BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
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NAME: Steele, Scott J.

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

POSITION TITLE: Associate Professor, Public Health Sciences, Director, Regulatory Science Programs, University of Rochester Medical Center

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
Union College (Schenectady, NY)	BS	06/1995	Biology
National Institutes of Health (Bethesda, MD)	Predoctoral	05/1998	Genetics
Princeton University (Princeton, NJ)	MA	01/2001	Molecular Biology
Princeton University (Princeton, NJ)	PhD	03/2003	Molecular Biology

A. Personal Statement

Scott Steele, PhD has an extensive background in science policy and translational research, including leading several collaborative initiatives to advance translational science, regulatory science and science policy. My primary roles with the University of Rochester Clinical and Translational Science Institute (CTSI) are as Director of Regulatory Science Programs and Co-Director of the Translational Specialization in Regulatory Science for the KL2 Career Development Program. I also serve as Associate Professor of Public Health Sciences and Program Director for the University of Rochester Certificate in Regulatory Science. In further supporting Regulatory Science, I have chaired two subcommittees of the FDA Science Board and was selected to serve as a member of the FDA Science Board.

I have held a number of leadership roles in the national NIH Clinical and Translational Science Award (CTSA) consortium of institutions over the last eight years, including prior chair of the Public-Private Partnerships committee and current Co-Chair of the CTSA-initiated Regulatory Science Workgroup, where I co-led the development of a set of Regulatory Science competences to guide training and education in this area. I currently co-chair a CTSA workgroup, Regulatory Science to Advance Precision Medicine. Additionally, I lead external engagement initiatives for the CTSA Coordinating Center for Leading Innovation and Collaboration, working across the CTSA network of over 50 institutions and external partners. Working with the Association for Clinical and Translational Science, Association of American Medical Colleges, Clinical Research Forum, American Federation of Medical Research and other organizations I also chaired or co-chaired the planning committee for the Translational Science 2017, 2018 and 2019 meetings. These meetings bring together a diverse community of over 1,000 individuals involved in translational science and are particularity focused on supporting trainees, from graduate students to early career faculty and other scholars.

As an associate professor in the Department of Public Health Sciences, I mentor students in a number of capacities, in areas from science and health policy to regulatory science and medical product development. I have also developed and teach a graduate course, Fundamentals of Science, Technology and Health Policy. This interactive course provides students exposure to the interaction between science and public policy, particularly exploring the role and impact of the Federal government in this process. Students also explore roles for scientists in the policy making process, while gaining the ability to objectively analyze science and health policy issues. This course is part of a broader Science and Technology Policy Pathway I lead for the University of Rochester's NIH supported Broadening Experiences in Scientific Training (URBEST) program, which seeks to broaden research training experiences and provides mentoring and career development opportunities for trainees. In this role, I provide mentoring and career advice to students and other trainees

interested in science and health policy. Additionally, I lead and advise several internship programs for trainees as part of the UR BEST program.

Other recent roles at the University of Rochester included serving as the Deputy Director of the Goergen Institute of Data Science and Director of the Rochester Center of Excellence in Data Science, where I led the development of research and educational initiatives, including developing BA, BS and MS programs in Data Science.

My previous experience includes 10 years focused on both developing and implementing science policies and plans, and developing government-university-industry collaborations, as well as 10 years conducting research in academia, industry and government labs before transitioning to focus on a career in science policy and research development. This has included national level experience serving as the Executive Director of the President's Council of Advisors on Science and Technology (PCAST) at the White House Office of Science and Technology Policy (OSTP).

B. Positions and Honors

Positions and Employment

2003	Research Associate, Woodrow Wilson School of Public and International Affairs and The Program on Science and Global Security, Princeton University, Princeton, NJ.
2003-2006	Senior Policy and Program Specialist, Federal Bureau of Investigation, Washington, DC.
2005-2008	Adjunct Professor, Department of Health Policy, School of Public Health, George Washington University, Washington, DC.
2006-2007	Policy Analyst, Office of Science and Technology Policy, Executive Office the President, The White House, Washington, DC.
2007-2008	Executive Director, President's Council of Advisors on Science and Technology (PCAST), Office of Science and Technology Policy, Executive Office the President, The White House, Washington, DC.
2008-2010	Acting Director, Office of Corporate Alliances, University of Rochester, Rochester, NY.
2009-present	Associate Professor, Department of Public Health Sciences, University of Rochester, Rochester, NY.
2009-2014	Director, Public-Private-Partnerships Key Function, Clinical and Translational Science Institute, University of Rochester Medical Center, Rochester, NY.
2010-present	Director, Government and Academic Research Alliances, University of Rochester, Rochester, NY.
2014-2018	Director, Rochester Data Science Center of Excellence and Deputy Director, Goergen Institute for Data Science, University of Rochester, Rochester, NY
2016-present	Director, Regulatory Science Programs, Clinical and Translational Science Institute, University of Rochester Medical Center, Rochester, NY.

Recent Teaching Experience

Course organizer/Instructor, Fundamentals of Science, Technology and Health Policy, Department of Public Health Sciences, School of Medicine and Dentistry, University of Rochester Medical Center. Spring 2015, 2016, 2018, 2019.

Co-lead/co-organizer, Personalized Medicine theme of the Process of Discovery Course for M.D. and M.D./Ph.D. students, University of Rochester School of Medicine and Dentistry. Spring 2010, Spring 2011.

Other Selected Experience and Professional Memberships

1999-present	Member, American Association for the Advancement of Science (AAAS).
2002	Organizer, "Academic Symposium on Bioterrorism: Science, Security, and Preparedness". Princeton University.
2003	Co-author, Carnegie Corporation grant to Princeton University on biodefense/biosecurity.
2004-2008	Ex Officio member, HHS National Science Advisory Board on Biosecurity
2005	Executive Program, Navigating Strategic Change, Kellogg School of Management.

2006-2008	Representative, National Science and Technology Council (Executive Office of the President).
2007-2008	Member, Department of Labor Interagency Aerospace Revitalization Task Force.
2007-2008	Advisor/Mentor, Scholars in the Nation's Service Initiative. Princeton University.
2007	Organizer, "Evolving Demands in Graduate Education, Training and Career Development for Future STEM Professionals- A Roundtable Discussion." The Office of Science and Technology Policy, The White House, Washington, DC.
2008-present	Member (and workgroup co-chair), The National Academies University-Industry Demonstration Partnership
2010	Organizer, National Clinical and Translational Science Award (CTSA) Industry Forum: Promoting Efficient and Effective Collaborations among Academia, Government and Industry, NIH, Bethesda, MD.
2011-2013	Co-chair, National CTSA Public-Private Partnerships Key Function Committee.
2012-2014	Board Member and Secretary, MedTech.
2013-present	Co-chair, CTSA-initiated Regulatory Science Workgroup.
2015-2016	Chair, FDA Science Board Subcommittee to Evaluate the Centers of Excellence in Regulatory Science and Innovation.
2016-present	Senior Editor, *Journal of Clinical and Translational Science.*
2016-2017	Co-Chair, Transitional Science 2017 Planning Committee, Association for Clinical and Translational Science.
2016	Chair, FDA Science Board Subcommittee to Evaluate Scientific Engagement at FDA.
2016-present	Member, FDA Science Board.
2017-2018	Chair, Transitional Science 2018 Planning Committee, Association for Clinical and Translational Science.
2018-2019	Chair, Transitional Science 2019 Planning Committee, Association for Clinical and Translational Science
2018-present	Member, External Advisory Board, Center for Clinical and Translational Science, The Ohio State University

Honors

1996-1998	NIH Technical Intramural Research Training Award (IRTA).
2002-2003	Fellow, New Jersey Commission on Cancer Research.
2003-2004	AAAS/Nuclear Threat Initiative Fellowship in Global Security (declined).
2006	Certificate of Merit, Federal Bureau of Investigation.

C. Contributions to Science

1. Translational Research, Regulatory Science and Precision Medicine. Over the last several years, I have focused on approaches to cultivate research collaborations and methods to speed the development and approval of medical products to improve public health. This has particularly involved novels ways to address emerging personalized medicine technologies and approaches, collaborating across academia, industry, government, foundations and other organizations. I have led and contributed to a number of projects to facilitate research and educational collaborations in Regulatory Science and Translational Science.

a) J. Adamo, R.V. Bienvenu, F. O. Fields, S. Ghosh, C. Jones, M. Liebman, M. Lowenthal, **S. J. Steele** (2018) The integration of emerging omics approaches to advance precision medicine: How can regulatory science help? Journal of Clinical and Translational Science. 2018 Oct; 2(5):295-300. Epub 2018 Dec 06.

b) J. Adamo, W. L. Grayson, H. Hatcher, J. Swanton Brown, A. Thomas, S. Hollister, **S. J. Steele**. (2018) Regulatory interfaces surrounding the growing field of additive manufacturing of medical devices and biologic products. Journal of Clinical and Translational Science. E 2018 Oct; 2(5):301-304. Epub 2018 Nov 29.

c) Adamo JE, Wilhelm EE, **Steele SJ**. 2015. "Advancing a Vision for Regulatory Science Training." Clin Transl Sci. Oct;8(5):615-8. doi: 10.1111/cts.12298. Epub 2015 Jun 17 PMID: 26083660.

d) Rose LM, Everts M, Heller C, Hafer N, Burke C, **Steele S**. 2014. "Academic Medical Product Development: An Emerging Alliance of Technology Transfer Organizations and the CTSA." Clinical & Translational Science Jun 14:cts.12175. PMCID: 4268266 PMCID: PMC4268266

e) **Steele S**, Holroyd KJ, Fadem TJ. 2013. "Creating Ethical, High-Value Industry-Academic Partnerships." In Translational Medicine – What, Why and How: An International Perspective, Eds; Alving B, Dai K, Chan SHH, Transl Res Biomed. Basel, Karger, v3, pp 82–88.

2. National Science and Technology Policy and Planning. As a policy analyst at the White House Office of Science and Technology Policy (OSTP) I developed, drafted, and led the coordination of interagency policies and programs focused on personalized medicine, translational research, nanotechnology, STEM education, national security, biodefense and public health preparedness. I later served as Executive Director of the President's Council of Advisors on Science and Technology (PCAST), coordinating and contributing to writing the following selected reports (available at PCAST Archives):

a) "The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel", 2008

b) "Priorities for Personalized Medicine", 2008

c) "University-Private Sector Research Partnerships in the Innovation Ecosystem", 2008

d) Bügl H, Danner JP, Molinari RJ, Mulligan JT, Park HO, Reichert B, Roth DA, Wagner R, Budowle B, Scripp RM, Smith JA, **Steele SJ**, Church G, Endy D. 2007. "DNA synthesis and biological security." Nature Biotechnology Jun;25(6):627-629. PMID: 17557094

3. Providing Scientific and Technical Advice to Federal Agencies. Over the last few years I have built on my previous scientific and policy experience in government and academia to serve on federal scientific advisory boards, providing advice to a range of federal agencies. For example, I serve on the FDA Science Board that provides advice to the FDA Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities.

a) Afshari CA, Ahsan T, Bahinski A, Byrne BJ, Monto AS, Nelson MR, Pipe SW, Psaty BM, Reiss TF, Sandberg SSB, Sarwal M, **Steele SJ**, Stowell CP. 2017. "Food and Drug Administration (FDA) Science Board Subcommittee Review of the Center for Biologics Evaluation and Research (CBER) Research Programs." FDA Science Board Subcommittee report.

b) Bahinski A, Freire MC, McLellan MR, Psaty BM, Roden DM, **Steele SJ**. 2016. "Scientific Engagement at FDA." FDA Science Board Subcommittee report.

c) Gabriel SE, Jackson R, Meagher E, Meyer RJ, Patterson A, Pinner RW, Reiss TF, Rosenblatt M, **Steele SJ**, Tosi LL. 2016. "Centers of Excellence in Regulatory Science and Innovation (CERSI)--Program Evaluation." FDA Science Board Subcommittee report.

4. Genomic imprinting in mice. My graduate research focused on elucidating the molecular mechanisms of genomic imprinting to further understand roles in developmental disorders and disease. This work on an imprinted gene cluster identified a differently methylated region required for proper imprinting of multiple genes in the region.

a) D. Mancini-DiNardo, **S.J. Steele**, J.M. Levorse, R.S. Ingram and S.M. Tilghman. 2006. "Elongation of the Kcnq1ot1 transcript is required for genomic imprinting of neighboring genes." Genes & Development, 20:1268-1282. PMCID: PMC1472902

b) **S.J. Steele,** D. Mancini-Dinardo, R.S. Ingram, and S.M. Tilghman. 2003. "A differentially methylated region within the gene Kcnq1 functions as an imprinted promoter and silencer." *Human Molecular Genetics,* Feb 1;12(3):283-94. PMID: 12554682

List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/scott.steele.1/bibliography/58071816/public/?sort=date&direction=ascending.

D. Research Support

Ongoing Research Support

U24TR002260 Zand/Ossip (MPI) 7/11/2017-6/30/2022
NIH/National Center for Advancing Translational Science
CTSA Coordinating Center for Leading Innovation and Collaboration (CLIC)
To actively assist the Clinical and Translational Science Award (CTSA) Consortium in translating research discoveries into therapeutic advances to improve public health and support public policy through optimizing use of Common Metrics, providing internal communication support, identifying research gaps, providing analytics based matchmaking for collaborations, creating and enabling access to training resources, and clearly communicating research activities and discoveries to national partners and the public.
Role: Co-Investigator, Engagement Team Leader

UL1 TR002001 Bennett/Zand (MPI) 8/15/2016 - 5/31/2020
NIH/National Center for Advancing Translational Sciences
The University of Rochester's Clinical and Translational Science Institute
The major goal of this project is to develop, demonstrate and disseminate methods and approaches to advance translational research, by providing education and training, supporting transdisciplinary teams, improving quality and efficiency, and engaging community stakeholders.
Role: Core Director, Regulatory Science

DP7 DE024857 Dewhurst (PI) 9/18/14- 8/31/19
NIH/OD
Broadening Experiences in Scientific Training Program (URBEST)
The goal of this project is to develop and implement a novel training program for predoctoral and postdoctoral biomedical research scientists, intended to prepare them for a greater breadth of career opportunities.
Role: Science and Technology Policy Pathway Leader

R13TR002412 Steele (PI) 4/4/2018 – 4/3/2019
NIH/ National Center for Advancing Translational Science
Translational Science 2018: Clinical Research Scholars and Educators Training
This conference project is part of the Translational Science 2018 meeting, helping provide a broad range of interactive and trainee-centered educational activities for trainees and educators to be better prepared and more confident to conduct research, seek career development opportunities, enhance training programs and pursue careers in translational science.
Role: PI

Completed Research Support

C160189 Kautz/Steele (MPI) 4/01/16- 6/30/20
NYSTAR
NYS Center of Excellence in Data Science at the University of Rochester
The goal of this project is to bring leading, highly talented researchers, engineers, and computer scientists together with the necessary resources to empower collaborations in data science across diverse fields, promote economic development and increase the pool of well-trained, highly skilled data scientists to meet national demands.
Role: MPI