CURRICULUM VITAE SUZANNE M. RIVERA, PH.D., M.S.W.

JULY 2018

PERSONAL INFORMATION

Name: Rivera, Suzanne Marie

Education

School: **Brown University**

Degree: Bachelor of Arts (American Civilization)

Dates: 1987-1991

University of California-Berkeley School:

Master of Social Welfare Degree:

Dates: 1991-1993

School: University of Texas at Dallas

Degree: Doctor of Philosophy, Public Affairs (Health Policy)

Dates: 2005-2008

Ph.D. Dissertation

Title: Social Inequality in Biomedical Research

Richard K. Scotch, PhD (Chair); Edward J. Harpham, PhD; John Z. Sadler, MD; Ph.D. Committee:

Sheryl L. Skaggs, PhD

Contact Information

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PROFESSIONAL APPOINTMENTS

Vice President for Research and Technology Management Position/Rank:

Institution/Department: Case Western Reserve University, Office of Research & Technology Management

> Dates: 2014-Present

Position/Rank: Senior Associate Vice President for Research and Strategic Alliances

Institution/Department: Case Western Reserve University, Office of Research Administration

> Dates: 2014

Position/Rank: Associate Vice President for Research

Institution/Department: Case Western Reserve University, Office of Research Administration

> Dates: 2011-2014

Vice President for Research Administration Position/Rank: Institution/Department: University of Texas Southwestern Medical Center

2010

Dates:

Position/Rank: Associate Vice President, Research Services Institution/Department: University of Texas Southwestern Medical Center

> Dates: 2008-2009

Position/Rank: Assistant Vice President, Research Services
Institution/Department: University of Texas Southwestern Medical Center

Dates: 2005-2008

Position/Rank: Director, Academic Support Services, Office of the Dean

Institution/Department: University of Texas Southwestern Medical Center

Dates: 2003-2005

Position/Rank: Director of Research Protections, Office of Research Administration

Institution/Department: University of California-Irvine

Dates: 1999-2003

Position/Rank: Associate Director, Office of Research Administration

Institution/Department: University of California-Irvine

Dates: 1998-1999

Position/Rank: Research Education and Review Officer, Office of Research Administration

Institution/Department: University of California-Irvine

Dates: 1996-1998

Position/Rank: Program Specialist-GS, Administration for Children and Families

Institution/Department: U.S. Department of Health and Human Services-ROIX

Dates: 1993-1996

ACADEMIC APPOINTMENTS

Position/Rank: Associate Professor

Institution/Department: Case Western Reserve University, Departments of Bioethics and Pediatrics

Dates: 2018- present

Position/Rank: Assistant Professor

Institution/Department: Case Western Reserve University, Departments of Bioethics and Pediatrics

Dates: 2011-2018

Position/Rank: Assistant Professor

Institution/Department: UT Southwestern Medical Center, Department of Clinical Sciences

Dates: 2008-2010

HONORS AND AWARDS

Julia Jacobsen Distinguished Service Award, National Council of University Research Administrators (NCURA), 2018

NCURA/European Association of Research Managers and Administrators Fellowship 2017

Distinguished Award for Latino Empowerment, La Alianza of Case Western Reserve University, 2015

Diversity Leadership Award, Case Western Reserve University, 2012

Ethics Table Fellow, Case Western Reserve University, 2011-2012

Pi Alpha Alpha (public affairs honor society), 2007

Leadership Development Institute, NCURA, 2004

Distinguished Alumni Service Award, Brown University, 2001

Presidential Management Internship, U.S. Office of Personnel Management, 1993

Commencement Orator, University of California-Berkeley, 1993

Social Welfare Alumni Association Award, University of California-Berkeley, 1992

Eva P. Moar Premium, Brown University, 1991

Commencement Orator, Brown University, 1991

MEMBERSHIP IN PROFESSIONAL SOCIETIES

American Association for Advancement of Science (AAAS), 2017- present

American Society of Bioethics and Humanities (ASBH), 2011- present

Association of American Medical Colleges (AAMC), Group on Research Advancement and Development, 2008- present

Association of American Universities (AAU), Senior Research Officers, 2014- present

Council on Governmental Relations (COGR), 2008- present

Federal Demonstration Partnership (FDP), 2011-2014

International Network of Research Management Societies (INORMS), 2014- present

National Council of University Research Administrators (NCURA), 1998- present

National Organization of Research Development Professionals (NORDP), 2011- present

Public Responsibility in Medicine and Research (PRIM&R), 1998- present

Scientists Center for Animal Welfare (SCAW), 2004-2010

Society of Research Administrators (SRA), 2013- present

University-Industry Demonstration Partnership (UIDP), 2014- present

PROFESSIONAL SERVICE

Editorial Boards

IRB: Ethics & Human Research, Contributing Editor (2018- present) *NCURA Magazine*, Contributing Editor (2014)

Ad Hoc Journal Reviews

Journal of Empirical Research on Human Research Ethics (2015- present)

IRB: Ethics & Human Research (2014- present)

Journal of Immigrant and Minority Health (2012- present)

COMMITTEE SERVICE

International

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University: Invited Member (2018-present)

Develop strategy and interventions designed to improve the integrity, safety, and rigor of global clinical trials.

National Council of University Research Administrators (NCURA) Select Committee on Global Affairs: Appointed Member (2017-present)

Establish strategic partnerships with non-US universities for the purpose of promoting international research collaborations.

National

Public Responsibility in Medicine and Research (PRIM&R): Appointed National Board Member (2017-present)

Provide leadership and strategic direction for national research ethics professional society. Includes fiduciary obligations and oversight of the Executive Director.

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP): Planning Committee for Annual National Meeting (2017)

Choose theme, plan, and execute national meeting, including speaker selection and other logistics.

National Council of University Research Administrators (NCURA): Planning Committees for Annual National Meeting or Annual National Pre-Award Conference (2008, 2009, 2011, 2012, 2013, 2014, 2016, 2017, 2018)

- Choose themes, plan, and execute large national meetings with over 5,000 attendees, including speaker selection, management of meeting budget and other logistics.
- National Council of University Research Administrators (NCURA): Nominating and Leadership Development Committee, Appointed Member (2016-2017)
 - Cultivate leadership talent and nominate candidates for national elections to lead the organization. Manage national elections, including updating of position descriptions and election by-laws.
- U.S. Environmental Protection Agency's Human Studies Review Board (EPA): Appointed Member (2014-2017)

 Reviewed scientific protocols and the associated published literature to advice the federal government about whether all applicable ethical standards were observed to permit use of the data in regulatory decision-making.
- National Council of University Research Administrators (NCURA): Education Scholarship Fund, **Chair** (2014-2016) Provided leadership to raise \$100K for awards to support professional development goals of the organization's members.
- Council on Governmental Relations (COGR): Appointed National Board Member (2014-present)

 Provide leadership and strategic direction for national research advocacy organization comprised of the nation's elite research universities. Includes fiduciary obligations and oversight of the Executive Director.
- University of Central Florida's Master of Research Administration Advisory Board: Appointed Member (2013-present)
 - Guide the development and growth of one of the nation's first Master's level degree programs in Research Administration. Approve curriculum, and recruitment and marketing strategy.
- National Council of University Research Administrators (NCURA): Elected At-large Member of the National Board (2013-2014)
 - Provided leadership and strategic direction for the preeminent organization of research administrators in the US. Included fiduciary obligations and oversight of the Executive Director.
- Council on Governmental Relations (COGR): Appointed Board Committee Member (2012-present)

 Provide expert advice to the Committee on research regulations and write policy guidance for member organizations.
- Federal Demonstration Partnership (FDP): Appointed CWRU Representative (2011-2014)

 Represented CWRU at meetings between US universities and federal funding agencies to pilot demonstration projects aimed at reducing regulatory burden for investigators.
- American Association for the Advancement of Science (AAAS), Scientific Freedom and Responsibility Award Selection Committee: Appointed Member and **Chair** (2011-2014)
 - Led a small committee of distinguished scientists and others to select winners from the international pool of candidates nominated for the prestigious Freedom and Responsibility Award.
- DHHS Secretary's Advisory Committee on Human Research Protections (SACHRP): Appointed Member (2010-2014)

 Provided expert advice to the DHHS Secretary about the regulations governing human research and the

 procedures of the Office for Human Research Protections (OHRP). Included significant contributions to the

 efforts to update the Common Rule.
- National Council of University Research Administrators: Elected At-large Member of the Regional Board (2006-2008)
 - Managed the operations of the Region V membership (Texas and Oklahoma) of the national organization. Included budget management, award nominations, and planning of a regional conference.

Regional

Fund for Our Economic Future (FFEF): Appointed CWRU voting representative (2015- present) and elected member of Executive Committee (2017- present)

Ohio Senior Research Officer's Council: Appointed CWRU representative (2014- present)

The Ohio Supercomputer Center Advisory Board: Appointed CWRU representative (2011-2012)

UT System IRB Oversight Committee: Chair (2010)

UT System Export Controls Task Force: Appointed Campus Representative (2009)

UT System Committee on Research Enterprise (SCORE): Appointed Campus Representative (2007-2010)

UT System Task Force on IRB "Mission Creep": Appointed Campus Representative (2007-2009)

Local

Cleveland Water Alliance: Elected Member, Board of Directors (2018- present)

Global Center for Healthcare Innovation: Appointed Member of Executive Advisory Council (2015-present)

Rainbow Babies and Children's Hospital-Center for Child Health and Policy: Member (2014-Present)

University

CWRU Undergraduate Moral Education Advisory Committee: Member (2018- present)

CWRU Provost Search Committee: Co-Chair (2017-2018)

CWRU Schubert Center for Child Studies: Faculty Associate (2017- present)

CWRU International Affairs Advisory Council: Member (2017-present)

CWRU Bioethics Department Faculty Search Committee: Member (2017)

CWRU Baker-Nord Humanities Research Prize Selection Committee: Member (2017)

CWRU SOM Faculty Council's Ad Hoc Committee on Conflict of Interests: Member (2016-2017)

CWRU University Strategic Plan Implementation Committee for Research: Co-Chair (2015-present)

CWRU Animal Resources Center (ARC) Advisory Committee: Member (2014-present)

CWRU Faculty Distinguished Research Award Selection Committee: Chair (2014-present)

CWRU Inamori Ethics Prize Selection Committee: Member (2014-present)

CWRU Chief Information Officer Search Committee: Member (2014)

CWRU Hispanic Faculty and Staff Employee Resource Group: Founder and Executive Sponsor (2013-present)

CWRU Faculty Seed Grant Review Committee: Member (2013-present)

CWRU Export Control Advisory Committee: Member (2013-present)

CWRU Advisory Committee to the SOM Office for Faculty Development and Diversity: Member (2013-present)

CWRU Diversity Leadership Council: Member (2012-present)

CWRU IRB Advisory Committee: Chair (2011-2015)

CWRU Ethics Alliance: Member (2011-present)

CWRU Conflict of Interests Committee: Ex Officio Member (2011-2014)

CWRU Faculty Senate Committees on Research and Graduate Studies: Member (2011-2015)

CWRU Export Controls Work Group: Chair (2011)

UT Southwestern Research Compliance Committee: Chair (2010)

UT Southwestern SACS Subcommittee on Academic Support Services: Chair (2007-2008)

UT Southwestern SACS Accreditation Subcommittee on Administration: Chair (2006-2009)

UT Southwestern Institutional Compliance Advisory Committee: Member (2005-2009)

UT Southwestern Radiation Safety Committee: Member (2005-2007)

UT Southwestern Institutional Review Boards 1, 2, 3 & 4: Ex Officio Member (2003-2010)

UT Southwestern Institutional Animal Care and Use Committee: Ex Officio Member (2003-2010)

UC-Irvine Medical Center Ethics Committee: Member (1997-1999)

UC-Irvine Research Conduct Policy Committee: Member (1996-2003)

TEACHING

CWRU

- 1. BETH 421- Research Ethics Practicum for MA Students, 1.5 credits (Spring 2014, 2015, 2016, 2017, 2018) This course is designed to place graduate students in meaningful research ethics internships and to help them develop the skills to apply their theoretical learning in a real-world setting. Number of students: 2-7
- BETH 503- Research Ethics and Regulation, 3 credits (Fall 2014)
 This team-taught course introduced graduate and medical students to the ethical and regulatory landscape of human research. Number of students: 7
- 3. BETH 315C/415C- International Bioethics: Policy and Practice, 3 credits (Fall 2013, 2015, 2016, 2017) This short-term study abroad course is taught in US and Costa Rica with a focus on comparing the healthcare systems and access to clean water in both countries. Number of students: 9-21
- 4. BETH 315E/415E- Cross-cultural Perspectives on Bioethics, 3 credits (Spring 2013)

 This short-term study abroad course is taught in US and in Salamanca, Spain with a focus on comparing the two cultures' approaches to thorny problems in bioethics such as euthanasia, brain death, ecoethics, abortion, and animal rights. Number of students: 13
- 5. BETH 602 Independent Study in Bioethics, 3 credits (Spring 2012)

This is a student project-based independent study within the curriculum of the Masters in Bioethics Program. Number of students: 1

- 6. BETH 315F/415F- Exploring Bioethics through Film, 3 credits (Spring 2012, 2016)
 This short-term study abroad course is taught in US and in San Sebastian, Spain with a focus on comparing the way bioethics issues are addressed in Spanish and American cinema. Number of students: 11-13
- 7. IBMS 500 The Responsible Conduct of Research (Spring 2011, 2012, 2013)
 This team-taught class is mandatory for graduate students on NIH-training grants in the School of Medicine and introduces them to a wide range of regulatory and policy matters concerning the responsible conduct of research. I delivered lectures and served as a discussion leader. Number of students: 71-88

UT Southwestern

- DCS 5107- Regulatory and Public Policy Considerations in Research (Fall 2008, 2009, 2010)
 I developed the syllabus, gained Registrar approval for, and taught this course, which was mandatory for all graduate students participating in the MA in Clinical Sciences degree program.
- 2. MED 101001- Clinical Ethics in Medicine (2006/7, 2007/8, 2008/9)

 This year-long, team-taught class is mandatory for all medical students at UTSW and introduces them to a variety of ethical case studies. I delivered lectures and served as a small group discussion facilitator.

UC-Irvine

- BioSci 194S- Safety and Ethics in Research (Fall 2001, 2002, 2003)
 I developed the syllabus and gained approval through the University Curriculum Committee for this course, which was mandatory for all Biology undergraduates prior to working in any laboratory on campus.
- 2. BioSci 30- Biomedical Ethics (Spring 2002, 2003)
 This course is the introduction to ethics for Biology undergraduates.

PRESENTATIONS & PANELS

National

- "Regulatory Requirements for Educating Investigators about Research Standards," presented at the Office for Protection from Research Risks (OPRR)/UCLA "Women as Research Subjects," national conference. November, 1997
- 2. "How Institutional Review Boards Implement and Comply with Regulations," presented at the US Food and Drug Administration's (FDA) "Conducting Successful Clinical Trials under Good Clinical Practice Regulations" national conference. September, 1998
- 3. **Invited** panel chair, "Beyond Compliance: Protection of Human Research Subjects," presented at the annual convention of the National Council of University Research Administrators (NCURA). November, 2002
- 4. "Federal Requirements for Conducting Off-Site Research," presented at the Advancing Ethical Research Conference of Public Responsibility in Medicine & Research (PRIM&R). November, 2002
- 5. "Legally Authorized Representatives (LARs) in Research: Crossroads of State Law and Federal Regulations," presented at the Applied Research Ethics National Association (ARENA) national convention. November, 2002

- Invited moderator, "Research Administration in a Post-9/11 World," panel presented at the joint conference of the National Council of University Research Administrators (NCURA) and the Council on Governmental Relations (COGR). July, 2004
- 7. "Doing More with Less: Managing an Effective Program and Balancing Resources," presented at the Advancing Ethical Research Conference of Public Responsibility in Medicine & Research (PRIM&R). December, 2005
- 8. "Use of Animals in Research: IACUCs, Animal Care, and More," presented at the national convention of the National Council of University Research Administrators (NCURA). November, 2007
- 9. **Invited** moderator, "Conflicts of Interest in Research: What's New and What You Should Do," a "Town Hall Meeting" at the annual convention of Public Responsibility in Medicine & Research (PRIM&R). November, 2008
- 10. "Access to Investigational Drugs: A Focus on Compassionate Use," **invited** panelist for national webinar sponsored by the Health Care Compliance Association (HCCA). April, 2009
- 11. "What Did the Belmont Drafters Mean by 'Justice' and How Can IRBs Reclaim the Forgotten Principle?" presented at the Advancing Ethical Research conference of Public Responsibility in Medicine & Research (PRIM&R). November, 2009
- 12. "Conflicts of Interest in Research: Ethical, Regulatory, and Practical Considerations," presented at the Health Care Compliance Association's (HCCA) National Research Compliance Conference. April, 2010
- 13. **Invited** discussant, PRIM&R national workshop on "Strategies for Returning IRBs to their Subject Protection Roots," Boston, MA. April, 2011
- 14. "When the Stakes are High: Managing Communication and Public Opinion in Research Settings," **invited** national webinar offered through Public Responsibility in Medicine & Research (PRIM&R). October, 2011
- 15. "Conflict Management and Resolution for IRB Staff Dealing with IRB Members and Researchers," presented at the Advancing Ethical Research conference of Public Responsibility in Medicine & Research (PRIM&R). December, 2011
- 16. "Reconsidering Privacy Protections in Human Research," presented at The Future of Human Subjects Research Regulation symposium, hosted by the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, June, 2012
- 17. "Practical Tools for Dealing with Conflict: Helping IRB Staff Communicate More Effectively with Investigators," presented at the Advancing Ethical Research conference of Public Responsibility in Medicine & Research (PRIM&R). December, 2012
- 18. "Practical Tools for Dealing with Conflict: Helping IRB Staff Communicate More Effectively with Investigators," presented at the Advancing Ethical Research conference of Public Responsibility in Medicine & Research (PRIM&R). November, 2013
- 19. "Policy and Practice Recommendations for Ethical Sharing and Use of Biospecimens/Data," **invited** presentation at the annual convention of Public Responsibility in Medicine & Research (PRIM&R). December, 2014
- 20. "Promoting Research by Improving IRB-Investigator Collaboration," **invited** national webinar offered through Public Responsibility in Medicine & Research (PRIM&R). May, 2014
- 21. "Challenges Associated with Sharing of Biospecimens and Data," **invited** presentation at the annual conference of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). May, 2015

- 22. "What Specimen Donors Want (and Other Considerations that May Matter More)," **invited** presentation at the Specimen Science symposium, hosted by the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, Cambridge, MA. November, 2015
- 23. "University Innovation Ecosystems," **invited** panelist at Deshpande Symposium on Innovation and Entrepreneurship in Higher Education, University of Massachusetts Lowell Campus, Lowell, MA. June, 2016
- 24. "Investigator Experiences and Attitudes about Research with Biospecimens," **invited** Plenary Speaker for the Cambridge Healthtech Institute's Leaders in Biobanking Congress: Applying Biospecimen Science to Advance Biomedical Research and Patient Care, Baltimore, MD. September, 2016
- 25. "Ethics in Biospecimen Research: Beyond Informed Consent," panel moderator and presenter at the annual meeting of the American Society for Bioethics and Humanities (ASBH), Washington, DC. October, 2016
- 26. "Bioethics Study Abroad: Using Critical Distance to Undo the "Medical Mission" Mentality," presented at the annual meeting of the American Society for Bioethics and Humanities (ASBH), Washington, DC. October, 2016
- 27. "Things that Keep an Institutional Official (IO) Up at Night," panel moderator and presenter at the Advancing Ethical Research Conference of Public Responsibility in Medicine & Research (PRIM&R), Anaheim, CA. November, 2016
- 28. **Invited** discussant, PRIM&R national workshop on "The Ethics of Data Access, Use and Sharing for Human Subjects Research," Boston, MA. March, 2017
- "Data Privacy: Biorepositories, Social Behavioral Research, and Biomedical Research," invited presentation at the national meeting of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), Detroit, MI. May, 2017
- 30. "All about the Common Rule," **invited** Grand Rounds presentation at UT Southwestern Medical Center, Dallas, TX. July, 2017
- 31. "Preparing for Research Collaboration between Cuba and the US," **invited** panelist at the national convention of the National Council of University Research Administrators (NCURA), Washington, DC. August, 2017
- 32. "IRB Issues and Challenges," **invited** presenter at the national convention of the National Council of University Research Administrators (NCURA), Washington, DC. August, 2017
- 33. "Research with Biospecimens: Balancing Individual Interests and Social Goods," presented at the annual meeting of the American Society for Bioethics and Humanities (ASBH), Kansas City, MO. October, 2017
- 34. "Forward-Looking Strategies for IRBs in the Genomic Age: Preparing for Shifting Concepts of Identifiability," invited national webinar offered through Public Responsibility in Medicine & Research (PRIM&R). May, 2018

Regional

- "Auditing Clinical Trials for Compliance," presented at University of California System-wide annual conference of auditors. 1999
- 2. "Risk Considerations of Human Subject Protection Programs," presented at a meeting of the Southern California Association for Healthcare Risk Management (SCAHRM). 2000
- 3. **Invited** discussant, regional meeting of the Institutes of Medicine (IOM) Committee on Clinical Research Involving Children. 2003
- 4. "Risk Assessment and Occupational Health: Humane Care and 'Use' of Employees," presented at the NIH Office of Biotechnology Activities' Southwest Regional Conference for IBC Best Practices. November, 2005

- 5. "Humane Care and 'Use' of Employees: Best Practices for Cooperation between IACUC, IBC and Occupational Health," presented at the "**Three I's Shaping our Future Conference**" of the Massachusetts Society for Medical Research (MSMR). February, 2008
- 6. "Conflicts of Interests in Research," **invited** presenter at a joint meeting of the Massachusetts and North Carolina Societies for Biomedical Research. September, 2011
- 7. "Strategies for Communicating Effectively with Investigators (and Everyone Else)," presented at the Midwestern States regional conference of the National Council of University Research Administrators (NCURA). April, 2011
- 8. "Same Team: Improving Communication between IRB's and Investigators," **invited plenary** speech at the annual Human Subjects Protection Meeting hosted by Schulman IRB and the University of Kentucky. September, 2013

Local

- 1. Contemporary Standards for Human Subject Protection," **invited** presentation (with Drs. Tom Beauchamp and Rosamund Rhodes) at the inaugural Public Forum Series at the University of Texas at Dallas' Center for Values in Medicine, Science, & Technology. November, 2006
- "Social Inequality in Biomedical Research," presented at Ethics Grand Rounds, UT Southwestern. September, 2008
- 3. "Protecting Human Subjects in Research," presented at Surgery Grand Rounds, UT Southwestern. 2010
- 4. "Proposed New Rules for Human Research," presented at the Conversations in Bioethics seminar series, CWRU Schools of Law and Medicine. October, 2011
- 5. "Privacy Is Overrated," **invited** presentation at the CWRU School of Law's Law-Medicine Fund Symposium, "Balancing Privacy, Autonomy and Scientific Progress: Patients' Rights and the Use of Electronic Medical Records for Non-Treatment Purposes." April, 2013
- "The Notice of Proposed Rulemaking (NPRM) on Federal Policy for the Protection of Human Research Subjects-An Overview," invited moderator for panel at DHHS Office for Human Research Protections (OHRP) Community Forum, Cleveland, OH. September, 2015
- 7. "Use of Biospecimens in Research: Ethical and Policy Implications," **invited** presentation at Department of Genetics and Genome Sciences Grand Rounds, CWRU School of Medicine, Cleveland, OH. December, 2015
- 8. "Women in STEM Fields," **invited** panelist, CWRU Weatherhead School of Management Leadership Lab, Cleveland, OH. October, 2016
- 9. "Financial Start-up Ventures," **invited** moderator, CWRU Weatherhead School of Management Entrepreneurship Series, Cleveland, OH. February, 2017
- 10. "The Importance of Resilience," **invited** presenter, NASA Glenn Research Center, 60th Anniversary Professional Development Series, Cleveland, OH. July, 2018

RESEARCH SUPPORT

- 1. The Cleveland Foundation, Cleveland IoT Collaborative, **Co-Principal Investigator** (with Kenneth Loparo) at 5% effort (Case Western Reserve University). \$1.75M total funding. (2018)
- 2. NIH 1-R01-HG008988, Addressing Ethical Challenges in Networked Biorepositories (PIs-Brothers and Goldenberg), **Co-investigator** at 5% effort (Case Western Reserve University). \$1.7M total funding. (2016-2019)

- 3. NIH 5-R01-HG005691, Advancing Collaborative Genetic Research: Ethical and Policy Challenges, **Principal Investigator** at 20% effort (Case Western Reserve University). \$1.7M total funding. (2013-2016)
- 4. NIH 5-UL1-RR024982, North and Central Texas Clinical and Translational Science Initiative (PI-Packer), **Core Function Director-Regulatory Knowledge and Support** at 5% effort (UT Southwestern). \$34M total funding. (2007-2010)

BIBLIOGRAPHY

Articles, Peer Reviewed

- 1. **Rivera, S.M.** "Clinical Research from Proposal to Implementation: What Every Clinical Investigator Should Know about the Institutional Review Board," *J Investig Med*, 56(8): 975-84, December 2008.
- 2. Rothwell, E., Maschke, K., Botkin, J., Goldenberg, A., Murray, T., and **Rivera, S.M.** "Biobanking Research and Human Subjects Protections: Perspectives of IRB Leaders," *IRB: Ethics & Human Research*, 37(2):8-13, March 2015.
- 3. Goldenberg, A.J., Maschke, K.J., Joffe, S., Botkin, J.R., Rothwell, E., Murray, T.H., Anderson, R., Deming, N., Rosenthal, B., and **Rivera, S.M.** "IRB Practices and Policies Regarding the Secondary Research Use of Biospecimens," *BMC Medical Ethics*, 16(1), 32, May 2015.
- 4. **Rivera, S.M.,** Goldenberg, A.J., Mashke, K., Joffe, S., Botkin, J.R., Rothwell, E., Anderson, R., Aungst, H. "Investigator Experiences and Attitudes about Research with Biospecimens," *Journal of Empirical Research on Human Research Ethics*, 10(5):449-456, December 2015.
- 5. **Rivera, S.M.,** Nichols, L., Brako, L, Croft, G, Russo, T., Phan, T. "CTSA Institution Responses to Proposed Common Rule Changes: Did They Get What They Wanted?" *Journal of Empirical Research on Human Research Ethics*, 12(2): 79-86, April 2017.
- 6. Nichols, L., Brako, L., **Rivera, S.M.**, Tahmassian, A., Jones, M.F., Pierce, H.H. and Bierer, B.E. "What Do Revised U.S. Rules Mean for Human Research?" *Science*, 357(6352): 650-651, August 2017.

Articles, Invited--Not Peer Reviewed

- 1. **Rivera, S.M.** "Privacy vs. Progress: Research Exceptionalism is Bad Medicine," *Health Matrix: Journal of Law-Medicine*, 24(1): 49-64, May 2014.
- 2. **Rivera, S.M.** and Brako, L. "Institutional Officials and the Price of Compliance," *Journal of Clinical Research Best Practices*, 13(4), April 2017.
- 3. **Rivera, S.M.**, Brothers, K.B., Cadigan, J., Harrell, H.L., Rothstein, M.A., Sharp, R.R., Goldenberg, A.J. "Modernizing Research Regulations Is Not Enough: It's Time to Think outside the Regulatory Box," *American Journal of Bioethics*, 17(7):1-3, June 2017.
- 4. **Rivera, S.M.** "Reasonable Research Oversight: A Work in Progress," *IRB: Ethics & Human Research*, 39(6):15-20, 2017.

Edited Books, Monographs or Journal Volumes

1. *Specimen Science: Ethics and Policy Implications*, volume **co-edited** with Barbara Bierer, I. Glenn Cohen and Holly Fernandez-Lynch, including a co-authored chapter with Heide Aungst and a co-authored chapter with Aaron Goldenberg. MIT Press, Cambridge, 2017.

Invited Book Chapters

- 1. **Rivera, S.M.** and Gilman, A.G. Drug Invention and the Pharmaceutical Industry. In, *The Pharmacological Basis of Therapeutics*, 12th Edition. Brunton, L., Chabner, B. and Knollman, B., eds. The Macmillan Co., New York, 2010.
- 2. **Rivera, S.M.** Institutional Review Board Approval. In, *Clinical Research: from Proposal to Implementation*. McPhaul, M.J. and Toto, R.D., eds. Lippincott Williams & Wilkins, Philadelphia, 2011.
- 3. Clark, A., **Rivera, S.M.**, and Sheppard, D. et al. Writing Informed Consent Documents and Obtaining Informed Consent. In, *Clinical Research: from Proposal to Implementation*. McPhaul, M.J. and Toto, R.D., eds. Lippincott Williams & Wilkins, Philadelphia, 2011.
- 4. **Rivera, S.M.** Reconsidering Privacy Protections for Human Research. In, *Human Subjects Research Regulation: Perspectives on the Future.* Cohen, G. and Fernandez-Lynch, H., eds. MIT Press, Cambridge, 2014.
- 5. **Rivera, S.M.** Women in Leadership. In, *Sponsored Research Administration: A Guide to Effective Strategies and Recommended Practices*. Atlantic Information Services, Washington, DC, 2016.
- 6. **Rivera, S.M.** and Aungst, H. What Specimen Donors Want (and Considerations that May Sometimes Matter More). In, *Specimen Science: Ethics and Policy Implications*, volume co-edited with Barbara Bierer, I. Glenn Cohen and Holly Fernandez-Lynch. MIT Press, Cambridge, 2017.
- 7. Goldenberg, A. and **Rivera, S.M.** Biospecimen Repositories and Precision Medicine: Implications for Underserved and Vulnerable Populations. In, *Specimen Science: Ethics and Policy Implications*, volume coedited with Barbara Bierer, I. Glenn Cohen and Holly Fernandez-Lynch. MIT Press, Cambridge, 2017.
- 8. **Rivera, S.M.** and Gilman, A.G. Drug Invention and the Pharmaceutical Industry. In, *The Pharmacological Basis of Therapeutics*, 13th Edition. Brunton, L.L., Hilal-Dandan, R. and Knollmann, B.C., eds. The Macmillan Co., New York, 2017.

Posters

- Lamm, A., Deming, N. and S.M. Rivera. "Bioethics and Cultural Competence Education for IRBs for Jointly Reviewed Protocols at International Study Sites," presented at the Advancing Ethical Research Conference of PRIM&R. 2013
- Aungst, H. and S.M. Rivera. "The Matrix: Going Beyond the Traditional Lit Review. Creating a New Type of Dynamic Literature Database to Understand the Motivations, Expectations, and Concerns of Biobanking Donors," presented at the annual meeting of the ASBH. 2015

Other

- 1. Bill of Health Science Policy Blog, Guest Blogger Series, 2012-2013: http://blogs.law.harvard.edu/billofhealth/
- 2. Managing Externally Funded Sponsored Programs: A Guide to Effective Management Practices, co-authored with members of the Research Compliance and Administration Committee of the Council on Governmental Relations, March, 2016: http://www.cogr.edu/Effective-Management-Practices
- 3. Panelist on "Sound of Ideas" radio program, WCPN Cleveland, January 31, 2017: http://www.ideastream.org/programs/sound-of-ideas/immigration-order-impact-right-to-try-law-ohio-budget-proposal
- 4. Op-ed piece in Cleveland Plain Dealer, "March for Science Supports Research for All Our Futures," April 14, 2017: http://www.cleveland.com/opinion/index.ssf/2017/04/marching in cleveland to suppo.html

- 5. Interview on "Ideastream," television program, WVIZ Cleveland, November 1, 2017: http://wviz.ideastream.org/programs/ideas/cwru-research-commercialization-middle-cities-issue-2
- 6. Op-ed piece with Nicholas Zingale in Crain's Cleveland Business, "Taking a Smart Approach to Our Vast Pool of Info," June 10, 2018: http://www.crainscleveland.com/article/20180610/news/164501/personal-view-taking-smart-approach-our-vast-pool-info

VOLUNTEER COMMUNITY SERVICE

Member, Say Yes to Education- Postsecondary Planning System Task Force, Indicators Workgroup, 2018- present Memtor, The Women's Launch Pad, a program of the Brown University's Women's Leadership Council, 2017- present Member, President's Advisory Committee to the Dean of the College, Brown University, 2016- present Member, Head's Council, Laurel School (independent K-12 school for girls), 2015- 2017

Member, Board of Directors, Esperanza, Inc. (scholarships and educational support for Latino youth), 2014- present

- Chair of Development Committee, 2016-present
- Mentor to college student, 2017-present

Member, Board of Directors, FrontLine Service, Inc. (homelessness and suicide prevention in NE Ohio), 2011-2017 Member and **Chair**, Parent Advisory Board, Grand River Academy (independent high school for boys), 2011-2012