KENNETH A. OYE
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Massachusetts Institute of Technology (MIT)
Professor, Political Science and Data, Systems and Society
Director, Program on Emerging Technologies (PoET)
Center for International Studies E40-437 Office: +1 617 253 3412
Massachusetts Institute of Technology Assistant: +1 617 253 3848
77 Massachusetts Avenue Mobile: +1 781 492 1121
Cambridge, Massachusetts 02139 Email: oye@mit.edu

École Polytechnique Fédérale de Lausanne (EPFL)
Visiting Professor, School of Life Sciences (AY 2018-2019)
Fellow, International Risk Governance Center (IRGC)
EPFL-SV-DO SV: +41 21 693 96 92
AAB 2 48 (Bâtiment AAB) IRGC: +41 21 693 82 90
Station 19 Mobile: +41 76 641 37 85
CH-1015 Lausanne Email: kenneth.oye@epfl.ch

EDUCATION

Harvard University Ph.D Political Science, with Chase Dissertation Prize; Swarthmore College B.A. Economics and Political Science, with Highest Honors; Inter-University Consortium for Political Research at Institute for Survey Research, University of Michigan; NSF Summer Institute Computer Mathematics at Moore School of Electrical Engineering, University of Pennsylvania.

PAST POSITIONS

Swarthmore College, Associate Professor Political Science; Princeton University, Assistant Professor Politics; Brookings Institution, Guest Scholar; University of California Davis, Lecturer Political Science; Harvard University, John F. Kennedy School of Government, Lecturer in Public Policy

TEACHING

Courses: Science, Technology and Public Policy; International Relations; International Political Economy; American Foreign Policy
Advising: 68 doctoral dissertations and 29 masters theses in Political Science (Princeton and MIT) and Engineering Systems (MIT).
Awards: 2018 School of Engineering: Martore Award for Educational Contributions; Faculty Appreciation Award, Technology Policy Program; 2011 School of Humanities, Arts and Social Sciences: Levitan Award for Excellence in Teaching; 2003 School of Engineering: Faculty Appreciation Award, Technology Policy Program; 1998 School of Humanities, Arts and Social Sciences: Graduate Council Teaching Award.

SELECTED ACTIVITIES AND PUBLICATIONS ORGANIZED BY SUBJECT AREA

BIOLOGICAL ENGINEERING

2018-present RIVM Netherlands, "SafeChassis," subgrant on regulatory issues and safeguards to limit environmental effects of release.
2017-present DARPA Safe Genes Grant N66001-17-2-4054 "Daisy Drive Systems for the Precise Alteration of Local Populations." Kevin Esvelt, MIT Media Lab PI. Oye organizing workshops on data needs and testing methods for localization safeguards.
2015-present Chairperson, Biosafety and Biosecurity Committee, Broad Institute Foundry
2013-present Faculty associate, MIT Synthetic Biology Center
2011-present Co-chairperson, iGEM Safety Committee
2006-2016 Director, Policy and Practices, NSF Synthetic Biology Engineering Research Center (SynBERC)
2016 Invited Expert, International Experts Group on Biosafety and Biosecurity Regulation (IEGBBR)
2015 Invited Expert, NIH National Science Advisory Board for Biosecurity
2013-2014 NSF, Molecular and Cellular Biology, "Creating a Research Agenda on Ecological Implications of Synthetic Biology," PI

"Considerations for the Governance of Gene Drive Organisms," Larisa Rudenko, Megan J. Palmer & Kenneth A. Oye, *Pathogens and Global Health*, DOI: 10.1080/20477724.2018.1478776. July 5, 2018 20 pp.
"A Roadmap for Gene Drives: Using Institutional Analysis and Development to Frame Research Needs and Governance in a Systems Context," J Kuzma, F Gould, Z Brown, J Collins, J Delborne, E Frow, K Esvelt, D Guston, C Leitschuh, K Oye, S Stauffer, *Journal of Responsible Innovation*, 2018, Vol 5 Issue Sup 1, pages S13-S39.
"Revisit NIH Biosafety Guidelines," Kenneth A. Oye, Maureen O'Leary and Margaret Foster Riley, *Science*, 18 Aug 2017, V 357 (6352) 627.
"On Sources and Implications of Accelerating Innovation in Biotechnology: U.S. Opportunities and Challenges," Testimony for the U.S.-China Economic and Security Review Commission, March 16, 2017. 12 pp.
"On Revisions of the Coordinated Framework for the Regulation of Biotechnology," A White Paper Prepared for Consideration by the Biotechnology Working Group, U.S. Emerging Technologies Interagency Policy Coordinating Committee, Kenneth A. Oye, Jane Maunsell, Shlomiya Bar-Yam Lightfoot, Kevin Esvelt, Nicholas Short, Caroline Liu, Samuel Weiss Evans, Todd Kuiken, Jeantine Lunshof, Yusuke Mori and Megan Palmer, January 20, 2016. 21pp.
"Regulate Home Brew Opiates," Oye KA, Lawson JC, Bubela T, *Nature*, 2015 May 21, pp 281-283.
"Regulating Gene Drives," Kenneth Oye, Kevin Esvelt, Evan Appleton, Flaminia Catteruccia, George Church, Todd Kuiken, Shlomiya Bar-Yam Lightfoot, Julie McNamara, Andrea Smidler, James Collins, *Science,* 8 August 2014.
"Designing Safety Policies to Meet Evolving Needs: iGEM as a Testbed for Proactive and Adaptive Risk Management" Julie McNamara, Shlomiya Bar-Yam Lightfoot, Kelly Drinkwater, Evan Appleton and Kenneth Oye, *ACS Synthetic Biology*, December 2014.
"Shaping Ecological Risk Research for Synthetic Biology," T. Kuiken, G. Dana, K. Oye, D. Rejeski, *Journal of Environmental Studies and Sciences* 4:191-199, published 22 May 2014
"What Rough Beast: Synthetic Biology and the Future of Biosecurity," Gautam Mukunda, Kenneth A. Oye and Scott Mohr, *Politics and the Life Sciences*, September 2009, Volume 28, Number 2, pp 2-26.
"Guide to US Federal Regulations Governing Synthetic Biology," Kenneth Oye et al in Markus Schmidt (editor), *Assessing Synthetic Biology Applications*, Wiley, 2012, 17 pages.
"The Intellectual Commons and Property in Synthetic Biology," Kenneth A. Oye and Rachel Wellhausen, in Markus Schmidt (ed), *Synthetic Biology: The Technoscience and Societal Consequences*, Springer, 2009, pp 121-140.
"Proactive and Adaptive Governance of Emerging Risks: The Case of DNA Synthesis and Synthetic Biology," Kenneth A. Oye, International Risk Governance Council, 23 pp.
"Creating a Research Agenda for the Ecological Implications of Synthetic Biology" Research Report, MIT Program on Emerging Technologies / Woodrow Wilson International Center, May 2014, 36 pp.

THERAPEUTICS

2010-present Faculty associate and regulatory research lead, MIT Center for Biomedical Innovation
2012-present Consultant, Tufts Clinical and Translational Science Institute, on drug licensing, efficacy and effectiveness
2017-2018 KAIST, Data Driven Innovation in Healthcare Systems: Consent, Privacy, IT Security and IP in Korea, Europe, US, PI.
2011-2013 Invited Expert, US President's Council of Advisors on Science and Technology, "Study on Propelling Innovation in Drug Discovery, Development and Evaluation."
2013 Invited Expert, World Health Organization, on addressing health effects of synthetic biology

"Efficacy and Effectiveness Too (EE2) Trials: Clinical Trial Designs to Generate Evidence on Efficacy and on Effectiveness in Wide Practice," H Selker et al, September 2018, paper in revision.
"Adaptive Biomedical Innovation: Evolving Our Global System to Sustainability and Safely Bring New Medicines to Patients in Need," G Hirsch, M Trusheim, E Cobbs, M Bala, S Garner, D Hartman, K Isaacs, M Lumpkin, R Lim, K Oye, E Pezalla, P Saltonstall, H Selker, *Clinical Pharmacology and Therapeutics*, 2016 Dec;100(6):685-698. doi: 10.1002/cpt.509. Epub 2016 Oct 22.
"The Next Frontier: Fostering Innovation by Improving Health Data Access and Utilization" Oye, KA, Jain G, Amador, M, Arnout R, Brown, JS, Crown W, Ferguson, J, Pezalla, E, Rassen JA, Selker JP, Trusheim, M and Hirsch G, *Clinical Pharmacology and Therapeutics.* 2015 November 5.
"Managing Uncertainty in Drug Development and Use: Enhancing Adaptability and Flexibility in Pharmaceuticals Regulation," Kenneth A. Oye (MIT), Mark Pearson (OECD), Theresa Mullin (FDA), Hans-Georg Eichler (EMA) and Anton Hoos (Amgen), pp. 63-80 *Improving Risk Regulation*, International Risk Governance Council 2015.
"From adaptive licensing to adaptive pathways: Delivering a flexible life-span approach to bring new drugs to patients," Hans-Georg Eichler et al, *Clinical Pharmacology & Therapeutics*, 2015 February 4.
"A Proposal for Integrated Efficacy-to-Effectiveness (E2E) Clinical Trials," H P Selker, K A Oye et al, *Clinical Pharmacology & Therapeutics*, (2014); 95 2, 147–153.
"Legal Foundations of Adaptive Licensing" K Oye, L G Baird, A Chia, S Hocking, PB Hutt, D Lee, L Norwalk, V Salvatore, *Clinical Pharmacology & Therapeutics*, (2013); 94 3, 309–311.
"Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval," H Eichler, K Oye et al, *Clinical Pharmacology & Therapeutics*, March 2013, pp. 426-437.

TECHNOLOGY FORECASTING AND RISK GOVERNANCE

2015-present Steering Committee, MIT Internet Policy Research Initiative, planning cyberrisks and infrastructure project.
2009-2016 Member, Scientific and Technical Council, International Risk Governance Council, Lausanne
2015 Invited Expert, Defense Intelligence Board, on International R&D and Threats to National Security
2011-2014 Member, NRC, Board on Global Science and Technology
2011-2014 Member, NRC, Committee on Ethical Implications of Security Applications of Emerging Technologies
2010-2013 Member, International Advisory Board, European Union iNTeg-Risk, Stuttgart
2004-2010 NSF, IGERT on Implications of Emerging Technologies, PI

"Planned Adaptation in Risk Regulation: An Initial Survey of United State Environmental, Health, and Safety Regulation," Lawrence McCray, Kenneth A. Oye and Arthur C. Petersen, *Technological Forecasting and Social Change*, Volume 77, Issue 6, pp. 951-959.
"The Precautionary Principle and International Conflict over Domestic Regulation: Mitigating Uncertainty and Improving Adaptive Capacity," Kenneth A. Oye, *Water Science & Technology*, Fall 2005; pp 59-64.
"Embracing Uncertainty," Kenneth A. Oye, *Issues in Science and Technology*, Vol XXVI, No 1, Fall 2009, pp 91-93.
"International Responses to Japanese Plutonium Programs," E Skolnikoff, T Suzuki, K Oye, CIS Working Paper C/95-5, August 1995, 54 pp.
"Explaining the End of the Cold War: Behavioral and Morphological Adaptations to the Nuclear Peace," Kenneth A. Oye, in Thomas Risse Kappen & R. Ned Lebow (eds), End of the Cold War & International Relations Theory (Columbia, 1995), pp 57-85.
"Research in Engineering Design: The Role of Mathematical Theory and Empirical Evidence," Research in Engineering Design, Daniel D. Frey, et al, 1995, Volume 21 Number 3, pp. 145-151.
Note: Advised on dissertations with Josephine Wolff, "Defense Classes of Computer Systems"; Jesse Sowell "Finding Order in a Contentious Internet"; Dietrich Falkenthal, "Improving Tradeoffs Across Information Securing and Sharing"; Shirley Hung "Cryptography and VOIP Policy"; Jon Lindsay "Cybersecurity: Fiction and Friction"; Robert Reardon "Containing Iran: Options for Addressing the Iranian Nuclear Challenge."

INTERNATIONAL COOPERATION AND CONFLICT / POLITICAL ECONOMY AND TECHNOLOGY TRANSFER

2018-present Invited Expert, National Academy of Sciences, Board of Behavioral, Cognitive & Sensory Sciences, ODNI Framework Study.
1993-present Member, Council on Foreign Relations
1993-present Director / Executive Committee member / session organizer, MIT Seminar XXI Program
1995-2001 MacArthur Foundation, Harvard-MIT Transnational Security Program, PI
2008-2009 Consultant, United Nations Industrial Development Organization, on technology transfer, development and climate change
1996-2002 Consultant, US Trade Policy Coordinating Committee, on Market Windows Institutions
1995-1996 Consultant, Peterson Institute for International Economics, on Export Financing Regimes
1999-2001 Member, US Export Import Bank, Chairperson's Advisory Council
2003-2005 Alliance for Global Sustainability, Grant on Regulatory Strategy & Environment, PI
1996-1999 Japan Foundation, Environmental Aid and Chinese Coal Combustion, PI
1996-1999 MITI New Energy Development Organization, China Desulfurization Policy, PI

Kenneth A. Oye, *Cooperation under Anarchy* (Princeton, 1986).
Kenneth A. Oye, *Economic Discrimination and Political Exchange* (Princeton, 1992).
Kenneth A. Oye et al, *Eagle Entangled 1979, Eagle Defiant 1983, Eagle Resurgent 1987, Eagle in a New World 1991.*
"Cooperation under Uncertainty." Commissioned paper for NAS and Office of the Director of National Intelligence, August 2018, 28 pp.
"Technology Transfer, Development and Climate Change," commissioned paper for UNIDO, January 2009, 38 pp.
"Co-Benefits of Climate Policy - Lessons Learned from a Study in Shanxi China," Kristin Aunan, Jinghua Fang, Haakon Vennemo, Kenneth Oye and Hans M. Seip, *Energy Policy*, May 2003; Pages 567-581.
"A Proposed Industrial Boiler Efficiency Program in Shanxi: Potential CO2 Mitigation, Health Benefits and Associated costs," Jinghua Fang, Guanghai Li, Kristin Aunan, Haakon Vennemo, Hans M. Seip, Kenneth A. Oye, János M. Beér *Journal Applied Energy*, April 2002, pp 275-285.
"Coal Utilization in Industrial Boilers in China - A Prospect for Mitigating CO2 Emissions," Jinghua Fang, Taofang Zeng, Lynn Yang, Kenneth A. Oye, Adel Sarofim, Janos Beer, *Journal of Applied Energy,* May 1999, pp 35-52.
"Market Windows Institutions: Government Sponsored Enterprises in Trade Finance," Kenneth A. Oye and Peter C. Evans, Commissioned Report for U.S. Trade Promotion Coordinating Committee, US Treasury, Commerce, Export Import Bank, January 2004.
"Regulatory Diversity: Can the World Trading System Cope?" Thomas Bernauer, Kenneth A. Oye, and David G. Victor, *Swiss Political Science Review*, Autumn 2000, Volume 6, Issue 3, pp 96-108.
"Self-Interest and Environmental Management," Kenneth A. Oye & James Maxwell, *Journal of Theoretical Politics*, V 6, No. 4, pp 593-624; and Robert O. Keohane and Elinor Ostrom, *Local Commons and Global Interdependence Heterogeneity and Collective Action* (Sage, 1995).
"Self-Interest and the Common Good in International Environmental Agreements," Kenneth A. Oye, in Susan Hassol, John Katzenberger (eds), Elements of Change 1995 (Aspen Global Change Institute, 1996), pp 157-160.