Adam C. Berger, PhD

6705 Rockledge Drive, Suite 630
Bethesda, MD 20892
301-827-9676
adam.berger@nih.gov

EDUCATION

National Cancer Institute, Bethesda, MD 20892 • Experimental Immunology Branch • Cancer Research Training Award Postdoctoral Fellow, 2005-2009

Emory University, Atlanta, GA 30322 • Departments of Cell Biology and Biochemistry • Postdoctoral Research Fellow, 2004-2005

Emory University, Atlanta, GA 30322 • Major field of study - Biochemistry, Cell and Developmental Biology • **PhD** degree conferred 2004

The Ohio State University, Columbus, OH 43210 • Major field of study - Molecular Genetics • **BS** degree conferred 1997

PROFESSIONAL EXPERIENCE

Director, Division of Clinical and Healthcare Research Policy • Office of Science Policy • Office of the Director • NIH • 2018–present

- Oversee and develop policies and provide advice on issues related to: 1) clinical trials oversight, safety monitoring, and dissemination of information; 2) bioethics, privacy, and confidentiality in research; 3) research participant protections; 4) healthcare services research; 5) translation and implementation of scientific discoveries into clinical care; 6) patient centered outcomes research; and 7) digital health

Biologist/Senior Staff Fellow • Personalized Medicine Staff • Office of In Vitro Diagnostics and Radiological Health (OIR) • Center for Devices and Radiological Health (CDRH) • FDA • 2015–2018

- Identified, anticipated, and developed policies for novel personalized medicine devices and enabled pathways for their regulation and review that protected public health and safety while enabling medical product developers to innovate, such as for Next-Generation Sequencing (NGS) and digital health devices

Senior Fellow • Office of the Secretary • HHS • 2015–2016

- Oversaw and managed the $200 million Precision Medicine Initiative (PMI), a precedent setting and transformational medical initiative to accelerate the development of disease treatments by taking into account patients' individual characteristics, across all operating and staff divisions of the Department of Health and Human Services (HHS), including FDA, NIH, OCR, and ONC

Senior Program Officer • Board on Health Sciences Policy • Institute of Medicine (now the National Academy of Medicine) • National Academies of Sciences, Engineering, and Medicine • 2009 –2015

- Conceptualized, planned, and developed proposals, workshops and discourses on health related topics with emphasis on the use of genomic and genetic discoveries and technologies for health; implementation of novel technologies into clinical research and practice; diagnostic technology development; drug discovery and development; coverage and reimbursement policy;

regulatory policy; health IT; data sharing; health economics; ethical, legal, and social issues; conflict of interest; and the development and use of stem cell-based therapies

PROFESSIONAL ACTIVITIES (Select List)

- Member, RECOVER Initiative Mobile Data Working Group, 2020-present
- Adviser, N3C governance team, 2020-present
- Member, VA Genomic Medicine Program Advisory Committee, 2019-present
- Member, Scientific Leadership Board, Digital Medicine Society, 2019-present
- Ex Officio Member (Alternate), Secretary's Advisory Committee on Human Research Protections, 2019-present
- Member, FDA-NIH Next Generation Sequencing and Radiomics Working Group, 2018-present
- Member, AHRQ Federal Workgroup on Health Services Research and Primary Care Research, 2018-2020
- FDA representative to the Global Alliance for Genomics and Health, 2017-2018
- FDA representative to the Medical Device Innovation Consortium Real World Evidence Working Group, 2017-2018
- FDA representative to the Interagency Precision Medicine Initiative Working Group, 2017-2018
- FDA alternate representative to ISO TC212, 2017-2018
- FDA sponsor representative for the National Academies of Sciences, Engineering, and Medicine Committee on the Return of Individual Specific Research Results Generated in Research Laboratories, 2017-2018
- OIR representative to Friends-Alexandria Blueprint for Breakthrough – Charting the Course for Precision Medicine planning committee, 2017
- Reviewer, Genetics in Medicine, 2017
- Reviewer, FDA Regulatory Science Extramural Research and Development Projects Broad Agency Announcement, 2017
- Member, CDRH Digital Health Software as a Medical Device Pre-certification Program Core Team, 2017-present
- Member, Regulatory Science to Advance Precision Medicine Working Group, 2017-present
- Member, HHS PMI Privacy and Security Working Group, 2016-2018
- Member, FDA Precision Medicine Initiative steering committee, 2015-2017
- Member, laboratory developed test (LDT) guidance steering committee, 2015-2017
- Member, Displaying and Integrating Genetic Information through the EHR Action Collaborative, 2015-2018
- Member, White House PMI Data Security Working Group, 2016
- Member, United States Digital Service NIH sprint team, 2016
- Member, HHS Cybersecurity Working Group, 2015-2016
- Selection Committee Member, FDA Tobacco Regulatory Science Fellowship, 2014-2019
- Reviewer, NIH Study Section - Determinants and Consequences of Personalized Health Care and Prevention (U01), 2013
- Discussant, Institute of Medicine Triennial Review Committee, 2011
- Mentor, The National Academies Christine Mirzayan Science & Technology Policy Graduate Fellowship Program, 2011 and 2012

AWARDS & COMMENDATIONS (Select List)

- NCATS Director's Award, N3C, 2021
- NIH Office of the Director Award, BESH, 2019
- NIH Office of the Director Award, OD Bioethics Fund, 2019
- FedHealthIT Innovation Award, precisionFDA, 2019

- FDA Group Recognition Award, precisionFDA, 2018
- CDRH Guidance/Policy Regulation Development Excellence Award, 2016
- National Institutes of Health Fellows Award for Research Excellence, 2008
- Ruth L. Kirschstein National Research Service Award Pre-doctoral Fellowship, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 2002-2004

TRAINING

- AAMI – Quality Systems Requirements and Industry Practice, 2017
- AAMI – Regulatory Requirements for Software Validation in the Medical Device Industry, 2017
- FDLI – Introduction to Medical Device Law, 2017
- MDUFA IV – CLIA Training, 2017
- MDUFA IV – Pre-Submissions, 2017
- MDUFA IV – 510(k), PMA, and De Novo, 2017
- MDUFA IV – Deficiency Letter and Four Part Harmony, 2017

PUBLICATIONS (Select List)

- Regulation of Genomic Technologies. Mansfield, E.A., Donigan, K., **Berger, A.C.** In *Genomic and Personalized Medicine* 3rd Edition, Volume 2, 2016.
- Making personalized health care even more personalized: Insights from activities of the IOM Genomics Roundtable. David, S.P., Johnson, S.G., **Berger, A.C.**, Feero, W.G., Terry, S.F., Green, L.A., Phillips, R.L., Jr., Ginsburg, G.S. Annals of Family Medicine. 13(4):373-380, 2015.
- Global implementation of genomic medicine: We are not alone. Manolio, T.A., Abramowicz, M., Al-Mulla, F., Anderson, W., Balling, R., **Berger, A.C.**, Bleyl, S., Chakravarti, A., Chantratita, W., Chisholm, R.L., Dissanayake, V.H.W., Dunn, M., Dzau, V.J., Han, B., Hubbard, T., Kolbe, A., Korf, B., Kubo, M., Lasko, P., Leego, E., Mahasirimongkol, S., Majumdar, P.P., Matthijs, G., McLeod, H.L., Metspalu, A., Meulien, P., Miyano, S., Naparstek, Y., O'Rourke, P.P., Patrinos, G.P., Rehm, H.L., Relling, M.V., Rennert, G., Rodriguez, L.L., Roden, D.M., Shuldiner, A.R., Sinha, S., Tan, P., Ulfendahl, M., Ward, R., Williams, M.S., Wong, J.E.L., Green, E.D., and Ginsburg, G.S. Science Translational Medicine. 7(290):290ps13, 2015.
- IOM (Institute of Medicine). 2015 *Genomics-enabled learning health care systems: Gathering and using genomic information to improve patient care and research: Workshop Summary*. Washington, DC: The National Academies Press. Sarah H. Beachy, Steve Olson, and **Adam C. Berger**, rapporteurs.
- IOM. 2015. *Improving genetics education in graduate and continuing health professional education: Workshop summary.* Washington, DC: The National Academies Press. **Adam C. Berger,** Samuel G. Johnson, Sarah H. Beachy, and Steve Olson, rapporteurs.
- IOM. 2014. *Assessing genomic sequencing information for health care decision making: Workshop summary.* Washington, DC: The National Academies Press. Sarah H. Beachy, Samuel G. Johnson, Steve Olson, and **Adam C. Berger**, rapporteurs.
- Genomics-enabled drug repositioning and repurposing: Insights from an IOM Roundtable activity. Power, A., **Berger, A.C.**, and Ginsburg, G.S. JAMA. 311(20):2063-2064, 2014.
- IOM. 2014. *Drug repurposing and repositioning: Workshop summary.* Washington, DC: The National Academies Press. Sarah H. Beachy, Samuel G. Johnson, Steve Olson, and **Adam C. Berger**, rapporteurs.
- IOM and NAS (National Academy of Sciences). 2014. *Stem Cell Therapies – Opportunities for ensuring the quality and safety of clinical offerings: Workshop summary.* Washington, DC: The National Academies Press. **Adam C. Berger**, Sarah H. Beachy, and Steve Olson, rapporteurs.

- IOM. 2014. *Conflict of interest and medical innovation – Ensuring integrity while facilitating innovation in medical research: Workshop summary.* Washington, DC: The National Academies Press. Sarah H. Beachy, Steve Olson, and **Adam C. Berger**, rapporteurs.
- IOM. 2014. *Improving the efficiency and effectiveness of genomic science translation: Workshop summary.* Washington, DC: The National Academies Press. Sarah H. Beachy, Samuel G. Johnson, Steve Olson, and **Adam C. Berger**, rapporteurs.
- IOM. 2014. *Refining processes for the co-development of genome-based therapeutics and companion diagnostic tests: Workshop summary.* Washington, DC: The National Academies Press. Sarah H. Beachy, Samuel G. Johnson, Steve Olson, and **Adam C. Berger**, rapporteurs.
- Disruption of multivesicular body vesicles does not affect major histocompatibility complex (MHC) class II-peptide complex formation and antigen presentation by dendritic cells. Bosch B., **Berger A.C.**, Khandelwal S., Heipertz E.L., Scharf B., Santambrogio L., Roche P.A. Journal of Biological Chemistry. 288(34):24286-24292, 2013.
- IOM. 2013. *Genome-based diagnostics – Demonstrating clinical utility in oncology: Workshop summary.* Washington, DC: The National Academies Press. **Adam C. Berger** and Steve Olson, rapporteurs.
- IOM. 2013. *The economics of genomic medicine: Workshop summary.* Washington, DC: The National Academies Press. **Adam C. Berger** and Steve Olson, rapporteurs.
- Harmonizing Reporting on Potential Conflicts of Interest: A Common Disclosure Process for Health Care and Life Sciences. Allen Lichter, Ross McKinney, Timothy Anderson, Erica Breese, Niall Brennan, David Butler, Eric Campbell, Susan Chimonas, Guy Chisolm, Christopher Clark, Milton Corn, Allan Coukell, Diane Dean, Susan Eringhaus, Phil Fontanarosa, Mark Frankel, Ray Hutchinson, Timothy Jost, Norm Kahn, Christine Laine, Mary LaLonde, Lorna Lynn, Patrick McCormick, Pamela Miller, Heather Pierce, Jill Hartzler Warner, Paul Weber, Dorit Zuk, **Adam C. Berger**, Isabelle Von Kohorn. Discussion Paper, Institute of Medicine, Washington, DC.
- IOM. 2012. *Genome-based therapeutics – Targeted drug discovery and development: Workshop summary.* Washington, DC: The National Academies Press. **Adam C. Berger** and Steve Olson, rapporteurs.
- IOM. 2012. *Genome-based diagnostics – Clarifying pathways to clinical use: Workshop summary.* Washington, DC: The National Academies Press. Steve Olson and **Adam C. Berger**, rapporteurs.
- IOM. 2012. *Integrating large-scale genomic information into clinical practice: Workshop summary.* Washington, DC: The National Academies Press. Steve Olson, Sarah H. Beachy, Claire F. Giammaria, and **Adam C. Berger**, rapporteurs.
- IOM. 2011. *Generating evidence for genomic diagnostic test development: Workshop summary.* Washington, DC: The National Academies Press. Theresa Wizemann and **Adam C. Berger**, rapporteurs.
- IOM. 2011. *Establishing precompetitive collaborations to stimulate genomics-driven product development: Workshop summary.* Washington, DC: The National Academies Press. Steve Olson and **Adam C. Berger**, rapporteurs.
- IOM. 2010. *Challenges and opportunities in using residual newborn screening samples for translational research: Workshop summary.* Washington, DC: The National Academies Press. Steve Olson and **Adam C. Berger**, rapporteurs.
- IOM. 2010. *The value of genetic and genomic technologies: Workshop summary.* Washington, DC: The National Academies Press. Theresa Wizemann and **Adam C. Berger**, rapporteurs.
- MHC class II transport at a glance. **Berger, A.C.** and Roche, P.A. Journal of Cell Science. 122:1-4, 2009.
- Identification of genes that function in the biogenesis and localization of small nucleolar RNAs in Saccharomyces cerevisiae. Qui, H., Eifert, J., Wacheul, L., Thiry, M., **Berger, A.C.**, Jakovljevic, J., Woolford, J.L., Jr., Corbett, A.H., Lafontaine, D.L., Terns, R.M., and Terns, M.P. Molecular and Cellular Biology. 28(11):3686-3699, 2008.
- The subcellular localization of the Niemann-Pick Type C proteins depends on the adaptor complex AP-3. **Berger, A.C.**, Salazar, G., Styers, M.L., Newell-Litwa, K.A., Werner, E., Maue, R.A., Corbett, A.H. and Faundez, V. Journal of Cell Science. 120:3640-3652, 2007.

- T cell-induced secretion of MHC class II-peptide complexes on B cell exosomes. Muntasell, A., **Berger, A.C.** and Roche, P.A.: The EMBO Journal. 26:4263-4272, 2007.
- *Saccharomyces cerevisiae* Npc2p is a functionally conserved homologue of the human Niemann-Pick disease type C 2 protein, hNPC2. **Berger, A.C.**, Vanderford, T.H., Gernert, K.M., Nichols, J.W., Faundez, V. and Corbett, A.H. Eukaryotic Cell. 4:1851-1862, 2005.
- A yeast model system for functional analysis of the Niemann-Pick type C protein 1 homolog, Ncr1p. **Berger, A.C.**, Hanson, P.K., Nichols, J.W. and Corbett, A.H. Traffic. 6:907-917, 2005.
- Mms22p protects Saccharomyces cerevisiae from DNA damage induced by topoisomerase II. Baldwin E.L., **Berger A.C.**, Corbett A.H., Osheroff N. Nucleic Acids Research. 33(3):1021-30, 2005

CLINICAL DECISION SUPPORT IMPLEMENTATION GUIDES

- DIGITizE (*Displaying and Integrating Genetic Information through the EHR)* Abacavir and TPMT CDS Implementation Guide, 2015: Establishing Connectivity and Pharmacogenomic Clinical Decision Support Rules to Protect Patients Carrying HLA-B*57:01 and TPMT Variants

INVITED TALKS, ORAL PRESENTATIONS, AND ABSTRACTS (Select List)

- Certificates of Confidentiality. **Adam C. Berger**. Invited Talk. Public Responsibility in Medicine and Research (PRIMR) Advancing Ethical Research 2019 Conference, Boston, MA 2019
- Federal Use Cases Panelist. **Adam C. Berger**. Invited Talk. FHIR Bulk Data Meeting, Boston, MA, 2019
- Collaborative Genomics Standards Development. **Adam C. Berger**. Invited Talk. Global Alliance for Genomics and Health 7th Plenary, Boston, MA, 2019
- The Future of Personalized Medicine at NIH's Office of Science Policy. **Adam C. Berger**. Invited Talk. Personalized Medicine Coalition Public Policy Committee Meeting, Washington, DC, 2018.
- FDA Software Pre-Certification Program Update. **Adam C. Berger**. Invited Talk. Personalized Medicine Coalition Public Policy Committee Meeting, Washington, DC, 2018.
- FDA NGS Webinar. **Adam C. Berger**. Presenter. Silver Spring, MD, 2018.
- Precision Medicine Under the Microscope: A Frank Look at the Impact of Precision Medicine on Patient Welfare Keynote Panel. **Adam C. Berger**. Invited Talk. World CDx Summit, Woburn, MA, 2017.
- Regulatory Landscape for Precision Medicine. **Adam C. Berger**. Invited Talk. A Blueprint for Breakthrough – Charting the Course for Precision Medicine, Friends of Cancer Research, Washington DC, 2017.
- Precision Medicine Update. **Adam C. Berger**. Invited Talk. Association of Medical Diagnostics Manufacturers Annual Meeting, North Bethesda, MD, 2017.
- Reference Materials/Samples for NGS-based Oncology Tests. **Adam C. Berger**. Invited Talk. American Association for Cancer Research, Washington, DC, 2017.
- precisionFDA: Advancing the Regulation and Science of Precision Medicine. **Adam C. Berger**. Webinar. Industry Pharmacogenomics Working Group. 2017
- Regulatory Considerations in Return of Genetic Test Results. **Adam C. Berger**. Invited Talk. Return of Genetic Results in the All of Us Research Program, Bethesda, MD, 2017.
- Precision Medicine Initiative. **Adam C. Berger**. Invited Talk. BIO Personalized Medicine Working Group Meeting, Washington, DC, 2016.
- The Precision Medicine Initiative. **Adam C. Berger**. Invited Talk. International Conference on One Medicine One Science, Minneapolis, MN, 2016.
- Developing an Adaptive, Modern Regulatory Framework for NGS Tests. **Adam C. Berger**. Invited Talk. Institute of Medicine, Washington, DC, 2015.

- Database Standards/Best Practices for Genetic Databases. **Adam C. Berger**. Invited Talk. FDA Workshop on Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants, Silver Spring, MD, 2015.
- Developing Analytical Standards for NGS-based Assays. **Adam C. Berger**. Session Moderator. FDA Workshop on Standards Based Approach to Analytical Performance Evaluation of Next Generation Sequencing In Vitro Diagnostic Tests, Silver Spring, MD, 2015.
- Interoperability and Genomic Data: The EHR Vendor Perspective from the IOM Action Collaborative. **Adam C. Berger**. Invited Talk/Session Moderator. HL7 Genomics Policy Conference, Washington, DC, 2015.
- Genomics and Education: An Update from the IOM Genomics Roundtable. **Adam C. Berger**. Invited Talk. NHGRI Inter-Society Coordinating Committee for Practitioner Education in Genomics. National Institutes Health, Bethesda, MD, 2014.
- Molecular medicine – Can we afford it? **Adam C. Berger**. Session Moderator. Scientific Plenary, College of American Pathologists Annual Meeting. Chicago, IL, 2014.
- Issues for NHANES. **Adam C. Berger**. Session Chair. Guidelines for Returning Individual Results from Genome Research Using Population-Based Banked Specimens. Washington, DC, 2014.
- Genomics and Our Future. **Adam C. Berger**. Invited Talk, Lead America. Johns Hopkins University, Baltimore, MD, 2013.
- Evidence. **Adam C. Berger.** Session Moderator, Genetic Testing and Data Management Summit: Improving Health Outcomes, Disease Management, and Accountable Care Delivery, Washington, DC, 2012.
- Stakeholder perspectives on genome-based diagnostic development: Regulatory, reimbursement, and evidence challenges. **Adam C. Berger**. Invited Talk, Personalized Medicine Coalition Policy Committee Meeting, Washington, DC, 2012.
- Development and Evaluation: Advancing technology development and evidence generation. **Adam C. Berger.** Session Facilitator, Developing Priorities for Public Health Genomics 2012-2017. North Bethesda, MD, 2011.
- Translating basic and applied research to field use. **Adam C. Berger**. Invited Talk, AAAS Center for Science, Technology, and Security Policy Forum on Biosurveillance: New Science for Security Needs. Washington, DC, 2011.
- How do we achieve the business model for appropriate utilization of whole genome technologies and how do we position pathology to be the leader? **Adam C. Berger**. Invited Talk, The future of pathology in personalized medicine: a stakeholder summit. Boston, MA, 2011.