Keynote Speakers

Sarah H. Kiskaddon, JD, MA

Ms. Kiskaddon is an attorney specializing in the human research protection field. She is the Vice President of Global Development and Public Affairs for the Association for the Accreditation of Human Research Protection Programs. She received her legal training at the University of Pittsburgh and Yale Law School, and has worked in human subject protections for 20 years. Before coming to AAHRPP she served as the Executive Director of the Office of Research Integrity at the New York State Psychiatric Institute, affiliated with Columbia University. Before that she served as Director of the Human Subject Protection Program at Connecticut Children’s Medical Center, and served as Vice-Chair of the Yale University School of Medicine Human Investigation Committee, and Director of the HRPP. She has also been a site visitor for AAHRPP since 2009.

Ms. Kiskaddon has conducted and published research in the field of human subject protections, and presented at numerous conferences primarily focusing on clinical research involving children. She earned her M.A. in Medical Anthropology from San Francisco State University.

Honorable Sara J. Smolenski

Judge Sara Smolenski is a Grand Rapids native. She earned an Associate of Arts Degree from Grand Rapids Junior College and a Bachelor of Arts Degree from the University of Michigan. In 1982, she earned a Juris Doctorate Degree from the Thomas M. Cooley Law School. She was elected to the bench in 1990. She was appointed by the Michigan Supreme Court as Chief Judge of the 63rd District Court in 1996.

Judge Smolenski has not only earned a reputation among her peers as a distinguished judge, but also is a proven strong community leader spending countless hours outside of the courtroom as a legal advocate, contributor and activist for several non-profit groups and organizations.

In addition to her legal work and community service, Judge Smolenski has established herself as a popular local humorist frequently exhibiting her unique “real life” humor for many organizations. Judge Smolenski is a strong advocate for education. She believes education improves lives and our community.

Among many community organizations, she has done work with American Cancer Society, Mental Health Foundation of West Michigan, Kids Food Basket, YWCA, Hospice of Michigan, Michigan Women’s Foundation, Senior Neighbors, and many others.

She is a frequent speaker at community events, educational programs, charitable organizations, and civic and community groups.
Session Speakers

Avery Avrakotos

Avery Avrakotos is a Master of Public Health candidate at the University Of Michigan School Of Public Health. Prior to starting at the University of Michigan, Avery worked as Education and Policy Manager at Public Responsibility, Medicine, and Research (PRIM&R), a nonprofit organization that works to advance ethical research. In that capacity, Avery developed educational programs, created resources, and reviewed proposed federal policies and guidance documents on topics related to the protection of human subjects. Avery continues to serve as a consultant to PRIM&R. She also works in the Office for Human Research Compliance Review at the University of Michigan, where she assists with efforts to strengthen the human research protection program at the university.

Theresa Bacon-Baguley, PhD, RN

Theresa Bacon-Baguley is Associate Dean for Research in the College of Health Professions at Grand Valley State University overseeing both faculty and student scholarly endeavors and IRB proposals. She has been a member of the GVSU IRB for 10 years, and presented the following talk at the 2014 PRIM&R meeting: “Ethically Valid Consent and Assent in Persons with Diminished Cognitive Capacity.” She holds a faculty appointment in the Physician Assistant Studies program, and personal area of scholarship is interdisciplinary focused around health care and education.

Ginette Borovicka

Ginette Borovicka is the Research Integrity Manager for the Office of the Vice President for Research. She joined the Research Integrity department at Wayne State University in May of 2010. Within the department of Research Integrity, she is responsible for the coordination of Financial Conflicts of Interest; assisting the Associate Vice President for Research Integrity with potential Research Misconduct investigations, and conducting For-Cause and Post-Approval Audits.

Kristen Burt, JD

Kristen Burt is the director of the Michigan State University (MSU) Human Research Protection Program (HRPP). Kristen has performed case management of human research projects, led MSU’s application processes to AAHRPP, and coordinated Institutional Review Board (IRB) education programs since joining the MSU IRB office in 2001. Ms. Burt currently leads policy and planning initiatives within the Office of Regulatory Affairs and is the director of the HRPP. Kristen Burt obtained a BS in human biology and a BA in general business administration from MSU and a JD from the MSU College of Law.
Karen Christianson, RN, BSN, CCRP

Ms. Christianson’s passion for research was ignited by her experience as a pregnant subject in a clinical trial. Following this experience, Ms. Christianson became a Research Nurse in a level 3 NICU where she spent several years managing and coordinating a mix of investigator-initiated, industry, and NIH-funded clinical and epidemiological research.

Ms. Christianson transferred from this role to one in research administration in 2006, developing and implementing Baystate Health’s research quality assurance and education programs. In 2009, Baystate formally established a Human Research Protection Program, naming Ms. Christianson as Director. Ms. Christianson led the program through a successful application for full AAHRPP accreditation in 2010 and reaccreditation without any observations in 2013. Ms. Christianson served as an AAHRPP site visitor from 2010 – 2013. Her dedication to best practices in research was honored at the 2011 PRIM&R AER conference when she was presented with IRBNet’s Ethics in Human Subject Protection Award.

Ms. Christianson joined HRP Consulting Group in 2013 and was named Associate Vice President in 2016. HRP Consulting Group provides consulting services and customized solutions for a diverse portfolio of clients including research sites, academic centers, hospital systems, independent IRBs, CROs, government, and industry.

Becky Gore, CIP

Becky Gore has worked for the MSU HRPP since October of 2006. She has an MS in Entomology and a BA from James Madison College at MSU. She is currently the MSU IRB Manager and has acquired her CIP. She has either worked or been a student at MSU since 1973.

Dr. M. Ammar Hatahet, MD, MPH, FACP

Dr. M. Ammar Hatahet, MD, MPH, FACP is board certified in Internal Medicine with over 20 years of clinical experience. He specializes in adult health care, including treatment for heart disease, hypertension, cholesterol management, asthma, and emphysema, with specific emphasis on diabetes and weight control. Dr. Hatahet is also a Clinical Professor at Michigan State University and the IRB Chairperson at McLaren Health Care.
Dr. Joseph R. Haywood

Dr. Joseph R. Haywood is the Assistant Vice President for Regulatory Affairs at Michigan State University. He joined Michigan State University as the Chair of Pharmacology and Toxicology, a position he held for 9 years. Through his career, he has published over 80 papers investigating central nervous system control of blood pressure and mechanisms of hypertension. He has been active in science policy, especially with respect to the use of animals in research and education. Dr. Haywood is a past member of the Council on Accreditation of the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and served on its Board of Trustees. He served on the Board of Governors for the International Council for Laboratory Animal Science (ICLAS). He also served as chair of the American Physiological Society Animal Care and Experimentation and Public Affairs Committees. He also served on the society’s governing council. Dr. Haywood has served on the Board of Directors for the Federation of American Societies for Experimental Biology (FASEB). For FASEB, he has held the positions of Vice President for Science Policy, President-Elect, and President. He is now Immediate Past President. He has served on two National Academy of Science panels, including the Committee on *Federal Research Regulations and Reporting Requirements: A New Framework for Research Universities in the 21st Century*.

Maya Kobersy, JD

Primary Practice Areas
- Affirmative Action and Diversity
- Election Law
- Privacy
- Research and Research Misconduct
- University Logo Issues
- In-State Tuition Guidelines for Students
- Domestic Academic Affiliation Agreements

Maya Kobersy’s primary practice areas include affirmative action and diversity, election law, privacy, research and research misconduct, University logo issues, in-state tuition guidelines for students, and domestic academic affiliation agreements. She is the OGC liaison to the Institutional Review Board-Health Sciences and Behavioral Sciences. She also serves on a number of University committees, including the IRB-HSBS Executive Committee, and the University Logos Committee. In addition, she is an active member of the National Association of College and University Attorneys. She has presented at University, state, and national conferences on issues relating to diversity, election law, Title IX, and the Family Educational Rights and Privacy Act, among other topics.

Prior to joining the Office of the Vice President and General Counsel in 2005, Maya worked in the Education Group of Hogan & Hartson, L.L.P. (now Hogan Lovells), where she advised clients on numerous K-12, higher education, and civil rights issues. She received her B.A. from the University of Michigan and her J.D. from Harvard Law School, where she was an Executive Editor of the Harvard Law Review and a finalist and oralist in the Ames Moot Court Competition. In recognition of her work to help ensure that Americans with limited English proficiency have meaningful access to federal and federally funded programs, Maya received the Mexican American Legal Defense and Education Fund’s Excellence in the Legal Profession Award in 2002 and the National Asian Pacific American Legal Consortium’s Distinguished Service Award in 2003.
Tiana Korley, JD

Primary Practice Areas

- Research
- Regulatory Initiatives
- Fraud and Abuse
- Conflict of Interest (Research and Clinical)
- Physician Compensation
- Strategic Planning/Legislative

Tiana Korley joined the University of Michigan Office of the Vice President and General Counsel in 2015. She provides legal advice on research-related matters, as well as regulatory issues, including interpretation and guidance on the fraud and abuse laws.

Prior to joining OGC, Tiana was a consultant at the MITRE Corporation, which operates CMS’s federally-funded research and development center, the CMS Alliance to Modernize Healthcare. In this role, Tiana advised CMS on various policy matters, including policy considerations related to the establishment of alternative payment models emerging from the Center for Medicare and Medicaid Innovation.

Tiana also has experience on various legislative matters and served as Senior Health Counsel for Representative Jim McDermott, the Ranking Member of the Ways and Means Subcommittee on Health in the United States House of Representatives. She also has Executive Branch experience and served as the Senior Advisor to the Deputy Administrator for Program Integrity at CMS. In this role, she assisted with developing various regulations and served as a liaison between the Center for Program Integrity and other CMS components on various policy initiatives.

Tiana also has broad experience as a regulatory health attorney, having worked in this capacity at the University of Chicago Hospitals, Bon Secours Health System, and at a national law firm.

She received her B.A. from The College of Wooster, a Master of Health Administration degree from The Ohio State University College of Public Health, and her Juris Doctor from Northwestern University School of Law, where she earned a concentration in Health Law.

Gayle Kusch, MSA

Gayle Kusch is the Sr. Director, Compliance, in Wayne State University’s Research Integrity Office, where she directs the operational and regulatory activities associated with the human and animal protection programs, financial conflict of interest, export control, and research misconduct. Gayle is also the Director, of the Michigan Neonatal Biobank. The Michigan Neonatal Biobank is a storage and management facility for the archive of dried blood spot cards. Newborn screening is a public health program required by Michigan law to find babies with rare but serious disorders that require early treatment.

Prior to the oversight of regulatory areas impacting research, Gayle worked as the manager for the clinical trials office, at the then Meyer L Prentis Comprehensive Cancer Center (now Karmanos) and was the project director for the National Heart, Lung, and Blood Institute’s Women’s Health Initiative – Detroit Clinical Center.

Monica C. Lareau, MS, CHPC

Monica Lareau is Trinity Health’s Director of HIPAA Compliance and also the Privacy Official. In this role she is responsible for the leadership of Trinity Health’s privacy program and ensuring the effectiveness and compliance of the enterprise privacy program. Ms. Lareau brings more than thirty years experience in healthcare with expertise in Privacy, Compliance, Clinical Quality, Process Excellence and HIM. She holds certifications in HIM and Privacy, and has a MS in Health Informatics. Ms. Lareau believes that her greatest insight comes from shared experiences with colleagues.
Monica Malian, R.Ph.

Monica Malian is currently the System Executive Director for Clinical and Translational Research at the Detroit Medical Center. Monica is a graduate of the Wayne State University College of Pharmacy. She completed a Residency at the Children's Hospital of Michigan Department of Pharmacy Services. Following her residency, Monica continued at Children's Hospital as a staff pharmacist later transitioning to the role of Pharmacy Investigational Drug Service Coordinator. Monica is an adjunct faculty member of Wayne State University. She has served as the Vice-Chair of the Wayne State University Institutional Review Board, as well served as a board member of the Ethics Committee of Essex County, Windsor, Ontario.

Dawn Pedinelli, RN, MBA, CCRC, CHRC

Dawn Pedinelli is Trinity Health's Director of Research, and is responsible for the national coordination of clinical research activities that span Trinity's 86 hospitals in 21 states. She brings over 20 years of research experience to her role, specializing in research administration, grant management and program planning. Ms. Pedinelli is a Registered Nurse, with BA in economics and an MBA. She is a Certified Clinical Research Coordinator (CCRC), and is also Certified in Healthcare Research Compliance (CHRC).

Cindy Shindledecker, CIP

Cindy Shindledecker is the Director of the Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) at the University of Michigan, Ann Arbor. The IRB-HSBS office supports two IRBs with jurisdiction over most non-clinical research at the Ann Arbor campus. Ms. Shindledecker has been instrumental in the development and implementation of policies designed to minimize regulatory burden while effectively protecting human subjects. Prior to joining the University of Michigan, she served as a project manager and paralegal at the U.S. Department of Energy (DOE). She became interested in human subjects protection issues as a member of the DOE research staff supporting President Clinton’s Advisory Committee on Human Radiation Experiments (ACHRE). Ms. Shindledecker holds a B.A. from Gettysburg College, paralegal certification from Georgetown University and is a Certified IRB Professional (CIP).

Kayte Spector-Bagdady, JD, M. Bioethics

Kayte Spector-Bagdady is a Postdoctoral Research Fellow at the Center for Bioethics & Social Sciences in Medicine. The overarching theme of her research is the collective impact of law, policy, and ethics on access to quality healthcare by disenfranchised populations. Before joining CBSSM as a Research Fellow, she served as Associate Director at the Presidential Commission for the Study of Bioethical Issues where she acted as a lead staff investigator and author for the report “Ethically Impossible”: STD Research in Guatemala from 1946 to 1948 on the unethical intentional infection research conducted by the U.S. Public Health Service. Kayte received her J.D. and M.Bioethics from the University of Pennsylvania Law School and School of Medicine respectively after graduating from Middlebury College.
Dr. Tom Tomlinson

Dr. Tomlinson is Professor in the Department of Philosophy and the Center for Ethics and Humanities in the Life Sciences, where he serves as Director. He received his Ph.D. in Philosophy from MSU in 1980. Dr. Tomlinson regularly speaks to professional and public audiences on a great variety of topics, including informed consent, advance directives, end-of-life decisions, organ donation, cost containment, and others. He has published articles in both medical and bioethics journals and anthologies concerning the determination of death, the ethics of futility judgments, the use of biological samples in medical research, advance directives, and many other issues.

Dr. Tomlinson also provides consultation to Michigan hospitals and health professionals. He serves on the Ethics Committees of Sparrow Hospital and McLaren-Lansing Hospital.

Current research projects include an examination of public attitudes regarding moral concerns about research uses of archived biological specimens, and a critical examination of cancer patients’ “right not to know” their prognosis.

Leah A. Voigt, JD, MPH

Leah A. Voigt is Chief Privacy Officer at Spectrum Health System in Grand Rapids, Michigan. Leah previously served as Senior Counsel to Spectrum Health and advised on matters relating to information privacy and security, clinical trials, human subject research protections, medical education, and conflicts of interest.

Prior to joining Spectrum Health, Leah was an attorney in private practice in the Washington, DC office of the global firm, Squire Sanders & Dempsey (now Squire Patton Boggs), as a member of both the Health Care and Life Sciences practice groups. Her clients included a diverse range of organizations, from large academic medical centers and health systems, to start-up health information technology companies, to global medical device and pharmaceutical manufacturers.

Prior to law school, Leah served as a grants and contracts officer for a biomedical research institute in Los Angeles, California. She currently serves as Vice Chair of the Academic Medical Centers & Teaching Hospitals Practice Group of the American Health Lawyers Association (AHLA). She frequently presents on topics related to information privacy, clinical research and conflicts of interest and has published articles on health care policy and FDA regulation. Her most recent speaking engagements include the February 2016 AHLA Physicians & Hospitals Law Institute in Austin, Texas (Legal, Regulatory and Compliance Issues in Physician Practice and Hospital-Based Clinical Research Programs) and the Fall 2015 MAGI Conference in San Diego, California (Recent Developments in Subject Data Privacy & Security).

Leah received dual undergraduate degrees in Biology and Dance from Smith College in Northampton, Massachusetts. She received a Masters in Public Health from the University of Michigan and her law degree magna cum laude from Loyola Law School in Los Angeles.

Betsy Wilson, BS, CIP

Betsy Wilson, BS, CIP, is a Regulatory Affairs Analyst and alternate IRB member at Spectrum Health. She joined the Spectrum Health IRB Office in 2008 to assist with achieving AAHRPP accreditation. Previously, she worked as a Clinical Research Coordinator Educator and as a Clinical Research Coordinator at Spectrum Health. Prior to joining Spectrum Health, she worked as a Clinical Data Manager at Abbott Laboratories in their Pharmaceutical Products Division for several years. Ms. Wilson holds a Bachelor of Science in Health Information Administration from Indiana University and has over 18 years of experience in various roles involving biomedical human subject research.
Dr. Christine A. Yalda

Dr. Christine A. Yalda is an associate professor at Grand Valley State University in the School of Criminal Justice. Dr. Yalda previously served as the Program Director for Four Rivers Indian Legal Services in Arizona and as a federal trial attorney for the Equal Employment Opportunity Commission. Dr. Yalda’s scholarship reflects her commitment to social and procedural justice. Recent research primarily involves community partnerships with local courts and social service agencies, including research on adult drug treatment courts, juvenile court risk assessment procedures, legal assistance to unrepresented litigants, services to the homeless and working poor, and child welfare removal and family preservation. Dr. Yalda currently serves as the Chair of the GVSU Human Research Review Committee (Institutional Review Board).

Dr. Corey Zolondek

Dr. Corey Zolondek is the IRB Operations Manager at Wayne State University. Dr. Zolondek makes exempt determinations and reviews expedited submissions for the Wayne State Social/Behavioral/Education IRB board. In addition, he reviews protocols for compliance with HIPAA regulations and makes HIPAA authorization waiver determinations. He provides community outreach related to human research participant protections and evaluates research-related community outreach efforts at Wayne State University and affiliate institutions. Dr. Zolondek earned his Ph.D. in Anthropology from Wayne State University with an interest in biocultural factors that influence food choice and physical activity in an urban population.