research in human genetics. The sessions addressed a variety of questions regarding human subjects protections in the domain of genetics research, including issues of privacy and confidentiality, potential family and community harms, federal research regulations, informed consent, duty to warn, and intellectual property (6/1/03-12/30/05).

Project Member, Intellectual Property Rights in Pharmaceutical and Biological Materials: Ensuring Innovation or Barring Access?" Funded by the Sasakawa Peace Foundation. Principal Investigator: Josephine Johnston. Participation at project meetings; presentation at 2006 Annual Meeting of The Association of University Technology Managers (March 3, Orlando, FL). Panel on "Bioethics for Technology Transfer Managers."

Research Participant, Project on Ethical Decision-making for Newborn Genetic Screening. Funded by the National Human Genome Research Institute, ELSI (Ethical, Legal and Social Implications of the Human Genome Project). Principal Investigator: Thomas Murray, The Hastings Center. Participation at project meetings; presentation at project meeting on ethical issues involving research with newborn screening blood samples; author of chapter "Ethical and Policy Issues Involving Research with Newborn Screening Blood Samples" for a project-developed book that is in progress; editorial review of selected manuscripts submitted for the project-developed book (6/1/03-6/30/06).

Research Participant, Ethics of Improving Health Care. Funded by the Agency for Healthcare Research & Quality (AHRQ). Principal Investigator: Mary Ann Baily, The Hastings Center. Participation at project meetings; author of book chapter on the HIPAA Privacy Rule and quality improvement activities for a project-developed book in progress; review of selected manuscripts submitted for the project-developed book; editorial review of project report (6/1/03-6/30/06).

Research Participant, Project on Ethical Issues in the Management of Financial Conflicts of Interest in Medical Research. Funded by The Patrick and Catherine Weldon Donaghue Foundation. Principal Investigator: Thomas Murray, The Hastings Center. Participation at project meetings; editorial review of selected manuscripts submitted for project-developed book (6/1/03-12/31/04).

Research Participant, Project on Ethical, Conceptual and Scientific Issues in the Use of Performance Enhancing Technologies in Sports. Funded by the United States Anti-Doping Agency. Principal Investigator: Thomas Murray, The Hastings Center. Participation at project meetings; presentation at project meeting on ethical issues in sports enhancement research; author of chapter "Ethical Issues in Sports Enhancement Research with Humans" for the forthcoming book, *The Use of Performance-Enhancing Technologies in Sports: Ethical, Conceptual, and Scientific Issues* (eds. Thomas H. Murray, Angela Wasunna, Erik Parens, Karen J. Maschke, forthcoming, Johns Hopkins University Press); editorial review of selected manuscripts submitted for projectdeveloped book (6/1/03-12/31/04).

# ETHICS ADVISORY ACTIVITIES

National Cancer Institute. CARE Ethics Subcommittee, Cancer and Leukemia Group B, 2006-

National Cancer Institute/National Human Genome Institute, Invited working member of The Data Release Workshop. The workshop developed a data-release policy to cover all data types generated for The Cancer Genome Atlas (TCGA) Project of the NIH and NHGRI. New York, NY, May 2006.

Center for Practical Bioethics. "Protection for Human Research Subjects with Diminished Cognitive Capacity." Gave a presentation on the history of protections for research subjects with diminished capacity and helped develop a policy brief that might serve as a template for new federal guidelines. Kansas, City, May 2006.

Vassar Brothers Medical Center, Institutional Review Board Member, 2005-

World Anti-Doping Association (WADA), Ethics review of research proposals (including informed consent documents) submitted to WADA for funding, 2004-

National Cancer Institute, Invited working member of Workshop on Biospecimen Access and Ethical, Legal, and Policy Issues. June 2005.

Yale University, Invited speaker and working member of Workshop on the Collection, Storage, and Research Use of Human Biological Materials. May 2005.

## **BIOETHICS-RELATED PRESENTATIONS**

"Ethical and Legal Issues in Genetic Research," NYU Graduate Program in Environmental Health Sciences, NYU Medical School, April 11, 2006.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, UCLA, November 11, 2005.

"Research Ethics and the Collection, Storage and Use of Human Tissues," New York University Medical Center, June 15, 2005.

"Tissue Repositories: Ethical and Policy Issues," Yale University Medical Center, May 5, 2005.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, Johns Hopkins University Medical Center, April 11, 2005.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, The Cleveland Clinic Foundation, March 22-23, 2005.

"Medical Certainty and Other Myths about Drug Trials and Treatments," Presented at the Hastings Center/Center for Religious Inquiry Seminar, "Vioxx, Celebrex and Aleve: Patients, Patents, Profits and the Public Interests." St. Bartholomew's Church, New York City, March 5, 2005.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments." EDGE Course, San Francisco, February 18-19, 2005.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, Yale University, November 15, 2004.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, University of Utah, November 11-12, 2004.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, National Institute for Environmental Health Sciences, Research Triangle Park, North Carolina, October 7, 2004.

"Overview of Ethical, Legal and Social Issues Raised by Research with Children," Working Group Meeting. Ethical, Legal and Social Issues Raised by Longitudinal Research with Children: Issues, Gaps and Paving the Way Forward. Institute of Human Development, Child and Youth Health and the Ethics Office. Canadian Institutes of Health Research. Montreal, Canada, June 1-2, 2004.

"Tissue Repositories and DNA Biobanking: Ethical Issues and Policy Developments," EDGE Course, The Broad Institute (MIT), Boston, April 23, 2004.

"Research with Newborn Screening Blood Samples: Ethical and Policy Issues," EDGE Course, Washington University, St. Louis, March 12, 2004.

"Genetic Research with Humans: Current Controversies and Policy Developments," American Association of University Women (Westchester, NY Branch), January 7, 2004.

"Research Issues that Arise in Newborn Screening Programs," Hastings Center Project on Ethical Decision-making for Newborn Genetic Screening, The Hastings Center, September 18, 2003. "Politics of Protection: Regulating Research with Decisionally-Impaired Individuals," Summer Ethics Institute. Conference on "Protecting Children and Decisionally-Impaired Adults in Biomedical and Behavioral Research: Is Bioethics Enough?" National Catholic School of Social Science, The Catholic University of America, Washington, D.C., June 2003.

"Performance Enhancing Technologies and the Ethics of Human Subjects Research," Presentation for The Hastings Center project on Ethical Conceptual and Scientific Issues in the Use of Performance Enhancing Technologies in Sports, The Hastings Center, May 23, 2003.

"The Gene Trials: Ethical Dilemmas, Policy Issues, and Regulatory Oversight," Molecular Biology Program, University of Missouri-Columbia, January 30, 2001.

"Developing Guidelines for Payment Practice—Moving From IS to OUGHT?" Panel on Unresolved Issues in Pediatric Research, Third Annual Meeting, American Society for Bioethics and Humanities, Salt Lake City, Utah, October 27, 2000.

"End-of-Life Decisionmaking in the Hospital: Current Practice and Future Prospects," Surgical Intensive Care Unit, Journal Club, Cleveland Clinic Foundation, May 24, 2000.

"Decisional Capacity, Informed Consent, and Treatment Decisions," Surgical Intensive Care Unit, Residents & Fellows, Cleveland Clinic Foundation, May 22, 2000.

"Artificial Nutrition and Hydration: Policy, Practice, and Empirical Evidence," Cardio-Thoracic Intensive Care Unit, Residents & Fellows, Cleveland Clinic Foundation, May 17, 2000.

"Payment to Pediatric Research Subjects: Current National Practice and Proposed Ethical Standards," (co-presenter Kathryn Weise, M.D.). Pediatric Residents, Cleveland Clinic Foundation, May 8, 2000.

"Bedside to Boardroom: Ethics Committees and Organizational Ethics," (co-presenter Martin L. Smith, S.T.D.) Ohio Hospital Association Education Summit, Columbus, Ohio, April 17, 2000.

"Ethical Issues in Organ Transplantation," Gifted Students Program, Mentor Public Schools. Mentor, Ohio, March 20, 2000.

"Physician-Assisted Suicide," Palliative Medicine Fellows and Interdisciplinary Team, Cleveland Clinic Foundation, February 26, 2000.

"Recent Studies on Informed Consent," Surgical Intensive Care Unit Journal Club, Cleveland Clinic Foundation, February 9, 2000.

"Basic Bioethics," Surgical Intensive Care Unit, Residents & Fellows, Cleveland Clinic Foundation, January 24, 2000. "Physician-Assisted Suicide," Cardio-Thoracic Intensive Care Unit, Residents & Fellows, Cleveland Clinic Foundation, December 15, 1999.

"Basic Bioethics," Surgical Intensive Care Unit, Residents & Fellows, Cleveland Clinic Foundation, November 30, 1999.

"Surrogate Decisionmaking," Cardio-Thoracic Intensive Care Unit, Residents & Fellows, Cleveland Clinic Foundation, November 17, 1999.

"Financial Reimbursement, Length-of-Stay, and Ethical Considerations," Surgical Intensive Care Unit, Journal Club, Cleveland Clinic Foundation, November 3, 1999. "Basic Concepts and Issues in Bioethics," Ohio University Osteopathic Medical Students, October 14, 1999.

"Bioethics and Health Policy," Graduate Course in Health Policy and Service Delivery, Mandel School of Applied Social Sciences, Case Western Reserve University, October 7, 1999.

"Liver Transplantation Policies in the United States," Pediatric Intensive Care Unit, Residents, Cleveland Clinic Foundation, September 22, 1999.

# **OTHER PROFESSIONAL ACTIVITIES**

## **Conference Presentations**

"Lobbying in the Supreme Court Confirmation Process," American Political Science Association. Washington, D.C., August 1991.

"Interpreting the Fourth Amendment: The Conservative Voice of Americans for Effective Law Enforcement." American Political Science Association. San Francisco, California, August 1990.

"State-Level Bureaucratic Responses to Requests for Information: Public Access and State Freedom of Information Laws," American Political Science Association. Washington, D.C., August 1988.

"Power, Position and Administrative Agencies," Northeastern Political Science Association. Philadelphia, Pennsylvania, November 1983.

### **Conference Sessions Chaired/Discussant**

Chair and discussant, "Age, Race and Gender Issues for Staff and Inmates," American Society of Criminology. Miami, Florida, November 1994.

Discussant, "Courts and the Public: Litigants, Organized Interests and Public Opinion," Southern Political Science Association. Atlanta, Georgia, February 1990.

Chair and discussant, "The Supreme Court and Its Constituencies, II," Midwest Political Science Association. Chicago, Illinois, April 1990.

Discussant, "Public Law and Judicial Process," Georgia Political Science Association. Savannah, Georgia, February 1990.

Discussant, "Data Sets of Federal Court Decisions," American Political Science Association. Atlanta, Georgia, August 1989. Discussant, "Supreme Court Legitimacy and Public Reaction to Its Decisions." American Political Science Association. Washington, D.C., August 1986.

## **Invited Seminar Participant**

Insiders, Outsiders and the Law. Sponsored by the American Bar Association Commission on College and University Legal Studies. Atlanta, Georgia. March 18-20, 1994.

Justice and Power in Legal Institutions and Legal Culture. Sponsored by the Law and Society Association. Amherst College. July 18-22, 1992.

Litigation, Justice, and the Public Good. Sponsored by the American Bar Association Commission on College and University Legal Studies. San Diego, California, April 25-27, 1991.

College Faculty Seminar on Civil Rights. Sponsored by the American Political Science Association. Atlanta, Georgia, August 28-30, 1989.

## **Training Sessions Conducted**

Law Related Education Summer Institute. Sponsored by the Georgia Civil Justice Foundation and the Georgia Law Related Education Consortium. Coordinated by the Carl Vinson Institute of Government, University of Georgia. Training session for high school teachers regarding legal doctrines developed by the U.S. Supreme Court surrounding the equal protection clause of the 14<sup>th</sup> Amendment. Athens, Georgia. June 25, 1996; June 20, 1995; June 21, 1994.

Domestic Violence: The Crucial Role of Law Enforcement. Sheriff's Department. Clarke County, Georgia. April 9 and 24, 1996.

The Law Enforcement Response to Family Violence. A state-approved training program for law enforcement officials sponsored by Georgia Advocates for Battered Women and Children. Training sessions on how to assess the lethality of domestic violence offenders and legal issues surrounding police officer liability in the context of domestic violence. Law Enforcement Training Center. Greensboro, Georgia. September 14, 1994. Sexual Assault Nurse Examiner Training. Sponsored by the Rape Crisis Center of Northeast Georgia and Athens-Clarke County. Training session for sexual assault examiners, law enforcement personnel, and others on the profile of offenders. Athens, Georgia. July 19, 1994.

## **GRANTS RECEIVED**

Cleveland Clinic Foundation Research Grant (with co-collaborators Kathy Weise, Martin Smith, and Liesel Copeland), 2000 (\$2500) University of Georgia Faculty Research Grant, 1990 (\$1500) Oakland University Faculty Research Grant, 1989 (\$250)

## FELLOWSHIPS

Clinical Bioethics Fellowship, The Cleveland Clinic Foundation, 1999-2000 National Endowment for the Humanities, Summer Teaching Fellowship, 1988 Department of Political Science, Johns Hopkins University. Graduate Fellowship, 1980-1983

### HONORS AND AWARDS

Bernard A. Loeschen Pastoral Care Award. For excellence as a teacher, advocate, and ethics consultant. Awarded by the Department of Pastoral Care, Cleveland Clinic Foundation, 2000. Cleveland Clinic, Clinical Bioethics Fellow, 1999-2000. National Endowment for the Humanities. Summer Faculty Award, 1988. Johns Hopkins University. Graduate Student Fellowship, 1980-1983.

## 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.